STANDARDS FOR PRODUCE SAFETY
Coverage and Exclusions/Exemptions for 21 Part 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of “farm” is subject to the produce rule.

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**Does your farm grow, harvest, pack or hold produce?**
Sections 112.1 and 112.3(c)
We define “produce” in section 112.3(c).

**NO**
Your farm is **NOT covered** by this rule.

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**Does your farm on average (in the previous three years) have $25k or less in annual produce sales?**
Section 112.4(a)

**YES**
Your farm is **NOT covered** by this rule.

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**Is your produce one of the commodities that FDA has identified as rarely consumed raw?**
Section 112.2(a)(1)

**NO**
This product is **NOT covered** by this rule.

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**Is your produce for personal/on-farm consumption?**
Section 112.2(a)(2)

**YES**
This produce is **NOT covered** by this rule.

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**Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a “kill step”)?**
Section 112.2(b)

**YES**
This product is eligible for exemption from the rule, provided you make certain statements in documents accompanying the produce, obtain certain written assurances, and keep certain documentation, as per Sections 112.2(b)(2) through (b)(6).

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**Does your farm on average (in the previous three years) have < $500k annual food sales, AND a majority of the food (by value) sold directly to “qualified end-users”?**
Section 112.3(c)

“Qualified End-User” as defined in Section 112.3(c) means:
• the consumer of the food OR
• a restaurant or retail food establishment that is located—
  (i) in the same State or the same Indian reservation as the farm that produced the food; OR
  (ii) not more than 275 miles from such farm.
  (The term “consumer” does not include a business.)

**NO**

**YES**
Your farm is eligible for a qualified exemption from this rule, which means that you must comply with certain modified requirements and keep certain documentation, as per Sections 112.6 and 112.7.

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YOU ARE COVERED BY THIS RULE.
FSMA Technical Assistance Network

At-a-Glance

The FDA Food Safety Modernization Act (FSMA) Technical Assistance Network (TAN) is now operational and providing technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation. The TAN will address questions related to the FSMA rules, FSMA programs, and implementation strategies after the rules are final. We encourage stakeholders to first visit FDA’s FSMA webpage at www.fda.gov/fsma, which contains detailed information on all aspects of FSMA, including implementation. The webpage includes Frequently Asked Questions about FSMA by topic area. FDA is implementing the TAN in two phases:

• Phase 1 addresses inquiries related to the publication of FSMA rules and is operational.
• Phase 2 will provide technical assistance to FDA and State staff performing inspections and supporting compliance activities; it will be implemented by 2017 when preventive controls inspections are targeted to begin.

Below are the key features of the TAN:

• Inquiries may be submitted through a web form. The web form can be accessed at www.fda.gov/fsma. Go to Contact Us and then How to Contact FDA on FSMA.
• Inquiries may also be submitted by mail if the Internet is not available at the following address:
  Food and Drug Administration
  5100 Paint Branch Pkwy
  Wiley Building, HFS-009
  Attn: FSMA Outreach
  College Park, MD 20740
  Note: the FSMA related mailboxes (e.g. FSMA@fda.hhs.gov and FSMAfaqs@fda.hhs.gov) are no longer active.
• Inquiries are answered by FDA Information Specialists or Subject Matter Experts, based on the complexity of the question. Complicated questions may require more time for a response. FDA will respond to inquiries received as soon as possible. However, response times may vary, due to complexity of question and the volume of inquiries we receive.
• Once a question is submitted, the inquirer will receive notification of receipt and a case number to be referenced in future correspondence.
• Questions will be tracked and trended using a Knowledge Management System (KMS) to assist FDA in prioritizing, in part, FSMA policy, guidance, and training. Additionally, repeat questions will be addressed in Frequently Asked Question or guidance documents posted on FDA’s website.
• Routine communication and data-sharing protocols with external TANs, e.g. Alliances (such as the Food Safety Preventive Controls Alliance), are vital for coordination and success.
KEY REQUIREMENTS:
Final Rule on Produce Safety

1. AGRICULTURAL WATER:

Water quality: The final rule adopts the general approach to water quality proposed in the supplemental rule, with some changes. The final rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic E. coli, which can indicate the presence of fecal contamination.

- No detectable generic E. coli are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing hands during and after harvest, water used on food-contact surfaces, water used to directly contact produce (including to make ice) during or after harvest, and water used for sprout irrigation. The rule establishes that such water use must be immediately discontinued and corrective actions taken before re-use for any of these purposes if generic E. coli is detected. The rule prohibits use of untreated surface water for any of these purposes.

- The second set of numerical criteria is for agricultural water that is directly applied to growing produce (other than sprouts). The criteria are based on two values, the geometric mean (GM) and the statistical threshold (STV). The GM of samples is 126 or less CFU of generic E.coli per 100 mL of water and the STV of samples is 410 CFU or less of generic E.coli in 100 mL of water.
  - The GM is an average, and therefore represents what is called the central tendency of the water quality (essentially, the average amount of generic E. coli in a water source).
  - STV reflects the amount of variability in the water quality (indicating E. coli levels when adverse conditions come into play—like rainfall or a high river stage that can wash waste into rivers and canals). Although this is an over simplification, it can be described as the level at which 90 percent of the samples are below the value.
• The FDA is exploring the development of an online tool that farms can use to input their water sample data and calculate these values.

• These criteria account for variability in the data and allow for occasional high readings of generic *E. coli* in appropriate context, making it much less likely (as compared to the originally proposed criteria for this water use) that a farm will have to discontinue use of its water source due to small fluctuations in water quality.

• These criteria are intended as a water management tool for use in understanding the microbial quality of agricultural water over time and determining a long-term strategy for use of water sources during growing produce other than sprouts.

• If the water does not meet these criteria, corrective actions are required as soon as is practicable, but no later than the following year. Farmers with agricultural water that does not initially meet the microbial criteria have additional flexibility by which they can meet the criteria and then be able to use the water on their crops. These options include, for example:
  - Allowing time for potentially dangerous microbes to die off on the field by using a certain time interval between last irrigation and harvest, but no more than four consecutive days.
  - Allowing time for potentially dangerous microbes to die off between harvest and end of storage, or to be removed during commercial activities such as washing, within appropriate limits.
  - Treating the water.

**Testing**: The final rule adopts the general approach to testing untreated water used for certain purposes proposed in the supplemental notice, with some changes. The rule still bases testing frequency on the type of water source (i.e. surface or ground water).

• In testing untreated surface water—considered the most vulnerable to external influences—that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of 20 samples, collected as close as is practicable to harvest over the course of two to four years. The initial survey findings are used to calculate the GM and STV (these two figures are referred to as the "microbial water quality profile") and determine if the water meets the required microbial quality criteria.

• After the initial survey has been conducted, an annual survey of a minimum of five samples per year is required to update the calculations of GM and STV.

• The five new samples, plus the previous most recent 15 samples, create a rolling dataset of 20 samples for use in confirming that the water is still used appropriately by recalculating the GM and STV.

• For untreated ground water that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of four samples, collected as close as is practicable to harvest, during the growing season or over a period of one year. The initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria.

• After the initial survey has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV.

• The new sample, plus the previous most recent three samples, create a rolling dataset of four samples for use in confirming that the water is still used appropriately by recalculating the GM and STV.

• For untreated ground water that is used for the purposes for which no detectable generic *E. coli* is allowed, the FDA requires farms to initially test the untreated ground water at least four times during the growing season or over a period of one year. Farms must determine whether the water can be used for that purpose based on these results.

• If the four initial sample results meet the no detectable generic *E. coli* criterion, testing can be done once annually thereafter, using a minimum of one sample. Farms must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criterion.

• There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements.
established in the rule (provided that the farm has Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in compliance with the rule’s treatment requirements.

2. BIOLOGICAL SOIL AMENDMENTS:

- **Raw Manure:** The FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of raw manure as a soil amendment and harvesting to minimize the risk of contamination. (A soil amendment is a material, including manure, that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.)
  - At this time, the FDA does not object to farmers complying with the USDA’s National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. The agency considers adherence to these standards a prudent step toward minimizing the likelihood of contamination while its risk assessment and research is ongoing.
  - The final rule requires that untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.

- **Stabilized Compost:** Microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* spp., fecal coliforms, and *E. coli* 0157:H7) have been established for processes used to treat biological soil amendments, including manure. The rule includes two examples of scientifically valid composting methods that meet those standards. Stabilized compost prepared using either of these methods must be applied in a manner that minimizes the potential for contact with produce during and after application.

3. SPROUTS

- The final rule includes new requirements to help prevent the contamination of sprouts, which have been frequently associated with foodborne illness outbreaks. Sprouts are especially vulnerable to dangerous microbes because of the warm, moist and nutrient-rich conditions needed to grow them.
  - Between 1996 and 2014, there were 43 outbreaks, 2,405 illnesses, and 171 hospitalizations, and 3 deaths associated with sprouts, including the first documented outbreak of *Listeria monocytogenes* associated with sprouts in the United States.

- Requirements specific to sprouts include, for example:
  - Taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, in addition to treating seeds or beans that will be 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, or in-process sprouts from each production batch, for certain pathogens. Sprouts cannot be allowed to enter commerce until it is ascertained that these required pathogen test results are negative.
  - Testing the growing, harvesting, packing and holding environment for the presence of *Listeria* species or *Listeria monocytogenes*.
  - Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive.

- Sprout operations will have less time to come into compliance with the rule than farms growing other produce. They will have one to three years to comply based on the size of their operation, with no additional time to meet the water requirements.
4. DOMESTICATED AND WILD ANIMALS

The rule addresses concerns about the feasibility of compliance for farms that rely on grazing animals (such as livestock) or working animals for various purposes. It establishes the same standards for these animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated.

- At a minimum, this requires all covered farms to visually examine the growing area 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 assessment during the growing season, and if significant evidence of potential contamination by animals is found, to take measures reasonably necessary to assist later during harvest. Such measures might include, for example, placing flags outlining the affected area.

Although the final rule does not require establishing waiting periods between grazing and harvest, the FDA encourages farmers to voluntarily consider applying such intervals as appropriate for the farm’s commodities and practices. The agency will consider providing guidance on this practice in the future, as needed.

As was stated in the supplemental notice, farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas. Nothing in the rule should be interpreted as requiring or encouraging such actions.

5. WORKER TRAINING AND HEALTH AND HYGIENE

Requirements for health and hygiene include:

- 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.
- 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.

Farm workers who handle covered produce and/or food-contact surfaces, and their supervisors, must be trained on certain topics, including the importance of health and hygiene.

Farm workers who handle covered produce and/or food contact surfaces, and their supervisors, are also required to have a combination of training, education and experience necessary to perform their assigned responsibilities. This could include training (such as training provided on the job), in combination with education, or experience (e.g., work experience related to current assigned duties).

6. EQUIPMENT, TOOLS AND BUILDINGS

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

- Required measures to prevent contamination of covered produce and food contact surfaces include, for example, appropriate storage, maintenance and cleaning of equipment and tools.

EXEMPTIONS

The rule does not apply to:

- Produce that is not a raw agricultural commodity. [A raw agricultural commodity is any food in its raw or natural state]

- The following produce commodities that FDA has identified as rarely consumed raw: 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; 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)

- Produce that is used for personal or on-farm consumption.

- Farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less.

The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

The rule also provides a qualified exemption and modified requirements for certain farms.

- To be eligible for a qualified exemption, the farm must meet two requirements:
  - The farm must have food sales averaging less than $500,000 per year during the previous three years; and
  - 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 [a] the consumer of the food or [b] 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 the qualified exemption must still 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 are also required to establish and keep certain documentation.

- A farm’s qualified exemption may be withdrawn as follows:
  - If there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, or
  - 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 that are material to the safety of the farm’s produce that would be 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 and injunction.
  - 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):
  - The FDA determines that the outbreak was not directly linked to the farm, and/or
  - The 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.

**VARIANCES**

The rule also permits states, tribes, or foreign countries from which food is imported into the U.S. to submit a petition, along with supporting information, to FDA requesting a variance(s) from one or more of the requirements of this rule.

- The rule enables a state, tribe, or country, if it concludes that meeting one or more of the rule’s requirements would be problematic in light of local growing conditions, to request variances to those
requirements. The state, tribe, or foreign country must demonstrate that the requested variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s) in the rule.

- The final rule makes it clear that federally recognized tribes may submit a variance petition.
- The request for a variance must be submitted by a competent authority, meaning a person or organization that is the regulatory authority for food safety for the state, tribe, or foreign country.
- A foreign government does not need to have a systems recognition arrangement or equivalence agreement with the FDA to obtain a variance.
- The variance request must include relevant and scientifically valid information specific to the produce or activity. Information could relate to crops, climate, soil, geography or environment, as well as the practices of that particular region.
- Examples of types of variances that may be granted include a variance from the agricultural water microbial quality criteria for water used during growing covered produce (other than sprouts) using a direct water application method, a variance from the microbial die-off rate used to determine the time interval between the last irrigation and harvest and/or the accompanying maximum time interval; and a variance from the approach or frequency for water testing for water uses subject to the rule’s microbial quality criteria.

COMPLIANCE DATES

Compliance dates for covered activities, except for those involving sprouts, after the effective date of the final rule are:

- Very small businesses, those with more than $25,000 but no more than $250,000 in average annual produce sales during the previous three year period: four years.
- 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: three years.
- All other farms: two years.
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the final rule.

Compliance dates for modified requirements for farms eligible for a qualified exemption are:

- For labeling requirement (if applicable): January 1, 2020.
- For retention of records supporting eligibility for a qualified exemption: Effective date of the final rule.
- For all other modified requirements:
  - Very small businesses, four years after the effective date of the final rule.
  - Small businesses, three years after the effective date of the final rule.

Compliance dates for covered activities involving sprouts after the effective date of the final rule are:

- Very small businesses: three years
- Small businesses: two years
- All other farms: one year

ENVIRONMENTAL IMPACT STATEMENT

The FDA has also released the Final Environmental Impact Statement (EIS), which places the Produce Safety rule in the context of its likely impact on the environment, including human health and socioeconomic effects. The Draft EIS was published in January 2015. The FDA considered public comments submitted in the two months that followed in drafting the Final EIS. The FDA considered the findings of the Final EIS in finalizing the produce rule.
The EIS evaluated actions that FDA proposed in the original and supplemental rules, as well as a number of alternative actions for each of the provisions identified as having the potential to result in significant environmental impacts. The provisions of the final rule represent FDA’s preferred alternatives, which are detailed in a Record of Decision (ROD). The ROD addresses how the EIS findings were incorporated into decisions about the final rule. The agency’s preferred alternatives are those that the FDA believes best fulfill the agency’s statutory mission and responsibility, giving consideration to economic, environmental, technical and other factors.

A significant beneficial impact on public health is expected due to the anticipated decrease in the number of illnesses tied to produce contamination.

As in the Draft EIS, the Final EIS notes that any produce regulation that causes a farmer to use ground water instead of surface water could exacerbate existing groundwater shortages, although added flexibility in the water provisions make such a management decision unlikely.

The Final EIS also concludes that Native American farmers may be disproportionately affected by any increases in operating costs necessitated by the produce rule since their average income is 30 percent less than that of other farmers.

**ASSISTANCE TO INDUSTRY**

The FDA is developing several guidance documents on subjects that include:

- General guidance on implementation and compliance
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.
- Other documents, including guidance on sprouts, are being considered and prioritized.

Plans for training and technical assistance are well under way. They include:

- Establishing the FDA FSMA Food Safety Technical Assistance Network, already operational, to provide a central source of information to support industry understanding and implementation of FSMA.
- The FDA is developing a comprehensive training strategy that includes collaboration with:
  - The Produce Safety Alliance;
  - The Sprout Safety Alliance;
  - The National Institute of Food and Agriculture in the U.S. Department of Agriculture (to administer a grant program to provide food safety training, education and technical assistance to small and mid-size farms and small food processors, beginning farmers, socially disadvantaged farmers, and small produce merchant wholesalers); and
  - Cooperative agreement partners (to develop training programs for sustainable agriculture and tribal operations).
- The FDA also plans to work with cooperative extension units, land grant universities, trade associations, foreign partners, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms.
- FDA has entered into a cooperative agreement with National Association of State Departments of Agriculture (NASDA) to help with the implementation of the produce safety regulations.

**MORE INFORMATION**


FDA’s Food Safety Modernization Act page at [www.fda.gov/FSMA](http://www.fda.gov/FSMA)
§ 1420.3 Requirements for four-wheel ATVs.

Alberta E. Mills,
Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–19341 Filed 9–12–17; 8:45 am]
BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

21 CFR Part 112

[Docket No. FDA—2011–N–0921]

RIN 0910–ZA50

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to extend, for covered produce other than sprouts, the dates for compliance with the agricultural water provisions in the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule. We are proposing to extend the compliance dates to address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration’s policies.

DATES: Submit either electronic or written comments on this proposed rule by November 13, 2017.

ADDRESSES: You may submit comments on the extension of the compliance period as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 13, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of November 13, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and
identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2011–N–0921 for “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION:
I. Background

This proposed extension of compliance dates concerns one of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111–353): “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the produce safety regulation), published in the Federal Register of November 27, 2015, 80 FR 74354 (https://www.fda.gov/fsma).

In the preamble of the final rule establishing the produce safety regulation, we stated that the produce safety regulation would be effective on January 26, 2017, and provided for compliance dates of 1 to 6 years from the effective date depending on farm size, commodity, and provision(s) (see table entitled “compliance dates” in the preamble of the final rule establishing the produce safety regulation, 80 FR 74354 at 74357, as corrected in a technical amendment at 81 FR 20466, May 3, 2016). (Some of the compliance dates identified in the technical amendment fall on weekends (i.e., January 26, 2019, is a Saturday and January 26, 2020, is a Sunday) and should therefore be read as referring to the next business day (i.e., January 28, 2019, and January 27, 2020, respectively). We use the latter dates throughout this document.)

For the majority of agricultural water provisions at subpart E (and for most of the other provisions in the rule), with respect to covered produce other than sprouts, we provided compliance periods of 4 years from the effective date of the rule for very small businesses, 3 years for small businesses, and 2 years for all other businesses. We provided an additional 2 years beyond those compliance periods for certain water quality requirements in §112.44 and related provisions in §§112.45 and 112.46. See table 1.

In a final rule, “The Food and Drug Administration Food Safety Modernization Act: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules” (81 FR 57784, August 24, 2016) we also extended the compliance date for certain “customer provisions” in the produce safety regulation (§112.2(b)(3)) and clarified the compliance dates for certain agricultural water testing provisions as originally established in the produce safety regulation.

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<tr>
<th>Compliance dates of 2–4 years applicable to the farm based on its size</th>
<th>Extended compliance date of additional 2 years beyond the compliance date based on size of farm</th>
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<tr>
<td>§112.45(a) with respect to safe and adequate standard</td>
<td>§112.46(b)(1) with respect to untreated ground water.</td>
</tr>
<tr>
<td>§112.46(a)</td>
<td>§112.46(b)(2) and (b)(3).</td>
</tr>
<tr>
<td>§112.46(b)(1) with respect to untreated surface water</td>
<td>112.46(c).</td>
</tr>
<tr>
<td>§112.47.</td>
<td></td>
</tr>
<tr>
<td>§112.48.</td>
<td></td>
</tr>
<tr>
<td>§112.49.</td>
<td></td>
</tr>
<tr>
<td>§112.50.</td>
<td></td>
</tr>
</tbody>
</table>
II. Proposed Extension of Subpart E Compliance Dates for Produce Other Than Sprouts

FDA has received feedback from numerous stakeholders raising issues regarding the practicality of some of the agricultural water requirements in the produce safety regulation as applied to covered produce other than sprouts. Many of these concerns relate to the testing requirements for pre-harvest agricultural water, which is different for sprouts than they are for other types of covered produce. We are proposing this extension in light of the feedback we have received and under Executive Orders 13777, 13771, and 13563. Additional time would allow us to consider approaches to address these issues, as well as opportunities there may be to reduce the cost and enhance the flexibility of these requirements beyond those reflected in the final rule.

As part of this proposed extension, we also propose to simplify the subpart E compliance period structure such that all the compliance dates for subpart E provisions as applied to non-sprout produce would occur at the same time, retaining date staggering based on farm size. Accordingly, covered farms would have 2 years beyond the previously published compliance dates for the water quality requirements in §112.44 and related provisions in §§112.45 and 112.46, to comply with all of subpart E. Put another way, we propose to extend the compliance dates for provisions in the first column of table 1 by 4 years, and propose to extend the compliance dates for provisions in the second column of table 1 by 2 years, so that the compliance dates for non-sprout covered produce for all provisions of subpart E would be those in table 2.

<table>
<thead>
<tr>
<th>Size of covered farm</th>
<th>Proposed time periods starting from the effective date of the November 27, 2015, produce safety final rule (January 26, 2016)</th>
<th>Compliance period</th>
<th>Compliance date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Small Business</td>
<td>8 years</td>
<td>January 26, 2024.</td>
<td></td>
</tr>
<tr>
<td>Small Business</td>
<td>7 years</td>
<td>January 26, 2023.</td>
<td></td>
</tr>
<tr>
<td>All Other Businesses</td>
<td>6 years</td>
<td>January 26, 2022.</td>
<td></td>
</tr>
</tbody>
</table>

We believe the simpler compliance date structure would alleviate confusion, and because we are proposing it as part of a proposal to provide additional time for compliance with all of the provisions, we expect it to alleviate burden. We do not anticipate that the change would result in any practical or logistical compliance challenges. We request comment on whether this change to the compliance date structure would be helpful.

This proposed rule is limited in scope to extending the compliance dates for covered produce other than sprouts. The proposed rule does not address the underlying requirements in subpart E, but only the compliance dates for those requirements (for covered produce other than sprouts). We will continue to work with stakeholders on the issues raised regarding the agricultural water requirements.

Our goal is to complete this rulemaking as quickly as possible. However, we are aware that many farms have been working well in advance of their compliance dates to come into compliance. As we continue to work with stakeholders on issues raised regarding the agricultural water requirements, we intend to exercise enforcement discretion for covered produce other than sprouts relative to the agricultural water provisions in subpart E of the produce safety regulation. This means that while we are considering these issues, we do not intend to enforce the requirements in subpart E of the regulation for covered produce other than sprouts. Thus, by announcing we intend to exercise enforcement discretion for covered produce other than sprouts relative to the agricultural water provisions in subpart E, farms may choose to continue with their current water testing programs or allocate their resources differently to avoid incurring additional costs based on our proposal to extend the agricultural water compliance dates. And, as explained above, when we finalize compliance dates, we intend to continue to work with stakeholders to address agricultural water questions and with farms to prepare for compliance.

This proposed rule also would not change the compliance dates for sprouts. In the final produce safety regulation, we provided staggered compliance periods based on farm size for covered activities involving sprouts. The compliance date for activities involving sprouts for very small businesses is January 28, 2019. The compliance date for activities involving sprouts for small businesses is January 26, 2018. The compliance date for activities involving sprouts for all other businesses is January 26, 2017. Because sprouts present a unique safety risk, the final produce safety regulation established sprout-specific requirements on multiple topics, including agricultural water. The agricultural water requirements for sprouts are different from the agricultural water requirements for other produce commodities (compare §§112.44(a)(1) and 112.44(b)). Moreover, based on the information available to us, many sprout farms use municipal water for growing activities; and under the produce safety regulation, covered farms are not required to test water from a public supply when certain conditions are met (see 21 CFR 112.46(a)(1) and (2)). We also established earlier compliance dates for sprouts than for other covered produce, and the first compliance date for covered sprout farms (January 26, 2017) has already passed. We have not received any significant feedback from sprout farms that subpart E has posed particular challenges. Accordingly, we are proposing to take no action with regard to compliance dates for activities involving sprouts and thus the compliance dates for covered farms with respect to sprouts are the original compliance dates, including for the agricultural water provisions in Subpart E.

Table 3 summarizes the compliance dates for the produce safety regulation as they would be if this proposed rule is finalized. Time periods start from effective date of the produce safety rule (January 26, 2016) except as otherwise specified.
III. Economic Analysis of Impacts

We have examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

Executive Order 13563 states the importance of quantifying costs and benefits, reducing costs and burdens, and harmonizing rules. We conclude that this proposed rule would not increase compliance costs and would instead reduce compliance costs by delaying certain compliance dates. Moreover, it would serve an important purpose of providing us an opportunity to consider how to reduce burdens on the public. We conclude that this proposed rule is an economically
significant regulatory action as defined by Executive Order 12866. This rule would extend, for non-sprout covered produce, the compliance date for all of the provisions of subpart E to 4 years after the relevant farm’s compliance date for all other provisions of the produce safety regulation (which varies based on establishment size). The estimated costs and benefits accrued in any given year of compliance with the produce safety regulation, relative to the first year of compliance, would not change. However, because the compliance dates for certain provisions would be extended, the discounted value of both total costs and total benefits would decrease.

There would be a reduction in costs (i.e., cost savings) associated with extending, for non-sprout covered produce, the compliance date for all of the provisions of subpart E to 4 years after the relevant farm’s compliance date for the rest of the produce safety regulation. With respect to their non-sprout covered produce, covered farms would have 4 years from the compliance date for the other provisions of produce safety regulation to comply with the provisions in subpart E. Thus, while all initial start-up costs and recurring costs would remain the same as estimated in the final regulatory impact analysis for the produce safety regulation (Ref. 1), the annualized total costs, discounted at 3 percent over 10 years, would decrease by about 3 percent from $404 million to $392 million, resulting in a savings of $12 million. No additional costs would be incurred by state, local, and tribal governments or the private sector as a result of this proposed rule.

There would be a reduction in benefits associated with extending the compliance dates as described previously. Consumers eating non-sprout covered produce would not enjoy the potential health benefits (i.e., reduced risk of illness) provided by the provisions of subpart E until 2 to 4 years (depending on the specific provision) later than originally established in the produce safety regulation. Thus, the annualized total benefits to consumers, discounted at 3 percent over 10 years, would decrease by $108 million from $1.033 billion to $925 million. Estimated changes in benefits and costs as a result of this proposed extension are summarized in the following table.

### TABLE 4—SUMMARY OF THE CHANGES IN BENEFITS AND COSTS AS A RESULT OF THIS PROPOSED RULE, ANNUALIZED OVER 10 YEARS, IN MILLIONS OF 2016 DOLLARS

<table>
<thead>
<tr>
<th></th>
<th>Costs to industry under 2015 final rule</th>
<th>Costs to industry with the proposed compliance extension</th>
<th>Benefits of reduced risk of illness under 2015 final rule</th>
<th>Benefits of reduced risk of illness with the proposed compliance extension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annualized 3%</td>
<td>$404</td>
<td>$392</td>
<td>$1,033</td>
<td>$925</td>
</tr>
<tr>
<td>Annualized 7%</td>
<td>$382</td>
<td>$370</td>
<td>983</td>
<td>874</td>
</tr>
<tr>
<td>Net Present Value 3%</td>
<td>$3,443</td>
<td>$3,340</td>
<td>8,811</td>
<td>7,886</td>
</tr>
<tr>
<td>Net Present Value 7%</td>
<td>2,681</td>
<td>2,598</td>
<td>6,901</td>
<td>6,143</td>
</tr>
</tbody>
</table>

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities when the agency publishes a general notice of proposed rulemaking.5 (5 U.S.C. 601(2)). We have analyzed this proposed rule under the Regulatory Flexibility Act and determined that, because it would only extend certain compliance dates for agricultural water provisions in the produce safety regulation, it would not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. We have determined that this proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. This proposed rule is expected to be an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the rule’s economic analysis.

For interested persons, the detailed preliminary regulatory impact analysis is available in the docket for this rule (Ref. 2) at https://www.regulations.gov, and at https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### V. Paperwork Reduction Act of 1995

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### VI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the proposed rule does not contain policies that have federalism implications as defined in
the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Executive Order 13175

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have determined that the proposed rule does not contain policies that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Accordingly, we conclude that the proposed rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

VIII. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. FDA has verified the Web site address, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


Dated: September 8, 2017.

Leslie Kux,
Associate Commissioner for Policy.
FDA FACT SHEET

EQUIVALENT TESTING METHODOLOGIES FOR AGRICULTURAL WATER

FDA has determined that the following methods are “scientifically valid” and “at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity”¹:


2. **Method 1604** – Total Coliforms and *Escherichia coli* in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium) (September 2002). U.S. Environmental Protection Agency. EPA-821-R-02-024.


¹ 21 CFR § 112.151(b)(1).

6. **Hach Method 10029 for Coliforms – Total and *E. coli***, using m-ColiBlue24® Broth PourRite Ampules.

7. **IDEXX Colilert® Test Kit**, but only if using IDEXX Quanti-Tray/2000 for quantification.


**For more information:**
- [FSMA Final Rule on Produce Safety](#)

Have you seen our Blog? [FDA Voice](#)
FDA FACT SHEET
Produce Safety Rule (21 CFR 112)

“RARELY CONSUMED RAW” PRODUCE

What is “Rarely Consumed Raw” Produce?

- “Rarely consumed raw” produce are fruits and vegetables that are almost always cooked before being consumed. Our use of produce that is “rarely consumed raw,” therefore, is intended to mean those produce commodities that are almost always eaten only after being cooked (i.e., heat treated in some form). Cooking is a kill-step that can adequately reduce the presence of microorganisms that are of public health significance.

Why is “Rarely Consumed Raw” Produce Exempt from the Produce Safety Rule?

- Cooking produce before it is consumed, whether commercially or by the consumer, can reduce the risk of serious adverse health consequences or death, which could occur if these commodities are consumed raw. Therefore, FDA concludes it is not reasonably necessary to subject produce that is “rarely consumed raw” to the requirements under the Produce Safety Rule.

While exempt from the Produce Safety Rule, produce that is “rarely consumed raw” is and will continue to be covered under the adulteration provisions and other applicable provisions of the Federal Food, Drug and Cosmetic (FD&C) Act, and any other applicable implementing regulations.

What Produce is Considered “Rarely Consumed Raw” by the Produce Safety Rule?

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; collard; 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.

If produce is not included in the exhaustive list above, then it is considered “covered produce” by the Produce Safety Rule, unless an exemption applies1.

How did FDA develop the “Rarely Consumed Raw” List?

The “rarely consumed raw” produce list was developed using survey data from the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA).

- NHANES/WWEIA is a national food survey conducted as a partnership between the U.S. Department of Health and Human Services (DHHS) and the U.S. Department of Agriculture (USDA).
- NHANES/WWEIA examines a nationally-representative sample of about 5,000 persons each year located across the country. The sample is selected to represent the U.S. population of all ages.

1 See 21 CFR §112.2 for discussion on exemptions

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Center for Food Safety and Applied Nutrition
College Park, MD, 20740
www.fda.gov
The dietary interview component of the NHANES/WWEIA survey incorporates two days’ worth of 24-hour dietary intake data. This is the data that FDA analyzed when writing the Produce Safety Rule.

In order for produce to be considered “rarely consumed raw”, consumption data had to be available from NHANES/WWEIA, and the consumption data had to show that:

- Produce is consumed uncooked by less than 0.1% of the United States population;
- Produce is consumed uncooked on less than 0.1% of eating occasions; and
- Produce consumption (in any form – raw, processed, or other) was reported by at least 1% of weighted number of survey respondents.

Certain limitations apply to the analysis of the NHANES data. For instance, consumption data were not available for some produce commodities. If consumption data were not available for a produce commodity, then FDA could not reliably determine if the commodity is “rarely consumed raw”.

**Relevant Terms and Concepts from the Produce Safety Rule:**

*Produce* means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs.

- A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower.

- A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).

Produce does not include “food grains,” meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion).

- Examples of food grains include 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).

**For more information:**


- ProduceSafetyNetwork@fda.hhs.gov


Have you seen our Blog? FDA Voice
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: What You Need to Know About the FDA Regulation: Guidance for Industry Small Entity Compliance Guide

Additional copies are available from:
Office of Food Safety
Division of Produce (HFS-317)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740.
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm or http://www.regulations.gov

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No: FDA-2011-N-0921 listed in the notice of availability that publishes in the Federal Register.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

September 2017
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Small Entity Compliance Guide

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The FDA Food Safety Modernization Act of 2011 (FSMA) directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety. As a key element of the preventive approach to better protect public health, FDA published in the Federal Register the final rule entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the produce safety rule, or the rule) (80 FR 74354, November 27, 2015). The produce safety rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing and holding of fruits and vegetables grown for human consumption. The regulations are found at Title 21 of the Code of Federal Regulations part 112 (21 CFR part 112). The rule became effective on January 26, 2016, but compliance dates are staggered – see section II. F “When Do I Have to Comply with the Rule?”

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. Law 104-121). This guidance

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1 This guidance has been prepared by the Office of Food Safety, Division of Produce Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.
document is intended to assist small entities in complying with the rule set forth in 21 CFR Part 112 concerning Produce Safety. The rule is binding and has the full force and effect of law.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

II. OVERVIEW OF THE RULE

A. Key Requirements

The key requirements include:

- Personnel Qualifications and Training (21 CFR Part 112, subpart C)
- Health and Hygiene (21 CFR Part 112, subpart D)
- Agricultural Water (21 CFR Part 112, subpart E)
- Biological Soil Amendments (21 CFR Part 112, subpart F)
- Domesticated and wild animals (21 CFR, Part 112, subpart I)
- Equipment, tools, and building (21 CFR, Part 112, subpart L)
- Sprouts (21 CFR, Part 112, subpart M)

B. Who Must Comply With The Rule?

Covered farms must comply with this rule. (21 CFR 112.4(a))

Farms or farm mixed-type facilities with an average annual monetary value of produce (as defined in 21 CFR 112.3) sold during the previous 3-year period of more than $25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year, are considered “covered farms” and are subject to the applicable requirements of part 112 when conducting a covered activity on covered produce. (21 CFR 112.4(a))

A farm is not a covered farm if it meets the requirements for a qualified exemption (see section III of this guidance for additional detail). (21 CFR 112.4(b))

C. What Produce Is Covered Under The Rule?

Unless it is excluded under 21 CFR 112.2, food that is produce within the meaning of part 112 and that is a raw agricultural commodity (RAC) is covered by part 112. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. (21 CFR 112.1(a))

Covered produce includes, but is not limited to, all of the following:
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 uniq 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, pluncots, 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), sweetpot, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams. (21 CFR 112.1(b)(1))

Mixes of intact fruits and vegetables, such as fruit baskets. (21 CFR 112.1(b)(2))

This list of covered produce is not intended to be an exhaustive, exclusive nor a complete list and serves only as examples of produce covered by the rule.

D. Key Terms

The produce safety rule uses a substantial number of terms in very specific ways. A full list of these terms appears in this guidance in section XV “Definitions.” Table 1 lists some of the key terms used in this document.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agricultural Water</td>
<td>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).</td>
</tr>
<tr>
<td>Biological Soil Amendment</td>
<td>Any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in</td>
</tr>
</tbody>
</table>
| Farm | (1) **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:
(i) Pack or hold raw agricultural commodities;
(ii) 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 (1)(iii)(B)(1) of this definition; and
(iii) Manufacture/process food provided that:
(A) All food used in such activities is consumed on that farm or another farm under the same management; or
(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
(1) 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);
(2) 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
(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or
(2) **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 as described in paragraphs (1)(ii) and (iii) of this definition. |
| Produce | Any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of |
A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include 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).

Qualified Exemption

A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:

1. During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in 112.3) the farm sold directly to qualified end-users (as defined in 112.3) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

2. The average annual monetary value of all food (as defined in 112.3) the farm sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

E. Which Commodities And Farms Are Exempt From The Requirements Of Part 112 Or Eligible For An Exemption?

Table 2 identifies products and farms that are exempt or eligible for an exemption from part 112.

Table 2 – Commodities and Farms Exempt From the Requirements of Part 112 or Eligible for an Exemption

<table>
<thead>
<tr>
<th>Exemption</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farms with limited sales are not covered by part 112</td>
<td>Farms with produce sales of ≤ $25,000 per year (during the previous 3 year period) are not</td>
</tr>
<tr>
<td>Exemption</td>
<td>Conditions</td>
</tr>
<tr>
<td>-----------</td>
<td>------------</td>
</tr>
<tr>
<td>21 CFR 112.4(a)</td>
<td>covered by part 112.</td>
</tr>
<tr>
<td>Food grains are not produce and therefore are not covered by part 112</td>
<td>Examples of food grains include 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).</td>
</tr>
<tr>
<td>21 CFR 112.3</td>
<td></td>
</tr>
<tr>
<td>Produce that is rarely consumed raw is not covered by part 112</td>
<td>Not subject to the requirements of part 112. (If you grow, harvest, pack, or hold more than one produce commodity, you should consider this question separately for each one to determine whether that particular produce commodity is covered by the produce safety rule).</td>
</tr>
<tr>
<td>Produce identified as rarely consumed raw: 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.</td>
<td></td>
</tr>
<tr>
<td>21 CFR 112.2(a)(1)</td>
<td></td>
</tr>
<tr>
<td>Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management is not covered by part 112.</td>
<td>Not subject to the requirements of part 112. Farms where the produce is not for sale.</td>
</tr>
<tr>
<td>21 CFR 112.2(a)(2)</td>
<td></td>
</tr>
<tr>
<td>Produce that is not a “raw agricultural commodity” is not covered by part 112.</td>
<td>Not subject to the requirements of part 112.</td>
</tr>
<tr>
<td>21 CFR 112.2(a)(3)</td>
<td></td>
</tr>
<tr>
<td>Produce that receives commercial processing (“kill step” or other process) that adequately reduces the presence of microorganisms of public health significance is eligible for an exemption from part 112.</td>
<td>You must disclose in documents accompanying the produce in accordance with the practice of trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;” annually obtain written assurances from the customer; and document compliance with required disclosures and written assurances.</td>
</tr>
<tr>
<td>21 CFR 112.2(b)(1)</td>
<td></td>
</tr>
<tr>
<td>Exemption</td>
<td>Conditions</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if: (1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in 21 CFR 112.3) the farm sold directly to qualified end-users (as defined in 21 CFR 112.3) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and (2) The average annual monetary value of all food (as defined in 21 CFR 112.3) the farm sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation. 21 CFR 112.5 | Farms eligible for qualified exemptions are subject to the requirements of:  
1. Subpart B (General Provisions)  
2. Subpart O (Records)  
3. Subpart Q (Compliance and Enforcement); and  
4. Subpart R (Withdrawal of Qualified Exemption)  
21 CFR 112.6(a)  
Farms eligible for qualified exemption are required to include the name and complete business address of the farm where the produce was grown on the food packaging label or display at the point of purchase, the name and complete business address of the farm where the produce was grown. 21 CFR 112.6(b)  
A farm’s qualified exemption may be withdrawn if there is an active investigation of an foodborne illness outbreak that is directly linked to the farm, or 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 that are material to the safety of the food that would be covered by the produce safety rule. 21 CFR 112.201(a) |

**F. When Do I Have To Comply With The Rule?**

Table 3 describes the general compliance dates for requirements under part 112.
Table 3 – Compliance Dates for Part 112

<table>
<thead>
<tr>
<th>Business Size</th>
<th>Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)</th>
<th>Covered activities involving all other covered produce (i.e. subject to part 112, except subpart M)</th>
<th>Compliance date for certain specified agricultural water* requirements</th>
<th>Compliance date for all other requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Business</td>
<td>January 26, 2018</td>
<td>January 26, 2021</td>
<td>January 28, 2019</td>
<td></td>
</tr>
<tr>
<td>All Other Businesses</td>
<td>January 26, 2017</td>
<td>January 27, 2020</td>
<td>January 26, 2018</td>
<td></td>
</tr>
</tbody>
</table>

* FDA has announced its intention to further extend the compliance dates for the agricultural water requirements. See [https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm561844.htm](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm561844.htm).

III. INFORMATION FOR FARMS ELIGIBLE FOR QUALIFIED EXEMPTIONS

A. How Can I Tell If My Business Is Eligible For A Qualified Exemption?

A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if (21 CFR 112.5(a)):

1. During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food the farm sold directly to qualified end-users during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

2. The average annual monetary value of all food (as defined in 21 CFR 112.3) the farm sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011. (21 CFR 112.5(b))

Qualified end-user means the consumer of the food (where “consumer” does not include a business); or a restaurant or retail food establishment located in the same state or Indian reservation as the farm, or located within 275 miles from the farm. (21 CFR 112.3)

B. What Records Must I Establish And Keep If My Farm Is Eligible For A Qualified Exemption?

If your farm is eligible for a qualified exemption, you must establish and keep records:

- Required in accordance with the requirements of subpart O of part 112, except that the requirement in 21 CFR 112.161(a)(4) for a signature or initial of the person performing
the activity is not required for sales receipts kept in the normal course of business. However, such receipts must be dated (21 CFR 112.7(a)); and

- Records necessary to demonstrate that your farm satisfied the criteria for a qualified exemption, including a written record reflecting that you have performed an annual review and verification of your farm’s continued eligibility for the qualified exemption. (21 CFR 112.7(b))

C. What Modified Requirements Are Farms Eligible For Qualified Exemption Subject To?

If your farm is eligible for a qualified exemption, you are subject to the requirements of:

- Subpart A of part 112 (General Provisions),
- Subpart O of part 112 (Records),
- Subpart Q of part 112 (Compliance and Enforcement); and
- Subpart R of part 112 (Withdrawal of Qualified Exemption). (21 CFR 112.6(a))

Subpart A establishes the eligibility criteria for a qualified exemption and the record keeping requirements for farms eligible for a qualified exemption.

Subpart O establishes the requirements for records required under part 112, including what documents satisfy the requirements, how documents must be stored, how records must be made available to FDA, and how long records must be kept.

Subpart Q establishes that failure to comply with the requirements of part 112 is a prohibited act and the criteria and definitions in part 112 apply in determining whether a food is adulterated (grown, harvested, packed or held in such conditions that it is unfit for food or food that has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health) or in violation of section 361 of the Public Health Service Act (42 U.S.C. 264). (21 CFR 112.192)

Subpart R outlines the circumstances and requirements for withdrawal of a qualified exemption.

In addition, if your farm is eligible for a qualified exemption you are subject to the following modified requirements:

- When a food packaging label is required on food that would otherwise be covered produce under the FD&C Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address (street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms) of the farm where the produce was grown. (21 CFR 112.6(b)(1) and (3))

- When a food packaging label is not required on food that would otherwise be covered produce under the FD&C Act, you must prominently and conspicuously display, at the
point of purchase, the name and complete business address (street address or post office
box, city, state, and zip code for domestic farms, and comparable full address information
for foreign farms) of the farm where the produce was grown, on a label, poster, sign,
placard, or documents delivered contemporaneously with the produce in the normal
course of business, or, in the case of Internet sales, in an electronic notice. (21 CFR
112.6(b)(2) and (3))

D. When Must Farms Eligible For A Qualified Exemption Comply With Part 112?

Table 4 – Compliance Dates for Part 112 for Farms Eligible for a Qualified Exemption

<table>
<thead>
<tr>
<th>Business Size</th>
<th>Farm Eligible for a Qualified Exemption (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Compliance Date for Retention of Records Supporting Eligibility in 21 CFR 112.7(b)</td>
</tr>
<tr>
<td>Small Business</td>
<td>January 26, 2018</td>
</tr>
<tr>
<td>All other Businesses</td>
<td>N/A</td>
</tr>
</tbody>
</table>

E. Can A Farm’s Qualified Exemption Be Withdrawn?

Yes, a farm’s qualified exemption can be withdrawn in the event of an active investigation of an
outbreak that is directly linked to the farm, or if FDA determines it is necessary to protect public
health based on conduct or conditions on the farm that may pose a risk to public health. (21 CFR
112.201(a))

Before FDA issues an order to withdraw a qualified exemption, FDA:

- May consider other actions to protect the public health and prevent or mitigate a
  foodborne illness outbreak, including a warning letter, recall, administrative detention,
  refusal or food offered for import, seizure, and injunction;

- Must notify the owner, operator, or agent in charge of the farm, in writing, of
  circumstances that may lead FDA to withdraw the exemption and provide an opportunity
  for the owner, operator, or agent in charge of the farm to respond in writing, within 15
  calendar days of the date of receipt of the notification, to FDA’s notification; and

- Must consider the actions taken by the farm to address the circumstance that may lead
  FDA to withdraw the exemption.

(21 CFR 112.201(b))
F. What Procedure Will FDA Use To Withdraw An Exemption?

FDA will issue an order to withdraw the exemption in writing to the owner, operator, or agent in charge of the farm. The order must be in writing, and signed and dated by the officer or qualified employee of FDA who is issuing the order. (21 CFR 112.202)

G. If My Qualified Exemption is Withdrawn, Under What Circumstances Would FDA Reinstate My Qualified Exemption?

If FDA determines that your farm has adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, FDA will, on its own initiative or at your request, reinstate the qualified exemption. (21 CFR 112.213(a))

You may ask FDA to reinstate a qualified exemption that has been withdrawn by submitting a request in writing and presenting data and information to demonstrate that you have adequately responded to any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm. (21 CFR 112.213(b))

If your qualified exemption was withdrawn because of an active foodborne illness outbreak directly linked to your farm and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption and will notify you in writing that your exempt status has been reinstated. (21 CFR 112.213(c))

IV. PERSONNEL QUALIFICATIONS AND TRAINING – SUBPART C

All personnel (including temporary, part time, seasonal, and contracted personnel) who handle (contact) covered produce or food contact surfaces, or who are engaged in the supervision thereof are required to:

- Receive adequate training, as appropriate to the person’s duties, upon hiring, and periodically thereafter, at least once annually. (21 CFR 112.21(a))
- Have a combination of education training, and experience necessary to perform the person’s assigned duties in a manner that ensures compliance with this part. (21 CFR 112.21(b))

A. What Are The Specific Requirements For Training Personnel?

The training must be appropriate to the person’s duties and conducted in a manner that is easily understood by personnel being trained to ensure compliance with the rule (21 CFR 112.21(c) and 112.22(a)(3)). Personnel must be trained on certain topics, including:

- The principles of food hygiene and food safety (21 CFR 112.22(a)(1)); and
• The importance of health and employee hygiene (21 CFR 112.22(a)(2)).

**B. What Additional Training Is Required For Persons Who Conduct Harvest Activities?**

Persons who conduct harvest activities for covered produce must also receive training on the following:

• Recognizing produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards (21 CFR 112.22(b)(1));

• Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so that they do not become a source of contamination (21 CFR 112.22(b)(2)); and

• Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor, as appropriate to the person’s job responsibilities (21 CFR 112.22(b)(3)).

**C. After the Initial Training, Is There A Requirement For Continuing Education?**

Yes, all personnel must receive training upon hiring and then periodically thereafter, at least once annually. The training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of the rule. (21 CFR 112.21(a) and (d))

**D. What Requirements Apply Regarding Supervisors?**

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of part 112 (21 CFR 112.23). Supervisors must also be trained according to the requirements under 21 CFR 112.21 and 112.22.

**E. Is There A Requirement To Maintain Records For Training?**

Yes. You must establish and keep records that document required training of personnel, including the date of training, topics covered, and the person(s) trained in accordance with subpart O (records). (21 CFR 112.30(b))

**V. HEALTH AND HYGIENE – SUBPART D**

**A. What Hygienic Practices Must Personnel Use?**

Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination. (21 CFR 112.31(a))

When handling or contacting covered produce or food contact surfaces, personnel must (21 CFR 112.31(b)):
• Maintain adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;

• Avoid contact with animals, other than working animals, and take appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;

• Wash hands thoroughly, including scrubbing with soap (or other effective cleanser) and running water that meets the requirements of the rule for water used to wash hands, as well as drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices. Hands must be washed:
  o Before starting work;
  o Before putting on gloves;
  o After using the toilet;
  o Upon return to the work station after any break or other absence from the work station;
  o As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and
  o At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of produce with known or reasonably foreseeable hazards.

• Remove or cover hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and

• Not eat, chew gum, or use tobacco products in an area used for an activity covered by the rule. However, drinking beverages is permitted in designated areas).

• If personnel use gloves when handling covered produce or food contact surfaces, the gloves must be changed often to ensure they are maintained in an intact and sanitary condition.

B. Are There Any Requirements To Restrict Ill Personnel?

Yes. You must exclude any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance. Ill or infected personnel must not be allowed to return to work until his/her health condition no longer presents a risk to public health. (21 CFR 112.31)

VI. AGRICULTURAL WATER – SUBPART E

Subpart E establishes requirements to ensure that all agricultural water is safe and of adequate sanitary quality for its intended use. (21 CFR 112.41) Please note that FDA has announced its
intention to explore ways to simplify the agricultural water standards in March 2017. See https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm546089.htm.

A. What Requirements Apply To Agricultural Water Sources, Water Distribution Systems, And Pooling Of Water?

At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces. The following should be taken into consideration during such an inspection (21 CFR 112.42):

- Nature of each agricultural water source;
- Extent of your control over each agricultural water source;
- Degree of protection of each agricultural water source;
- Use of adjacent and nearby land; and
- Likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before it reaches the covered farm.

B. What Is The Microbial Water Quality Profile?

The microbial water quality profile consists of two numerical values of generic \(E. coli\) in the water, the GM and the STV.

1. What is the GM?

The GM is an average, and therefore represents what is called the central tendency of the water quality (essentially, the average amount of generic \(E. coli\) in a water source).

2. What is the STV?

The STV reflects the amount of variation in water quality during the sampling timeframe. The STV value is a representation of the 90\(^{th}\) percentile of the total population size of generic \(E. coli\) in the sampled agricultural water.

3. Is there an online tool to help calculate the GM and STV?

The FDA is exploring the development of an online tool that farms can use to input their water sample data and calculate these values. (See 80 FR 74443 (Comment 213) for further explanation.)

4. What about the variability of these values?

These criteria account for variability in the data and allow for occasional high readings of generic \(E. coli\) in appropriate context, making it much less likely (as compared to the originally proposed criteria for this water use) that a farm will have to discontinue use of its water source due to small fluctuations in water quality. These criteria are intended as a water management
tool for use in better understanding the microbial quality of agricultural water over time in order to determine a long-term strategy for use of water sources during growing produce other than sprouts.

C. What Are The Requirements For Water Quality?

Part 112 establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination:

- No detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing hands during and after harvest, water used on food contact surfaces, water used to directly contact produce (including to make ice) during or after harvest, and water used for sprout irrigation. You must not use untreated surface water for any of these purposes. (21 CFR 112.44(a))

- The second set of numerical criteria is for agricultural water that is directly applied to growing produce (other than sprouts). The criteria are based on two values, the geometric mean (GM) and the statistical threshold value (STV). (21 CFR 112.45(b))
  - The GM of samples is 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (21 CFR 112.44(b)(1)); and
  - STV of samples is 410 CFU or less of generic *E. coli* in 100 mL of water (21 CFR 112.44(b)(2)).

D. What If The CFU’s Exceed The Established Numerical Criteria?

If the water does not meet the microbial criteria for growing produce other than sprouts, corrective actions are required as soon as is practicable, but no later than the following year. The rule provides farmers with additional flexibility by which they can meet the criteria and then be able to use the water on their crops. (21 CFR 112.45(b)) These options include:

- Allowing time for potentially dangerous microbes to die off on the field by using a standardized microbial die-off rate of 0.5 log per day between last irrigation and harvest, but this rate can be utilized for no more than four consecutive days. The rule also allows for an alternative die-off rate (with accompanying maximum time interval), in accordance with 21 CFR 112.49. (21 CFR 112.45(b)(1)(i))

- Allowing time for potentially dangerous microbes to die off between harvest and end of storage, and/or to be removed during commercial activities, such as washing, within appropriate limits, and provided you have adequate scientific support. (21 CFR 112.45(b)(1)(ii))

- Re-inspecting the affected agricultural water system to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards, make necessary
changes, and take adequate measures to determine if changes were effective. (21 CFR 112.45(b)(2))

- Treating the water. (21 CFR 112.45(b)(3))

If generic E. coli is detected, such water must be immediately discontinued and corrective actions taken before re-use for any purposes in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. (21 CFR 112.45(a))

E. What Are The Testing Requirements For Agricultural Water?

You must develop a water quality profile in accordance with 21 CFR 112.46 unless your agricultural water is:

- Sourced from a Public Water System that meets certain requirements (21 CFR 112.46(a)(1)),
- Sourced from a public water supply that meets the microbial quality requirement (21 CFR 112.46(a)(2)), or
- Treated in accordance with the requirements in 21 CFR 112.43 (21 CFR 112.46(a)(3)).

The testing frequency required for a water quality profile is based on the type of water source (i.e., surface or ground water) and the use of the water:

- **Untreated surface water** directly applied to growing produce (other than sprouts): A minimum of 20 samples, representative of the agricultural water that is used for production and under your control must be collected as close as practicable (but prior) to harvest over the course of two to four years. These initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria. (21 CFR 112.46 (b)(1)(i)(A))

- **Untreated ground water** directly applied to growing produce (other than sprouts): A minimum of four samples, collected as close as is practicable (but prior) to harvest, during the growing season or over a period of one year. These initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria. (21 CFR 112.46 (b)(1)(i)(B))

1. **What requirements does the produce rule establish for testing public water?**

There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements established in the rule (provided that the farm has Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in compliance with the rule’s treatment requirements. (21 CFR 112.46(a))
2. **Does the produce rule require annual testing of untreated surface water?**

Yes, after your initial water quality profile for untreated surface water that is directly applied to growing produce (other than sprouts) has been conducted, annual testing of a minimum of five samples per year is required to update the calculations of GM and STV. The five new samples, plus a minimum of the previous most recent 15 samples, create a rolling dataset of at least 20 samples for use in confirming that the water is still used appropriately by recalculating the GM and STV. (21 CFR 112.46 (b)(2)(i)(B))

3. **Does the produce rule require annual testing of untreated ground water?**

Yes, after the initial water quality profile for untreated ground water that is directly applied to growing produce (other than sprouts) has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV. The new samples, plus a minimum of the previous most recent three samples, create a rolling dataset of at least four samples for use in confirming that the water may still be used by updating the GM and STV. (21 CFR 112.46(b)(2)(i)(A))

For untreated ground water that is used for the purposes listed in 21 CFR 112.44(a) for which no detectable generic *E. coli* is allowed, FDA requires farms to initially test the untreated ground water at least four times during the growing season or over a period of one year. Farms must determine whether the water can be used for the intended purpose based on these results.

- If the four initial sample results meet the no detectable generic *E. coli* criterion, testing can be done once annually thereafter, using a minimum of one sample.
- If any annual test fails to meet the microbial quality criterion, farms must resume testing at least four times per growing season or year.

(21 CFR 112.46(c))

F. **Are There Alternatives To The Quality And Testing Requirements For Agricultural Water?**

You may establish alternatives to certain specific requirements of subpart E, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement. (21 CFR 112.49)

Examples of alternative requirements may include:

- Alternatives to the microbial quality criteria using an appropriate indicator of fecal contamination;
- Alternative microbial die-off rate and accompanying maximum allowed time interval; or
- Alternative number of samples used in the initial survey and subsequent annual survey for untreated surface water sources.
1. **What type of data or information can I rely on?**
Scientific data and information used to support an alternative to a requirement may be developed by you, available in scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely. (21 CFR 112.12(c))

2. **Must I notify FDA of my decision to use an alternative?**
No. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative (21 CFR 112.12(c)).

**VII. BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE – SUBPART F**

Subpart F of part 112 establishes requirements for the use of biological soil amendments of animal origin (BSAAO) and human waste. A soil amendment is a material, including manure that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.

**A. How Do You Determine The Status Of A BSAAO?**

A BSAAO is considered treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the standards set by 21 CFR 112.54. (21 CFR 112.51(a))

A BSAAO is considered untreated in several circumstances including if it:

- Has not been processed to completion in accordance with 21 CFR 112.54;
- Has become contaminated after treatment;
- Has been recombined with an untreated BSAAO;
- Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard that has been associated with foodborne illness; or
- It is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

(21 CFR 112.51(b))

**B. What Are The Requirements For Untreated BSAAO?**

FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of untreated BSAAO (e.g., raw manure) and harvesting to minimize the risk of contamination.
At this time, FDA does not object to farmers complying with the United States Department of Agriculture (USDA) National Organic Program Standards related to raw manure use, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for the crops not in contact with the soil.

Untreated BSAAO, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with produce after application. (21 CFR 112.56(a)(1))

**C. What Are The Requirements For Treated BSAAO?**

Part 112 establishes microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* species, fecal coliforms, and *E. coli* O157:H7) for processes used to treat BSAAO, including manure.

1. **Are there microbial testing requirements for BSAAO?**

   No. The produce safety rule has established microbial standards only to validate treatment processes. If the scientifically valid treatment processes listed in 21 CFR 112.54 (e.g., physical, chemical, biological, or in combination) have been documented to meet the respective microbial standards in 21 CFR 112.55, then the application requirements and minimum application intervals in 21 CFR 112.56(a) apply to the BSAAO in question.

2. **What regulations apply to stabilized compost?**

   The produce safety rule includes two examples of scientifically valid composting methods, 21 CFR 112.54(b)(1) and (b)(2), that meet the microbial standard in 21 CFR 112.55(b). Growers that prepare their own stabilized compost only need to document the process controls (e.g. time/temperature and turnings). If the stabilized compost was purchased from a third party supplier, annual documentation would also be required that a valid process was used to treat the compost as well as documentation that the product was handled, conveyed and stored in a manner and location to minimize the risk of re-contamination (21 CFR 112.60(b)(1)(i) and (b)(1)(ii)). Stabilized compost that meets treatment requirements of 21 CFR 112.54(b) to meet the microbial standard in 21 CFR 112.55(b) may be applied with a zero day application interval, but must be applied in a manner that minimizes the potential for contact with produce during and after application. (21 CFR 112.56(a)(2))

Examples of scientifically valid composting methods include:

- Static composting that maintains aerobic (i.e. oxygenated) conditions at a minimum of 131°F (55°C) for 3 consecutive days and is followed by adequate curing; and

- Turned composting that maintains aerobic conditions at a minimum of 131°F (55°C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

(21 CFR 112.54)
D. Can I Use Human Waste?

No. You may not use human waste for growing covered produce, except sewage sludge biosolids used in compliance with U.S. Environmental Protection Agency (EPA) regulations (40 CFR part 503) or equivalent regulatory requirements. (21 CFR 112.53)

VIII. DOMESTICATED AND WILD ANIMALS – SUBPART I

Subpart I of Part 112 addresses concerns about the feasibility of compliance for farms that rely on grazing animals (such as livestock) or working animals for various purposes. It establishes the same standards for these animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated. (21 CFR 112.83)

A. What Must I Do When Contaminated Produce Is Identified?

If significant evidence of potential contamination by animals is found (e.g. significant amounts of excreta or crop destruction), you must identify and not harvest such contaminated crops. You must also take measures which might include, for example, placing flags outlining the affected area to identify, and not harvest, produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. (21 CFR 112.112 and 112.83(b)(2)).

B. What If My Farm Allows Grazing Between Harvests?

Although the produce rule does not require establishing waiting periods between grazing and harvest, the FDA encourages farmers to voluntarily consider applying such intervals as appropriate for the farm’s commodities and practices.

C. Are Animals Required To Be Excluded From The Growing Areas?

No. Farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas. Nothing in the rule should be interpreted as requiring or encouraging such actions. (21 CFR 112.84)

IX. GROWING, HARVESTING, PACKING, AND HOLDING ACTIVITIES – SUBPART K

A. What Measures Must I Take If I Grow, Harvest, Pack, or Hold Both Covered And Excluded Produce?

If you grow, harvest, pack or hold produce that is not covered in this part (i.e., excluded produce in accordance with 21 CFR 112.2) and also conduct activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with the regulations, you must take measures to:

- Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and
• Adequately clean and sanitize, as needed, any food contact surfaces that contact excluded produce before using the surface for covered activities on covered produce. (21 CFR 112.111)

B. What Measures Must I Take Immediately Prior To And During Harvest Activities?

You 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, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. (21 CFR 112.112)

C. How Must I Handle Harvested Covered Produce During Covered Activities?

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards, for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil. (21 CFR 112.113)

D. What Requirements Apply To Dropped Covered Produce?

You must not distribute dropped covered produce that has fallen to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds). (21 CFR 112.114)

E. Are There Any Packaging Requirements?

Yes. You must package covered produce in a manner that prevents the formation of *Clostridium botulinum* toxin if such toxin is a known or reasonably foreseeable hazard (such as mushrooms). (21 CFR 112.115)

F. Are There Any Requirements For Food-Packing Material?

Yes. You must use food-packing material that is adequate for its intended use, is cleanable or designed for single use and is unlikely to support the growth or transfer of bacteria. (21 CFR 112.116 (a))

G. Can I Reuse Food-Packing Material?

Yes. If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner. (21 CFR 112.116 (b))

X. EQUIPMENT, TOOLS, AND BUILDING – SUBPART L

Subpart L of part 112 establishes standards related to equipment, tools, and buildings to prevent these sources, and inadequate sanitation, from contaminating produce.
A. What Are the Requirements for Equipment and Tools?

You must ensure that appropriate measures are taken to use equipment and tools that are of adequate design and construction to enable adequate cleaning and maintenance and prevent contamination of covered produce and food contact surfaces including, for example, appropriate storage, maintenance and cleaning of equipment, tools, instruments (including transport equipment) and building structures. (21 CFR 112.123)

Equipment and tools include those that are intended to, or likely to, contact covered produce. Examples include knives, mechanical harvesters, cooling equipment, grading belts, dump tanks, and vehicles or other equipment for transport. (21 CFR 112.121)

B. What Are the Requirements for Buildings Used for Covered Activities?

The produce safety rule covers any fully or partially-enclosed buildings that are used for covered activities, as well as storage sheds, buildings or other structures used to store food contact surfaces (such as harvest containers and food packing materials. (21 CFR 112.122)

Buildings must be suitable in size, construction, and design to facilitate maintenance and proper sanitation to reduce the potential for contamination from, for example, condensate, domesticated animals, and pests. (21 CFR 112.126 – 112.128)

Adequate and readily accessible toilet and hand washing facilities are required. (21 CFR 112.129 and 112.130)

And proper disposal of sewage and other trash, litter, and waste in areas used for covered activities is also required. (21 CFR 112.131 – 112.132)

XI. SPROUTS – SUBPART M

Subpart M of Part 112 includes requirements to help prevent the contamination of sprouts. The requirements of subpart M apply to the growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots. (21 CFR 112.141)

A. Why Are There Different Requirements For Sprouts?

Sprouts have been frequently associated with foodborne illness outbreaks and are especially vulnerable to dangerous microbes because of the warm, moist and nutrient-rich conditions needed to grow them.

B. What Requirements Apply to Seeds or Beans Used To Grow Sprouts?

Requirements that apply to seeds or beans used to grow sprouts include:

- Taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, and
C. What Requirements Apply To The Growing, Harvesting, Packing and Holding Of Sprouts?

Requirements that apply to the growing, harvesting, packing, and holding of sprouts include:

- Sprouts must be grown, harvested, and packed in fully enclosed buildings and have established written and implemented sampling plans to test water or sprouts for pathogens, as well as corrective actions if pathogens are detected. (21 CFR 112.143)

- Using a valid testing method to test of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch (if testing water is not practical), for *E. coli* O157:H7, *Salmonella* species and any other pathogen meeting the criteria in 21 CFR 112.144(c). (21 CFR 112.44)
  
  o Validated testing methods for the growing, harvesting, packing, and holding environments and spent sprout irrigation water (or sprouts) can be found in 21 CFR 112.152 and 112.153.

- Testing the growing, harvesting, packing, and holding environment for the presence of *Listeria* species or *L. monocytogenes*. (21 CFR 112.44)

- Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive. (21 CFR 112.146 and 112.148)

D. When Must I Comply With The Requirements for Sprouts?

Sprout operations will have less time to come into compliance with the rule than farms growing other produce. They will have one to three years to comply based on the size of their operation, with no additional time to meet the water requirements. See section II.F “When Do I Have To Comply With The Rule?”

XII. ANALYTICAL METHODS – SUPBART N

A. What Methods Must I Use To Test The Quality of Water For 21 CFR 112.46?

You must test the quality of water using:

- The method of analysis published by the U.S. Environmental Protection Agency (EPA), or
• A scientifically valid method that is at least equivalent to the method of analysis in 21 CFR 112.151(a) in accuracy, precision, and sensitivity; or

• For any other indicator of fecal contamination you may test for pursuant to 21 CFR 112.49(a), a scientifically valid method.

(21 CFR 112.151)

B. What Methods Must I Use To Test The Growing, Harvesting, Packing, and Holding Environment for Listeria species or L. monocytogenes for 21 CFR 112.144(a)?

You must test the growing, harvesting, packing and holding environment for Listeria species or L. monocytogenes using:

• The method of analysis described in “Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples,” FDA, or

• A scientifically valid method that is at least equivalent.

(21 CFR 112.152)

C. What Methods Must I Use To Test The Growing, Harvesting, Packing, and Holding Environment for Listeria species or L. monocytogenes for 21 CFR 112.144(b) and (c)?

You must test spent sprout irrigation water (or sprouts) from each production batch using:

• The method of analysis described in “Testing Methodologies for E. coli O157:H7 and Salmonella species in Spent Sprout Irrigation Water (or Sprouts), Version 1, October 2015, FDA, or

• A scientifically valid method that is at least equivalent

(21 CFR 112.153)

XIII. RECORDS – SUBPART O

A. What Are The General Records Requirements For The Produce Rule?

All records under part 112 must be created at the time an activity is performed or observed; be accurate, legible, and indelible; be dated, and signed or initialed by the person who performed the activity documented; and include the following, as applicable:

• The name and location of your farm,

• Actual values and observations obtained during monitoring,

• An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record, and
• The date and time of the activity documented.

(21 CFR 112.161(a))

**B. Must I Store My Records Onsite?**

No. Offsite storage of records is permitted if the records can be retrieved and provided onsite within 24 hours of a request for official review. (21 CFR 112.162(a))

**C. Are Electronic Records Acceptable?**

Yes. Electronic records are acceptable and are considered to be onsite at your farm if they are accessible from an onsite location at your farm. (21 CFR 112.162(b))

**D. How Long Must I Keep Records?**

You must keep records required by this part for at least 2 years past the date the record was created. (21 CFR 112.164(a)(1))

Records that relate 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. (21 CFR 112.164(b))

**E. Does The 2 Year Period Also Apply to Records Used To Be Eligible For A Qualified Exemption?**

No. 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 21 CFR 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year. (21 CFR 112.164(a)(2))

**XIV. VARIANCES – SUBPART P**

**A. Can A Farm Apply For A Variance?**

No. The produce rule permits States, tribes, or foreign countries to submit a petition, along with supporting information, to FDA requesting a variance(s) from the requirements of the produce rule.

**B. Who May Request a Variance?**

States, tribes, or foreign countries from which food is imported into the United States may submit a petition, along with supporting information, to FDA requesting a variance(s) from one or more of the requirements under the produce rule if the state, tribe, or country concludes that meeting one or more of the requirements would be problematic in light of local growing
conditions. The state, tribe, or foreign country must demonstrate that the requested variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s) in the produce rule. (21 CFR 112.171)

C. How May a Variance Be Requested?

To request a variance from one or more requirements of this rule, the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under 21 CFR 10.30. (21 CFR 112.172)

In addition to the requirements of 21 CFR 10.30, a Statement of Grounds must be included in a petition for a variance. (21 CFR 112.173)

D. When Does a Variance Approved by FDA Become Effective?

A variance approved by FDA becomes effective on the date of FDA’s written decision on the petition. (21 CFR 112.179)

E. Under What Circumstances May FDA Modify or Revoke an Approved Variance?

FDA may modify or revoke a variance if it is determined that the variance is not reasonably likely to ensure that the produce is not adulterated under section 401 of the FD&C Act and to provide the same level of public health protection as the requirements of this rule. (21 CFR 112.180)

XV. DEFINITIONS (21 CFR 112.3)

*Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.

*Adequately reduce microorganisms of public health significance* means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

*Agricultural water* means 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).

*Animal excreta* means solid or liquid animal waste.

*Application interval* means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.
**Biological soil amendment** means any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

**Biological soil amendment of animal origin** means 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.

**Composting** means a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

**Covered activity** means 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 "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** means produce that is subject to the requirements of part 112 in accordance with 21 CFR Part 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

**Direct water application method** means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.

**Farm means:**

(1) **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:

(i) Pack or hold raw agricultural commodities;

(ii) 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 (1)(iii)(B)(1 ) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or
(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

1. 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);

2. 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

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

(2) 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 as described in paragraphs (1)(ii) and (iii) of this definition.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

Food contact surfaces means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food contact surfaces” includes food contact surfaces of equipment and tools used during harvest, packing and holding.

Ground water means the supply of fresh water found beneath the Earth's surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include
cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

**Hazard** means any biological agent that has the potential to cause illness or injury in the absence of its control.

**Holding** means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

**Known or reasonably foreseeable hazard** means a biological hazard that is known to be, or has the potential to be, associated with the farm or the food.

**Manufacturing/processing** means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

**Manure** means animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

**Microorganisms** means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

**Mixed-type facility** means 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.
Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

Non-fecal animal byproduct means solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Sewage sludge biosolids means the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of “sewage sludge” in 40 CFR 503.9(w).

Small business means a farm that is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than $500,000; and the farm is not a very small business as defined in this section.

Soil amendment means any chemical, biological, or physical material (such as elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).
Spent sprout irrigation water means water that has been used in the growing of sprouts.

Stabilized compost means a stabilized (i.e., finished) biological soil amendment produced through a controlled composting process.

Surface water means all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.

Turned composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.

Very small business means a farm that is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than $250,000.

Visitor means any person (other than personnel) who enters your covered farm with your permission.

Water distribution system means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.

We means the U.S. Food and Drug Administration (FDA).

You, for purposes of part 112, means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of part 112.
Executive Summary

The FDA Food Safety Modernization Act (FSMA) is transforming the nation’s food safety system into one that is based on the prevention of foodborne illnesses. It will be a system in which the food industry systematically puts in place measures proven effective in preventing contamination.

Keeping food safe to eat is paramount, no matter where it is produced, whether conventional or organic, whether the operation is small, medium or large, whether it’s produce or processed foods.

The FDA has finalized the foundational rules that will implement FSMA, including the Preventive Controls rules for Human and Animal Food, the Produce Safety rule, and the Foreign Supplier Verification Programs (FSVP) rule. There will be extensive outreach to industry to help ensure that everyone who seeks to comply with these rules, whether legally required to or not, understands the new requirements. The compliance dates vary, in part, according to the size of the business.

Food industry training will be an important component of successful implementation. The Produce Safety Rule and the Preventive Controls rules all have training components, although they are not the same for each rule. There will be ample time for farmers and food producers to come into compliance. Compliance dates for the rules are staggered according to the size of the business.

While members of the food industry are ultimately responsible for getting the training they need to comply with the FSMA rules, the FDA recognizes the importance of its role in facilitating that training. For the agency, this means joining with public and private partners in state, federal, tribal and international governments, industry, and academia in the development and delivery of training.

One size doesn’t fit all. The most important goal that the FDA expects of any training program is the outcome—that it advances knowledge among the food industry to meet FSMA requirements. There is more than one way to get there and there will be a variety of training options and delivery formats:

- The vision of FSMA training began in 2010-2012 with the creation of public-private Alliances funded primarily by the FDA as a resource for industry and to facilitate widespread understanding of the new standards to support compliance. Training through the Alliances is now available.

- Recognizing the great diversity among members of the food industry, the FDA is building on that investment by funding cooperative agreements that will develop training options for local food production systems and tribal operations.
The FDA has partnered with the U.S. Department of Agriculture’s National Institute of Food and Agriculture (NIFA) to provide grants to fund a National Coordination Center (NCC) and four Regional Centers (RCs) to provide training opportunities for owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers.

FSMA training will encompass various members of the food industry, including domestic and foreign food producers and domestic importers. The FDA will work with partners around the world—including the Alliances, regulatory counterparts, and multinational organizations—to promote training to the global community of food suppliers. Participants will likely receive documentation of completion for any of the above mentioned training options.

The following is a description of the evolving training strategy. There is a glossary of frequently used terms and a listing of some of the FDA’s training partners at the end.

Summary of the Major Components of the Training Strategy

The FDA is striving for transparency as this multi-faceted training plan for the food industry, outlined below, takes shape.

Crafting the FSMA Alliance Curricula

The Produce Safety Alliance (PSA), Food Safety Preventive Controls Alliance (FSPCA), and Sprout Safety Alliance (SSA) have developed training programs to help domestic and foreign food businesses—including small and very small farms and facilities—understand the requirements of the preventive controls regulations and the Produce Safety rule. The Alliances are composed of representatives from the government, including FDA, USDA, and state regulatory agencies, the food industry, and academia.

The Alliances initially conducted extensive outreach to gain an understanding of training needs, including a consideration of food safety training available prior to FSMA. Since then, the Alliances have actively engaged over the past several years with hundreds of stakeholders—including food processors, the farming community, academia, cooperative extension, and regulators—to develop industry training curricula. Numerous working groups assessed course content needs, established learning objectives, and defined critical elements for the curricula. The Alliances also conducted pilot sessions with these partners to review training materials.

The curricula developed through the Alliances focuses on the FSMA rules and the foundational reasons for the rules’ existence to foster an understanding of both what is required and why it is required. They were designed to be model curricula with training modules that can be added to meet unique needs.

The Alliances are working to ensure that training opportunities available to international food businesses are consistent with those being provided domestically. FSPCA—working with PSA, as well as representatives of importers and foreign governments, and others—has established an International Subcommittee to address the training, education and technical assistance needs of global stakeholders.
More on the individual Alliances:

- The most longstanding is the **Produce Safety Alliance (PSA)**, a partnership created between Cornell University, the U.S. Department of Agriculture (USDA) and FDA in 2010. PSA’s role includes offering:
  
  o A Grower Training course to assist the domestic and foreign produce industry, including but not limited to small and very small farms, as well as regulatory personnel, by providing a foundation of Good Agricultural Practices (GAPs) and co-management information, FSMA Produce Safety Rule requirements, and details on how to develop a farm food safety plan.
  
  o A Train-the-Trainer (TTT) course and PSA Lead Trainer process to develop trainers who are qualified to deliver the curriculum to produce growers. The TTT course includes principles of adult learning, how to form training partnerships, and information to guide trainers on teaching concepts related to GAP, and the FSMA Produce Safety standards.
  
  o A network of trainers to support the produce industry and the dissemination of produce safety trainings

- **The Food Safety Preventive Controls Alliance (FSPCA)**, initiated in 2011 and coordinated by Illinois Institute of Technology’s Institute for Food Safety and Health, developed a standardized training and education program and technical information network to help the domestic and foreign food industry, including certain mixed-type facilities on farms, comply with the requirements of the Preventive Controls rules for human and animal food, as well as the rule on Foreign Supplier Verification Programs (FSVP). This work includes:
  
  o Two separate standardized hazard analysis and preventive controls training courses and distance education modules—one for human food industry and regulatory personnel and another for animal food industry and regulatory personnel.
  
  o A training curriculum that addresses:
    
    ▪ resources for and preliminary steps in developing a food safety plan,
    
    ▪ types of hazards, conducting a hazard analysis, preventive controls for hazards,
    
    ▪ monitoring preventive controls, verification and validation, and corrective actions/corrections,
    
    ▪ recordkeeping, and
    
    ▪ regulatory requirements.
  
  o Two separate Train-the-Trainer courses for those interested in helping to train food facilities—one course for human food and another for animal food.
  
  o A module on the FSVP rule for processors who import foods, and a full FSVP course for non-processor importers. The Alliance is also encouraging all importers to take the complete Preventive Controls training.
• **The Sprout Safety Alliance (SSA)**, initiated in 2012 and coordinated by Illinois Institute of Technology’s Institute for Food Safety and Health, is serving as a network hub and resource for the sprout industry, and federal and state regulatory agencies. SSA has developed:

  o Sprouter training that will provide best practices to enhance the safe production of sprouts, and facilitate implementation of relevant requirements in the Produce Safety rule.
  
  o A Train-the-Trainer course for those interested in helping to train farms on safe sprout production.

The Alliance-developed materials will be publicly available for use in training activities and as benchmarks for others developing equivalent curricula.

**Alternate Training Options**

The three FDA-funded Alliances (Produce Safety, Food Safety Preventive Controls, and Sprout Safety) have developed models, standardized curricula that are intended to meet the needs of, and be used by, the majority of those affected by the FSMA rules.

By the same token, the FDA recognizes that traditional training activities may not work for all groups, and there are certain instances in which alternate curricula and training delivery may be appropriate.

The FDA is funding the development of certain training programs for specific target audiences through cooperative agreements, as discussed further below. The agency will work closely with the participants in those agreements and expects to recognize the training programs that are developed through these collaborations.

The agency intends that the standardized curricula being developed by the Alliances and any alternate curricula developed through cooperative agreements are the only ones that will be officially recognized by the FDA. The agency encourages those developing other training courses to work with the Alliances, the NCC and the RCs to ensure consistency and completeness of training. The agency plans to provide additional information regarding how such training programs will be evaluated.

**Cooperative Agreements**

FDA-funded cooperative agreements encompass a range of actions to support implementation of the FSMA rules.

• To accommodate alternate approaches to FSMA readiness, the FDA is funding the development of several specific training programs through cooperative agreements. The agency’s goal is to work with groups that understand the special needs of and have direct access to businesses that face unique circumstances and challenges in implementing FSMA. These training programs would include providing an awareness of the underlying reasons for the new standards and would ensure that training addresses the unique needs of the target audiences.

Specifically, cooperative agreements have been awarded to support curricula development and dissemination among two such communities: local food producers, including those engaged in direct marketing (see glossary below for more information), and tribes.

• The agency has allocated Fiscal Year 2016 funds for the development of training curricula and
delivery, in addition to education and outreach, with a focus on small and mid-size businesses involved in local food production, including those that engage in sustainable and organic farming. The Local Food Producer Outreach, Education, and Training to Enhance Food Safety and FSMA Compliance cooperative agreement has been awarded to the National Farmers Union Foundation. The award provides one year of support at $1.5 million.

- The FDA is funding a similar cooperative agreement for the development of training curricula and dissemination in tribal communities. This agreement reflects the cultural practices associated with produce farming and food manufacturing and processing within tribes relevant to their status as sovereign nations. The Native American Tribes Outreach, Education, and Training to Enhance Food Safety and FSMA Compliance cooperative agreement has been awarded to the University of Arkansas at Fayetteville. The award provides one year of support at $750,000.

- Each agreement includes recommended support for two additional years, contingent upon satisfactory performance and the availability of federal fiscal year appropriations.

- The FDA will be involved in facilitating communications between the Alliances and the participants in the new cooperative agreements to maximize use of materials that are already developed, when appropriate.

- The agency has entered into a five-year cooperative agreement with the National Association of State Departments of Agriculture (NASDA) that brings together a range of state partners to collaboratively plan implementation of the forthcoming Produce Safety rule.

- Experts from FDA and NASDA are working together to develop a set of best practices for implementation of the produce rule, including education and outreach activities to both regulators and industry. A coalition of states with strong interest in leading this implementation is actively participating in the development of these practices.

- The agency also announced in September 2016 the awarding of $21.8 million to support 42 states in the implementation of the Produce Safety Rule.

- The cooperative agreement between the FDA and the states provides awardees with the resources to formulate a multi-year plan to implement a produce safety system, develop and provide education, outreach and technical assistance, prioritizing farming operations covered by the produce safety rule, and develop programs to address the specific and unique needs of their farming communities, among other goals.

Establishing the National Coordination and Regional Centers to Support Training Delivery

In January 2015, the FDA announced that it had joined with USDA’s National Institute of Food and Agriculture (NIFA) in a collaborative partnership to establish the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program, as mandated in Section 209 of FSMA.

As mandated in FSMA, this competitive grant program will provide food safety training, education, extension, outreach, and technical assistance to owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers.

https://www.fda.gov/food/guidanceregulation/fsma/ucm461513.htm updated • 1/27/2017
Grants issued through this program are funding a **National Coordination Center (NCC)** and four Regional Centers (RCs), which will be involved in both key components of training—primarily facilitating training delivery but also, in certain situations, facilitating curricula development targeted to specific audiences.

- FDA has awarded the International Food Protection Training Institute a grant of up to $600,000 over three years to establish the NCC, which will lead coordination of curriculum development and delivery to those food businesses covered by the FSMA Section 209 mandate for implementation of FSMA.

- The NCC will coordinate and support the delivery of standardized and/or alternate training curricula through the RCs.

- The RCs are charged with understanding and communicating the landscape of training opportunities available to target businesses in their region. They will identify any need to develop or tailor curricula to meet specific unmet regional needs and/or to target a specific audience. Training programs may differ to meet those needs. The NCC will facilitate communication between the RCs, the Alliances and other partnering groups about the development of such region- and/or audience-specific materials.

- The regional centers are being established with separate grant money in the Southern, Western, North Central and Northeast regions of the country. These centers will work with representatives from non-governmental and community-based organizations, as well as representatives from cooperative extension services, food hubs, local farm cooperatives and other entities that can address specific needs of the communities they serve.
  - The grants for the regional centers have been awarded. In October 2015, NIFA issued grants for the Southern and Western regional centers to the **University of Florida** and **Oregon State University**.
  - In February 2016, the FDA issued grants for the North Central and Northeast centers to **Iowa State University** and the **University of Vermont and State Agricultural College**.

### Delivering the Training

Communication between organizations involved in curriculum development and delivery will strengthen the delivery of training and will involve coordination between the Alliances, NCC, RCs, and other training providers. Other organizations have had key roles in the development and/or delivery of training, as well as training certificates.

- The three Alliances—**Produce Safety Alliance (PSA)**, **Food Safety Preventive Controls Alliance (FSPCA)**, and **Sprout Safety Alliance (SSA)**—have developed Train-the-Trainer programs to ensure that lead trainers are familiar with, and prepared to deliver, the curricula and that they understand the requirements of the FSMA rules.
  - Lead trainers—selected based on their education, work experience and training experience—who complete Train-the-Trainer programs will, in turn, deliver training to industry through an established process in which a certificate of completion of the PSA, FSPCA or SSA training is issued to participants.

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https://www.fda.gov/food/guidanceregulation/fsma/ucm461513.htm updated • 1/27/2017
• The FDA intends that funding of organizations and tribes through cooperative agreements will finance both the development of training curricula and initial delivery of that training.

  o Training delivery for industry— and possibly trainers—will be coordinated through the cooperative agreement and these organizations will interact with the NCC, RCs, Alliances, Extension and other partners to increase awareness of recognized training programs.

  o These programs may also provide a certificate of completion to food industry participants.

• An important partner in the delivery of the recognized training programs, including the standardized and alternate curricula, is the well-established network of cooperative extension offices affiliated with land-grant universities. This key group supports training efforts.

• Other key partners on training delivery include:

  o PSA’s four Regional Extension Associates, which will deliver training curricula developed by PSA.

  o NASDA, state agencies, and other state regulatory stakeholder associations, including the Association of Food and Drug Officials, the Association of Public Health Laboratories, the Association of American Feed Control Officials, and the Association of State and Territorial Health Officials. These state stakeholder groups participate in the Alliances and will help facilitate FDA-recognized industry training, as well as the training of state regulators.

  o The Joint Institute for Food Safety and Applied Nutrition (JIFSAN) for international training programs. JIFSAN is a partnership between the FDA and the University of Maryland. JIFSAN would be expected to:

    ▪ Have a leading role in overseeing the implementation of international education, outreach, and training.

    ▪ Coordinate the efforts of international organizations interested in working with FDA to provide education, outreach, and training to farms that are covered by the Produce Safety rule.

    ▪ Deliver international trainings, predominately offering the Train-the-Trainer standardized curriculum course developed by PSA.

    ▪ Establish relationships with organizations that may provide technical assistance to the foreign farming community.

  o Other training entities, such as other government agencies, cooperative extension, universities, trade associations, nonprofit and community-based organizations, and consultants, who will deliver domestically and internationally both the standardized and alternate curricula recognized by FDA.

• The NCC will coordinate training delivery to food businesses covered by the FSMA Section 209 mandate through the RCs and will ensure the involvement of partners during the development of and dissemination of training.

  o The RCs will coordinate and facilitate the delivery of curricula.

  o The RCs may also coordinate with multiple training entities to deliver the curricula in the most effective way for a target audience.
FSMA Collaborative Training Forum

The FDA intends to establish an informal FSMA Collaborative Training Forum, co-chaired by the FDA and USDA, to provide an opportunity for dialogue between the agencies, centers, associations and others involved in this training. The forum’s first meeting is tentatively planned for January 2017.

- It will be a chance for representatives of these groups to come together, share information about their programs, provide updates about the work, and discuss issues of common concern. The purpose is not to come to a consensus on issues but to have an open dialogue about them and, to the greatest extent possible, eliminate duplication and maximize the use of limited resources.

- Participants will represent the FDA, USDA, the Alliances, the NCC, JIFSAN, NASDA, and the organizations who have received cooperative agreements. Others may be invited to join where appropriate.

- It is anticipated that meetings will be held on a quarterly basis.

Conclusion

FDA is on a path to working with public and private partners globally to ensure that training programs meet the needs of those who must comply with the new FSMA standards, no matter their size, nature or location.

It will take time and effort to make this work, and to get it right. FDA is committed to making sure that everyone involved in the food supply chain knows what training and education resources are available, and how to gain access to them.

Glossary of Terms Often Used in FSMA Training Documents

Standardized training curriculum: A structured program in which the training materials will be recognized by the FDA as meeting the training standards and requirements in the Produce Safety rule and the Preventive Controls rules. The three FDA-funded Alliances (Produce Safety, Food Safety Preventive Controls, and Sprout Safety) have developed model, standardized curricula designed to meet the needs of, and be used by, the majority of stakeholders who must comply with the FSMA rules.

Alternate curriculum: FDA-recognized training programs to be developed through cooperative agreements. The agreements currently planned will support curricula development and dissemination among local food producers and tribes. The agency plans to provide additional information regarding how training programs developed by other entities (including universities, trade associations, and non-profit organizations) will be evaluated.

Train-the-Trainer: Programs offered to those interested in becoming trainers and providing training for others on the FSMA regulations. The lead trainers would be schooled in foundational food safety principles, the applicable FSMA regulations, the content of the training curriculum and how to deliver it, conducting working group exercises (as appropriate), and the principles of adult education. These are being developed by the Alliances and may also be part of alternative training programs.

Training delivery: The dissemination of training curricula. (The approach may vary as appropriate for the target audience.)
Regional needs: Regions may have unique needs based on target audiences and the nature of their food operations. This could include environmental differences, cultural considerations, the type of product, and marketing strategies. Examples include dry-climate farming practices, organic products, and direct-marketing channels.

Cooperative agreements: An FDA cooperative agreement is a grant funding mechanism that involves significant FDA participation during the performance of the work. These usually involve FDA-funded partnerships with entities in the public or private sector, or both, that are designed, in this case, to lay the groundwork for FSMA implementation.

Local food production: Food marketing channels that focus on providing food to a community or region directly or through intermediated markets. The farms and food enterprises that utilize these market channels include diversified, sustainable, organic, and identity-preserved agricultural operations; owner-operated and family farms; beginning and socially disadvantaged farmers; value-added farm businesses and small-scale processors; and direct and intermediated supply chain participants.

Setting the Stage for FSMA Implementation

The following organizations working in partnership with FDA have important roles in providing training to the food industry in preparation for implementation of FSMA:

Produce Safety Alliance (PSA): This Alliance was created by FDA and USDA, in cooperation with Cornell University, to develop a standardized training and education program to increase produce safety knowledge and prepare the produce industry and associated groups for FSMA implementation.

Food Safety Preventive Controls Alliance (FSPCA): This Alliance was created by a grant from FDA to the Illinois Institute of Technology’s Institute for Food Safety and Health, to develop a standardized training and education program that will help industry comply with the Preventive Controls rules for human and animal food for animals under FSMA.

Sprout Safety Alliance (SSA): This Alliance was created by FDA, in cooperation with the Illinois Institute of Technology’s Institute for Food Safety and Health, to develop a standardized training and education program and help sprout producers identify and implement best practices in the safe production of sprouts and prepare for FSMA implementation.

National Institute of Food and Agriculture (NIFA): Part of the U.S. Department of Agriculture, NIFA is partnering with the FDA to provide grants to fund food safety training, education, extension, outreach, and technical assistance to owners and operators of farms; small food processors; and small fruit and vegetable merchant wholesalers.

National Coordination Center (NCC): This center, funded by the FDA, will lead the coordination of training delivery, outreach, education and technical assistance to reach small and medium-size farms, beginning and socially disadvantaged farmers, small processors, and small fruit and vegetable merchant wholesalers.
Regional Centers (RCs): These regional centers will work with the NCC to increase the understanding and adoption of established food safety standards, guidance, and protocols. They will identify region and audience-specific training, education, outreach and technical assistance needs and deliver training to food producers covered by the FSMA Section 209 mandate, in addition to ensuring the availability of informed trainers.

International Food Protection Training Institute (IFPTI): Established in 2009, IFPTI is a public-private partnership that addresses public health needs and collaborates with industry, federal, state and international governments, and other organizations. IFPTI, which builds training and certification systems for food safety professionals, has been awarded the contract to establish the NCC described above.

Cooperative Extension and Land-Grant Universities: More than 100 land-grant colleges and universities have extension programs through which they bring science-based information to agricultural producers and small business owners, among others. Members of the Cooperative Extension System will have key roles in the delivery of FSMA training.

Cooperative Agreement Partners: The recipients of FDA funding to support curricula training and delivery to local food producers, including sustainable and organic farms, and tribes.

National Association of State Departments of Agriculture (NASDA): This association of state officials is in partnership with the FDA to collaboratively plan implementation of the produce safety rule under FSMA. NASDA will help facilitate industry training and will also play a role in the delivery of training to state regulators.

Additional Organizations: These state stakeholder organizations will also have roles in facilitating regulatory and industry training:

• Association of Food and Drug Officials, whose members include state and local officials involved in critical food safety issues;

• Association of Public Health Laboratories, which works to strengthen laboratories serving public health; and

• Association of American Feed Control Officials, whose members include state, local and federal officials involved in the safety of animal feed, and

• Association of State and Territorial Health Officials, which represents public health agencies and professionals.

Joint Institute for Food Safety and Applied Nutrition (JIFSAN): This partnership between the FDA and the University of Maryland strives to increase global knowledge of effective food safety practices.

FSMA Collaborative Training Forum: Co-chaired by the FDA and USDA, this forum will facilitate communication and coordination between the groups involved in FSMA training and give the groups an opportunity to share information about their programs and address common concerns. In addition to the two agencies, represented groups will include the Alliances, the NCC, JIFSAN, NASDA, and the organizations that have received cooperative agreements with FDA. Other stakeholder groups may also be included.
The U.S. Department of Agriculture’s Agricultural Marketing Service (AMS) provides the agriculture industry with valuable tools and services that help create marketing opportunities. AMS ensures the quality and availability of wholesome food and agricultural products for consumers in domestic and export markets.

American agriculture is extremely diverse and includes urban and rural operations of every size. It supports 1 in 12 U.S. jobs and provides safe, affordable food to consumers across the globe. The last 4 years represent the strongest in U.S. history, with U.S. agricultural product exports exceeding $478 billion.

Nearly 4,000 AMS professionals work every day to support agriculture, from individual farmers to international businesses, helping American agriculture remain competitive in a global marketplace. AMS’ services and grant investments also create opportunities by supporting economic development in small towns and rural communities that stand as the backbone of American values.

Marketing Agreements and Orders
Marketing agreements and orders are initiated by industry to help provide stable markets for dairy products, fruits, vegetables, and specialty crops. They help maintain the quality of produce being marketed; standardize packages/containers; and authorize advertising, research, and market development. Each order and agreement is tailored to the needs of local market conditions for producing and selling.

Commodity Procurement
AMS purchases a variety of food products in support of USDA’s National School Lunch Program and other food assistance programs. These purchases also help to stabilize prices in agricultural commodity markets. The purchases include around 250 different items, such as fresh fruits, vegetables, beef, and poultry. Each year, AMS issues over 2,000 contracts to purchase about 1.5 billion pounds of food, with about half of the contracts supporting U.S. small businesses.

AMS awards more than $60 million each year through its Organic Cost Share programs, the Farmers Market Promotion Program, Specialty Crop Block Grant Program, and Federal-State Marketing Improvement Program.

www.ams.usda.gov
Quality Standards, Grading, Certification, Auditing, and Inspection

AMS quality standards, grading, certification, auditing, and inspection are voluntary tools and services that industry can use to help promote and communicate quality and wholesomeness to consumers. These services assist businesses in differentiating themselves from their competition. Examples of USDA grades include USDA Prime, USDA Grade A, and U.S. No. 1. Annually, AMS grades, audits, certifies and/or inspects over $150 billion worth of agricultural products, ensuring the quality of domestic goods and helping American farms and businesses export goods to over 100 different countries.

USDA Market News

For 100 years, AMS has provided free, unbiased price and sales information to assist in the marketing and distribution of farm commodities. Each year, Market News issues thousands of reports providing the industry with key wholesale, retail, and shipping data. The reports give farmers, producers, and other agricultural businesses the information they need to evaluate market conditions, identify trends, make purchasing decisions, monitor price patterns, evaluate transportation equipment needs, and accurately assess movement. The information captures data for cotton, fruits, vegetables and specialty crops, livestock, meats, poultry, eggs, grain and hay, milk and dairy, and tobacco.

National Organic Program

Organic certification verifies that farms and handling facilities comply with the USDA organic regulations and allow farmers and businesses to sell, label, and represent their products as organic. The program protects the integrity of organic products through auditing certifiers, investigating complaints, and enforcement. The program also helps American farmers and processors tap into the growing international organic market through trade partnerships with several countries. Today, the industry encompasses over 17,000 organic businesses and has grown to $35 billion in annual U.S. retail sales.

Plant Variety Protection (PVP)

The PVP office grants certificates of intellectual property protection (similar to patents) to developers of new varieties of plants which are reproduced sexually by seed or are tuber propagated. This protection enables a breeder to market the variety exclusively for 20 years (25 years for trees and vines), which creates an incentive for the development of new varieties. The PVP office has issued more than 8,700 certificates of protection since 1970.

Farmers Markets and Local Food

AMS works to improve marketing opportunities for producers through the combination of research, technical services, and grants. Each year, AMS helps hundreds of agricultural food businesses, including farmers markets, food hubs, wholesale markets, retailers, State agencies, community planning organizations, and other agri-food focused groups, enhance their local food marketing efforts. Through the National Farmers Market Directory, AMS connects consumers to producers at over 8,000 farmers markets, providing location and operation information.

Research and Promotion

Research and Promotion programs, authorized by Congress, are industry-driven and industry-funded. AMS oversees over 20 research and promotion boards that empower farmers, ranchers, and agricultural businesses. The programs establish a framework to pool resources to develop new markets, strengthen existing markets, and conduct important research and promotion activities. AMS provides oversight, ensuring fiscal responsibility, program efficiency, and fair treatment of participating stakeholders.

Seed Regulatory and Testing Services

AMS helps support the $12 billion U.S. seed industry by educating and training analysts from State governments, industry organizations, and private companies on Federal or State seed laws, changes in industry rules, and both common and advanced testing and, identification techniques with the goal of promoting uniformity in seed testing throughout the United States. This support helps seed companies remain competitive both domestically and abroad.

Laboratory Approval and Testing Services

AMS National Science Laboratories (NSL) is a full-service testing facility that provides analyses on raw and processed agricultural commodities. NSL provides chemical, microbiological, bimolecular, and physical testing services in support of grading, commodity purchases, research, and domestic and export marketing. Also, AMS administers laboratory approval programs to enhance market access for U.S. commodities, domestically and internationally. This service verifies that products meet various customers’ or countries’ testing requirements.

Perishable Agricultural Commodities Act (PACA)

PACA was enacted at the request of the fruit and vegetable industry to promote fair trade in the industry. The PACA protects businesses dealing in fresh and frozen fruits and vegetables by establishing and enforcing a code of fair business practices and by helping companies resolve business disputes.

Front page photos: Girl picking tomatoes and hillside with dairy cows courtesy Gunnar Magnusson.

Photos on this page: cotton field courtesy Kimberly Vardeman; San Francisco Farmers Market courtesy Gary Yost

www.ams.usda.gov

USDA is an equal opportunity employer and provider.
GOOD AGRICULTURAL PRACTICES (GAPs)

The USDA Agricultural Marketing Service’s Specialty Crops Inspection (SCI) Division is a team of professionals who provide quality assurance reviews, inspections, and food safety audits, and develop national standards for both fresh and processed fruits and vegetables, and related products, to support the global specialty crops market.

WHAT ARE GAPs

GAPs are principles and practices applied at the farm level to reduce the risk of microbial contamination of fruits and vegetables during production, harvest, and packaging. The principles are based on the Food and Drug Administration’s “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.” SCI’s GAPs audits verify that your operation follows and maintains the processes and practices you have put in place to minimize potential food safety risks. GAPs audits cover:

- Farm/Greenhouse
- Harvest
- Packing house and cooler/cold storage
- Storage and distribution
- Transportation
- Traceability

SCI — YOUR AUDIT PROVIDER

A few reasons to choose SCI as your GAPs audit provider:

- Nationwide team of experts that provides fast, cost-effective services.
- Proven record of buyer acceptance of our customers’ product.
- Effective way to communicate to your customers your commitment to food safety and adherence to best practices.
- USDA auditors receive robust training, and are constantly evaluated to ensure their performance.
- Ongoing verification of your continued compliance and performance.

BENEFITS OF GAPs CERTIFICATION

- Broadens your market opportunities by satisfying buyers’ demands for suppliers to be GAPs certified.
- Reduces your risk of not complying with national and international regulations, standards, and guidelines.
- Reduces the risk of your product introducing foodborne illnesses into the supply chain.

FOR MORE INFORMATION

USDA Specialty Crops Inspection Division
1400 Independence Avenue, SW
Room 1536-S, Stop 0240
Washington, DC 20250-0240

Email: SCI@ams.usda.gov
Phone: 202-720-5870
www.ams.usda.gov
GOOD AGRICULTURAL PRACTICES - HARMONIZED GAPs

WHAT IS HARMONIZED GAPs

Developed under the leadership of the United Fresh Food Safety & Technology Council to drive harmonization of several GAP standards, and to reduce audit fatigue by suppliers, and allow operations to focus their food safety resources on achieving food safety.

- The Produce GAPs Harmonization Initiative, was an all-industry effort including growers, shippers, produce buyers, government agencies, audit organizations and other stakeholders.
- The result is Good Agricultural Practices standards and audit checklists for pre and post-harvest operations, applicable to all fresh produce commodities, and all sizes of on-farm operations and all regions in the U.S.

THE BENEFITS OF HARMONIZED GAPs

- Brings together many audit schemes
- Developed and recognized by major institutional buyers and sellers and minimizes “audit creep”
- Are risk-based, science based, attainable, auditable and verifiable
- Takes into account regional food safety needs
- Not commodity specific - allowing for adaptability to generally all commodity groups
- Harmonized audits reduce the number of multiple audits for the same operations.
- Evaluates and measures a Grower Risk Assessment
- Includes an evaluation and assessment of worker health and hygiene
- USDA acceptance criteria includes a section for “Global Markets Program” - an added step to meet international requirements. Including:
  - Farm supplies are traced and reviewed
  - Chemical storage and chemical origination
  - Food Defense
Along with a number of programs and services that facilitate marketing, the United States Department of Agriculture’s (USDA) Agricultural Marketing Service (AMS) helps create opportunities for growers and buyers through its Good Agricultural Practices (GAP) and Good Handling Practices (GHP) Audit Programs, which verify that operations follow industry-recognized food safety practices and recommendations from the Food and Drug Administration (FDA).

After 3 years of field testing, AMS is launching GroupGAP, a new food safety certification option that will increase opportunities for the entire industry to supply and buy GAP-certified produce.

**Benefits to Buyers and Retailers**

The GroupGAP Program is an innovative solution that helps retailers and buyers meet the increasing consumer demand for local food while maintaining strong food safety standards.

- USDA-AMS certifies that the grower groups are following industry-recognized food safety practices.
- More small and mid-sized farmers can demonstrate that they have met retailer food safety requirements for “buy local” programs.
- These new suppliers help stores build an inventory of local food from growers who previously couldn’t access mainstream retail markets.
- GroupGAP efficiencies allow buyers and retailers to broaden their base of suppliers, so they are more resilient in the face of supply challenges or disruptions.
- Diverse product offerings are available from a group of growers rather than a single grower, and
- Importantly, GroupGAP will comply with upcoming FDA requirements under the Food Safety Modernization Act.

**Paving a New Path for Small Growers To Reach the Retail Market**

At the same time that retailers need assurances that vendors are complying with food safety guidelines, demand for local food is expanding beyond farmers markets into grocery stores, restaurants, schools, and other institutions. As more and more retailers require these types of audits, demand for AMS services has increased, with the agency performing over 3,800 GAP/GHP audits in 2014.
Many small and mid-sized farmers currently face challenges paying for the food safety certification needed to participate in these larger markets. The GroupGAP Audit Program makes it easier for growers and cooperatives, particularly small growers, to afford GAP certification. Under the program, an entire group of growers can be certified, potentially saving money and time by leveraging economies of scale in the marketplace. GroupGAP helps smaller operations comply with food safety requirements. Members of a group can:

- Fully leverage existing resources and share certification costs.
- Develop and implement their own quality management systems and food safety programs.
- Reduce individual documentation and maintenance requirements, and
- Maintain compliance via internal audits by a single, shared USDA-trained food safety manager, with verification by USDA-licensed auditors.

AMS is working with its long-time partner, the Wallace Center at Winrock International, to implement GroupGAP. Moving forward, GroupGAP will partner with State extension agencies and other organizations that support small and mid-sized growers through outreach to buyers, retailers, and food hubs.

Visit www.ams.usda.gov/gapghp for information about GroupGAP certification. You can also contact the Specialty Crops Inspection Division at: (202) 720-5870.

Visit www.ams.usda.gov/services/local-regional for information about AMS’ support of the local food sector. You can also contact the Transportation and Marketing Program at: (202) 720-8326.
<table>
<thead>
<tr>
<th>Services</th>
<th>Contact</th>
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<tbody>
<tr>
<td>USDA AMS Specialty Crops Program (SCP) provides customized solutions to enhance the competitive, efficient, and transparent marketing of all specialty crops. We offer a full range of quality assurance and audit verification services providing our clients and their customers with confidence that products are grown, processed, and distributed under the most favorable conditions. Our range of services include:</td>
<td></td>
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<tr>
<td>- Commodity Standards Development</td>
<td>Sonia Jimenez, Deputy Administrator, (202) 720-4722, <a href="mailto:sonia.jimenez@ams.usda.gov">sonia.jimenez@ams.usda.gov</a></td>
</tr>
<tr>
<td>- Grading, Inspection, Certification and Audit-based Verification Services</td>
<td>Melissa Bailey, Associate Deputy Administrator, (202) 720-8577, <a href="mailto:melissa.baily@ams.usda.gov">melissa.baily@ams.usda.gov</a></td>
</tr>
<tr>
<td>- Domestic and International Commodity Market News</td>
<td>Christopher Purdy, Associate Deputy Administrator, (202) 720-3203, <a href="mailto:christopher.purdy@ams.usda.gov">christopher.purdy@ams.usda.gov</a></td>
</tr>
<tr>
<td>- Commodity and other technical training programs</td>
<td>Legane Skelton, Liaison to FDA on FSMA, (202) 720-4982, <a href="mailto:legane.skelton@ams.usda.gov">legane.skelton@ams.usda.gov</a></td>
</tr>
<tr>
<td>- Marketing Order and Agreements administration</td>
<td>Jeffrey Davis, Business Development, (202) 260-5519, <a href="mailto:jeffrey.davis4@ams.usda.gov">jeffrey.davis4@ams.usda.gov</a></td>
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<tr>
<td>- Economic Analysis</td>
<td>Leanne Skelton, Liaison to FDA on FSMA, (202) 720-4982, <a href="mailto:leanne.skelton@ams.usda.gov">leanne.skelton@ams.usda.gov</a></td>
</tr>
<tr>
<td>- Perishable Agricultural Commodities Act (PACA) enforcement</td>
<td>Jeffrey Davis, Business Development, (202) 260-5519, <a href="mailto:jeffrey.davis4@ams.usda.gov">jeffrey.davis4@ams.usda.gov</a></td>
</tr>
<tr>
<td>- Fresh and processed produce quality/condition inspection and grading services.</td>
<td>Lorenzo Tribbett, Division Director, (202) 720-2011, <a href="mailto:lorento.tribbett@ams.usda.gov">lorento.tribbett@ams.usda.gov</a></td>
</tr>
<tr>
<td>- Fresh and processed produce quality/condition inspection and grading services.</td>
<td>Randle Macon, Associate Director, (202) 720-4593, <a href="mailto:randle.macon@ams.usda.gov">randle.macon@ams.usda.gov</a></td>
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<tr>
<td>- Audit-based solutions to enhance food safety practices, including Good Agricultural Practices (GAP), Good Handling Practices (GHP), and Good Manufacturing Practices (GMP) for processors and fresh cut operations.</td>
<td>Nathaniel &quot;Chip&quot; Taylor, Associate Director, (202) 720-2333, <a href="mailto:nathaniel.taylor@ams.usda.gov">nathaniel.taylor@ams.usda.gov</a></td>
</tr>
<tr>
<td>- Quality Monitoring Program (QMP) to verify supplier contract compliance.</td>
<td>Lorenzo Tribbett, Division Director, (202) 720-2011, <a href="mailto:lorento.tribbett@ams.usda.gov">lorento.tribbett@ams.usda.gov</a></td>
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<tr>
<td>- The Qualified through Verification (QTV) program to assist food processors enhance their Hazard Analysis Critical Control Point (HACCP) plan to ensure its continual effectiveness through unannounced audits.</td>
<td>Lorenzo Tribbett, Division Director, (202) 720-2011, <a href="mailto:lorento.tribbett@ams.usda.gov">lorento.tribbett@ams.usda.gov</a></td>
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<tr>
<td>- Market News Division</td>
<td>Terry Long, Division Director, (202) 720-2175, <a href="mailto:terry.long@ams.usda.gov">terry.long@ams.usda.gov</a></td>
</tr>
<tr>
<td>- Collects and disseminates detailed information on market conditions for hundreds of agricultural commodities at major domestic and international wholesale markets.</td>
<td>Terry Long, Division Director, (202) 720-2175, <a href="mailto:terry.long@ams.usda.gov">terry.long@ams.usda.gov</a></td>
</tr>
<tr>
<td>- Price and movement data and related services.</td>
<td>John Okoniewski, Deputy Director, (202) 720-9932, <a href="mailto:john.okoniewski@ams.usda.gov">john.okoniewski@ams.usda.gov</a></td>
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<tr>
<td>Program and Division</td>
<td>Services</td>
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<tr>
<td><strong>Perishable Agricultural Commodities Act (PACA) Division</strong></td>
<td>PACA proactively works for the fruit and vegetable industry promoting interstate and foreign commerce through dispute resolution, mediation, arbitration, licensing, and outreach programs facilitating fair trade practices. The PACA enforces federal regulations outside the civil court system by upholding contract requirements, mandating full and prompt payment, by removing unscrupulous individuals from the trade when needed, and providing advice on trust protection.</td>
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<tr>
<td><strong>Marketing Order and Agreement Division</strong></td>
<td>MOAD helps fruit, vegetable and specialty crop producers and handlers achieve marketing success through industry driven programs. Marketing orders and agreements improve returns to producers by:  * Targeting domestic and foreign markets with industry funded promotion, advertising, publicity, production and marketing research, and market information programs;  * Maintaining a consistently high quality of produce on the market;  * Standardizing packages and containers;  * Regulating the flow of product to market.</td>
</tr>
<tr>
<td><strong>Promotion and Economics Division</strong></td>
<td>Administration of nationwide research and promotion programs for the fresh fruit and vegetable industry. Authorized by federal legislation, Research and Promotion Programs are designed to strengthen the position of the industry in the marketplace and to maintain and expand domestic and foreign markets. The programs are all fully funded by industry assessments. Analysis of economic information and programs related to federal food purchase and other programs.</td>
</tr>
<tr>
<td><strong>AMS Commodity Procurement Division</strong></td>
<td>Purchase of fresh and processed products from approved vendors for school lunch and other government food programs.</td>
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The U.S. Department of Agriculture’s Natural Resources Conservation Service (NRCS) partners with farmers to support conservation on their farms. Both conservation of natural resources and assuring a safe food supply are essential for produce farmers. NRCS Conservation Planners identify and address resource concerns related to soil, water, air, plants, animals, and energy, as well as social and economic factors.

Many NRCS conservation practices address pathogen movement in the environment. For example, by slowing and filtering runoff, filter strips and riparian vegetation protect surface water from pathogen contamination. Other conservation practices assist farmers in managing animal waste or wildlife movement patterns. NRCS Conservation Planners recognize that their central mission of supporting farmers’ conservation stewardship may intersect with food safety management activities.

When a farmer expresses concerns about the design, installation or management of a conservation practice for any reason, NRCS staff strive to include farmers’ considerations of complex production, market and regulatory factors in the planning process, and seek ways to best support conservation while allowing farmers to make other management decisions necessary in their farm and ranching operations.

Once a conservation plan is completed, NRCS Conservation Practice Standards (CPS) and other supporting documents are used to ensure that the best possible science and technology are used to guide site-specific implementation of a conservation plan. Typically, a conservation plan includes a suite of practices individually tailored to the unique needs of the setting, and the landowner’s interest and ability to implement the plan.

NRCS Certified Conservation Planners provide producers with technical assistance for their farm and help to determine if they are eligible for NRCS financial assistance to address their conservation goals. A conservation plan, developed through the planning process may qualify the producer for various Farm Bill conservation financial assistance programs.
Resources to co-manage conservation and food safety

Research scientists and extension specialists, working together with food safety and conservation professionals, have created a series of educational and training resources to support produce farmers as they make food safety sensitive conservation management decisions. These resources can be found here: http://ucfoodsafety.ucdavis.edu/Preharvest/Co-Management_of_Food_Safety_and_Sustainability/

These include:

- An on-line training course for food safety professionals with USDA-Agricultural Marketing Service (AMS) Good Agricultural Practices (GAPs) auditor training CEUs offered;
- A series of resource sheets for food safety auditors that describe conservation practices commonly used in agriculture’s production environment; and
- Educational materials for produce growers, buyers and food safety professionals.

General information about pathogens available from NRCS

Nutrient Management Technical Note No. 9  March 2012
Introduction to Waterborne Pathogens in Agricultural Watersheds


Information from FDA about Produce Safety Rule

Information about the Produce Safety Rule can be found at the U.S. Food and Drug Administration (FDA) website: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

A Printer Friendly Fact Sheet on the main provisions of the rule is available here: http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472887.pdf

For detailed information about NRCS services in your area, please contact your local Field Office.
http://www.nrcs.usda.gov/wps/portal/nrcs/main/national/about/