Sprout Safety Alliance (SSA) Webinar

Updates to the FDA Guidance for Sprout Growers

Sprout Safety Alliance

Welcome and introductions

Dr. Jason Wan

Associate Director, Institute for Food Safety and Health; Director, FSPCA

Agenda

DESCRIPTION	PRESENTER	TIME
Housekeeping	Jason Wan	9:00 – 9:05 CT
SSA Updates	Yuqiao Jin	9:05 – 9:10 CT
2023 Final Guidance: Introduction; Background; Cleaning and Sanitizing; and Agricultural Water in Sprout Operations	Courtney Mickiewicz	9:10 – 10:10 CT
2023 Final Guidance: Seeds for Sprouting; Environmental Monitoring; and Recordkeeping	Patricia Homola	
2023 Draft Guidance: Personnel Qualifications, Training, and Hygienic Practices; Equipment, Tools, and Buildings; and Sampling and Testing of Spent Sprout Irrigation Water (or In-Process Sprouts)	Insook Son	
Q&A	All	10:10 – 10:30 CT

- Yuqiao Jin, Ph.D., Co-lead, Sprout Safety Alliance, IFSH/IIT
- Courtney Mickiewicz, M.S., Biologist, CFSAN/OFS/DPS/PPB
- Patricia Homola, Ph.D., Consumer Safety Officer, CFSAN/OFS/DPS/PPB
- Insook Son, Ph.D., Microbiologist, CFSAN/OFS/DPS/PPB

Webinar Presentation and Recording

- The following will be available on the SSA Website:
  - A PDF of the webinar presentation
  - A link to a recording of the webinar
    - The webinar recording is view only, download is not available
- Please allow 5 business days for the presentation and recording to be published

Accessing the SSA Website
https://www.iit.edu/ssa

Q&A

- All attendees are muted
- Ask questions by typing into the Chat box
  - Click on the Chat icon
    - To pose a question, begin by typing into the box that is provided on the screen and tap “Enter”
  - We will do our best to answer as many questions as time allows but we may not be able to address every question
  - Questions not relevant to this webinar topic, or questions that the presenters cannot provide a response to at this time will not be addressed

SSA UPDATES

Yuqiao Jin, Ph. D., Co-lead, Sprout Safety Alliance, IFSH, IIT

Sprout Safety Alliance

Overview and Progress

Yuqiao Jin, Ph.D.
SSA co-lead & coordinator
Institute for Food Safety and Health

SSA Webinar
June 26, 2024

Sprout Safety Alliance (SSA)

- Created through a partnership grant from FDA to Institute for Food Safety and Health (IFSH)

- Objectives of the Sprout Safety Alliance

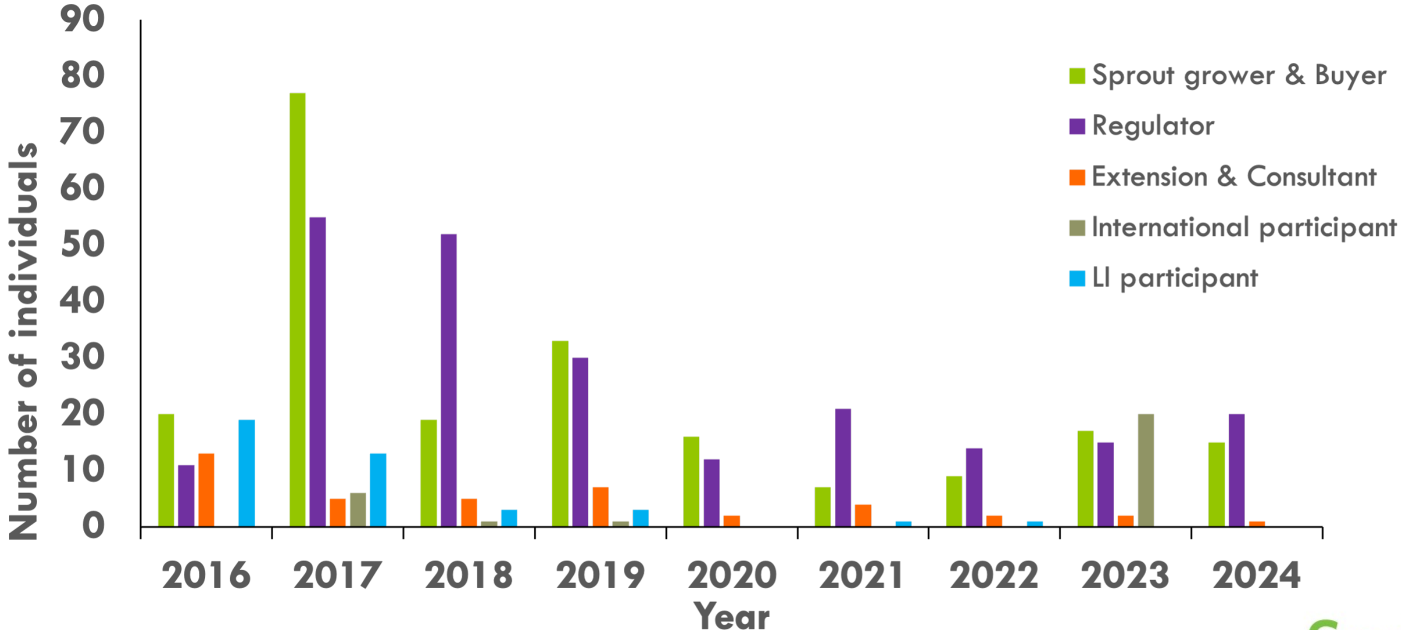
Training in 2024

- The SSA conducted Sprout Grower Training Blended Course Part 2 (Virtual) on April 17-18, 2024.
- Sprout Grower Training Blended Course Part 2 (In-Person) in Tennessee on April 18, 2024.
- The SSA conducted Sprout Grower Training Blended Course Part 2 (Virtual) on May 21-22, 2024.

SSA Training Metrics

June, 2024

Sprout grower & buyer (U.S.)	Regulator (U.S.)	Extension specialist (U.S)	International participant	LI participant
213	230	41	28	40



Activities

Support sprout growers

- SSA training and outreach
- e-mails and SSA TAN
- Webinar
- Filming SSA video series

Seed Safety Conference

- **"Ensuring the Safety of Seeds for Sprouting and Other Applications"** will be held on August 13-14, 2024, at the Chicago Marriott Southwest at Burr Ridge, IL.
- Showcases best practices for the production, sourcing, handling and management of seeds used to grow sprouts.
- The registration fee is $50.
- Please contact Dr. Tong-Jen Fu (tongjen.fu@fda.hhs.gov) for any questions or additional information.

Registration link: https://www.eventbrite.com/e/seed-safety-conference-registration-878123820987?aff=oddtdtcreator

Thank you for attending!

For more information, please contact:

Yuqiao Jin, Ph.D.
sproutalliance@iit.edu

Institute for Food Safety and Health
Illinois Institute of Technology

Sprout Safety Alliance

Innovation Through Collaboration
IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH

UPDATES TO THE FDA GUIDANCE FOR SPROUT GROWERS

Courtney Mickiewicz, M.S., Biologist, CFSAN/OFS/DPS/PPB
Patricia Homola, Ph.D., Consumer Safety Officer, CFSAN/OFS/DPS/PPB
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Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption

Sprout Safety Alliance Webinar

June 26, 2024

Navigating the 2023 Guidance Documents

Final
- Cleaning and Sanitizing
- Agricultural Water in Sprout Operations
- Seeds for Sprouting
- Environmental Monitoring
- Recordkeeping

Draft
- Personnel Qualifications, Training, and Hygienic Practices (New)
- Equipment, Tools, and Buildings
- Sampling and Testing of Spent Sprout Irrigation Water (or In-Process Sprouts)

Once finalized, the sections of the 2023 Draft Guidance will be incorporated into the 2023 Final Guidance.

Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with Docket No. FDA-2017-D-0175.

For questions regarding this document contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

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

September 2023

Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2017-D-0175 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

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

September 2023

Changes to the 2023 Final Guidance

- Clarifies the recommendations regarding the frequency of cleaning and sanitizing
- Provides additional recommendations on seed for sprouting, including seed treatment and corrective actions
- Removes language on voluntary periodic sampling and testing of sprouts, and clarifies our expectations for corrective actions after an operation detects *Listeria* spp. or *Listeria monocytogenes* in an environmental sample
- Simplifies the guidance: removed section III (General Sprout Production) found in the Jan 2017 Draft Guidance
  - most of the language in this section was repeated elsewhere
- Editorial changes to improve clarity and removes certain recommendations based on impracticality

Introduction

- The Guidance documents are used to assist sprout operations in complying with Sprout-specific requirements in subpart M
- Some coverage of other applicable parts of the Produce Safety Rule
- Some topics covered in the Sprout Guidance (e.g., records, cleaning and sanitizing) are also discussed in the Produce Compliance and Implementation Draft Guidance

Background:
Coverage of the Produce Safety Rule

FDA

- Covers produce that is a RAC
- Sprouts are produce and subject to applicable requirements of the Produce Safety Rule unless exempt or excluded
- Raw sprouts that will later be processed w/o a kill step are still subject to the Produce Safety Rule while in their RAC form, unless an exemption applies
- Extension for agricultural water requirements does not apply

Background: Coverage of Subpart M

- Applies to growing, harvesting, packing and holding of all sprout types <u>except</u> sprouts harvested above the soil or substrate line without their roots
- Sprouts sold w/roots attached, e.g., wheatgrass in a tray, are subject to subpart M, however,
  - if sold to the commercial entity that receives them that will cut the sprouts above the soil or substrate line before use or sale to the consumer, we would use enforcement discretion PROVIDED you annually collect written assurances from the commercial entity.

Cleaning and Sanitizing

- Cleaning and sanitizing are different and important steps that are critical to the safety of your finished sprouts
- <u>Cleaning</u>: removing visible organic material and other debris from surfaces
- <u>Sanitizing</u>: adequately treating cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer
- A surface must be clean before it can be sanitized

Cleaning and Sanitizing

- You must inspect, maintain, clean, and sanitize FCSs (§ 112.123(d)(1))

- Any FCS used to grow, harvest, pack or hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts (§ 112.143(b))

Cleaning and Sanitizing

- Examples of when you must incorporate a cleaning and sanitizing step for FCSs:
  - Before contact with a different production batch of sprouts
  - Before the first time it is used in your sprouting operation to contact seeds for sprouting or sprouts
  - Before contact with seeds or sprouts after storage for an extended period (e.g., several days)
  - Before contact with seeds or sprouts after the FCS has been exposed to a source of contamination
  - Before contact with seeds or sprouts after contacting food other than sprouts

Cleaning and Sanitizing

- You must establish and keep records of the date and method of cleaning and sanitizing of equipment used during growing operations for sprouts and all covered harvesting, packing, or holding activities (§ 112.140(b))
- We recommend developing cleaning and sanitizing policies
- We recommend that you conduct verification sampling of recently cleaned and sanitized surfaces to monitor overall sanitation effectiveness
- Cleaning and sanitizing is required or recommended as a corrective measure under certain situations (§§ 112.148, 112.146)

Agricultural Water in Sprout Operations

- Numerical Microbial Quality Criterion for Agricultural Water Used in a Sprouting Operation (§ 112.44(a))
  - Agricultural water uses in sprouting operations:
    - ✓ Used as sprout irrigation water
    - ✓ Applied in any manner that directly contacts produce during or after harvest activities
    - ✓ Used to contact FCSs of equipment and tools or to make ice
    - ✓ Used for washing hands and supplied to hand-washing facilities at sprouting operations
- Agricultural Water Sources Type and Treatment Status
  - Identify the type(s) of Ag water source(s)
  - Inspect Ag water sources and distribution systems
  - Adequately maintain these systems
- Safe and of Adequate Sanitary Quality for Its Intended Use (§ 112.41)
  - All agricultual water must be safe and of adequate sanitary quality for its intended use.

Agricultural Water in Sprout Operations

- Reuse of Sprout Irrigation Water
  - Recommend against re-using the SSIW collected from one production batch to irrigate subsequent batches of sprouts without any form of water treatment in between batches
- Agricultural Water Testing Frequency, Sampling, and Test Methods
  - Test each such water source a minimum of 4 times over a period of one year
  - All such samples to be representative of the intended use(s)
  - Must be analyzed for compliance with the § 112.44(a) microbial quality criterion using a method set forth in § 112.151
- Post-Harvest Water Management
  - Manage the water used by establishing and following water-change schedule for re-circulated water to maintain its safety and adequate sanitary quality
  - Visually monitor the quality of water

Seeds for Sprouting: Seed Sourcing

Knowing your seed supplier(s) and establishing specifications for the seeds you receive (such as being grown under GAPs and handled under sanitary conditions during storage and distribution or transport) can help improve the safety of the seeds you receive.

- Seeds for sprouting should be grown under GAPs and handled according to food safety best practices.
- You should ask your seed supplier about their practices if a portion of a lot of seed tests positive for a pathogen prior to distribution.
- You should ask your seed supplier what is the most efficient and effective way to notify them of any positive test results you receive (e.g., of SSIW tests).

Seeds for Sprouting: Seed Receiving

- You must visually examine seeds and their packaging for signs of potential contamination.
- You should develop SOPs you follow to receive and inspect seed upon receipt and the criteria you use in determining whether to accept a shipment.
- Each bag should be examined upon arrival for physical damage that could result in contamination (e.g., holes from rodents) and other signs of contamination (e.g., stains, insects, presence of feces or urine, or foreign material).
- If you observe obvious signs of damage or contamination, you should reject the seeds and contact the supplier.
- After storing seed at your operation, you should reinspect the bags of seeds for signs of contamination before using them.

§ 112.142(d)

Seeds for Sprouting:
Seed Handling and Storage

- You must
  - Take measures reasonably necessary to prevent the introduction of hazards into or onto seeds for sprouting.
  - Store seed in a fully-enclosed building, of sound construction and in good repair. This area is subject to applicable requirements for buildings in Subpart L.
  - Store open packages of seed in closed containers with tight-fitting lids, or otherwise protected from contamination.
  - Clean and sanitize food contact surfaces (FCS) of containers other than the original packaging used to hold seeds prior to use.
  - Take measures to exclude pests from the building and you must routinely monitor for pests.
- The seed storage area should be clean, dry, and dedicated to seed storage.
- You should store seeds off the floor and away from walls to facilitate pest control inspection, and regularly inspect seed packaging and containers.

§ § 112.142(a), 112.122(a), 112.143(b), 112.126, 112.128(b), 112.128

Seeds for Sprouting: Seed Treatment

- Seeds for sprouting must be treated using a scientifically valid method to reduce *Salmonella* and *E. coli* O157:H7.
- This treatment can be done by you or by another entity earlier in the supply chain. If you rely on prior treatment, you must obtain documentation that:
  - the prior treatment was conducted using a scientifically valid method to reduce pathogens; and
  - the treated seeds were handled and packaged following the treatment in a manner that minimizes the potential for contamination.
- We recommend the use of a seed treatment that achieves at least a 3-log reduction in *Salmonella* and *E. coli* O157:H7.
- If you treat seeds at your own operation, you should develop a written seed treatment SOP to ensure treatments are applied consistently and correctly.
- You must establish and keep records of your seed treatment.

§ § 112.142(e), 112.150(b)(1)

Seeds for Sprouting: Corrective Actions

- If you learn that a lot of seeds has been associated with foodborne illness, or if you learn that a lot of seeds may be contaminated with a pathogen based on microbial test results, you are required* to take corrective actions with respect to that seed lot and sprouts grown from that seed lot:
  - you must discontinue use of all seeds from that lot for sprout production,
  - You must ensure that sprouts grown from that lot of seeds do not enter commerce, and
  - You must report the information to the seed grower, distributor, supplier, or other entity from whom the seed was purchased.
- You are required to maintain records related to corrective actions taken on seed for sprouting.

- There are some exceptions, in* ***very limited circumstances**. Review the guidance chapters for more information.*

§ § 112.142(b), 112.150(b)(6)

Environmental Monitoring: Written Sampling Plan

- <u>Required</u> components:
  - What you will test for
    - *Listeria* spp. or *L. monocytogenes*
  - Sample collection frequency
    - No less than monthly
  - Point during production samples will be collected
  - Number and location of sample collection sites
    - Food and non-food contact surface sampling sites
  - Corrective action plan, and when and how you will accomplish those actions

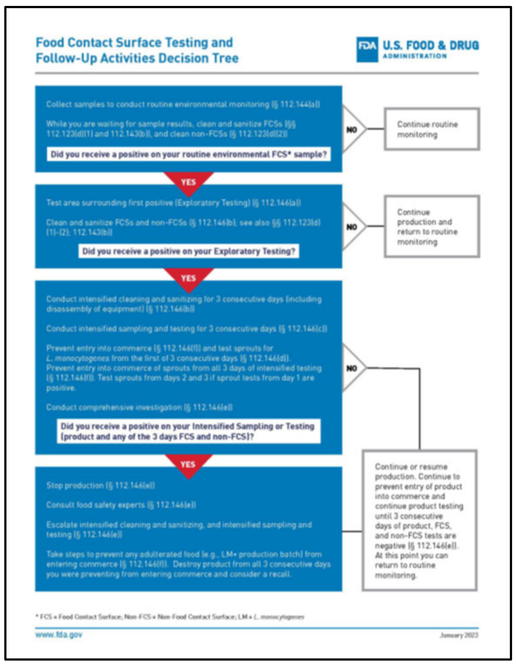
§ 112.145(c)

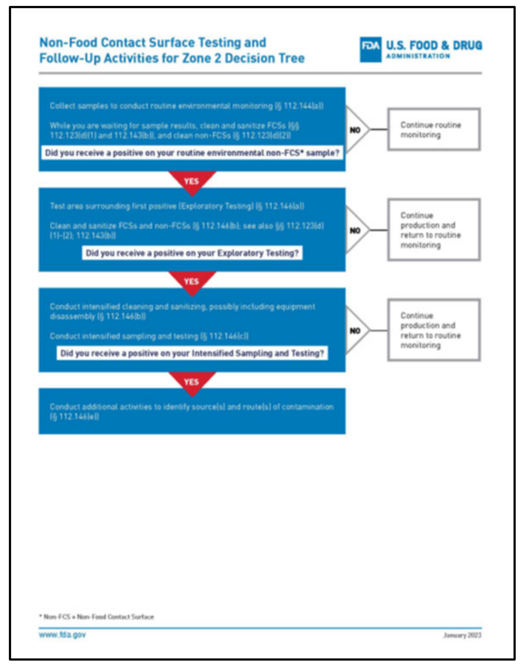
Environmental Monitoring: Written Sampling Plan

- Recommended components:
  - List of all FCS and non-FCS sites at a level of detail that facilitates your identification of sampling sites
  - Identify specific test method
  - Identify person(s) responsible for sample collection and any specific training that the person(s) should have
  - Procedures for aseptic sample collection
    - Appropriate materials and steps to prepare for sample collection
  - Sample collection method used and sample sizes to be collected
  - Identify the laboratory you are using
  - Identify records for each sample collected

Environmental Monitoring: Corrective Actions

- Must develop a Corrective Action Plan and take corrective actions
- Specific testing and follow-up actions for findings of *Listeria* spp. or *L. monocytogenes* on non-FCSs and FCSs can be found in the final guidance





§ 112.145(e) and § 112.146

Environmental Monitoring: Corrective Actions for *L.* spp-positive FCS

- Collect samples to conduct routine environmental monitoring (§ 112.144(a))
- While you are waiting for sample results, clean and sanitize FCSs (§§ 112.123(d)(1) and 112.143(b)), and clean non-FCSs (§ 112.123(d)(2))

Did you receive a positive on your routine environmental FCS* sample?

NO → **Continue** routine monitoring

YES ↓

- Test area surrounding first positive (Exploratory Testing) (§ 112.146(a))
- Clean and sanitize FCSs and non-FCSs (§ 112.146(b); see also §§ 112.123(d) (1)-(2); 112.143(b))

Did you receive a positive on your Exploratory Testing?

NO → **Continue production** and return to routine monitoring

YES ↓

- Conduct intensified cleaning and sanitizing for 3 consecutive days (including disassembly of equipment) (§ 112.146(b))
- Conduct intensified sampling and testing for 3 consecutive days (§ 112.146(c))
- Prevent entry into commerce (§ 112.146(f)) and test sprouts for L. monocytogenes from the first of 3 consecutive days (§ 112.146(d)).
- Prevent entry into commerce of sprouts from all 3 days of intensified testing (§ 112.146(f)). Test sprouts from days 2 and 3 if sprout tests from day 1 are positive.
- Conduct comprehensive investigation (§ 112.146(e))

Did you receive a positive on your Intensified Sampling or Testing (product and any of the 3 days FCS and non-FCS)?

NO → **Continue or resume production.** Continue to prevent entry of product into commerce and continue product testing until 3 consecutive days of product, FCS, and non-FCS tests are negative (§ 112.146(e)). At this point you can return to routine monitoring.

YES ↓

- Stop production (§ 112.146(e))
- Consult food safety experts (§ 112.146(e))
- Escalate intensified cleaning and sanitizing, and intensified sampling and testing (§ 112.146(e))
- Take steps to prevent any adulterated food (e.g., LM+ production batch) from entering commerce (§ 112.146(f)).

* FCS = Food Contact Surface; Non-FCS = Non-Food Contact Surface; M = L. monocytogenes

Environmental Monitoring: Corrective Actions for *L.* spp-positive non-FCS

- Collect samples to conduct routine environmental monitoring (§ 112.144(a))
- While you are waiting for sample results, clean and sanitize FCSs (§§ 112.123(d)(1) and 112.143(b)), and clean non-FCSs (§ 112.123(d)(2))

Did you receive a positive on your routine environmental non-FCS* sample?

NO → **Continue** routine monitoring

YES

- Test area surrounding first positive (Exploratory Testing) (§ 112.146(a))
- Clean and sanitize FCSs and non-FCSs (§ 112.146(b); see also §§ 112.123(d)(1)-(2); 112.143(b))

Did you receive a positive on your Exploratory Testing?

NO → **Continue production** and return to routine monitoring

YES

- Conduct intensified cleaning and sanitizing, possibly including equipment disassembly (§ 112.146(b))
- Conduct intensified sampling and testing (§ 112.146(c))

Did you receive a positive on your Intensified Sampling and Testing?

NO → **Continue production** and return to routine monitoring

YES

- Conduct additional activities to identify source(s) and route(s) of contamination (§ 112.146(e))

* Non-FCS = Non-Food Contact Surface

Environmental Monitoring: Corrective Actions for *L. monocytogenes*-positive FCSs

- If you detect *L. monocytogenes* on an FCS, § 112.146(f) requires to you take appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering into commerce.

Recordkeeping

As applicable, all required records must include:

- The name and location of your sprout operation
- Actual values and observations obtained during monitoring
- An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record
  - For sprouts, we recommend including a production batch lot number that includes the product name (e.g., sandwich blend), variety (e.g., alfalfa sprouts and/or clover sprouts), and brand name that your operation uses to identify the product.
- The location of a growing area or other area (for example, a specific sprouting room and/or growing unit) applicable to the record
- The date and time of the activity documented

§ 112.161(a)

Recordkeeping - continued

Required records must also:

- Be created at the time an activity is performed or observed
- Be accurate, legible, and indelible
- Be dated, and signed or initialed by the person who performed the activity documented
- Certain records (e.g., related to sanitation, seed treatment, analytical tests, and corrective actions) must be reviewed, dated, and signed within a reasonable time by a supervisor or responsible party

§ 112.161(a)

Recordkeeping – Subpart M

- Records related to seed treatment
- Written environmental monitoring plan, including corrective action plan
- Written sampling plan for testing spent sprout irrigation water (or, where that is not practicable, sprouts) from each production batch of sprouts, including corrective action plan

§ 112.150(b)

Recordkeeping – Subpart M

- Documentation of analytical test results for all testing done under Subpart M
- Documentation of analytical methods used in lieu of those incorporated by reference in the rule for sprout-specific testing requirements
- Corrective action records

§ 112.150(b)

Recordkeeping Example– Seed Treatment

- Actual values and observations obtained during monitoring
  - Observations of treatment conditions and key parameters monitored during preparation and application of treatments (e.g., chemical composition of treatment solution, heating temperature, equipment used, concentration of solution, treatment time, pH of treatment solution, presence of agitation)
- Adequate description of covered produce
  - Type of seed, lot number
- Location
  - Seed treatment room
- Date and time of activity documented
  - Date and time treatment was applied

§ 112.161(a)

Recordkeeping Example– Seed Corrective Actions

- Actual values and observations obtained during monitoring
  - Date/time and person who provided notification to seed supplier, information provided, responses from seed supplier
- Adequate description of covered produce
  - Type of seed affected, lot number
- Date and time of activity documented
  - Date and time of notification of seed supplier, returning affected seed lot to supplier, destroying sprouts grown from affected seed lot, etc.

§ 112.161(a)

Other Required Records

- Records relating to commercial processing exemption
- Records relating to eligibility for qualified exemption
- Training records
- Records related to agricultural water
- Records related to biological soil amendments of animal origin
- Records of cleaning and sanitizing

§ § 112.2, 112.7, 112.30, 112.50, 112.60, 112.140

2023 Draft Sprout Guidance

<u>Sections:</u>

- Personnel Qualifications, Training, and Hygienic Practices **(New)**
- Equipment, Tools, and Buildings
- Sampling and Testing of Spent Sprout Irrigation Water (or In-Process Sprouts)

✓ We welcome comments on any aspect of the draft guidance.
✓ We are particularly interested in receiving info about any testing of SSIW (or sprouts) that sprout operations are doing for non-O157 STEC, including test kit names

Personnel Qualifications, Training, and Hygienic Practices

- Personnel who handle sprouts or FCSs, and supervisors, must:
  - have the education, training, and experience necessary to perform their assigned duties in a way that ensures compliance with the PSR.
  - receive adequate training as appropriate to the person's duties, **upon hiring**, and periodically thereafter, **at least once annually**.
- At least one supervisor or responsible party for your sprout operation must successfully complete food safety training at least equivalent to the standardized curriculum recognized by the FDA (e.g., SSA training).

§ § 112.21, 112.22(c)

Personnel Qualifications, Training, and Hygienic Practices

- Training must be repeated when observations or information indicate personnel are not meeting standards established in the PSR.

- Training must be conducted in a manner that is easily understood by personnel being trained.

§ § 112.21

Personnel Qualifications, Training, and Hygienic Practices

- All personnel who handle sprouts or FCSs during covered activities, or supervise such activities, must receive training that includes all of the following:
  - Principles of food hygiene and food safety;
  - The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of sprouts or FCSs; and
  - The standards in the PSR that are applicable to the employee's job responsibilities.

§ 112.22(a)

Personnel Qualifications, Training, and Hygienic Practices

- All personnel who handle sprouts or FCSs during covered activities, or supervise such activities, must receive training that includes all of the following:
  - Principles of food hygiene and food safety;
  - The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of sprouts or FCSs; and
  - The standards in the PSR that are applicable to the employee's job responsibilities.

§ 112.22(a)

Personnel Qualifications, Training, and Hygienic Practices

- People who harvest sprouts must receive additional training that includes the following:
  - Recognizing sprouts that must not be harvested, including sprouts that may be contaminated;
  - Inspecting harvest containers and equipment to ensure that they are functioning properly, clean and maintained so as not to become a source of contamination; and
  - Correcting problems with harvest containers or equipment or reporting such problems to the supervisor.

§ 112.22(b)

Personnel Qualifications, Training, and Hygienic Practices

- Subpart D includes requirements for Health and Hygiene, including:
  - measures that must be taken to prevent ill workers from contaminating sprouts,
  - hygienic practices that must be used, and
  - measures you must take to prevent visitors from contaminating sprouts and FCSs.
- All personnel who handle sprouts or FCS, and supervisors, must be trained on the requirements of Subpart D.
- All personnel in a sprout operation must use hygienic practices while on duty to the extent necessary to protect against contamination.
  - This applies to personnel who handle sprouts, seeds for sprouting or FCSs, including personnel who enter, but may not be assigned to, production or storage areas, such as personnel with shipping, delivery or other duties.

§ 112.22(a)(3), 112.31, 112.32, 112.33

Equipment, Tools, and Buildings

- Requirements for Buildings
  - Must conduct sprout production in a fully-enclosed building.
  - Requirements of Subpart L
- Pest Control
  - Must take measures to protect covered produce, FCSs, and food-packing materials from contamination by pests in buildings
- Toilet and Hand-Washing Facilities
  - Adequate, readily accessible to workers

Equipment, Tools, and Buildings

- Plumbing Systems
  - An adequate size and design
  - Maintain to distribute water under pressure as needed
  - Maintain to properly convey sewage and liquid disposable waste
  - Must not allow backflow

- Sewage and Waste Management
  - Dispose of sewage into an adequate sewage system
  - Maintain in a manner that prevents contamination

- Equipment and Tools
  - Examples: growing units, irrigation systems, cooling equipment, equipment used to store or convey harvested sprouts, wash tanks, balances, packing tables, forklifts, vehicles or other equipment used for transport

Sampling and Testing of SSIW (or In-Process Sprouts)

- Microbial testing of SSIW (or sprouts) is important part of a multi-hurdle approach to ensure contaminated sprouts do not enter the marketplace.
- The PSR requires sprout operations to test SSIW (or sprouts) from each production batch of sprouts for *E. coli* O157:H7 and *Salmonella* species.
- **Required components of a written sampling plan**
  - Whether testing SSIW or in-process sprouts
  - Sample collection locations (§ 112.147(a))
  - The number of samples of SSIW (or in-process sprouts) from each production batch of sprouts (§ 112.147(a))
  - Corrective action plan (§ 112.147(c))

Sampling and Testing of SSIW (or In-Process Sprouts)

- **Additional recommended components**
  - Pathogens to be tested (*Salmonella* and *E. coli* O157:H7 are required)
  - Test methods used
  - Person who is responsible for sample collection
  - Timing of sample collection
  - Volume of SSIW (or sprouts) per each sample
  - Procedure for aseptic sample collection
  - Information about sampling tools and materials necessary for aseptic sample collection
  - Procedures for delivering to the testing lab
  - Specify that the production batch of sprouts must not enter into commerce until testing results are obtained and those results are negative
  - Person who is responsible for implementing the corrective action plan
  - Any additional considerations for SSIW (or sprouts) sampling and testing

Sampling and Testing of SSIW (or In-Process Sprouts)

Collecting a Representative Sample

- Definition for production batch of sprouts
- Effectiveness of SSIW (or sprouts) testing: depends on a sample that represents the entire production batch
- When: as close to 48 hrs from the start of sprouting as practicable
- How much and how many samples: 1.5 liters of SSIW or 1500 grams of sprouts, up to 30 subsamples from every drainage point
  - Collect additional samples from a particularly large production batch of sprout
- Where: assess the configuration of growing units, flow of irrigation water, location of water outlets, and product distribution

Sampling and Testing of SSIW (or In-Process Sprouts)

- **Choosing a lab**: a qualified lab to test SSIW (or sprouts) for *E. coli* O157:H7 and *Salmonella* species using methods that meet PSR requirements.
- **Choosing a test method:** § 112.153(a)
  - the method of analysis described in "Testing methodologies for *E. coli* O157:H7 and *Salmonella* species in SSIW (or sprouts)"- FDA reference method; or
  - a scientifically valid method that is at least equivalent to this method in accuracy, precision, and sensitivity.
- **Testing results**
  - A confirmed positive result: when a presumptive positive result is confirmed by confirmatory testing; or
  - A negative result: presumptive negative result or negative confirmatory testing
- **Developing a corrective action plan and take corrective actions** (§ 112.148)

Final Summary

- The Sprout Guidance documents (Final and Draft):
  – provide recommendations to assist operations covered by Subpart M in complying with the requirements in the Produce Safety Rule
- Once finalized, the sections in the 2023 Draft Guidance will be incorporated into the 2023 Final Guidance creating one complete final guidance document.
- We encourage sprout operations to use these guidance documents to assist with complying with the Produce Safety Rule.

Questions?