



WELCOME!

Overview of Draft Guidance to Industry: Compliance with and Recommendations for Implementing FDA's Produce Safety Rule for Sprout Operations





AGENDA

- **Overview of Draft Guidance to Industry: Compliance with and Recommendations for Implementing FDA's Produce Safety Rule for Sprout Operations**

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- **Q&A**



NEED TO KNOW

- **This webinar is recorded. The presentation will be available on the SSA website.**
- **All the participant lines are on mute.**



NEED TO KNOW

Q&A

The Q&A will begin at ~ 1:40 PM CST. You may type your questions or comments in the Q&A box on your screen prior to 1:40 PM.

Overview of Draft Guidance to Industry:
Compliance with and Recommendations for
Implementing FDA's Produce Safety Rule for
Sprout Operations

Sprout Safety Alliance Webinar

March 6, 2017

Introduction

- Draft Guidance to assist sprout operations in complying with Sprout-specific requirements in subpart M
- Some coverage of other applicable parts of the Produce Safety Rule
- Recommendations should be adapted to your operation
- Does not cover best practices or other hazards outside the scope of the Produce Rule

Background:

Coverage of the Produce Safety Rule

- Covers produce that is a RAC
- Sprouts are produce and subject to applicable requirements of the Produce Rule unless exempt or excluded
 - E.g., Commercial processing w/ a kill step
 - Not eligible for “rarely consumed raw” (see list)
- Raw sprouts that will later be processed w/o a kill step are still subject to the Produce Rule while in their RAC form, unless an exemption applies

Background:

Coverage of Subpart M

- Applies to growing, harvesting, packing and holding of all sprout types except 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 a customer who will harvest w/o roots, we would use enforcement discretion PROVIDED you annually collect written assurances from the customer

Background:

Compliance Dates for Sprouts

- Very Small Firms (average annual produce sales >\$25,000 but <\$250,000): January 2019
- Small Sprout Firms (>\$250,000 but <\$500,000): January 2018
- “Large” Sprout Firms (>\$500,000): January 2017

- Requirements for sprout operations eligible for a Qualified Exemption based on sales and market channels, or an exclusion because sprouts will be processed w/ a kill step are also earlier
- Extension for certain ag water requirements does not apply

Navigating the Guidance

- General Sprout Production
- Buildings, Tools and Equipment
- Cleaning and Sanitizing
- Agricultural Water in Sprout Operations
- Seeds for Sprouting
- Sampling and Testing of Spent Sprout Irrigation Water
- Environmental Monitoring
- Recordkeeping

General Sprout Production

Typical Sprout Production Processes:

Seed Receipt → Seed Storage → Initial Seed Rinse →
 Seed Treatment → Pre-germination Seed Soak →
 Germination & Growth → Microbial testing of SIW (or in-
 process sprouts) → Harvest → Wash/Drain Sprouts → Bulk
 Cool/Spin Dry → Pack and/or Package → Cooling & Storage
 → Distribution

- Highlights requirements specific to each production step and makes recommendations for compliance
- Introduces requirements for ag water across processes (detail in Sec. VI)

Buildings, Tools and Equipment

- Requirements for Buildings
- Toilet and Hand Washing Facilities
- Plumbing Systems for Water
- Sewage and Waste Management
- Equipment and Tools

Cleaning and Sanitizing

- Cleaning and sanitizing are different and important steps that are critical to the safety of your finished sprouts
- Cleaning: removing visible organic material and other debris from surfaces
- Sanitizing: 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))
- At a minimum, we recommend cleaning and sanitizing:
 - At least daily to meet the requirements of §§ 112.123(d)(1) and 112.143(b)
 - Between each production batch of sprouts
 - Prior to resuming production after more than a day of FCSs not being used

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 Sanitation Standard Operating Procedures (SSOPs)
- 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 Systems and How the Source Type and Treatment Status Affect Relevant Requirements
- Safe and of Adequate Sanitary Quality (§ 112.41)
- Reuse of Sprout Irrigation Water
- Agricultural Water Testing Frequency, Sampling, and Test Methods
- Post-Harvest Water Management (§ 112.48)



Seeds for Sprouting:

Seed Receiving, Handling and Storage

- Seeds for sprouting should be grown under GAPs (although this is not a Produce Rule requirement)
- We recommend you perform the required visual examination of seeds (§ 112.142(d)) upon receipt
- If you observe obvious signs of damage or contamination, you should reject the seeds and contact the supplier
- You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds for sprouting (§ 112.142(a)).



Seeds for Sprouting: Seed Treatment

- Seeds for sprouting must be treated using a scientifically valid method to reduce microorganisms of public health significance (§ 112.142(e)).
- This treatment can be done by the sprout operation, or by another entity earlier in the supply chain
- A prudent sprout operation would not rely only on a treatment that achieves a low level of reduction if other, more effective, treatments are available.
- We recommend sprout operations use the most efficacious seed treatment available to reduce the presence of microorganisms of public health significance on seeds for sprouting.

Sampling and Testing of SSIW



- Required components of a written sampling plan
 - Sample collection locations (§ 112.147(a))
 - The number of samples of SSIW (or in-process sprouts) per each production batch of sprouts (§ 112.147(a))
 - Corrective action plan (§ 112.147(c))
- Additional recommended components include:
 - Whether testing SSIW or in-process sprouts and volume per each sample
 - Pathogens to be tested (*Salmonella* and *E. coli* O157:H7 are required)
 - Test Methods used
 - Timing of sample collection

Collecting a Representative Sample

- Definition for production batch of sprouts
- Recommended volume for sample collection (1.5 liters of SSIW or 1500 grams of sprouts)
- Collect additional samples from a particularly large production batch of sprouts
- Considerations for irrigation flow rates and number of drainage points

Sampling and Testing of SSIW



- Must collect samples aseptically (§ 112.147(b))
- Must use a method in accordance with § 112.153
- Must develop a corrective action plan and take corrective actions (§ 112.148)
- Record keeping (§ 112.150(b)(3) to (b)(6))
 - Written sampling plan
 - Analytical method used
 - The results of analytical tests
 - Corrective action taken

Environmental Monitoring: Written Sampling Plan



- Required components:
 - What you will test collected samples for (i.e., *Listeria* species or *L. monocytogenes*) (§ 112.145(c)(1))
 - Specify the number and location of sample collection sites (§ 112.145(c)(3))
 - Food contact surface and non-food contact surface sampling sites
 - Sample collection frequency (§ 112.145(c)(2))
 - No less than monthly
 - Must specify at what point during production you will collect the samples (§ 112.145(c)(2))
 - Corrective action plan that, at a minimum, requires you to take actions in § 112.146, and how you will accomplish those actions

Environmental Monitoring: Written Sampling Plan

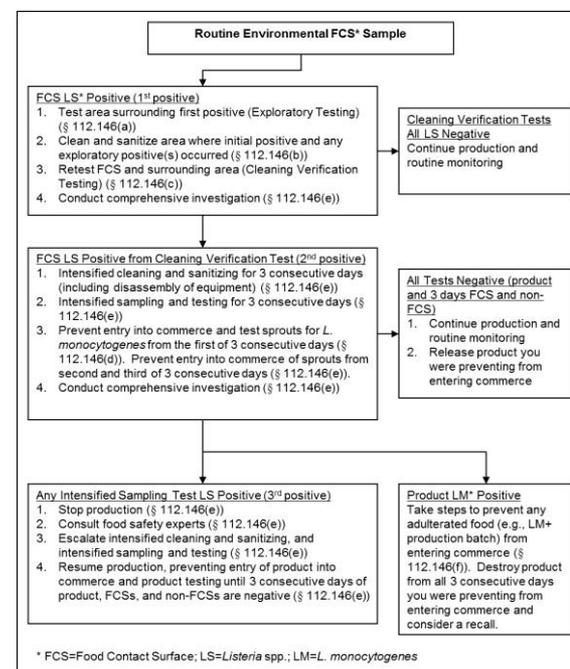
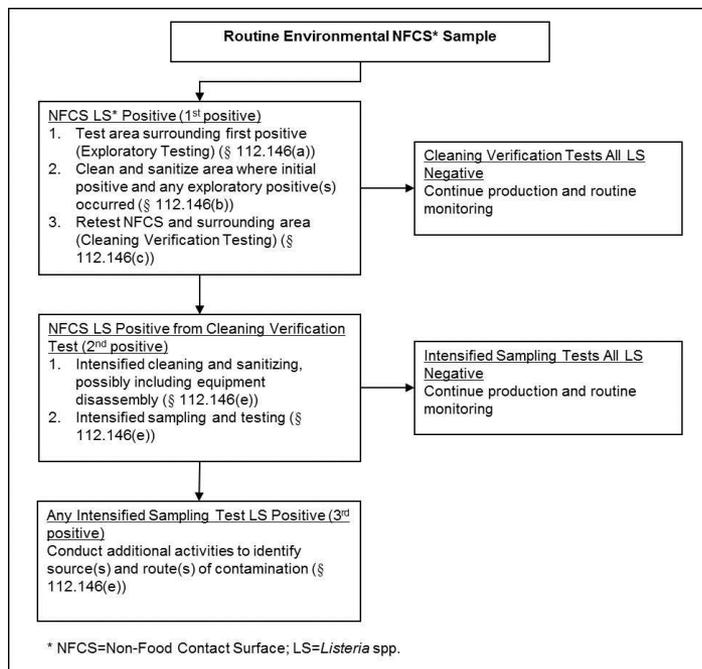


- Additional recommended components include:
 - Identify the specific test method by which collected samples will be tested
 - Identify the person(s) responsible for sample collection and any specific training that the person(s) should have
 - Identifying sample collection locations
 - Sampling from all identified sites within a specified time period or a representative subset of all identified sites
 - Specify the requirement of § 112.145(d) that samples must be collected aseptically
 - Sample collection method and sample sizes to be collected
 - Identify the laboratory that conducts testing
 - Identify the records to be kept

Environmental Monitoring: Corrective Actions



- Must develop a Corrective Action Plan (§ 112.145(e)) and take corrective actions (§ 112.146)
- Testing and follow-up actions for specific positive finding of *Listeria* spp. on a non-FCS and FCS during one sampling period can be found in the draft guidance



Environmental Monitoring



- Recordkeeping
 - Your written environmental monitoring plan (§ 112.150(b)(2))
 - Documentation of the results of all analytical tests (§ 112.150(b)(4))
 - Records of any analytical methods you use in lieu of FDA's method in § 112.152(a) (§ 112.150(b)(5))
 - Documentation of corrective actions you take in accordance with § 112.146 (§ 112.150(b)(6))

Recordkeeping

As applicable, all required records must include:

- The name and location of your sprout operation (§ 112.161(a)(1)(i))
- Actual values and observations obtained during monitoring (§ 112.161(a)(1)(ii))
- 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 (§ 112.161(a)(1)(iii))
- The location of a growing area or other area (for example, a specific packing shed) applicable to the record (§ 112.161(a)(1)(iv))
- The date and time of the activity documented (§ 112.161(a)(1)(v))

Recordkeeping continued

Required records must also:

- Be created at the time an activity is performed or observed (§ 112.161(a)(2))
- Be accurate, legible, and indelible (§ 112.161(a)(3))
- Be dated, and signed or initialed by the person who performed the activity documented (§ 112.161(a)(4))

Recordkeeping – Subpart M

- Records related to seed treatment: § 112.150(b)(1)
- Written environmental monitoring plan, including corrective action plan: § 112.150(b)(2)
- 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)(3)

Recordkeeping – Subpart M cont.

- Documentation of analytical test results for all testing done under Subpart M: § 112.150(b)(4)
- Documentation of analytical methods used in lieu of those incorporated by reference in the rule for sprout-specific testing requirements: § 112.150(b)(5)
- Corrective action records: § 112.150(b)(6)

Other Required Records

- Records relating to commercial processing exemption: § 112.2
- Records relating to eligibility for qualified exemption: § 112.7
- Training records: § 112.30
- Records related to agricultural water: § 112.50
- Records related to biological soil amendments of animal origin: § 112.60
- Records of cleaning and sanitizing: § 112.140

Summary

- This draft guidance:
 - provides recommendations to assist operations covered by Subpart M in complying with the requirements in the Produce Safety Rule
 - discusses certain other Rule requirements from the perspective of a sprout operation (e.g., Agricultural Water, and Equipment, Tools, Buildings, and Sanitation).
- The draft guidance will be available for public comment for 180 days starting January 19, 2017.
- The FDA will consider all comments before completing a final version.
- Submit electronic comments on <http://www.regulations.gov> to docket folder FDA-2017-D-0175.



A Few Words from the SSA

- **Highly suggest you to read the Sprout Guidance**
 - **Seed Treatment: page 47-54**
 - **Corrective Actions for Seeds: page 54-58**
 - **Spent Irrigation Water Sampling: page 61-76**
 - **Environmental monitoring: page 77-103**
- **Submit your comments on this draft guidance**



Sprout Safety Training

- **The FSMA Produce Safety Rule requires that at least one supervisor or responsible party for each sprout operation must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA.**

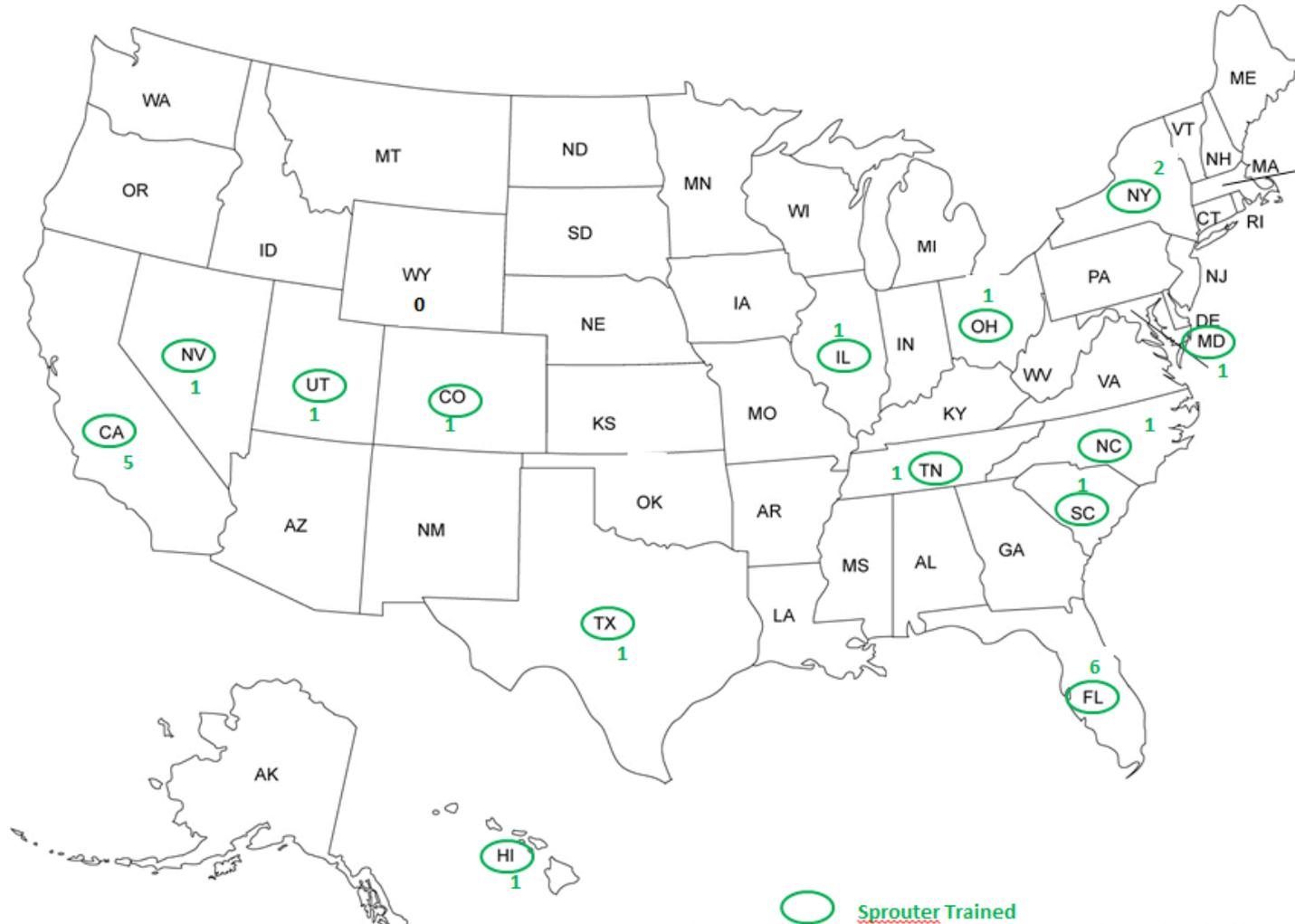


SSA Training Summary

Courses Held	Sprouter Training & Lead Instructor Combo Courses	1
	Lead Instructor Courses	2
	Sprouter Training Courses	4
SSA Lead Instructors Trained	SSA Lead Instructor Candidates Trained	28
	SSA Lead Instructors Approved	24
	International SSA Lead Instructors Approved	3
Sprouters Trained	Sprout Companies	25
	Individual Sprout Growers Trained	35
Regulators Trained	Federal Regulators Trained	7
	State Regulators Trained	6



Geographic Distribution of Trained Sprouters





Upcoming SSA Courses

2017	Location	Course Type
April 11 - 13	Chicago, IL	Sprouter Training Course + Lead Instructor Combo Course
April 27 - 29	Victoria, BC, Canada (in conjunction with ISGA convention)	Sprouter Training Course

For more information about the SSA training, please visit the SSA Training webpage:

<https://www.ifsh.iit.edu/ssa/resources/ssa-training>



Q & A Section

Type in your questions in the Q&A box

Panelists

FDA Division of Produce Safety



Thank you for your participation!

The presentation will be posted on
the SSA website.

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www.iit.edu/ifsh/sprout_safety