CHAPTER 03 FOODBORNE MICROBIOLOGICAL HAZARDS

SUBJECT:	**Sprout Safety Inspections**
IMPLEMENTATION DATE:	10/1/2024 Correction Date: 9/18/2025, 9/23/2025
Product Codes:	Use Appropriate Product Codes
Product/Assignment Codes:	03060 – SPROUT SAFETY ACTIVITES

FIELD REPORTING REQUIREMENTS:

Complete inspection reporting, including the Sprout Inspection Protocol (Sprout IP) and Establishment inspection report (EIR) 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 actions taken during inspections must be documented in the Observation and Corrective Action Reporting (OCAR) system within eNspect.

Contents

PART I – BACKGROUND 4
1. History 4
2. Scope of Compliance Program 4
3. Summary of Requirements 4
4. Exemptions and Modified Requirements 10
5. Compliance Dates and Enforcement Discretion 10
PART II - IMPLEMENTATION 12
1. Objectives 12
2. Inspectional Priorities 12
A. Priority 1 Outbreak History 12
B. Priority 2 Recall and Positive Sample History 12
C. Priority 3 Reinspection 13
D. Priority 4 Initial Inspections of Sprout Operations 13
E. Priority 5 Other Routine Sprout Inspections 13
3. Planning Instructions 13
A. Inspections 13
B. Training Requirements 13
C. Specific Planning Instructions for Inspections 13
D. Inspecting Farm Mixed-Type Facilities 14
E. Regulatory Technical Assistance Network (rTAN) 14
F. Compliance Programs and/or Assignment Interactions 14
G. Interactions with other Federal Agencies, State, and Local Counterparts 16
H. Resource and Reporting Instructions 16
PART III - INSPECTIONAL 18
1. Operations 18
A. Inspections 18
B. Investigations 31
C. Sample Collections 31
D. Import Activities 33
E. Other 33
2. Reporting 33

PART IV - ANALYTICAL 34
1. Analyzing Laboratories 34
2. Analyses to be Conducted 34
3. Methodology 34
E. coli O157:H7 and other pathogenic *E. coli* (STEC): 34
Salmonella: 36
Listeria monocytogenes: 37
Additional analyses when pathogens are recovered: 39
4. Reporting 40
PART V - REGULATORY/ADMINISTRATIVE STRATEGY 42
1. Findings 42
2. Citations/Charges 42
3. Enforcement Strategy 42
A. Product Actions 43
B. Warning Letter 43
C. Regulatory Meetings 43
D. Injunctions 44
4. Regulatory Follow-up 44
5. Communication and Coordination for Compliance and Enforcement 44
PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS 45
1. References 45
2. Program Contacts 46
A. HFP Program Contacts 46
B. OII Program Contacts 46
PART VII - HFP RESPONSIBILITIES 48

PART I – BACKGROUND

1. History

The Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) of 2011 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 standards for the safe growing, harvesting, packing, and holding of fruits and vegetables, including sprouts, 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 microbiological hazards into or onto produce and to provide reasonable assurances that produce is not adulterated on account of such hazards.

Sprouts have been frequently associated with foodborne illness outbreaks. While poor sanitation and unhygienic practices at the sprout operation can contribute to contamination of sprouts, studies indicate that contaminated seed is the likely source of most sprout-related outbreaks. Subpart M of the PSR sets forth specific requirements for sprout growers to minimize foodborne illness associated with the consumption of sprouts. During sprout inspections, the FDA will identify opportunities to educate sprout growers about the PSR, the supporting science, and the regulatory process before, during, and after inspections. The FDA works collaboratively with state partners and sprout growers to achieve prompt and sustainable compliance and will assist growers with implementing preventive measures by sharing information and providing resources such as guidance documents and fact sheets. The FDA also observes industry practices and gathers information related to growing, harvesting, packing, and holding sprouts to enhance the Agency's understanding and ability to provide targeted outreach and to help prevent future sprout-related foodborne illness outbreaks.

2. Scope of Compliance Program

This compliance program (CP) covers inspections of all sprout growers subject to Subpart M of the PSR. Subpart M covers all hydroponically grown sprouts, as well as soil- or substrate-grown sprouts that are harvested with the root. Sprouts include, for example: alfalfa sprouts, clover sprouts, mung bean sprouts, broccoli sprouts, soybean sprouts, radish sprouts, and others. Because the compliance dates have passed, sprout growers covered by Subpart M are required to be in compliance with applicable components of the PSR.

3. Summary of Requirements

Inspections will be conducted by the FDA Office of Inspections and Investigations (OII) staff who have completed training on conducting sprout inspections. States performing sprout inspections under the Produce Safety Implementation Cooperative Agreement Program (referred to in this document as the "Produce State CAP") are expected to adhere to the inspection approach communicated in the Produce State CAP funding agreement (e.g., state grantees may only conduct sprout inspections under the Produce State CAP as joint inspections with FDA where FDA is the lead for the inspection).

The FDA webpage for the FSMA Final Rule on Produce Safety can be found at the following link: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety. This webpage includes links related to produce and sprout safety, including the final PSR. In addition, it is recommended that all investigators review additional FSMA guidance documents and other information on the main FSMA guidance webpage and within resources in **Part VI** of this CP. A basic summary of the PSR subparts and corresponding guidance documents are outlined below.

In 2023, FDA released two guidance documents that outline recommendations for how sprout growers may comply with the Produce Safety Rule. The 2023 Final Guidance for Sprout Growers updates and finalizes the following sections: Cleaning and Sanitizing, Agricultural Water in Sprout Operations, Seeds for Sprouting, Environmental Monitoring, and Recordkeeping. The 2023 Draft Guidance for Sprout Growers includes recommendations on re-issued sections (Equipment, Tools, and Buildings, Sampling and Testing of Spent Sprout Irrigation Water (or In-Process Sprouts)) and one new section (Personnel Qualifications, Training, and Hygienic Practices). Both Guidance documents should be shared with sprout growers during inspections.

See **Part III**, "Inspection Approach" to review the inspection approach for sprout 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 sprout grower is covered or excluded from the PSR, or whether the sprouts are covered by Subpart M, review the *Standards for Produce Safety Coverage and Exemptions/Exclusions* Flowchart and *Determining Coverage under Subpart M of the Produce Safety Rule* Flowchart.

The regulation includes monetary values, adjusted for inflation, as the basis for a sprout grower 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. Qualified exempt sprout growers are subject to certain requirements under the PSR. The requirements for qualified exempt sprout growers are included under the PSR within 21 CFR 112.4-112.7.

If the sprout operation grows, harvests, packs, or holds covered sprouts that are going for commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., a kill step), the sprouts may be eligible for an exemption from the requirements of the PSR (see 21 CFR 112.2(b) for conditions and record requirements).

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 establishes a framework for alternatives to these requirements that could be permitted under specific conditions.

C. **Subpart C – Personnel Qualifications and Training**

Subpart C establishes minimum personnel qualifications and training requirements for personnel who handle (contact) covered produce, including sprouts, or food contact surfaces. It includes additional requirements for persons who conduct harvest activities for covered produce, including sprouts, and explains that at least one supervisor or responsible party for the grower must have successfully completed food safety training at least equivalent to that received under a standardized curriculum recognized as adequate by FDA. FDA recognizes the Sprout Safety Alliance (SSA) Grower Training as an adequate standardized training curriculum under 21 CFR 112.22.

For additional information and recommendations on how sprout growers can comply with Subpart C, see the 2023 Draft Guidance for Sprout Growers, and the PSR Draft Guidance.

D. **Subpart D – Health and Hygiene**

Subpart D establishes minimum measures and practices sprout growers must implement for personnel, supervisors, and visitors to prevent contamination of covered produce and food contact surfaces.

For additional information and recommendations on how sprout growers can comply with Subpart D, see the 2023 Draft Guidance for Sprout Growers and the PSR Draft Guidance.

E. **Subpart E – Agricultural Water**

Note: FDA issued a final rule in May 2024 that amends certain pre-harvest agricultural water requirements for covered produce (other than sprouts). The issuance of the final rule does not impact sprout operations subject to Subpart M, because it does not substantively alter the standards established in Subpart E for agricultural water used for sprouts. Because the compliance dates for all sprout operations covered by subpart M of the Produce Safety Rule have passed, including compliance dates for meeting the agricultural water provisions in Subpart E, all covered sprout operations must be in compliance with the agricultural water provisions that apply to their operations.

Subpart E establishes science-based minimum standards for agricultural water, including requirements for water quality and testing. Certain provisions of part 112 relate to agricultural water used in sprout production, most notably the requirements in Subpart E that agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41); the numerical microbial quality criterion that is relevant to sprouting operations (no detectable generic *E. coli* per 100 ml) (§ 112.44(a)); and the related requirements for agricultural water testing frequency (§ 112.46). Agricultural water uses in sprout operations that are subject to this standard include instances where water is:

- Used as sprout irrigation water (§ 112.44(a)(1));
- Applied in any manner that directly contacts covered produce during or after harvest activities (e.g., water that is applied to covered produce for washing or cooling activities such as at entry to a wash tank, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities (§ 112.44(a)(2));

- Used to contact food contact surfaces of equipment and tools used in growing, harvesting, packing, and holding activities of sprouts (§ 112.43(b)), or to make ice that will contact food contact surfaces (§ 112.44(a)(3)); and
- Used for washing hands (i.e., during and after harvest activities (§ 112.44(a)(4))) and supplied to hand-washing facilities at sprout operations (§ 112.130(a)).

For additional information and recommendations on how sprout growers can comply with Subpart E, see the 2023 Final Guidance for Sprout Growers.

F. **Subpart F – Biological Soil Amendments of Animal Origin and Human Waste**

If a sprout operation uses soil or substrate as growth media, the operation must comply with the applicable requirements in Subpart F. 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.

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

G. **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 sprout operations 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 handling of 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 material

For additional information and recommendations on how a sprout operation 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*.

H. **Subpart L – Equipment, Tools, Buildings, and Sanitation**

Subpart L establishes requirements for preventing equipment, tools, buildings, and inadequate sanitation from contaminating covered produce, including sprouts. 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. There are also sprout-specific requirements relating to buildings, tools, and equipment in Subpart M (§ 112.143(a) and (b)).

For additional information and recommendations on how a sprout operation can comply with Subpart L, see the 2023 Final Sprout Guidance and the 2023 Draft Sprout Guidance.

I. **Subpart M – Sprouts**

Subpart M establishes requirements for all sprouts, except soil- or substrate-grown sprouts that are harvested without their roots, such as:

- Taking measures to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans used for sprouting;
- Taking certain actions if there is reason to believe a lot of seeds is contaminated with a pathogen (except in a few limited circumstances as described in § 112.142(c));
- Treating seeds or beans that will be used for sprouting (or relying on prior treatment by another entity, with appropriate documentation);
- Growing, harvesting, packing, and holding sprouts in a fully-enclosed building;
- Cleaning and sanitizing food contact surfaces used to grow, harvest, pack, or hold sprouts before they contact sprouts, or seeds or beans used to grow sprouts;
- Testing of spent sprout irrigation water (SSIW) or in-process sprouts from each production batch of sprouts, for *E. coli* O157:H7 and *Salmonella* species (and any pathogens meeting the criteria in §112.144(b)(c)). Sprouts cannot enter commerce until it is determined that these required pathogen test results are negative;
- Testing the growing, harvesting, packing, and holding environment for the presence of *Listeria* species or *Listeria monocytogenes*;
- Taking corrective actions if SSIW, sprouts, and/or environmental samples test positive; and
- Records requirements, including written plans for SSIW testing and environmental monitoring, seed treatment records, test records, and corrective action records.

For additional information and recommendations on how a sprout operation can comply with Subpart M, see the 2023 Final Sprout Guidance and the 2023 Draft Sprout Guidance.

J. **Subpart N – Analytical Methods**

Subpart N includes requirements for methods of analysis for:

- Testing the quality of agricultural water;
- Testing the growing, harvesting, packing, and holding environment for the presence of *Listeria* species or *Listeria monocytogenes*; and
- Testing of SSIW or sprouts from each production batch of sprouts or in-process sprouts.

Subpart N also requires sprout growers to conduct confirmatory testing on any screening test results presumptive positive for *E. coli* O157:H7 or *Salmonella spp.* in SSIW or in-process sprouts. Under FDA's reference method, confirmation of a presumptive positive result from the screening test must be conducted on the same enrichment sample that resulted in the presumptive positive result. To understand more about how sprout growers should respond to test results from SSIW testing, please review the fact sheet *Responding to Results Obtained from Testing Spent Sprout Irrigation Water (or In-Process Sprouts) for E. coli* O157:H7 or *Salmonella to meet the requirements of the Produce Safety Rule*.

Subpart N allows testing in accordance with a scientifically valid alternative method that is at least equivalent to the reference methods in accuracy, precision, and sensitivity. Lists of

alternative analytical methods that meet the requirements for subparts E and M can be found on the FDA website:

- Equivalent Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water or Sprouts Samples
- Equivalent Testing Methodologies for *Listeria* species and *Listeria monocytogenes* in Environmental Samples
- Equivalent Testing Methodologies for Quantifying Generic *E. coli* in Agricultural Water Samples

If the sprout operation test sprouts for *Listeria monocytogenes* as part of corrective actions, FDA recommends that the sprout operation use the procedures described in FDA's Bacteriological Analytical Manual Online (BAM), Chapter 10 – "*Listeria monocytogenes*," "Detection and Enumeration of *Listeria monocytogenes* in Foods" for preparing food samples and testing them for the presence of *L. monocytogenes*.

A decision tree related to test methods requirements of *Salmonella* and *E. coli* O157:H7 in SSIW (or sprouts) to help to determine whether an alternative test method may meet the requirements of the PSR can be found on the FDA website: Decision Tree for Test Methods Requirements of *Salmonella* and *E. coli* O157:H7 in Spent Sprout Irrigation Water (or Sprouts).

K. **Subpart O – Records**

Subpart O specifies the general requirements for records, including those related to training, agricultural water, exemptions, cleaning and sanitizing, written sampling plans, testing, seed treatment, and corrective actions. This subpart 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 sprout operation can comply with Subpart O, see the 2023 Final Sprout Guidance.

L. **Subpart P – Variances**

Subpart P describes the process for submitting a variance from a provision of the PSR. The PSR permits states, tribes, or foreign countries from which food is imported into the U.S. to submit a petition, along with supporting information, to FDA requesting a variance from one or more of the requirements of the PSR when the variance is necessary in light of local growing conditions. Since the PSR requires that sprouts be grown in a fully-enclosed building, we do not expect Subpart P to apply to sprout operations often, if at all.

M. **Subpart Q – Compliance and Enforcement**

Subpart Q reiterates the FD&C Act provisions establishing that failure to comply with the PSR is a prohibited act under Section 301 and thus the regulatory 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.

N. **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 sprout operation.
- 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 sprout operation material and to the safety of food that would otherwise be covered produce, such as sprouts.

In addition, this subpart describes the procedures FDA would use to withdraw an exemption and the process whereby a sprout operation 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.

4. Exemptions and Modified Requirements

If the sprout operation grows, harvests, packs, or holds covered produce, including sprouts, 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 below).

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

5. 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, with phased in compliance dates based on the size of the sprout operation. All sprout operations subject to the PSR are required to be in compliance with the PSR at this time. An overview of the compliance dates for the PSR is available on the FDA Website. FDA published guidance in January 2018, exercising enforcement discretion from the written assurances provisions related to the commercial processing exemption in Section 112.2 (b).

Some sprout operations may sell certain soil- or substrate-grown sprout types (such as wheatgrass) in a tray that was used for growing, with the soil/substrate and root intact, to commercial entities. In such cases, the operation has harvested the sprouts with the roots and these

sprouts are ordinarily subject to Subpart M (see § 112.141). However, we understand that, in some cases, such sprouts may then be cut above the soil and/or substrate line at the commercial entity immediately before use or sale to the consumer. When a sprout operation sells sprouts with the roots intact in soil or substrate, and the commercial entity that receives them will cut the sprouts above the soil or substrate line before use, we intend to exercise enforcement discretion for the requirements of Subpart M if the sprout operation annually collects written assurances from the commercial entity stating that the sprouts will be cut above the soil or substrate line before use (for more information about this enforcement discretion, refer to the 2023 Final Guidance for Sprout Growers).

PART II - IMPLEMENTATION

1. Objectives

- Conduct inspections of covered sprout operations subject to Subpart M of 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 sprout operations 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 sprout-related foodborne illness outbreaks.
- Provide information and educational resources to sprout operations as needed (e.g., Sprout Safety Alliance (SSA), guidance, fact sheets, etc.).
- 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 sprout contamination.
- Take appropriate regulatory action on inspectional findings and/or sampling results, when warranted.

2. Inspectional Priorities

Sprout operations covered by this CP should be inspected at least once every 3 years. This CP covers inspections of all sprout growers subject to Subpart M of the PSR and does not cover inspections of sprout growers that are eligible for a qualified exemption or are not subject to the PSR. For information about inspecting sprout growers that are eligible for a qualified exemption, or are not subject to the PSR, refer to Table 2.

Office of Human Food Inspectorate (OHFI) should refer to the annual list of priority sprout firms for inspection assigned by HFP (refer to the FDA Sprout Safety Inspections Compliance Program Resources Page (or ORAPP for States)) and use the inspection priorities listed below to plan sprout inspections as needed.

A. Priority 1 Outbreak History

Inspections of all covered sprout operations that have been implicated in or linked to a foodborne illness outbreak within the past 12 months.

- Sprout operations that were implicated are those from which FDA determined the contaminated sprouts originated.
- Sprout operations that were linked are those that appear on the FDA Office of Coordinated Outbreak Response, Evaluation, & Emergency Preparedness (CORE+EP) final traceback diagram; however, FDA did not determine which operation(s) produced the contaminated sprouts.

B. Priority 2 Recall and Positive Sample History

Inspections of all covered sprout operations that in the past year have either recalled product from the market due to potential pathogen contamination or produced sprouts that were

sampled after they were introduced into commerce and found to contain pathogen(s) of public health significance.

C. Priority 3 Reinspection

Inspections of all covered sprout operations 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 or expedited next inspections.

D. Priority 4 Initial Inspections of Sprout Operations

When planning for routine inspections, prioritize initial inspections of sprout operations, as well as inspections of sprout operations under new ownership, over other routine sprout inspections. If the number of sprout operations exceeds the number of inspections to be conducted, operations should be selected for inspection in order from largest to smallest.

E. Priority 5 Other Routine Sprout Inspections

Conduct routine inspections of all covered sprout operations that received initial inspections in previous years. If the number of sprout operations exceeds the number of inspections to be conducted, operations should be selected for inspection based on the timing of their most recent inspection (i.e., prioritize firms that have not been inspected within the past 3 years) and size (in order from largest to smallest).

3. Planning Instructions

A. Inspections

FDA will identify the number of sprout operation inspections for FDA to perform via the annual OII Field Work Plan. The annual firm list for inspections under this CP will be provided to OHFI through the FDA Sprout Safety Inspections Compliance Program Resources Page and firms will be assigned via eNSpect. The Sprout-Specific Inspectional Protocol (IP) is available in eNSpect and should be filled out during every inspection under this CP.

B. Training Requirements

The lead investigator must be trained to conduct sprout operation inspections. Their training must include successful completion of FD225 “Sprout 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. The Compliance Officers assigned to sprout cases should also successfully complete FD225 “Sprout Inspections for Regulators”.

C. Specific Planning Instructions for Inspections

While planning the inspection, the lead investigator should determine if the sprout operation is also subject to another FDA CP or food regulation, such as the Produce Safety Inspections CP, 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 the firm is or may be subject to multiple CPs or food regulations, the investigator should discuss with their management whether resources and appropriately trained personnel are available to inspect the other portions of the business during the same visit (refer to the applicable parts of Table 2 in this CP for more information).

If the sprout operation was subject to an enforcement action, recalled product from the market due to potential pathogen contamination, had a product sample that was positive for pathogen(s) of public health significance, was implicated or possibly linked to a foodborne illness outbreak, or had other significant event(s) since the previous PSR inspection, investigators can coordinate with HFP for assistance planning the inspection. This includes farm mixed-type facilities with such a history within the last five years related to manufactured food, even if there is no such history related to activities covered by the PSR. When necessary, the OII Division will use the list of Program Contacts found in Part VI to set up a conference call with HFP Office of Compliance and Enforcement (OCE) Produce Enforcement Branch (PEB), HFP Office of Microbiological Food Safety (OMFS) Office of Produce Safety (OPS), and the OII/OHFI, Division Director of Investigations Branch (DIB), and Emergency Response Coordinator (ERC), as applicable, before starting the inspection to discuss the possible inspection focus and enforcement strategies, as appropriate.

D. Inspecting Farm Mixed-Type Facilities

A "farm mixed-type facility" is an establishment that is a farm, but 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"*).

Inspections of the farm and facilities elements of the farm mixed-type facility can be combined to reduce the number of trips to a mixed-type facility (for coordination of farm and facility inspection activities, see Table 2: Instruction for Inspection by Type of Operation, Products Produced and Coverage (status) under Subpart M and the Produce Safety Rule).

E. Regulatory Technical Assistance Network (rTAN)

The rTAN is a resource for FDA investigators to request advisory assistance during sprout inspections. It is not intended to replace the current enforcement communication mechanism between the FDA investigators, OII management, and HFP/OCE.

The rTAN is designed to connect investigators with a Subject Matter Expert (SME) to receive answers to FSMA rule interpretation questions and scientific or technical questions related to current inspections. Investigators can contact SMEs before and/or during an inspection to discuss questions or to obtain clarifications on the PSR. To reach an SME through the rTAN, please contact: SproutsQuestions@fda.hhs.gov.

F. Compliance Programs and/or Assignment Interactions

If a sprout operation is inspected under this program and they also produce food that is subject to additional regulations, CPs, or assignments outside the scope of this compliance program, then additional inspection, sampling, analytical, and reporting requirements may be covered

per the respective interacting programs/assignments. For information related to coordination between programs, refer to Table 2: Instruction for Inspection by Type of Operation, Products Produced and Coverage (status) under Subpart M and the Produce Safety Rule. Programs and Assignments that interact with this CP include the following:

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

The main purpose of the 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 regulation (ST rule), [(21 CFR part 1, subpart O)]. The CGMP&PCHF 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.

(2) 7303.080 Produce Safety Inspections CP

The main purpose of the Produce Safety Inspections CP is to provide overall instructions for conducting inspections at produce farms subject to 21 CFR 112, other than sprout growers that are covered by Subpart M. The majority of Produce Safety Inspections are performed by state agencies under the Produce State CAP. For information related to coordination between programs, refer to Table 2: Instruction for Inspection by Type of Operation, Products Produced and Coverage (status) under Subpart M and the Produce Safety Rule.

(3) 7303.050 Sampling for Foodborne Biological Hazards, and Filth – Domestic and Import CP (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 Sprout Safety Inspections CP, refer to Part III.1.C (Sample Collections) and Part IV (Analytical) of this CP for instructions. For instructions covering sprout sampling operations not covered in this CP, refer to the Micro Sampling CP 7303.050.

(4) Interacting Assignments

This compliance program may interact with field assignments. See Active Assignments (sharepoint.com) for a list of active assignments.

G. Interactions with other Federal Agencies, State, and Local Counterparts

(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

States coordinating with the FDA on sprout inspections under the Produce State CAP are expected to adhere to the inspection approach communicated in the 2021 Produce State CAP funding agreement (e.g., Produce State CAP partners may only conduct sprout inspections under the Produce State CAP as joint inspections with FDA where FDA is the lead for the inspection). Produce State CAP partners who are interested in conducting sprout inspections under the Produce State CAP should contact their FDA State Liaison or their project manager with the Office of Partnerships for more information (refer to the FDA Sprout Safety Inspections Compliance Program Resources Page (or ORAPP for States). If states perform inspections of sprout operations using state funding (e.g., outside of the Produce State CAP), they should ensure state inspectors are adequately trained. They may also opt to share reports of their inspections with their FDA state liaison. In general, sharing information and collaborating with state partners on inspections and enforcement actions will help improve the safety of sprouts.

If the sprout operation also handles other covered produce subject to the PSR, coordination may be needed with the state (e.g., if the state handles the PSR inspections under the Produce State CAP) or with other parts of FDA. For information related to coordination between programs, refer to Table 2: Instruction for Inspection by Type of Operation, Products Produced and Coverage (status) under Subpart M and the Produce Safety Rule.

H. 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 State CAP reporting.

Routine sampling is not conducted under this program; however, if warranted, sampling will be for-cause or as directed.

All sprout growers, regardless of PSR coverage, should be identified with the following codes:

- DUC: SP
- Establishment type/Industry code: G-24

Sprout growers **covered by the PSR/Subpart M** and therefore **subject to this CP** should be identified as:

- Workload obligation: YES
- DUC: SP
- Establishment type/Industry code: G-24

Sprout growers **not covered by the PSR/Subpart M** (for example, they do not meet the monetary threshold to be covered by the PSR, or the firm is eligible for a qualified exemption under the PSR) and therefore **not subject to this CP** should be identified as:

- Workload obligation: NO
  - Please provide documentation in the comment field describing the reason, for example, exempt from the PSR, qualified exemption, etc.
- DUC: SP
- Establishment type/Industry code: G-24

Growing sprouts is not a manufacturing/processing activity. Sprout growers should **not** be identified as M-24 unless they also perform other activities that are considered manufacturing/processing (e.g., making tofu). Firms engaged **only** in holding or re-packing sprouts should **not** be identified as G-24 and should **not** be assigned the DUC: SP. Use the appropriate codes based on the activities conducted by the firm.

Table 1: Resources and Reporting (for FDA)	
Reporting PAC	03060 SPROUT SAFETY ACTIVITIES
Planning PAC	Domestic Inspections:
OP Code – Inspection **OP Code – Investigation** **OP Code – Sample**	12 (domestic) 13 (domestic) 31 (collection), 41 (analysis)
PAF	MIC PAR VIR

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..

Inspections will assess the sprout operation's compliance with the PSR. This CP covers inspections of all sprout growers subject to Subpart M of the PSR and does not cover inspections of sprout growers that are eligible for a qualified exemption or are not subject to the PSR. For information about inspecting sprout growers that are eligible for a qualified exemption, or are not subject to the PSR, refer to Table 2. The focus of the inspection should be on conditions and practices that could result in adulterated sprouts. Make every reasonable effort to discuss all observations with the operation's management as they are observed to provide the operation an opportunity to take immediate corrective action and to minimize surprises, errors, and misunderstandings. Include in the FDA-483, Inspection Observations form, the violations and the significance of each violation that may impact public health. One way to establish the significance of an observation is to identify a potential source and route of contamination associated with the violation. Investigators should document verification of corrections to any current and previous observations and related to verbal discussion items in the EIR.

(1) Personal Safety

There are situations where it is advisable to take precautions for personal safety. Before inspecting a sprout operation, FDA investigators should review safety information associated with the firm in the OSAR personal safety tab. 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 sprout operation is required to comply with the PSR and if the operation should be inspected under this CP. It also optimizes inspection productivity by ensuring the sprout operation is operational, and it provides time for the sprout operation to ensure necessary personnel are available and to assemble the appropriate records. Unless otherwise directed, inspections will be pre-announced and scheduled with the owner, manager, or person in charge. 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.

Prior to conducting the pre-announcement call, you should inform the local Division Investigations Branch of your plans to conduct the inspection at the sprout operation and coordinate with that Division as needed.

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 sprout operation had previous PSR violations or contamination issues and the issues have not been corrected and verified.
- If you plan to collect environmental swabs at the sprout operation, an unannounced inspection may work best to capture the true working conditions at the operation.
- 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:

- Inform the sprout operation that the information available shows their sprout operation 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 sprout operation 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/foodsafety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs):
    - For the monetary exclusion, the sprout operation is not covered if the average annual gross produce sales during the previous three years ≤$25,000.
    - For the qualified exemption, the sprout operation may be eligible if the average annual monetary value of all food sold was <$500K during the previous three years and the other requirements are met (refer to the decision tree listed above).
- To assist with prioritizing inspections, ask the sprout operation 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
- Apply the FDA decision tree entitled "Determining Coverage under Subpart M of the Produce Safety Rule" found at https://www.fda.gov/media/133546/download to assist with determining if the sprout operation is growing sprouts that are subject to Subpart M.

- **If it is determined that the sprout operation should not be inspected,** for example the sprout operation is not subject to the PSR, is qualified exempt, does not grow sprouts that are covered by Subpart M, or is using the commercial processing exemption for all covered commodities (see 21 CFR part 112.2(b)), the investigator should:

  - Thank the grower for their time and inform the grower why their operation will not be inspected at this time. Note: If the sprout operation won't be inspected at this time because it is eligible for a qualified exemption, inform the sprout operation of the modified requirements per 21 CFR part 112.6 and records they must establish and keep per 21 CFR part 112.7.
  - Report the activity as an investigation (Op13) and review and update the eNSpect and Field Management System (FMS) data fields for the sprout operation.

- **If the sprout operation is subject to the PSR and is to be inspected**, the investigator should:
  - Explain what the grower can expect during the inspection, discuss logistics of the inspection and request that the sprout operation compile records that can help verify their compliance.
  - Obtain the sprout operation's mailing address or email address and send the following resources:
    - FDA Produce Safety Rule, with an explanation of where to find the codified requirements
    - 2023 Final Guidance for Sprout Growers
    - 2023 Draft Guidance for Sprout Growers
    - Sprout Safety Alliance link
  - Conclude by asking if the grower has any questions and thanking the grower.
  - If the investigator has made a reasonable attempt to contact the sprout operation and has been unsuccessful, provide notification to the firm 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 sprout operation respond prior to the start date and time. If the sprout operation doesn't respond ahead of the inspection, upon arrival at the sprout operation the investigator should verify that the sprout operation is subject to the PSR and should be inspected.

(3) Additional Planning Instructions for Coordination with State Regulatory Agencies

In states in which state government staff have attended the FDA FD225 Sprout Training for Regulators course and are interested in participating in a sprout inspection, Divisions should work with the states to plan joint inspections with the trained state staff, make state agencies aware of the requirements of this CP (in advance of beginning an inspection), and communicate deadlines for deliverables. In states that do not have staff that have attended the FDA sprout training, divisions will offer state agencies an opportunity to shadow FDA inspections/sample collections or assist as necessary.

The Division State Liaison is responsible for notifying the Department of Public Health or the Department of Agriculture for each state where the sprout inspection takes place. After work planning activities are complete, the State Liaison will notify the appropriate Produce State CAP POC for that state and invite them to plan and conduct a joint sprout inspection led by FDA (refer to the FDA Sprout Safety Inspections Compliance Program

Resources Page (or ORAPP for States) for State contact information). Because sprouts are regulated under the Produce Safety Rule, state grantees may use Produce State CAP funds to participate in joint inspections with FDA. The FDA is encouraging the states to use FDA pocket credentials to participate in these joint inspections. State inspectors participating in a joint inspection should have successfully completed FD225 prior to the inspection.

If someone from a Produce State CAP reaches out to the State Liaison with a question about scheduling sprout inspections, the State Liaison should check with Division management to identify the CSO assigned to the sprout inspection. The State Liaison should then put the Produce State CAP partner in touch with the Investigator from the Division that is completing the inspection. The State Liaison can contact the Produce Branch within the Office of Integrated Food Safety System Partnerships (OIFSSP) with any questions related to Produce State CAP contacts (refer to Part VI for program contacts).

(4) Inspection Approach

The information in this section and the Sprout IP are provided to assist with consistency as well as to ensure that all PSR-relevant areas of the sprout operation have been addressed. Investigators should use the Sprout IP and this CP as a reference for all inspections. If investigators have questions regarding inspection coverage and/or approach as they prepare to initiate an inspection, they should contact the rTAN.

Key Areas to Focus on During Sprout Inspections

(a) 21 CFR 112 Subpart A: General Provisions

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

To assist with determining if a sprout grower is covered or excluded from the PSR, or whether the sprouts are covered by Subpart M, review the *Standards for Produce Safety Coverage and Exemptions/Exclusions* Flowchart and *Determining Coverage under Subpart M of the Produce Safety Rule* Flowchart.

If investigators have questions regarding whether a certain type of processing is eligible for the commercial processing exemption, they should contact the rTAN. If the sprout operation handles sprouts destined for commercial processing, review how the sprout

operation is disclosing to its customers that the sprouts are not processed to adequately reduce the presence of microorganisms of public health significance.

The regulation requires the sprout operation 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 violations relative to the written assurance requirement (see 21 CFR 112.2(b)). For more information see https://www.fda.gov/files/food/published/FSMA-Guidance-for-Industry--Enforcement-Policy-%28PDF%29.pdf

(b) 21 CFR 112 Subpart B: General Requirements

Sprout growers must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce. This includes 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 Federal Food, Drug, and Cosmetic Act on account of such hazards.

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

- Identify the person assigned by the sprout operation to be responsible for food safety requirements, specifically those covered by the PSR.
- Confirm that at least one supervisor or responsible party has completed sprout safety training equivalent to a standardized curriculum recognized by FDA, such as the Sprout Safety Alliance training. If the grower is using a different curriculum to meet this requirement, contact the HFP sprout rTAN to consult with SMEs about the adequacy of the training.
- Identify responsibility for training and monitoring of food safety practices. If the sprout operation uses contract personnel for any covered activities (e.g., cleaning), determine who trains the contractors.
- Observe personnel at work who handle or contact covered sprouts during covered activities, with particular attention to traffic patterns, hand washing, glove use, basic hygiene, actions during harvest, and equipment and containers used to harvest. If employees are not performing their jobs in a manner 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.
- Review records related to training to ensure that the records meet the requirements of Subpart O, and specifically include date of training, topics covered, and persons trained.

(d) 21 CFR 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 sprout operation handles ill employees with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).
- When possible, observe employee practices in all production areas, 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 being a source of contamination
  - Contact with animals
  - General hygiene practices
- Ensure that employees working with covered sprouts 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

- Identify sources of water used by the sprout grower, specifically water that comes into direct contact with covered sprouts or food contact surfaces.
- Evaluate agricultural water sources and distribution systems for conditions that could cause a public health concern, such as cross-connections between agricultural water sources and potential contaminant sources.
- Review systems in place to mitigate risk from water, such as test results or treatment systems, if used.
- When possible, observe all water sources and distribution systems (including wells, municipal connections, holding tanks, etc.) for signs of contamination.
- Review records related to agricultural water testing, treatment, corrective actions, and test methodology to ensure that they meet the requirements of Subpart O.

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

- If the sprout operation uses soil or substrate as growth media, the operation must comply with the applicable requirements in Subpart F.

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

Subpart I does not apply to covered activities that take place in a fully-enclosed building, such as for sprouts.

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

- Document the growing, harvesting, packing, and holding activities the sprout operation performs.
- Observe, when possible, the sprout operation's growing, harvesting, packing, and holding operations and evaluate whether the sprout operation handles sprouts in a manner to protect against contamination.

- Determine the steps taken prior to and during harvest activities to identify covered sprouts that are likely to be contaminated and steps taken to avoid harvesting that product.
- Determine if the sprout operation handles harvested sprouts in a manner that protects against contamination with known or reasonably foreseeable hazards during covered activities.
- Determine if the sprout operation handles both covered and excluded produce per 21 CFR 112.111.
- If the sprout operation does not grow, harvest, pack, or hold both covered and excluded produce, or if the sprout operation 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.
- If the sprout operation 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 sprout operation keeps covered produce separate from the excluded produce when conducting covered activities.
    - Determine the sprout operation's practices to prevent cross-contamination by cleaning and sanitizing food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered sprouts, or seed for sprouting (21 CFR 112.111(b)). In addition, consider shared surfaces or equipment, tools, transportation methods, and packing/packaging materials.
- Determine if practices satisfy the requirements of the PSR that the sprout operation does not distribute covered sprouts that drop to the ground before harvest into the fresh market.
- Determine if covered sprouts are packaged in a manner that prevents the formation of *Clostridium botulinum* toxin if such toxin is a known or reasonably foreseeable hazard. *C. botulinum* toxin may form in sprouts that are packaged in modified atmosphere or other reduced-oxygen packaging and not adequately refrigerated.
- Identify food-packing (including food packaging) materials and determine if they are adequate for the 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 sprout operation 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 (see also Subpart M below)

- 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. Determine whether automated equipment (e.g., automated packing/bagging machines, shakers) are adequately cleaned and sanitized per manufacturer's guidelines.
- Inspect conveyor belts for build-up of residual materials and backets of residue in corners and under belts. Look in inspection ports and hard-to-reach places inside, underneath, and behind equipment for evidence of filth, insects, and/or rodent contamination.
- 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 may contaminate adjacent equipment.

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 sprouts. Consider equipment such as pallets, forklifts, equipment used between growing/harvesting, packing and storage locations, etc.

Buildings (see also Subpart M below)

- 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 sprouts 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 sprouts, food contact surfaces, and production areas.
- 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 sprouts and activities.

Sewage and Septic Systems

Determine the type of sewage system(s) used by the sprout operation 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 sprout operation 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 sprouts, food contact surfaces, and production areas.

Waste Disposal

Determine if the sprout grower is appropriately conveying, storing, and disposing of trash and litter. Observe areas around the building 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 sprouts to ensure that they meet the requirements of Subpart O, and specifically include the date and method of cleaning.

(j) 21 CFR 112 Subpart M: Sprouts

Coverage

If the sprout operation grows sprouts that are not covered by Subpart M, do not inspect those products to determine compliance with this subpart under this CP. Inspections of soil- or substrate-grown sprouts that are harvested without their roots are covered under CP 7303.080.

Seed for Sprouting

- Evaluate whether the sprout operation stores and handles seed for sprouting in a manner to protect against contamination. Observe seed, seed packaging, and seed storage area, for signs of potential contamination, taking into account whether the stored seeds have already been treated (see bullet below).
- Determine whether the sprout operation takes appropriate corrective actions when they know or have reason to believe that a lot of seeds or beans may be contaminated with a pathogen.
- If the sprout grower conducts their own seed treatment: Observe seed treatment when possible, and collect information related to the treatment, including: the method used, the rate or concentration, how the treatment is applied and monitored, and how the sprout operation determined the treatment is scientifically valid to reduce pathogens on seed. Assess whether the treatment is applied consistently and in accordance with the sprout operation's own procedures. Please refer to supplementary compliance and enforcement strategy information located on the FDA Sprout Safety Inspections Compliance Program Resources Page (or in ORAPP for States) for more details.
- If the sprout grower relies on prior treatment of seeds conducted by another entity: Review documentation related to the treatment and post-treatment handling of seed. Collect information related to the treatment and post-treatment handling.

Buildings (see also Subpart L above)

Determine if building(s) where sprouts are grown, harvested, packed, and held are fully-enclosed and evaluate any temporary or permanent openings for pest activity.

Tools and Equipment (see also Subpart L above)

Check the sanitary condition of all food contact surfaces used to grow, harvest, pack, or hold sprouts. Determine if these food contact surfaces are cleaned and sanitized before contact with sprouts or seeds used to grow sprouts.

Environmental Monitoring for *Listeria* species or *Listeria monocytogenes*

- Review the sprout operation's written environmental monitoring plan and determine if it includes all the required components (see § 112.145).
- Assess whether the sprout operation conducts environmental monitoring in accordance with the PSR requirements and their own written plan.
- Identify the test method used.
- Identify sample collection sites, including food contact surfaces and non-food-contact surfaces.
- Identify timing of sample collection for environmental samples, including whether it takes place during production or after sanitation activities.
- Assess whether the sprout operation completes necessary corrective actions if *Listeria* species or *L. monocytogenes* is detected in the growing, harvesting, packing, or holding environment (see § 112.146).

Spent Sprout Irrigation Water (SSIW) or In-Process Sprouts Testing

- Review the sprout operation's written sampling plan and determine if it includes all the required components (see § 112.147).
- Assess whether the sprout operation collects SSIW or sprout samples in accordance with the PSR requirements and their own written plan.
- Identify the test method used. If the sprout operation uses a screening test (see Subpart N section below), review test records to determine whether presumptive positive results are confirmed before sprouts enter commerce.
- Identify the size of the production batch of sprouts represented by the samples collected by the sprout operation.
- Assess whether the sprout operation completes necessary corrective actions if SSIW or sprouts test positive for *Salmonella* or *E. coli* O157:H7.

Records

Review seed treatment monitoring records, documentation of all required analytical tests, and documentation of corrective actions. Document lapses in treatment, testing, or corrective actions.

(k) 21 CFR 112 Subpart N: Analytical Methods

- Review the test methods used by the sprout operation and/or third-party laboratory.
- For SSIW or in-process sprout testing: FDA has identified test methods that are equivalent to the reference methods described in the PSR: Equivalent Testing Methodologies for *E. coli* O157:H7 and *Salmonella* in Spent Sprout Irrigation Water or Sprouts Samples. All the equivalent test methods identified in that list, except for Bacteriological Analytical Manual (BAM) methods, are screening tests. Presumptive positive results from screening tests must be confirmed before sprouts from that batch enter commerce.

- For environmental monitoring: FDA has identified test methods that are equivalent to the reference method described in the PSR: Equivalent Testing Methodologies for *Listeria* species and *Listeria monocytogenes* in Environmental Samples.
- For agricultural water samples: FDA has identified test methods that are equivalent to the reference method described in the PSR: Equivalent Testing Methodology for Agricultural Water.
- A decision tree related to test methods requirements of *Salmonella* and *E. coli* O157:H7 in SSIW (or sprouts) to help to determine whether an alternative test method may meet the requirements of the PSR can be found on the FDA website: Decision Tree for Test Methods Requirements of *Salmonella* and *E. coli* O157:H7 in Spent Sprout Irrigation Water (or Sprouts).

(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.

(m)21 CFR 112 Subpart P: Variances

- We do not expect that Subpart P: Variances will be employed by sprout operations since they are required to be grown in fully-enclosed buildings. If a sprout operation claims to be employing a variance, please contact the HFP rTAN (Sproutsquestions@fda.hhs.gov) to discuss.

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

If the sprout operation has received an order withdrawing its qualified exemption, the sprout operation 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 the inspection, some of which would be **outside 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 sprout operation may need to be inspected under another regulation and communication across and within agencies is paramount.

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

Type of Operation	Inspection Approach
Operation produces sprouts covered by Subpart M of the PSR and meets the criteria for sprout	The investigator should conduct the inspection using the Sprout IP and share

Type of Operation	Inspection Approach
operations that must be in compliance with the PSR.	educational resources with the sprout operation.
Operation produces sprouts that would have been covered by Subpart M, but has an average (in the previous three years) of less than $25K in annual produce sales, adjusted for inflation. Such operation is exempt from the PSR.	Collect and review records the sprout operation relies on to support this exemption. This sprout operation cannot be inspected under the PSR. The investigator may conduct the inspection under the FD&C Act, referring to the Sprout IP to guide the inspection, and share educational resources with the sprout operation. However, findings would need to be cited under the FD&C Act* rather than the PSR. If you observe egregious conditions, please contact the HFP Program Contacts and the sprouts RTAN.
Operation produces sprouts that would have been covered by Subpart M, but is eligible for qualified exemption from the PSR (< $500k annual food sales, adjusted for inflation, and > 50% of sales directly to qualified end users).	Collect and review records the sprout operation relies on to support a qualified exemption. If the operation is eligible for a qualified exemption, the inspection should only cover the modified requirements that these sprout operations are required to follow (described in sections I.B.1 and II.B.2.i above and in §112.6 of the PSR). The investigator may choose to conduct an inspection under the FD&C Act*, referring to the Sprout IP to guide the inspection, and share educational resources with the sprout operation. However, these findings would need to be cited under the FD&C Act* rather than the PSR. If you observe egregious conditions, please contact the HFP Program Contacts and the sprouts RTAN.
Operation produces sprouts that would have been covered by Subpart M except that the sprouts will be commercially processed with a kill step, e.g., mung bean sprouts that will be canned.	Collect and review records the sprout operation relies on to support the commercial processing exemption from the PSR. If all sprouts produced by this sprout operation meet the requirements for the commercial processing exemption, then this sprout operation should not be

Type of Operation	Inspection Approach
	inspected under this CP. If only a portion of the sprouts produced by this sprout operation meet the requirements for the commercial processing exemption, the inspection should cover the growing, harvesting, packing, and holding of the covered sprouts at the operation (i.e., the sprouts that are not intended for commercial processing with a kill step) under this CP.
Operation does not produce sprouts covered by Subpart M. Operation grows soil and/or substrate-grown sprouts harvested without roots that are excluded by Subpart M, but would be produce covered by the PSR. **OR** Operation only produces non-sprout produce, such as microgreens, hydroponic lettuce, or tomato transplants, which are not subject to Subpart M, but are produce covered by the PSR.	These products should not be inspected under this CP. Document activities conducted by the operation that do not fall under Subpart M, but generally under the PSR, to update the farm inventory. We recommend contacting OII Division of Produce Safety (DPS) (Travis.Chapin@fda.hhs.gov) in this situation.
The operation produces sprouts covered by Subpart M, as well as other produce.	The investigator should only inspect growing and harvesting operations covered by this CP, i.e., sprouts covered by Subpart M. We recommend contacting OII DPS (Travis.Chapin@fda.hhs.gov) in this situation to ensure the sprout operation's information is captured in either the FDA OEI or state farm inventory (for states participating in the Produce State CAP).
The sprout operation is a farm mixed-type facility, i.e., the operation is both producing sprouts and conducting manufacturing/processing activities outside the "farm" definition (such as making tofu or noodles).	Manufacturing/processing activities outside the "farm" definition and related products are outside the scope of the PSR and should not be inspected as part of this CP. Only sprout production at these sprout operations mixed-type facilities should be inspected as part of this CP.

*Contact HFP Office of Compliance and Enforcement PEB (HFP-OCE-Produce@fda.hhs.gov) if there are questions regarding how to structure citations on the FDA 483 under the FD&C Act.

In the event that a sprout operation's exemption status is not established during the pre-call, but it is established during an inspection that the sprout operation is exempt from the PSR or has a qualified exemption, the investigator may still cite violations of the FD&C Act that are reasonably likely to have resulted in the contamination of sprouts with filth or pathogens. To do this, identify a potential source and route of contamination associated with the violation and describe them on the FDA-483. For example: "Your manager indicated that the packing table had been cleaned. However, your packing table, which comes into direct contact with sprouts, was visibly dirty with black organic residues and sprouts from the prior day's production. Sprouts are covered by the Produce Safety Rule. The dirty table is the potential source of contamination and the fact that it is a food contact surface also makes it a route of contamination." Do not include conclusions, such as "Your product is adulterated," in the FDA-483.

The Sprout-Specific Inspectional Protocol (IP) is available in eNSpect and should be filled out during every inspection under this CP. The data collected through the IP is used to track compliance progress and make policy decisions. Hardcopy references are available at Paper IPs (sharepoint.com). For operations that produce sprouts that would have been covered by Subpart M, but the sprout operation is otherwise exempt (i.e., due to size or qualified exemption), investigators can use the IP in eNSpect, but they must not use the FDA 483 functionality. See instructions above for citing violations of the FD&C Act.

(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 sprout operation or commodity, such as in response to an outbreak, positive sample, recall, consumer complaint, or previous inspection findings (i.e., expedited next inspection). Domestic for-cause inspections may be performed at sprout operations 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/PEB.

B. Investigations

A domestic investigation (OP 13) should be performed to document operational conditions at sprout operations covered by this CP, if a sprout operation is no longer operational, does not manufacture products that fall under FDA jurisdiction, or does not ship or receive products in interstate commerce. See IOM subchapter 8.10 General Investigation Reporting for guidance covering how to conduct and report an investigation.

C. Sample Collections

There are times when sampling may be warranted to support significant observations related to potential contamination of sprouts 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 when there is a credible complaint or whistleblower or as requested to meet the objectives within FDA-issued assignments (e.g., in response to foodborne illness outbreaks). For more instructions related to sample size and sample collection, please refer to the Sampling Instructions

document which is hosted on the FDA Sprout Safety Inspections Compliance Program Resources Page (or in ORAPP for States).

Please contact HFP-OCE-Produce@fda.hhs.gov and SproutsQuestions@fda.hhs.gov for questions about whether for-cause sampling is appropriate. Some examples of situations and observations that may warrant for-cause sampling are listed below:

Seeds

Seeds should be collected under the following conditions:

- Seeds were pre-treated and not subsequently stored or packaged in a way to prevent them from becoming contaminated.
- There is evidence suggesting that seeds are contaminated (for example, SSIW or in-process sprouts samples corresponding to the lot of seeds yield *Salmonella* or STEC, or there are insanitary conditions in the seed storage area).
- Finished product samples that correspond to the lot of seeds yield *Salmonella* or STEC.
- Traceback and epidemiological evidence suggest that a lot of seeds is involved in an outbreak.

Spent Sprout Irrigation Water (SSIW)

SSIW should be collected when there is evidence suggesting that the production batch of sprouts may be contaminated, including:

- There is evidence that seed may be contaminated, such as: samples collected from the corresponding seed lot yield *Salmonella* or STEC, SSIW (or in-process sprouts) samples from the corresponding seed lot yield *Salmonella* or STEC, seeds or seed containers show signs of contamination; and/or insanitary conditions in the seed storage area.
- Finished product samples from a corresponding seed lot yield *Salmonella* or STEC
- There is evidence that the production batch of sprouts may have become contaminated from the environment (i.e., potential source and route of contamination is observed)
- The operation is not conducting seed treatment and does not have documentation (e.g., Certificate of Conformance) that seeds were treated by grower, distributor or supplier.
- Traceback and epidemiological evidence suggest a lot of seeds is involved in an outbreak.
- Operation is not conducting any SSIW (or in-process sprouts) testing, or their testing is not adequate to meet PSR requirements.
- Operation has not taken corrective actions after positive SSIW (or in-process sprouts) test results (e.g., cleaning and sanitizing, discontinuing use of affected seed lots), or corrective actions were not adequate to meet the PSR requirements.

Finished Product Sprouts and/or In-process Sprouts

In-process sprouts should be collected when there is evidence that the seeds or sprouts may be contaminated and it is not possible to collect 2-liters of SSIW (e.g., the sprouts are grown in trays with very little water).

Finished product sprouts should be collected when there is evidence that sprouts may be contaminated, including:

- There is evidence that seed may be contaminated, such as: samples collected from the corresponding seed lot yield *Salmonella* or STEC, SSIW (or in-process sprouts) samples from the corresponding seed lot yield *Salmonella* or STEC, seeds or seed containers show signs of contamination; and/or insanitary conditions in the seed storage area.
- There is evidence that the production batch of sprouts may have become contaminated from the environment (i.e., potential source and route of contamination is observed in growing, packing, or holding environment)
- Traceback and epidemiological evidence suggesting that a lot of seeds is involved in an outbreak.
- Operation is not conducting any SSIW (or in-process sprouts) testing, or their testing is not adequate to meet PSR requirements.

Environmental Sampling

Environmental samples should be collected to analyze for *L. monocytogenes* if any of the following conditions apply:

- When there is evidence that the cleaning and sanitizing conducted at the sprout operation are inadequate and you can document a source and a route of contamination of sprouts. For example, if you see residues of a prior day's production on food contact surfaces and you document that sprouts contact those surfaces or if standing water from a drain splashes up onto finished sprouts.
- Sprout operation did not perform environmental monitoring for *Listeria* (either *Listeria spp.* and/or *L. monocytogenes*) or environmental monitoring was not adequate (for example, the sprout operation does not collect samples from FCS and/or Non-FCS).
- *Listeria* spp./*L. monocytogenes* was detected by the sprout operation in the production environment but no corrective actions were taken, or corrective actions were not adequate to meet the PSR requirements.

(1) Sample Collection Instructions

Instructions for sampling are included in the Sampling Instructions document which is hosted on the FDA Sprout Safety Inspections Compliance Program Resources Page (or in ORAPP for States).

D. Import Activities

There are no specific import activities under this CP.

E. Other

Intentionally left blank.

2. Reporting

N/A

PART IV - ANALYTICAL

1. Analyzing Laboratories

Divisions are required to coordinate with the servicing laboratory prior to sample collection. Refer to the Laboratory Servicing Table (LST Dashboard) to help determine an analyzing laboratory. Choose a laboratory (where PAF = MIC) that has the least amount (%) of capacity.

Notify the appropriate laboratory sample custodian(s) via email prior to shipping samples.

Divisions must notify laboratories of pending sample shipments. Because in-process and finished sprouts are highly perishable, ship refrigerated samples overnight via UPS Next Day Air Early A.M. for earliest arrival to servicing laboratories. Laboratory notification requires the inclusion of sample tracking information for samples in route. Do not ship samples on Friday (unless prior arrangements are made with the laboratory). Investigators should plan such that samples collected can be shipped Monday through Thursday to a microbiology field laboratory for analysis within 24 hours. These samples should be stored refrigerated prior to shipment. Ship samples in an insulated transport container with frozen gel packs to keep the samples cold, but not frozen. Investigators may choose to separate samples from cold packs using cardboard or similar item to prevent direct contact and freezing of sample.

2. Analyses to be Conducted

Laboratories will perform (for cause only) testing for *Salmonella*, *Listeria monocytogenes*, *E. coli* O157:H7 and other pathogenic *E. coli* (STEC).

Please review the detailed instructions for SSIW sample preparation available on the FDA Sprout Safety Inspections Compliance Program Resources Page.

3. Methodology

***E. coli* O157:H7 and other pathogenic *E. coli* (STEC):**

Screening Test:

Use the rt-PCR method described in BAM Chapter 4A, Section K.

Positive PCR results are regarded only as “cannot be ruled out” (CRO). However, be aware that not all CRO results will confirm to contain STEC; hence, it is critical to confirm CRO results before sprout operations are notified.

Isolation and Confirmatory Tests:

Sprouts contain high levels of normal flora, hence the use of O157-immunomagnetic separation (IMS) prior to plating should be pursued to facilitate isolation if the presence of O157:H7 is suspected. IMS may be performed as described in LIB4205 or under Section titled “Optional” in BAM, Chapter 4A, Section N, prior to plating onto Tellurite-Cefixime-Sorbitol MacConkey (TC SMAC) agar. Follow steps outlined beginning in Section K of BAM, Chapter 4A to isolate and identify *E. coli* O157:H7 and other STEC isolates.

Sample Preparation:

Seeds:

- Aseptically weigh 25 g of seeds into a stomacher bag. Add 225 ml of 1x mBPWp + CV (Note: This is a modification of BAM M192a in that acriflavin is not included).
- Repeat with the second 25 g analytic unit from a second subsample.
- Proceed with testing by following the steps outlined below.

Spent Sprout Irrigation Water (SSIW):

- Aseptically transfer 100 ml of the homogenous SSIW into a sterile l L flask containing 100 ml of 2X mBPWp + CV (Note: This is a modification of BAM M192a in that acriflavin is not included). Swirl to mix thoroughly.
- Repeat with the second 100 ml aliquot.
- Proceed with testing by following the steps outlined below.

NOTE: Any positive results should be followed-up by performing enumeration as instructed under Section 4 "Enumeration of Pathogens in SSIW" below. After removal of the appropriate volume of SSIW for analysis of STEC, store the leftover SSIW in the refrigerator until enumeration is carried out. Optionally: in an effort to save time, MPN analysis could be started before final confirmation on samples that initially screened as CROs.

In-Process Sprouts/Finished Product Sprouts:

- Aseptically weigh 25 g of sprouts into a stomacher bag. Add 225 ml of 1x mBPWp + CV (Note: This is a modification of BAM M192a in that acriflavin is not included).
- Repeat with the second 25 g analytic unit from a second subsample.
- Proceed with testing by following the steps outlined below.

Agricultural Water (e.g., water used to irrigate sprouts, wash sprouts, or wash food-contact surfaces:

- Aseptically transfer 225 ml of water into a sterile l L flask containing 225 ml of 2X mBPWp + CV (Note: This is a modification of BAM M192a in that acriflavin is not included). Swirl to mix thoroughly.
- Repeat with the second 225 ml aliquot.
- Proceed with testing by following the steps outlined below.

Testing:

Incubate the enrichment broth mixtures for 24 hrs at 42 °C±1 °C (107.6 °F), with shaking at 140 RPM.

After incubation, test each enrichment broth mixture for the presence of STEC, using the rt-PCR method in BAM (Sec. O, Chap. 4A) and see BAM, Chap. 4A, Sec. O, to interpret results.

Follow steps outlined in Sections P, Q and R of BAM, Chapter 4A to isolate and identify *E. coli* O157:H7 and other STEC isolates.

Positive *E. coli* O157:H7 and/or other STEC - Laboratories must perform whole genome sequencing using OII SOPs immediately upon confirmation of any STEC, including *E. coli* O157:H7.

Please contact Julie Ann Kase, HFP for any questions or concerns.

NOTE: The fluorescence-tagged *E. coli* O157:H7 must be used as a positive control. The control strain is commercially distributed by Microbiologics (available at Microbiologics : 01227UV-S

Escherichia coli (O157:H7) EC43 derived from FDA ESC1177 (STEC) UV-BioTAG). Also, you can contact: Karen Jinneman, FDA/HFP/OLOAS/ORTS/SEAHAFL, 425-487-5384 to obtain the control strain.

Please contact Julie Ann Kase, HFP for any questions or concerns.

Julie Ann Kase,
FDA/HFP/OLOAS/OAMT/DFES/MMDB
5001 Campus Drive, HFS711
College Park, MD 20740
240-402-2923
Julie.Kase@fda.hhs.gov

***Salmonella*:**

Analysis of seeds, SSIW, in-process sprouts, and finished product sprouts samples should be initiated upon receipt of samples.

Screening Test:

Rapid screening methods (AOAC OMA 2004.03 VIDAS *Salmonella* and AOAC OMA 2011.03 VIDAS *Salmonella* Easy) are currently only authorized for use on seed samples collected under this compliance program. Note, laboratories must maintain matrix extension/validation study documentation that supports the use of the desired rapid screening method(s) for seeds and appropriate management authorization. Otherwise, laboratories must follow BAM Chapter 5 cultural method throughout.

If rapid screening is used, follow the sample preparation and pre-enrichment instruction for seeds below; followed by the rapid method instruction for selective and or post-enrichment and screening. CROs must be confirmed via BAM Chapter 5 for isolation and confirmatory testing.

Currently, only BAM Chapter 5 *Salmonella* cultural method is authorized for SSIW and in-process sprout/finished product sprout samples. Rapid screening methods are NOT authorized for these two sample types (SSIW & sprouts).

Isolation and Confirmatory Tests:

Follow BAM Chapter 5 *Salmonella* cultural method for the isolation and identification/confirmation.

Sample Preparation and Testing:

Seeds:

- Remove one 25 g analytical unit from each sub-sample (100 g) to form two 375 g composites from 2 sets of fifteen 25 g analytical units.
- Add 375 g seeds directly to a 4 L Erlenmeyer flask (or any appropriate flask) containing 3,375 ml Universal Pre-enrichment Broth (UPB). Do not blend.
- In a separate flask, repeat this procedure with the second 375 g seed composite.
- Incubate UPB at 35 °C for 22-26 hours; continue to RV & TT, isolation, and confirmation per BAM Chapter 5.

Spent Sprout Irrigation Water (SSIW):

- Two (2) 375 ml composites will be analyzed for *Salmonella*.

- Add 375 ml composite of SSIW directly to a 2 L Erlenmeyer flask (or any appropriate flask) containing 1,125 ml Universal Pre-enrichment Broth (UPB). Swirl to mix thoroughly.
- In a separate flask, repeat this procedure with the second 375 ml composite.
- Incubate UPB at 35 °C for 22-26 hours; continue to RV & TT, isolation, and confirmation per BAM Chapter 5.

NOTE: Any positive results should be followed-up by performing enumeration as instructed under Section 4 "Enumeration of Pathogens in SSIW" below. After removal of the appropriate volume of SSIW for analysis of *Salmonella*, store the leftover SSIW in the refrigerator until enumeration is carried out.

In-Process Sprouts/Finished Product Sprouts:

- Remove one 25 g analytical unit from each sub-sample (100 g) to form two 375 g composites from 2 sets of fifteen 25 g analytical units.
- Add 375 g of composite sprouts directly to a 6 L Erlenmeyer flask (or any appropriate flask) containing 3,375 ml prewarmed Universal Pre-enrichment Broth (UPB). Do not blend.
    - UPB should be prewarmed to 35 – 37 °C to help the sample enrichment reach the elevated incubation temperature in a suitable time. Do not prewarm at temperatures above 37 °C (such as 42 °C) as this may heat shock any *Salmonella* cells present.
- Repeat procedure with a second 375 g sprout composite.
- Incubate UPB at 42 °C for 22-26 hours; continue to RV & TT, isolation, and confirmation per BAM Chapter 5.

Agricultural Water (e.g., water used to irrigate sprouts, wash sprouts, or wash food-contact surfaces:

Please refer to EPA method 1200: Analytical protocol for non-typhoidal *Salmonella* in drinking water and surface water (May 2012): https://www.epa.gov/sites/production/files/2015-08/documents/epa817r12004.pdf

Serotyping: If the sample is positive for *Salmonella*, prepare slants and provide hard copy information requested under BAM online Ch.5 section E-11, Submission of cultures for serotyping. Isolate(s) should be submitted to your local serotyping group for WGS and SeqSero analysis.

Please contact Hua Wang, HFP for further instruction.

Hua Wang
FDA/HFP
5001 Campus Drive, HFS711
College Park, MD 20740
240-402-1932
hua.wang@fda.hhs.gov

***Listeria monocytogenes*:**

Sample preparation

Finished Product:

- Two (2) of the 50 g subsamples should be analyzed for the presence of *L. monocytogenes*. Aseptically transfer 25 g of sprouts from each sub in a sterile stomach bag, add 225 ml Buffered *Listeria* Enrichment Broth (BLEB) and mix in stomacher at medium speed for 2 minutes.
- Repeat procedure with the second subsample.

Testing:

- Incubate the enrichment mixtures for 4 h at 30 °C and then add selective agents (acriflavin, 10 mg/L; sodium nalidixate, 40 mg/L; cycloheximide 50 mg/L or natamycin 25 mg/L). Continue incubation at 30 °C for another 44 h.
- NOTE: Alternatively, AOAC OMA 999.06 (VIDAS LIS Listeria), AOAC OMA 2010.02 (VIDAS *Listeria* species LSX), 2013.10 (VIDAS LPT Listeria) or 2004.06 (Modified VIDAS LIS *Listeria*) can be used for rapid screening. Perform in-house validation if these methods are not validated for any of the above matrices. Follow manufacturer's instructions to perform the test kit analyses. Please note that the enrichment broth is not BLEB for most of the alternative methods.
- For all samples, at 24 h and 48 h of culture enrichment, streak enrichment broth to two agar plates and incubate. One agar plate can be OXA, PALCAM, modified LPM or MOX agar plates and the other plate can be ALOA, BCM, Rapid L. mono agar.
- Pick up to five typical colonies from the esculin based selective agar plates and up to two typical colonies from chromogenic agars and transfer onto TSAYE agar plates. Incubate the TSAYE plates at 30 °C for 24 to 48 h. The plates can be incubated at 35 °C for 24 to 48 h if colonies will not be used for wet mount motility test.
- Use the procedures described in BAM Chap. 10, to identify pure culture from TSAYE plates. Conventional methods, PCR, or rapid kits can be used.
- If samples are confirmed positive for *L. monocytogenes*, perform serotyping according to FDA, BAM Chap. 11.
- Perform WGS as soon as possible upon confirmation of *L. monocytogenes*.
- If a finished sprouts sample tests CRO for *L. monocytogenes*, use a reserve portion of sprouts for enumeration. Mix the reserve portion thoroughly. Follow BAM Chap, 10 Sec. J: Enumeration. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071400.htm. MPN and direct plating will be performed. MPN can start with triplicates of 10 g, 1 g, 0.1 g and 0.01 g and add to the enrichment broth at a ratio of 1:9 (w/w).

***L. monocytogenes* from environmental samples:**

Preferred methods:

- The BAM Method, now validated for *Listeria monocytogenes* Environmental Sampling and Analysis https://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm071400.htm.

Alternative Methods:

- AOAC OMA 999.06 *Listeria* spp. in Selected Foods and Environmental Surfaces
- AOAC PTM (No. 981202) VIDAS LIS, *Listeria* in environmental samples

Note: Follow the sampling preparation procedures described in the instructions. If the package insert does not clearly describe how to prepare environmental samples, please refer to BAM Chapter 10 Section (D)(1)(c).

If AOAC methods are used, culture should be confirmed using the culture confirmation methods of the BAM Chapter 10. When picking presumptive colonies from agar plates, analysts need to keep in mind that the goal is to pick all *Listeria* spp., including *L. monocytogenes*.

If samples are confirmed positive for *Listeria monocytogenes*, perform serotyping according to BAM Chapter 10, section I, Subtyping of *Listeria monocytogenes* isolates.

No enumerations will be performed on environmental swab/sponge samples.

Perform WGS analysis upon confirmation of *Listeria monocytogenes*.

HFP contacts for WGS are Eric Brown, Director, Division of Food Safety Genomics (DFSG) and James Pettengill, Director, Division of Surveillance and Data Integration (DSDI). Questions regarding screening, confirmation, and speciation may be directed to Yi Chen.

Please contact Yi Chen, HFP for further instruction.

Yi Chen
FDA/HFP
5001 Campus Drive, HFS711
College Park, MD 20740
240-402-2783
yi.chen@fda.hhs.gov

Additional analyses when pathogens are recovered:

Enumeration of Pathogens in SSIW: A three tube MPN method will be used to enumerate the level of contamination in SSIW that test positive for *Salmonella* or STEC.

MPN analysis of the *Salmonella*/STEC positive samples:

STEC

- Prepare the MPN enrichment samples according to the following tables. The left-over SSIW sample from above will be used.
- For the 10^{-1} dilution, 25 ml of SSIW will be mixed with 225 ml of BPB (Butterfield's Phosphate-Buffered Dilution water). The 10^{-2} dilution will be made using 25 ml of 10^{-1} dilution mixed with 225 ml of BPB.
- Incubate the enrichment broth mixtures for 24 h at 42 °C, with shaking at 140 RPM
- Follow the BAM protocol in Chapter 4a as described above in Section 1 of this document to determine the presence of *E. coli* O157:H7 and other STEC in each of the enrichments.
- Determine the level of *E. coli* O157:H7 and other STEC using MPN table (BAM Appendix 2: Most Probable Number from Serial Dilutions | FDA)

Concentration	3-Tube MPN
10^2	3 x 100 ml of SSIW in 100 ml 2X mBPWp +CV
10^1	3 x 10 ml of SSIW in 10 ml 2X mBPWp +CV

Concentration	3-Tube MPN
10^{0}	3 x 1 ml of SSIW in 1 ml 2X mBPWp +CV
10^{-1}	3 x 1 ml of 10^{-1} dilution of SSIW in 1 ml 2X mBPWp +CV
10^{-2}	3 x 1 ml of 10^{-2} dilution of SSIW in 1 ml 2X mBPWp +CV

Salmonella

- Prepare the MPN pre-enrichment samples according to the following tables. The left-over SSIW from above will be used.
- For the 10^{-1} dilution, mix 25 ml of SSIW with 225 ml of BPB (Bufferfield's Phosphate-Buffered Dilution water).
- Incubate all pre-enrichment samples at 35 °C ± 2 for 24 h.
- Follow the selective enrichment (in RV and TT), plating (onto XLD, HE, BS), confirmation and isolation protocols as described in the BAM.
- Determine the level of *Salmonella* using MPN table (BAM Appendix 2: Most Probable Number from Serial Dilutions | FDA)

Concentration	3-tube MPN (100, 10, 1, 0.1 mL)
10^{2}	3 x 100 ml of SSIW in 900 UPB
10^{1}	3 x 10 ml of SSIW in 90 ml UPB
10^{0}	3 x 1 ml of SSIW in 9 ml UPB
10^{-1}	3 x 1 ml of 10^{-1} dilution in 9 ml UPB

Whole Genome Sequencing (WGS): Positive isolates for *Salmonella*, *Listeria monocytogenes*, *E. coli* O157:H7 and other pathogenic *E. coli* (STEC) must have whole genome sequencing performed. All sequence data must be submitted to HFP and to the national GenomeTrakr database.

Serotyping of Positive Isolates: *Salmonella* positive isolate(s) must have SeqSero analysis performed to predict isolate serotype.

4. Reporting

Analytical results (CROs, Negatives, and Confirmed positive findings) will be reported in an expeditious manner after an appropriate quality assurance review has been performed by laboratory management as required by the Laboratory Manual of Quality Policies (ISO 17025 Requirements) to meet the requirements for laboratory accreditation of the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025.

Report all analytical findings into FACTS using the "MIC" PAF code. Please refer to SOP-000529 Communicating Laboratory Analytical Findings for Food Products and Environmental Samples Standard Operating Procedure for reporting analytical results when Dealers are voluntarily holding product.

As per SOP-000529, the laboratories will communicate confirmed sample results to the home Division and HFP OCE via the established email address within 24 hours of completing sample

analysis and in advance of sending the FDA Form 1551, Report of Sample Analysis, to the sprout operation.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

1. Findings

Unless otherwise instructed, all significant noncompliance with the FD&C Act or FDA regulatory requirements should be cited on the FDA-483 observational inspection form. Please refer to supplementary compliance and enforcement strategy information located on the FDA Sprout Safety Inspections Compliance Program Resources Page (or in ORAPP for States) for more details. You may choose to annotate the FDA-483 in accordance with 5.5.11.5 of the IOM if violations are satisfactorily corrected prior to the close out of the inspection. Document all corrections undertaken during the inspection in the EIR.

Contact HFP OCE Produce Enforcement Branch (PEB) (HFP-OCE-Produce@fda.hhs.gov) if there are questions regarding how to structure citations on the FDA 483 under the FD&C Act.

2. Citations/Charges

Citations/charges that may be applicable to this program include the following:

- 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)].
- An article of food is adulterated under section 402(a)(1) of the FD&C Act [21 U.S.C. 342(a)(1)] if it bears or contains any poisonous or deleterious substance which may 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 epidemiological 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. The criteria and definitions of 21 CFR Part 112 apply in determining whether a food is adulterated within the meaning of Section 402(a)(4) of the FD&C Act (21 CFR 112.92(b)).

3. Enforcement Strategy

This section outlines possible actions FDA may consider in response to adverse findings during an inspection. With the progressive enforcement strategy, uncorrected violations of public health significance, where the sprout operation is either unwilling or unable to make voluntary corrections, may warrant consideration of increased enforcement actions to include injunctions. Our enforcement response will be commensurate with the significance of the of the observations and the adequacy of the sprout operations' corrective action.

If the Field Division anticipates a need for advisory/regulatory actions, they must coordinate with HFP OCE and HFP OMFS OPS (refer to program contacts in Part VI) to discuss.

A. Product Actions

Product actions should be taken to remove unsafe product from the market even if there is no prior notice. 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 sprout operation to recall the produce (see RPM Chapter 7). If the sprout operation 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, administrative detention/seizure or complementary state action. Because sprout operations are farms, not facilities, mandatory recall is not an option for sprout operations. (Mandatory recall does not apply to farms, including sprout operations.) Sprouts corresponding to findings of pathogens in SSIW are adulterated and should be subject to product actions.

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 document conditions related to sources and routes of produce contamination that would support an adulteration charge.

B. Warning Letter

If, after review of the inspection report, inspectional observations, evidence and firm's written response FDA determines significant violations from the Produce Safety Rule and/or Food, Drug, and Cosmetic Act were observed and the firm's stated corrective actions are not adequate to address those violations, FDA may send a Warning Letter to the sprout operations.

Violations that are adequately corrected and documented within 15 working days from the close of the inspection may be omitted from a Warning Letter under consideration. If such violations are included in the Warning Letter, the correction already taken by the sprout operation should be acknowledged in the Warning Letter. 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) citation. Immediate action should be taken to address any contaminated produce in the market or with the potential to be distributed (see Product Actions above).

Reinspection should occur between six months and a year following issuance of a Warning Letter.

C. Regulatory Meetings

Consider a regulatory meeting if, upon reinspection following a Warning Letter, we determine the corrective actions implemented were not adequate to address our concerns, were not lasting enough to prevent violations from recurring, or additional violations were observed. A regulatory meeting can also be considered to communicate documented violations that do not warrant the issuance of a Warning Letter. Where possible, engage officials from the corresponding State ahead of the regulatory meeting.

If the regulatory meeting does not result in satisfactory correction of identified violations, FDA will consider additional actions to achieve corrective action and a follow-up inspection will often be scheduled. HFP OMFS OPS should be invited to participate in all regulatory meetings (see Part VI below for POC to contact).

D. Injunctions

FDA should consider an injunction for sprout operations that receive an OAI classification following a Warning Letter. Injunctions are resource intensive and therefore efforts should be made to obtain voluntary corrective action where possible. An injunction should be considered when a sprout operation is unwilling or unable to take corrective action in their operation to produce sprouts that are not adulterated. Most of the injunctions FDA has filed against sprout operations have been associated with findings of *Listeria monocytogenes* in product and the environment of the sprout operation and documentation of conditions and practices that are likely to have resulted in contamination of sprouts with *Listeria monocytogenes*. Follow up inspections should be conducted yearly to make sure the sprout operation is in compliance with the consent decree.

4. Regulatory Follow-up

Regulatory follow-up will depend on several factors, including the nature of the non-compliance observed, and the sprout operation's response. 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, sprout operation inspection assignments are issued by FDA, there may be additional instructions included in the assignment to complement the instructions in this CP.

Sprout operations that receive an OAI classification should be targeted for reinspection within 6 months. Inspection assignments for OAI sprout operations are created by HFP OCE PEB.

5. Communication and Coordination for Compliance and Enforcement

As provided in section 419 of the Act, 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, OII OHFI Division Investigations Branch will keep HFP OCE PEB and HFP OMFS OPS informed of any FDA actions with the sprout operation, and will coordinate with state regulators, as applicable. HFP OCE PEB will consult with HFP OMFS OPS regarding potential enforcement actions for sprout operations.

PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. References

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

A. FDA Sprout Safety Inspections Compliance Program Resources Page
B. Investigations Operations Manual (IOM)
C. Regulatory Procedures Manual (RPM)
D. *FSMA Final Rule on Produce Safety* (Federal Register Notice)
E. Sprout Safety Alliance
F. 2023 Final Guidance for Sprout Growers: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption
G. 2023 Draft Guidance for Sprout Growers: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption
H. Draft PSR Guidance: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
I. 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
J. FSMA Produce Safety Rule Landing Page
K. *Standards for Produce Safety Coverage and Exemptions/Exclusions*
L. *Determining Coverage under Subpart M of the Produce Safety Rule*
M. PSR inflation adjusted cut-offs
N. *FDA Factsheet: Produce Safety Rule Fact Sheet on Dropped Covered Produce*
O. Equivalent Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water or Sprouts Samples
P. Equivalent Testing Methodologies for *Listeria* species and *Listeria monocytogenes* in Environmental Samples
Q. Equivalent Testing Methodologies for Quantifying Generic *E. coli* in Agricultural Water Samples
R. FDA's Bacteriological Analytical Manual Online (BAM), Chapter 10 – "*Listeria monocytogenes*," "Detection and Enumeration of *Listeria monocytogenes* in Foods"
S. *Responding to Results Obtained from Testing Spent Sprout Irrigation Water (or In-Process Sprouts) for E. coli* O157:H7 or *Salmonella to meet the requirements of the Produce Safety Rule*
T. Decision Tree for Test Methods Requirements of *Salmonella* and *E. coli* O157:H7 in Spent Sprout Irrigation Water (or Sprouts)
U. Written Assurances Enforcement Discretion Guidance
V. Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Draft Guidance for Industry
W. 7303.040 Preventive Controls and Sanitary Human Food Operations (CGMP&PCHF) CP
X. 7303.080 Produce Safety Inspections CP
Y. 7303.050 Micro Sampling CP
Z. 2021 Produce State CAP funding agreement

2. Program Contacts

A. HFP Program Contacts

Purpose	Name	Organization	Contact
General Program Guidance	Teja Patel	HFP/OCE/OCOI/DCI/CPAB	240-402-2339
Enforcement Contact	HFP OCE Produce Team	HFP/OCE/OE/PEB	HFP-OCE-Produce@fda.hhs.gov
Program Office Contact	Patricia Homola	HFP/OMFS/OPS/DPFBS	240-402-4937
Outbreak Response Contact	Madison Rohrbaugh	HFP/OCOREEP/DODMS	240-402-6206
Technical and policy assistance during inspections	Sprouts regulatory TAN (rTAN)	HFP/OMFS/OPS/DPFBS	SproutsQuestions@fda.hhs.gov
Work planning	Arnaldo Rosado	HFP/OCE/OCOI/DCO	240-402-5369
Salmonella	Hua Wang	HFP/OLOAS/OAMT/DFES	240-402-1932
Listeria	Yi Chen	HFP/OLOAS/OAMT/DFES	240-402-2783
E. coli O157:H7	Julie Kase	HFP/OLOAS/OAMT/DFES	240-402-2923
WGS Support	Eric Brown	HFP/OLOAS/OAMT/DFSG	240-701-5269
Bioinformatic Support	James Pettengill	HFP/OSSRP/DSDI	240-402-1992
Laboratory Operations	Darcy Brillhart	HFP/OLOAS/ORTS/DSPC	404-253-2294
State Programs	Travis Goodman	HFP/OIFSSP/ODP/DDPCI	317-226-6500

B. OII Program Contacts

Purpose	Name	Organization	Contact
Inspection Guidance	Travis Chapin	OII/OHFI/OGSHFI	813-915-7971
Inspection Guidance	Audrey De La Cruz	OII/OHFI/OHFIC/DHFICI	312-596-4208

Purpose	Name	Organization	Contact
Regulator Training	Allen Gelfius	OII/OTED/DPT	240-672-1351

PART VII - CENTER RESPONSIBILITIES

The Office of Microbiological Food Safety will provide subject matter expertise in the maintenance and evaluation of the Compliance Program and provide guidance to the Office of Compliance and Enforcement with regard to program priorities, relevant evaluation questions, and recommended program changes. The Office of Compliance and Enforcement will lead the effort and work in conjunction with the Office of Microbiological Food Safety 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 Office of Compliance and Enforcement will make these evaluations available as well as FSMA Tracker reports that can be run annually or as frequently as needed to track accomplishments. Instructions on how to access these reports are available at:

FACTS Accomplishments (sharepoint.com)

Compliance Program Summaries (sharepoint.com)