CHAPTER 03-FOODBORNE MICROBIOLOGICAL HAZARDS

SUBJECT:	**Produce Safety Inspections**
IMPLEMENTATION DATE:	5/22/2023
Product Codes:	**USE APPROPRIATE PRODUCT CODES**
Product/Assignment Codes:	**03080** (PRODUCE SAFETY NETWORK PSN ACTIVITIES) **03G080** (VOLUNTARY STATE PRODUCE SAFETY INSPECTIONS)

FIELD REPORTING REQUIREMENTS:

FDA INVESTIGATORS

Complete inspection reporting, including the Produce Safety Inspection Protocol (PS IP) and Produce Farm Inspection Report (PFIR) in eNSpect per the Investigations Operations Manual (IOM), Subchapter 5.11 *Reporting*. Citations are available in eNSpect and must be used for written observations and verbal discussion items. Corrective action statuses must be documented in the Observation and Corrective Action Reporting (OCAR) system within eNSpect. See Part **III.4** for additional instructions.

STATE INSPECTORS

Complete a Produce Farm Inspection Report Summary (PFIRS) (see **Attachment B**) or state equivalent inspection report (Path C), and, when necessary, include additional material to document observations. See Part **III.4.** for additional instructions.

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Change History

Item	Change	Date
	• Updated Format to reflect CP Changes • Remove references to ORA, change to OII • Remove references to CFSAN, change to HFP • Remove links to guidance for COVID-19 • Changed references to FSDX from ORAPP	09/24/2025

PART I – BACKGROUND

1. History

The Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA), amended the Federal Food, Drug, and Cosmetic (FD&C) Act to add Section 419, granting FDA the authority to promulgate regulations to establish science-based minimum standards for the safe production and harvesting of fruits and vegetables. FDA established 21 CFR part 112 "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," also known as the Produce Safety Rule (PSR), to provide those standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

The PSR sets forth requirements for procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that produce is not adulterated on account of such hazards.

The FDA's goal is to minimize foodborne illness associated with the consumption of produce. The FSMA explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve our public health goals. Under this compliance program (CP), inspections will be conducted by FDA and states to monitor and assess the compliance of produce farms with the PSR, FD&C Act, and state equivalent laws and regulations. States have partnered with the FDA to implement the PSR under the FDA-State Produce Implementation Cooperative Agreement Program (Produce CAP). This collaborative effort between FDA and states will ensure that inspection regulatory programs support an integrated food safety system that focuses on quality and consistency.

During farm inspections, the FDA and states will "educate before and while we regulate" by identifying opportunities to educate farmers about the PSR, the supporting science, and the regulatory process before, during, and after inspections. The FDA and states work collaboratively with farmers to achieve prompt and sustainable compliance and will assist farmers with implementing preventive measures by sharing information and providing resources to farmers such as guidance documents and fact sheets. The FDA and states also observe farm practices and gather information related to growing, harvesting, packing, and holding produce to enhance the Agency's understanding and ability to provide targeted outreach and to help prevent future produce-related foodborne illness outbreaks.

2. Summary of Requirements

This CP covers inspections of all farms subject to the PSR, except sprout operations subject to Subpart M of the regulation and those noted in Part I.4. of this CP as subject to enforcement discretion. As mentioned above, inspections will be conducted by the FDA OII DPS or other FDA staff, and State partners conducting produce safety inspections under the Produce CAP. The Produce CAP establishes two paths for states with regulatory programs – Path B and Path C. Path

B state grantees conduct inspections under FDA authority and are commissioned and credentialed by FDA to conduct produce regulatory activities. Path B states must follow the instructions in this CP. Path C state grantees conduct produce regulatory activities under their own state authority. However, Path C state grantees are strongly encouraged to review this CP and use the instructions within this CP to inform their processes for prioritizing, planning, and conducting PSR inspections, intra-agency coordination, and to determine the need for compliance and enforcement action. The review and use of this CP will support national consistency and to meet other requirements of the Funding Opportunity Announcement (FOA).

The FDA webpage for the FSMA Final Rule on Produce Safety includes links related to produce safety, including the final PSR. In addition, it is recommended that all investigators/inspectors review additional FSMA guidance documents and other information on the main FSMA guidance webpage and within resources in **Part VI.1.** of this CP. A basic summary of the PSR subparts and corresponding guidance documents are outlined below. See **Part III.1.A.(4)** to review the inspection approach for produce farm inspections under the PSR.

A. Subpart A – General Provisions

Subpart A establishes the scope of the regulation, provides definitions applicable to this regulation, and identifies the operations and produce subject to the requirements of the regulation. To assist with determining if a farm or produce is covered or excluded, review the *Standards for Produce Safety Coverage and Exemptions/Exclusions Flowchart* and FDA Factsheet: "Rarely Consumed Raw" Produce.

If the farm grows, harvests, packs, or holds covered produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., a kill step), the produce may be eligible for an exemption from the requirements of the PSR (see 21 CFR 112.2(b) for conditions and record requirements). Note: currently, certain record keeping requirements related to written assurances are subject to enforcement discretion; see Part 4, Compliance Dates and Enforcement Discretion).

The regulation includes monetary values, adjusted for inflation, as the basis for a farm to determine if it is subject to the requirements of this part or eligible for a qualified exemption. For more information see the PSR inflation adjusted cut-offs.

The requirements for qualified exempt farms are included under the PSR within 21 CFR 112.4-112.7. Qualified exempt farms are subject to certain requirements under the PSR. For additional information and recommendations on how a farm can comply with Subpart A, see PSR Draft Guidance, *At a Glance: Key Points in Chapter 1*.

B. Subpart B – General Requirements

Subpart B establishes the general requirements applicable to persons who are subject to the PSR. Section 112.11 specifies that they must take measures to prevent the introduction of hazards into covered produce and ensure that produce is not adulterated under Section 402 of

the FD&C Act. This subpart also specifies what is required to establish alternatives to the requirements of Subpart E, Agricultural Water (see below).

C. Subpart C – Personnel Qualifications and Training

Subpart C establishes minimum personnel qualifications and training requirements for personnel who handle (contact) covered produce or food contact surfaces. It includes additional requirements for persons who conduct harvest activities for covered produce and explains that at least one supervisor or responsible party for the farm must have successfully completed produce safety training at least equivalent to that received under a standardized curriculum recognized as adequate by FDA. Currently, FDA recognizes the Produce Safety Alliance (PSA) Grower Training as an adequate standardized training curriculum under 21 CFR 112.22(c). FDA recommendations on the factors that covered farms should consider if selecting an alternative curriculum training to meet 21 CFR 112.22 (c) are available through draft guidance "Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Produce Safety Rule: Guidance for Industry."

For additional information and recommendations on how a farm can comply with Subpart C, see PSR Draft Guidance, *At a Glance: Key Points in Chapter 2* and Factsheet: *Required Training for Covered Farms*.

D. Subpart D – Health and Hygiene

Subpart D establishes minimum measures and practices farms must implement for personnel, supervisors, and visitors to prevent contamination of covered produce and food contact surfaces. For additional information and recommendations on how a farm can comply with Subpart D, see PSR Draft Guidance, *At a Glance: Key Points in Chapter 3*.

E. Subpart E – Agricultural Water

The summary of requirements for Subpart E can be found within Attachment C of this CP.

F. Subpart F – Biological Soil Amendments of Animal Origin (BSAAO) and Human Waste

Subpart F establishes required practices to reduce the risk of produce contamination from the use of certain soil amendments that consist of, or contain, materials of animal origin, such as manure or non-fecal animal byproducts. Topics in this subpart include:

- Requirements for handling, conveying, and storing BSAAOs
- Prohibitions regarding use of human waste
- Treatment processes and microbial standards that apply to those processes
- Application requirements for BSAAOs
- Records requirements

For additional information and recommendations on how a farm can comply with Subpart F, see PSR Draft Guidance, *At a Glance: Key Points in Chapter 4*.

G. Subpart I – Domestic and Wild Animals

Subpart I establishes minimum standards to assess relevant areas on the farm for potential contamination and to evaluate significant evidence of potential contamination. Topics covered in this subpart include:

- Requirements necessary to reduce the likelihood that working animals, grazing animals, or general animal intrusions will contaminate covered produce
- Necessary action a farm must take if significant evidence of potential contamination is found
- Clarification that the rule does not require farms to take measures to exclude animals or to destroy animal habitats to protect covered produce

For additional information and recommendations on how a farm can comply with Subpart I, see PSR Draft Guidance, *At a Glance: Key Points in Chapter 5*.

H. Subpart K – Growing, Harvesting, Packing, and Holding Activities

Subpart K establishes standards for growing, harvesting, packing, and holding activities. Topics covered in Subpart K include:

- Measures farms must take if they grow, harvest, pack, or hold both covered produce and produce that is not covered (see §112.2) including the transition points between those produce items and separation of covered and not covered produce
- Identifying and not harvesting contaminated covered produce
- Handling harvested covered produce
- Dropped covered produce
- Packaging covered produce
- Food-packing (including food packaging) material

For additional information and recommendations on how a farm can comply with Subpart K, see PSR Draft Guidance, *At a Glance: Key Points in Chapter 6* and *FDA Factsheet: Produce Safety Rule Fact Sheet on Dropped Covered Produce*.

I. Subpart L – Equipment, Tools, Buildings, and Sanitation

Subpart L establishes requirements for preventing equipment, tools, buildings, and inadequate sanitation from contaminating covered produce. This part includes requirements for toilet and hand-washing facilities; requirements related to buildings, including pest control; and, the appropriate storage, maintenance, and cleaning of equipment and tools.

For additional information and recommendations on how a farm can comply with Subpart L, see PSR Draft Guidance, *At a Glance: Key Points in Chapter 7*.

J. Subpart M – Sprouts

Subpart M includes the sprout-specific requirements which apply to growing, harvesting, packing, and holding all sprouts, except sprouts grown in soil or substrate harvested without their roots. Inspections under this CP **will not include inspections of sprout operations subject to Subpart M** of the PSR.

When a CP is implemented for sprout firm inspections, the Produce Safety Inspections CP will be updated. Under the Produce Safety Inspections CP, investigators/inspectors should plan to inspect covered produce activities at farms that also handle sprouts in coordination with the OII Office of Human Food Directorate (OHFI) Division, as appropriate. If it is determined during the inspection that the covered produce farm also handles sprouts, see instructions within Table 2 of this CP.

K. Subpart N – Analytical Methods

Subpart N includes requirements for methods of analysis for testing the quality of agricultural water, as well as analytical requirements that apply only to sprouts. In light of the agricultural water compliance dates and inspection approach (see Attachment C), Subpart N applies to farms that are subject to the requirements of Subpart E for harvest and postharvest agricultural water.

Information on analytical methods: Equivalent Testing Methodology for Agricultural Water | FDA

L. Subpart O – Records

Subpart O specifies the general requirements for records, including those required for training, agricultural water, exemptions, cleaning, and sanitizing. This subpart also includes requirements describing how records must be established and maintained, including record retention, storage, and verification, as well as official review and public disclosure.

For additional information and recommendations on how a farm can comply with Subpart O, see PSR Draft Guidance, *At a Glance: Key Points in Chapter 8* and *Chapter 8: Records Chart*.

M. Subpart P – Variances

Subpart P describes the process for submitting a variance from a provision of the PSR. The PSR permits states, federally recognized 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 from one or more of the requirements of the PSR when the variance is

necessary in light of local growing conditions. The variance requests 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. FDA intends to share information on approved variances, when applicable.

Note: Variance petitions for the PSR must be submitted following the procedures outlined in 21 CFR 10.30 – Citizen Petitions. For additional information and recommendations on how a farm can comply with Subpart P, see PSR Draft Guidance, *At a Glance: Key Points in Chapter 9*.

N. Subpart Q – Compliance and Enforcement

Subpart Q reiterates the FD&C Act provisions that failure to comply with the PSR is a prohibited act under Section 301 and thus the tools linked to prohibited acts are available to FDA. It further explains that the criteria and definitions in the PSR apply in determining whether a food is adulterated within the meaning of the FD&C Act or in violation of section 361 of the Public Health Service Act.

Subpart Q also includes provisions for coordination relative to education and enforcement activities between FDA and state, territorial, tribal, and local authorities.

O. Subpart R – Withdrawal of Qualified Exemption

Subpart R establishes procedures whereby FDA may issue an order withdrawing a qualified exemption, as well as circumstances whereby FDA would reinstate a qualified exemption. Those circumstances where withdrawal of the qualified exemption may be appropriate are limited to:

- An active investigation of a foodborne illness outbreak that is directly linked to the farm
- A determination (by FDA) that withdrawal is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm material and to the safety of food that would otherwise be covered produce.

In addition, this subpart describes the procedures FDA would use to withdraw an exemption and the process whereby a farm would submit a written appeal of an order to withdraw a qualified exemption, as well as the procedures for appeals, hearings, and issuing decisions on appeals.

3. Exemptions and Modified Requirements

If the farm grows, harvests, packs, or holds covered produce that is going for commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., a kill step), the produce may be eligible for an exemption from the requirements of the PSR (see 21 CFR 112.2(b)(1)). To be eligible for the exemption, the requirements in 112.2(b) must be

met, with the exception of the written assurance requirements, which are under enforcement discretion pending rulemaking (see **Part I.4.** below).

The rule provides for a qualified exemption if a farm meets certain eligibility criteria. This includes monetary values, adjusted for inflation, as the basis for a farm to determine if it is eligible for a qualified exemption (see FSMA Inflation Adjusted Cut Offs**)**. If a covered farm is eligible for a qualified exemption in accordance with § 112.5 of the PSR, the farm is subject to the modified requirements in § 112.6 and records requirements in § 112.7.

4. Compliance Dates and Enforcement Discretion

The final PSR was published in the Federal Register on November 27, 2015. The effective date was 60 days after publication, January 26, 2016. All farms subject to the PSR (except sprout operations) had to be in compliance by January 27, 2020. Extended compliance dates were established for certain agricultural water provisions in Subpart E – see Attachment C.

An overview of the compliance dates for the PSR is available on the FDA Website.
FDA published Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry in January 2018, exercising enforcement discretion from the written assurances provisions related to the commercial processing exemption in Section 112.2 (b). FDA also published guidance *Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds,* in March 2019, exercising enforcement discretion from the PSR for hops, wine grapes, pulse crops, and almonds. Farms that only perform covered activities on these commodities are not to be inspected under this program. Inspections at farms that grow these commodities in addition to other covered produce should only focus on the other covered produce.

The proposal published in December 2021 does not include changes to the harvest and post-harvest requirements for agricultural water. In July 2022, the FDA issued a supplemental notice of proposed rulemaking to extend the compliance dates for the pre-harvest agricultural water requirements for non-sprout covered produce. In this same notice, the agency also announced end dates for the enforcement discretion provided for the harvest and post-harvest agricultural water requirements, to begin on January 26, 2023, for the largest farms.

PART II – IMPLEMENTATION

1. Objectives

- Conduct inspections of covered domestic and foreign farms subject to 21 CFR part 112 to document inspectional findings and assess compliance with applicable provisions of the PSR.
- Gather and assess information about conditions, practices, and procedures at farms relative to applicable requirements of the PSR to enhance the Agency's understanding and ability to provide targeted outreach and to minimize or prevent future produce-related foodborne illness outbreaks.
- Provide information and educational resources to farmers, as needed (e.g., Produce Safety Alliance (PSA), guidance, state resources, etc.) to educate while we regulate.
- Identify issues related to non-compliance, encourage voluntary corrective actions, and verify implementation of corrective actions taken during and after an inspection.
- Perform for-cause sampling (or sampling as directed) and applicable analyses to help determine possible sources and routes of covered produce contamination.
- Take appropriate regulatory action on inspectional findings and/or sampling results, when warranted.

2. Inspectional Priorities

FDA and Path B state grantees must use the domestic farm inspection priorities listed below to plan their produce farm inspections. Path C grantees are strongly encouraged, although not required, to use these priorities. The requirement for Path B and Path C grantees to use a risk-based prioritization model for planning inspections is described in the Funding Opportunity Announcement (FOA). The Produce Decision Analysis Tool (PDAT) is a risk-based prioritization model developed by FDA using criteria identified through an FDA/National Association of State Departments of Agriculture (NASDA)/state workgroup. Foreign produce farm inspection prioritization is for FDA only.

A. Domestic Farm Inspection Priorities

(1) **Priority 1 Outbreak history**

Inspections of all covered farms that have been implicated in or possibly linked to a foodborne illness outbreak within the past year.

- Farms that were implicated are those where FDA determined the contaminated produce came from.
- Farms that were possibly linked are those that appear on the FDA Coordinated Outbreak Response & Evaluation (CORE) final traceback diagram; however, FDA did not determine which farm(s) produced the contaminated produce.

(2) **Priority 2 Recall/Positive Sample History**

Inspections of all covered farms that in the past year have either recalled product from the market due to potential pathogen contamination or produced produce that was sampled and found to contain pathogen(s) of public health significance.

(3) **Priority 3 Reinspection**

Inspections of all covered farms to follow-up on Official Action Indicated (OAI) inspections or significant violations noted during the previous PSR inspection. Inspections included in this priority may be compliance follow-up inspections, which are directed to OII Division of Produce Safety (DPS) or Path B grantees by the compliance branch (i.e., Human Food Program, Office of Compliance and Enforcement, Office of Enforcement). Inspections in this priority may also be expedited next inspections (a for-cause type of inspection) that are expedited at the request of an OII DPS Branch Chief or as determined by Produce CAP grantee's management (Path B and Path C).

(4) **Priority 4 Initial inspections of large and small farms**

- Priority 4A Large and small leafy greens farms
  When planning for routine inspections, prioritize initial inspections of large and small leafy greens farms over initial inspections of other farms. See Priority Commodities for PSR Inspections which includes the priority leafy green commodities to consider on the Produce Safety Inspections Compliance Program Resources. Documents hosted on this page will be available on FSDX for States. If the number of large and small leafy greens farms exceeds the number of inspections to be conducted, farms should be selected for inspection by applying the (PDAT).

- Priority 4B Remaining large farm inventory
  Prioritize initial inspections of any remaining large farms over initial inspections of small farms. If the number of large farms exceeds the number of inspections to be conducted, farms should be selected for inspection by applying the PDAT.

- Priority 4C Remaining small farm inventory
  Conduct initial inspections of any remaining small farms. If the number of small farms exceeds the number of inspections to be conducted, farms should be selected for inspection by applying the PDAT.

(5) **Priority 5 Other routine farm inspections**

Conduct routine inspections of large and small farms that received initial inspections in previous years and conduct initial inspections of verified covered very small farms. If the number of farms in this category exceeds the number of inspections to be conducted, farms should be selected for inspection by applying the PDAT. Farm size is one of the PDAT criteria. Farms of all sizes in this category should be included in one PDAT run.

The above priorities are not intended to include farms eligible for a qualified exemption or a processing exemption for all covered produce as these farms should not be inspected under this CP except as noted in Table 2. However, if a covered farm grows other covered crops that are not subject to a processing exemption and the farm is not eligible for a qualified exemption, then the priorities above apply and that farm should be inspected under this CP. The PDAT will not indicate if a farm is qualified exempt.

B. Foreign Farm Inspection Priorities

FDA continues to develop the foreign farm inventory and utilizes the methodology in the PDAT and available data to prioritize foreign produce farms for inspection. FDA largely relies on information provided during import and prior notice processes to inform inspection prioritization.

When prioritizing foreign farms for inspection, considerations include:

- Compliance history (may consider outbreak data, prior inspection results, FDA sample results, recalls, and other pertinent information),
- Foreign farm size (may be estimated based on the value, quantity, and frequency of shipments, as well as the average declared value of imported fresh produce over the previous three years),
- Priority commodities for inspection found at the Produce Safety Inspections Compliance Program Resources. Documents hosted on this page will be available on FSDX for States,
- Farm location, harvest season, and the requirement to comply with the PSR are confirmed by OII's Division of Foreign Food Investigations and Global Operations via communications with the management of farms selected.

C. Selection of Produce for Coverage During the Inspection

The FDA HFP developed and uses a risk algorithm that is based upon and considers criteria such as commodity outbreak history, recalls, positive sample findings, consumption rates, geographical distribution, commodity/pathogen pairing, typical agricultural practices, as well as recent research findings to periodically evaluate and determine selection of priority commodities.
Priority commodities are a factor in the PDAT and are considered as part of the prioritization of farms for inspection. Leafy greens farms are a specific inspectional priority (see **Part II.2.A**). Additionally, the Priority Commodities for Produce Safety Inspections document which is hosted on the Produce Safety Inspections Compliance Program Resources and on FSDX should be a focus when selecting produce to observe during inspections. FDA HFP may update the priority commodities annually (preferably between July 01 – December 31); FDA and Produce CAP grantees should review the link during their work-planning each year to ensure they are utilizing current information.

3. Planning Instructions

A. Inspections

FDA will identify the number of produce farm inspections for FDA to perform via the annual FDA Field Workplan. Annual inspection targets for Path B and Path C grantees are outlined in the Produce CAP FOA; the specific number is determined by the grantee's verified inventory of covered farms, annually, on or about May 1st, for inspections to be conducted in the forthcoming July 1 – June 30 budget period. OII DPS, Path B, and Path C are each responsible for identifying their inventory and farms to inspect in accordance with this CP (see **Part II.2.A**.).

Domestic PSR inspections will be conducted by FDA and Produce CAP Path B and Path C grantees. Foreign inspections will be conducted by the FDA. Inspections of produce farms will be prioritized as indicated in **Part II.2.A** of this CP.

To perform PSR inspections under FDA authority, state individuals must be commissioned by FDA and hold FDA produce credentials. Commissioning is usually handled by contacting the local FDA State Liaison; the Produce CAP Office of Domestic Partnerships, Division of Domestic Partnership Investments (DDPI) Project Manager can also act as a point of contact. When planning inspections, states should be aware that commissioning can take some time.

Resources for commissioning:

- FDA website: https://www.fda.gov/ForFederalStateandLocalOfficials/CommunicationsOutreach/ucm472941.htm
- Regulatory Procedures Manual, Chapter 3: https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074334.pdf

B. Training Requirements

The lead investigator/inspector must be trained to conduct produce farm inspections. Their training must include successful completion of FD226 "Produce Inspections for Regulators." Additional personnel (e.g., OII investigators, HFP SMEs, and state inspectors) with appropriate credentials may accompany and assist with the inspections. For inclusion of additional personnel without appropriate credentials on the inspection see IOM Section 5.2.2 for instruction.

Additional personnel who participate in inspections are required to complete the following:

- Introduction to Horticulture for Human Consumption (FD8011W)
- Produce Safety Rule Web Course (FD8012W)

It is also recommended that those accompanying the lead investigator/inspector complete produce safety training at least equivalent to that received under a standardized curriculum recognized as adequate by FDA. Currently, FDA recognizes the PSA Grower Training as an adequate standardized training curriculum (see https://producesafetyalliance.cornell.edu/training/grower-training-courses).

For a quick review, investigators/inspectors and those accompanying and assisting with inspections can view the "Produce Inspections for Regulators Virtual Produce Tour". They can also review *FDA FACT Sheet: What to Expect of a Regulatory Inspection*, which provides an overview of the steps conducted during PSR inspections.

A webinar covering the content of this compliance program is under development. Once complete, this section will be updated to include a link to the webinar recording.

C. Specific Planning Instructions for Inspections

If the farm was subject to an enforcement action, recalled product from the market due to potential pathogen contamination, had a sample that was positive for pathogen(s) of public health significance, (including samples collected via the FDA funded Laboratory Flexible Funding Model program) was implicated or possibly linked to a foodborne illness outbreak, or had other significant event(s) since the previous PSR inspection, investigators/Path B grantees will coordinate with the OII DPS Branch Chief for the state where the inspection will be conducted. This includes farm mixed-type facilities with such a history since the previous PSR inspection related to manufactured food, even if there is no such history related to activities covered by the PSR. The OII DPS Branch Chief should review the history and, as appropriate, set up a conference call with HFP/OCE/OE/DPIE/Produce Enforcement Branch (PEB) (contact HFP-OCE-Produce@fda.hhs.gov), HFP OMFS/Office of Produce Safety contacts (see **Part VI.3.A**), and the OII OHFI Division Supervisory Senior Advisor, and Office of Field Operations and Response/ Office of Emergency Response Emergency Response Coordinator (ERC), as applicable, before starting the inspection to discuss the possible inspection focus and enforcement strategies, as appropriate.

D. Coordinating Inspections of Farm Mixed-Type Facilities

A "farm mixed-type facility" (farm MTF) is an establishment that is a farm and also conducts activities outside the farm definition that require the establishment to be registered (see "Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Guidance for Industry *Draft Guidance"*). Produce farm MTFs are inspected on the farm side by either the produce CAP state grantee (Path B/C) or OII DPS (Path A/non-CAP), and on the facility side by either the FDA OII/OHFI division or a state agency under FDA contract.

Path B and C state grantees and OII DPS are encouraged to share their farm inspection workplans with FDA OII/OHFI divisions to identify produce farm MTFs that are also on

OII/OHFI division or state contract workplans. Grantees might share only the produce farm MTFs they are aware of and plan to inspect, rather than sharing their entire workplan. Path B and C state grantees, contact OII DPS to facilitate workplan sharing with FDA OII/OHFI divisions. OII DPS will work with FDA OII/OHFI division personnel, including state liaisons, to determine whether produce farm MTFs are on the division workplan or a state contract workplan. Workplan sharing is expected to lead to:

- Communication of relevant information between regulatory entities about the respective sides of the inspected operation.
- Awareness of inspection scheduling, such that:
  - If the farm and facility inspections will be conducted separately, scheduling can be coordinated to prevent overlap.
  - If the farm and facility sides will be inspected at the same time, the regulators involved can schedule their investigators/inspectors to conduct the joint inspection.

When considering a joint inspection of a produce farm MTF, the regulators involved should agree that it will be beneficial from a regulatory perspective (e.g. based on compliance history). A joint inspection would also be acceptable if it is believed that it will reduce burden on the produce farm MTF, if scheduling and resources permit.

E. Regulatory Technical Assistance Network (rTAN)

The rTAN is a resource for FDA investigators and state inspectors to request assistance during produce safety inspections. It is not intended to replace the current enforcement communication mechanism between the FDA investigators/Path B state grantees, the OII DPS Branch Chief, and HFP/OCE/OE.

The rTAN is designed to connect investigators/inspectors with a Subject Matter Expert (SME) to receive answers to FSMA rule interpretation questions related to current inspections. Investigators/inspectors can call the rTAN SMEs before and/or during an inspection to discuss questions or to obtain clarifications on the PSR.

When an inspection date/time is determined, FDA investigators and Path B inspectors must contact the rTAN at ProduceRegulatorTAN@fda.hhs.gov to request an appointment with the rTAN to ensure that a SME will be available for those inspection dates.

Note for Path C grantees: Path C inspectors are strongly encouraged but are not required to utilize the rTAN during produce safety inspections. If Path C inspectors anticipate using the rTAN or would like to ensure an SME is available on that date, an appointment should be made in advance using the process described above.

(1) Pre-Inspection

FDA Investigators and State Path B inspectors must request an appointment with the

Regulatory Technical Assistance Network (rTAN) at ProduceRegulatorTAN@fda.hhs.gov as soon as an inspection date/time is determined to ensure that a subject matter expert (SME) will be available for the inspection date. Requests should be submitted in advance of the inspection, preferably five (5) days in advance, to allow for time to find and schedule the appointment with an SME. Path C inspectors are encouraged to use this service to assist during inspections, but it is not required.

In the request, the investigator/inspector should include:

- Investigator/Inspector name, agency, and contact information (i.e., e-mail and phone number)
- Date(s) and time of the planned inspection
- If known beforehand, the commodities grown, harvested, packed, or held at the farm The rTAN coordinator will respond to the request with the scheduled rTAN contacts for those dates, along with the timeframes of their availability.

(2) **Day of Inspection**

- The scheduled SMEs from FDA will be available as indicated on the scheduling confirmation email to discuss questions.
- If the inspector/investigator has questions, or if they'd like to confirm their understanding of the regulation, they can call the SME.
    - Inspectors/investigators are encouraged to contact the rTAN as early as possible during the inspection, in case additional information is needed.
    - The SME may not be able to answer the call immediately. Inspectors/investigators are encouraged to leave a detailed message and/or reach out to the alternate SME, as available.
- If the Inspector/Investigator does not have questions, then there is no need to call the SME. The rTAN SME will be able to provide feedback and clarify on topics such as:
    - The farm definition
    - PSR provisions and associated guidance
    - Corrective actions (e.g., questions on discussions with grower, next steps, etc.)
    - Inspectional approach

As needed, the rTAN SME may consult with others at FDA when providing feedback/clarity on the topics above to ensure consistency and accuracy of their response. It is also possible that the rTAN SME may refer the inspector/investigator to other experts at FDA.

F. Compliance Programs and/or Assignment Interactions

If a farm is inspected under this program and the covered food is subject to additional regulations, CPs, or assignments outside the scope of this CP, then additional inspection, sampling, analytical, and reporting requirements may be covered per the respective interacting programs/assignments. Programs and assignments that interact with this CP include the following:

(1) **CP 7303.040 Preventive Controls and Sanitary Human Food Operations (CGMP&PCHF)**

The main purpose of this CGMP&PCHF CP is to provide overall instruction for conducting inspections at human food facilities subject to 21 CFR part 117 and/or subject to the Sanitary Transportation of Human and Animal Food (ST rule), [(21 CFR part 1, subpart O). The CGMP&PC CP covers, in part, processed produce not covered under the PSR, and includes instructions to coordinate, as appropriate, with investigators/inspectors prior to conducting inspections at farm mixed-type facilities.

See Part II.3.D. for additional information on conducting inspections at mixed type facilities.

(2) **CP 7303.878 Import Food Operations (IFO)**

Includes instruction for conducting Foreign Supplier Verification Program (FSVP) inspections for importers of food subject to the FSVP regulation. The IFO CP covers, in part, FSVP inspections of importers of covered produce. Importers are required to have and implement a FSVP with adequate assurance that the supplier (if a farm) is in compliance with the PSR or provides the same level of public health protection. If a covered produce farm is also an importer subject to the FSVP requirements, an inspection of the farm for compliance with the FSVP requirements may be conducted under the IFO CP by the appropriate OII Import Division. If this is determined prior to inspection, FDA investigators should coordinate the inspection with the OII Import Division DIB and others, as needed. If it is determined during the inspection that the covered produce farm is also covered under FSVP, see instructions within Table 2 of this CP.

(3) **CP 7304.004A Pesticides and Industrial Chemicals in Food – Domestic and Import**

This CP covers, in part, pesticide sampling of foods including covered produce. When a pesticide sample is collected during operations covered by this Produce Safety Inspections CP, refer to CP 7304.004A.

(4) **CP 7303.050 Sampling for Foodborne Biological Hazards, and Filth – Domestic and Import (referred to as the Micro Sampling CP)**

The Micro Sampling CP was developed to support FSMA implementation by providing streamlined instructions to FDA personnel for conducting activities covering domestic and imported food products, including ready-to-eat produce, for foodborne biological hazards associated with public health risk. The Micro Sampling CP provides instruction for sampling and analysis of (1) food for microbiological hazards such as *Listeria monocytogenes*, *Salmonella spp*., and pathogenic *Escherichia coli*, (2) environmental samples (e.g., swabbing within facilities or indoor farm operations) for pathogens; and (3) food for filth. In the event for-cause samples are collected under the Produce Safety Inspections CP, refer to the Micro Sampling CP for additional collection and analytical instructions. Instructions covering produce sampling operations not covered in CP 7303.050 are found within this Produce Safety Inspections CP in **Part IV** and the Produce Sampling Instructions hosted on the Produce Safety Inspections Compliance Program Resources and on FSDX. Path B and Path C grantees can utilize the information within the Micro Sampling CP and Produce Sampling Instructions, as needed.

(5) **Interacting Assignments**

This CP may interact with field assignments. For FDA employees, see Active Assignments (sharepoint.com) for a list of active assignments. For Produce CAP state grantees, contact your ODP/DDPI Project Manager to obtain a copy of interacting assignments.

G. Interactions with other Federal agencies, State and local counterparts, and foreign authorities

(1) **Federal Agencies**

Follow IOM Section 3.1.2 and Section 5.1.1. when federal officials from other agencies are present during FDA inspections or investigations. See IOM subchapter 3.2 *Federal Agency Interaction* for a list of Memorandums of Understanding (MOUs) between the FDA and other Federal agencies that may be applicable to inspections conducted under this program. A complete list of MOUs may be found here.

(2) **State and Local Counterparts**

An increased level of cooperation between federal, state, and territorial regulatory and food safety produce entities is required to meet the goals of FSMA and the PSR. For PSR implementation, FDA provides funding to states and territories through the Produce CAP. Each state agency grantee is enrolled in the Produce CAP by their chosen Program Path (A, B, or C).

- Path A: Jurisdictions that will not conduct produce safety inspections (non-regulatory programs).
- Path B: Jurisdictions that will conduct produce safety inspections under FDA's authority.

- Path C: Jurisdictions that will conduct produce safety inspections under their own authority.

FDA will lead inspections in non-CAP states and U.S. Territories (states and territories that don't participate in the Produce CAP), Path A states, and on federally recognized tribal lands.

Path B state grantees are commissioned and credentialed by FDA to conduct produce farm inspections under FDA authority and must conduct inspections according to this CP and pertinent FDA guidance or operating instructions for conducting produce safety inspections.

Path C state grantees are provided funding to implement inspection regulatory programs focused on quality and national consistency. To this purpose, Path C grantees are strongly encouraged to conduct inspections according to this CP and pertinent FDA guidance for conducting all aspects of produce safety inspections.

As necessary, the FDA may also lead and/or participate in inspections, investigations, or sampling in Path B and Path C states. When FDA leads an inspection in a Path B or Path C state, FDA will communicate and coordinate with the grantee. The grantee will also be invited to participate in the inspection.

See Table 2 for other examples of when coordination may need to occur between FDA and states. As needed, FDA and states should refer to FMD-152 "Produce Safety Dispute Mitigation and Resolution Procedures".

(3) **Foreign Authorities**

Follow IOM Section 5.1.1 when foreign competent authorities are present during FDA foreign inspections or investigations.

4. Resource and Reporting Instructions

The reporting PACs that FDA Investigators should use for reporting inspection activities are listed in Table 1 below. States may use their own operational data tracking procedures, in addition to Produce CAP reporting.

Routine sampling (produce and/or environmental) is not conducted under this CP; however, if warranted, sampling will be for-cause only or as directed and should be conducted according to the Micro Sampling CP and the Produce Sampling Instructions P

Table 1:Resources and Reporting (for FDA)

Reporting PAC	03080 PRODUCE SAFETY NETWORK (PSN) ACTIVITIES 03G080 VOLUNTARY STATE PRODUCE SAFETY INSPECTIONS
Planning PAC	03080 PRODUCE SAFETY NETWORK (PSN) ACTIVITIES
OP Code – Inspection **OP Code – Investigation**	12 (domestic), 11 (foreign) 13 (domestic), 15 (foreign)

PART III – INSPECTIONAL

1. Operations

A. Inspections

The FDA Investigations Operations Manual (IOM) and specifically Chapter 5 – Establishment Inspections provides general operating instructions for FDA field operations: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual. See Standardized Approach to Produce Farm Inspections on the Produce Safety Inspections Compliance Program Resources for additional instructions for performing routine produce farm inspections. Documents hosted on this page will be available on FSDX for States.

Inspections will assess the farm's compliance with the PSR. The focus of the inspection should be on conditions and practices that could result in adulterated produce. Make every reasonable effort to discuss all observations with the management of the farm as they are observed to provide the farm an opportunity to take immediate corrective action and to minimize surprises, errors, and misunderstandings. Include in the FDA 4056, Produce Farm Inspection Observations form, the deviations and the significance of each deviation to enable compliance officers to establish adulterations charges as appropriate. One way to establish the significance of an observation is to identify a potential source and route contamination associated with the deviation. For example, "We observed harvest workers return to picking blueberries without washing their hands after using the latrine. By so doing, workers may contaminate covered produce with human pathogens." Investigators/inspectors should document in the PFIR or appropriate State document, verification of corrections to any previous observations and/or verbal discussion items in addition to capturing any new observations.

(1) Personal Safety

FDA recognizes that there are situations where it is advisable to take precautions for your personal safety. To review potential farm safety hazards and suggestions for mitigating these risks, refer to Appendix 2 of Standardized Approach to Produce Farm Inspections on the Produce Safety Inspections Compliance Program Resources. Documents hosted on this page will be available on FSDX for States. If a safety concern arises during an inspection, immediately notify your supervisor. For further guidance, please refer to the IOM Chapter S.

(2) Pre-announcement

Pre-announcement enables the inspection personnel to verify if the farm is required to comply with the PSR and if the farm should be inspected under this CP. It also optimizes inspection productivity by ensuring the inspection is scheduled when the farm is operational, and it provides time for the farm to ensure necessary personnel are available

and to assemble the appropriate records. Unless otherwise directed, inspections will be pre-announced and scheduled with the farm owner, manager, or person in charge. For FDA-led inspections, the OII DPS Branch Chief will make the decision about pre-announcement. The inspection should be scheduled within five (5) business days of the pre-announcement call unless a longer amount of time is required due to travel and other logistical considerations.

In certain situations, an inspection may be conducted without being pre-announced. The following are some examples of when an unannounced inspection may occur:

- If the farm had previous produce safety issues and the issues have not been corrected and verified.
- If a follow-up inspection is needed and an unannounced inspection may work best to observe the necessary changes being made.
- In response to a complaint, recall, or foodborne illness outbreak.

Instructions for pre-announcement are outlined below:

- Review Standardized Approach to Produce Farm Inspections and its Appendix 4 "Pre-Inspection Call with Farmer – Job Aid" on the Produce Safety Inspections Compliance Program Resources. Documents hosted on this page will be available on FSDX for States. For FDA investigators, complete the Produce Farm Pre-Announcement form located on the Produce Safety Inspections Compliance Program Resources.
- Inform the farm that the information available shows their farm appears to be subject to the PSR and may be inspected to assess and monitor compliance with the PSR after the information is confirmed.
- Apply the FDA decision tree entitled "Standards for Produce Safety Coverage and Exemptions" found at https://www.fda.gov/media/94332/download to assist with determining if the farm is subject to the PSR or eligible for an exemption.
- Two values under the PSR are adjusted for inflation and averaged over three years (refer to the FSMA Inflation Adjusted Cut-Offs at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs):

    - For the monetary exclusion, a farm is not covered if the average annual gross produce sales during the previous three years ≤$25,000.
    - For the qualified exemption, a farm may be eligible if the average annual monetary value of all food sold was <$500K during the previous three years and other requirements are met.

- Ask the farm to confirm which of the following categories they fall into by estimating the average value of produce sold for each of the last three years.

    - Very Small Farms: Average annual produce sales >$25,000 and ≤$250,000
    - Small Farms: Average annual produce sales >$250,000 and ≤$500,000

- Large Farms: Average annual produce sales >$500,000

- **If it is determined that the farm should not be inspected,** for example the farm is not subject to the PSR, is qualified exempt, only grows commodities for which FDA is exercising enforcement discretion (i.e., hops, wine grapes, pulse crops, and almonds), or is using the processing exemption for all covered commodities (see 21 CFR part 112.2(b)), the investigator/inspector should:

  - Thank the farmer for their time and inform the farmer why the farm will not be inspected at this time. **Note:** If the farm won't be inspected at this time because it is eligible for a qualified exemption, inform the farm of the modified requirements per 21 CFR part 112.6 and records they must establish and keep per 21 CFR part 112.7.
  - FDA Investigators: Report the activity as an investigation (Op13) and review and update the eNSpect and Field Management System (FMS) data fields for the farm.
  - State Inspectors: This would be considered an update to your verified inventory and captured as an inventory verification activity.

- **If the farm is subject to the PSR and is to be inspected,** the investigator/inspector should**:**

  - Determine if the farm is also subject to Subpart M (Sprouts), or another FDA food regulation, such as, the *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls in Human Foods* (CGMP&PC) rule (21 CFR Part 117) or juice HACCP (21 CFR Part 120) (e.g., a farm mixed-type facility). If so, refer to the applicable parts of Table 2 in this CP.
  - Following instructions in Standardized Approach to Produce Farm Inspections on the Produce Safety Inspections Compliance Program Resources and its Appendix 4 "Pre-Inspection Call with Farmer – Job Aid" (Documents hosted on this page will be available on FSDX for States) explain what the farmer can expect during the inspection, discuss logistics of the inspection and biosecurity practices at the farm, and cover the discussion items listed in the Job Aid.
  - Determine when the farm is performing at least one of the covered activities (growing, harvesting, packing, or holding) on covered produce. The inspection should be scheduled during a time the farm is performing a covered activity on covered produce, with a focus on harvesting and/or packing. In addition, whenever possible, schedule the inspection to focus on the produce listed in Priority Commodities for PSR Inspections on the Produce Safety Inspections Compliance Program Resources and on FSDX.
  - Notify the farmer if any member of the inspection team will be in uniform (e.g., USPHS Commissioned Corps Officer) during the inspection and explain why the uniform will be worn.
  - Obtain the farm mailing address or email and send the farm the following resources:

- What to Expect of a Regulatory Inspection
- FDA Produce Safety Rule
- Requirements for Harvest and Post-Harvest Agricultural Water in Subpart E for Covered Produce Other than Sprouts | FDA
- Link to the Produce Safety Alliance (PSA)

- Conclude by asking if the farmer has any questions and thanking the farmer.
- If the investigator/inspector made a reasonable attempt to contact the farm and has been unsuccessful, provide notification via voicemail/e-mail/letter of the planned start date and time of the inspection at least 48 hours before the start of the inspection and request that the farm respond prior to the start date and time. If the farm doesn't respond ahead of the inspection, upon arrival at the farm, the investigator/inspector should ask the farm about any biosecurity practices at the farm and verify that the farm is subject to the PSR and should be inspected.

(3) **Additional planning instructions for FDA only (all inspections, domestic and foreign)**

As soon as pre-announcement is concluded and it is confirmed that a farm will be inspected, the lead investigator will e-mail the cell phone number for the lead investigator, the farm name, farm city and state, farm FDA Establishment Identifier (FEI) number, the covered activities and commodity/commodities the investigator(s) plans to focus on during the inspection (if known), and planned dates for the inspection to:

- **Email 1:**
  - The respective OII/OHFI Division Director and the State Liaison
  - Copy the OII DPS Branch Chief (see Part VI.3.) that oversees the state where the inspection will take place.

- **Email 2:**
  - The rTAN, ProduceRegulatorTAN@fda.hhs.gov (see rTAN instructions in Part II.3.E.)
  - The HFP/OMFS/OPS/DFPS program contacts (see Part VI.3.)
  - The HFP/OCE/OE contact at HFP-OCE-Produce@fda.hhs.gov
  - Copy their OII DPS Branch Chief and the OII DPS Branch Chief (see Part VI.3.) that oversees the state where the inspection will take place.

(4) **Inspection Approach**

The information in this section and the Produce Safety IP (FDA only) are provided to assist with consistency as well as to ensure that all PSR-relevant areas of the farm have been addressed. Investigators/inspectors should use the Standardized Approach to Produce Farm Inspections on the Produce Safety Inspections Compliance Program Resources as a

reference for all inspections. Documents hosted on this page will be available on FSDX for States.

In addition to instructions in Standardized Approach to Produce Farm Inspections related to initiating the inspection, FDA investigators and Path B inspectors will display FDA credentials and present a properly signed, completed original of the Form FDA 482, *Notice of Inspection* to the top management official on site (i.e., the owner, operator, or agent in charge). Only the first page of the FDA 482 requires information to be entered. For an example of a completed FDA 482, see IOM Exhibit 5-1 and additional instructions in IOM Section 5.2.2 *Notice of Inspection*.

When possible, inspections should begin with the cleanest areas of the farm and move towards less-clean areas (e.g., field). However, the investigator/inspector should ensure that appropriate areas of the farm are observed, which may require deviation from the "cleanest areas first" prioritization in order to accommodate the farm's schedule.

Inspections are typically comprehensive, covering all applicable provisions of the PSR and should ensure the inspector/investigator's evaluation is representative of the farm's operations. FDA recognizes each farm is unique (e.g., size, commodities, complexity); if inspectors/investigators have questions regarding inspection coverage and/or approach as they prepare for or initiate an inspection, they should contact the rTAN.

Key Areas to Focus on During Produce Safety Inspections:

(a) 21 CFR 112 Subpart A: General Provisions

- Confirm the information provided by the farm during the inspection pre-announcement call and determine if the farm is conducting a covered activity on covered produce.
- If the farm also grows, harvest, packs or holds covered produce that is intended for commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., a kill step), the produce may be eligible for an exemption from the requirements of the PSR for that covered produce (see 112.2(b)(1)).
- Determine if the farm distinguishes between produce intended for processing (eligible for exemption) and covered produce not intended for processing (subject to the PSR) (see also 112.111).

If the farm does not handle the produce for processing according to PSR requirements, review how the farm is disclosing to its customers that the produce is not processed to adequately reduce the presence of microorganisms of public health significance.

The regulation also requires the farm to obtain written assurances from the consignee; however, FDA is currently exercising enforcement discretion for the written assurance

requirement. Do not request information about written assurances and do not cite deviations relative to the written assurance requirement (see 21 CFR 112.2(b)). For more information see https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM590661.pdf.

(b) 21 CFR 112 Subpart B: General Requirements

The PSR allows for the use of alternatives to requirements of Subpart E, Agricultural Water pertinent to water used for growing. Since FDA has proposed revisions to the agricultural water provisions, alternatives will not currently be reviewed during inspections.

(c) 21 CFR 112 Subpart C: Personnel Qualifications and Training

- Identify the person assigned by the farm to be responsible for food safety requirements, specifically those covered by the PSR.
- Confirm that at least one supervisor or responsible party has completed produce safety training equivalent to a standardized curriculum recognized by FDA, such as the Produce Safety Alliance training (see *Draft Guidance for Industry: Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Produce Safety Rule* if a farm is using a curriculum that differs from the PSA training).
- Training:
  - Observe personnel at work who handle or contact covered produce during covered activities, with particular attention to traffic patterns, hand washing, glove use, basic hygiene; the produce they are harvesting; and, the containers and equipment they are using to harvest. If employees are not performing their jobs consistent with food safety principles, review training records to determine if the employees are adequately trained, as appropriate to their duties.
  - Determine if re-training occurs when observations or information indicates that PSR requirements are not being met.
  - Training records must include the date of training, topics covered, and persons trained.
  - Identify responsibility for training and monitoring of food safety practices. If the farm uses contract personnel for any covered activities, determine who trains the contractors.

(d) 21 CFR 112 Subpart D: Health and Hygiene

- Determine if the operation has a health and hygiene policy for personnel and visitors, and that all visitors are made aware of this policy (policies and procedures do not have to be written).
- Determine how the farm handles ill employees.
- When possible, observe employee practices in all production areas (e.g., field, harvesting, transport, storage, and packing), with special attention to:

  - appropriate handwashing/glove practices
  - consumption of food and/or tobacco in product handling areas
  - hand jewelry
  - outer garments suitable to protect against contamination
  - contact with animals
  - general hygiene practices

- Ensure that employees working with covered produce and food contact surfaces use appropriate hand-washing techniques and that both employees and visitors have access to toilet and hand-washing facilities.

(e) 21 CFR 112 Subpart E: Agricultural Water

Determine if the farm uses agricultural water. If not, no further review is needed under this section. If the farm uses agricultural water, please see Attachment C for the inspection approach.
FDA and Path B states: Contact the rTAN to discuss observations related to agricultural water before including such observations on an FDA 4056.

Path C states: Please consider contacting the rTAN to discuss observations related to agricultural water before including such observations on an FDA 4056 state equivalent form.

(f) 21 CFR 112 Subpart F: Biological Soil Amendments of Animal Origin and Human Waste

- Determine if the farm uses BSAAO or human waste.

  - The term "Biological Soil Amendments of Animal Origin", or BSAAO, is not a term that has been historically used by the produce industry. It may not be sufficient to simply ask a farm if they use BSAAOs without first explaining the meaning. The investigator/inspector should define the term BSAAO to the farm. The investigator/inspector must learn what materials a farm is adding to their soil and what ingredients are included in those materials. From that, the investigator/inspector can determine if the materials would be classified as BSAAOs.

  - The only human waste that may be used for growing covered produce is sewage sludge biosolids that are used in accordance with 40 CFR part 503, subpart D or equivalent regulatory requirements (see §112.53).

- If the farm does not use BSAAO or human waste, no further review is needed under Subpart F. If the farm uses soil amendments that are not BSAAO, please see the section directly below titled "Key areas to focus on related to soil amendments that do NOT fall under Subpart F (i.e., soil amendments of non-animal origin)".
- If the farm uses BSAAO, determine what type and how BSAAO are currently applied to soils where covered produce is grown. In addition, the investigator/inspector should ask about historical land applications of BSAAO (including any biosolids applications for non-PSR covered commodities) for the previous 12 months on the property, especially pertaining to land where covered commodities are currently grown, were grown during the previous 12 months, or are planned to be grown (e.g. the farm is planning to transition).
- For farms using BSAAOs, the potential for contact with the harvestable portion of the crop (both during and after BSAAO application) will determine the necessary treatment status of the BSAAO (per §112.56) and necessary records (per §112.60).
- Agricultural teas: Agricultural teas are soil amendments and are BSAAO if they are made from biological materials of animal origin. Please note that the term "agricultural tea" has not been historically used by the produce industry and growers may not realize that the amendments they are currently using (e.g. agricultural sprays or biostimulants) are covered under Subpart F provisions if they contain components of animal origin.

  In some cases, growers may apply their agricultural tea (liquid biostimulants are included in this category) onto the foliage and stems as well as the harvestable/harvested portion of their covered commodity for various reasons beyond the scope of Subpart F (e.g., not applied to soils). In these cases, especially where the agricultural tea was prepared from feedstock of animal origin, untreated surface water and/or agricultural tea additives, the investigator/inspector should inquire about preparation, storage, handling, and application to determine whether the agricultural tea could be considered an untreated BSAAO.

- Records:

  - If the farm uses BSAAO (treated or untreated) withing the allowable application methods for untreated BSAAO (112.56(a)(1)), no records are currently required.
  - When the farm uses BSAAO that may require the use of a treated BSAAO (see 112.56(a)(2) and 112.56(a)(3)), the investigator/inspector should review

the required records. If it is determined that the BSAAO application methods utilized by the grower require that the BSAAO be treated to meet one of the two treatment levels (per application restrictions in §112.56 that require certain treatment levels of §112.54(a) or (b)) – proper documentation of the treatment status is required (per §112.60).

- Where documentation of BSAAO treatment status is required:
  - If the BSAAO is treated by a third party, review records (such as a Certificate of Conformance) from the third party that document the BSAAO is treated using a scientifically validated process to meet one of the two codified treatment levels (§112.54(a) or §112.54(b)).
  - If the farm treats its own BSAAO, review documentation that process controls were achieved to meet one of the two codified treatment levels (§112.54(a) or §112.54(b)).

- If the BSAAO is treated (per either 112.54(a) or 112.54(b)) and stored properly, there are zero 'days to harvest' restrictions on usage, but the required methods by which the treated BSAAO may be applied differ by treatment status:
  - BSAAO that meet 112.54(a) treatment level have no application restrictions. BSAAO that meet §112.54(a) may be utilized for root crop production (e.g., carrots), where the edible or harvested portion of the crop is grown in direct contact with the soil to which the BSAAO has been applied.
  - BSAAO that meet §112.54(a) may be directly sprayed or applied in a manner that directly contacts the edible or harvested portion of the covered produce.
  - BSAAO that meet 112.54(b) treatment level must be applied in a manner that <u>minimizes contact</u> with the harvestable portion of the crop both during and after application.

- BSAAO storage:
  - Treated BSAAO: Review the storage and handling of treated BSAAO to determine if appropriate precautions are taken to prevent re-contamination of the treated BSAAO (especially if the grower intends to continue to use in accordance with the allowed uses for treated BSAAO).
  - Untreated BSAAO: Review the storage and handling of the untreated BSAAO used on the farm to determine if appropriate precautions are taken to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments (per §112.52).

Key areas to focus on related to soil amendments that **<u>do NOT fall under Subpart F</u>** (i.e., soil amendments of non-animal origin):

- If a farm is utilizing soil amendments, the investigator/inspector must learn what materials a farm is adding to their soil.
- All soil amendments (including those of non-animal origin) have the potential, once contaminated, to harbor and disseminate foodborne pathogens into the growing environment. Agricultural teas (including biostimulants[1]) or other aqueous extracts of non-animal origin) are of particular concern for produce safety. Therefore, FDA recommends all investigators/inspectors document the usage and/or on-farm production of any soil amendments of non-animal origin.
- Although Subpart F is not applicable to farms that only utilize soil amendments of non-animal origin, if these soil amendments are used in the growing of covered produce, the investigator/inspector should still evaluate the handling, conveyance, and storage of these soil amendments. Best practice would be for a farm to handle, convey, and store their soil amendments of non-animal origin in accordance with the requirements of Subpart F. If an investigator/inspector has food safety concerns related to soil amendments of non-animal origin, they should consult with the rTAN SME.
- Important note: any food safety concerns related to soil amendments that are not BSAAOs or human waste must not be cited under Subpart F.

(g) 21 CFR 112 Subpart I: Domesticated and Wild Animals

- Determine if the farm conducts covered activities in outdoor areas or a partially enclosed building.
- Determine if the farm's animal monitoring procedures for domestic and wild animals and their identification of trends or activity areas satisfy the requirements of the PSR.
- Walk as much of the perimeter of the growing areas as possible and outdoor or partially enclosed operations, noting any evidence of animal intrusion such as animals, animal excreta, bedding areas, animal tracks, and crop destruction.
- Note whether domesticated animals have unrestricted access to areas where growing, harvesting, packing, and/or holding activities take place, and if there is potential contamination indicated by vulnerability of the crop, conditions and practices.

[1] Biostimulants are a class of materials that are better defined by what they do than what they are made from, as the list of materials used to prepare biostimulants is quite diverse and continues to expand. While the definition of biostimulants is likely to change over time, The USDA Farm Bill 2018 (H.R.2 §10111) provides a working definition of plant biostimulants "to be a substance or micro-organism that, when applied to seeds, plants, or the rhizosphere, stimulates natural processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality and yield…" Please note that while this definition is currently accurate, it is not an official FDA definition as we currently include most of these biostimulants under the definition of Agricultural Teas.

- Determine (by observation or interview) how the farm responds to evidence of animal intrusion, how produce is evaluated for potential contamination, and how potentially contaminated produce is handled during harvest.

(h) 21 CFR 112 Subpart K: Growing, Harvesting, Packing, and Holding Activities

- Document the growing, harvesting, packing, and holding activities the farm performs and the crops on which the activities are conducted. Identify if the farm uses contractors for any of these activities.
- Observe, when possible, the farm's growing, harvesting, packing, and holding operations and evaluate whether the farm handles produce in a manner to protect against contamination.
- Determine the steps the farm takes immediately prior to and during harvest activities to identify covered produce that is likely to be contaminated and steps taken to avoid harvesting that produce. For example, determine if the farm performs a visual assessment of growing areas prior to and during harvest for evidence of animal excreta.
- Determine if the farm handles 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.
- Determine if the farm handles both covered and excluded produce per 21 CFR 112.111.
- If the farm does <u>not</u> grow, harvest, pack, or hold both covered and excluded produce, or if the farm grows, harvests, packs, and holds excluded produce in accordance with the provisions of the PSR, then the requirements of 21 CFR 112.111 are not applicable to the farm.
- If the farm grows, harvests, packs, or holds covered produce that is not covered by the PSR (i.e., excluded produce in accordance with 21 CFR 112.2) and the excluded produce is grown, harvested, packed, or held in a manner that is not in accordance with 21 CFR 112.111:

    - Assess to ensure that the farm keeps covered produce separate from the excluded produce when conducting covered activities (except when they are placed within the same container for distribution, such as gift baskets).
    - Determine the farm's practices to prevent cross-contamination by adequately cleaning and sanitizing, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce (21 CFR 112.111(b)). In addition, consider shared surfaces or equipment, tools, transportation methods, and packing (including packaging) materials.

- Determine if practices satisfy the requirements of the PSR that the farm does not distribute covered produce that drops to the ground before harvest into the fresh market.
- Determine if covered produce is packaged in a manner that prevents the formation of *Clostridium botulinum* toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).
- Identify food-packing (including food packaging) materials and determine if they are adequate for intended use, which includes being:

  - Cleanable or designed for single use
  - Unlikely to support the growth or transfer of bacteria

- If food-packing materials are reused, determine the steps the farm takes to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner. Consider materials, single use versus repeated use, liners, storage and packing conditions.

(i) 21 CFR 112 Subpart L: Equipment, Tools, Buildings, and Sanitation

Tools and Equipment

- Observe both use and cleaning of tools and equipment, when possible. Tools and equipment should be used and stored appropriately and be maintained in good condition.
- Cleaning should be conducted with appropriate products and should remove potential sources of contamination, such as soil, grease, and food residues.
- Examine all equipment and utensils to determine the following: design, materials, workmanship, maintenance, suitability, and ease of cleaning and sanitization.
- Check the sanitary condition of all machinery. Determine if equipment is cleaned prior to each use (as appropriate) and the method of cleaning.
- Inspect conveyor belts for build-up of residual materials and pockets of residue in corners and under belts. Look in inspection ports and hard-to-reach places inside, around, underneath, and behind equipment and machinery for evidence of filth, insects, and/or rodent contamination.
- Determine how brushes, scrapers, brooms, and other items used on product contact surfaces are cleaned and stored appropriately.
- Observe how cleaning occurs and if there is a possibility of contamination by the cleaning practices used. For example, the use of high-pressure hoses on one system that is idle may contaminate an adjacent system that is operational.
- If the farm has food contact materials that are not cleanable, determine how the farm ensures the materials aren't contaminating the produce. For example, does the farm use liners in its containers?

Vehicles and Transport Equipment

Observe use (when possible) and determine if the structural design is appropriate; if the vehicle is adequate for use, clean, well maintained and not contributing to potential contamination of covered produce. Consider equipment such as pallets, forklifts, tractors, trailers, equipment used between growing/harvesting, packing and storage locations, etc.

Buildings (Includes all fully or partially enclosed buildings (including minimal structures) used for covered activities)

- Determine if the building is of suitable size, construction, and design for covered activities. Buildings, fixtures, and other physical facilities must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent produce from becoming adulterated.
- Consider storage (appropriate in size for equipment and materials), drainage, plumbing (adequate water pressure, lack of cross-connections and appropriate backflow devices), general construction (walls, floors, fixtures, ducts, and pipes), and pest control. Observe whether the building design/layout minimizes the potential for contamination of covered produce, food contact surfaces, and production areas.
- Check placement of equipment, storage of materials, lighting, ventilation, and placement of partitions and screening to eliminate product contamination by bacteria, birds, vermin, etc.
- Observe traffic patterns, build-up of dust and debris, condensation or evidence of dripping, and indications of pest presence (or potential ingress/egress points) in relation to covered produce and activities.
- If the farm keeps domesticated animals, determine if they are appropriately excluded or separated from covered produce and activities. Ensure that animal excreta and litter is controlled to prevent contamination of covered produce, food contact surfaces, water sources and areas used for covered activities.

Sewage and Septic Systems

Determine type of sewage system(s) used by the farm and determine if the system(s) are appropriately maintained and provide effective waste disposal on the premises. Observe for indications of leaks, spills or overflows and determine how the farm would address a spill and how a significant event would be addressed.

Toilets and Hand-washing Facilities

Consider the number, location, design and condition of toilet and hand-wash facilities. Observe use by employees. Determine if hand-washing facilities are adequate and supplies available. Determine if waste is properly handled to prevent contamination of water sources, covered produce, food contact surfaces, and production areas.

Waste Disposal

Determine if the farm is appropriately conveying, storing, and disposing of trash and litter. Observe areas around buildings and fields for trash, around hand-wash facilities for overflowing trash cans, and for discarded materials that may act as pest attractant or harborage.

Records

Review records related to the cleaning and sanitizing of equipment used to grow, harvest, pack, and hold covered produce to ensure that they meet the requirements of Subpart O, and specifically include the date and method of cleaning.

(j) 21CFR 112 Subpart M: Sprouts

Do not inspect farms to determine compliance with this subpart under this CP. Inspections of sprout operations are covered under an FDA issued field assignment. Some covered hydroponic/aquaponic operations that grow produce other than sprouts may voluntarily follow subpart M. If so, the inspector may review results of any product or environmental testing and, if there are positives, discuss corrective actions with the firm.

(k) 21 CFR 112 Subpart N: Analytical Methods

This subpart includes one section for agricultural water and two related to sprouts. Since FDA has reproposed Subpart E, compliance with Subpart N should only be assessed as it applies to farms responsible for compliance with the harvest and post-harvest agricultural requirements in Subpart E.
Information on analytical methods: Equivalent Testing Methodology for Agricultural Water | FDA

(l) 21 CFR 112 Subpart O: Records

- Evaluate a representative sample of required records for the minimum required information, as addressed in § 112.161.
- Review records to determine if required records were reviewed, signed, and dated within a reasonable time by the supervisor or responsible party.
- For more information about records required under the PSR, see the PSA document, "Records Required by the FSMA Produce Safety Rule."

(m) 21 CFR 112 Subpart P: Variances

- If the farm employs a variance, ensure that the variance is approved by HFP/OMFS/OPS. Updates on the status of the petitions will be made public. HFP/OMFS/OPS will share approved petitions with OII DPS Branch Chiefs for distribution (for contact information see Part VI.3.)
- Review the farm's implementation of the variance to determine if it aligns with the parameters of the approved variance. If there are questions about how the farm is applying the variance, consult with the rTAN SME.

(n) 21 CFR 112 Subpart R: Withdrawal of Qualified Exemption

If the farm has received an order withdrawing its qualified exemption, the farm is required to meet the full requirements under 21 CFR 112 unless the order is under appeal.

(5) **Inspection Approach Summary Table**

Table 2 provides the inspection approach for situations that may occur at the time of inspection, some of which would be **outside of the scope of this CP**. The approaches outlined in Table 2 are to ensure consistent communication in each of the situations listed. This communication is especially important when the firm/farm may need to be inspected under another regulation and communication across and within agencies is paramount. For additional information on methods for inspecting a farm subject to the PSR see Standardized Approach to Produce Farm Inspections on the Produce Safety Inspections Compliance Program Resources additional instructions for performing routine produce farm inspections. Documents hosted on this page will be available on FSDX for States.

Table 2: Instruction for Inspection by Type of Farm, Products Produced, and PSR Coverage (status) under the Produce Safety Rule

Type of Farm/Products Produced/PSR Coverage	Inspection Approach
The farm is subject to PSR and conducts covered activities on covered produce.	Conduct the inspection and share educational resources with the farm. Significant observations should be cited under the PSR or the FD&C Act, as appropriate to the observation, and included on the FDA 4056. For-cause sampling should only be conducted by investigators/Path B inspectors at the direction of an FDA OII DPS Branch Chief and with concurrence from HFP.
The farm is conducting covered activities on covered produce but has an average of less than	This farm is not subject to the PSR and cannot be inspected under the PSR. However, the farm may be inspected for-cause under the FD&C Act with concurrence from HFP/OCE/OE.

Type of Farm/Products Produced/PSR Coverage	Inspection Approach
or equal to $25K in annual produce sales averaged over the previous three years, adjusted for inflation (exempt from the PSR).	
The farm is conducting covered activities but meets the criteria for a qualified exemption.	Farms that meet the criteria for a qualified exemption will not be included in the workplan for an inspection under this CP. If the qualified exempt status of a farm is determined during an inspection (not already known or determined during pre-announcement) and the covered produce is not currently under enforcement discretion, the investigator/inspector should consult their supervisor and do one of the following: • Issue an FDA 482 (if not already issued), inform the farm they will be conducting a limited inspection, and verify relevant sections of the PSR (21 CFR 112.6 and 21 CFR 112.7) for compliance (see Standardized Approach to Produce Farm Inspections, Appendix 5 "Regulatory Inspection Approach, Qualified Exemption" on the Produce Safety Inspections Compliance Program Resources or in FSDX for States). Issue an FDA 4056 at the close of the inspection and mark the inspection type as Other: Limited (in addition to any other applicable inspection types). • Notify the farm the inspection will not be conducted at this time and wash out the inspection (i.e., for FDA, the activity will be reported as an investigation (Op13); for Path B grantees, this is considered an update to the verified inventory and documented as an inventory verification activity).
The farm is conducting covered activities with covered produce, and the produce will be commercially processed with a kill step, e.g., oranges will be processed to make pasteurized juice.	If **all** the farm's covered produce meets the requirements for the commercial processing exemption, then the farm will not be included in the workplan for an inspection under this CP. However, if any of the farm's covered produce will not be processed per PSR section 112.2(b), the farm should be inspected to assess compliance with the applicable PSR provisions.

Type of Farm/Products Produced/PSR Coverage	Inspection Approach
	If the commercial processing exempt status is determined during an inspection (not determined during pre-announcement) and the covered produce is not currently under enforcement discretion, the investigator/inspector will issue an FDA 482 (if not already issued), inform the farm they will be conducting a limited inspection, and verify relevant sections of the PSR (21 CFR 112.2(b)) for compliance (see *Standardized Approach to Produce Farm Inspections*, Appendix 6 "Regulatory Inspection Approach, Commercial Processing Exemption"). Issue an FDA 4056 at the close of the inspection and mark the inspection type as Other: Limited (in addition to any other applicable inspection types).
Farm does not conduct covered activities on covered produce.	The farm is not subject to the PSR and cannot be inspected under the PSR. However, the farm may be inspected for-cause under the FD&C Act with concurrence from HFP/OCE/OE.
Farm has worker housing on the premises.	If the investigator/inspector reviews information or makes observations that suggest the need to enter worker housing (e.g., the farm's handwashing and toilet facility for packinghouse employees is in the worker housing) – Review IOM Section 5.1.1.9 and consult with your supervisor and the rTAN before proceeding.
The farm produces sprouts covered by Subpart M and other covered produce.	Do not inspect products covered by Subpart M of the PSR under this CP. Inspections of sprout operations are currently covered under an FDA issued field assignment (see **Part II.4.F.** for assignment interaction information). If the FDA investigator has any questions related to the inspection of sprout operations, they should contact HFP/OCE/OCOI/DCI/CPAB (see **Part VI.3.**). If it is known during planning that a farm is also a sprout operation, see **Part II.4.** for planning instructions. If it is determined during the inspection that the farm is also a sprout operation and FDA was not aware, the FDA investigator should include that information in their PFIR and ensure the Official Establishment Inventory (OEI) is appropriately updated. State inspectors should inform the FDA OII State Liaison of any operations subject to Subpart M.

Type of Farm/Products Produced/PSR Coverage	Inspection Approach
The farm produces sprouts that are considered covered produce but are not covered by Subpart M, (e.g., due to enforcement discretion such as wheatgrass sold with soil and/or substrate intact).	If the farm is a covered farm, the farm should be inspected under this CP. If there are questions about whether the produce should be covered under this program or under the FDA *Sprout Firm Inspection and Sampling Assignment* (see **Part II.4.F**) contact the rTAN. If it is determined during the inspection that the farm falls under this category and FDA was not aware, the FDA investigator should include that information in their PFIR and ensure the OEI is appropriately updated.
The farm is a farm mixed-type facility. **Note:** A "farm mixed-type facility" is an establishment that is a farm and also conducts activities outside the farm definition that require the establishment to be registered.	Instructions for planning inspection of a farm mixed-type facility see Part II.3.D. Review "OHAFO Issuance of the Form FDA 4056 or Form FDA 483 during Inspections of Produce Farms and/or Farm Mixed-Type Facilities (**Formerly Field Bulletin 67**)". This document will also be hosted on FSDX for States. If it is determined during the inspection that the farm is a farm mixed-type facility and the facility is not currently registered, the investigator/inspector should inform the firm of the need to register and provide them with the required information (see *Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities*). In farm mixed-type facilities, there may be shared space, equipment, etc. between the farm and facility sides of the operation. During domestic inspections at such facilities investigators/inspectors are expected to inspect any shared area where a covered activity is occurring. See Part II.3.D. for additional information on coordinating farm mixed-type facility inspections with FDA or within the state. Farm mixed-type facility inspections with FDA or within the state. For FDA ONLY during foreign inspections, coverage of these shared areas will be dependent on resources and other considerations, so investigators will need to obtain concurrence from an OII DPS Branch Chief.

Type of Farm/Products Produced/PSR Coverage	Inspection Approach
	The investigator should document the activities the farm conducts and the activities that were not covered under their inspection and include that in their PFIR.
A facility has opted to comply under the PSR instead of 21 CFR Part 117 (see 117.8).	Review "OHAFO Inspections of Human Food Off-Farm Produce warehouses/Packinghouses/Terminal Facilities and other Facilities that Conduct Farm-Related Activities (**Formerly Field Bulletin 69**)". This document will also be hosted on FSDX for States. • If the firm opts to be covered under the PSR and qualifies as such, the OII OHFI Division with notify OII DPS. • If the facility should be inspected under the PSR, it may be inspected by OII DPS (e.g., for foreign farms and Path A states) or by a Produce CAP grantee (Path B or C). If the farm should be inspected by a Produce CAP grantee, OII DPS will provide the Produce CAP grantee with the firm information so the Produce CAP Grantee can add the firm into their inventory and include the firm in future work-planning.
The farm performs covered activities at multiple locations, i.e., a farm located in one state may also pack produce grown in other states or a farm may grow, and harvest produce in one state but packs it in a packing house located in a neighboring state.	The inspection should only cover the operations occurring at the location being inspected. Findings from the inspection that may inform an inspection at another location should be shared with the jurisdiction covering the other farm location.
Covered produce farms with fields that overlap state borders.	If discovered prior to the inspection: • FDA led inspections (non-CAP or Path A): the FDA lead investigator should coordinate with the grantee (Path B or Path C) in the neighboring state. • Path B or Path C grantee led inspections: the state program leading the inspection should coordinate with the grantee (Path B or Path C) in the neighboring state, or with the OII DPS Branch Chief covering the state if non-CAP or Path A. If discovered during the inspection:

Type of Farm/Products Produced/PSR Coverage	Inspection Approach
	• FDA led inspections (non-CAP or Path A): continue with the inspection. • Path B or Path C grantee led inspections: advise the grantee in the neighboring state (or the OII DPS Branch Chief if non-CAP or Path A) and determine with the grantee and the OII DPS Branch Chief how to proceed.
Covered produce farms with fields that overlap international borders.	The inspection will cover the farm in the country in which it was assigned. The investigator will not cover the farm in other countries.
Covered produce farms on tribal lands.	FDA is responsible for inspecting farms on tribal land. If the state is aware of covered farms on tribal land, we encourage them to share those with FDA so they can be added to the inventory. States should contact the OII DPS Branch Chief for their state with this information.
Covered produce farm also covered under FSVP.	Inspection of the farm should be conducted under this CP; however, the FSVP aspect should not be covered during the PSR inspection. If this is determined prior to inspection, see **Part II.4**. If the investigator determines during a PSR inspection that the farm is also an importer of food, and, thus, subject to FSVP, the FDA investigator should include that information in their PFIR and ensure the Official Establishment Inventory (OEI) is appropriately updated. State inspectors should inform the OII State Liaison.
Covered produce farms handle food by-products for animal food	Inspection of the farm should be conducted. FDA investigators should include that information in their PFIR and ensure the Official Establishment Inventory (OEI) is appropriately updated.
Covered produce farms conducting retail activities.	Generally, retail activities (e.g., holding produce in sales bins in retail space) would not fall under the purview of the PSR and should not be included as part of the farm inspection. If this is a covered farm, then any covered farm activities conducted on covered produce, regardless of any retail establishment activities conducted within the same location or shared space (such as in a walk-in cooler), would need to be in

Type of Farm/Products Produced/PSR Coverage	Inspection Approach
	compliance with applicable provisions of the PSR and would need to be observed during a farm inspection. PSR inspections may also extend into areas primarily used for retail activities if activities covered under the PSR are being conducted in those areas.

(6) **For-Cause Inspections**

For-cause inspections are carried out in response to specific information that raises questions, concerns, or problems associated with an FDA regulated farm or commodity, such as in response to an outbreak, positive sample, recall, consumer complaint, or previous inspection findings (i.e., expedited next inspection). Domestic and foreign for-cause inspections may be performed at farms covered by this CP.

Expedited next inspections based on prior inspection findings would be a for-cause inspection type and may be determined and assigned by HFP/OCE/OE, an OII DPS Branch Chief, or the Produce CAP grantee's (Path B or Path C) respective management. For any other type of for-cause inspection under this CP, Path B grantees will coordinate with a OII DPS Branch Chief to obtain HFP/OCE/OE concurrence.

B. Investigations

Domestic or foreign investigations (OP 13 or OP 15, respectively) may be performed at farms covered by this CP. See IOM subchapter *8.2.5 Farm Investigations* for instructions on how to conduct and report an investigation related to a foodborne illness outbreak.

An OII DPS Branch Chief, after consult with HFP/OCE/OE as appropriate, will inform the investigator/inspector on when an investigation should be performed. Specific instructions for farm investigations may be provided by an OII DPS Branch Chief or within an FDA issued assignment.

Scenarios, in addition to investigations related to foodborne illness outbreaks, that may result in an investigation are identified in Table 2.

C. Sample Collections

There are times when sampling may be warranted to support significant observations related to potential contamination of produce or food contact surfaces. Collection of product and/or environmental samples should be considered when the results are likely to support that a source and route of contamination are present. Sampling may also be considered if there is a

credible complaint or whistleblower or as requested by FDA to meet the objectives within FDA-issued assignments (e.g., in response to foodborne illness outbreaks). Some examples of situations/observations that might warrant for-cause sampling are listed in Produce Sampling Instructions which is hosted on the Produce Safety Inspections Compliance Program Resources or in FSDX for States the which may be referenced when for-cause sampling is being considered, even outside of for-cause inspections.

Sampling conducted by FDA investigators and Path B inspectors require concurrence from HFP/OCE/OE. Such requests will generally be evaluated in terms of strength in supporting observed conditions as well as enforcement actions.

(1) **Requesting Concurrence to Collect Compliance (For-Cause) Samples**

The instructions below are specifically for FDA investigators and Path B inspectors. Although Path C inspectors are not expected to request concurrence, they can utilize the instructions below if there are questions regarding sampling (e.g., capacity, training, etc.).

- Contact the appropriate OII DPS Branch Chief (see Part VI.3.) who will coordinate contact with the assigned rTAN SME contact and HFP/OCE/OE.
- FDA Investigators: For collection of samples at foreign farms, the OII DPS Branch Chief will also contact the OII Division of Foreign Food Investigations and Global Operations Branch Chief to coordinate shipping from a foreign country.
- Explain the conditions and practices observed and evidence to support those observations. Include this information within the request provided to the OII DPS Branch Chief to assist with expediting a response to the request.
- Send photos (when possible) with narrative descriptions that support the observations to the OII DPS Branch Chief.

(2) **Sample Collection Instructions**

Instructions for produce sampling are included in the Micro Sampling CP (see Part II.4.) and instructions for environmental farm sampling (e.g., soil and water) are included in Produce Sampling Inspections hosted on the Produce Safety Inspections Compliance Program Resources and in FSDX for States.

Path C Inspectors - Follow state sample collection procedures; instructions above can be utilized as a reference. Instructions for sharing sampling results with FDA are within the above referenced documents.

(3) **Sample Shipping**

FDA Investigators – Refer to the Micro Sampling CP (see Part II.4.) and Produce Sampling Inspections hosted on the Produce Safety Inspections Compliance Program Resources and in FSDX for States.

For state CAP partners:
If the sample is collected using FDA authority, all FDA sample procedures must be followed, and FDA will assist in identifying the servicing laboratory.

If the sample is collected using state authority, all state sample procedures must be followed, and the state will identify the servicing laboratory.

2. Recall Activities

If during an inspection a recall is initiated by the farm, notify the OII DPS Branch Chief and they will coordinate with the appropriate FDA OHFI Division.

3. Import Activities

There are no specific import activities under this CP. However, if a farm that is inspected imports covered produce, follow instructions within Table 2.

4. Reporting

For all produce safety inspections conducted by FDA or Path B grantees, the investigator/inspector will issue an FDA 4056 "Produce Farm Inspection Observations Form" to the farm at the conclusion of the inspection and prior to leaving the farm. Observations on the FDA 4056 should focus on those conditions that have a direct impact on food safety or that, if not corrected, could have an effect on food safety. Observations made by investigators/inspectors are critical in supporting charges under 402(a)(4) of the FD&C Act in Warning Letters, injunctions, and administrative detentions (see **Part V**). As such, investigators/inspectors should document how each violation may result in the contamination of covered produce with human pathogens (refer to IOM Section 5.3, *Evidence Development*).

For example, failure of a worker to wash their hands after using the toilet facilities and prior to returning to harvest and handling (contacting) covered produce or food contact surfaces may be cited under §112.32(b)(3) on the FDA 4056 and in a Warning Letter, but the significance of the observation is that the worker hands may have been contaminated with human feces, a known source of human pathogens, and then the worker touched covered produce without an intervening handwashing step—a potential route. It is not enough to document that the worker did not wash their hands after using the toilet facilities; it is critical to document that unwashed hands came in contact with covered produce and/or food contact surfaces.

Non-reportable observations (i.e., observations not listed on the FDA 4056) are to be discussed with farm management and included in the inspection report under the "General Discussion with Management" section.

Per the FDA 4056 instructions, found on the Produce Safety Inspections Compliance Program Resources (documents hosted on this page will be available on FSDX for States),corrective

actions taken by the farm during an inspection to any observations listed on the FDA 4056 must be noted on the FDA 4056. Per current policy, for FDA inspections, all corrective actions (for written observations and verbal discussion items) must be documented in the inspection notes, inspection report, and in the Corrective Action Report (CAR) system within eNSpect.

A. Instruction for Review of the FDA 4056

When applicable, FDA investigators and state inspectors are encouraged to request assistance (i.e., rTAN) with evaluating the public health significance of conditions at the farm (**Part II.4.E.**). FDA investigators will submit draft FDA 4056 forms with written observations to their OII DPS Branch Chief for review.

- For FDA led inspections, OII DPS must submit the FDA 4056 to HFP/OCE/OE for review prior to FDA 4056 issuance.
- When the FDA 4056 observation(s) indicate the inspection is likely to trigger a regulatory response (e.g., certain VAI and OAI; **see Part V.**), Path B state grantees are to submit a copy of the signed and issued FDA 4056 to FSDX as soon as possible, but no more than two business days after the issuance of the FDA 4056; and notify via email the OII DPS Branch Chief for their state.

B. Instruction for Issuing the FDA 4056

A FDA 4056 (FDA and Path B states) or state-equivalent (for Path C grantees) will be issued at the conclusion of every produce safety inspection prior to leaving the farm premises. Voluntary corrections should be encouraged, and corrective actions taken by the farm in response to reportable significant observations before the close of the inspection should be verified (time permitting) and documented on the FDA 4056. Upon issuance of the FDA 4056, if observations were included, the investigator/inspector will recommend that the farm respond in writing to the FDA 4056 observations within 15 business days from issuance to address observations listed on the FDA 4056. FDA investigators will provide the farm the FDA's response memo for the farm's use. Path B inspectors will not use the FDA's response memo (but should create an equivalent response memo; OII DPS can assist); the farm sends their response to the state.

Additional instructions can be found in:

- Form FDA 4056 Produce Farm Inspection Observations Instructions
- OHAFO Issuance of the Form FDA 4056 or Form FDA 483 during Inspections of Produce Farms and/or Farm Mixed-Type Facilities (**Formerly Field Bulletin 67**) FDA only

Note: The FDA 483, Inspectional Observations, will not be issued for produce safety inspections.

C. Instructions for the Farm Response to the FDA 4056

- **For FDA-led inspections**, domestic and foreign farms should send their response by e-mail to producefarminspection@fda.hhs.gov with "4056 Response" in the Subject line. The Division of Foreign Food Investigations and Global Operations (DFFIGO) will have access to the e-mail box listed above for review of foreign firm responses. In addition, HFP OCE/OE/DPIE/PEB will forward all firm responses from foreign firms (upon receipt) to FDA483responseinternational@fda.hhs.gov.
- **For Path B state inspections**, the farm's response to the FDA 4056 should be addressed to the State's produce program office address. The address to the State Office should be the address listed on the FDA 4056.
- **For FDA and Path B state inspections**, if an investigator/inspector is contacted by a farm after the close of the inspection regarding the farm's response to inspectional observations or any planned follow-up action and a regulatory action is being considered, the investigator/ inspector should not respond to the farm and must notify producefarminspection@fda.hhs.gov immediately.

D. Inspection Reports

(1) FDA Inspection Reports

The Produce Safety Inspection Protocol (IP) is available for FDA investigators in eNSpect and must be completed for every FDA inspection covered under this CP and used to generate the Produce Farm Inspection Report (PFIR).

(2) Path B Inspection Reports

Path B state grantees will not submit full reports for inspections that are not likely to trigger a regulatory response (e.g., NAI and VAI) to FDA on a routine basis. FDA may request an individual report on an as-needed basis. Reports for inspections that are not likely to trigger a regulatory response (e.g., NAI and VAI) should consist of the following:

- Produce Farm Inspection Report Summary (PFIRS) Form (Attachment B)
- Attachments – Forms 482, 4056 and 484 (if samples collected); See IOM Section 5.11.4.3.20 *Attachments*
- Exhibits – See IOM Section 5.11.5 *Exhibits*

For each inspection where the FDA 4056 includes any written observations, Path B state grantees will submit the FDA 4056 to the FDA via FSDX on the 1st business day of the next month (for example, 4056 was issued on January 5, so it would be uploaded to FSDX on February 1).

When the FDA 4056 observation(s) indicate the inspection is likely to trigger a regulatory response (e.g., certain VAI and OAI; **see Part V.**), Path B state grantees are required to

submit a copy of the signed and issued FDA 4056 to FSDX as soon as possible, but no more than two business days after the issuance of the FDA 4056; and notify via email the OII DPS Branch Chief for their state. For such inspections, in addition to the FDA 4056, Path B state grantees will also submit all inspection report documents in FSDX within 15 business days of the close of the inspection. Inspection report documents for potentially violative inspections should consist of the following:

- Produce Farm Inspection Report Summary (PFIRS) Form (Attachment B)
- Produce Farm Inspection Report (PFIR) Violative Inspection Template for Produce Path B Grantees in FSDX. This template contains the typical report headings needed in a violative inspection. The appropriate use of headings should not result in repetition of the same information in different sections. The inspector is encouraged to create headings as necessary to present the inspectional findings in the most concise manner.
- Responses received from the farm to the 4056.
- Attachments – Forms 482, 4056 and 484 (if samples collected). See IOM Section 5.11.4.3.20
- Exhibits – See IOM Section 5.11.5

Information obtained during an inspection by a commissioned official is an official FDA record and is subject to confidentiality commitments and may not be further disclosed by state agencies without permission by the FDA's Division of Information Disclosure (DID) at FDAinfoshare@fda.hhs.gov. Public requests for FDA information obtained pursuant to a commission are processed by FDA under the Freedom of Information Act (FOIA).

For FOIA requests for records from activities performed under FDA commissioning authority, grantees can send an email to FDA's Division of Information Disclosure (DID) at FDAinfoshare@fda.hhs.gov, with a Subject line "State Referral to FDA FOIA" and attach a copy of the FOIA request and a copy of the records. FDA OSPOP will log and process the request.

E. Inspection Classifications

To classify inspections, refer to Field Management Directive (FMD) 86 "Establishment Inspection Report Conclusions and Decisions" at https://www.fda.gov/downloads/ICECI/Inspections/FieldManagementDirectives/UCM382035.pdf

PART IV – ANALYTICAL

In the event for-cause samples are collected under this Produce Safety Inspection CP, refer to the Micro Sampling CP for additional analytical instructions. Instructions covering produce sampling operations not covered in the Micro Sampling CP are found within Produce Sampling Instructions found in the Produce Safety Inspections Compliance Program Resources (this document will be

available in FSDX for States). Path B and Path C grantees can utilize the information within the Micro Sampling CP, as needed.

1. Analyzing Laboratories

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2. Analyses to be Conducted

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3. Methodology

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4. Reporting

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PART V - REGULATORY/ADMINISTRATIVE STRATEGY

This program emphasizes voluntary correction at each step as the most efficient way to achieve food safety and protection of public health. However, FDA will take product actions to remove food from commerce or prevent the introduction of adulterated food into interstate commerce, when necessary, for the protection of public health.

FDA will make decisions on and lead compliance actions resulting from inspections conducted by FDA investigators and Path B inspectors, including immediate product actions, advisory actions such as regulatory meetings and Warning Letters (WL), as well as judicial actions such as injunctions. A progressive approach to enforcement actions will be utilized, where appropriate, while allowing for action to address situations with significant public health risk.

To promote a uniform compliance response to violations of the PSR, the "Compliance and Enforcement (C&E) Action Template for the Produce Safety Program" was developed by NASDA, FDA, and states. This document outlines general enforcement principles, progressive enforcement, and compliance and enforcement decision factors important to the regulatory strategy for the PSR. Similarly, the "Compliance and Enforcement Decision Table" (see Attachment A) includes information on enforcement considerations. These documents may be used as a reference to help determine the most appropriate action(s).

1. Findings

FDA HFP/OCE/OE and/or Produce CAP state grantee compliance staff will need to consider the urgency of need for a compliance action. Attachment A outlines main categories of findings: (1) conditions that are likely to cause an imminent public health hazard if not corrected or conditions that directly contaminate produce, (2) conditions that may cause produce contamination or repeat/continued technical violations of the rule, and (3) technical violations of the PSR which will not likely cause produce contamination. In some cases, FDA may consider multiple actions. For example, if there is an imminent public health hazard, FDA would first act to remove the affected product from the market or prevent the affected product from entering the market. Afterwards, FDA may consider a Warning Letter in addition to the product action.

2. Charges

Charges that may be applicable to this program include the following, which are also discussed in the "Actions" section below:

- The failure to comply with 21 CFR Part 112, issued under section 419 of the FD&C Act [21 U.S.C. 350h], is a prohibited act under section 301(vv) of the FD&C Act [21 U.S.C. 331(vv)]. By itself, this citation is not sufficient to pursue a product action (i.e., does not support an action that relies on a determination that the produce is adulterated. See adulteration charges below.)
- An article of food is adulterated under section 402(a)(1) of the FD&C Act [21 U.S.C. 342(a)(1)] in that it bears or contains any poisonous or deleterious substance which may render it injurious to health.
  Note that in the case that such substance is not an added substance, such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health. The 402(a)(1) charge is normally supported by analytical findings, such as pathogen findings; however, it may also be supported by traceback and epi evidence demonstrating that the produce resulted in a foodborne outbreak.
- An article of food is adulterated under section 402(a)(4) of the FD&C Act [21 U.S.C. 342(a)(4)] if it 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.

3. Actions

It is not possible to outline every circumstance that a compliance officer, or the state equivalent, will encounter. FDA evaluates each circumstance on a case-by-case basis. This section outlines possible compliance actions that FDA may consider and the circumstances for each type of action as examples. Compliance actions available to Path C grantees will vary by state.

The first consideration is the quality of the evidence and whether the evidence establishes a violation of the law/regulation. This is not unique to produce, and compliance officers should rely on their evidence development training and experience.

FDA will also consider whether lasting corrective actions have been implemented. For example, deviations that are corrected and documented within 15 working days from the close of the inspection, to the satisfaction of CFSAN, maybe omitted from a Warning Letter under consideration. If such deviations are included in the Warning Letter, the correction already taken by the farm should be acknowledged in the Warning Letter.

If Path B state grantees, operating under FDA authority, anticipate a need for advisory/regulatory actions, they must coordinate with an OII DPS Branch Chief who will set up discussions with HFP/OCE/OE.

A. Product Actions

If there is adequate evidence that there is adulterated produce (within the meaning of section 402(a)(1) or 402(a)(4) of the Act, for example) on the market, FDA (in conjunction with the State contacts) may ask the farm to recall the produce (see RPM Chapter 7). If the farm isn't willing to recall affected produce, FDA, in conjunction with the State contacts, will consider other available tools to ensure consumers are protected, such as public notification or administrative detention/seizure (mandatory recall does not apply to farms).

Note that all FDA product actions, such as seizure and administrative detention, hinge on a finding of adulteration (or misbranding). While 21 CFR 112.192 states that failure to comply with the requirements of that part is a prohibited act, a violation of 21 CFR Part 112 does not automatically cause the product to be adulterated. To establish adulteration, it is critical that the investigators/inspectors document 402(a)(4) conditions related to sources and routes of produce contamination.

For additional information, refer to possible actions listed within Part V of the "Sampling for Foodborne Biological Hazards, and Filth – Domestic and Import" CP.

B. Regulatory Meetings

If the farm does not take adequate action to correct significant deviations that can cause a public health concern, but there is no evidence to establish that the produce is immediately impacted, FDA, in conjunction with State contacts, will consider holding a regulatory meeting with the farm to encourage corrective action.

If the regulatory meeting does not result in satisfactory correction, FDA will consider additional actions to achieve corrective action and a follow-up inspection will often be scheduled. The enforcement response will reflect the significance of the observations, the farm's response, and whether the farm was advised of the issue during a previous inspection.

C. Warning Letter/Injunction

If, during an inspection conducted in follow up to a regulatory meeting, FDA determines that lasting corrections have not been implemented by the farm, and that the observations noted

may lead to adulterated produce, FDA may send a warning letter to the farm. Conversely, depending on the significance of the findings and the farm's response to violations, the warning letter may precede a regulatory meeting. A finding of pathogens on produce [402(a)(1)] may be used in conjunction with other observations e.g., a violation of Part 112 or a source and a route of contamination, to bolster a citation under Part 112 and to support a 402(a)(4) charge in a warning letter or other action(s). With the progressive enforcement strategy, uncorrected violations of public health significance, where the farm is either unwilling or unable to make voluntary corrections, may warrant consideration of increased enforcement actions to include injunctions.

D. Foreign Farm Actions

In addition, for foreign farms, FDA may consider Import Alerts, modifying Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) scores, increased screening, and/or contacting foreign government authorities to recommend follow-up as appropriate.

4. Regulatory Follow-up

Regulatory follow-up will depend on several factors, including the nature of the non-compliance observed, growing season, and farmer's response (see Attachment A**)**. As indicated above, FDA will utilize a progressive enforcement strategy to determine the appropriate regulatory follow-up activities.

When for-cause and, including follow-up, farm inspection assignments are issued by FDA, there may be additional instructions included in the assignment to complement the instructions in this Compliance Program.

5. Communication and Coordination for Compliance and Enforcement

As initiated in section 419 of the Act, defined in the CAP, and emphasized in this document, the coordination and cooperation between the FDA and States to enforce the PSR is paramount. As such, clear delineation of roles and communication channels is crucial to the success of the program.

In the event a significant public health situation is identified and likely to trigger a regulatory response,

- During an FDA-led inspection in a non-CAP state: HFP/OCE/OE, through OII DPS, will keep the OII OHFI Division informed of any FDA enforcement action with the farm.
- During an FDA-led inspection in a Path A, B, or C state: HFP/OCE/OE, through OII DPS, will keep the OII OHFI Division and the State CAP PI (as appropriate) informed of any FDA enforcement strategy/corrective action with the farm. OII DPS Branch Chiefs facilitate this communication.

- During a Path B state grantee-led inspection: The Path B state grantee will inform the OII DPSPSN Branch Chief for the state where the farm is located (see **Part VI.3.**), so that the state can discuss the findings with FDA. FDA will consider the findings and will include the State agency in any discussions about any FDA enforcement strategy/corrective action with the farm.

PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. References

Major guidance and reference materials pertaining to this program are listed below:

- FSMA Final Rule on Produce Safety (Federal Register Notice)
- FDA Food Safety Modernization Act (FSMA)
- FSMA Final Rule on Produce Safety Webpage
- Produce Safety Network Directory
- Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
- Small Entity Guidance for Industry: 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: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs
- FSMA Rules & Guidance for Industry Webpage
- Produce Safety Inspections
- Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds (Guidance for Industry)
- Standards for Produce Safety Coverage and Exemptions/Exclusions Flowchart
- Factsheet: Rarely Consumed Raw Produce
- FSMA Inflation Adjusted Cut Offs
- Guidance for Industry: Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Produce Safety Rule
- Factsheet: Required Training for Covered Farms
- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E (FDA Final Rule)
- Fact Sheet: Produce Safety Rule Fact Sheet on Dropped Covered Produce
- Compliance Dates: Produce Safety (Part 112)
- Produce Safety Alliance (PSA)
- FSMA Collaborative Training Forum
- Produce Decision Analysis Tool (PDAT)
- Produce Inspection for Regulators Virtual Tour
- Fact Sheet: What to Expect of a Regulatory Inspection
- Investigations Operations Manual
- FDA-State Produce Implementation Cooperative Agreement Program (CAP)
- Requirements for Harvest and Post-Harvest Agricultural Water in Subpart E for Covered Produce Other than Sprouts | FDA
- FDA 4056 Produce Farm Inspection Observations Form

- Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry
- OHAFO Issuance of the Form FDA 4056 or Form FDA 483 during Inspections of Produce Farms and/or Farm Mixed-Type Facilities (**Formerly Field Bulletin 67**)
- Records Required by the FSMA Produce Safety Rule
- Regulatory Procedures Manual
- FDA Fact Sheet: Equivalent Testing Methodology for Agricultural Water
- OHAFO Inspections of Human Food Off-Farm Produce warehouses/Packinghouses/Terminal Facilities and other Facilities that Conduct Farm-Related Activities (**Formerly Field Bulletin 69**).
- FDA 482, Notice of Inspection – Path B state grantees should contact their local FDA State Liaison. (not accessible from the internet)
- FDA 484 Receipt for Samples – Path B state grantees should contact their local FDA State Liaison. (not accessible from the internet)

2. Attachments

A. Compliance and Enforcement Decision Table
B. Produce Farm Inspection Report Summary and Instructions
C. Agricultural Water Compliance Dates and Inspectional Instructions

3. Program Contacts

A. HFP

Purpose	Name	Organization	Contact
General Program Information	Mark Farrell Jacob Reynolds	HFP/OCE/OCOI/DCI/CPAB	240-402-2483 202-617-5227
Enforcement Contact	HFP OCE Produce Team	HFP/OCE/OE/DPIE/PEB	240-402-4651
Program Office Contact	Michael Mahovic	HFP OMFS/OPS/DFPS/FPPB	240-402-2563

B. OII

Purpose	Name	Organization	Contact
Domestic Inspection Information	Brittany Nork (primary) Kevin Gerrity	OII/OHFI-W/DPS/PSB2 OII/OHFI-W/DPS	Brittany.Nork@fda.hhs.gov; #312.315.5536 Kevin.Gerrity@fda.hhs.gov; #858-401-0242
Foreign Inspection Information	Christian Witkovskie	OII/OHFI-E/DFFIGO	Christian.Witkovskie@fda.hhs.gov
State Programs	Travis Goodman	ODP/DPPI	Travis.Goodman@fda.hhs.gov

PART VII - CENTER RESPONSIBILITIES

The Human Foods Program's Office of Microbiological Food Safety (OMFS)will provide subject matter expertise in the maintenance and evaluation of the Compliance Program and provide guidance to the HFP/OCE with regard to program priorities, relevant evaluation questions, and recommended program changes. The HFP/OCE will lead the effort and work in conjunction with the OMFS to prepare routine compliance program evaluations. Evaluation will be conducted on a periodic basis and outline the program office's current objectives, general and specific program evaluation questions, list recommendations for process improvement, and highlight data patterns and trends for better targeting and resource allocation. The HFP/OCE will make these evaluations available as well as FSMA Tracker reports that can be run annually or as frequently as needed to track accomplishments.

ATTACHMENT A – Compliance and Enforcement Decision Table

Attachment A
Compliance and Enfo

ATTACHMENT B – Produce Farm Inspection Report Summary and Instructions

Produce Farm Inspection Report Sun

ATTACHMENT C – Agricultural Water Compliance Dates and Inspectional Instructions

This attachment includes information related to agricultural water, including compliance dates, and should be used by FDA investigators and Produce CAP grantees for planning and conducting inspections to assess compliance with Subpart E (Agricultural Water) of the PSR.

1. Subpart E: Proposed Revisions and Current Status

- In March 2017, FDA announced its intent to review of the requirements for agricultural water in subpart E of the final Produce Safety Rule.
- In the Federal Register on March 18, 2019, FDA published a final rule to extend the compliance dates for Subpart E for all produce other than sprouts (see https://www.federalregister.gov/documents/2019/03/18/2019-04652/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-extension).
- On December 6, 2021, FDA published a proposed rule to amend Subpart E (see 86 FR 69120). For additional information on the proposed rule see FSMA Proposed Rule on Agricultural Water and the Federal Register Notice announcing the Proposed Rule on Agricultural Water. FDA also announced that it intended to exercise enforcement discretion for the agricultural water requirements pending further consideration.
- In a Federal Register notice issued July 19, 2022, FDA proposed new compliance dates for the pre-harvest water provisions of Subpart E (see section (2), Compliance Dates) The December 6, 2021, proposed rule did not include proposed changes to the requirements for harvest and post-harvest uses of agricultural water**.** Therefore, in the July 19, 2022, notice, FDA also announced that it would begin lifting enforcement discretion for harvest and post-harvest water requirements as noted in Section (2) below.
- FDA published a Fact Sheet for more information: Requirements for Harvest and Post-Harvest Agricultural Water in Subpart E for Covered Produce Other than Sprouts | FDA.

2. Summary of Requirements for Subpart E

Subpart E establishes science-based minimum standards for agricultural water, including requirements for water quality, testing, and records. This subpart also establishes the measures a farm must take if their agricultural water does not meet specific requirements.

A. Pre-harvest agricultural water requirements:

FDA intends to exercise enforcement discretion for the pre-harvest requirements of Subpart E in the produce safety regulation for produce other than sprouts while this subpart undergoes rulemaking. In the interim, farms should continue to focus their attention on good agricultural practices (GAPs) to maintain and protect the quality of their water sources. See FDA Guidance for Industry: *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. Note: farms should not be cited on the FDA 4056 for not following the GAPs in this Guidance.

In conjunction with the proposed rule, FDA has developed an Agricultural Water Assessment Builder. This tool is designed to help farms understand the proposed requirements for an agricultural water assessment in the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water" proposed rule, and is available for farms to use and provide feedback on.

Since farms covered by the PSR are also covered by the general provisions in Subpart B, 21 CFR 112.11, farms must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards. There may be other citations that are appropriate to the situation; the rTAN can assist if needed to identify the most appropriate citations.

B. Harvest and post-harvest agricultural water requirements:

Agricultural water must be safe and of adequate sanitary quality for its intended use (see § 112.41). As noted above, there are no proposed changes to the requirements for harvest and post-harvest agricultural water. Therefore, as farms reach their compliance dates, they will be responsible for compliance with the relevant provisions in Subpart E (and related provisions in Subpart N and O) that apply specifically to agricultural water used during and after harvest, as well as those requirements pertaining to all agricultural water used. These provisions include:

- § 112.41: Quality standard
- § 112.42: Inspections and maintenance
- § 112.43: Treatment
- § 112.44(a): Microbial quality criterion
- § 112.45(a): Measures
- § 112.46(a) and (c): Testing
- § 112.47: Who may test
- § 112.48: Additional management and monitoring
- § 112.50: Records
- § 112.151: Test methods
- § 112.161: Records requirements

3. Compliance Dates

On December 6, 2021, FDA published a proposed rule to amend Subpart E (see 86 FR 69120). For additional information on the proposed rule see FSMA Proposed Rule on Agricultural Water and the Federal Register Notice announcing the Proposed Rule on Agricultural Water. FDA also announced that it intended to exercise enforcement discretion for the agricultural water requirements.
In a supplemental notice published July 19, 2022, FDA announced continued enforcement discretion for harvest and post-harvest water requirements until:

- Very small businesses: January 26, 2025
- Small businesses: January 26, 2024
- All other businesses (larger than small): January 26, 2023

In the final rule for pre-harvest agricultural water, FDA established the following compliance dates:

- Very small businesses: April 5, 2027
- Small businesses: April 6, 2026
- All other businesses (larger than small): April 5, 2027.

4. Inspection dates

A. Pre-harvest agricultural water:

- FDA has issued a final rule to amend some of the requirements for pre-harvest agricultural water in Subpart E.
- Until the applicable compliance dates are reached, based on farm size, FDA intends to continue to exercise enforcement discretion for pre-harvest agricultural water. During this time, **farms should not be evaluated against the pre-harvest water provisions in Part 112 Subpart E and no citations under 21 CFR 112 Subpart E related to pre-harvest water (or related requirements in Subpart N or O) should be included** on the observation form (FDA Form 4056 or state equivalent) at this time.

B. Harvest and post-harvest agricultural water:

Enforcement discretion will end for the harvest and post-harvest provisions of the current Subpart E, starting with large farms in January 2023 (see section (2), Compliance Dates, for more information).

- **Surveillance Inspections:** During this first year (January 26, 2023- January 25, 2024) after the end of the enforcement discretion period for large farms, FDA plans to use an educational approach for harvest and post-harvest agricultural water and will work closely with industry and partners to provide education, training and technical assistance. Routine inspections of large farms beginning after January 25, 2024 should assess compliance with the harvest and post-harvest provisions of Subpart E.
- **For-cause inspections**: During for-cause inspections conducted after the relevant enforcement discretion end date, farms should be evaluated for compliance with the harvest and post-harvest requirements of Subpart E.

Prior to the relevant enforcement discretion end dates, farms should not be inspected for compliance with the harvest and post-harvest provisions of Subpart E. Instead, these covered farms should be evaluated for compliance with Subpart B, 21 CFR 112.11 and section 402 of the FD&C Act.

5. Key Areas to Focus on During Inspections

A. Coverage During All Farm Inspections

Regardless of compliance dates, all covered farms should be familiar with their water sources and are required to provide reasonable assurances that water is appropriate for use (e.g., the farm complies with Subpart B, 21 CFR 112.11 and the produce produced or handled by the farm is not adulterated under section 402 of the FD&C Act). Therefore, during all farm inspections, inspection staff should:

- Identify sources of water used by the farm, specifically water that may come into direct contact with covered produce or food contact surfaces.
- Assess the farm layout and evaluate agricultural water sources and distribution systems for conditions that could cause a public health concern, such as significant animal intrusion; damage to a seepage irrigation system; and cross-connections between agricultural water sources and potential contaminant sources.
- Review systems in place to mitigate risk from water, such as protecting water source and distribution systems and treatment systems, if used.
- When possible, observe all water sources and distribution systems (including wells, springs, irrigation canals, municipal connections, holding tanks and ponds, reservoirs, pumps, etc.) for signs of gross contamination.
    - Please note that many water sources may be located or extend on property not controlled by the regulated entity. The inspection should not extend off-farm without prior approval. FDA investigators and Path B inspectors should seek approval to extend their inspection off-farm from the OII DPS Branch Chief, who will consult HFP OCE as needed.
- Identify any measures the farm uses to assess or maintain water quality or to treat the water before use.

B. When evaluating farms for compliance with the harvest and post-harvest provisions of Subpart E (see Compliance and Inspection Date information above), inspections should address the following elements for harvest and post-harvest water:

- Does the farm use agricultural water for harvest or post-harvest activities and, if so, what are those uses?
- What is the source(s) of the agricultural water used for activities conducted during and after harvest?
    - Includes water applied in any manner that directly contacts covered produce, food contact surfaces, or used for handwashing during and after harvest activities (see 112.44).)
- Observe agricultural water sources and water systems used for harvest and post-harvest activities for compliance with the relevant provisions of Subpart E.

- Are there conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces? (see 112.42(a))
- Are the agricultural water distribution systems adequately maintained to prevent them from being a source of contamination? (see 112.42(b))

- Review the farm's determine compliance with relevant requirements of Subpart E and discuss the farm's use of and activities related to agricultural water.

  - Has the farm inspected its water systems at least annually to identify conditions reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces? If so, were any deficiencies identified and what were they? What corrective actions were done in response to the deficiencies? (See 112.42, 112.50)
  - Does the farm treat its agricultural water? If so, what methods were used, and does the method(s) make the water safe and of adequate sanitary quality? Does the farm monitor the treatment of the water? (see 112.43, 112.50)

- What products are used, at what rate, and is this appropriate according to the product label for this specific use? (see 112.43)

  - Does the farm use untreated surface water that contacts produce or food contact surfaces or for handwashing? (See 112.44(a))

    - Note: Farms must not use untreated surface water:

      - In any manner that directly contacts produce during or after harvest
      - For food contact surfaces
      - To make ice that will contact food contact surfaces
      - For handwashing during or after harvest

  - Does the farm perform testing (for water other than untreated surface water) to ensure the water meets the microbiological standard of no detectable *E. coli* in 100 mL of water? (see 112.44(a), 112.46)

    - Testing is NOT required if the agricultural water used during or after harvest is:

      - Sourced from a Public Water System that meets certain requirements (112.46(a)(1))
      - Sourced from a public water supply that meets the microbial criterion of no detectable generic E. coli per 100 mL of water (112.46(a)(2)); or
      - Treated in accordance with the requirements in 112.43.

    - Testing IS required if using untreated ground water for activities conducted during or after harvest. Inspector should determine:

- What is the frequency and most recent date of the testing?
- What testing method(s) are used?
- If the water doesn't meet the standards, what corrective action has the farm taken? (112.45)
- If corrective actions were taken, were these documented according to 112.50?

- Does the farm manage the water used during harvest, packing and holding activities in a manner to maintain its safety and adequate sanitary quality, and minimize the potential for contamination of covered produce and food contact surfaces? (see 112.48(a))
- Does the farm visually monitor the quality of harvest and post-harvest water for build-up of organic matter? How does the farm determine when to change the water or otherwise address the build-up? (see 112.48(b))
- Does the farm monitor and maintain temperatures of the water for harvest/ post-harvest activities as appropriate for the commodity and operation? (see 112.48(c))
- Does the farm keep required records? (See 112.50). Required records include, as applicable:

  - records of findings from water system inspections,
  - water testing results and/or annual certificates from public water systems
  - monitoring of water treatments, and
  - any corrective actions taken.

- Are the records in compliance with the requirements of 112.50 and Subpart O?

6. Form FDA 4056 observations:

- **FDA investigators and Path B state inspectors:** Contact rTAN to discuss observations related to agricultural water before including such observations on a form FDA 4056.
- **Path C state inspectors:** Consider contacting the rTAN to discuss observations related to agricultural water before including such observations on a state form FDA 4056 equivalent.