

Safer Sprout Production for Produce Safety Rule Compliance



Second Edition – 2017



Version 2.3

Public Version

SPROUT SAFETY ALLIANCE (SSA)

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This publication was developed by the Sprout Safety Alliance (SSA) and was supported, in part, by a grant from the Food and Drug Administration to the Illinois Institute of Technology's Institute for Food Safety and Health. The views expressed herein do not necessarily reflect the views of these organizations. Direct all inquiries to the SSA at sproutalliance@iit.edu.

Safer Sprout Production for Produce Safety Rule Compliance

TRAINING CURRICULUM

Second Edition – 2017

Developed by the



Foreword: Sprout Safety Alliance

The Sprout Safety Alliance (SSA) was formed in 2012 through the voluntary participation of industry, government and academic members to enhance the sprout industry's understanding and implementation of best practices for improving sprout safety. The group was coordinated through the efforts of the Institute for Food Safety and Health (IFSH), at Illinois Institute of Technology (IIT), with the support of the U.S. Food and Drug Administration (FDA).

The purpose of SSA is to develop a core curriculum and training and outreach programs to assist sprout growers in understanding the requirements set forth in the FDA Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (i.e., the Produce Safety Rule) that are specifically applicable to sprout operations.

The structure and the delivery of the SSA Sprout Safety training course were built on successful examples from previous alliances – Seafood HACCP, Juice HACCP, and Food Safety Preventive Controls Alliance. The Organizing Committee managed the SSA operations and training resources. The Steering Committee directed the overall strategies of the Alliance and determined the scope of work.

The Alliance established two primary working groups. The Technical Working Group developed the training materials that reflect best practices for risk reduction in the production of sprouts, and that facilitate industry understanding and compliance with the Produce Safety Rule. The Education/Outreach Working Group established a strategic plan to deliver the training and educational materials to targeted stakeholders.

DISCLAIMER

The information provided by the Sprout Safety Alliance (SSA) is for training purposes only. The SSA cannot provide you with legal advice. The SSA curriculum is intended as a training tool to assist companies in complying with the FDA Food Safety Modernization Act (FSMA) as it applies to the Produce Safety Rule; however, following this curriculum does not ensure compliance with the law or FDA's regulations. For advice regarding the legal compliance with FSMA, please consult your legal counsel.

The information provided by the SSA will vary in applicability to each sprout grower. It is not possible for the SSA training curriculum to address every situation. Companies should implement practices and programs that will function the best to produce safe sprouts based on the nature of their individual operations. SSA materials do not outline the only approach to implementing the Produce Safety Rule. Companies can follow any approach that satisfies the requirements of the applicable statutes and regulations related to FSMA. The information provided by SSA does not create binding obligations for the FDA or industry.

SSA does not guarantee the accuracy, adequacy, completeness or availability of any information provided in its curriculum and is not responsible for any errors or omissions or for any results obtained from the use of such information. SSA gives no express or implied warranties, including but not limited to, any warranties of merchantability or fitness for a particular purpose or use. In no event shall SSA be liable for any indirect, special or consequential damages in connection with any use of this training curriculum.

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Module 1. Introduction to the Sprout Safety Alliance Safer Sprout Production for *Produce Safety Rule* Compliance Course

1.1 OBJECTIVES OF THE SSA COURSE

Learning Objectives

In this module, you will learn:

- Objectives of the Sprout Safety Alliance (SSA) course
- Overview of the SSA curriculum
- Course manual and slide format
- SSA training offered
- Where to find a Glossary of terms used



Welcome to the Sprout Safety Alliance *Safer Sprout Production for Produce Safety Rule Compliance* course. This course was developed to assist sprout growers in understanding FDA’s requirements for sprout production. This module covers the overall objectives of this course, an overview of the format of the course, such as cues to indicate what is required versus what is good practice. It also discusses different training formats for the course and where to go for technical assistance. The appendix for this module also includes a glossary for terms frequently used in the course. Many of these terms are from the *Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption* rule (hereafter called the *Produce Safety Rule*), but other terms are included for clarity.

SSA Course Objectives

- Understand food safety hazards associated with sprout production
- Understand the requirements of the *Produce Safety Rule*
- Learn about implementing best practices to prevent sprout contamination
- Observe examples of written documents that are required by the regulation



The objectives of this course overall are addressed in upcoming modules. For example, Module 3: Sprout Safety Hazards, provides an introduction to food safety hazards associated with sprout production. Module 2: The *Produce Safety Regulation Overview* walks through the provisions of the rule and references other modules that address specific provisions in more detail. Subsequent modules address not only regulatory requirements but also best practices that can help sprouters to implement a program to help prevent sprout contamination. Examples of written documents that are required by the regulation are also addressed in subsequent modules. Because each operation is different, development of specific documents for each operation is difficult to achieve during a course. However, the examples provided and exercises conducted throughout the course can be used as a starting point for operation specific documentation.

Food Safety of Sprouts

- Food safety concerns associated with sprouts
 - Seed can be contaminated on farm
 - Sprout germination conditions also encourage the proliferation of pathogens
 - Sprouts can be contaminated during production
 - Outbreaks associated with sprouts have occurred



Definition

Pathogen: Any microorganism of public health significance.

- 21 CFR 117.3

Sprouts are germinated from seeds under warm, humid and nutrient-rich conditions. Seeds can become contaminated with **pathogens** during growing in the field or during subsequent handling and distribution. Bacterial pathogens, if present in or on seeds can multiply rapidly during sprouting. An unsanitary sprout production environment, poor worker hygiene and dirty water can also contribute to the contamination of sprouts. Foodborne illness outbreaks associated with different types of sprouts have occurred. Pathogens and how to control them are discussed further in Module 3: Sprout Safety Hazards.

Multi-hurdle Strategies

- Sanitary production environment
- Good worker health and hygiene practices
- Safe seed and water
- Seed treatment
- Verification of control measures
 - Spent sprout irrigation water testing
 - Environmental monitoring



Sprouts are commonly consumed raw and there is typically no kill step applied prior to consumption. Consequently, it is necessary to

ensure safe production of sprouts by preventing or minimizing contamination of incoming seeds, in the production environment and in the finished products. While no single step will reliably eliminate all pathogenic microorganisms that may survive on sprouts, using a multi-hurdle approach implementing a series of preventive and risk-reduction steps can greatly reduce the food safety risks that may be associated with sprouts. These steps include: maintaining a sanitary production environment, following good employee health and hygiene practices, using seeds that are grown following Good Agricultural Practices, using water that meets the FDA *Produce Safety Rule* standard for sprouts, treating seeds prior to sprouting using scientifically valid methods, testing spent sprout irrigation water to verify the effectiveness of the control measures, and implanting an environmental monitoring program for *Listeria* spp. or *Listeria monocytogenes*. Each of these is discussed in other modules.

Definition

Produce: Any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. (see glossary or rule for full definition)

- 21 CFR 112.3

Produce Safety Rule

- *Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*
 - Produce Safety Rule (21 CFR 112)
- Produce includes sprouts
- Operations growing, harvesting, packing and holding sprouts are considered farms
- Final Rule was published on November 27, 2015



The Food Safety Modernization Act (FSMA) rule *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (abbreviated as the *Produce Safety Rule*) was published in November 2015. It establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. Sprouts are included as a type of produce under this rule.

Standards for Produce Safety

- Focus on conditions and practices identified as potential contributing factors for microbial contamination
 - Agricultural water
 - Biological soil amendments of animal origin
 - Worker health and hygiene
 - Equipment, tools, buildings and sanitation
 - Domesticated and wild animals
 - Growing, harvesting, packing and holding activities
 - Sprouts requirements



Several specific sections in the *Produce Safety Rule* focus on common routes of contamination. They include: agricultural water (i.e., water that is intended to or likely to contact covered produce or food contact surfaces during covered activities); biological soil amendments of animal origin; worker health and hygiene; equipment, tools, buildings and sanitation; and domesticated and wild animals. There are also additional requirements for growing, harvesting, packing, and holding activities and those specifically for sprouts.

Subpart M: Additional Requirements for Sprouts

- Beans and seeds
- Buildings and sanitation
- Seed treatment
- Sample/test spent sprout irrigation water
- Environmental sampling for *Listeria*
- Maintaining records

Details are covered in subsequent modules



Sprout operations are subject to all relevant requirements of the *Produce Safety Rule*, and because sprouts have a unique risk profile, the Rule includes additional sprout-specific provisions. Subpart M applies to growing, harvesting, packing, and holding of all sprouts,

except soil- or substrate-grown sprouts harvested without their roots (§ 112.141). The requirements include:

- Taking measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans used for sprouting (§112.142(a));
- growing, harvesting, packing, and holding sprouts in a fully enclosed building (§112.143(a));
- any food-contact surfaces used to grow, harvest, pack, and hold sprouts be cleaned and sanitized before contact with sprouts or seeds or beans (§112.143(b));
- testing the growing, harvesting, packing, and holding environment for *Listeria* and spent sprout irrigation water from each production batch of sprouts, or the sprouts themselves, for *E. coli* O157:H7 and *Salmonella* species and take appropriate follow-up actions (§ 112.144); and
- maintaining records, including documentation of seed treatment, the written environmental monitoring plan and sampling plan, test results, and certain methods used (§ 112.150).

These requirements are discussed in Module 2: The Produce Safety Regulation Overview and other modules.

1.2 OVERVIEW OF THE SSA CURRICULUM

The section symbol § indicates regulatory requirements and notations such as §112.141 refer to a specific section in the regulation, which is in Appendix 1 of this manual.

SSA Course

- SSA curriculum is the “standardized curriculum” recognized by FDA
- § 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
- Successfully completing this course is one way to meet the requirements for training under the Produce Safety Rule




The Sprout Safety Alliance (SSA) course is the “standardized curriculum” recognized by FDA to help sprouters understand and

implement the *Produce Safety Rule*, specifically the requirements applicable to sprout operations. Successfully completing this course is one way to meet the requirements for training under the *Produce Safety Rule*, which 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 Food and Drug Administration (§112.22(c)).

The SSA course is intended not only to assist sprout growers in achieving compliance with the *Produce Safety Rule*, but also to help the industry in adopting best practices for risk reduction in the production of sprouts.

<h2>Course Modules</h2>	
Overview	Sprout Specific Risk Reduction Measures
1. Introduction	8. Seed Purchasing, Receiving and Storage
2. <i>Produce Safety Rule</i> Overview	9. Seed Treatment
Hazards	10. Spent Sprout Irrigation Water and Sprout Testing
3. Sprout Safety Hazards	Other Programs
Hygienic Production Environment	11. Additional Control Programs
4. Sprout Production Environment	12. Recordkeeping
5. Employee Health and Hygiene Practices	
6. Cleaning and Sanitizing of Buildings and Equipment	
7. Environmental Monitoring for <i>Listeria</i> species or <i>L. monocytogenes</i> in a Sprout Operation	



The SSA curriculum is divided into the five segments, as listed above. The first segment provides an overview of the course and the provisions in the *Produce Safety Rule* that are applicable to sprout operations. The module also provides references to the specific rule requirements.

The next segment provides a brief overview of the different types of food safety hazards encountered with sprouts and the importance of their control, with emphasis on food safety hazards that are “known or reasonably foreseeable” in sprouts. Understanding food safety hazards and the ability to identify those hazards are the foundation for establishing an effective food safety program.

Maintaining a hygienic production environment that minimizes the potential for cross-contamination is critical to ensure sprout safety. Modules 4 through 7 describe proper operation construction, water safety, employee health and hygiene, and cleaning and sanitizing procedures and verification. Environmental monitoring for *Listeria* in a sprout operation is specifically covered in Module 7, which also

discusses the key elements of an environmental monitoring plan that is required by the *Produce Safety Rule*.

Sprout specific requirements are covered in Modules 8 to 10; including seed purchasing, receiving and storage, seed treatment, and spent sprout irrigation water or in-process sprout testing.


Module 11 covers additional control programs, such as management commitment, employee training, supplier verification programs, product labeling, trace and recall procedures, sanitary transportation, allergen controls, and food defense. Module 12 describes recordkeeping required by the *Produce Safety Rule*.

The Appendix of the SSA curriculum provides additional resources, including the codified *Produce Safety Rule*; regulation fact sheets; FDA guidance documents on sprouts; contacts for technical assistance; and sample documents relevant to each module. Sprout growers may use the sample documents as templates to develop written plans, sanitation protocols, testing forms, corrective action plans, or to modify their existing food safety documents to achieve compliance with the *Produce Safety Rule*.

1.3 COURSE MANUAL AND SLIDE FORMAT

Course Manual Format

- The course manual is designed as a reference
- To differentiate rule requirements and best practices
 - “must” means requirement
 - “should” means best practice
 - § (the section symbol) indicates a requirement on slides
- The provision number is provided for each rule requirement
- Rule definitions are frequently cited in text boxes
- The Glossary provides regulation and other definitions




The SSA course manual can be used to help understanding the presentations during a training class. It can also be used as a reference and kept in a sprout operation.

To differentiate the rule requirement from best practices in the text, “must” is used to mean it is required by the *Produce Safety Rule*, while “should” is used to mean it is a best practice and is recommended to be implemented in sprout operations. Provision numbers associated with specific rule requirements are also

provided. Sprouters may use these numbers to look up the specific requirements stated in the *Produce Safety Rule* in Appendix 2A. The important terms in the text that are defined in the *Produce Safety Rule* are inserted in the margin throughout the manual. A glossary of definitions and acronyms used in the SSA training is listed in Appendix 1.

Rule Requirements Noted on Slides

- Section symbols (§) differentiate rule requirements and best practices
- § Symbol as a bullet point indicates the item is a specific requirement
- Symbol at the top left corner of slide indicates the information on the slide is required




Rule requirements are also marked in the training slides with a section “§” symbol. If a slide contains both the rule requirements and best practices, the “§” symbol is placed next to each rule requirement. The “§” symbol is placed at the upper left corner of a slide if it contains only requirements. For example, the regulation requires all bullets on the “Training Requirements” slide. Conversely, the regulation requires only three of the bullets on the “Management Responsibilities – General” slide; the fourth bullet is a best practice to avoid issues.

§ Training Requirements

- Requirements include:
 - All personnel who contact covered produce or food-contact surfaces
- Establishes minimum content expectations for training
 - Training for supervisors
 - SSA curriculum or equivalent
 - Record requirements

All bullets required, as applicable




Management Responsibilities-General

- § Communicate the hygiene and health policies to ALL employees
- § Exclude ill employees from work and from handling sprouts
- § Ensure that ALL employees follow proper hand washing procedures and good hygiene practices when working in the sprout operation, especially in the production environment
- Communicate that employees will not be fired if they stay home when sick with diarrhea, vomiting, intestinal cramps etc.

Required

Best practice



1.4 SSA TRAINING

SSA Training

- Sprouter Training Course
 - Classroom training
 - Online + one-day classroom training
- SSA Lead Instructor (LI) Course
 - Three-day classroom training
- Sprouter-LI Combo Course
- Certificates issued to participants upon completion of a recognized SSA course



The SSA training includes three types of courses:

1. Sprouter Training Course,
2. SSA Lead Instructor (LI) Course,
3. Sprouter + LI Combo Course.

Sprouters may attend the Sprouter Training Course. The Sprouter Course is offered in a formal classroom setting (approximately two or two and a half days) and potentially as a self-guided, online version coupled with a one-day, instructor lead session that covers sprout-specific risk reduction measures. Individuals who are interested in becoming an SSA Lead Instructor (LI) must submit a Lead Instructor application and attend a Lead Instructor Course or Sprouter + LI Combo Course. Upon successful completion of the SSA Lead Instructor or Combo Course, and approval by the SSA LI Selection Committee, SSA Lead Instructor candidates will be qualified to be an SSA Lead Instructor.

The Association of Food and Drug Officials (AFDO) and the International Food Protection Training Institute (IFPTI) administer certificates for all participants who complete a recognized SSA course. Information on SSA training programs, training session schedule, and lead instructor qualifications are posted on the SSA website (http://www.iit.edu/ifsh/sprout_safety/).

Introduction Summary

- The Sprout Safety Alliance Course reviews:
 - Food safety hazards associated with sprouts and how to reduce risk
 - Regulatory requirements (§) of the *Produce Safety Rule*, including the sprout-specific requirements in Subpart M
 - Best practices that help to reduce risk
 - Example documents required by the regulation
- Successful completion of this course is one way to meet *Produce Safety Rule* training requirements
 - Lead Instructor training for qualified candidates is available
- A glossary of terms is in Appendix 1.



In summary, the FDA FSMA *Produce Safety Rule* establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of certain produce grown for human consumption. Unless specifically exempt or excluded, sprout growing operations are subject to the *Produce Safety Rule*, including the sprout-specific requirements in Subpart M. The SSA training includes this *Safer Sprout Production for Produce Safety Rule Compliance* (Sprouter) course, a Lead Instructor (LI) course, and LI-Sprouter Combo course. For sprouters, successful completion of the Sprouter Training course is one way to meet the requirements for training under the *Produce Safety Rule*.

1.5 REFERENCES AND SAMPLE DOCUMENTS

Appendix 1: Glossary – Definitions and Acronyms

NOTES:

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Module 2. Regulation Overview: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

2.1 INTRODUCTION

Learning Objectives

- In this module, you will develop an awareness of:
 - How to navigate the *Produce Safety Rule*
 - How the *Produce Safety Rule* applies to sprout operations
 - Sprout specific requirements in the *Produce Safety Rule* and where to find them
 - Where to get answers to regulatory questions



In November 2015, FDA published a final rule *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* in the Federal Register. This regulation, commonly known as the *Produce Safety Rule* (the regulation or the rule) established, for the first time, requirements for the growing, harvesting, packing and holding of produce, including sprouts (21 Code of Federal Regulations part 112 (21 CFR part 112)). A copy of the entire text of the regulation is in Appendix 2a of this curriculum and online at: <https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption>.

This module focuses on the specific requirements of the regulation. You will learn about how to navigate the regulation, specific provisions relevant to sprout operations, where to find these requirements in the rule, and where to get answers to regulatory questions.

2.2 REGULATION FORMAT – HOW TO NAVIGATE THE RULE

Throughout the curriculum, you will notice this § symbol. This is a special symbol, meaning “section” and appears before the sections of the rule being referenced.

Regulation Format

- November 27, 2015 Federal Register notice of the rule is divided into 2 parts
 - Preamble: discussion of requirements
 - Codified: the requirements in 21 CFR part 112
- The regulation is part of Title 21 of the *Code of Federal Regulations* (CFR), Part §112, and is subdivided into 15 subparts




The *Produce Safety Rule* is divided into two parts. The **preamble**, which represents the bulk of the document, outlines FDA’s thinking during the development of the final rule, the rationale for the provisions in the codified language, public comments received and FDA responses, and references that FDA used. If you are interested in more detail about the thinking behind certain provisions in the codified language, the preamble serves as a resource to provide that information.

The final rule includes the **codified language**, which states the specific legal requirements related to growing, harvesting, packing and holding produce for human consumption that FDA established in new Title 21 of the *Code of Federal Regulations* (CFR) part §112. This is a relatively short section of the entire Federal Register document. 21 CFR part 112 is divided into 15 subparts, beginning with Subpart A. If you are primarily interested in the rule requirements, this section would be a good place to start reading the rule.

§ 21 CFR Part 112 Produce Safety Rule Subparts	
Subpart A – General Provisions	Subpart K – <i>Growing, Harvesting, Packing and Holding Activities</i>
Subpart B – Requirements	Subpart L – <i>Equipment, Tools, Buildings, and Sanitation</i>
Subpart C – Personnel Qualifications and Training	Subpart M – Sprouts
Subpart D – <i>Health and Hygiene</i>	Subpart N – Analytical Methods
Subpart E – <i>Agricultural Water</i>	Subpart O – Records
Subpart F – <i>Biological soil amendments of animal origin</i>	Subpart P – Variances
Subpart G & H – Reserved*	Subpart Q – Compliance and Enforcement
Subpart I – <i>Domesticated and Wild Animals</i>	Subpart R – Withdrawal of Qualified Exemption
Subpart J – Reserved	

Note:

- *Green and italics subparts focus on potential contributing factors*
- Reserved sections are currently blank



The rule's specific subsections listed on this slide address requirements for each of these topics. The module discusses certain provisions that are relevant to sprouters. The regulation focuses on conditions and practices identified as potential contributing factors to microbial contamination of produce (similar to the areas covered by the 1998 Good Agricultural Practices Guide, the 1999 Sprout Guidance and other guidance). Several of the specific areas focus on common routes of contamination (italics above). They include:

- Worker health and hygiene (Subpart D)
- Agricultural water – water that is intended to or likely to contact covered produce or food contact surfaces during covered activities (Subpart E)
- Biological soil amendments of animal origin (Subpart F)
- Domesticated and wild animals (Subpart I)
- Equipment, tools, buildings and sanitation (Subpart L)

There are also additional requirements for growing, harvesting, packing and holding activities that may cut across the five routes of contamination.

Because the unique practices and conditions for growing sprouts present unique hazards, the regulation establishes additional sprout-specific requirements in Subpart M.

2.3 SUBPART A – GENERAL PROVISIONS

Definitions

Covered activity: growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/ processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of “farm” as defined in this module.

Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in §112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 110 of this module.

- 21 CFR 112.3

Covered produce: produce that is subject to the requirements of this part in accordance with §§112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

- 21 CFR 112.3

Raw agricultural commodity (RAC) means “any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing” (section 201(r) of the Federal Food, Drug, and Cosmetic Act (the Act)).


- 21 CFR 112.3

§ Subpart A
General Provisions

Regulation addresses:

- What is covered and not covered
- Definitions
- Qualified exemptions

This module also reviews compliance dates





The provisions in Subpart A address basic information answer the following questions:

- What food is covered by this part? (§ 112.1)
- What produce is not covered by this part? (§ 112.2)
- What definitions apply to this part? (§ 112.3)
- Which farms are subject to the requirements of this part? (§ 112.4)
- Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing? (§ 112.5)
- What modified requirements apply if my farm is eligible for a qualified exemption in accordance with §112.5? (§ 112.6)
- What records must I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5? (§112.7)

We also address compliance dates in this part of the module.

2.3.1 Coverage of the Rule

Coverage of the Rule

<p>Covers</p> <ul style="list-style-type: none"> § Domestic and imported produce § Produce for human consumption <p>Does not cover</p> <ul style="list-style-type: none"> • Produce for personal or on-farm consumption • Produce no longer a “raw agricultural commodity” • Certain specified produce rarely consumed raw • Farms with produce sales of ≤\$25,000 per year 	<p>Eligible for exemption (with modified requirements)</p> <ul style="list-style-type: none"> • Produce that will receive commercial processing (“kill-step” or other process that adequately minimizes hazards) • Qualified exemption <div style="text-align: center; margin: 10px 0;">  </div> <div style="text-align: right; margin-top: 20px;">  </div>
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It is important to note this is an overview and *does not cover all the details within each subpart*. We encourage you to review the rule (Appendix 2a) to understand all the requirements. First, produce that is subject to this rule is discussed, which is referred to as **covered produce**. Only produce intended for human consumption is covered by this rule, and this includes produce grown domestically and imported produce grown internationally.

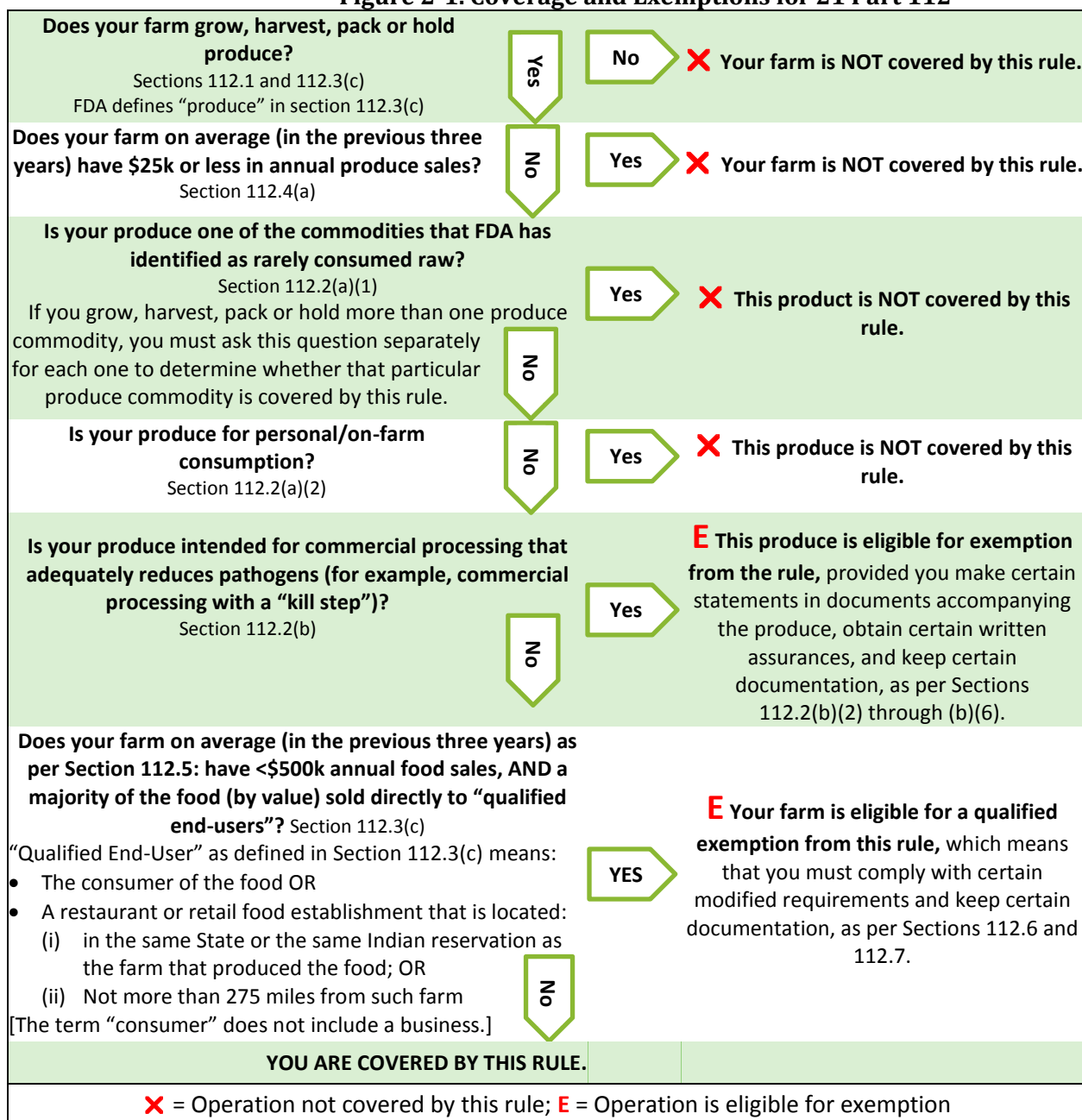
Certain produce and certain farms are eligible for exemption from the rule, if specific conditions are met (See Figure 2-1 and the rule) and certain records are maintained. Each of these is briefly discussed.

- Produce for personal or on-farm consumption is not subject to the rule (§112.2(a)(2)).
- Once produce becomes a processed food it is no longer a **raw agricultural commodity** (RAC) and it is not considered covered produce for this rule (§112.2(a)(3)) (see sidebar).
- Additionally, commodities that are rarely consumed raw (e.g., potatoes) are not covered by the rule. The rule provides FDA’s exhaustive (all inclusive) list of these commodities (§112.2(a)(1)).
- The rule does not cover farms that have an average annual value of produce sold during the previous 3-year period of \$25,000 or less. (§112.4(a)).
- Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., via a “kill step”) is also exempt as long as certain disclosures are made and appropriate documentation occurs (§ 112.2(b)(1)).

- There is also a qualified exemption (based on total food sales and direct marketing) which is discussed below.

Even if an operation is exempt from the final produce rule, it must still meet the requirements in the *Federal Food, Drug, and Cosmetic Act* (the Act); meaning it must produce food that is safe, using sanitary conditions.

Figure 2-1. Coverage and Exemptions for 21 Part 112*




The *Preventive Controls for Human Food Rule* clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the *Produce Safety Rule* (section 112.3(c)).
*Adapted from FDA Standards for Produce Safety: Coverage and Exemptions/Exclusions for 21 Part 112. December 21, 2015

2.3.2 Definitions (§112.3)

For many aspects of the rule, definitions are an important part of understanding the regulatory approach. The codified section, §112.3, provides definitions for many terms associated with the rule. This manual displays many of the relevant rule definitions in note boxes in the side margins of each module as the definitions appear in the text. Appendix 1 also contains an alphabetical listing of important definitions used in the course, from the regulation and other sources.

§ Definition of Farm

- “Farm” definition clarifies that the relevant entity is the farm business
- Two types of farms
 - A primary production farm
 - A secondary activities farm
- Sprout operations are primary production farms under the *Produce Safety Rule*



FDA considers operations that grow sprouts to be farms. Sprouters that participate *only* in activities that meet the definition of a farm do not need to register with FDA.

See Appendix 2A. §112.3(b) for the full definition of “farm.”

It is especially important to understand which operations, and which activities within an operation, are covered by which of the two Food Safety Modernization Act (FSMA) rules, the *Produce Safety Rule* or the *Preventive Controls for Human Foods Rule*.

The FDA’s definition of a farm originated in association with the Bioterrorism Act of 2002 and was used to outline facility registration and recordkeeping requirements. Through FSMA, Congress directed FDA to determine whether an operation is required to register with FDA as a manufacturing/processing facility as the determining factor for which of the two FSMA rules would apply. Farms (and retail operations) are exempt from FDA facility registration requirements. Note: Some states require sprout operations to register with the state as facilities. Regardless of registration requirements at the state level, FDA considers operations that grow sprouts to be farms, subject to the *Produce Safety Rule*, unless otherwise exempt.

The rule clarifies the definition and expands it further to cover two kinds of farming operations: primary production farms and secondary activities farms.

Definition

Mixed-type facility: An establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

- 21 CFR 117.3

§ **Activities That Do Not Fall Under Farm Definition**

- Manufacturing/processing that goes beyond activities within the farm definition
- Examples include:
 - Making noodles and tofu
 - Chopping herbs and fresh-cut processing
 - Making snack chips from legumes
 - Roasting peanuts or tree nuts
- Above activities are subject to *Preventive Controls for Human Food* rule requirements



Sprouters may participate in activities that are outside the scope of the farm definition, for example, by making noodles or tofu. These operations would be considered ***mixed-type facilities*** that are required to register and should review applicable requirements of the *Preventive Controls for Human Food Rule*. More information on these requirements is available from the Food Safety Preventive Controls Alliance (FSPCA) (<https://www.ifsh.iit.edu/fspca>) and FSMA website (<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>).

2.3.3 Qualified Exemption

§ **Qualified Exemption**

- Farms are eligible for a qualified exemption (and must meet certain modified requirements) if:
 - Less than \$500,000 annual food sales; and
 - Majority of food sales directly to “qualified end-users”, i.e.,
 - Directly to the consumer* of the food (at any location); or
 - Directly to a restaurant or retail food establishment located in the same state or Indian reservation, or located within 275 miles of farm

*The term “consumer” does not include a business.



Some farms may be eligible for a qualified exemption. There are several requirements associated with this exemption, including that

the farms earn less than \$500,000 in annual food sales (adjusted for inflation) averaged over the previous 3 years and the majority of food sold by these farms is sold to **qualified end-users** (§112.5(a)).

§ Modified Requirements for Qualified Exemptions – General

- Farm eligible for a qualified exemption are still subject to the requirements of:
 - Subpart A (General Provisions)
 - Required records related to exemption eligibility must meet records requirements in Subpart O (Records)
 - Subpart Q (Compliance and Enforcement)
 - Subpart R (Withdrawal of Qualified Exemption)



Definition

Qualified end user: with respect to a food means the consumer of the food; or a restaurant or retail food establishment (as those terms are defined in §1.227) that is located:

- (i) In the same State or the Same Indian reservation as the farm that produced the food; or
 - (ii) Not more than 275 miles from such farm.
- The term “consumer” does not include a business.

- 21 CFR 112.3

The required records related to exemption eligibility must meet records requirements in Subpart O. These farms are also still subject to the requirements of Subpart A (General Provisions), Subpart Q (Compliance and Enforcement), and Subpart R (Withdrawal of Qualified Exemption), which sets out the circumstances under which a qualified exemption may be withdrawn.

§ Modified Requirements for Qualified Exemptions – Labeling

- When a food packaging label is required:
 - You must include the name and the complete business address of the farm where the produce was grown on the food packaging label
- When a food packaging label is not required:
 - You must display the name and complete business address of the farm where the produce was grown at the point of purchase
 - This can be on a label, poster, sign, placard, or in documents delivered with the produce or in an electronic notice for Internet sales.



Farms with a qualified exemption are also required to comply with some minimum labeling or disclosure requirements and keep certain documentation (§112.6 and §112.7). A qualified exemption may also


be withdrawn by FDA under certain circumstances associated with public health protection.

2.3.4 Compliance Dates

§ **Compliance Dates for Sprouters**

Size of Operation	Average Annual Produce Sale	Compliance Date
Large	>\$500k	January 26, 2017
Small	\$250k-500k	January 26, 2018
Very Small	\$25k-250k	January 26, 2019

Extended dates for facilities with qualified exemptions are discussed in the text



Compliance dates for operations of different sizes are listed above. If a date falls during the weekend, the next business day will be the effective compliance date. Sprouters eligible for a qualified exemption have the following compliance dates:

- January 26, 2016, records to support qualified exemption eligibility (§112.7(b),
- January 1, 2020, compliance date for modified requirements in §112.6(b)(1), and
- compliance dates for all other requirements in §112.6 and §112.7
 - January 26, 2019 for very small sprouters
 - January 26, 2018 for small sprouters.

2.4 SUBPART B – GENERAL REQUIREMENTS

Subpart B

§ **General Requirements**

- Sprouters must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, their sprouts

Sprout
Safety Alliance

The provisions in Subpart B answer the following questions:

- What general requirements apply to persons who are subject to this part? (§112.11)
- Are there any alternatives to the requirements established in this part? (§112.12)

Under §112.11, sprouters must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Act on account of such hazards.

Section §112.12 provides an option for farms to establish alternatives for certain limited requirements for water quality, sampling and testing provisions for the agricultural water that they use to grow produce other than sprouts. This would not apply to a sprout operation unless it is also growing non-sprout covered produce.

2.5 SUBPART C – PERSONNEL QUALIFICATIONS AND TRAINING


At least one supervisor or responsible party for the farm must successfully complete food safety training at least equivalent to the standardized curriculum recognized by FDA such as this Sprout Safety Alliance course.

Subpart C

§ Training Requirements

- Requirements include:
 - All personnel who contact covered produce or food-contact surfaces
 - Establishes minimum content expectations for training
 - Training for supervisors
 - Record requirements

See Module 11: Additional Control Programs



The provisions in Subpart C answer the following questions:

- What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces? (§112.21)
- What minimum requirements apply for training personnel who conduct a covered activity? (§112.22)
- What requirements apply regarding supervisors? (§112.23)
- Under this subpart, what requirements apply regarding records? (§112.30)


The rule requires all personnel who contact covered produce or food contact surfaces to have a combination of education, training and experience necessary to perform their assigned duties in a manner that ensures compliance with this part (§112.21). The rule also specifies the minimum content for this training (§112.22). This training requirement applies to all types of personnel including temporary, seasonal, part-time, and contracted individuals and must be appropriate for the employees’ duties (§112.21(a)). These training activities must be performed at hiring and at least annually, thereafter (§112.21(a)). In addition, sprouters must assign or identify personnel to supervise (or otherwise be responsible for) their operations to ensure compliance with the requirements of *The Produce Safety Rule* (§112.23). At least one supervisor or responsible party for the sprout operation must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA (§112.22(c)). This Sprout Safety Alliance curriculum fulfills this requirement. Training is discussed further in Module 11: Additional Control Programs.

2.6 SUBPART D – HEALTH AND HYGIENE

§ Subpart D
Worker Health and Hygiene

- Pathogens may be transmitted from workers to food
- Requirements include:
 - Preventing contamination by ill persons
 - Hygienic practices
 - Farms must make visitors aware of policies and give them access to toilet and hand washing facilities

See Module 5: Employee Health and Hygiene Practices in Safe Sprout Production




Subpart D includes measures sprouters must take to prevent ill or infected persons from contaminating covered produce (§112.31); hygienic practices personnel must use (§112.32); and measures sprouters must take to prevent visitors from contaminating covered produce and food contact surfaces (§112.33). This is covered in Module 5: Employee Health and Hygiene Practices in Safe Sprout Production.

2.7 SUBPART E – AGRICULTURAL WATER

§ Subpart E
Agricultural Water

- Safe and adequate sanitary quality of water
- Inspection of water system under farm's control
- Water treatment, if a farm chooses to treat water
- Tiered approach to water testing
 - For post-harvest wash and sprout irrigation, no detectable generic *E. coli*
- Corrective measures
- Records requirements

See Module 4: Sprout Production Environment



Overall, Subpart E includes the agricultural water provisions with a focus on understanding **agricultural water** sources and distribution systems, including water use as well as water quality. This is

Definition

Agricultural water: Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

- 21 CFR 112.3

covered, as it pertains to sprout growers, in the Use of Water section of Module 4: Sprout Production Environment.

2.8 SUBPART F – BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE

Subpart F

§ Biological Soil Amendments of Animal Origin

- Standards for “treated” and “untreated”
- Restrictions on application method depending on treatment status
- Any scientifically valid treatment process that meets the standards of §112.55(a) may be applied without restrictions, and could involve physical, chemical or biological treatment process, or a combination of these



Sprouts that are grown in soil or a substrate and cut from their roots are not covered by the sprout-specific requirements in Subpart M. However, they are subject to the other requirements of the rule, including the requirements for biological soil amendments of animal origin in Subpart F. FDA defines biological soil amendments of animal origin as a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term “biological soil amendment of animal origin” does not include any form of human waste. If a sprouter uses biological soil amendments of animal origin and/or human waste on the sprout farm, they should take measures to ensure that these activities do not result in contamination of sprouts and food contact surfaces, such as isolating growing and handling of those products produced using biological soil amendment of animal origin from other sprout growing, harvesting, packing and holding activities.

2.9 SUBPART I – DOMESTICATED AND WILD ANIMALS


Subpart I provisions generally do not apply to sprout growers because sprouts are grown within a building. Pests in buildings are covered under Subpart L below.

2.10 SUBPART K – GROWING, HARVESTING, PACKING, AND HOLDING ACTIVITIES

Subpart K

§ Growing, Harvesting, Packing & Holding Activities

- Requirements include:
 - Separate covered and excluded produce not grown in accordance to the rule
 - Identify and do not harvest covered produce that is reasonably likely to be contaminated
 - Not distributing covered produce that drops to the ground before harvest
 - Food-packing material appropriate for use



The provisions in Subpart K answer the following questions:

- What measures must I take if I grow, harvest, pack or hold both covered and excluded produce? (§112.111)
- What measures must I take immediately prior to and during harvest activities? (§112.112)
- How must I handle harvested covered produce during covered activities? (§112.113)
- What requirements apply to dropped, covered produce? (§112.114)
- What measures must I take when packaging covered produce? (§112.115)
- What measures must I take when using food-packing (including food packaging) material? (§112.116)

This category captures important considerations that may cut across other subparts of the rule.

2.10.1 Handling Excluded and Potentially Contaminated Produce

To minimize risk of transferring contamination from excluded produce to covered produce, covered produce must be kept separate from produce that is excluded from the rule and that is not grown in accordance with the rule requirements (§112.111). Sprouters must also clean and sanitize food contact surfaces, as necessary, after contact with such excluded produce before using the food contact surfaces for covered produce (§112.111(b)).

Identifying and not harvesting covered produce that is reasonably likely to be contaminated includes, but is not limited to, taking steps

to identify and not harvest covered produce visibly contaminated with animal excreta (§112.112). Furthermore, produce that drops to the ground before harvest must not be distributed (§112.114).

2.10.2 Packing Materials

FDA does not make a determination as to what type of packing materials may be used (wood, burlap, plastic, etc.), only that they must be adequate for their intended use, including being cleanable or designed for single use and unlikely to support growth or transfer of bacteria (§112.116). The regulation also does not require all packing materials to be sanitized; however, sprouters must take measures to ensure that the food-contact surfaces of reusable containers are clean (§112.116).

2.11 SUBPART L – EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION

Subpart L

§ **Equipment, Tools, Buildings & Sanitation**

- Requirements include:
 - Equipment/tools: designed and constructed to allow adequate cleaning and maintenance
 - Food contact surfaces of equipment and tools for sprouts must be inspected, maintained, cleaned, and sanitized as necessary
 - Buildings for sprouts
 - Must be fully-enclosed
 - Size, design and construction must facilitate maintenance and sanitary operations
 - Toilet and hand-washing facilities must be adequate, and readily accessible during covered activities

For more information, see Module 4: Sprout Production Environment and Module 6: Cleaning and Sanitizing Buildings and Equipment



The standards in Subpart L resemble current Good Manufacturing Practices (cGMPs). This subpart includes specific requirements related to the design, cleaning, and maintenance of buildings, equipment, and tools. It includes requirements related to pest control, toilet facilities, hand washing facilities, sewage, and plumbing. The requirements in Subpart L are discussed in more detail in relevant modules of this curriculum.

For example:


- Cleaning and sanitizing (§112.123, §112.125, §112.126) is covered in more detail in Module 6
- Module 4: Sprout Production Environment addresses:
 - Building, equipment, and tools design and construction (§112.123, §112.125, §112.126)

- Animals and pests (§112.127, §112.128)
- Toilet and hand washing facilities (§112.129, §112.130)
- The control and disposal of sewage and trash (§112.131, §112.132, §112.134)
- Plumbing (§112.133)
- Calibration of instruments and controls used to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions to control or prevent growth of pathogens (§112.124) is covered in modules related to the use of specific instruments.

2.12 SUBPART M – SPROUTS

§ Subpart M
Sprouts

- Sprout operations are subject to **all relevant requirements** of the *Produce Safety Rule*
- Because sprouts have a unique risk profile, additional sprout-specific provisions are covered in Subpart M.
- Applies to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots (§112.141).



Sprout operations are subject to all relevant requirements of the produce rule, and because sprouts have a unique risk profile, the *Produce Safety Rule* also includes additional sprout-specific provisions in Subpart M. This subpart applies to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots (§112.141).

Questions addressed in Subpart M include:


- What commodities are subject to this subpart? (§112.141)
- What requirements apply to seeds or beans used to grow sprouts? (§112.142)
- What measures must I take for growing, harvesting, packing, and holding sprouts? (§112.143)
- What testing must I do during growing, harvesting, packing, and holding sprouts? (§112.144)

- What requirements apply to testing the environment for *Listeria* species or *L. monocytogenes*? (§112.145)
- What actions must I take if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*? (§112.146)
- What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens? (§112.147)
- What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen? (§ 112.148)
- Under this subpart, what requirements apply regarding records? (§112.150)

2.12.1 General Operations

§ **General Operations**

- Grow, harvest, pack, and hold sprouts in a fully-enclosed building
- Food contact surfaces must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts



Sprouters must grow, harvest, pack, and hold sprouts in a fully enclosed building (§112.143(a)). In addition, any food-contact surfaces sprouters use to grow, harvest, pack, and hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts (§112.143(b)).

2.12.2 Controls Directed Toward Preventing Seed as a Source of Contamination

§ Controls Directed Toward Seed

- Visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination
- Do not use seeds known to be contaminated with pathogens
- Treat seed and beans before sprouting

See Module 8: Seed Purchasing, Receiving and Storage and Module 9: Seed Treatment



Sprouters must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that they use for sprouting (§112.142(a)). If sprouters know or have reason to believe that a lot of seeds or beans has been contaminated with a pathogen, they must not use that lot of seeds or beans to produce sprouts, and must report the information to the seed supplier (§112.142(b)). Sprouters must also visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards (§112.142(d)).

2.12.3 Seed Treatment

Seeds and beans used to grow sprouts must be treated using a scientifically valid method to reduce microorganisms of public health significance. Treatment may be done at the sprout operation immediately before sprouting. Alternatively, sprouters may rely, in whole or in part, on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans provided certain conditions are met. Specifically, sprouters must obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that the prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance and the treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination (§112.142(e)). This represents increased flexibility compared to the 1999 Sprout guidance where the focus was limited to seed treatment conducted at sprout operations.

2.12.4 Testing for Pathogens

§ Testing for Pathogens

- Test spent sprout irrigation water (or in-process sprouts) for specific pathogens subject to the Rule
- Monitoring the growing, harvesting, packing and holding environment for *Listeria* species or *L. monocytogenes*

See:

- *Module 7: Environmental Monitoring for Listeria species or L. monocytogenes in a Sprout Operation* and
- *Module 10: Sampling and Microbiological Testing of Spent Irrigation Water and Sprouts*



Sprouters must test either spent sprout irrigation water or in-process sprouts from each production batch of sprouts for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria listed in §112.144(c) (§112.144(b)). Sampling and testing spent sprout irrigation water (or sprouts) and development of the written sampling and testing plan is required by §112.147. Section §112.148 describes the corrective actions that need to be taken if the spent sprout irrigation water (or in-process sprouts) test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria listed in §112.144(c).

If the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in §112.144(c), sprouters must take appropriate action to prevent any food that is adulterated from entering into commerce; clean and sanitize the affected surfaces and surrounding areas; and perform any other actions necessary to prevent reoccurrence of the contamination. Spent sprout irrigation water (or in-process sprout) testing and corrective actions are discussed in detail in Module 10.

In addition, except as allowed under §112.142(c), when spent sprout irrigation water or sprouts are associated with a positive pathogen finding sprouters must stop using affected lots of seeds or beans (§112.142(b)) and report the information to the seed grower, distributor, supplier, or other entity from whom the sprouter received the seeds or beans (§112.148(b)).

Sprouters must also have and implement a written environmental monitoring plan for the growing, harvesting, packing and holding environment that involves testing for either *Listeria* species or the pathogen *Listeria monocytogenes* (§112.145). Section 112.146

describes the corrective actions that need to be taken if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*. Environmental monitoring is addressed in detail in Module 7.

2.12.5 Records

Section 112.150 describes certain requirements for records that sprouters must establish and keep regarding sprouts under Subpart M, specifically:

- Documentation of the sprouters treatment of seeds or beans at their operation to reduce microorganisms of public health significance in the seeds or beans, or alternatively, documentation (such as a Certificate of Conformance) from their seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e);
- Written environmental monitoring plan in accordance with the requirements of §112.145;
- Written sampling plan for each production batch of sprouts in accordance with the requirements of §112.147(a) and (c);
- Documentation of the results of all analytical tests conducted for purposes of compliance with this subpart;
- Any analytical methods used in lieu of the methods that are incorporated by reference in §112.152 and §112.153; and
- Documentation of corrective actions taken in accordance with §112.142(b) and (c), §112.146, and §112.148.

Sprouters must establish and keep records required under Subpart M in accordance with the requirements of Subpart O – Records (discussed below and in Module 12) (§112.150(a)).


2.13 SUBPART N – ANALYTICAL METHODS

Subpart N
Analytical Methods

§

- Covers the methods that must be used to test:
 - The quality of water (§112.151)
 - The growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* (§112.152)
 - Spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens (§112.153)

See Module 7: Environmental Monitoring for *Listeria* species or *L. monocytogenes* in a Sprout Operation and
Module 10: Sampling and Microbial Testing of Spent Irrigation Water and Sprouts



The provisions in Subpart N answer the following questions:

- What methods must I use to test the quality of water to satisfy the requirements of §112.46? (§112.151)
- What methods must I use to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of §112.144(a)? (§112.152)
- What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of §112.144(b) and (c)? (§112.153)


Copies of the methods for testing spent sprout irrigation water and environmental samples can be found at the following links:

- Testing Methodologies for the Quality of Water: The U.S. Environmental Protection Agency (EPA), “Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC), EPA-821-R-09-007,”
- Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts) (PDF: 622KB):
<http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM467055.pdf>
- Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples (PDF: 109KB):
<http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM467056.pdf>

2.14 SUBPART O – RECORDS

§ Other Subparts

- Subpart O: Records
 - Also see Module 12
- Subpart P: Variances
 - For states, tribes, or foreign governments
- Subpart Q: Compliance and Enforcement
- Subpart R: Withdrawal of Qualified Exemption



The provisions in Subpart O answer the following questions:

- What general requirements apply to records required under this part? (§112.161)
- Where must I store records? (§112.162)
- May I use existing records to satisfy the requirements of this part? (§112.163)
- How long must I keep records? (§112.164)
- What formats are acceptable for the records I keep? (§112.165)
- What requirements apply for making records available and accessible to FDA? (§112.166)
- Can records that I provide to FDA be disclosed to persons outside of FDA? (§112.167)

Subpart O covers the requirements that are applicable to all records required by the *Produce Safety Rule*. Subpart O describes how records must be established and maintained, including the general requirements for making, reviewing and retaining records, along with requirements for official review and public disclosure of records required by this rule. The requirements in Subpart O are discussed in more detail in Module 12 of this curriculum.

2.15 SUBPART P – VARIANCES

The provisions in Subpart P answer the following questions:

- Who may request a variance from the requirements of this part? (§112.171)

- How may a State, tribe, or foreign country request a variance from one or more requirements of this part? (§112.172)
- What must be included in the Statement of Grounds in a petition requesting a variance? (§112.173)
- What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available? (§112.174)
- Who responds to a petition requesting a variance? (§112.175)
- What process applies to a petition requesting a variance? (§112.176)
- Can an approved variance apply to any person other than those identified in the petition requesting that variance? (§112.177)
- Under what circumstances may FDA deny a petition requesting a variance? (§112.178)
- When does a variance approved by FDA become effective? (§112.179)
- Under what circumstances may FDA modify or revoke an approved variance? (§112.180)
- What procedures apply if FDA determines that an approved variance should be modified or revoked? (§112.181)
- What are the permissible types of variances that may be granted? (§112.182)

One approach in the *Produce Safety Rule's* framework that incorporates flexibility is the allowance for variances. The rule allows a *U.S. state, tribe or foreign country* to request a variance from some or all provisions of the regulation through a formal petition process that requires a submission to FDA. The petition submitted by a state, tribe, or foreign country would need to include a statement of grounds explaining why the petitioner has determined that the variance is necessary in light of local growing conditions and describe with particularity the variance requested, including the persons to whom the variance would apply and to which provision(s) the variance would apply. The petition must also present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure the same level of public health protection as the requirements of the regulation without increasing the risk of adulteration of covered produce (§112.173). Subpart P also provides a process by which FDA would consider such requests and approve or deny them.

2.16 SUBPART Q – COMPLIANCE AND ENFORCEMENT

Questions addressed in Subpart Q include:

- What is the applicability and status of this part? (§112.192)
- What are the provisions for coordination of education and enforcement? (§112.193)

Subpart Q covers certain provisions regarding how the criteria and definitions in the *Produce Safety Rule* relate to the *Federal Food, Drug, and Cosmetic (FD&C) Act* and the *Public Health Service (PHS) Act*, the consequences of failing to comply with this part (§112.192), and coordination of education and enforcement (§112.193). Specifically, §112.192(b) establishes that the criteria and definitions in the *Produce Safety Rule* apply in determining whether a food is: (1) Adulterated within the meaning of: (i) Section 402(a)(3) of the *Federal Food, Drug, and Cosmetic Act* in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or (ii) Section 402(a)(4) of the *Federal Food, Drug, and Cosmetic Act* in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (2) In violation of section 361 of the *Public Health Service Act* (42 U.S.C. 264).

2.17 SUBPART R – WITHDRAWAL OF QUALIFIED EXEMPTION

Questions addressed in Subpart R include:

- Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of §112.5? (§ 112.201)
- What procedure will FDA use to withdraw an exemption? (§112.202)
- What information must FDA include in an order to withdraw a qualified exemption? (§112.203)
- What must I do if I receive an order to withdraw a qualified exemption applicable to my farm? (§112.204)
- Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm? (§112.205)
- What is the procedure for submitting an appeal? (§112.206)
- What is the procedure for requesting an informal hearing? (§112.207)
- What requirements are applicable to an informal hearing? (§112.208)
- Who is the presiding officer for an appeal and for an informal hearing? (§112.209)
- What is the timeframe for issuing a decision on an appeal? (§112.210)
- When is an order to withdraw a qualified exemption applicable to a farm revoked? (§112.211)

- If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption? (§112.213)

The qualified exemptions that were discussed in Subpart A may be withdrawn under certain circumstances associated with public health protection. Subpart R establishes the procedures that govern the circumstances and process whereby FDA may issue an order withdrawing a qualified exemption applicable to a farm in accordance with the requirements of §112.5, a process where farms may submit a written appeal of an order to withdraw a qualified exemption, and under what circumstances FDA would reinstate the qualified exemption.


2.18 ADDITIONAL INFORMATION

2.18.1 FDA Guidance and Information on the *Produce Safety Rule*

FDA Guidance

- *Implementation and Compliance Guide*
- *Sprout Guidance*
- *Small Entity Compliance Guide*
- *Updated Good Agricultural Practices (GAPs) Guidance*

Access the latest FDA Guidance on the FDA website



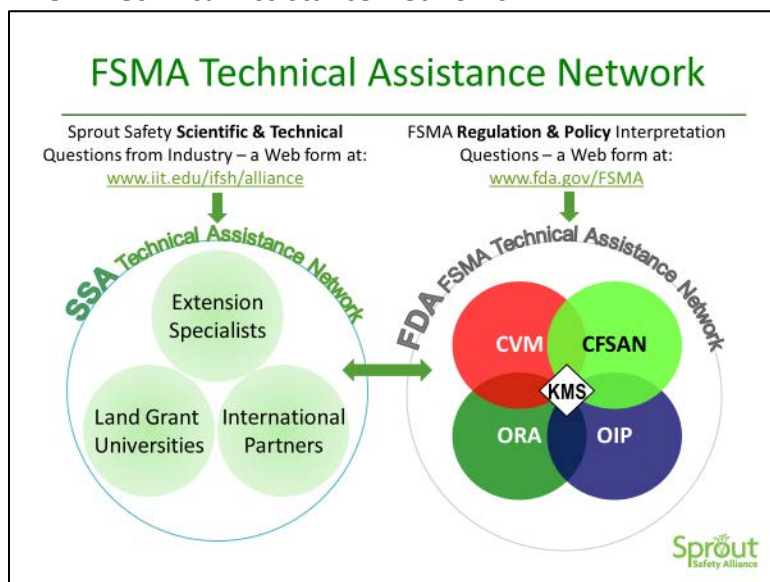
FDA issues guidance documents to assist industry with complying with regulations. Guidance of interest to sprouters may include a Compliance and Implementation guidance for the *Produce Safety Rule* as well as specific guidance related to sprouts, a small entity compliance guide, and an updated version of the 1999 Good Agricultural Practices (GAPs) guidance. This guidance provides information to farms, including sprout operations, regarding how to comply with the *Produce Safety Rule*.

For More Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us

The FDA FSMA website also contains fact sheets on the *Produce Safety Rule* subject areas and a link to the FSMA Technical Assistance Network (TAN) other FSMA related information, including final and proposed rules, guidance, presentations, fact sheets and other information applicable to sprouters and other FDA regulated operations and facilities. The FSMA website can be found at the following address: www.fda.gov/FSMA. There is a subscription feature to sign-up for updates, including information about newly released guidance and other information.

2.18.2 Technical Assistance Networks



To provide answers to technical or regulatory questions from growers and food processors, the FDA FSMA Technical Assistance Network (TAN) has been operational since September 9, 2015. For

more information, please visit the FSMA website and click on “Contact Us” to access FDA’s TAN.

The Sprout Safety Alliance and FDA Technical Assistance Networks work together – with FDA addressing answers to regulation and policy interpretation questions, SSA addressing scientific and technical questions, and interaction, as appropriate.

Questions submitted to the FDA TAN are answered using input from several parts of FDA to ensure that a consistent answer is provided and answers are maintained in the Knowledge Management System (KMS). Sometimes this takes time, but the process provides consistent answers. Answers to frequently asked questions may be posted for general use. FDA groups involved in the TAN include:

- CVM = Center for Veterinary Medicine
- CFSAN = Center for Food Safety and Applied Nutrition
- OIP = Office of International Programs
- ORA = Office of Regulatory Affairs

Sprouters may also contact the Sprout Safety Alliance for sprout-specific, non-regulatory technical questions through the SSA website: <https://www.ifsh.iit.edu/ssa>.

The SSA is in the process of setting up a SSA community website for SSA Lead Instructor application and communication among individuals from the sprout industry, government agencies and academia.

2.19 REFERENCES AND SAMPLE DOCUMENTS

FDA, 2017. FDA Food Safety Modernization Act (FSMA) webpage.
www.fda.gov/fsma

Appendix 2: FDA Regulation on Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption

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Module 3. Sprout Safety Hazards

3.1 INTRODUCTION

Learning Objectives

- In this module, you will learn:
 - Food safety hazards associated with sprouts
 - Biological hazards
 - Chemical hazards
 - Physical hazards
 - The importance of controlling these hazards to your sprout operation



This module provides a brief overview of the different types of food safety hazards and the importance of their control, with an emphasis on **known or reasonably foreseeable hazards** that have been previously associated with sprouts and thus require appropriate controls. Specific hazards and their respective controls can differ by product types and processes. Understanding food safety hazards and identifying those hazards in sprout operations are the foundation for establishing an effective food safety program and for implementing best practices to prevent those hazards from occurring. More details about these best practices can be found in subsequent modules.

Definition

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

- 21 CFR 112.3

General Types of Hazards

- Biological hazards (*The focus of the Produce Safety Rule*)
 - Include harmful bacteria, viruses or parasites
- Chemical hazards
 - Compounds or ingredients that cause acute/chronic illness or allergies
- Physical hazards
 - Foreign objects, such as glass or metal fragments



Examples of potential food safety hazards may include biological hazards, such as harmful bacteria, viruses and parasites; chemical hazards, such as chemical compounds or ingredients that can cause illness or allergic reaction due to immediate or long-term exposure; and physical hazards, such as glass, metal fragments, or other foreign objects.

Produce Safety Rule Hazard Definitions

- **Hazard:**
 - Any biological agent that has the potential to cause illness or injury in the absence of its control
- **Known or reasonably foreseeable hazard:**
 - A biological hazard that is known to be, or has the potential to be, associated with the farm or the food.

Note: Hazards not covered by the *Produce Safety Rule* (e.g., chemical (including radiological and food allergens) and physical hazards) are still covered by the *Food Drug and Cosmetic Act*



Definitions

Hazard: Any biological agent that has the potential to cause illness or injury in the absence of its control
- 21 CFR 112.3

Pathogen: Any microorganism of public health significance.
- 21 CFR 117.3

Most food safety definitions of the term *hazard*, such as that used in the *Preventive Controls for Human Food Rule* include biological, chemical or physical agents that have the potential to cause illness or injury in the absence of its control, through the practices, processes and conditions under which food is produced. The *Produce Safety Rule* focuses on biological hazards and defines **hazard** as “any biological agent that has the potential to cause illness or injury in the

absence of its control” and, as previously discussed, a **known or reasonably foreseeable hazard** as a hazard that is known to be, or has the potential to be, associated with the farm or the food. Available data clearly establish that human pathogens cause the vast majority of foodborne illnesses known to be associated with produce consumption. Therefore, the rule and this module focus on biological hazards.

Keep in mind that potential contamination of produce from physical or chemical (including food allergen and radiological) hazards are covered under the Food, Drug & Cosmetic Act and implementing regulations. Under section 402(a)(1) of the Act, a food is adulterated if it bears or contains any added poisonous or deleterious substance, which may render it injurious to health. Such substances may include physical and chemical contamination.

Insanitary Conditions

- Insect fragments
- Hair
- Filth
- Spoilage bacteria



The presence of insect fragments, hair, filth or spoilage is highly undesirable in food. Economic fraud and violations of regulatory food standards are equally undesirable. Sprouters should have programs in place to ensure the basic conditions and activities necessary to maintain a hygienic environment. However, to the extent these conditions are related to the quality rather than the safety of the product, they are not considered food safety “hazards” and will not be covered in this module.

Goals

Understanding food safety hazards and identifying those hazards in sprout operations facilitates:

- Establishing an effective food safety program
- Implementing the *Produce Safety Rule* and best practices
- Reducing or eliminating those hazards



The goals of this module are to help sprouters develop an awareness of the kinds of unintended or accidental food safety hazards that may occur in sprout operations and to learn some of the general controls to prevent these hazards. This will help sprouters to implement the requirements of the *Produce Safety Rule* and the Act. Sprouters may find it beneficial to work with technical experts with more knowledge and experience in addressing potential food safety hazards for various sprout products and operations.

Definition

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

- 21 CFR 112.3

3.2 BIOLOGICAL HAZARDS

Biological Hazards

- Most microorganisms are not hazardous
- Pathogens are hazardous microorganisms
- Foodborne pathogens that may be associated with sprouts include bacteria, viruses, and parasites
- Yeast and molds generally do not pose a food safety hazard in sprouts
- Sources of biological hazards include people, ingredients, and the environment



Microorganisms are found everywhere: in air, soil, fresh and salt water, in skin and hair, in animals and on plants. Although thousands of different microorganisms exist, only a few pose hazards to

humans. It is important to understand the different types of microorganisms that cause foodborne illnesses and the severity of the illnesses they may cause.

Microorganisms that are of public health significance are called pathogens (FDA, 2016). Pathogens that are transmitted by food are called foodborne pathogens. Among microorganisms, certain bacteria, viruses and parasites are typically considered the types that can make food unsafe. Generally, yeast and molds do not pose a food safety hazard in sprouts.


Sources of biological hazards in general include people, ingredients, and the environment. For example, people can carry certain human pathogens even when they are not ill. They can also introduce pathogens into food when they touch a contaminated surface, like dirty equipment or an animal, and then touch food or a food contact surface without washing their hands (see Module 5: Employee Health and Hygiene Practices in Safe Sprout Production). Raw materials, like seeds and water, can also introduce pathogens especially if the safety of these ingredients is not evaluated prior to use.

The following section on biological hazards discusses pathogenic bacteria, viruses and parasites, including potential sources and methods for control.

3.2.1 Foodborne Illnesses Associated with Sprouts

Foodborne Illness

- Foodborne illness
 - Illnesses that result from eating food that contains pathogens
- Symptoms of foodborne illness
 - Diarrhea, vomiting, stomach cramps, sometimes fever
- Serious life long complications may occur , especially for very young, elderly, and immunocompromised populations
 - e.g., paralysis, kidney failure, or death
- Many illnesses are not reported



Foodborne illnesses are those illnesses that result from eating food that contains pathogens. These pathogens can cause symptoms such as diarrhea, vomiting, and stomach cramps. Sometimes fever or jaundice also occurs. These illnesses can cause serious health problems. Certain groups, such as the very young, the elderly and the immune-compromised may be more susceptible to serious

complications of foodborne illness, such as paralysis, kidney failure, or even death.

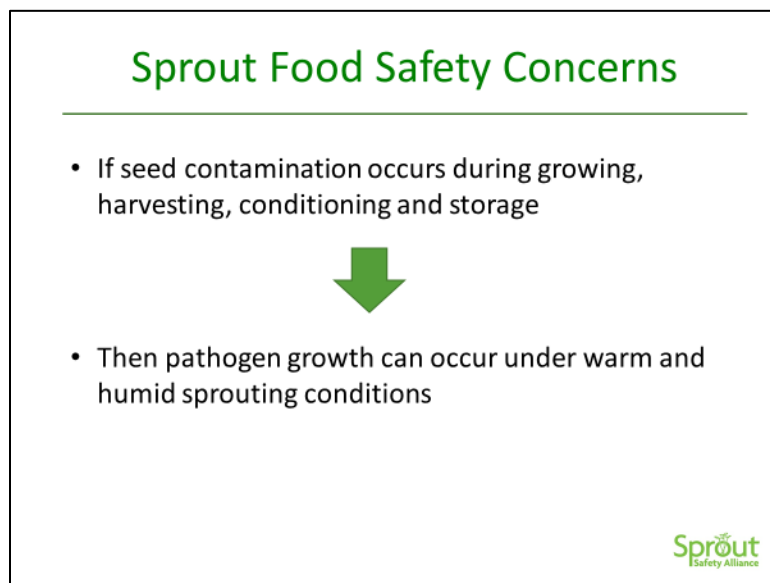
For each case of illness that is reported to health authorities, many other illnesses occur but are never reported. Doctors or laboratories report illnesses to health authorities, so if an ill person does not seek medical care or the doctor does not send a sample from the ill person to the laboratory, the illness will probably not be reported. For example, in most foodborne illness outbreaks caused by the pathogen *Salmonella*, it is estimated that, for each reported case of illness, there are another 30 illnesses that go unreported (Scallan et al., 2011). This means that in a “small” outbreak involving 20 reported illnesses, several hundred people may actually have become ill. Overall, it is estimated that about 48 million foodborne illnesses occur in the U.S. each year, resulting in 128,000 hospitalizations and 3,000 deaths (Scallan et al., 2011).

Outbreaks represent a variety of sprout types, suggesting that it is the process of sprouting, rather than the type of seed that contributes to the potential for an outbreak.

Table 3-1 Selected outbreaks associated with sprouts

Date	Sprout Type	Pathogen type	Illness Reported	Outbreak Scale and Website
Aug. 2016	Alfalfa Sprouts	<i>Salmonella</i> spp.	30	Multistate, U.S. http://www.cdc.gov/salmonella/reading-08-16/index.html
Nov. 2015	Alfalfa Sprouts	<i>Salmonella</i> spp.	13	Multistate, U.S. https://www.cdc.gov/salmonella/paratyphi-b-12-15/index.html
Sep. 2014	Mung Bean Sprouts	<i>Salmonella</i> spp.	115	Multistate, U.S. http://www.cdc.gov/salmonella/enteritidis-11-14/index.html
Aug. 2014	Mung Bean Sprouts	<i>Listeria monocytogenes</i>	5 (2 deaths, 3 hospitalized)	Multistate, U.S. http://www.cdc.gov/listeria/outbreaks/bean-sprouts-11-14/index.html
May 2014	Clover Sprouts	<i>E. coli</i> O121	19	Multistate, U.S. http://www.cdc.gov/ecoli/2014/O121-05-14/index.html
Feb. 2012	Clover Sprouts	<i>E. coli</i> O26	29	Multistate, U.S. http://www.cdc.gov/ecoli/2012/O26-02-12/index.html
Jun. 2011	Alfalfa Sprouts and Spicy Sprouts	<i>Salmonella</i> spp.	25	Multistate, U.S. http://www.cdc.gov/salmonella/2011/alfalfa-spicy-sprouts-7-6-2011.html
May 2011	Fenugreek Sprouts	<i>E. coli</i> O104:H4	4321 (50 deaths, 852 HUS cases)	Europe, Canada & US. http://www.cdc.gov/ecoli/2011/travel-germany-7-8-11.html
Nov. 2010	Alfalfa Sprouts	<i>Salmonella</i> spp.	140	Multistate, U.S. http://www.cdc.gov/salmonella/2010/alfalfa-sprouts-2-10-11.html
Jun. 2010	Alfalfa Sprouts	<i>Salmonella</i> spp.	44	Multistate, U.S. http://www.cdc.gov/salmonella/2010/newport-alfalfa-sprout-6-29-10.html
Jun. 1997	Alfalfa Sprouts	<i>E. coli</i> O157:H7	82	Multistate, U.S. http://wwwnc.cdc.gov/eid/article/7/6/01-0609_article

Sprouts have repeatedly been associated with foodborne illness outbreaks, usually caused by the bacteria *Salmonella*, pathogenic *E. coli* (CDC, 2012; CDC, 2014), or *Listeria monocytogenes* (FDA, 2015b). Foodborne illness outbreaks associated with contaminated sprouts in the U.S. and elsewhere have resulted in thousands of laboratory-confirmed illnesses and a number of deaths (see Table 3-1 for a list of notable outbreaks). Some of these outbreaks were quite large and affected people living in multiple states. Alfalfa sprouts, which are often consumed raw and are one of the more commonly consumed types of sprouts in the U.S., are also the sprout type most frequently linked to foodborne illness outbreaks in the U.S. However, dozens of types of seed are sprouted in the U.S. and any type of sprout can become contaminated with pathogens and cause illness, including both green sprouts (most often consumed raw) and bean sprouts (which may be only lightly cooked before consumption).



Sprouts pose special food safety challenges because of the unique way in which they are grown. The same conditions that encourage seed to sprout can also encourage the growth of bacterial pathogens if they are present. Seed has been identified as the likely source of contamination in many sprout-associated outbreaks. Bacterial pathogens that may be present at low levels on seed can multiply to very high levels during the sprouting process.

Definition

Adequate: That which is needed to accomplish the intended purpose in keeping with good public health practice
 - 21 CFR 112.3

Pest: Any objectionable animals or insects, including birds, rodents, flies, sand larvae
 - 21 CFR 112.3

Potential Sprout Contamination Sources

- Contaminated seed
- Other contamination sources
 - Poor worker hygiene
 - Dirty equipment
 - Poor cleaning and sanitation
 - Contaminated water
 - Other insanitary conditions

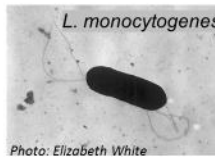
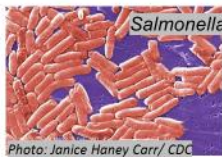


Besides contaminated seed, poor hygienic practices and conditions within a sprout operation can also lead to product contamination. For example, *Listeria* can be brought into and persist in the sprout production environment. Poor worker hygiene, dirty equipment, ineffective cleaning and sanitation practices, lack of **adequate pest control**, contaminated water and other insanitary conditions can also contribute to contamination of seed and sprouts.

3.2.2 Pathogens Associated with Sprouts

Pathogens Associated with Sprouts

- *Salmonella*
- Pathogenic *E. coli*
- *Listeria monocytogenes*



This section discusses foodborne bacterial pathogens associated with sprout outbreaks, including *Salmonella*, pathogenic *E. coli* and *Listeria monocytogenes*. However, sprouts are also vulnerable to other pathogens that may contaminate other fresh produce, including virus and parasites, which are discussed in Section 2.5.

3.2.2.1 *Salmonella*

Salmonella – Route of Contamination

- Seed contamination during growing, harvesting, conditioning and storage
 - Animals, contaminated water, contaminated harvest equipment
 - Poor hygiene conditions or poor pest control during seed conditioning and distribution
- Contamination of equipment, seeds and sprouts through insanitary practices at sprout operations



Salmonella is naturally occurring in the digestive tract of domestic and wild birds and other animals. Seeds for sprouting can become contaminated with *Salmonella* through contact with animal fecal material, contaminated **agricultural water** or soil, or contaminated harvesting equipment during growing or harvesting operations. Poor hygiene conditions or poor pest control at facilities used for seed conditioning, storage and distribution are the other potential sources of *Salmonella* contamination for seeds. Sprouts can be contaminated with *Salmonella* from the use of contaminated seed, through contaminated equipment or insanitary conditions present at a sprout operation.

Definition

Agricultural water: Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

- 21 CFR 112.3

Salmonella – Illness

- Low infective dose
 - Thousands of sub-types
 - Depends on host health and strain virulence
- Nausea, vomiting, abdominal cramps and fever



Salmonella is the cause of most sprout-associated illness outbreaks (Table 3-1). *Salmonella* infection typically causes nausea, vomiting, abdominal cramps, headache and fever. The infective dose of *Salmonella* may be as low as 15-20 cells, depending on a person's age and health and the serotype of *Salmonella* (FDA, 2012). CDC (Scallan et al., 2011) estimated that 1,027,561 cases of domestically acquired salmonellosis occur annually in the U.S., when under-reporting and under-diagnosis are considered.

3.2.2.2 Pathogenic *E. coli*

Pathogenic *E. coli* – Route of Contamination

- Hundreds of strains of *Escherichia coli*
 - Most are harmless and live in the intestines of healthy humans and animals
- *E. coli* O157:H7 is the Shiga-toxin producing *E. coli* (STEC) strain most often seen in sprout outbreaks
 - Found in water, food, soil or on surfaces that have been contaminated with animal or human feces



Most strains of *E. coli* are harmless and live in the intestines of healthy humans and animals. However, *E. coli* O157:H7 and non-O157 Shiga toxin-producing *E. coli* (STEC), such as O104:H4, O26 (CDC, 2012) and O121 (CDC, 2014), have been associated with sprout-related outbreaks. Among all STECs, *E. coli* O157:H7 remains the strain most frequently linked to sprout-associated outbreaks. Like *Salmonella*, *E. coli* O157:H7 is a pathogen that lives in the intestines of apparently healthy cattle and other animals, and can be found in water, food, soil, or on surfaces that have been contaminated with animal or human feces.

Pathogenic *E. coli* – Illness

- Low infective dose
- Produce a powerful toxin that can cause severe illness
- Symptoms usually begin 2 to 5 days after ingestion
- Symptoms include severe diarrhea (often bloody) and abdominal cramps
- Complications in children and elderly include:
 - Hemolytic Uremic Syndrome (HUS)
 - Kidney failure, sometimes death



The infective dose of *E. coli* O157:H7 is estimated to be very low, in the range of 10 to 100 cells, because the bacteria is acid tolerant and can grow in the intestines. The O157:H7 strain produces a powerful toxin that can cause severe illness. Symptoms of *E. coli* O157:H7 infection include severe diarrhea (often bloody) and abdominal cramps. In many cases, infection may not include fever or vomiting. Symptoms usually begin 2 to 5 days after ingestion of the bacteria. Sometimes people infected with *E. coli* O157:H7 have no symptoms at all, but can still pass the bacteria to others. In some people, especially in children under 5 years old and the elderly, *E. coli* O157:H7 infections can cause a serious complication called Hemolytic Uremic Syndrome (HUS), which can lead to kidney failure, other lifelong health problems or even death (Scallan et al., 2011).

3.2.2.3 *Listeria monocytogenes*

Listeria monocytogenes – Route of Contamination

- Widely found in nature
 - e.g., in soil, decaying vegetation, silage, and water
- Can establish in wet production environments, floor drains, etc.
- Outbreaks, positive samples and recalls associated with sprouts
- Able to grow at refrigeration temperatures as low as 31°F



Listeria monocytogenes is a bacterium widely found in nature and has been isolated from soil, decaying vegetation, silage and water. *Listeria* can be easily and frequently introduced into sprout operations on dust or on shoes, hands, seed or equipment, because it is widespread in the environment.

L. monocytogenes – Illness

- Most healthy people have mild or no symptoms
- Infective dose is lower for high risk individuals
- Severe listeriosis affects immunocompromised individuals and pregnant women
 - May cause meningitis, abortions, septicemia and death
- Listeriosis is the leading cause of death from foodborne illness in the U.S.

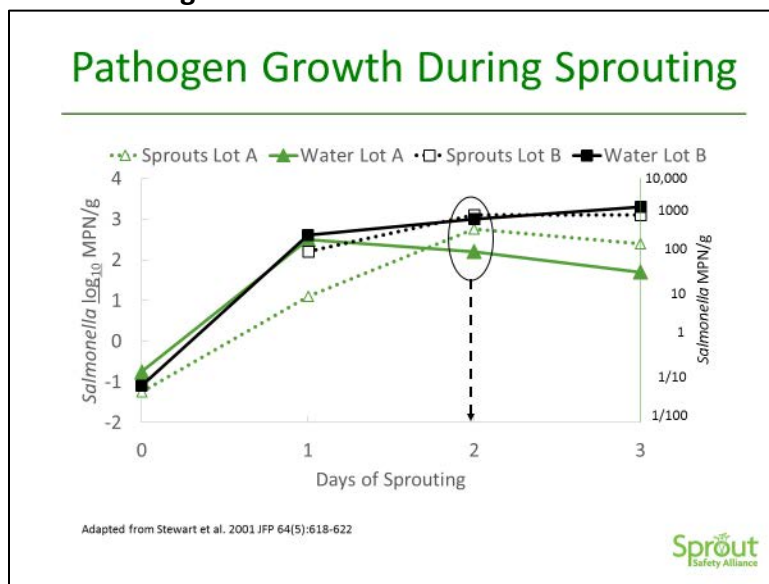


Most healthy individuals are either unaffected by *L. monocytogenes* or experience only mild flu-like symptoms. However, in susceptible people, it may lead to invasive listeriosis, which is a severe, sometimes life-threatening, illness. The infective dose of *L. monocytogenes* is lower for individuals prone to infection. People who have the greatest risk of experiencing listeriosis are pregnant

women and their unborn children, infants, the elderly, and persons with compromised immune systems.

Individuals with AIDS, cancer patients, individuals taking drugs that suppress the body's immune system, alcoholics and persons with low stomach acidity are at risk. Severe listeriosis can cause meningitis, spontaneous abortions, septicemia and a number of other maladies and can lead to death. Although not a leading cause of foodborne illness in terms of the number of cases, *L. monocytogenes* is among the leading causes of death from foodborne illness in the U.S.

3.2.3 Pathogen Growth and Survival



Sprouts are commonly eaten raw with little or no cooking prior to eating. Therefore, controls that prevent or reduce pathogen contamination during production and handling are especially important. Under the warm, humid, and nutrient-rich sprouting conditions, bacteria grow rapidly. The figure above illustrates growth of *Salmonella* during the sprouting of two different lots of naturally contaminated alfalfa seed that had been involved in foodborne illness outbreaks. *Salmonella* reaches the highest level within 48 hours of the start of sprouting. Non-pathogenic bacteria also grow, reaching even higher concentrations.

This slide illustrates that bacterial pathogens present at low levels on seed (in this case, less than 1 *MPN*/10g of seed) can multiply during the sprouting process to levels that can cause illness.

Definitions

Colony forming unit (CFU): A unit of measure of microbial populations when the method uses solid media, in which one bacterium or a small group of bacteria replicate many times to form a single, visible colony on growth media.

Most Probable Number (MPN): A unit of measure of microbial populations when the method uses dilution in multiple tubes of liquid media to estimate numbers.

Typically, MPN methods can detect lower numbers than CFU methods.

3.2.4 Control Measures for Bacterial Pathogens

Controls for Bacterial Pathogens

- Reducing or preventing contamination
 - § Examining seeds and packaging upon receipt
 - § Seed treatment
 - § Spent irrigation water testing
 - § Effective cleaning and sanitizing practices
 - § Employee practices/good hygiene
 - Prevent ill persons from handling sprouts

Subsequent modules discuss each of these



Definition

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

- 21 CFR 112.3

To control bacterial pathogens in food, three basic strategies are usually used: preventing contamination, killing them and controlling their growth. In the case of sprouts that are usually consumed raw, the primary control strategy for bacterial pathogens is to reduce or prevent contamination. This includes: obtaining seed from reliable sources, e.g., sourcing seed grown under Good Agricultural Practices (GAP) and handled under sanitary conditions; examining seed and packaging for signs of possible contamination upon receipt (§112.142(d)); ensuring seed is treated before sprouting using a scientifically validated method to reduce the level of pathogens, if present (§112.142(e)); testing spent sprout irrigation water for the presence of pathogens (§112.143(f)); following appropriate sanitary practices throughout all operations (§112.11); prohibiting people who are ill or are carriers of communicable diseases from working around food or **food contact surfaces** (§112.31); and preventing cross-contamination of finished product.

Refrigeration of Sprouts

- Proper refrigeration of finished product <41°F (5°C)
 - Controls growth of most pathogens but does not prevent their presence
 - *Listeria monocytogenes* can grow slowly at refrigeration temperatures



Proper refrigeration of finished product at the operation and during distribution (e.g., holding chilled sprouts $\leq 41^{\circ}\text{F}$ (5°C)) is required by the *FDA Food Code* and therefore by many retailers. While temperature control may inhibit or slow the growth of most bacterial pathogens, it is NOT a measure for controlling their presence.

Raw sprouts are considered a time/temperature control for safety (TCS) food and therefore require refrigeration.

- FDA Food Code 2013
 (<http://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm374275.htm>)

Additional Considerations for Controlling *L. monocytogenes*

- A ubiquitous environmental microorganism
- A recurrent source of product contamination once established
- Preventing *L. monocytogenes* from becoming established
 - Comprehensive cleaning and sanitizing programs
 - Effective environmental monitoring program
 - Focusing on the areas where *L. monocytogenes* is likely to become established

Further discussion in Module 6: Cleaning and Sanitizing and Module 7: Environmental Monitoring



Listeria monocytogenes is naturally soil borne and common in the environment. It is inevitable that it will occasionally enter sprout operations. If *Listeria* becomes established in an operation, it can serve as a source of repeated product contamination and potentially lead to foodborne illness outbreaks. According to CDC, pregnant women are 10 times more likely than other people to get *Listeria*

Definition

Monitor: To conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

- 21 CFR 112.3

infection, and the infection can cause miscarriages, stillbirths and preterm labor.

Listeria is likely to become established and grow in places that are consistently wet (either warm or cold) and difficult to effectively clean and sanitize. This includes such places as drains, cooling units, drip lines, dripping condensate and cold rooms. In order to effectively control the pathogen, sprouters must develop an environmental **monitoring** program of sampling and testing for *Listeria* designed to find *L. monocytogenes* if it is present in the operation (§112.143(d) and §112.145) and take certain actions to eliminate it (§112.143 (e) and §112.146), preferably before it has a chance to become established. Effective *Listeria* environmental monitoring programs routinely swab and test for the presence of *Listeria*, focusing on places where it is likely to become established and grow. More details about environmental monitoring can be found in Module 7: Environmental Monitoring for *Listeria* species or *L. monocytogenes* in a Sprout Operation in addition to other general control measures for bacterial pathogens, such as good sanitation in Module 6: Cleaning and Sanitizing Buildings and Equipment.

3.2.5 Other Pathogens of Concern

3.2.5.1 Viral Hazards

Viruses

- Highly infective
- Norovirus and Hepatitis A virus
- Control – proper employee hygiene, especially by preventing ill employees from working with or around food




Viruses are the most common cause of foodborne illness in the U.S. due to their highly infective nature. The viruses most commonly associated with foodborne illness are norovirus and Hepatitis A virus. Viruses do not grow in food and do not cause spoilage, but are very infectious, and generally require fewer than 100 virus particles to cause infection.

Viruses are readily transmitted through person-to-person contact, contact with contaminated surfaces and via contaminated food or water. They can be found in people who were previously infected but are no longer ill (i.e., carriers). Transmission of viruses to foods is usually related to poor hygienic practices, for example, by food handlers who fail to wash their hands properly. Contamination with viruses can be prevented by using proper employee hygiene practices, including exclusion of ill workers and carriers. More details about employee hygiene practices can be found in Module 5: Employee Hygiene and Health.

Norovirus

Norovirus

- Leading cause of illness from contaminated food in the U.S.
- Infected food handlers often involved in spreading the virus
- Symptoms include nausea, vomiting, diarrhea, abdominal cramps and, occasionally, fever
- Control: Proper employee hygiene practices
 - Handwashing
 - Excluding infected workers



Norovirus is the leading cause of acute gastroenteritis in the U. S. About 50% of all outbreaks of food-related illness are caused by norovirus. In many of these cases, infected food handlers are the source of the virus. People working with food while experiencing a norovirus illness or even a few days after they recover are highly likely to spread the virus to others by contaminating the food product or food contact surfaces.


Norovirus is highly infective, and only requires a very small number of virus particles (fewer than 100) to infect someone. Food can become contaminated with norovirus when infected people touch food or food contact surfaces, or if tiny drops of vomit from an infected person travel through the air.

Norovirus causes nausea, vomiting, diarrhea, abdominal cramps and occasionally fever. Symptoms usually begin 1 or 2 days after ingesting the virus, but may appear as early as 12 hours after exposure. The illness often comes on suddenly. The infected person may feel very sick and vomit often. They can continue to shed the virus for a few days after their symptoms resolve.

Hepatitis A Virus

Hepatitis A Virus

- A viral hazard in food
- Symptoms include weakness, jaundice, fever and abdominal pain
- Control: Proper employee hygiene practices



Hepatitis A virus is another example of a viral hazard that may be found in food. Hepatitis A virus often causes symptoms that include weakness, jaundice, fever and abdominal pain, and may sometimes cause serious illness in immunocompromised people.


3.2.5.2 Parasite Hazards

Agricultural water used as sprout irrigation water must have no detectable generic *E. coli* in 100mL.
- 21 CFR 112.44

Parasites of Concern

- Parasitic worms
- Protozoa (waterborne parasites)
 - *Cryptosporidium*
 - Oocysts can survive high levels of chlorine treatment
 - *Giardia*
 - *Cyclospora*

Agricultural water (§112.44) must be used in sprouting –
discussed in Module 4: Sprout Production Environment



Parasites are organisms that need to be on or in a host to survive and multiply. Outside the host, they exist in a dormant form (e.g., cyst or oocyst) that is resistant to environmental conditions. Two types of parasites can infect people through food or water: parasitic worms and protozoa. Parasitic worms may be associated with some animal products but are not likely to occur in sprouts. The waterborne

protozoans that have caused human illness are *Cryptosporidium*, *Giardia* and *Cyclospora* (FDA, 2012).

Using parasite-contaminated water in sprout production could potentially cause foodborne illness. Water that meets the Produce Safety Rule agricultural water standard (§112.44) must be used in sprout production. More details on agricultural water standard is discussed in Module 4: Sprout Production Environment.

Cryptosporidium

The principal source of *Cryptosporidium* is animals, both domestic and wild. *Cryptosporidium* is relatively widespread in the environment and is commonly found in rivers and lakes, especially when the water is contaminated with animal waste. *Cryptosporidium* oocysts resist conventional water disinfection methods, surviving the chlorine treatment levels typically used in post-harvest processes such as washing and cooling. Water that has been contaminated with *Cryptosporidium* should be filtered to remove it.

Giardia

Giardia is a parasite that causes a diarrheal illness called giardiasis. Giardiasis is one of the most common waterborne diseases in the U.S. The parasite is frequently found in untreated water from lakes, rivers, streams, ponds, or contaminated wells. As with *Cryptosporidium*, sanitizer levels typically used in post-harvest processes do not kill *Giardia* cysts.

Cyclospora

Cyclospora can be found in water contaminated with feces. It is a parasite that causes an illness called cyclosporiasis. In the U.S., foodborne outbreaks of cyclosporiasis have been linked to various types of imported fresh produce. The parasite usually causes watery diarrhea, with frequent, sometimes explosive, bowel movements.

3.3 CHEMICAL HAZARDS

Chemical Hazards

- Intentionally added chemicals or ingredients
- Unintentional chemical contamination
 - Seed treatment chemical residues
 - Cleaning and sanitizing chemical residues
 - Maintenance chemicals (e. g., lubricants)
- Food allergens
 - See Module 11: Additional Control Programs



Definition

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

- 21 CFR 112.3

Chemicals have many beneficial uses in food operations but can also pose a hazard if their presence and use is not appropriately controlled. Chemical hazards can introduce risk through intentional but inappropriate use, unintentional use or accidental misuse. Examples of chemical hazards include chemicals used to clean and **sanitize** tools and equipment, and chemicals used to maintain machinery. Food allergens are also considered chemical hazards under certain circumstances.

3.3.1 Intentionally Added Chemicals or Ingredients

Intentionally added chemicals include process aids and ingredients that are approved or recognized for use with food products or processes. Some intentionally added chemicals used with sprouts include sprout growth aids. They should be used in an appropriate or specified manner, consistent with their intended use, regulatory limits and/or expert advice. Likewise, they should comply with established food grade standards or guidelines that assure safe sources and composition.

Improper use or use of chemical compounds from unreliable sources can result in foodborne hazards that cause intoxication, allergic-type reactions or other adverse reactions.

3.3.2 Unintentional Chemical Contamination

Chemicals can contaminate food without being intentionally added. Seed treatment chemicals, cleaners, sanitizers, machine lubricants or inks that come in direct contact with ingredients or the product can be a source of unintentional or accidental chemical contamination. Depending on the type and amount of the chemical involved, contamination may be incidental, having little or no effect on food

safety, such as a sanitizer residue remaining on a food contact surface when applied per label instructions. In contrast, product contact with significant amounts of sanitizer residues on food contact surfaces when applied above label use instructions could represent a food safety hazard. Accidental additions of prohibited substances such as poisons, insecticides or other cleaning chemicals that may not be allowed at any level could result in food safety hazards.


3.3.3 Food Allergens

Many foods contain allergenic proteins that can pose a health risk to certain sensitive individuals; however, food allergen regulations do not apply to raw agricultural commodities. Food allergens are discussed in Module 11: Additional Control Programs.

3.3.4 Chemical Hazards Controls

Chemical Hazards Controls

- Train employees on chemical handling
- Obtain documentation from chemical suppliers (e.g., Safety Data Sheets)
- Maintain written procedures for chemical use
- Label chemicals
- Segregate chemical storage
 - Seed treatment chemicals, cleaners and sanitizers, maintenance chemicals (e.g., lubricants)
- Maintain a chemical inventory



Chemical hazards can be effectively controlled through documentation, employee training on their use and restricted access. It is important to review the Safety Data Sheet (SDS) accompanying each chemical to understand where each chemical comes from and make sure the operation has appropriate controls to manage possible hazards. Chemicals for different uses (e.g., seed treatment, equipment maintenance, cleaning and sanitizing) should be clearly labeled and stored separately. Never store chemicals in other than their original containers. When chemical solutions are mixed, store them in clearly labeled containers. Chemicals should be securely stored, such as in a locked cabinet or other secure area, when not in use. Access should be restricted to authorized personnel only. Operations should also limit the presence of chemicals to those that are necessary and approved for use in a food establishment. A current list of all chemicals present in the operation should be maintained.

3.4 PHYSICAL HAZARDS

Physical Hazards

- Any potentially harmful extraneous matter not normally found in food
- Including:
 - Glass (from glass breakage)
 - Metal (from equipment breakage)
 - Wood (chipping off from wooden surfaces)
 - Stones (present in incoming seed)
 - Plastic



Physical hazards include any potentially harmful extraneous matter not normally found in food. When a consumer mistakenly ingests the foreign material or object, it may cause choking, injury or other adverse health effects. While rare in food, physical hazards are the most commonly reported consumer complaints because the injury occurs during or soon after eating, and the source of the hazard is often easy to identify.

Physical hazards such as stones, debris, hard seeds, glass, metal and plastic may be present in incoming seed. Glass, brittle plastic, wood, metal fragments, nuts, bolts, rust and peeling paint inside the sprout operation could also become physical hazards in sprouts.

Controls for Physical Hazards

- Minimize glass in production areas
- Use shatter proof type of glass or cover with shield
- Regular inspection for signs of breakage and equipment wear
- Physical hazard detection
 - Inspect seed and finished products
- A regularly scheduled preventative maintenance program



Glass fragments can cause injury to the consumer. Overhead lighting, glass thermometers and all other sources of glass represent potential hazards. Normal handling and packaging and the movement of people, tools and equipment can result in glass breakage. While some glass, such as windows, may be unavoidable, the use of glass in the production environment should be minimized to reduce the potential hazard. Where glass is present, controls could include using safety type glass, installing light bulb protectors or other protections against breakage and a regular inspection plan for signs of damage. A glass control log that lists sources of glass in the operation, may assist in regular inspection for damage. Glass fragments originating from other sources should be addressed, where applicable, in pre-cleaning, rinsing and cleaning steps of sanitation.

Metal-to-metal contact, especially in mechanical cutting and blending operations, and in equipment that has parts that can break or fall off, such as wire-mesh belts, can introduce metal fragments into products. Such fragments serve as a hazard to the consumer. This hazard can be controlled by subjecting the product to metal detection devices and by regular inspection and maintenance of equipment.

Wood pieces can chip off from wooden surfaces. Wood is also difficult to clean and sanitize. Bacteria can persist on wood surfaces. Sprouters should work towards eliminating wood from all food contact areas of their operations due to microbial and physical hazards. A regularly scheduled maintenance program should be in place to effectively identify and address physical hazards.

Sprout Safety Hazards Summary

- Sprouts have been associated with foodborne illness outbreaks
- FD&C Act food safety hazards include biological, chemical and physical hazards
- Understanding and identifying hazards associated with sprout productions helps with:
 - Developing effective food safety programs
 - Implementing the *Produce Safety Rule* and best practices
 - Controlling the hazards



In summary, sprouts have been associated with foodborne illness outbreaks through the years. Food safety hazards that require

controls per the Food Drug and Cosmetic Act (FD&C) include biological, chemical and physical hazards. The *Produce Safety Rule* requires control of biological hazards because they have been associated with sprouts more commonly than other hazards. Control measures can differ by hazard types and product types. Understanding and identifying different types of food safety hazards in a sprout operation is the foundation for establishing and implementing effective food safety programs, and enhancing sprout safety.

3.5 REFERENCES

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Module 4. Sprout Production Environment

4.1 INTRODUCTION

Learning Objectives

- In this module, you will learn about requirements and recommendations for:
 - Building construction and design
 - Safe water
 - Pest control
 - Cross-contamination prevention
 - Preventive maintenance
 - Corrective actions for the above
- Importance of written Standard Operating Procedures (SOPs)



Maintaining an environment that promotes the hygienic production of sprouts and minimizes the potential for contamination is essential for sprout safety. Proper location and construction of buildings is important in protecting against potential sources of external contaminants (e.g., air contamination and pests) that may compromise the safety of food. Safe water, pest control and effective sanitation help to minimize the transfer of microbial, chemical and physical hazards in the operation. Contamination prevention and an effective preventive maintenance plan are also components of safe sprout production. Corrective actions for each of these programs are necessary when deviations from required performance occur.

4.1.1 Written Standard Operating Procedures

Standard Operating Procedures (SOPs)

- Detailed, written procedures for activities routinely performed
- Not required, but highly useful
- Importance of SOPs
 - Provide consistent instructions
 - Promote quality through consistent implementation
 - Minimize miscommunication and variation
- SOPs should be reviewed and modified if needed



Preparing written Standard Operating Procedures (SOPs) is an effective way to describe and manage processes that address sources of contamination. SOPs are detailed, written procedures for activities routinely performed in the operation.

While not required by the *Produce Safety Rule*, there are many benefits to having written SOPs. An SOP provides instructions on how to properly perform the activity or to follow a process. The development and use of SOPs are integral parts of a successful food safety system because they provide individuals with the information required to properly perform their jobs. Furthermore, the use of SOPs promotes quality through consistent implementation of a process, task or job. Also, when clearly written, SOPs can minimize miscommunication and variation among individuals within the sprout operation.

SOPs should be reviewed and updated, as appropriate, when operational conditions change, such as installation of new equipment. Annual SOP audits are also useful to identify changes in practices or conditions that may require SOP modification or re-training if changes are not appropriate.

Requirements for Sprout Production Environment

- Construction
- Building layout
- Sanitary facilities
- Use of water
- Pest control
- Waste management



The key requirements for the sprout production environment include:

- Sprouters must grow, harvest, pack and hold sprouts in a fully-enclosed building (§112.143 (a));
- The layout of sprout production must be designed to prevent contamination of sprouts or **food contact surfaces** (FCS) (§112.126(a)(1));
- Hand-washing stations must be adequate and readily accessible to facilitate the workers being able to wash their hands whenever necessary (§112.130(a));
- Toilet facilities must be equipped with hand-washing stations providing clean water, soap, and paper towels or other suitable drying devices (§112.130(b));
- All water must be safe and of adequate sanitary quality for its intended use (§112.41);
- Pests must be excluded at all times from sprout production buildings and from related buildings, such as storage sheds for packaging materials (§112.128(b)); and
- All waste material must be properly collected, stored and disposed of (§112.132).

Definition

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

- 21 CFR 112.3

Goal

- To prevent or minimize environmental contamination of sprout products to ensure sprout safety



In this module, in addition to the *Produce Safety Rule* requirements, recommended best practices for ensuring sprout product safety are discussed. The goal of having a safe sprout production environment is to prevent or minimize contamination of sprout products from the environment to ensure sprout safety.

4.2 BUILDING CONSTRUCTION AND DESIGN

4.2.1 Building Site and Construction

A variety of governmental agencies may regulate building construction and design at the federal, state, and local levels. Prior to remodeling or undertaking new construction, it is wise to contact the appropriate state and/or local jurisdiction to obtain required building permits and any necessary approvals. For example, a local city jurisdiction may require a plumbing permit and a building official may conduct an on-site inspection. This type of inspection is often required to confirm that the plumbing system has been properly installed to meet current code requirements.

The site selected for sprout production should meet current needs for safe production of sprouts, and have sufficient space for future growth. The site should be located where an **adequate** supply of water meeting the *Produce Safety Rule* requirements of §112.44(a), and proper waste disposal facilities (§112.132) are present.

Definition

Adequate: That which is needed to accomplish the intended purpose in keeping with good public health practice.

- 21 CFR 112.3

Considerations for Buildings

- § **Fully enclosed**, preventing ingress of pests, filth and other contaminants
- § Supply of water is safe and of adequate sanitary quality for its intended use
 - Leak-free roof and walls



The sprout production buildings must be fully enclosed (§112.143(a)) and have barriers to prevent ingress of **pests** (§112.128(b)), filth and other contaminants. The buildings should not have unprotected openings to the outside. For example, if holes in the walls around pipes are larger than the diameter of a pencil, they should be sealed with insulating foam sealant to prevent entry of pests. Supply of water in the building must be safe and of adequate sanitary quality for its intended use (§112.41). The buildings' roofs, ceilings and walls should not leak.

Definition

Pest: Any objectionable animals or insects, including birds, rodents, flies, and larvae.

- 21 CFR 112.3

Considerations for Doors and Windows

- Doors
 - Tight-fitting; open outward; production doors do not open directly to the outside
- Windows
 - Fit properly; kept closed or screen intact



Photo source: USDA



Doors should be tight fitting and kept closed when not in use. They should open outward because pressure forces inside air out when a door opens outward as opposed to outside air flowing into the operation when a door opens inward. An outward opening door can

reduce the likelihood of airborne contaminants (e.g., microorganisms and filth) entering the operation. Buildings should be constructed so sprout production rooms do not open directly to the outside. Rather, entrances into the operation should lead to hallways and anterooms that provide an additional physical barrier. Where high rodent pressure exists, wire mesh (minimum of one foot below ground level) may be needed along walls where building foundations are not adequate to prevent entry of pests.

Windows should be shatter proof, properly fitted and kept closed at all times unless screened. Screens should be intact and of a small enough mesh size to prevent entry of small insects. Operations located in dusty areas, or in areas likely to have airborne particulate matter from industrial sites, should keep windows shut.

Other buildings on the property that are used as part of the sprout operation, such as sheds, greenhouses and storage buildings, should also be constructed, designed and maintained in a suitable manner. For example, storage buildings need to protect packing material and food contact surfaces of equipment from known or reasonably foreseeable hazards (§112.126(a)(1)(ii)), and should be enclosed, clean and in good repair. Conversely, a building that stores a tractor does not need to be enclosed.

4.2.2 Building Interior

Building Interior

§ Floors, walls and ceilings

- Durable, impervious, smooth and cleanable

§ Adequate drainage

- Ventilation, temperature and humidity controls
 - No dripping or condensation build-up
 - No airflow from dirty to clean areas
- Adequate lighting





Photo source: USDA



Within the sprout production buildings, sprouters must implement measures to prevent contamination of the sprouts and food contact surfaces from floors, walls, ceiling, fixtures, ducts, pipes, drip or condensate (§112.126(b)). Good practices include having floors, walls and ceilings that are constructed of materials that are durable, impervious, smooth, cleanable, and suitable for the production conditions in the area. Adequate drainage must be provided in all


areas where normal operations release or discharge water or other liquid waste on the ground or floor (§112.126(a)(2)). The floors should be sloped towards trapped drains with covers because water must not accumulate in low spots (§112.126(a)(2)). Stagnant water accumulated on floors can harbor pathogens, especially *Listeria monocytogenes*. The floors and walls should be cleanable and kept in good repair.

Design ventilation, temperature and humidity controls to minimize the potential for condensate to form on the ceiling and drip onto sprouts, food contact surfaces and food packaging materials. Measures must be implemented to prevent contamination of sprouts and food contact surfaces in the buildings by dripping/condensation (§112.126(b)(2)). The ventilation duct systems should be constructed to avoid airflow from dirty areas to clean areas and should be designed to allow for adequate cleaning and maintenance. They should have close-fitting screens or filters installed.

Lighting should be adequate and lights should be shatterproof or protected (with shatterproof covers) from shattering onto food or food contact surfaces. Extra lighting may be needed for sanitation and inspection.

Building Layout

- § Size, construction, design facilitates maintenance and sanitary operations
- § Layout **must** prevent contamination of sprouts and food contact surfaces, e.g.,
 - Separate production and packaging area from others
 - Enough space to access and clean equipment
 - Design for traffic flow
- Dedicated area for “positive” sample lots



The layout of the sprout production buildings must be designed to prevent or minimize contamination (§112.126(a)(1)). This can be accomplished by separating seed storage, seed sanitation, seed germination/sprout production and packaging areas by walls, curtains or other clear designations. Enough space must be available to allow for accessing, cleaning and storing equipment and facilities (§112.126(a)(1)(i)). Sprouts that are found to be potentially contaminated should be separated from other production lots. Traffic flow (i.e., employee and equipment movement throughout the building) should not lead to contamination. More information about

traffic flow can be found in the “Prevention of Cross-contamination” section of this module.

4.2.3 Sanitary Facilities

§ Hand-washing Stations

- Easily accessible
- Sufficient numbers
- Running water that meets the *agricultural water* standard
- Equipped with soap and hand-drying devices



Definition

Agricultural water: Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

- 21 CFR 112.3

Hand-washing stations should be located at all entrances into the sprouting and packaging room(s). The hand-washing stations in the sprouting and packaging rooms must be adequate and readily accessible to facilitate the workers being able to wash their hands whenever necessary (§112.130(a)). Water used for hand-washing must meet ***agricultural water*** standards; i.e., have no detectable generic *E. coli*/100 mL of water as required under §112.44(a), and preferably at a comfortable temperature. Soap and disposable paper towels or other suitable drying devices that do not contribute to post hand-washing contamination (§112.130(b)) must also be provided. In addition to hand-washing stations, an operation may wish to have hand sanitizer dispensers, aerosol spray devices, or simply hand-dip bowls of solution for quick hand sanitation. However, use of hand sanitizers of any kind are not permitted/allowed as substitutes for proper and timely hand-washing (§112.130(d)).

Toilet Facilities

- § Functional
- § Located in enclosed buildings
- § Equipped with hand-washing stations, soap and hand-drying devices
- § Routinely cleaned and maintained
 - Shouldn't open directly to the production areas



Sprout
Safety Alliance

Toilet facilities must be designed, located, and maintained to prevent contamination of the sprouts, food contact surfaces in sprout production, water sources and water distribution systems with human waste (§112.129(b)(1)). The toilet facilities in enclosed buildings (§112.129(c)), must be equipped with hand-washing stations providing clean water, soap, and paper towels or other suitable drying devices (§112.130(b)). An adequate supply of toilet paper at each toilet is necessary. The toilets must be functional and convey waste to properly discharge sewage or septic plumbing systems (§112.131(a)). The toilets must not leak onto the floor when flushed and must be routinely cleaned and maintained (§112.129(b)(2)). Clogged, leaking, and broken toilets must be repaired immediately (§112.129(b)(2) and §112.131(c)). Restrooms should not open to sprout production areas.

Hand-washing and toilet facilities should be checked at least once per day to ensure that they are clean, functioning properly and have the necessary supplies. If supplies are depleted, the facilities must be restocked (§112.129(b)(2) and §112.130(b)).

Sanitizer concentrations must be prepared by following the manufacturer's label instructions. These labels state the concentration and contact time for different types of materials being treated.

Other Facility Considerations

- Dedicated footwear and/or foot bath
 - For preventing introduction of contamination
 - With effective sanitizer concentrations
- Lunchrooms, break areas and locker rooms
 - Separated from production areas
 - Routinely cleaned and maintained



A system for preventing introduction of contamination on footwear into production areas should be in place. When a sprout operation decides to use foot-sanitizing devices such as troughs or mats (“foot baths”), automatic sprayers, or automatic boot washers, they should be located at entrances to production areas. Sanitizing solutions should be prepared at effective concentrations following the product label, and monitored and replenished throughout the day as necessary. Dedicated footwear for sprout production areas could also be used to minimize cross-contamination, regardless of the use of footwear sanitizer systems.

Lunchrooms, employee break areas and employee locker rooms should be separated from sprout production areas by walls, curtains or other clear separators. These areas should be kept clean and orderly in order not to contribute to cross-contamination by employees moving into the operation and not to serve as attractants and/or harborage areas for pests.

4.2.4 Building Construction Corrective Actions

Corrective Actions – Building Construction

- Seal gaps in walls or doors
- Improve cleaning
- Increase ventilation
- Insulate pipes, walls or ceilings
- Physically prevent condensation



When conditions other than those required by the *Produce Safety Rule* are observed in practice, actions must be taken to correct the situation. As an example of a **corrective action**, if gaps or openings are observed in the walls or doors of sprout production rooms, they should be sealed to prevent the entry of pests.

Growing, packing rooms and seed storage rooms, should be monitored, on a schedule based on a review of the risks, for:

- possible condensation dripping on food or food contact surfaces and
- mold growing on wet or damp surfaces.


When a problem is noted, corrective actions may include removing the mold, increasing ventilation, insulating pipes or walls or ceilings, and/or physically preventing condensation from dripping onto sprouts or food contact surfaces.

4.3 SAFE WATER

4.3.1 Water Sources

§ Agricultural Water

- Water must be safe and of adequate sanitary quality for its intended use:
 - Numerical criteria: **no detectable *E. coli*/100 mL**
- **Must** meet these requirements if used for:
 - Seed treatment
 - Sprout irrigation, and post-harvest washing of sprouts
 - Cleaning of equipment and food contact surfaces
 - Ice-making
 - Hand washing



Water requirements are covered in Subpart E - Standards directed to agricultural water in the *Produce Safety Rule*. Regulation citations are provided in the discussion that follows to enable sprouters to review the details, if desired.

The primary consideration regarding the quality of **agricultural water** (“ag water”) is that it comes from a stable, consistent source, and that the plumbing and holding systems do not introduce microbial contamination into the water. The basic requirement is that all water must be safe and of adequate sanitary quality for its intended use (§112.41).

Sprouters must ensure that the quality of agricultural water meets the requirements in §112.44(a) using a quantitative method (outlined in §112.151) to ensure that there is no detectable generic *E. coli* in 100 mL of agricultural water. Exceeding the numerical criteria under §112.44(a) also violates §112.41.

Ag water requirements apply when water is:

- 1) used to rinse or presoak seed
- 2) used as sprout irrigation water;
- 3) applied in any manner that directly contacts sprouts during or after harvest activities, including when used to make ice that directly contacts sprouts during or after harvest activities;
- 4) used on food-contact surfaces, or to make ice that will contact sprouts or food-contact surfaces; or
- 5) used for washing hands.

Definition

Agricultural water: Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

- 21 CFR 112.3

Use of Municipal Water

- National drinking water standards meet or exceed ag water requirements
- Public water system test results or certificates of compliance with the *Safe Drinking Water Act* also demonstrate ag water standard compliance



Many sprout operations use municipally treated or public (community) water that meets or exceeds nationally established drinking water standards in the *Safe Drinking Water Act*. There is no requirement to test any agricultural water when sprouters receive water from a public water system or supply that furnishes water that meets the microbial quality requirement of the *Safe Drinking Water Act*, the regulations of a State approved to administer the Act (§112.46(a)(1)), or §112.44(a) of the *Produce Safety Rule* (§112.46(a)(2)). However, sprouters must have public water system results or certificates of compliance that demonstrate that the water meets the requirements in §112.46(a)(1) or §112.46(a)(2). For regulation of drinking (potable) water, see the standards established by the U.S. Environmental Protection Agency (EPA, 2004).

§ Requirements for Agricultural Water

- Inspect water systems at **least once a year**
 - Water source
 - Water distribution system
 - Facilities
 - Equipment
- Adequately maintain the ag water distribution systems and sources under sprouter control
- Implement measures to reduce the potential for contamination



Definition

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

- 21 CFR 112.3

Sprouters must identify sources of agricultural water used during production to ensure that all water sources are included in inspection activities. Additionally, the **water distribution system** that is under the control of the operation must also be inspected (§112.42). Inspection of agricultural water sources and distribution systems is required at least once per year (§112.42(a)). Elements to evaluate, consider and observe during inspection include surveying conveyances, water impoundments, and delivery systems from municipalities and wells. Consideration should also be given to water delivery to the operation, such as delivery systems from municipalities and piping systems from off-farm wells. These can influence water quality. Under 112.42(b) and 112.42(c), sprouters must adequately maintain the agricultural water distribution systems and sources that are under their control. Maintenance activities include, but are not limited to, inspecting the source, correcting any deficiencies observed through the inspection and keeping the source free of debris. Sprouters must implement measures reasonably necessary to reduce the potential for the water they use serving as a source of contamination of the sprout products.

Definition

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

- 21 CFR 112.3

Safety of Well Water

§ Private water wells providing untreated ground water must:

- Meet agricultural water standard
- Be properly constructed and maintained
- Be inspected once a year
- Meet maintenance requirements
- Best practice:
 - Inspected twice a year or after adverse event such as flooding



Private water wells providing untreated **ground water** on a sprouter's property or on an adjacent or a nearby property may also be used as an agricultural water source. Wells should be properly located and constructed to avoid contamination from underground or above-ground pollution or hazardous materials. The well, its piping and casing should be properly constructed to protect against environmental contamination, and must be adequately maintained (§112.42(b)).

Well Water Testing

§ Meet agricultural water standard

- Tested 4 times a year initially
- Tested at least once/year if initial sampling results meet agricultural water standard
- Consider seasonality and location to determine frequency of sampling
- Best practice:
 - Use a qualified lab for water testing



Sampling strategies should consider the agricultural water source, extent of control, seasonality, location and water uses among other factors. If the untreated ground water is used for agricultural water purposes (§112.44(a)), sampling and analysis must be performed according to §112.46(c). This provision outlines that the microbial quality of each agricultural water source must initially be tested at least four times during the growing season or throughout the year. §112.46 outlines how samples must be collected and analyzed. If initial sampling results meet the *Produce Safety Rule* requirement of no detectable generic *E. coli* in 100 mL of agricultural water, the required water sampling frequency is reduced to testing at least once annually thereafter.

An operation's agricultural water sampling plan must consider all sources and uses of agricultural water, and may include multiple sampling points to evaluate water quality over time (§112.46(b)(2)). Requirements for testing frequency are outlined in §112.46(c). Samples must be aseptically collected and handled in a manner to prevent contamination (§112.47(b)). Accredited laboratories commonly provide advice on appropriate sample containers and sampling procedures. A qualified laboratory (see the laboratory discussion in Module 7: Environmental Monitoring) should analyze the samples for compliance with required microbial criteria using the method outlined in §112.151. If a new well is drilled and there are chemical concerns, chemical testing is advisable.

4.3.2 Water Treatments

§ Water Treatment Considerations

- When ag water exceeds *E. coli* requirements, water treatment may be applied
- The treatment must follow the manufacturer's instructions and regulatory requirements
- Treatment systems must be monitored to ensure effective performance



If the agricultural water used in a sprouting operation exceeds the no detectable generic *E. coli* limit, two corrective action options are outlined in §112.45(a). One of those options is to treat the agricultural water, as described in §112.43, so that it meets the *E. coli* limit. For example, sprouters may treat their ag water with chlorination, filtration, ultraviolet (UV) light, reverse osmosis or other methods. Treatments must follow manufacturer's instructions and regulatory requirements under the *Produce Safety Rule* (§112.43). The treatment must be effective and delivered to consistently render the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria, as applicable, under §112.44. Water treatment systems must be monitored at a sufficient frequency and in a manner to meet required standards and criteria under §112.43(b). For example, the concentration of chlorine may need to be monitored at regular intervals throughout the day to ensure that it remains at an effective level.

4.3.3 Plumbing Systems for Water and Water Storage

Plumbing and Water Storage


§ Plumbing systems:

- Delivery of safe water
- Designed to prevent backflow from, or cross-connection between, sewage and ag water

• Water storage:

- Container design and construction should protect against contamination

§ Properly maintained and regularly inspected



The plumbing system within the operation must not be a source of contamination (§112.133 (c)). All water lines with hose attachments, faucets and other such outlets used to carry water for sprout production, sanitary operations or hand-washing facilities must be designed or equipped with suitable devices to prevent backflow (§112.133(d)). There must not be backflow or cross-connections between pipe systems that discharge wastewater or sewage and pipes that carry water used for sprouting operations (§112.133(d)). Some sprouters use both municipal and untreated ground water drawn from a well in their operations. In this case, the water systems for each source should be separable to allow for isolation of each system.

Routine inspection of plumbing cross-connections may be sufficient, but if a problem is identified, more frequent observation may be required. Improper practices such as leaving open-ended hoses on the floor or submerged in tanks of liquid should be avoided. The EPA's *Cross-Connection Control Manual* (EPA, 2003) is an excellent reference regarding situations leading to contamination through cross-connections and backflow, as well as proper devices and prevention procedures.

When it is necessary to store agricultural water, such as in holding tanks, the storage containers should be designed and constructed using materials that prevent them from becoming a source of contamination. They must be adequately maintained and regularly inspected to prevent known or reasonably foreseeable hazards (§112.42(b)).

4.3.4 Post-harvest Agricultural Water Uses

§ Post-harvest Agricultural Water Use

- Manage the water to minimize the potential for contamination of sprouts and food contact surfaces
 - e.g., follow water-change schedule
- Visually monitor the water quality
 - Minimize build-up of organic materials (e.g., soil or sprout debris)



Definition

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

- 21 CFR 112.3

There are provisions related to water used to wash or cool down sprouts during harvest, packing, and holding, such as requirements to establish and follow water-change schedules for re-circulated water to maintain its safety and adequate sanitary quality and to minimize the potential for contamination of the sprouts and food contact surfaces with **known or reasonably foreseeable hazards** (§112.48(a)). Sprouters must visually monitor the quality of water that is used during harvest, packing, and holding activities of sprouts (for example, water used for washing sprouts in dump tanks) for buildup of organic material (§112.48(b)).

4.3.5 Agricultural Water Safety Corrective Actions

§ Corrective Actions –
Agricultural Water Safety

- | | |
|--|--|
| <ul style="list-style-type: none"> • Take corrective actions when: <ul style="list-style-type: none"> - Safety of the source has been compromised - <i>E. coli</i> is detected in 100mL of water | <ul style="list-style-type: none"> • Corrective actions: <ul style="list-style-type: none"> - Re-inspecting / treating water system - Make necessary changes - Determine the changes were effective • Document all actions |
|--|--|

Dispose of seeds and sprouts that may have been exposed to contaminated water



If the safety of a water source has been compromised- and/or *E. coli* is detected in 100 mL of water (i.e., exceeds criteria in §112.44(a)), the operation must immediately discontinue use of the agricultural water and take corrective actions before using the water again. Options for required corrective measures related to water are outlined in §112.45(a) and include:

- inspecting the water system, identifying any conditions that are reasonably likely to introduce hazards, making necessary changes, and determining whether changes were effective; or
- treating the water from the compromised source in accordance with §112.43, which was discussed in section 4.3.2 of this manual.

Microbiological testing of the agricultural water source is one method for confirming that corrective actions were effective. Corrective actions may also involve the use of a different water source that has been shown to meet the microbial quality criteria of §112.44(a).

Disposal of seeds and sprouts that may have been exposed to contaminated water may be necessary. Sprouters must maintain records of any corrective actions in response to exceeding required microbial limits. For example, water inspection and treatment documents are discussed in §112.50(b)(6) and the next section.

4.3.6 Recordkeeping for Agricultural Water


Water Records

§ Records that must be kept:

- Water quality analysis reports
- Corrective actions
- Water system inspection (once a year)
- Water treatment if treated
- Must be kept for at least 2 years

• Other records that should be kept:

- Water bills



Water quality analytical reports (e.g., annual test result documentation from municipalities, or certificates of compliance from a public water system or from laboratories) must be retained (§112.50(b)(7)). Sprouters must retain results of the examination of


its water source and distribution system under §112.42 (§112.50(b)(1)). The records of any analytical testing done as a part of meeting the agricultural water numerical criteria (§112.44(a)) and water testing requirements (§112.46) (§112.50(b)(2)). Sprouters must maintain records of any corrective actions in response to microbial exceedance under §112.45(a) (§112.50(b)(6)). Any water treatment that the sprout operation employs under §112.43) must be documented (§112.50(b)(3) and §112.50(b)(4)). Records of inspections, such as plumbing monitoring records, must be completed at least annually §112.50(b)(1). All required records must be kept for at least two years past the date the record was created §112.164(a)(1)).

Module12: Recordkeeping, provides additional information on recordkeeping requirements.

4.4 PEST CONTROL

Pest Control

- Four components of an effective pest control program:
 - Elimination of shelter and attractants outside and inside
 - Exclusion of pests from the sprouting operation
 - Detection and elimination of pests that gain entry into the operation
 - Monitoring for pests



Pests must be excluded at all times from sprout production buildings and from related buildings, such as storage sheds for packaging materials (§112.128(b)). Pests include insects (such as flies, roaches, and larvae) or animals, including rodents and birds. These pests can be carriers and sources of many types of bacterial pathogens and parasites that can cause foodborne illness. Thus, the presence of pests in sprout production buildings can lead to microbial contamination of the sprouts and result in illness to consumers. In addition, pests can be sources of filth in sprouts, including insect parts, hair, and excreta. Birds and rodents can be attracted to seeds used for sprouting. Protect seed from pest contact and clean up any spilled seed immediately.

4.4.1 Elimination of Shelter and Attractants

Eliminate Pest Shelters & Attractants

- Well maintained and drained grounds outside sprout production buildings
 - Clear border around building
- § No animals allowed (*see exceptions in text*)
- § No debris or litter, no attractants near entrance or loading dock
- Sufficient space allowed for personnel to monitor for pests



Sprouters must take measures to prevent pests from becoming established in the operations (§112.128). Well-maintained grounds around sprout production buildings can discourage pests. The grounds in the immediate vicinity should be mowed and free of tall weeds, grass and brush. A border around the building should be cleared of all vegetative material and filled with stones or other non-compostable material. The property should be well drained and have smooth parking areas and driveways to minimize standing, stagnant water that can serve as a breeding ground and water source for pests.

Proper housekeeping is important for pest control. Animals must be excluded from the operation (§112.127). An exception is guard or guide dogs if their presence is unlikely to contaminate the sprouts, food contact surfaces or food-packing materials. Eliminate any attractants inside and outside, especially near entrances and loading docks. Trash, debris and clutter that rodents and flies find desirable for hiding and nesting must be removed frequently to minimize the potential for them to attract and harbor pests (§112.132(a)(1)). Compostable waste should be removed from the operation daily and protected from pest infestation.

Pre- and/or post-operation inspections should be made every production day. There should be sufficient space in the sprout production buildings to allow for personnel to thoroughly monitor for pests, particularly around the perimeter of the rooms. Any old or unused equipment, packaging, or other items not being actively used should be removed from the production environment.

4.4.2 Exclusion of Pests from the Sprouting Operation

Exclusion of Pests

§ Proper maintenance of walls, floors and ceilings

- Preventing insects entering the building
 - Self-closing doors
 - Tight-fitting doors, screens and windows
 - Air curtains or overhead fans at entry ways
- Employee training
- Clean and covered waste containers



A sprouting operation is highly attractive to birds, rodents and flies. Proper maintenance of walls, floors and ceilings must be implemented to ensure that pests are prevented from entering the operation (§112.128(b)). Doors should be self-closing; windows, doors and screens should be tight-fitting. Workers should be instructed not to leave doors open for ventilation or while on breaks. Screens should have a mesh size small enough to prevent flies from entering. Air curtains or overhead fans may be used at entry ways. Workers should be trained for pest control. Waste containers should be clean and remain closed. More details about waste management can be found in a later section.

4.4.3 Elimination of Pests that Enter the Buildings

Elimination of Pests

§ Pests that gain entry into the buildings must be eliminated from production areas

- Elimination devices:
 - Rodent traps
 - Insect sticky traps
 - Black-light traps for flies (*zappers not recommended*)
- No bait stations with poisonous chemicals inside the operation



Pests that get in the building must be eliminated from production areas (§112.128(c)). Many devices are available that, if used and located appropriately, can help exclude pests from sprout production areas in buildings and eliminate those pests that gain entry. These devices include rodent traps and insect sticky traps.

Since many flies are attracted to light, black-light traps with replaceable sticky boards used at night or in rooms with no natural light can be effective in trapping flies that have gained entrance. Electric “zapper” black lights are not recommended since flies and other insects can explode on contact, causing contamination to become airborne, and may contaminate a large area near the trap.

Generally, no pesticides should be used inside the operation. If a serious pest issue exists inside the operation and pesticide application may be necessary, use the services of a licensed pest control professional.

4.4.4 Pest Monitoring Program and Documentation

Monitoring and Recordkeeping for Pests

- Monitoring
 - Inside and outside the operation
 - Train pest monitoring personnel
 - Use proper detection equipment
- Pest control documentation
 - Monitoring records and corrective actions
 - Diagrams of traps and baits locations
 - Detailed pest control activities



It is imperative that a strong monitoring program is instituted for pests. This includes both outside and inside the operation. Two key things to define are: 1) what to look for and 2) where to look for it. Personnel who monitor for pests should be trained to identify evidences of pest activities. For example, they should be able to identify rodent droppings, rodent hairs, and rodent gnawed materials. They should have the proper equipment to look for pests, such as flashlights and black lights for detecting rodent urine stains. Personnel should know where to look for pests, such as cluttered areas inside and outside the operation, dark areas (with a flashlight), spare rooms that are rarely used or opened, behind and underneath equipment, “dead” areas on equipment where food can be trapped, electrical panel boxes (particularly for roaches) and drain traps.

Bait stations with poisonous chemicals should never be used inside the operation where they can contaminate seeds, sprouts, packaging or equipment, and endanger workers. Traps, such as sticky boards, can be used indoors for rodents and cockroaches. A cockroach or rodent sighting during daylight is a sign of widespread infestation of the operation and a licensed pest-control service should be contacted.


Sprouters should maintain records showing the results of pest exclusion monitoring and corrective actions. It is helpful to have diagrams and schematics showing the locations of traps and bait stations.

Sprouters should request and retain detailed records from commercial pest control companies showing the pests they found, where they were found, what areas they treated, and the pesticides and baits they used. Some pest control companies provide detailed trend analysis that enables both the applicator and the sprout operation to target areas for additional treatment and to track the effectiveness of current application regimes. If a sprouter uses a contractor for pest control, the contractor must be made aware of the policies and procedures of the operation (112.33(a)).

4.4.5 Pest Control Corrective Actions

Pest Control Corrective Actions

- Investigate and identify the source of the pests
- Understand the cause of the problem
- Review historical pest control records
- Pay attention to seasonality and activities around the building
 - Mowing
 - Crop harvesting on adjacent land
 - Construction activities




Sprouters must take measures reasonably necessary to protect sprout products, food contact surfaces and packaging materials from contamination by pests (§112.128). Therefore, if pests gain entry into the operation, corrective action is necessary. Sprouters should investigate and identify the source of the pests, how they gained entry into the operation, and where they were located so the firm can make appropriate corrections to prevent or minimize future occurrences. In addition, it can be useful to review historical pest

control records to determine if pest detection and/or ingress have been frequent in the identified locations and to identify the reasons for a higher incidence of pest activity. Factors such as seasonality, activities around the building (e.g., mowing and construction activities) and sources of pests may impact the activity and movements of pests.

4.5 CONTAMINATION PREVENTION

Contamination Prevention

- Potential contamination sources
 - Soil and soil amendments
 - Waste
 - Floors and floor-splash
 - Traffic flow
 - Employees
 - See Module 5: Employee Health and Hygiene Practices in Safe Sprout Production
 - Unclean equipment
 - See Module 6: Cleaning and Sanitizing Buildings and Equipment



Several potential sources of contamination exist in the sprout production environment. In addition to topics previously discussed in this module, other potential sources of contamination exist. For example, when used to grow sprouts, soil and soil amendments are potential sources of contamination that should be managed as appropriate to the potential risk for contaminating the sprout environment. Waste generated during the sprouting process can also be a potential source of contamination, especially if it is not managed to prevent a harborage site for pests, as previously discussed. Floors and floor-splash can also contaminate sprouts if not effectively managed. Improper traffic flow could be another potential cause of contamination that should be addressed to minimize the potential of contamination. Employees and unclean equipment are also potential sources of contamination that are addressed in subsequent modules. This section addresses consideration to minimize the potential for contamination from other sources listed above.

Contamination must be minimized in a sprout production environment through awareness and prevention of potential avenues of such contamination.

4.5.1 Soil Amendments and Soil-grown Sprouts

Soil- or substrate-grown sprout shoots that are harvested above the soil or substrate line without their roots are excluded from Subpart M requirements (§112.141). However, soil- or substrate-grown sprouts harvested above the soil line are subject to all other applicable requirements of the *Produce Safety Rule*.

Contamination Considerations for Soil-grown Sprouts

- Soil is a potential source of contamination
- Grow and package soil-grown sprouts in a separate area from other sprouts
 - Restrict worker and equipment flow
- § Clean and sanitize soil-grown sprout packaging areas between uses
- § Handle and store growth media to prevent contamination
- Treat growth media (e.g., compost/vegetable waste) to eliminate pathogens



Definition

Growth media: Material that acts as a substrate during the growth of covered produce (such as mushrooms and some sprouts) that contains, may contain or consists of components that may include any animal waste (such as stabilized compost, manure, non-fecal animal byproducts or table waste).

- 21 CFR 112.3

Some operations grow sprouts or sprout shoots, such as sunflower sprouts, in soil or other **growth media** (see definition and text box). The potential for soil and growth media contamination should be considered. For example, a sprout-associated salmonellosis outbreak (CDC, 2011) was traced to a facility where run-off from a compost pile containing vegetative waste was located near an employee walkway. The outbreak strain of *Salmonella* was isolated from the runoff water near a walkway, and employees walked between production and compost areas.


Sprouters must implement measures to ensure that growth media and media-grown sprouts (or other products) do not serve as a source of contamination to other sprouts or the areas used to grow or package them. This may include measures to prevent cross-contamination of growing areas through the movement of workers, tools or equipment (§112.132). Ideally, media-grown sprouts should be grown and packaged in a separate area that is cleaned and sanitized between uses. If the same room is used to package media-grown sprouts and other sprouts, media-grown sprouts should be brought in when no other product is being packaged. All surfaces must be cleaned and sanitized before they contact sprouts (§112.143(b)), including surfaces that contact media or media-trays.

When growth media is known to contain significant animal feces (manure), it is considered a Biological Soil Amendment of Animal Origin, which is subject to the requirements in Subpart F (discussed below). Vegetative waste that does not contain materials of animal origin are not subject to the requirements in Subpart F; however, sprout operations should consider Subpart F requirements that are appropriate for their operation to ensure vegetative waste is treated and handled in a manner that prevents contamination. For example,

if a sprouter produces their own green waste-based growth medium, it should be treated using procedures for reducing or eliminating pathogens. In addition, treatment and holding areas for vegetative waste should be located far enough from sprout production areas to prevent contamination by pests, water runoff, airborne contaminants or worker movement between production rooms.

§ Biological Soil Amendments of Animal Origin (BSAAO)

- Must maintain pertinent documentation
- The records (e.g., Certificate of Conformance) must verify that:
 - Scientifically validated method used
 - Amendment being handled, conveyed and stored properly



If a sprouter receives treated **biological soil amendments** of animal origin from a third party, they must maintain documentation consistent with requirements in §112.60(b)(1). The records (e.g., Certificate of Conformance) must verify that:

- 1) the process used to treat the soil amendment of animal origin is a scientifically valid process that was carried out with appropriate process monitoring; and
- 2) the soil amendment was handled, conveyed and stored in a manner and location to minimize the risk of contamination after the treatment of the amendment.

Process verification records are not required for biological soil amendments containing only vegetative waste, but this may be useful for enhanced assurance.

Definition

Biological soil amendment:
A biological amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

- 21 CFR 112.3

4.5.2 Waste Management

§ **Waste Management**

- Must convey, store and dispose of trash, litter and waste to:
 - Minimize the potential to attract or harbor pests
 - Protect against contamination of sprouts, food contact surfaces and water sources
- Must adequately operate systems for waste treatment and disposal



Sprouters must prevent contamination of sprouts, food contact surfaces and water sources with pathogens from trash, litter and waste (§112.132). Trash containers, both small and large, should be leak-proof, durable, clearly labeled, kept as clean as is practical and tightly covered. An operation must minimize the potential for trash to attract or harbor pests (§112.132(a)(1)). Avoid placing outside trash containers near entrances into the operation and loading docks, particularly if the containers are dirty and contain decomposing waste materials. Such a situation provides an excellent opportunity for flies, birds and rodents to be attracted to the area and gain access into the building.

All waste material should be properly collected, stored and disposed (§112.132(a)). It is important to keep the grounds outside free of waste; for example, by picking up any waste spilled while emptying containers. Sprouter must operate systems for waste treatment and disposal so that they are not a potential source of contamination in the operation (§112.132(b)). Sprout production waste should be removed from floors and drains and taken from the production area at least daily. Food waste containers inside the operation should be tightly covered and be emptied daily (or more often, if necessary) to avoid being an attractant to pests. Waste should never move through sprout production or packaging areas when there is risk of cross-contamination with the products.

4.5.3 Floor Splash

Contamination from Floor Splash

- Prevent transfer of pathogens through water and aerosols
- § Prevent contamination of food contact surfaces or products
 - During cleaning
 - During human and equipment movement (e.g., foot spray and wheel spray)
- Remove or protect products from the areas being cleaned
- Use pressure washing equipment with care




Floor splash can transfer pathogens from standing water on the floor onto food contact surfaces or sprouts. To prevent contamination from floor splash, items such as buckets, bins, barrels or growing equipment should be kept raised off the floor. Care should be taken to prevent contamination of sprout product or food contact surfaces with splash from high pressure hoses used during cleaning or from wheels of carts going through the sprout production rooms. Measures should be taken to prevent the products from being exposed to splash during cleaning. This may include removal of sprouts from areas being cleaned or protecting sprouts using guards or barriers. It is important that sprouters be careful when using pressure washing equipment, since water under pressure tends to create water splash and aerosols that can carry harmful organisms from a floor onto equipment and walls.

4.5.4 Traffic Flow

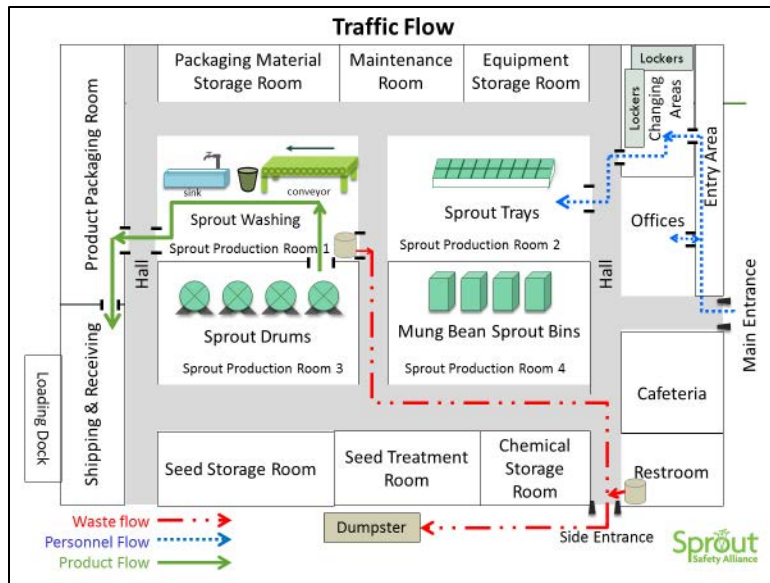
Traffic Flow

- Poorly designed traffic patterns can spread contamination
- Minimize risks posed by traffic patterns:
 - Identify traffic routes
 - Identify potential risks for each route
 - Implement control measures such as:
 - Identifying a different route
 - Posting signage
 - Adding handwashing stations
 - Adding footbaths
 - Setting up barriers



Workers' boots and equipment wheels can pick up contamination on the floor and spread the contamination throughout the entire production area if sprouters do not control traffic patterns effectively in their operation. There are several strategies to mitigate the risks posed by traffic routes. The first step is to identify potential routes. This can be done by drawing a schematic map of the operation, and identifying each type of route (raw material, finished products, waste, forklift, and personnel) with a different color on the map.

The second step is to identify risk factors in these routes (e. g., waste, untreated seed and other areas with contamination-prone materials). When a route has been identified as posing a risk, the next step is to implement control measures to minimize cross-contamination by identifying a different route, posting signage, adding more hand-washing stations or footbaths, etc. In some cases, the addition of barriers, such as partitions, may be needed.



The schematic above illustrates a simple diagram that could be used to assess traffic patterns in a sprout operation.

4.5.5 Contamination Corrective Actions

Contamination Corrective Actions

§ Re-train employees to use appropriate practices and procedures

- Develop written procedures, if necessary
- Alter the facility layout, if necessary

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If improper employee practices and procedures (such as inappropriate handling of soil amendments, mishandling of waste, failure to protect sprouts and food contact surfaces from splash, or violating traffic flow patterns) result in failure to comply with the requirements of the *Produce Safety Rule*, employees must be re-trained to use appropriate practices and procedures (§112.21(d)). Appropriate practices and procedures can be included in a written Standard Operating Procedure (SOP), if this is needed to ensure consistent practice. For example, written SOPs for the storage and removal of waste from both production and outside areas, including


the frequency of removal of the waste, may be useful. If necessary, the operation layout should be altered to provide physical separation that prevent cross-contamination.

4.6 PREVENTIVE MAINTENANCE

**§ Preventive Maintenance –
Cleaning and Sanitizing**

- Equipment and tools designed and constructed to be adequately cleaned
- Installed and maintained to facilitate cleaning of equipment and adjacent surfaces
- Stored and maintained to protect sprouts from contamination

See Module 6: Cleaning and Sanitizing Buildings and Equipment



Definition

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

- 21 CFR 112.3

To minimize equipment breakdown, and to reduce biological, chemical and/or physical food safety risks, sprouters should implement a Preventive Maintenance Program. Maintaining the building and equipment in a clean or cleanable state that minimizes the potential for cross-contamination is required (§112.123). Preventive maintenance must ensure that equipment and tools are installed and maintained to facilitate cleaning of the equipment itself and all adjacent spaces (§112.123(b)(1)). Food safety risks can increase if the equipment is not maintained in a clean or cleanable condition. For example, worn, cracked gaskets that are inaccessible for cleaning can harbor bacteria; and worn moving parts, such as disintegrating bearings, can create metal fragments that contaminate seeds and/or sprouts. Seams on food contact surfaces of equipment and tools must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles and organic material (§112.123(c)). Areas that commonly need attention are cracked or worn belts and conveyors, chipped or cracked guards, and cracked, chipped or worn equipment. Sprouters must inspect, maintain, clean and **sanitize** all food contact surfaces of equipment and tools as frequently as reasonably necessary to protect against contamination of sprouts (§112.123(d)(1)). More information on cleaning and sanitizing is in Module 6: Cleaning and Sanitizing Buildings and Equipment.

Other Preventive Maintenance

- Use only food grade lubricants
- § Calibrate monitoring devices and meters
- Prevent seed and sprout contamination during maintenance
- Preventative Maintenance Plan can include:
 - Tasks, schedules, trouble shooting procedures, spare part inventory, maintenance records, etc.



Preventive maintenance also applies to equipment inspections, calibration, lubrication, operational adjustments and minor component replacements. All relevant repair parts and materials used in the production of food should be of food-grade quality. For example, only food-grade lubricants should be used. Excess lubricant dripping off equipment may contaminate other surfaces.

Ineffective treatment or chemical residues on the final product can occur if monitoring equipment (e.g., chlorine meters or pH meters) is not calibrated regularly. These instruments must be accurate, as precise as necessary and appropriate in keeping with their purpose (§112.124(a)), adequately maintained (§112.124(b)), and adequate in number for their designated uses (§112.124(c)).

During repair of sprout production equipment, seeds and sprouts should be removed from the repair area. Avoid contamination introduced by workers (including contractors and temporary workers) or their equipment and tools.

A Preventive Maintenance Plan can be developed with written descriptions of tasks, schedules, troubleshooting procedures, corrective maintenance (repair), spare parts inventory, and periodic maintenance, such as mowing lawns, replacing worn conveyor belts and changing filters. Records of procedures performed, corrective actions taken, equipment tag information, replacement parts, special tools, lubrication requirements, service providers, warranty information, etc. should be maintained.

Summary

Sprout Production Environment

- Maintaining a hygienic sprout production environment and minimizing the potential for cross-contamination is important
- Areas with regulatory requirements include:
 - Building construction and design
 - Sanitary facilities
 - Safe water
 - Pest control
 - Waste management



In summary, maintaining a hygienic sprout production environment and minimizing the potential for cross-contamination from the environment to sprout products is important to ensure sprout safety. Regulatory requirements for building construction and design, sanitary facilities, use of water, pest control and waste management must be met. Sprouts must be grown in an enclosed building that is maintained in a sanitary condition. Water that meets agricultural water standards (no generic *E. coli*/100 mL) must be used for sprout production. Pests must be controlled in the sprout production environment. Further waste must be managed in a hygienic manner that prevents cross-contamination. Preventive maintenance is important to support these sprout production environment requirements.

4.7 REFERENCES

- Canadian Food Inspection Agency, 2014. *Food Safety Practices Guidance for Sprout Manufacturers*. <http://www.inspection.gc.ca/food/safe-food-production-systems/haccp-generic-models-and-guidance-documents/guidance-sprouts/eng/1367121536967/1367122439564?chap=0>
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- FDA, 2015, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Produce Safety Rule). <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

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Module 5. Employee Health and Hygiene Practices in Safe Sprout Production

5.1 INTRODUCTION

Learning Objectives

In this module, you will learn about:

- The importance of good employee health and hygiene practices
- Management responsibilities regarding employee health and hygiene
- Specific employee health and hygiene practices to prevent sprout contamination



This module covers information related to employee health and hygiene practices that are important for safe sprout production.

Importance of Good Employee Health & Hygiene Practices

- Sprouts are often consumed raw
- People are a known source of contamination



People can harbor pathogens on their skin and hands, and in their digestive system or respiratory tract. Ill food workers not properly washing their hands and then coming into contact with food using

Definitions

Food contact surfaces:

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

- 21 CFR 112.3

Adequate: That which is needed to accomplish the intended purpose in keeping with good public health practice.

- 21 CFR 112.3

bare hands are among the most important causes of foodborne illness outbreaks. Human contamination of the sprouts during any phase of the production process, from germination through packaging, can be the cause of an outbreak of foodborne illness. Everyone working in direct contact with food and **food contact surfaces** (FCS) must adhere to good hygienic practices to protect the sprouts from contamination (§112.32(b)).

Good employee health and hygiene practices are an integral part of an overall food safety program to help prevent food workers from spreading microbial pathogens to sprouts. Achieving this includes having a healthy, clean, and properly trained workforce that understands the importance of proper hand-washing techniques and personal hygiene. **Adequate** training programs and management supervision are critical to the preparation of safe sprouts.

Goal

- To prevent the transmission of pathogens from employees to sprouts and food contact surfaces.




5.2 MANAGEMENT RESPONSIBILITIES

5.2.1 General Responsibilities

Employee Health & Hygiene
Management Responsibilities

- Set a good example
- Communicate hygiene and health policies, such as:
 - § Exclude ill employees from work
 - § Employees reporting illness
 - Employees with infectious illness will not be fired if they stay home
 - § Ensure that **all** employees follow proper hand-washing and good hygiene practices
- Ensure that **all** employees follow bare hand contact or/and glove use policies



Conditions and symptoms that require exclusion are address later in this module.

Managers play a very important role in helping their employees prevent contamination of food products. They should continually emphasize the importance of maintaining a high level of cleanliness and good health, and should serve as a role model for good work habits and hygienic practices.

Managers should also provide a clear understanding of the personal hygiene practices and company policies regarding illness and other health conditions, such as hands serving as a vehicle to transmit contamination and their potential to contaminate sprouts through contact. They may do this themselves or contract a third party to conduct training. Managers should also communicate policies that provide assurance that employees will not lose their jobs if they report an illness or a communicable disease. See Appendix 5.1 for an example of an infectious disease policy. Specific symptoms and conditions are described later in this module.

§ Management Responsibilities – Visitors

- Make visitors aware of policies and procedures to protect sprouts and food contact surfaces from contamination by people
- Take all steps reasonably necessary to ensure that visitors comply with such policies and procedures



Definition

Visitor: Any person (other than personnel) who enters your covered farm with your permission

- 21 CFR 112.3

Management must also ensure that **visitors** are aware of food safety policies of the sprout operation to protect covered produce and food contact surfaces from contamination by people (§112.33 (a)). See Appendix 5.3 for an example of a visitor policy. The operation should also have policies in place that prevent unauthorized people from being in sprout production areas.

§ Training Responsibilities

- New employees must receive training upon hiring
 - As appropriate to their duties
 - Personal health and hygiene
 - Principles of food safety
- Refresher training, at least once annually
- Documentation of all required training



The sprout operation must ensure safe employee handling and good hygiene practices through employee training, monitoring and intervention, and by providing adequate facilities and supplies. Management should also provide written procedures and training programs designed to help employees understand exactly what is expected of them. New employees must receive training prior to beginning employment. Principles of personal hygiene and

sanitation must be periodically reviewed with all employees and refresher training is required at least once annually (§112.21(a) and §112.22(a)(2)). Training must be documented (§112.30(b)) and should be reviewed whenever improper practices are observed.

5.2.2 Well Maintained Facilities and Supplies

Facilities and Supplies

- Designated employee break or eating areas
- Secure areas for storing personal belongings
- Adequate and maintained rooms for changing, if applicable
- Laundry or uniform services (if applicable)



Employees are less likely to follow good personal hygiene expectations when facilities and equipment are poorly maintained and cleaning supplies are insufficient. Management should provide a designated employee break room or lunch area for employees. Lockers should be available for workers to store their clothes, purse and other personal belongings. If protective clothes are to be used, a properly maintained locker room should be big enough for changing. Laundry service should be routinely provided.

5.2.3 Toilet and Hand-Washing Facilities

§ Toilet and Hand-Washing Facilities

- Must be accessible to **all** employees during work hours
- Must be well-stocked
 - Toilet tissue, soap, disposable towels or other sanitary hand drying devices, waste removal
- Must be clean and well maintained
- Must have running water
- Must have adequate sewage disposal system



Management must provide properly supplied, located and maintained toilet and hand-washing facilities that will allow employees and visitors to adhere to personal hygiene requirements (§112.129 and §112.130). Toilet and hand-washing facilities must be conveniently located and accessible to employees during all hours of operation, but should not open directly into production areas. Toilet and hand-washing facilities near work areas promote good personal hygiene, reduce lost productivity, and permit closer supervision of employees. Materials used in the construction of toilet rooms and toilet fixtures should be durable and easily cleanable. The floors, walls and fixtures in toilet areas must be clean and well maintained. Toilet tissue, sanitary hand drying devices, soap, and running water that meets the agricultural water standard of no detectable generic *E. coli* in §112.44(a) must be supplied along with sanitary disposal of waste (§112.131 and 112.132).

Toilet and Hand-Washing Facilities (cont.)

- Should NOT open directly into production areas
- Signs should be posted to remind employees to wash hands effectively
- No food, packaging materials, tools or garments stored in toilet areas



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The References section has information on where this and other food safety icons are available.

Poor sanitation in toilet areas can spread disease and can have a negative effect on the attitudes and work habits of the employees. These areas should be included in routine cleaning programs to assure that they are kept clean and in good repair. Signs or posters placed in proximity to areas where handwashing is required are useful reminders; e.g., at entrances, in restrooms and near handwashing stations in sprout areas. Food or food packaging materials, production garments or tools should never be brought to toilet areas.

5.3 EMPLOYEE HEALTH

5.3.1 Importance

Importance of Employee Health

- Employees with illness can shed pathogens that might contaminate:
 - sprouts
 - the production environment
 - other employees
- This can potentially result in an outbreak


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Workers can carry, introduce and spread contamination through many routes. However, the fecal-oral route is the most common. Food handlers with symptoms of vomiting, diarrhea or fever, or with wounds or open lesions could be a source of foodborne pathogens, and must not perform jobs that require contact with food or food contact surfaces (§112.31 (b)(1)).

Pathogens Transmitted by Infected Food Handlers*

<ul style="list-style-type: none"> • Bacteria - <i>Bacillus cereus</i> - <i>Campylobacter jejuni</i> - <i>Clostridium perfringens</i> - <i>Cryptosporidium</i> spp. - Shiga toxin-producing <i>E. coli</i> - Enterotoxigenic <i>E. coli</i> - Nontyphoidal <i>Salmonella</i> - <i>Salmonella</i> Thyphi - <i>Shigella</i> species - <i>Staphylococcus aureus</i> - <i>Streptococcus pyogenes</i> - <i>Vibrio cholera</i> - <i>Yersinia enterocolitica</i> 	<ul style="list-style-type: none"> • Parasites - <i>Entamoeba histolytica</i> - <i>Giardia intestinalis</i> - <i>Taenia solium</i> – cysticercosis <ul style="list-style-type: none"> • Viruses - Astrovirus - Hepatitis A virus - Norovirus - Rotavirus - Sapovirus
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* Adapted from CDC, 2014



Definition

Hazard: Any biological agent that has the potential to cause illness or injury in the absence of its control


- 21 CFR 112.3

The above list of pathogens that are transmitted by food contaminated by infected food handlers was compiled by the Centers for Disease Controls and Prevention (CDC, 2014). Employees with gastrointestinal illness or symptoms can carry and shed these microorganisms, and many are severe health **hazards**. Person-to-person spread is also possible for many of these pathogens, which can impact your workforce when ill individuals continue to work.


5.3.2 Health Policy

§ **Employee Health Policy**

- Any infectious illness must be reported to the supervisor
 - Medical report
 - Diarrhea, vomiting, fever
 - Dark urine, jaundice
 - Exposed lesions, boils
- **Exclude** employee from operations that may contaminate sprouts or food contact surfaces until condition no longer presents a risk



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Employees must be instructed to report any infectious illnesses they may have to their supervisor, for example by including this practice in the company policy and training (§112.31(b)(2)). Any employee with a communicable illness, e.g., open lesion and acute gastrointestinal illness which often presenting with symptoms such as vomiting, diarrhea or fever, must be excluded from any tasks that may result in contamination of sprouts or food contact surfaces. The employee may be reassigned to another task that does not require contact with food or food-contact surfaces, but due to the concern of cross-contamination, should be restricted from contacting others who work with sprouts, and must be excluded from contacting sprouts and food contact surfaces (§112.31(b)(1)). Exposed areas of arms, wrists, and forearms that contain open wounds should be completely covered by a dry, tight-fitting, impermeable bandage if the employee is to contact food or food contact surfaces. The operation should have procedures in place to ensure that in the event of an injury, any blood or bodily fluids are removed, all affected surfaces are cleaned and sanitized, and all affected products are disposed of.

Workers with colds, exhibiting symptoms of coughing and sneezing, should not be allowed to be around food or food contact surfaces.

5.4 EMPLOYEE HYGIENE

To minimize the risk of contaminating food or food contact surfaces, employees must follow hygienic practices while employed at the sprout facility (§112.32).

FDA's *Food Code* §2-201.12 Exclusions and Restrictions has information on when to exclude an employee from the operation or restrict them to reassigned tasks. You can download the *Food Code* at: <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm>

5.4.1 Hand-Washing

Importance of Hand-Washing

- People who look healthy could still carry and shed foodborne pathogens
- It is important to prevent the contamination of the following by employee’s hands:
 - Food contact surfaces
 - Packaging materials
 - Sprouts



Definition

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

- 21 CFR 112.3

People who look healthy can carry and shed foodborne pathogens and hands are a well-known vehicle for cross-contamination. Hands may become contaminated with harmful *microorganisms* and in some cases harmful chemical substances. These microorganisms or chemicals can contaminate sprouts or food contact surfaces if effective hand-washing techniques are not employed.

§

When To Wash Hands

- Immediately before working with sprouts, seeds or clean food contact surfaces
- Upon return to work station after any break or other absence from the work station
- After using toilet facility
- Before putting on gloves
- **At any other time when the hands may have become contaminated**



Employees must know when to properly wash their hands (§112.32(b)(3)). Signage should be posted in the break area, lunchrooms and bathrooms depicting how to properly wash hands.

After using the restroom, employees must wash hands (§112.32(b)(3)(iii)). Employees must wash hands upon return to the

work station after any break or other absence from the work station (§112.32(b)(3)(iv)), and at any other time when the hands may have become contaminated (§112.32(b)(3)(vi)). The visibility of hand wash stations, signage and behavior of other employees can promote a culture of good hygiene habits throughout the operation.

Other Hand Contamination Examples

- After handling soiled items (trash, etc.)
- After touching untreated seeds
- After touching your face or hair
- After touching animals
- When switching sprout products (allergen control)



Other examples of when to wash hands in a sprout operation are listed above. Control of food allergen cross-contact through hand-washing may be applicable in facilities that handle sprouts or seeds that are known allergens, such as soybeans.

How To Wash Hands

1. Use designated hand-washing sinks in production room
2. Roll up sleeves and wet hands in running water
3. Using soap, lather hands and forearms
4. Rub lathered hands vigorously for 20 seconds
 - Pay particular attention to finger tips
5. Rinse in running water
6. Dry with clean, disposable paper towels or forced air dryer
7. Turn off faucet with foot pedal, paper towels or automated shut off faucet



When washing hands, the steps listed above should take place.

§

Antiseptic Hand Rubs

- May not be used as a substitute for soap (or other effective surfactant) and water



According to the *Produce Safety Rule*, antiseptic hand rubs may not be used as a substitute for soap (or other effective surfactant) and water (§112.130(d)). In other words, hand sanitizers may be applied, but only after washing with soap and water, and not as a substitute for hand-washing.

5.4.2 Clothing and Accessories

Clothing

- Clothing worn in the food production areas should be clean and free from dirt
- The use of clean outer garment or apron helps to minimize contamination



Clothing worn by employees in food production areas should be kept clean. Dirty clothes can be a source of contamination of food. Clean uniforms, aprons or other outer garments that are put on before an employee begins work can help to minimize contamination from sources outside the operation. Sprouters should have a policy and procedures in place to ensure that outer garments are clean and

sanitary. Laundering of re-usable protective clothing should be the responsibility of the employer.

Personal belongings such as clothing, food or snacks should not be stored in areas where sprouts are produced and exposed, or where equipment or utensils are washed and stored. These should be stored in a separate and secure area.

Accessories

§ You must remove or cover hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand

- Examples: ring, bracelet, fake nails



Accessories such as rings, bracelets, necklaces, earring, piercings, watches and other body ornaments can harbor microorganisms that cause foodborne illness. Jewelry can also fall into food, creating a potential physical hazard. Hand jewelry that cannot be adequately cleaned or sanitized, such as wedding bands and rings, must be removed or covered when sprouts are directly handled (§112.32(b)(5)).

5.4.3 Footwear

Footwear

- Foot baths
 - Maintained at an effective concentration and volume
 - Maintained at entrance to production area and transition points
 - Changed regularly
- Shoe sanitizers
 - Maintained at an effective concentration
 - Used properly
- Designated footwear in production areas



Definition

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

- 21 CFR 112.3

NOTE:

Chlorine (i.e., bleach) is not an effective sanitizer for a footbath because of its sensitivity to organic material.

Footwear sanitizing devices, or “footbaths”, located at the entrance of production areas can be used to **sanitize** footwear to prevent introduction of contamination from the outside. Effective concentration of sanitizing solutions can be determined by following the manufacture’s label instructions. Sanitizer concentrations should be monitored regularly and adequately maintained.

Shoe sanitizers are sometimes used to sanitize the bottom of boots or shoes when an employee moves from one part of the operation to another. Shoe sanitizer choices in the marketplace include liquid solutions, granular materials and foaming sanitizers. When properly maintained, shoe sanitizers can reduce the spread of microorganisms, particularly *Listeria*, throughout an operation. However, the sanitizing solution can easily become depleted during use and should be monitored to ensure that proper level and concentration are maintained. For granular sanitizers, the concentration is predetermined. However, to be effective the amount used and how it is used needs to be monitored. The same is true for foaming sanitizers, which are spread via a device onto the floor at the entrance to production areas. When sanitizing devices are used, an SOP should be in place for monitoring and maintaining these devices.

Designated footwear in production areas can be used to prevent contamination of the operation from an outside area. Waterproof shoe-covers may also be used. Visitors must follow policies and procedures of the operation (§112.33(a)), including footwear policies.

5.4.4 Hair

Hair Covering

- Hair can be a source of contamination
- Hair should be covered at all times in the food production environment, for example,
 - use hair nets
 - wear beard nets



Hair can be a source of contamination, including foreign material, therefore food workers should keep their hair clean and wear appropriate hair and beard restraints (as appropriate) in the production areas to prevent contamination of the sprouts.

5.4.5 Employee Eating (Lunch/Breaks) in Designated Areas

Designated Break Areas

- § Eating, chewing gum or tobacco is **not** allowed in sprout production area
- Designated break areas should be available for eating and drinking
- § All employees **must** wash their hands after breaks and before returning to work




Employees must *not* eat food, chew gum or use tobacco in any sprout production or handling area. However, drinking beverages is allowed in designated areas (§112.32(b)(6)). As previously discussed, seemingly healthy people can harbor pathogens in their mouths and respiratory tracts. These can be transferred to employee's hands when they engage in activities where hand-to-

mouth contact occurs. These activities should not occur in food production areas, and hands must be washed when employees return to work after a break (§112.32(b)(3)(iv)).

5.4.6 Glove Use

Gloves Use

- If gloves are used in the sprout operation:
 - § Hands must be washed before putting on gloves
 - § Gloves must be maintained in an intact and sanitary condition and replaced when unable to do so



Gloves are not required in the *Produce Safety Rule*; however, if gloves are used, operations must follow hygienic requirements described in §112.32(b)(3)(ii) and §112.32(b)(4), including washing hands before putting gloves on and maintaining gloves in an intact and sanitary condition. The sprout operation should have a policy to ensure proper use of gloves. Employees should understand the importance of maintaining clean gloves.

§ Single Use or Non-disposable Gloves

<div style="background-color: #4CAF50; color: white; padding: 2px 5px; margin-bottom: 5px; font-weight: bold;">Single-Use Gloves</div> <ul style="list-style-type: none"> • Changed after activity that may contaminate the gloves; e.g., <ul style="list-style-type: none"> - Touching face/nose - Handling non-food item or surfaces - Handling a food allergen 	<div style="background-color: #4CAF50; color: white; padding: 2px 5px; margin-bottom: 5px; font-weight: bold;">Non-disposable Gloves</div> <ul style="list-style-type: none"> • Kept in an intact and sanitary condition • Sanitized after contamination activity
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Single-use gloves are frequently used to avoid direct hand contact with food, but gloves may create a false sense of security for food handlers. Dirty gloves, like dirty hands, can contaminate products. Single-use gloves should *never* be washed; they should be discarded when they need to be changed. Remember, an employee must thoroughly wash his or her hands before putting on gloves (§112.32(b)(3)(ii)).

Employees who choose to use gloves must maintain gloves in an intact and sanitary condition (replacing them when necessary) (§112.32(b)(4)). For example, employees must change single-use gloves after any activity that may contaminate them. In other words, single-use gloves must be changed as often and for the same reasons as an employee would wash their bare hands. For employees using non-disposable gloves, such as rubber gloves, they should be washed as frequently as bare hands, and kept in an intact and sanitary condition.


5.5 EMPLOYEE HYGIENE PROCEDURES

Documented employee hygiene procedures covering hand washing, clothing and accessories, footwear, hair, use of gloves and other hygiene practices is useful not only for training purposes but also for consistent implementation. Appendix 5.2 provides an example of a procedure that could be adapted to a specific facility.

Summary

Employee Health and Hygiene Practices

- Good employee health and hygiene practices prevent transmission of pathogens
- Management must train employees and provide sanitary facilities
- Employees must report infectious illness to supervisors
- Visitors must follow employee hygiene requirements




In summary, good employee health and hygiene practices are essential in sprout operations to prevent the transmission of pathogens from employees to sprouts and food contact surfaces. Management must provide training for employees on appropriate health and hygiene practices and must provide appropriate sanitary facilities. Because infected people can shed pathogens, employees

must report infectious illness to supervisors. Visitors must also follow employee hygiene practices.

Summary Continued

Employee Health and Hygiene Practices

- Handwashing is essential to prevent contamination
 - Immediately before working with sprouts, seeds or clean food contact surfaces
 - After using the toilet, before putting on gloves, any time hands may become contaminated
- Clothing must be adequately clean
- Gloves, when used, must be sanitary
- Footbaths, when used, must be maintained



Handwashing is essential to prevent contamination. Wash hands immediately before working with sprouts, seeds or clean food contact surfaces; after using the toilet; before putting on gloves; and any time hands may become contaminated. Clothing must be adequately clean and gloves, when used must be sanitary to prevent contamination. Footbaths can help prevent the spread of environmental pathogens only when they are maintained.

5.6 REFERENCES AND SAMPLE DOCUMENTS

California Department of Public Health, Food and Drug Branch and US FDA Center for Food Safety and Applied Nutrition. 2000. Safer Processing of Sprouts <https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF-8#q=You+Tube+Safer+Sproutts>

Centers for Disease Control and Prevention, 2014. Diseases Transmitted Through the Food Supply. <https://www.cdc.gov/foodsafety/pdfs/pathogens-by-food-handlers-508c.pdf>

International Association for Food Protection. Food Safety Icons. Available at: <http://www.foodprotection.org/resources/food-safety-icons>

Appendix 5: Employee Health and Hygiene Practices Supplemental Information

- A5.1 Infectious Disease Policy Example
- A5.2 Sanitary Practice Examples
- A5.3 Visitor Policy Example

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Module 6. Cleaning and Sanitizing Buildings and Equipment

6.1 INTRODUCTION

Learning Objectives

- In this module, you will learn:
 - The importance of cleaning and sanitizing
 - The difference between cleaning and sanitizing
 - Proper cleaning and sanitizing procedures
 - Cleaning and sanitizing verification approaches
 - Cleaning and sanitizing chemical storage
 - Recordkeeping



A poorly cleaned sprout production environment, including building interior, equipment surfaces and utensils, provides a suitable growing environment for microorganisms. Seeds, sprouts, hands and gloves that contact dirty surfaces can be contaminated with pathogenic or food spoilage microorganisms. Inadequate cleaning and **sanitizing** can lead to product contamination and can decrease sprout quality, safety and shelf life.

Definition

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

- 21 CFR 112.3

Goals

- Proper cleaning and sanitizing of buildings and equipment will:
 - Prevent cross-contamination
 - Improve food safety
 - Extend shelf-life
 - Enhance brand protection



6.2 SURFACES TO CLEAN AND SANITIZE

Food Contact Surfaces

- § Must be cleaned and sanitized before contact with sprouts or seeds used to grow sprouts
- § Food contact surfaces of equipment and utensils must also be:
 - Properly maintained
 - Inspected
- Food contact surface materials should be:
 - Non-toxic
 - Durable
 - Non-porous



Definition

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

- 21 CFR 112.3

Food contact surfaces (FCS) are surfaces of equipment or utensils that come into contact with food. Any food contact surface used to grow, harvest, pack or hold sprouts must be cleaned and sanitized before contact with sprouts, and seeds or beans used to grow sprouts per §112.143(b). Surfaces from which water may drain, drip or splash into or onto food, or onto a food contact surface, are also considered food contact surfaces. Keep in mind that in addition to equipment and utensils, food contact surfaces may include employee garments, gloves and hands. The materials used for equipment, utensils and other food contact surfaces should be non-toxic, durable

and non-absorbent. Proper storage of equipment used is important to maintain it in a clean and sanitary state.

Non-food Contact Surfaces

- Interior, non-food contact surfaces of the production and handling room(s)
 - Include walls, ceilings, floors, drains and light fixtures
 - Should be waterproof and nonporous
- § Must be cleanable
- § Non-food contact surfaces must be cleaned as frequently as is reasonably necessary



The internal structures and fittings of production rooms, including ceilings, walls, floors, cooling units and light fixtures, should not compromise the safety and suitability of food. Details of these requirements can be found in Module 4: Sprout Production Environment. The surfaces of these structures and fittings should be waterproof, nonporous and easily cleanable. The use of wood, which is absorbent and is not easily cleanable, should be minimized.

Hard-to-Clean Surfaces

- Can be harborage or growth site for microorganisms and biofilms
- § Equipment must be:
 - Accessible or easily disassembled
 - Able to be adequately cleaned
- Surfaces that are difficult to clean and sanitize include:
 - Wood, sheet rock and other absorbent materials

See Appendix 6-1 General Characteristics of Some Food Contact Surfaces for more information



Inaccessible or hard-to-clean places may provide harborage or growth sites for microorganisms. To properly clean and sanitize equipment, utensils, food contact surfaces and adjacent spaces, buildings and equipment must be designed, constructed, installed

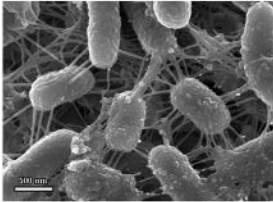
and stored in a manner that enables them to be adequately cleaned and properly maintained (§112.123(a) and (b)).

Certain surfaces may be difficult to adequately clean, sanitize and maintain. Some examples of such surfaces include wood, sheet rock and other absorbent materials. Replacing difficult to clean surfaces can not only enhance cleaning and sanitizing effectiveness but also reduce the time it takes to achieve an acceptable result. In addition, equipment should be designed to be accessible for cleaning and sanitizing or be easily disassembled to allow for cleaning and sanitizing. Appendix 6.1 has information on general characteristics of some surface commonly found in food processing and sprouting operations, along with recommendations related to cleaning and sanitizing.


6.2.1 Biofilms

What is a Biofilm?

- A community of bacteria or a mixture of microorganisms that attaches to surfaces
- Held together and protected by glue-like substances produced during growth called polysaccharides
- More resistant to sanitizers than free cells



Biofilm *Pseudomonas putida* (6 days old)
<http://mtrmika.technion.ac.il/gallery/>



The importance of proper equipment construction and adequate cleaning and sanitizing can be summed up in one word: *biofilms*. The photo above illustrates a biofilm and the polysaccharide structure that holds the cells together and adheres to surfaces. Common examples of biofilms in everyday life include the plaque that can grow on teeth or the algae growing on rocks in a stream. Biofilms are more resistant to sanitizers than free microbial cells.

Biofilm Formation

- The presence of nutrients facilitates formation of biofilms on food contact surfaces
- Accumulate over time due to inadequate or infrequent cleaning and sanitizing



As it relates to sprouts, biofilms can form when collections of bacterial cells attach to equipment or other surfaces in a sprout operation and surround themselves with a protective layer of complex carbohydrates. Various pathogens, such as *Salmonella*, *Listeria*, and *E. coli* O157:H7, have been shown to form biofilms that can contaminate food products during production. Biofilms can be found on the surfaces of product lines, growing trays or drums, spinner baskets, stainless steel and plastic conveyor systems and other areas that are hard to reach or clean.

Preventing Biofilms

- Hard to detect and to remove
- Prevention requires effective **cleaning**:
 - Scrub product contact surfaces daily
 - Scour framework weekly (minimum)
 - Chemicals are not a substitute for mechanical action
- Follow written SSOPs to prevent biofilm formation
- Repair or replace rusted or damaged equipment and food contact surfaces



Bacteria in biofilms are difficult to detect and remove. Once established, biofilms are extremely resistant to sanitizers, disinfectants and heat treatment. Because biofilms take time to build up, the best defense against biofilm development is to employ

prompt, regular and complete cleaning and sanitizing of all food production surfaces, focusing on physical scrubbing to remove soils and other organic material that can lead to biofilm formation.

It is also important to repair or replace any equipment and food contact surfaces that are rusted, pitted or otherwise damaged, because these make equipment and surfaces difficult to clean. Residual material on surfaces may support the growth of bacteria and promote the formation of biofilms.



Sanitary design of equipment is also important to prevent biofilm formation. Hollow rollers on conveyors are a known site for biofilm formation in many types of food facilities. The roller on the left looks clean and well maintained. However, when the roller is dismantled, a biofilm in the center of the hollow roller is exposed. Sanitary design principles using solid rollers can prevent this situation.

6.3 SANITATION = CLEANING + SANITIZING



The term “sanitation” is frequently refers to the combined cleaning and sanitizing process. For example, a Sanitation Standard Operating Procedure documents both the cleaning and sanitizing steps to perform. A general schematic of the cleaning and sanitizing process is illustrated above. The full sanitation process is not achieved until all of the steps are performed. The pre-clean step removes particulate matter and gross soil, followed by a pre-rinse to wet the surface. Washing then takes place, followed by rinsing to remove the cleaner. Before sanitizing, equipment is inspected to verify that it is clean prior to sanitizing. Agricultural water must be used for cleaning and sanitizing of food contact surfaces and should be used for other surfaces. The next section discusses why each of these steps is important for effective cleaning and sanitizing.

6.3.1 Cleaning

Cleaning vs. Sanitizing

- Cleaning and sanitizing are separate steps
 - **Cleaning** – removing visible soil, food residue, dirt, grease or other objectionable matter
 - **Sanitizing** – Killing microorganisms of public health significance
- You cannot sanitize a dirty surface!
 - Cleaning always comes before sanitizing



It is important to understand the difference between cleaning and sanitizing. Cleaning is defined as “the removal of soil, food residue, dirt, grease or other objectionable matter.” It is vital to properly clean surfaces prior to sanitizing, because sanitizers will not be effective unless all traces of food and dirt have been removed from a surface. As previously discussed, effective cleaning is also essential to prevent biofilm formation.

Cleaning and Sanitizing Process

CLEANING

- Pre-clean 
- Pre-rinse 
- Washing 
- Post-rinse 

- Inspect 
- Sanitize 



Definition

Cleaning: The removal of soil, food residue, dirt, grease or other objectionable matter

- 21 CFR 117.3

Cleaning involves washing and rinsing, usually with detergents and soaps, and physical scrubbing or agitation, followed by a water rinse. Pre-cleaning steps may include removing particulate residue, such as sprouts that remain in a drum, and disassembling some equipment to expose difficult to clean surfaces. Pre-rinsing with water may

remove additional material but also provides a liquid medium that helps to distribute the cleaner across the full surface.

Factors Affecting Cleaning Effectiveness

- Debris to be removed
- Equipment surface material
- Pre-rinse effectiveness
- Type, strength and temperature of cleaning solutions
- Exposure time
- Physical scrubbing mechanical force



Factors that influence the effectiveness of any cleaning program include:

- Debris to be removed
- Surface material
- Equipment pre-rinse
- Type, strength and temperature of cleaning solutions
- Exposure time
- Amount of physical scrubbing or other mechanical force

Cleaning Agents and Tools

- Use appropriate and effective cleaning agents
 - Foaming cleaners enhance cleaning
 - Caustic alkaline or acidic cleaners may be corrosive
 - Consult chemical supplier for guidance
- Keep mops and brushes in good condition




Sprout producers should consult with reputable chemical or cleaning product suppliers for guidance in the choice of food grade cleaners for their particular operation, because no one product is best in every application. Always follow label instructions when using chemicals.

The optimum choice of cleaning chemicals depends on the type of unwanted soil to be removed. Sugar, salt and starch are soluble in water and should be easily removed. For fat or protein soils, alkaline chemicals should be used.

A foaming cleaner enhances cleaning because the bubbles assist in removing food and soil by lifting them off the surface and keeping them in suspension. Introducing air into a cleaning solution using a foamer can create cleaning foam. A wall mounted foaming cleaner system can be used where compressed air is available. A manual pump style sprayer can be used to create foam when compressed air is not available. In addition to the lifting action, the foaming cleanser also has a mild scrubbing action when it is sprayed on a surface and moves down a surface such as a wall. Keep in mind, a clean surface is required and physical scrubbing may still be needed.

Surface Compatibility with Cleaners

Surface Material	Concerns	Recommendations
Aluminum	Readily attacked by acidic and highly alkaline cleaners.	Use only soft metal-safe, moderately alkaline cleaners
Black iron or cast iron	Acid or chlorinated detergents can cause rust. Lacks strength	Not recommended in food processing. If present in drains, acid cleaners are corrosive – use moderately alkaline cleaners.
Brass, copper, mild steel	All less corrosion resistant than stainless steel.	Acidic cleaners encourage steel rusting; use moderately alkaline cleaners with corrosion inhibitors.
Concrete	Often etched by acidic products and cleaning compounds. Can crack	Concrete should be dense and acid resistant. Materials should not loosen from surface. Use alkaline cleaners
Galvanized metals	See Appendix 6.1 for full list and consult cleaning product suppliers for guidance on cleaning chemicals for your operation. No one product is best for every application.	



While it is important to use cleaning agents that efficiently remove soils and organic debris, it is also important to consider the type of surface to be cleaned. Appendix 6.1 lists compatibilities between various materials and chemicals common for cleaning. Caustic alkaline or acidic cleaners easily remove food debris, but they can be corrosive to metals such as aluminum, copper or lower grades of steel. Stress fractures and clouding can also occur when hard plastics are repeatedly cleaned with corrosive cleaning agents. If cleaning agents cause the materials that are being cleaned to deteriorate, it may become much more difficult to clean and sanitize those surfaces and they can become harborage sites for foodborne pathogens. Thus

it is important to use cleaning agents that are effective, but do not pit, crack, corrode or otherwise damage equipment and food contact surfaces. A reputable cleaning chemical supplier can recommend cleaners appropriate for your operation.

Mops, brushes and other equipment used for cleaning and sanitizing should also be durable and replaced immediately if damaged, cracked or worn, to prevent the colonization of those tools by microorganisms.

6.3.2 Sanitizing



After cleaning steps are conducted, surfaces that were cleaned should be inspected before the sanitizing process begins. Inspection is important because residual material on surfaces can prevent the sanitizer from reaching the surface to be sanitized. Additionally, the effectiveness of some sanitizers decreases in the presence of organic material, such as sprout residues, as well as residual cleaners.

§ Definition of Sanitize

- To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
- 21 CFR 112.3



Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer (§112.3). When food contact sanitizers are evaluated for efficacy for EPA registration, a minimum 5-log reduction for bacteria listed on the label must be achieved. This is equal to a 99.999% reduction in number of bacteria. A sanitized surface is not necessarily a sterile surface. Sanitized means that the number of microorganisms has been reduced to an “acceptable” level. Sterile means that there are no living microorganisms present.

Considerations for Sanitizing

- § All food-contact surfaces must be cleaned and sanitized before contact with sprouts, or seeds and beans used to grow sprouts
- Surfaces must first be clean for sanitizers to be optimally effective
 - Sanitizers do not necessarily kill all microorganisms
 - Pre-operational cleaning and sanitizing should be performed on food contact surfaces



As previously mentioned, some sanitizers (e.g., chlorine) are not effective in the presence of organic material, such as sprout residue on food contact surfaces. This is one reason food contact surfaces must be clean before application of sanitizers.


Additionally, since sanitizers do not necessarily destroy all pathogens present on a surface, under conditions where water, nutrients and temperature are optimal, surviving bacteria can grow, doubling every 20 minutes in some situations. This is another reason surfaces should be clean before sanitizing. If there is organic matter on a surface, the few remaining bacterial cells present after sanitizing may have sufficient nutrients to support their growth. Because of this, pre-operational cleaning and sanitizing should be performed on food contact surfaces.

Choosing a Sanitizer

§ **Must** follow EPA-registered label use instructions

- Factors to consider:
 - Concentration and exposure time
 - Employee safety
 - Temperature, pH and hardness of water in the facility
 - Sanitizer compatibility with cleaning chemicals and surfaces
 - Effect on sprout products
- Consult chemical suppliers for guidance in choosing appropriate cleaners and sanitizers

Appendix 6.2 compares commonly used sanitizers



Sanitizing solutions that may be safely used on food-processing equipment, utensils and other food contact surfaces are specified in 21 CFR Part 178, which requires labeling meeting the requirements of the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA). The Environmental Protection Agency (EPA) reviews sanitizer labels for efficacy and FIFRA requirements. It is a violation of federal law to use sanitizers in a manner inconsistent with these label instructions, including concentrations and exposure times for the sanitizing process.


Appendix 6.2 summarizes advantages and disadvantages of commonly used sanitizers. Chemical suppliers should be consulted for guidance when choosing cleaners and sanitizers. To ensure employee safety, product effectiveness and regulatory compliance, it is critical to follow all label instructions when mixing and applying sanitizers. Sprouters should refer to Safety Data Sheets (SDS, formally called Material Safety Data Sheets (MSDS)) for specific information, and management must make the SDS available to

employees handling the chemical, according to Occupational Safety and Health Administration (OSHA) regulations. The SDS can be obtained from chemical vendors.


Common Sanitizer Concentrations

Sanitizer	Food Contact Surfaces	Non-food Contact Surfaces
Chlorine	100-200*ppm	400 ppm
Iodine	12.5-25*ppm	12.5-25 ppm
Quats	200*ppm	400-800 ppm
Chlorine dioxide	100-200**ppm	100-200*ppm
Peroxyacetic acid	200-315*ppm	200-315 ppm

* The higher end of the listed range indicates the maximum concentration permitted without a required rinse (surfaces must drain)
 + Includes mix of oxychloro compounds
 Source: 21 CFR 178.1010



Sanitizer labels specify the concentration that may be applied to different surfaces. The table above illustrates sanitizer concentrations commonly used in the food industry. Note that concentrations used on non-food contact surfaces may be higher than those for food contact surfaces. Always follow sanitizer label instructions.

- ### Sanitizer Concentration Monitoring
- Test sanitizer concentrations periodically
 - Use an appropriate test kit
 - § Analytical instruments **must** be calibrated and properly maintained
 - Results of verification should be documented
- 

Check all sanitizer levels using an appropriate test method and record the results. Commercially available test strips can be used and the results recorded to confirm that the appropriate sanitizer concentration was prepared and used for each application. If


analytical instruments are used to measure sanitizer concentrations, there must be a program in place to conduct proper calibration of those instruments to ensure accuracy and precision (§112.124(a)). The operation must also ensure that the analytical instruments are adequately maintained (§112.124 (b)) and are adequate in number for their designated uses (§112.124 (c)).

6.4 SANITATION STANDARD OPERATING PROCEDURES

SSOPs

Sanitation Standard Operating Procedures


- SSOP definition
 - Written procedures describing a sanitation process or activity that an establishment develops and implements to achieve a hygienic environment
- Separate SSOPs are needed to cover:
 - Specific pieces of equipment
 - Production environment areas
- Separate SSOPs are needed for routine and periodic deep cleaning of equipment



An SSOP is a procedure that explains exactly how a certain cleaning and sanitizing task is to be completed. Sprouters may need several SSOPs describing various tasks throughout the production area.

Benefits of SSOPs

- Why a written SSOP is needed
 - A recipe for how a task is to be properly performed
 - To be used for training
 - Describes a procedure that can be validated




There are three compelling reasons to use written SSOPs:

- 1) An SSOP provides a recipe for how a task is to be properly performed. When the usual person is not available to perform the task, a substitute worker can read and follow the SSOP.
- 2) A written SSOP can be used for training and to ensure that the procedure is being followed completely, properly and consistently.
- 3) Finally, written SSOPs can be validated, which provides confidence in the efficacy of the procedure. A properly followed SSOP should result in a clean and sanitary surface. The sanitary status of the surface can be validated through visual observation of cleanliness of all surfaces (as a minimum) and potentially tests, as described in the subsequent section on how to verify sanitation. Once validated, the SSOP can be followed with confidence that the result will be a sanitary surface.

Written SSOP

- Details in a written SSOP
 - **Who** is responsible for cleaning and sanitizing tasks
 - Tools and cleaning and sanitizing chemicals needed
 - **How** chemicals to be prepared
 - **How** chemicals to be used and precautions
 - **How** to clean and sanitize a piece of equipment or work area
 - **When** each routine and periodic task should be completed
- SSOP should be reviewed by management periodically



Each SSOP should be written clearly to provide enough detail so that employees can perform the task correctly by reading the procedure without any additional instruction. It also shows an auditor exactly how the task should be performed. The titles of workers responsible for cleaning and sanitizing should be clearly listed in the SSOP.

Details to be included in an SSOP include the tools and chemicals used for the task, how and when they are to be mixed and applied (consistent with the label instructions), precautions to be taken when using each chemical, how often the procedure is performed and a list of specific steps to be performed. SSOPs should also detail the equipment and utensils used for the procedure, and where these are stored when not in use.

Because areas or equipment, such as refrigerators or dry storage areas, may require cleaning and sanitizing less often than food contact surfaces or higher risk areas, it is important to include a schedule for when and how often each SSOP needs be performed. This applies for different areas within the operation, and for each piece of equipment, utensil or food contact surface. During production, it is important that all food contact surfaces are cleaned and sanitized at least once per day. Some pieces of equipment may need separate SSOPs for routine and deep cleaning.

Table 6.1 from FDA’s draft guidance to the sprout industry (FDA, 2017) summarizes recommended frequencies for cleaning and sanitizing different surfaces, areas or equipment. If results from environmental monitoring, spent sprout irrigation water or product testing indicate a food safety concern, consider increasing cleaning and sanitizing frequency of as part of an overall corrective action plan.

Table 6.1. Recommended Frequency of Cleaning and Sanitizing (FDA, 2017)

Surface, Area or Equipment	Frequency of Cleaning and Sanitizing ^a
Drains and floors	Daily
Pallets	Daily
Waste containers	Daily
Cleaning tools (e.g., mops, brushes)	Daily
Surfaces that have a greater potential to become a source of <i>L. monocytogenes</i> contamination (e.g., surfaces likely to be touched by employees who touch product or food-contact surfaces during operations, or areas where there may be a build-up of moisture or product residue)	Daily
Condensate drip pans	Monthly
Motor housings, external surfaces of enclosed processing systems	Monthly
Overhead piping, ceilings and walls ^b	Semi-annually
Freezers (e.g., spiral, blast, tunnel) containing exposed RTE foods ^c	Semi-annually
Interiors of ice makers	Semi-annually
^a Since production environments vary, it may be appropriate to increase cleaning frequencies depending on the specific circumstances of the product area. ^b We recommend that that you clean and sanitize some walls and ceilings (e.g., those in close proximity to a production line) at the same time as the production equipment (e.g., daily). ^c If the manufacturer of the equipment recommends cleaning on a more frequent basis, we recommend that you increase this frequency to match the recommendations of the manufacturer.	

The SSOP should periodically be reviewed by management (usually at least annually) to ensure the activities are being performed consistent with the SSOPs and to allow for changes, if needed, including retraining of employees. The SSOPs should be updated as needed.

Dedicated equipment and utensils may be required for certain areas of the plant, especially in the finished product area. Each employee who cleans and sanitizes must receive training at least annually to ensure they understand why their task is important and how to perform it properly and consistently with the SSOP (§112.21(a)).

SSOP Example – Appendix 6.3

Purpose: An effective sanitation program prevents the contamination or re-contamination of food that may impact the food quality, safety and shelf life.


Frequency: Before the beginning of every operation, after the end of production cycle of each types of sprout, and at the end of daily overall production.

Who: Sanitation team member

Cleaning and Sanitizing Procedure:

1. Remove/cover food items, sensitive electrical equipment/ motor and packaging materials to prepare the area.
2. Remove items on the surface to be cleaned.
3. Disassemble, if needed, and dry/wet clean equipment.
4. Pre-rinse the equipment with warm Doesn't include specific chemicals and concentrations as was stated in the Module. Do we want to update this using a more specific example?

Continued in appendix



An example SSOP can be found in the Appendix 6.3. The slide above is extracted from the appendix. No specific format is required.

6.5 VERIFICATION OF SANITATION EFFECTIVENESS

Verification Sanitation Effectiveness

- Verify the efficacy of cleaning and sanitizing procedures
- Verification may include:
 - Visual observation for residues on surfaces
 - ATP swabs, contact plates, microbial count swabs
 - Environmental monitoring for environmental pathogens
 - See Module 7: Environmental Monitoring for *Listeria* species or *L. monocytogenes* in a Sprout Operation



Because of the important role that cleaning and sanitizing play in the safe production of sprouts, sprout producers should implement a program to verify that the procedures are effective. Several approaches can be used for this purpose.

At a minimum, equipment surfaces should be visually checked to verify that the surfaces are clean. Observing residual sprouts or slime on surfaces clearly indicates that cleaning was not effective and the process should be repeated.

Another optional approach is the application of a rapid method such as an adenosine tri-phosphate (ATP) monitoring system. These systems measure the presence of ATP, a chemical produced in all living cells (including sprouts), as an indirect measure the amount of organic residue that remains on a surface after cleaning. An ATP test typically takes only a few minutes to perform, so results are available for immediate feedback and can pinpoint areas that need more thorough attention.

A variety of microbiological testing formats and sampling techniques can also be used for verification. For example, bacterial swab testing for aerobic colony counts indicate levels of viable microorganisms remaining on a surface after cleaning and sanitizing. High counts indicate insufficient or poor sanitation. This type of test takes a few days to complete, thus immediate feedback to reclean and sanitize surfaces is not possible. However, results obtained can identify trends. They may also be useful to identify potential sources of spoilage microorganisms, if the operation is experiencing issues.


Testing the sprouting environment for *Listeria* spp. or *L. monocytogenes* is another verification method and is required by the

regulation. This is discussed in Module 7: Environmental Monitoring for *Listeria* species or *L. monocytogenes* in a Sprout Operation.

Appendix 6.4 provides an example form that could be used to conduct a cleaning and sanitizing self-assessment.

Possible Reasons for Unacceptable Results


- The SSOP was not properly followed
- The SSOP was not effective as designed
- Presence of biofilms that routine cleaning cannot remove



A verification procedure may identify unacceptable results when 1) the SSOP was not appropriately followed; 2) the SSOP was not effective; and 3) there might be a biofilm on a surface. If the SSOP was not effective, the cleaning and sanitizing protocol should be examined and revised to include new procedures, new chemicals or new chemical concentrations, as appropriate to the situation. If the potential presence of a biofilm is suspected, dismantling equipment may be needed to conduct deeper cleaning and identify the potential source of the issue.

Corrective Actions

- Reclean and sanitize surfaces, then verify results before running product
- § Retrain all employees on the new SSOP
- Replace or repair equipment that cannot be reliably cleaned



Often corrective action requires workers to be retrained in their duties. All personnel, including temporary, part-time, seasonal and contracted employees, managers and supervisors must receive ongoing training at least annually (§112.21(a)). Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting the rule requirements (§112.21(d)), which would apply if a new SSOP is developed or if an individual is not following an SSOP.

If investigations identify equipment that can no longer be reliably cleaned and sanitized due to damage, rust or other deterioration, replacing or repairing it may be necessary.

6.6 CLEANING AND SANITIZING CHEMICAL STORAGE

Cleaning and Sanitizing Chemical Storage

- Properly label chemicals
- Store chemicals:
 - separate from food and food contact equipment
 - in a locked area where only authorized personnel have access
- Do not store in containers that were used or will be used to hold food
- Follow label instructions and consult chemical suppliers for any questions



All chemical containers should be labeled properly and stored in a manner that prevents contamination of food, seeds, ingredients and packaging. Chemical storage areas should be separate from food and food contact equipment. Further, chemicals should not be stored in containers that were used or will be used to hold food. Likewise, seeds and sprouts should not be stored in a container that previously stored chemicals.

It is a violation of federal law to use sanitizing chemicals in a manner inconsistent with label instructions. Check the labels and Safety Data Sheets for all cleaning and sanitizing chemicals and do not hesitate to contact the chemical supplier if you have questions. This is important not only to prevent contamination of sprouts but also to protect the health and safety of people who handle these chemicals. Personal protective equipment may be required for handling cleaning and sanitizing chemicals.

6.7 SANITATION RECORDS

Cleaning and Sanitizing Recordkeeping

- § Document the date and method of cleaning and sanitizing of equipment used for growing, harvesting, packing and holding sprouts
- § Records **must** include:
 - Chemicals used, concentration and contact time, as applicable
 - Date and time of cleaning and sanitizing
 - Operators' name and signature/initials
 - Reviewer's name and signature/initials
- Records should also include:
 - SSOPs
 - Invoice or other proof of chemical purchase
 - Cleaning areas




Cleaning and sanitizing records must be maintained in a sprout operation (§112.140). These records must include the date and method of cleaning and sanitizing of equipment used in sprout operations (§112.140(b)). These records should include a checklist of the steps outlined in the SSOP, including contact time of cleaner and sanitizer on equipment, and a check of sanitizer concentration. Procedures should be monitored daily and noted as to whether they are being performed properly and as scheduled. To aid internal examination of cleaning and sanitizing procedures, keeping records of the activities performed and the chemicals used can help a sprout operation ensure activities are performed appropriately and consistently. These records provide documentation to show others (e.g., auditors or inspectors) that these activities were properly performed.

Example Cleaning and Sanitizing Record

XYZ Sprout Company 123 Sprout Street, Yourtown, USA						
Cleaning and Sanitizing Log						
Area Cleaned						
Date (mm/dd/yyyy)						
Sanitation Area and Goal	Pre-Op Time:	Start Time:	Lunch Break Time:	Post-Op Time:	Comment/Corrective Actions	Operator Initials
SSOP XYZ: Condition & Cleanliness of Food Contact Surfaces						
• Equipment cleaned and sanitized (S/U)						
• Sanitizer type ____						
• Sanitizer concentration ____						

See Appendix 6.5 for full form



An example of a Cleaning and Sanitizing Record is illustrated in Appendix 6.5. The format for this type of records can vary considerably. Recordkeeping requirements are addressed further in Module 12: Recordkeeping.

6.8 SUMMARY

Cleaning and Sanitizing Summary

- Cleaning and sanitizing are important to prevent cross-contamination and improve sprout safety
- § Sprouters must clean and sanitize all food contact surfaces before contact with sprouts or seeds used for sprouting



In summary, cleaning and sanitizing sprout production equipment and building interior are important to prevent cross-contamination and improve sprout safety. All food contact surfaces must be cleaned and sanitized before contact with sprouts or seeds used for sprouting (§112.143(b)). Producing sprout products in sanitary environment and food contact surfaces is essential for ensuring food safety, extending shelf-life and eventually protecting the brand.

Summary
Cleaning and Sanitizing (continued)

- Cleaning and sanitizing is a stepwise process
- Cleaning removes material from surfaces that can:
 - Reduce effectiveness of sanitizers
 - Promote establishment of biofilms
- Sanitizing kills microorganisms



Sanitation is a stepwise process involving both cleaning and sanitizing. First, cleaning removes material from surfaces that can reduce the effectiveness of sanitizers and promote establishment of biofilms. Then sanitizing take place to reduce microorganisms to an acceptable level.

Summary
Cleaning and Sanitizing (continued)

- Sanitation verification includes:
 - Measuring sanitizer concentrations
 - Ensuring surfaces are clean through visual inspection and potentially other tests
- Recordkeeping is required for:
 - The date and method of cleaning
 - Sanitizer concentrations



Verification of sanitation includes measuring sanitizer concentration to ensure that they are applied at effective concentrations. It also includes visual inspection of surfaces to ensure that the surface is clean. Other tests, such as microbiological testing or application of rapid methods such as ATP tests may also be useful sanitation verification procedures. Required sanitation records include the date and method of cleaning and sanitizing.

6.9 REFERENCES AND SAMPLE DOCUMENTS

- California Department of Public Health, Food and Drug Branch and US FDA Center for Food Safety and Applied Nutrition, 2000. Safer Processing of Sprouts.
<https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF-8#q=You+Tube+Safer+Sproutts>
- FAO/WHO, 2003. General Principles on Food Hygiene. CAC/RCP 1-1969. Rev.4-2003.
- FDA, 2017. *Draft Guidance for Industry: Compliance with and Recommendations for Implementation of the Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations.*
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm510578.htm>
- FDA, 2015. FSMA Final Rule on Produce Safety.
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
- FDA, 2013. Food Code 2013.
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm>
- Iowa State University Extension, 2004. On-Farm Food Safety: Guide to Cleaning and Sanitizing.
http://ndfarmersmarkets.com/doc/On_Farm_Food_Safety_cleaning.pdf
- Ontario Ministry of Agriculture, Food and Rural Affairs, 2006. Foods of Plant Origin: Cleaning and Sanitation Guidebook.

Appendix 6: Cleaning and Sanitizing Buildings and Equipment Supplemental Information

- A6.1. General Characteristics of Some Food Contact Surfaces
- A6.2 Types of Sanitizers
- A6.3 Sanitation Standard Operating Procedures (SSOP) – Example
- A6.4 Cleaning and Sanitation Self-Assessment – Example
- A6.5 Cleaning and Sanitizing Log Sheet – Example

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Module 7. Environmental Monitoring for *Listeria* Species or *L. monocytogenes* in a Sprout Operation

7.1 INTRODUCTION

Learning Objectives

- In this module, you will learn:
 - Objectives of environmental monitoring
 - *Listeria* spp. or *L. monocytogenes* environmental monitoring requirements
 - Key components of an environmental monitoring plan
 - How to choose a testing laboratory
 - How to interpret results and determine corrective actions
 - Records to maintain



Module 6: Cleaning and Sanitizing Buildings and Equipment discussed general methods, such as ATP and aerobic colony counts to verify the effectiveness of sanitation processes. This module addresses environmental monitoring for the detection of *Listeria* species (spp.) or *L. monocytogenes* in a sprout operation, which is required by the *Produce Safety Rule* for sprout operations.

The module begins with a brief introduction to the objectives of an environmental monitoring program to provide an understanding of why it is in a sprouter's interest to diligently try to find the organism during testing. The module also addresses environmental monitoring requirements and key components of an environmental monitoring plan. A discussion on how to choose a testing laboratory is included, and the considerations discussed apply not only to testing for *Listeria* but also to other pathogen testing done by a sprouter. Interpretation of environmental monitoring results, including corrective actions, is also discussed, as well as record requirements for an environmental monitoring program.

7.1.1 Why Is Environmental Monitoring Required?

L. monocytogenes Concerns

- Involved in outbreaks and recalls
 - Specific concern for FDA
 - § Required for sprout growers
- Naturally soil borne, thus easily introduced into an operation
- Able to grow at low temperature
- Once established in a production environment, can persist




L. monocytogenes is a pathogen of concern in a sprout operation. As discussed in Module 3: Sprout Safety Hazards, *L. monocytogenes* is a leading cause of death from foodborne illness in the U.S. Once *L. monocytogenes* becomes established in an operation, it can serve as a source of repeated product contamination and potentially lead to foodborne illness outbreaks. A number of sprout recalls involved contamination with *L. monocytogenes*.

Testing for the presence of *L. monocytogenes* or *Listeria* spp. in the sprout environment is more useful than testing for other pathogens. *L. monocytogenes* is naturally soil borne and can enter a sprout operation in many ways and at any time. It can grow slowly at cold temperatures as low as 32°F (0°C), though it grows faster at warmer temperatures. While *L. monocytogenes* may be found almost anywhere in a sprout production environment, it is most likely to become established in areas that are wet, relatively undisturbed, may trap organic material and are difficult to access such as weld seams, metal cracks and rollers. These might include drains, cooling units, drip pans, condensation on walls or ceilings, or other areas that are difficult to access or to clean. Once established, *L. monocytogenes* can persist for long periods of time.

7.1.2 Transient and Resident Microorganisms

Types of Biological Contaminants

Transient Microorganisms	Resident Microorganisms
<ul style="list-style-type: none">• Introduced via raw materials, personnel, packaging materials• Removed through normal cleaning and sanitizing• Typically do not become established in the production environment	<ul style="list-style-type: none">• Become established in the production environment• May persist for long periods• Normal cleaning and sanitizing may control numbers but may not eliminate



The first step in understanding environmental pathogens is to understand how microorganisms behave in a food production environment. Simplistically, there are two basic types of microbial contaminants – transient and resident microorganisms. Transient microorganisms can enter a food establishment on ingredients, raw materials, personnel and other incoming items. Essentially, they hitchhike. Normal cleaning and sanitizing should remove transient strains so they do not persist or become established in a sprout operation. Even with good sanitation procedures, transient strains will appear from time to time in an operation and may be detected occasionally through testing. This is to be expected.

Conversely, resident microorganisms become established in the production environment. They frequently find their way into nooks and crannies, referred to as environmental niches or harborages, and persist for long periods of time. These niches are often difficult to clean, thus resident strains may form a colony that periodically contaminates sprouts.

The objective of an environmental monitoring program is to detect environmental niches and thus target corrective actions to remove resident strains. This requires vigilant sanitation practices and an understanding of the importance of setting up a rigorous program to detect resident strains.

7.1.3 Environmental Monitoring Requirements

§ Rule Requirement

- Each sprout operation must test the growing, harvesting, packing and holding environment for *Listeria* spp. or *L. monocytogenes* to prevent the introduction of hazards into sprouts (§112.144)



Sprouters must test for the presence of *L. monocytogenes*, or *Listeria* spp. (§112.144(a)), which is considered an appropriate indicator for the possible presence of *L. monocytogenes*. There are several species of *Listeria* but only *L. monocytogenes* causes disease in humans.

§ Rule Requirement

- Sprout operation must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing or holding environment (§112.145(a))
- Written plan must direct sampling and testing for either *Listeria* spp. or *L. monocytogenes* (§112.145 (b))



The *Produce Safety Rule* requires each sprouting operation to establish and implement a written environmental monitoring plan that tests the growing, harvesting, packing and holding environment for *Listeria* spp. or *L. monocytogenes*. Such a program is intended to prevent the introduction of this hazard into sprouts (§112.145). Even if a sprout operation is exempt from the rule, an environmental monitoring program is a good idea to protect customers and the business.

Listeria spp. or *L. monocytogenes*?

- FDA expects *Listeria* spp. testing because:
 - *Listeria* spp. found more frequently, which helps identify potential harborage sites
 - *Listeria* spp. indicates potential *L. monocytogenes* presence
 - *L. monocytogenes* specific testing may be more costly
- Effective environmental monitoring diligently tries to identify harborage sites to reduce risk



Testing for *Listeria* spp. is frequently recommended because it detects both *L. monocytogenes* and other *Listeria* species that are more common than *L. monocytogenes*. Keep in mind that the purpose of this testing is to detect situations that can potentially contribute to a food safety incident. A diligent environmental monitoring program allows a sprouter to correct situations that could eventually lead to contamination with *L. monocytogenes*.

A positive test result for *Listeria* spp. on a food contact or non-food contact surface indicates the *potential* for contamination of the surface with *L. monocytogenes*. It further suggests that conditions are suitable for survival and growth of the pathogen *L. monocytogenes*. However, a positive test result for *Listeria* spp. on a surface *does not* establish the presence of *L. monocytogenes* on the surface.

An effective environmental monitoring program diligently tries to find *Listeria* to correct situations before they escalate to product contamination.

Effective Environmental Monitoring Program Essentials

- Easy-to-follow written monitoring plan
- Detailed map of the operation
- Expertise of sampling team
- Proper sample collection
- FDA reference method or equivalent test methods
- Qualified testing lab
- Corrective action plan for responding to positive test results



An easy to follow, written monitoring plan is important to ensure that the plan is continually implemented in a consistent manner. Drawing a detailed map of the operation, such as illustrated in traffic flow discussion in Module 4: Sprout Production Environment, is important for developing an effective environmental monitoring plan.

The effectiveness of an environmental monitoring program for *Listeria* also relies on proper sampling of the sprout production environment as well as the use of reliable testing methods, and depends on factors, including:

- Developing and implementing a sampling plan that maximizes the chance of detecting pathogens or indicator organisms, if present,
- The expertise of the sampling team,
- Working with a qualified testing laboratory to ensure samples are received quickly and at the proper temperature, and analyzed using scientifically valid methods for the types of samples being tested, and
- Taking and documenting appropriate corrective actions in response to positive findings.

The corrective action required depends on many factors, such as how frequently environmental monitoring is done, the historical trends observed in results, the operation layout and other operation specific factors.

Goal

- To prevent contamination of food contact surfaces and sprouts by detecting *Listeria* and taking timely actions *before* it becomes established in the operation's environment.



The goal of environmental monitoring for *Listeria* is to prevent contamination of sprouts and **food contact surfaces** by identifying potential harborage sites for the pathogen and ensuring your corrective actions have eliminated the pathogen before it contaminates product.

7.2 ENVIRONMENTAL MONITORING PROGRAM

7.2.1 Environmental Monitoring Plan Elements

Under the *Produce Safety Rule*, each sprouting operation is required to have a *written plan* for environmental monitoring (§112.145). A written procedure will help ensure that the sampling and testing are performed properly and consistently.

§ Environmental Monitoring Plan Required Elements

- A sampling plan that specifies:
 - What to test for (*L. monocytogenes* or *Listeria* spp.)
 - When to collect samples
 - Number of samples
 - Frequency of sampling (monthly minimum)
 - Sampling locations (food contact and non-food contact surfaces)
- Test methods
- Corrective action plan that describes:
 - Actions to be taken in response to positive results
 - When and how these actions will be accomplished
- Required records



Definition

Food contact surfaces:

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

- 21 CFR 112.3

The written environmental monitoring plan must specify (§112.145(c)):

- What to test for (i.e., *Listeria* spp. or *L. monocytogenes*) (§112.145(c)(1)),
- The frequency of sampling (no less than monthly) and when to collect samples (e.g., during production) (§112.145(c)(2)),
- The sample collection sites, noting that the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact and non-food contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment (§112.145(c)(3)), and
- Corrective actions to take in response to positive samples, including details on when and how you will accomplish those actions (§ 112.145(e)).

Environmental Monitoring Plan Recommended Elements

- Designate trained individual or sampling team for sample collection
- Designate responsible person for direction and oversight (e.g., food safety manager)
- Describe steps to prepare for sample collection
- Describe aseptic procedures for collecting samples
- Identify lab for conducting tests



In addition to the required elements, it is recommended a written plan also:

- Designate a trained individual or sampling team for sample collection and responsible person(s) to provide direction and oversight, and describe any training that individual or team should have,
- Include steps to prepare for sample collection,
- Specify the sample collection method used (e.g., sponge versus swab sampling, whether any samples will be composited) and sample sizes collected (if appropriate) at the various sample collection sites,


- Describe aseptic procedures (required under §112.145(d)) used for collecting environmental samples,
- Identify the specific test method by which collected samples will be tested for the test microorganism (must use a method as set forth in §112.152),
- Identify the laboratory conducting the testing, and
- Identify the records kept for each sample collected, including the documentation of analytical test results and actions to take in accordance with §112.146.

Sprouters must maintain records of any analytical methods used (§112.152). For example, incorporate this information into the written sampling plan, or maintain this information in conjunction with the records of the analytical test results (§ 112.150 (b)).

7.2.2 Management Responsibilities

Management Responsibilities

- Ensure appropriate environmental monitoring procedures are established and implemented
- Regularly update written plan and procedures
- Designate sampling team
- § Ensure a qualified laboratory uses scientifically valid test methods for samples
- Regularly review and verify data and records
- § Ensure a corrective action plan is developed and implemented in response to a positive test result



The sprout operation should also designate one or more people to provide direction and oversight to ensure the environmental monitoring program is adequately implemented. Depending on the task and the operation, the responsible person(s) may be the manager, the supervisor or the QA or Food Safety Team lead. Duties include:

- Ensuring appropriate environmental monitoring procedures are established and implemented,
- Ensuring that the written plan and procedures are regularly updated,
- Designating a sampling team,
- Ensuring that samples are submitted to and tested by a qualified laboratory employing a scientifically valid method that is at least equivalent to the method of analysis in

§112.152(a) in accuracy, precision, and sensitivity for detecting *Listeria* spp. or *L. monocytogenes* in environmental samples (discussed further in Section 7.2.10 How to Choose a Testing Laboratory),

- Reviewing and verifying data or records frequently to ensure all sampling records and test result documents are complete and comply with §112.161(b) review requirements, and
- Ensuring a corrective action plan is developed and implemented in response to positive test results.

7.2.3 Sampling Team Roles and Responsibilities

Responsibilities of the Sampling Team

- Read and understand the sampling plan
 - Follow aseptic sampling procedure
 - Label sampling containers
 - Conduct sampling procedure
 - Complete sample submission forms
 - Pack and submit samples in a timely manner



Designate a sampling team that includes at least one person who is trained to collect samples for microbiological analysis. Roles and responsibilities of sampling team members generally include working with the food safety leadership to make sure the sampling plan and procedures are accurately executed, such as:

- Following aseptic sample collection procedures (§112.145(d), including use of disposable gloves),
- Labeling sample containers with locations and sample numbers (which may be done in advance),
- Conducting sampling procedures,
- Completing sample submission forms,
- Packing samples for shipping/transport per laboratory requirements to meet appropriate receipt temperature, and
- Ensuring timeliness of sample delivery to the testing laboratory.

Responsibilities of Sampling Team (cont.)

- Communicate with the Food Safety Manager about updating sampling plan
- Communicate with the testing lab
 - Verify proper sampling kits are used
 - Confirm what to test for
 - Confirm shipping conditions and address
- Collect and maintain all records



- Maintaining constant communication to identify areas of the plan and procedures that may need to be modified or updated,
- Communicating with the laboratory performing analyses, including:
 - a) Asking any questions that need to be answered prior to sampling,
 - b) Verifying that the appropriate sampling kits are being used,
 - c) Confirming that the desired test to conduct (*Listeria* spp. or *L. monocytogenes*) is on paperwork,
 - d) Shipping details (e.g., required temperature), and
 - e) Informing the lab in advance of the number of samples to be delivered and the time of arrival,
- Collecting and maintaining the records of sampling date/time/lot/results.

7.2.4 Equipment, Materials and Aseptic Techniques

Sampling Preparation

- Training in aseptic technique
- Sampling supplies preparation, including:
 - Sampling kit
 - Sterile sample bags, sterile sponges or swabs and neutralizing buffer
 - Disposable gloves
 - Coolers with ice packs
 - Cleaned working surface



Definitions

Aseptic procedure:
Practices and procedures applied to prevent microbiological contamination of samples.

Sterile: Free from viable microorganisms.

It is important that employee(s) collecting samples follow aseptic sampling procedures to ensure that samples are not contaminated during sampling. Instructions regarding aseptic procedures can be found in the Appendix 7.1: **Aseptic Procedure** for Sampling. If a sample falls on the floor, leave it on the floor until the collection process is complete to avoid contaminating hands. A sample that has fallen on the floor should not be used.

All sample collection supplies should be obtained from reputable vendors. Supplies may include:

- **Sterile** sample collection bags,
- Sterile pre-hydrated or un-hydrated sponges, swabs or sponge-stick containing, e.g., D/E Neutralizing broth or neutralizing buffer,
- Plastic disposable gloves,
- Coolers with ice packs to maintain acceptable temperature requirements during shipment,
- Cleaned working surface (e.g., counter top or rolling cart), and
- Any forms or records that need to be completed.

The most common environmental sampling devices are pre-hydrated and unhydrated swabs and sponges. Other options are available and new sampling devices continue to be introduced in the marketplace. It is important that any device selected is appropriate for environmental sampling and that the label directions provided with the sampling materials are followed.

Residues of cleaning agents and sanitizers may be picked up during swabbing. Because of this, swabs treated with neutralizing broth


(e.g., Dey/Engley neutralizing broth, D/E broth) should be used to preserve viability of the microbial cells. The residues that may be left behind on equipment by D/E broth are negligible and do not present a risk of contamination for sprout products that may come into contact with the swabbed area. While a sprout operation may choose to wash, rinse and sanitize an area that has been swabbed before resuming production, it is not necessary.

7.2.5 When to Sample

When to Sample

§ Samples must be collected during production

- Samples should not be collected after cleaning
- Vary the day of week and the time of day for sampling



Routine environmental sampling for *Listeria* spp. or *L. monocytogenes* must be performed during production (§112.145 (c)(2)), rather than after production when the environment has been cleaned and sanitized. Environmental samples should not be taken immediately after surfaces were sanitized, because the sanitizer may affect the test results. If *L. monocytogenes* is in a harborage site, e.g., from sites within equipment, it can dislodge and spread during operations, making it more likely to be detected. Taking environmental samples several hours into production (e.g., 3-4 hours) and preferably towards the end of production, just prior to cleanup, results in a greater likelihood of detecting any *Listeria* coming from a harborage site. It may also be useful to vary the day of the week and the time of day for sampling to provide a better indication of overall conditions within the production environment.

7.2.6 Where to Sample – Environmental Sampling Zones

Selection of Sampling Location

- § Sample collection sites must be specified in the written sampling plan
- § Must include both food-contact and non-food-contact surfaces
 - Selection of sampling locations should be carefully planned
 - Zone concept is commonly used



The written environmental monitoring procedures must specify the sites where samples will be collected (§112.145(c)(3)). The selection of appropriate sampling sites should be well thought out, and include locations in which the pathogen may become established in the production environment such as where sprout or process water is exposed or areas where the development of a harborage niche is likely. *Listeria* grow and survive well in a wide range of environmental conditions, especially those that are moist and either warm or cool.

Sampling Zones

- Zone 1- Food contact surfaces in production area
 - e.g., sprout washer interior, conveyor surface
- Zone 2- Non-food contact surfaces *in close proximity* to food contact surfaces
 - e.g., conveyor exterior, floor drains
- Zone 3- Areas immediately surrounding Zone 2
 - e.g., maintenance tools, floor, doors
- Zone 4- Areas outside of the production area
 - e.g., break room, loading dock area



A common industry practice for environmental monitoring is to use the zone concept, starting with food contact surfaces as Zone 1 and progressively moving out from there to cover the entire production

operation. The zones, described below, have different levels of corresponding food safety risk. For example, *Listeria* on a food contact surface in Zone 1 poses a more immediate risk of contaminating product compared to *Listeria* on a non-food contact surface in a more remote zone. Nevertheless, sampling outside Zone 1 is important because *Listeria* can be spread from non-food contact surfaces to food contact surfaces through a many routes, including foot traffic, shared equipment, water splash and improper airflow.

Zones 1 – 4 are described below. It is best to collect more samples from Zones 1 and 2 than from other, lower risk, zones. Floor drains are a good “catch point” or red flag for contaminants that may be in the production environment because they are usually wet, difficult to access and clean, and collect water that exits production area. See Table 1 for additional examples of potential sampling sites for each zone.

Zone 1: Direct food contact surfaces, such as all parts of food contact conveyors, worktables, utensils, bins and inside the sprouting drums and trays.

Zone 2: Non-food contact surfaces in the production area and areas directly adjacent to or close to food contact surfaces (Zone 1). Examples include table legs, pallets, non-food conveyors, finished product refrigerated storage areas, exterior surfaces of sprouting drums and trays, floors, floor drains, bottoms of reusable food containers and ventilation equipment. A far corner of the production room could be considered Zone 2 if foot traffic or forklifts move through that area and the traffic pattern goes near to a production line where exposed food is conveyed or held. This may also apply if ventilation patterns cause airflow from remote areas to move through production areas where product is exposed.

Zone 3: Areas immediately surrounding Zone 2. Zone 3 is an area that, if contaminated with a pathogen, could lead to contamination of Zone 2 via actions of humans or movement of machinery. Examples include non-food contact surfaces such as walls, floors, doors and doorways leading into food production areas, or wet areas in a cooler.

Zone 4: Areas outside of the production area, generally considered remote areas. Examples include employee locker rooms, dry goods storage areas, break rooms and loading docks. Contamination in Zone 4 could be spread to other zones through movement of people or equipment.

Table 7.1. Possible Environmental Sampling Locations in a Sprout Operation

Sample Location	Zone				Notes
	1	2	3	4	
Barrel	X				
Interior of cart, crate and drum	X				
Rack	X				
Rake	X				
Scale	X				Floor or table mounted
Sprout washer - Interior	X				
Utensil (scoops, tongs, etc.)	X				
Wheelbarrow - Interior	X				
Work table	X				
Conveyor	X	X			Including cables, belts, joints where product residue accumulates, exposed bearings and rollers
Ice maker	X	X			Inside, scoops & underside of top of ice chamber
Equipment	X	X	X	X	Especially areas difficult to reach and clean; nooks and crannies; inside hollow equipment legs; metal joints; cracked equipment
Conveyor & washer framework & housing		X			
Doorways		X	X		Especially floor area leading directly into production area
Floors		X	X		
Floor drains		X	X	X	Essential sampling site
Floor mops and squeegees (from Zone 4 only if they move into other zones)		X	X	X	
Forklift that moves into Zone 2		X	X	X	Wheels are known harborage sites for <i>Listeria</i>
Holes in walls or coolers		X	X		
Maintenance equipment & tools		X	X		
Motor & electrical housings		X	X		Especially those that do not appear to be routinely cleaned and sanitized
Pallets (From Zone 4 if they may be used in Zone 2)		X	X	X	
Pallet jack (From Zone 4 if they may be used in Zone 2)		X	X	X	Wheels are known harborage sites for <i>Listeria</i>
Phone		X	X		
Refrigerated storage area for finished products; Walk-in coolers		X	X		
Sanitizing footbath mat		X	X		Can be a harborage area if proper sanitizer levels are not maintained
Scissor ladder lifts		X	X		
Sinks or safety stations – Underside		X	X		e.g., under hand wash or eye wash stations, especially if they appear to be cracked or leaking
Table legs		X	X		
Walls		X	X		e.g., in production areas, coolers, or freezers
Waste container		X	X		Especially the underside
Wheelbarrow - Exterior		X	X		Wheels are known harborage sites for <i>Listeria</i>
Dry goods storage warehouse				X	
Employee break room				X	
Employee locker room				X	
Loading dock area				X	

It is generally NOT necessary to collect samples from:

- Dry surfaces – Most areas in Zones 3 and 4 may be dry and hence will not support growth of *Listeria*. Only surfaces that accumulate condensate or are periodically wet should be sampled.
- New, unused packaging materials - clamshells, lids, etc.
- Raw material – product raw materials, etc. unless there is a specific reason to do so.
- Outside the plant – roof, parking lot, walkways, etc.

7.2.7 Number of Sampling Site and Sampling Frequency

How Many Samples to Collect

§ The number of sampling sites must be sufficient to determine whether measures are effective

- Sample number should be proportionate to risk
 - More samples from Zone 1 and Zone 2
 - Fewer from Zone 3
 - Very few or none from Zone 4 and dry areas
- Rotating sites periodically
- Food Safety Manager should review and approve site designation and numbers



The written environmental monitoring plan must include the number of sampling sites taken from each zone, i. e., including food contact surfaces and non-food contact surfaces (§112.145(c)(3)). In general, when sampling for *L. monocytogenes* or for *Listeria* spp., the majority of samples should be collected from Zones 1 and 2, fewer should be collected from Zone 3, and very few or none from Zone 4. There is the greater risk of food contamination if the organism is present in Zones 1 and 2 (See Table 7.1 for examples of sites within each zone). Note that these are potential sampling sites, and might not be sampled every time. Rather, a plan could record potential sampling sites that are rotated through periodically (see Appendix 7.4: Environmental Monitoring Plan for *Listeria* – Example). If a representative set, rather than all, sites identified in the plan is sampled and tested each month, the written sampling plan should be designed so that all sites identified in the list of potential sampling sites are tested within a predetermined interval appropriate to the operation (e.g., quarterly). The number of samples taken each time

will vary by operation, based on the size and complexity of the operation, along with conditions, practices and history.

While larger sprout operations will likely have more sampling sites than smaller operations, even the smallest sprout growers should collect samples from at least 5 food contact surface and 5 non-food contact surface sites from each production area (e.g., each growing room) per sampling event. Sampling the same locations over time can be used to identify trends. Additional (non-routine) testing may be necessary in response to positive sample results (See Section 7.3: Corrective Actions).

Food safety management should approve the designated sample sites, and may choose to increase or decrease the number of sites actually sampled, including adding new sites not on the current list. Additional sites from specific areas where *Listeria* is known to be, or likely to be problematic should be included. Sprouters may also enlist a food safety expert to assist with identifying suitable sites.

Sampling Frequency

- § Minimum acceptable frequency – monthly from food contact and non-food contact surfaces
 - For operations showing control of *Listeria* over time
 - More frequent
 - When an operation is just starting sampling
 - When multiple *Listeria* positives are found
 - When *Listeria* is found on any FCS
 - Resume regular sampling frequency only when test results are consistently negative




Environmental samples must be collected no less than monthly (§112.145(c)(2)) for facilities that have proven to control *Listeria* over time. When an operation is just starting to collect environmental monitoring data, sampling should be conducted more frequently to establish an environmental monitoring profile, until monitoring shows no *Listeria* positive results. If sprouters go through a period when they have *Listeria* positives, sampling should be done more frequently until there is confidence that all resident *Listeria* have been removed. Testing frequency can be reduced going forward.

7.2.8 How to Sample

Sampling Procedure

<ul style="list-style-type: none"> • Label each sample bag • Put on a new pair of gloves • Follow kit instructions • Remove a sampling sponge or swab from the sampling bag and swab a pre-determined area <ul style="list-style-type: none"> - Look for “worst case” areas 	<ul style="list-style-type: none"> • Return sponge or swab to the original sample bag and seal the bag • Place samples in the cooler with ice packs and submit for testing within 24 h • Keep samples refrigerated at all times
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Instructions from manufacturers of environmental sampling kits should be strictly followed. Above is an example of sampling procedure. Another example is in Appendix 7.4: *Listeria* Environmental Monitoring Plan - Example. Send the samples to the lab the same day as sampling if possible, but no later than 24 hours after collecting the samples. Keep the samples refrigerated throughout. Check with the lab in advance to make sure that they can receive and process the samples on the day of receipt.

7.2.9 Compositing Samples

Compositing Samples

<ul style="list-style-type: none"> • Advantage <ul style="list-style-type: none"> - Allows a larger number of sites while minimizing lab cost • Disadvantages <ul style="list-style-type: none"> - Cannot identify a specific contaminated site if positive result is obtained - FDA method does not allow compositing 	<ul style="list-style-type: none"> • Food contact surface samples should not be composited • When compositing samples, use a separate swab or sponge for each sample and put all to be composited in a single bag
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Definition

Monitor: To conduct a planned sequence of observations or measurements or measurements to access whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement



- 21 CFR 112.3

Compositing environmental samples refers to the common technique of combining analytical portions from multiple individual


samples and analyzing the mixture of the portions (i.e., a “composite”), rather than testing each sample individually. Compositing environmental samples from more than one sampling site allows an operation to **monitor** a larger number of sites while minimizing laboratory costs. Composite samples consist of combining multiple swabs/sponges in the same lab receptacle that for testing together. A single swab/sponge should not be used for multiple locations as this could spread *Listeria* should it be present. The disadvantage of composite sampling is that if a composite sample is positive, the firm is not able to determine with any certainty which one or more of the locations sampled was contaminated. Do not composite more than 5 sponges or swabs.

Zone 1 Samples

- Zone 1 samples should **not** be composited
- Each Zone 1 sample should be from its own specific, identified site

Photos provided by sprout grower



Sprouters should *not* composite samples taken from food contact surfaces (Zone 1). Each food contact surface sample should be from its own specific, identified site to allow the operation to quickly identify the location that is contaminated and take appropriate and immediate corrective actions when needed.

Compositing Samples – Other Zones

- Compositing samples from non-food contact surfaces sites is accepted *for an operation that is in control*
 - Requires validated method for compositing
- Individual sampling is strongly recommended if a composite sample tests positive for *Listeria* spp.



Sprout
Safety Alliance

Compositing environmental samples from non-food contact surfaces sites is an accepted practice for an operation that is in control, with no recent positive results. However, if a composite sample tests positive for the presence of *Listeria* spp., individual sampling is strongly recommended as a follow-up until the specific location of the organism is identified and eliminated. The test method used must be validated to produce accurate results when compositing is used.

7.2.10 How to Choose a Testing Laboratory

Criteria of a Reliable Testing Lab

- Laboratory qualified for *Listeria* testing
- Qualified for microbial testing
- Trained and experienced staff
- § FDA standard, or equivalent, testing methods

Sprout
Safety Alliance

A qualified, third party lab should be used for testing for pathogens. Modern microbiological testing techniques require a high level of training and sophistication. In addition, growing possible human

pathogens in proximity to a food production facility is inherently risky. The laboratory should be:

- Qualified for microbial testing, e.g., a laboratory that is accredited to comply with proficiency testing systems such as the American Association for Laboratory Accreditation (A2LA), ISO/IEC 17025 of the International Organization for Standardization (ISO), the International Electro-technical Commission (IEC) or other appropriate state or national authority;
- Staffed by personnel with training and experience in analytical microbiology techniques to ensure that tests are performed correctly and that all appropriate safety precautions, including appropriate waste disposal, are followed. The laboratory staff must be conversant with the FDA (2015b) “Testing Methodology for *Listeria* spp. or *L. monocytogenes* in Environmental Samples” or a scientifically valid method that is at least equivalent to FDA’s method in accuracy, precision and sensitivity (§112.152);
- Equipped with appropriate resources and a demonstrable quality management system.


7.3 CORRECTIVE ACTIONS

Corrective Actions

§ Corrective action plan must be written in the environmental monitoring plan

§ Corrective actions must be taken immediately if *Listeria* is detected

- Positive test results should be communicated to appropriate management
- A team should be assembled and implement the corrective plan



A corrective action plan must be included in the written environmental monitoring plan (§112.145(e)). If *Listeria* spp. or *L. monocytogenes* is detected in the growing, harvesting, packing or holding environment, then corrective actions must be taken immediately (§112.146). The corrective action plan must detail when and how the actions in §112.146 (discussed below) will be performed when *Listeria* is found. Having a corrective action plan in

place helps ensure that corrective actions are taken quickly in response to finding *Listeria* spp. or *L. monocytogenes* in the sprouting environment.

§ Required Corrective Actions When *Listeria* is Detected

- Sample and test affected surface and surrounding area to evaluate the extent of the problem
- Clean and sanitize affected surfaces and surrounding areas
- Conduct additional sampling and testing to determine whether the *Listeria* has been eliminated
- Conduct finished product testing when appropriate
- Perform necessary actions to prevent recurrence of the contamination
- Take appropriate action to prevent any adulterated food from entering into commerce



Positive test results should be communicated to appropriate management. Sprouters should assess the event and implement their corrective action plan along with any additional corrective actions indicated by observations during the assessment. The corrective action plan must specify how and when the sprouter will:

- Conduct additional exploratory testing of surfaces and areas surrounding the area where the positive test result was detected to evaluate the extent of the problem, including the potential for *Listeria* spp. or *L. monocytogenes* to be established in a niche (§112.146(a)),
- Clean and sanitize the affected surfaces and surrounding areas (§112.146(b)),
- Conduct additional sampling and testing (referred to as “cleaning verification testing”) to determine whether the *Listeria* spp. or *L. monocytogenes* was eliminated (§112.146(c)),
- Conduct finished product testing when appropriate (§112.146(d)),
- Perform any other actions necessary to prevent recurrence of the contamination (§112.146(e)) and what some of those actions may be, and
- Take appropriate action to prevent any sprouts that are contaminated with *L. monocytogenes* from entering into commerce (§112.146(f)).

In addition to the above, the corrective action plan should specify additional steps to determine the source and route of contamination if cleaning verification testing yields positive results for *Listeria* spp. or *L. monocytogenes*. The corrective action plan should also identify the person(s) responsible for corrective actions in the operation and any specific training that the person(s) should have.

7.3.1 Corrective Actions for Positive Finding of *Listeria* spp.

Finding *Listeria* spp. General Considerations

- Indicates the *potential* presence of the pathogen *L. monocytogenes*
- Further testing is needed to determine if it is a transient or resident strain
- Assess environmental conditions that could support establishment of *L. monocytogenes*, e.g.
 - Review and observe sanitation practices
 - Review traffic patterns, equipment layout, employee practice, etc.



A positive for *Listeria* spp. indicates the *potential* presence of *L. monocytogenes*, but the pathogen may or may not actually be there. Remember, the positive result could be from a transient strain that already passed through the system or a resident strain that is established in the production environment. Therefore, the written corrective action plan for finding *Listeria* spp. should focus on assessing potential contributing practices and conditions that could support establishment of *Listeria* in the environment. These contributing practices and conditions may include:

- Checking maintenance records for modifications or repairs to major equipment,
- Interviewing and observing sanitation, maintenance and production employees to determine whether appropriate procedures are being followed,
- Reviewing production, maintenance and sanitation procedures to determine whether to modify the procedures to prevent contamination, and implementing modifications identified by the review, and
- Reviewing traffic patterns, equipment layout and adherence to employee hygiene procedures.

7.3.2 Corrective Actions for *Listeria* spp. on a Non-food Contact Surface



Escalation of environmental monitoring tests is required when *Listeria* is identified through routine environmental monitoring. The flow diagram above summarizes action escalation that applies when *Listeria* spp. are identified on non-food contact surfaces. A flow diagram from FDA (2017a) that includes regulatory citations is in Appendix 7.2. Three phases of corrective action are described, including an Exploration phase, an Intensified Cleaning and Sampling phase, and, if needed, an Escalate Investigation phase.

7.3.2.1 1st Positive: Exploration

Actions to take for the first *Listeria* spp. positive on a non-food contact surface include the following:

- 1) *Exploratory testing*: Sprouters must conduct additional testing of surfaces and areas surrounding the area where *Listeria* spp. was detected to evaluate the extent of the problem, including the potential for *Listeria* to be established in a niche (§112.146(a)).
- 2) *Cleaning and sanitizing*: Sprouters must clean and sanitize the affected surfaces and surrounding areas (§112.146(b)).
- 3) *Cleaning verification testing*: Sprouters must conduct additional sampling (during production) and testing to determine whether the *Listeria* spp. was eliminated (§112.146(c)).

When all cleaning verification tests are negative, this suggests that the first positive was likely due to a transient strain, and that routine cleaning and sanitizing procedures were effective in removing the

microorganism. Therefore, sprouters may continue production and routine environmental monitoring. However, if any cleaning verification tests result in a second positive, corrective action escalates to the next level in which cleaning and sanitizing are intensified.

7.3.2.2 2nd Positive: Intensified Cleaning and Sampling

Sprouters must take action to prevent recurrence of the contamination (§112.146(e)), and detecting *Listeria* spp. through cleaning verification testing indicates that routine cleaning and sanitizing procedures are inadequate to prevent recurrence of contamination. Actions to take in response to this second *Listeria* spp. positive from cleaning verification testing of non-food contact surfaces include the following:

Intensified cleaning and sanitizing includes sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continued findings of positive samples. Intensified cleaning and sanitizing can include increasing the frequency of cleaning and sanitizing for certain pieces of equipment and breaking down the equipment into its parts for deeper cleaning.

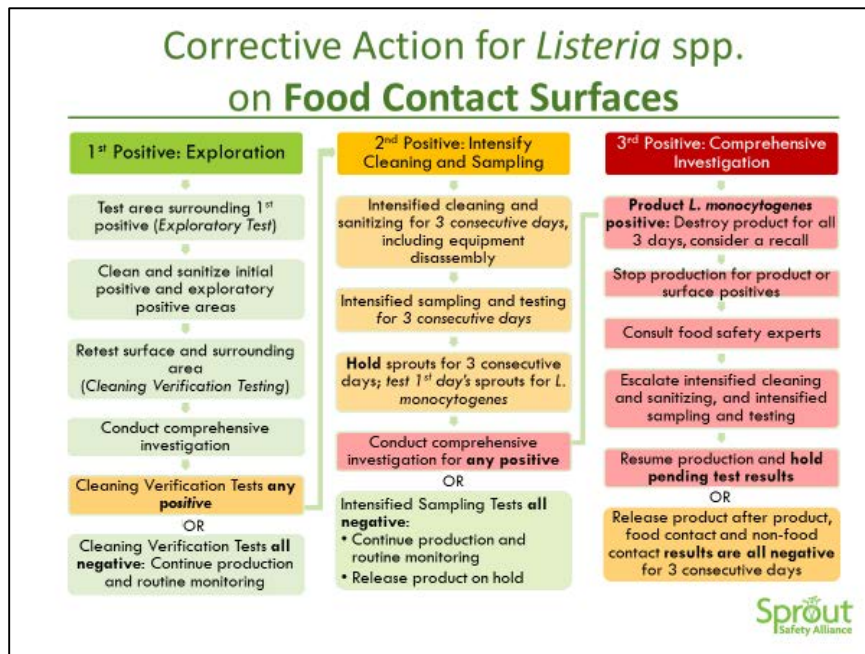
- 1) *Intensified cleaning and sanitizing*: FDA (2017a) recommends that, sprouters perform intensified cleaning and sanitizing in the affected areas.
- 2) *Intensified testing*: FDA (2017a) also recommends that sprouters conduct intensified sampling (during production) and testing at this stage (“intensified testing”) to verify the effectiveness of the intensified cleaning and sanitizing, and to look for possible harborage sites in the affected area.

If all intensified testing results are negative, this suggests that the intensified cleaning and sanitizing was successful in removing a potential source of contamination. Therefore, sprouters may continue production and routine environmental monitoring. However, if any cleaning verification tests result in a third positive event, corrective action escalates to the next level in which investigation is escalated.

7.3.2.3 3rd Positive: Escalate Investigation

As an action to prevent recurrence of the contamination (§112.146(e)), FDA (2017a) recommends that sprouters conduct additional activities to determine the source and route of contamination, including activities involved in a comprehensive investigation. These actions could vary depending on the risk that a food contact surface or sprouts could become contaminated from the positive non-food contact surface site. Examples of such actions include escalating mitigation efforts to identify and eliminate the *Listeria* spp. source, and considering consultation with a *Listeria* control expert.

7.3.3 Corrective Actions for *Listeria* spp. on a Food Contact Surface



Detecting Listeria spp. in a rotary drum or similar food contact surface heightens the risk of sprout contamination with L. monocytogenes. This is because 1) the mixing action spreads contamination throughout the drum or similar equipment and 2) the warm moist conditions for sprouting also support growth of Listeria. Thus FDA (2017a) recommends that a Listeria spp. positive result from such a site during routine sampling should trigger corrective actions described for intensified cleaning and sampling (2nd positive), and the production batch associated with the positive routine sample site (and any other potentially affected product) should be placed on hold while intensified cleaning and sampling takes place.

The focus of this next section is on appropriate corrective action for detection of *Listeria* spp. on food contact surfaces. Actions for food contact surfaces are different because the risk of product contamination increases when *Listeria* is isolated from a food contact surface rather than a non-food contact surface. The flow diagram above summarizes action escalation that applies when *Listeria* spp. are identified on food contact surfaces. As with the previous discussion, an FDA (2017a) flow diagram that addresses the above and includes regulatory citations is in Appendix 7.3.

7.3.3.1 1st Positive: Exploration

Actions to take for the first *Listeria* spp. positive on a food-contact surface typically include the following:

- **Exploratory testing:** Sprouters must conduct additional testing of surfaces and areas surrounding the area where *Listeria* spp. was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to be established in a niche (§112.146(a)).
- **Cleaning and sanitizing:** Sprouters must clean and sanitize the affected surfaces and surrounding areas (§112.146(b)).
- **Cleaning verification testing:** Sprouters must also conduct additional sampling and testing to determine whether the *Listeria* spp. was eliminated (§112.146(c)).
- **Comprehensive investigation:** In contrast to non-food contact surface actions, following a positive finding of *Listeria* spp. on

a food-contact surface, sprouters should conduct a comprehensive investigation to identify and mitigate *Listeria* sources, and modify procedures where appropriate. This is an action to prevent recurrence of the contamination (§112.146(e)). Sprouters may need to stop production to conduct the comprehensive investigation. Also note that for some food contact surfaces at increased risk, such as a rotary drum.

7.3.3.2 *2nd Positive: Intensified Cleaning and Sampling*

When a food contact surface sample from the cleaning verification test yields a 2nd *Listeria* spp. positive result, FDA (2017a) recommends the following intensification of cleaning and sampling:

- *Three production days of intensified cleaning and sanitizing:* An action to prevent recurrence of the contamination is required by §112.146(e). FDA recommends sprouters perform intensified cleaning and sanitizing in the affected areas for the next three production days.
- *Three production days of intensified sampling and testing:* FDA (2017a) also recommends that, as an action to prevent recurrence of the contamination (§112.146(e)), sprouters conduct three additional rounds of sampling and testing at affected areas during production (“intensified testing”) for the next three production days both to verify the effectiveness of intensified cleaning and sanitizing, and to look for possible harborage sites in the affected area.
- *Finished product testing and other product actions:* Sprouters must conduct finished product testing when appropriate (§112.146(d)), for example, when a 2nd food contact surface is positive for *Listeria* spp. When this occurs, a sprouter should **hold** production batches associated with the positive food contact surface for *three consecutive production days* and test the *first day’s production batch* for *L. monocytogenes*. A statistically-based sampling plan and methods that provide an appropriate level of confidence (e.g., 95% confidence) of detecting *L. monocytogenes* present in the batch should be used. FDA (2017b) discusses considerations for selecting the number of samples to analyze. Sprouters should consult this guidance and work with a qualified laboratory to determine the number of samples and sample size to collect for a specific situation. In any event, samples representative of the production batch (e.g., a sample from each section of a rotary drum) should be submitted to the laboratory.
- *Comprehensive investigation:* As an action to prevent recurrence of the contamination (§112.146(e)), sprouters should also conduct a comprehensive investigation to

identify and mitigate *Listeria* sources, and modify procedures where appropriate. Sprouters may need to stop production to conduct the comprehensive investigation (see Section 7.3.3.4 Detecting *Listeria* spp. in a Rotary Drum or Similar Equipment).

- *Returning to production:* If all results from three production days of intensified testing are negative, and finished product testing is also negative, sprouters should return to routine environmental monitoring. All three production days of sprouts on hold can enter commerce, provided there is no other reason for concern (e.g., other testing requirements in §112.147 are satisfied for these batches). Sprouters should target surfaces where positives were previously found for sampling and testing during the next routine environmental sampling event.
- If any of the intensified environmental testing or product testing results are positive, further steps should be taken to prevent potentially contaminated product from entering commerce.

7.3.3.3 3rd Positive: Comprehensive Investigation

- When *L. monocytogenes* is detected in product or when any intensified sampling *Listeria* spp. test is positive (3rd or subsequent positive), a comprehensive investigation is warranted. FDA (2017a) recommended actions include the following:
 - *Product Actions:* If a production batch of sprouts tests positive for *L. monocytogenes*, §112.146(f) requires sprouters to prevent it from entering into commerce. FDA (2017a) recommends that sprouters destroy any *L. monocytogenes* positive production batch. If any of the samples from the three production days of intensified sampling and testing of food contact surface and non-food contact surface sites for *Listeria* spp. is positive, sprouters should consider the possibility that the production batches representing all three production days may also be adulterated. FDA (2017a) recommends that sprouters destroy any such batches in light of all of the positive findings in the sprouting environment. Sprouters should also evaluate whether any other sprout production batches (either at the operation or in distribution) should be recalled or destroyed.
 - *Stop production and investigate:* When intensified sampling and testing continues to detect *Listeria* spp. on food contact or non-food contact surfaces, or if *L. monocytogenes* is detected in product, sprouters should assume that a harborage site exists. As actions to prevent recurrence of

contamination (§112.146(e)), sprouters should stop production, and destroy and consider recalling any potentially contaminated sprouts (or other food). It is also recommended that sprouters consult with food safety experts familiar with troubleshooting *L. monocytogenes* contamination problems in operations to conduct a comprehensive investigation and make recommendations for appropriate actions based upon that investigation.

- *Returning to production:* After all corrective actions are implemented and production begins again, sprouters should test sprouts from each production batch, and conduct intensified sampling and testing of food contact and non-food contact surfaces on each production day, until three consecutive days of negative test results for food contact and non-food contact surfaces, and for sprouts are obtained. This helps to assure that the situation is resolved and expanded recalls can be avoided.

7.3.4 Corrective Actions for Finding of *L. monocytogenes*

L. monocytogenes Corrective Action

§ If *L. monocytogenes* is found on a food contact surface, prevent implicated sprouts from entering commerce; i.e.,

- Destroy sprouts associated with the contaminated surface(s)
- Recall previously shipped product, if necessary
- Follow previous discussed procedures on returning to production



If *L. monocytogenes* is detected, especially if it was on a food contact surface, there is a good chance that product is contaminated. In general, FDA (2017a) expects that sprout operations will test food contact surfaces and non-food contact surfaces for *Listeria* spp. rather than *L. monocytogenes*. There is likely minimal value in determining whether *Listeria* spp. detected during routine environmental monitoring is *L. monocytogenes* because typically the focus should be on eliminating *Listeria* harborage sites regardless of whether an isolate is *L. monocytogenes* or *Listeria* spp. However, in certain cases, such as finding *Listeria* spp. in a drum, sprouters should consider conducting further tests to determine whether a *Listeria* spp. positive in environmental samples is *L. monocytogenes*.

If a sprouter detects *L. monocytogenes* on a food contact surface, §112.146(f) requires the sprouter to “take appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering into commerce” (see text box). Destruction of any potentially affected production batch of sprouts associated with the contaminated food contact surface (as part of a recall, if applicable) and following procedures outlined above on “returning to production” in corrective actions for a 3rd positive on a food-contact surface should be followed.

7.4 RECORDS

Listeria Monitoring Records

- § Written environmental monitoring plan
- § Documentation of all test results
 - All results by zone, location (site) and date
 - All positive results by site and date
 - Results of follow-up testing
- § Analytical methods used
- § Corrective actions taken
- § Available for review by inspectors and maintained for at least two years
 - Reviewed for trends by management at least annually



A food shall be deemed to be *adulterated*— 1 (a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health... (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...

- Section 402 of the Food, Drug and Cosmetic Act

While conducting environmental sampling, it is important to document the sampling program. A review of records could provide a possible link between the location of a positive environmental sample and a potential route of contamination of the sprouts that contacted that surface.

The *Produce Safety Rule* describes requirements for records to establish and keep for environmental monitoring in sprout operations. Specifically, the following records associated with environmental monitoring must be established and kept:

- Written environmental monitoring plan (§112.150(b)(2)),
- Documentation of the results of all analytical tests conducted (§112.150(b)(4)),
- Any analytical methods used (§112.150(b)(5)), and
- Corrective actions (§112.150(b)(6)).

In the event of a positive result on a *Listeria* spp. or *L. monocytogenes* test, continual review of the records should be part of the corrective action plan. All records should be reviewed for trends by

management from time to time, and at least annually. Environmental monitoring records must be available for review by FDA and their designee. More details about recordkeeping and are discussed in Module 12: Recordkeeping.

Environmental Monitoring Summary

- Development and implementation of an environmental monitoring plan for *Listeria* are required
- Effective environmental monitoring for *Listeria* helps with:
 - Detecting *Listeria* before it becomes established in the production environment
 - Monitoring *Listeria* contamination trends
 - Preventing contamination of sprouts



In summary, sprouters must develop and implement an environmental monitoring plan. Effective environmental monitoring for *Listeria* allows sprouters to detect *Listeria* within equipment and the production environment if present. It helps in monitoring the trend of *Listeria* contamination in the operation and preventing contamination of sprout products.

7.5 REFERENCES AND SAMPLE DOCUMENTS

- FDA, 2017a. Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry. <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM537031.pdf>
- FDA, 2017b. XIII.F.3 "Hold and Test: Procedures for RTE Food, in *Control of Listeria monocytogenes in Ready-To-Eat Foods: Guidance for Industry (Draft Guidance)*, <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>
- FDA, 2015a. FSMA Final Rule on Produce Safety. <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
- FDA, 2015b. Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples. <http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM467056.pdf>
- FDA, 2014. FDA's Bad Bug Book. 2nd Edition. <http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/>
- FDA, 2008. Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm#contam>

Appendix 7: Environmental Monitoring for *Listeria* spp. or *L. monocytogenes* in a Sprout Operation

A7.1: Aseptic Procedure for Sampling

A7.2: Non-food Contact Surface Testing and Follow-up Actions
for Zone 2 – Example

A7.3: Food Contact Surface Testing and Follow-up Actions for
Zone 1 – Example

A7.4: Environmental Monitoring Plan for *Listeria* – Example

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Module 8. Seed Purchasing, Receiving and Storage

8.1 INTRODUCTION

Learning Objectives

- In this module, you will learn:
 - The food safety considerations when purchasing seeds
 - How to choose a seed supplier
 - Seed receiving and inspection procedures
 - Seed testing and quarantine
 - Seed storage conditions
 - Recordkeeping



Sprout safety is not only influenced by the conditions at the sprouting operation, but also by conditions growing, storing and handing seed prior to receipt. This module covers food safety considerations for purchasing, receiving, inspecting, testing and storage of seed, and associated records.

Food Safety Concerns for Sprout Seed

- Seed has been implicated in many sprout-related outbreaks
- Seed can be contaminated during growing, processing, transportation or storage




While many of the topics in this module are best practices rather than requirements, food safety considerations for seed should not be overlooked. The presence of pathogenic bacteria on sprout seed has been implicated in many sprout-related outbreaks. As previously discussed in Module 3: Sprout Safety Hazards, even low levels of these bacteria on seeds can present a public health risk to consumers because the warm and humid conditions used for sprouting are an excellent growing environment for pathogens if they are present.

Because seeds can become contaminated at any point, the conditions used during growing, harvesting, sorting, cleaning, storage and transportation of seed are critical to ensure the high quality and microbiological safety of seed delivered to a sprouter. Some seed growers and distributors are aware of the importance of growing and handling of seed under sanitary conditions if it is for sprouting. Others are not, especially if their primary customers are buying seed for agricultural use.

Goal

- Only high quality and non-contaminated seeds are used for sprout production



Sprouters should purchase seed that is of high quality (free of filth and with minimal seed damage) and has been handled properly up to the time of receipt. It is important to build close relationships with seed suppliers and to request assurances (such as audit certificates, testing results and letters of guarantee) that seed has been produced and handled safely prior to sale. It is also essential for each sprout operation to develop and implement a plan that outlines the seed receiving and storage procedures, to ensure that only high quality seeds are introduced into the sprouting process and the potential for producing unsafe sprouts is minimized.

8.2 SEED PURCHASING

How to Choose a Seed Supplier

- Ask questions such as:
 - How was the seed grown?
 - How was the seed handled?
 - Was the seed tested for pathogens?

See the appendix for sample questions:

Appendix 8.1 Example Questions for Seed Growers

Appendix 8.2 Example Questions for Seed Suppliers



Sprouters cannot directly control the conditions under which seed destined for sprouting are handled, but they can ask questions, and ensure that they receive pertinent documentation from the seed supplier prior to purchasing the seed. Example questions are in Appendix 8.1: Example Questions for Seed Growers and Appendix 8.2: Example Questions for Seed Suppliers.

Request Documentation

- Examples
 - Assurance that seed was grown according to GAPs
 - Seed tag
 - Certificate of Analysis (CoA)
 - Letter of Guarantee
 - Seed testing results
 - Trace-back procedure and records



Sprouters should obtain assurances that they are purchasing seed of high quality and that the proper food safety measures have been implemented by seed growers, conditioners and suppliers throughout the seed growing, harvesting, processing and transportation steps. Examples are listed in the slide above. To

choose a reliable seed supplier, the sprouter should request assurances that the seed was produced following Good Agricultural Practices (GAPs) guidelines and that it was handled in a safe and sanitary manner after harvest. Documenting potential supplier responses to questions such as those in Appendix 8.1 is useful during the supplier selection process, and could be included in a purchase agreement.

8.2.1 Seed Production

Contamination Sources During Production

- Contaminated water
- Animal waste and manure
- Poor sanitation of equipment



Definition

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

Sprouters should have basic food safety knowledge of seed production and conditioning. Possible sources of contamination during seed production include contaminated irrigation water, animal waste and *manure*, and poor sanitation of equipment.

Good Practices for Seed Growers

- Follow Good Agriculture Practices (GAPs)
- Use only chemicals approved for application to seeds intended for human consumption
- Useful FDA reference
 - *The Guide to Minimize Microbial Food Safety Hazards: The Guide at a Glance*



Seed for sprout production should be grown under GAPs to minimize the likelihood that they will carry pathogenic bacteria. Seed growers should have documentation demonstrating adherence to GAPs and make it available to sprouters or seed distributors upon request. More about GAPs is available in FDA's GAPs overview document *The Guide to Minimize Microbial Food Safety Hazards: The Guide at a Glance* (FDA, 2015a) and their more detailed *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (FDA, 1998).

8.2.2 Seed Conditioning

Good Practices for Seed Conditioning

- Follow good handling practices
- Clean and sanitize equipment
- Do not mix cracked or broken seeds with whole seeds
- Maintain lot identity when mixing seed lots
- Have trace-back records and recall procedures in place



Good handling practices should be followed in seed processing and conditioning operations. To the extent possible, seed for sprouting should be free from foreign matter including soil, insect fragments, bird and rodent droppings.

Seed conditioning is a process to remove debris and dirt from seed by using different kinds of equipment. The process can potentially cause seed damage. Seed damage increases the likelihood of seed quality and safety concerns. Severely damaged seeds, which may be more susceptible to microbial contamination, should not be used for production of sprouts. Conditioning should be carried out in a hygienic manner to minimize potential spread of any localized contamination to an entire seed lot.

Seed conditioners should have trace-back records and recall procedures in place to be able to effectively respond to public health concerns. Mixing seed lots can complicate product tracing, unless the firm can provide sufficient information to indicate that they can adequately identify the source of each seed lot, and trace the sites and agricultural inputs associated with each lot. Any seed lot that may present a hazard (e.g., a recalled lot or blended lots that may

contain seed from a recalled lot) should be sequestered until properly disposed of and should not be sold for sprouting.

8.2.3 Purchasing from Foreign Suppliers

Purchasing from Foreign Suppliers

- Is the seed from a seed importer or broker?
- Be familiar with the FSMA *Final Rule on Foreign Supplier Verification Programs (FSVP)*
- Ensure compliance with U.S. standards
- Ask suppliers of imported seed questions regarding FSVP compliance
- Request and retain relevant documents



Definitions

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

- 21 CFR 112.3

Importer: The U.S. owner or consignee of an article of **food** that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under 21 CFR Part 1 Subpart L.

- 21 CFR 1.500

If sprouters purchase seed originating from countries outside of the U.S., they should be familiar with the FSMA *Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals* (FDA, 2016). **Importers** must develop, maintain and follow an FSVP that provides adequate assurances that the foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under U.S. regulation regarding hazard analysis and risk-based preventive controls for certain foods, standards for produce safety, if either is applicable, and the implementing regulations, and is producing the food in compliance with U.S. regulation regarding adulteration and, if applicable, misbranding with respect to labeling for the presence of major food pathogens (§1.502(a)).

If sprouters purchase imported seeds, they may question suppliers of imported seed and request appropriate documentation. Example questions follow:


- Are you a direct importer?
- Do you know about the FDA *Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals*?
- Do you follow foreign supplier verification procedures to ensure that the seeds you import are safe for sprouting?
- May I see the documentation of the foreign supplier verification activities that you conducted?

8.3 SEED RECEIVING

8.3.1 Seed Receiving SOP

Seed Receiving SOP

- A receiving Standard Operating Procedure (SOP) should include:
 - Receiving procedures
 - Inspection procedures
 - Documents to request



Sprouters should develop a Standard Operating Procedure (SOP) for receiving seed, including acceptance criteria and records such as receiving logs. The SOP for these inspections should also include specific procedures for handling and documenting any issues identified during the inspection. This record may be needed for recall or traceability purposes.

Personnel responsible for receiving shipments should be trained to conduct inspections of incoming shipments and identify possible issues of concern. They should also adhere to good hygiene and sanitary practices to prevent cross-contamination. When in the shipping and receiving area, truck drivers should comply with the same good hygiene and sanitation practices expected of the sprout operation's shipping and receiving personnel.

8.3.2 Receiving a Seed Shipment

Examining and Accepting a Shipment

- Condition of transport vehicle
- Physical characteristics of the shipment
 - Conditions of packaging
 - Indication of pest infestation
- Documentation related to seed shipment; e.g.,
 - Seed tag
 - Certificates of Analysis (CoA)
 - Seed test results



Before receiving incoming seeds, sprouters should ensure that they are from known distributors and match those listed on the purchase order. Sprouters should be aware that seed bags can become contaminated during transportation. Any strange or foul odors coming from the delivery vehicle may indicate contamination with filth or chemicals, or infestation from a previous load. Anything suspicious should be questioned and reported to a supervisor.


Information supplied by the seed distributor with a shipment may include:

- Tag (i.e., certification card)
- Certificates of Analysis (CoA)
- Seed testing results

Seed bag labels should include supplier information, lot number, seed type and country of origin.

Certified Seed Tag Example

ABC Association	
Certificate Sample Form	
Seed ID	
Applicant	
Conditioner	
Variety	
Cert Number	
Lot Number	
Weight in Lot	
Class	
Cert Year	
Crop	
Remarks	
Sample Drawn By	



A Certified Seed Tag, such as the blank form illustrated in this slide, can be useful documentation to keep for each lot of seed.

Inspect incoming shipments for evidence of tampering, lot numbers that do not match the bill of lading, and evidence of adulteration, theft or other questionable activities. In addition, shipping records should be examined, and suspicious records (e.g., strange alterations, additions, or deletions, or fake records) should be investigated.

8.3.3 Seed Inspection

Seed Package Inspection

- § Visual inspection
 - Water stains
 - Damaged bags
 - Insect, rodent or bird droppings
- Black light inspection
 - Urine contamination
- Reject any non-compliant bags



Prior to use, sprout operations must complete a visual examination of seeds/beans and their packaging for potential contamination (e.g., visual exam and/or black light/UV exam of seed and seed bags for evidence of insects, rodents, or other contamination) (§112.142(d)).

Damaged packages and containers may indicate mishandling and/or exposure of the product to insects, rodents, chemicals, or other contaminants before or during shipping. Damaged or soiled containers should be rejected.

Open Bag Inspection

- Open the bag in a hygienic manner!
- What to inspect:
 - Visible moisture
 - Presence of foreign material
 - Insects, rodent droppings, bird droppings
 - Fungus/mold contamination
 - High levels of damaged seed

See Appendix 8.3 for Seed Receiving Checklist Examples



Sprouters should open one or more bags, inspect for presence of insect, bird or rodent droppings, examine for unusually high moisture level, sift for physical contaminants (e.g., mud balls, sticks, glass, metal shavings) and inspect under a binocular microscope for signs of excessive cracks or damage, fungus or mold. If large numbers of damaged or infested seeds are found, the shipment should be rejected.

A seed receiving and inspection checklist for seed safety may include:

- Verify supplier name and address on packages to see if they match those on purchase order
- Verify delivery schedule and amount
- Obtain and verify seed specifications (name, ID, year, etc.)
- Inspect for evidence of tampering
- Inspect for evidence of water damage
- Note any strange or foul odor
- Visually inspect for presence of insect, bird or rodent droppings
- Inspect for vermin urine using a black light
- Check for damaged or moldy packages
- Open one or several bags and inspect for cracked or chipped seeds and the presence of foreign materials in the seeds (mud balls, sticks, glass, etc.)

- Check seed treatment record, if available


Seed receiving and sampling checklists are included in Appendix 8.3.

8.3.4 Seed Testing

Seed Testing

- To ensure the seeds are suitable for sprouting:
 - Ask for test results
 - e.g., Certificate of Analysis for the specific lot number
 - Include seed testing questions in the purchasing agreement
 - Send seed samples for testing in a lab
 - Conduct seed sprouting tests in your operation

See Appendix 8.4 for a seed sampling and testing procedure example



Seed can be contaminated with pathogens during production and distribution, therefore it is important to assess whether seed is likely to be contaminated with pathogens. Seed for sprouting should be screened for pathogens and handled separately from seed intended for other purposes.

Ideally, seed for sprouting should come from a supplier that implements a seed testing program, and the results should be made available upon request. Sprouters may inquire if the seed was tested for pathogens by the seed supplier. Microbiological testing results for seed (e.g., Certificate of Analysis (CoA)) may be requested if the seed supplier conducts seed testing. It is useful to maintain testing results by lot number.

An alternative approach to testing dry seed is to test water used to sprout a seed sample. Sampled seed is placed in a bucket of water to initiate seed germination. The soaking water is sampled after 48 hours and tested for pathogens. Since the sprouting process supports the growth of bacterial pathogens present, this type of testing may have a higher probability of detecting pathogens than direct testing of seed. This approach can be done by seed suppliers or by sprouters.


It is important that any seed sampling and testing be conducted separately from the production area to avoid contamination of finished sprout products. The seed lot should also be put on hold pending seed testing results. An example of a seed sprouting test

protocol and seed sampling plan is available from International Specialty Supply (2014) and an example is in Appendix 8.4.

8.3.5 Seed Quarantine

Seed Quarantine

- Reduces the risk of potential cross-contamination
- Where
 - In an area separate from sprout production areas
- How
 - Posted a sign on that particular lot
- How long
 - Until the suitability of the seeds has been determined
 - Until the shipment inspection procedure has been completed



Incoming seeds should be received in an area separate from sprout production areas. Until the suitability of the seeds has been determined, the shipment should be clearly identified, segregated and held to reduce the risk of cross-contamination. A sign can be posted on the lot in quarantine.

A seed shipment that fails to meet the predetermined specifications should be rejected and returned to the supplier or destroyed. The disposition should be documented. Segregate and hold procedures should specify that seed should be held in quarantine until it has been determined that it is to be used, sent back or destroyed.

8.4 SEED STORAGE

Seed Storage

§ Must take reasonably necessary measures to prevent the introduction of known or reasonably foreseeable hazards into or onto seed

- For example:
 - In a designated clearly labeled area
 - Clean, dry and sanitary
 - Off the floor and away from the wall
 - Protected from insects, rodents, birds and animals



Sprouters should store seed under clean and sanitary conditions and inside buildings of sound construction and in good repair. Seed should not be stored near packaging material, chemicals or finished product. Seed that has received prior treatment should be stored separately from untreated seed to avoid recontamination. Sprouters must take reasonably necessary measures to prevent the introduction of **known or reasonably foreseeable hazards** into or onto seed to be used for sprouting (§112.142(a)). Seed should be stored off the floor and away from walls to prevent water damage and to allow pest control devices to be monitored. Bird, rodent and insect inspection and control programs should be carried out to prevent seed contamination during storage. The storage area, and any surface that contacts the seeds or containers of seeds, should be kept dry and clean.

Definition

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

- 21 CFR 112.3

Seed Storage (cont.)

- Should not re-use seed bags for seed storage
- Clearly label seed bags
- Protect opened bags from contamination



Bags for storing seeds should be considered single use and should not be re-used. Each bag should be clearly marked to identify the supplier, seed type, and batch or lot number that will trace back to the seed supplier, and if possible the seed grower, field number and country of origin. Open bags should be stored in tight-fitting containers or otherwise protected from contamination. If you use containers other than original packaging to hold seeds, these containers should be emptied, and their food contact surfaces must be cleaned and sanitized in between uses (§112.143(b)).

8.5 RECORDKEEPING

Seed Records

- Importance of keeping seed records
 - Safe and high quality seed supply
 - Effective trace back programs
- Records should be obtained for **all** incoming seed lots
- Seed records should be kept beyond the inventory on hand for that lot
- Record should be available for inspectors and auditors

See Appendix 8.5 for a Seed Receiving Log Sheet Example



To continuously receive a safe and high quality seed supply and to support an effective trace back procedure, sprouters should

maintain a seed-receiving log documenting seed lot receipt and screening. For example, the following information should be recorded for all incoming seed shipments:

- Truck conditions, shipping protection
- General information (seed type, origin)
- Lot information (original lot size, trace-back to supplier)
- Packaging (condition and size of bags)
- Initial screening (percent damaged seed, evidence of contamination)
- Testing (amount of sample tested, details of tests performed, test results, laboratory)
- Certificates of analysis

The receiving log should be used as a basis for a trace-back program for sprouts grown and sold from these seeds. Records related to each seed lot should be maintained for at least two years after the last used of the seed lot. Records need to be accessible for inspections, audits or recalls. Appendix 8.5 includes an example of a seed receiving log sheet.


**Seed Purchasing, Receiving and Storage
Summary**

§ Must take measures to prevent introduction of pathogens onto seed

- Ask questions and request documents from seed distributors

§ Visually inspect seed and packaging for signs of contamination

- Store seed under sanitary conditions
- Use only good quality seed for production



In summary, sprouters must take measures reasonably necessary to prevent the introduction of pathogens into or onto seed or beans used for sprouting. To accomplish this, sprouters should ask questions and request relevant documentation from seed distributors to obtain assurance that proper food safety measures have been implemented during seed growing, conditioning and distribution. Upon receiving the seed, sprouters must visually inspect seed and packaging for signs of contamination (§112.142(d)). The seed should be stored under dry and sanitary

conditions in the sprout operation. The goal is to use only good quality seed with a low risk of contamination for sprouting.

8.6 REFERENCES AND SAMPLE DOCUMENTS

FDA, 2017. The Guide to Minimize Microbial Food Safety Hazards: The Guide at a Glance.

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm187676.htm>

FDA, 2016. *Final Rule on Foreign Supplier Verification Programs (FSVP)*.

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm>

FDA, 1998. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.

<http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlantProducts/UCM169112.pdf>

Food Safety Authority of Ireland. Guidelines on Safe Production of Ready-to Eat Sprouted Seeds (Sprouts).

https://www.iit.edu/ifsh/sprout_safety/resources/pdf/ireland2011_sproutguidelines.pdf

International Specialty Supply, 2014. ISS Seed Screening Procedures.

<http://www.sproutnet.com/Iss-Seed-Screening-Procedures>

Appendix 8: Seed Purchasing, Receiving and Storage Supplemental Information

A8.1 Example Questions for Seed Growers

A8.2 Example Questions for Seed Suppliers

A8.3 Example Checklists for Seed Receiving and Sampling

A8.4 Example Pathogen Testing Using a Seed Sprouting Procedure

A8.5 Example Seed Receiving Log Sheet Example

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Module 9. Seed Treatment

9.1 INTRODUCTION

Learning Objectives

In this module, you will learn:

- The importance of treating the seeds prior to sprouting
- The *Produce Safety Rule* requirements for scientifically valid seed treatment methods to reduce pathogens
- Considerations for safe and effective seed treatment
- Record keeping requirements related to seed treatment



As discussed in Module 3: Sprout Safety Hazards, contaminated seed has been implicated in foodborne illness outbreaks associated with sprouts. Pathogenic bacteria, if present on seed, can multiply and reach high numbers under the warm, moist conditions used to produce sprouts. The application of Good Agricultural Practices (GAPs) during seed production, Good Handling Practice (GHP) during seed storage and transport, visual seed inspection upon arrival at sprout operations and periodically thereafter, and sampling and testing of seed prior to use can all play a role in reducing the risk of pathogens on seed. However, even with these preventive steps, there is no guarantee that seed will be pathogen free. Therefore, seed treatment using a scientifically valid method to reduce *microorganisms* of public health significance is an important step to further decrease the risk due to pathogenic bacteria on seed.

Definition

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

- 21 CFR 112.3

§ Sprout Growers Responsibility

- To ensure that seeds intended for sprouting are treated to reduce possible contamination with human pathogens



Definitions

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

- 21 CFR 112.3

Scientifically valid: Using an approach that is based on scientific information, data or results published in, for example, scientific journals, references, textbooks or proprietary research.

- Preamble of the final *Produce Safety Rule*

It is *the sprouter's responsibility* to ensure that seed intended for sprouting are treated to reduce the risk of pathogen contamination using a **scientifically valid** method (§112.142(e)). FDA (2017) issued guidance that helps seed growers and sprouters to identify **known or reasonably foreseeable hazards**, and recommends preventive measures, including growing seed using Good Agricultural Practices; cleaning, conditioning and storing seed under sanitary conditions; and applying a pathogen reduction treatment to seed immediately before sprouting.

§ Seed Treatment

- Must treat seed using a scientifically valid method to reduce microorganisms of public health significance
- Treatment may be applied, in whole or in part:
 - by the sprouter or
 - by a seed grower, distributor or supplier provided sprouter obtains documentation



The *Produce Safety Rule* requires sprouters subject to the rule to use seed treated to reduce microorganisms of public health significance using a scientifically valid method (§112.142(e)). The rule provides increased flexibility for sprouters and serves as an incentive for

developing additional seed treatment options because seed treatment may be applied:

- 1) by the sprouter before sprouting or
- 2) in whole or in part by a grower, distributor or supplier of the seed prior to receipt.

If the sprouter relies on prior treatment, they must obtain specific documentation (discussed in the Records section of this Module) from the grower, distributor or supplier. Treatment by another entity can be used to fulfill the seed treatment requirement completely or prior treatment can be considered by a sprouter when applying an additional seed treatment at their operation before sprouting (§112.142(e)).

Important Seed Treatment Considerations

- Variables that impact efficacy of method
 - Chemical concentration
 - Treatment time
 - Complete exposure of all seed
 - Post-treatment rinsing
- Using a scientifically valid seed treatment SOP
- Protecting treated seed from re-contamination



Whatever treatment the sprouter or seed supplier uses, it is important to evaluate variables such as chemical concentration, treatment time and post treatment rinsing to ensure that the treatment is effective and does not impact the quality or yield of the resulting sprouts. A written seed treatment SOP is recommended and all seed treatment methods should be documented. It is also important that treated seed is packaged and handled in a manner that minimizes contamination, both by the seed supplier (§112.142(e)(2)(ii)) and at the sprout operation, to ensure that treated seed does not become contaminated between seed treatment and its use for sprouting. Assuring that all personnel handling seed adhere to hygiene standards, that ill employees do not handle seed, that all employees wash hands before handling seed or seed bags/containers, and that treated seed is not comingled with untreated seed, are all important in preventing contamination of seed.

Goals

The goals of seed treatment prior to sprouting are to:

- Reduce or eliminate pathogens (e.g., *Salmonella* and *E. coli* O157:H7) potentially present on seeds
- Reduce the risk of seed being a source of sprout product contamination



The purpose of treating the seed prior to sprouting is to reduce or eliminate the pathogens such as *Salmonella* and *E. coli* O157:H7 that may be present on seed. This minimizes the risk of seed being a source of sprout product contamination. Washing the seed during treatment also removes dead seed, seed fragments and non-seed material in a seed lot.

9.2 SELECTING SEED TREATMENTS

Selecting a Seed Treatment Method

- § Use a scientifically valid method
 - Suitable for the production practices
 - Compliant with applicable requirements such as organic or kosher rules
- § Use of a chemical requires EPA registration for this purpose



Sprouters should consider their production system when determining which scientifically valid treatment method to use for pathogen reduction. For example, organic sprout producers may prefer to use non-chlorine methods for seed treatment.

The Environmental Protection Agency (EPA) has regulatory authority over seed or bean treatment chemicals, i.e., pesticides. When a sprouter uses a chemical seed treatment, the chemical must be EPA-registered for pathogen reduction use on seed or beans for sprouting (EPA, 1996).

FDA approves use of irradiation (up to 8 kiloGray) to reduce pathogens on seed or beans prior to sprouting. Physical treatments, such as heat or hot water, do not require EPA registration or FDA approval.

Numerous studies on effective seed treatment options exist (e.g., Ding et al.; 2013; Fransisca and Feng, 2012). These include chemicals, temperature control, irradiation, competitive exclusion and combination of methods. While chemical treatments have been studied, such treatments require EPA registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) before they may be used for such purposes. Information on current EPA-registered pesticides is available on EPA's website (EPA, 2017).

In this module, chemical method is described as an example.

9.3 CHEMICAL HANDLING AND PERSONAL PROTECTIVE EQUIPMENT (PPE)

9.3.1 Chemical Handling

Chemical Handling Considerations

- Well-ventilated application area or room
- Only workers wearing Personal Protective Equipment (PPE) in the area during application
- Only trained, authorized personnel have access to chemicals
- Strictly follow manufacturer's label instructions
- Store chemicals in a designated area away from sprout production



When handling seed treatment chemicals, a well-ventilated area or room should be used. Only workers who wear the Personal Protective Equipment (PPE) recommended by the chemical manufacturer should be allowed in the area when preparing and applying the chemical. All employees who handle chemicals should be trained in their proper use and safe handling. Only trained,

authorized personnel should have access to the chemicals. General information on employee training can be found in Module 12: Additional Control Programs.

The level of protective practices needed depends on the treatment used. When treating seed with a strong chemical, safe chemical handling and personal protection must be followed. Directions for use on a chemical label must be strictly followed for safety and regulatory compliance. Chemical handling and PPE requirements for using strong chemicals, such as high levels of chlorine, are listed below.

Only authorized and properly trained personnel should have access to, prepare and dispense chemicals. Chemicals should be mixed in clean, correctly labeled containers, in the correct concentrations. Clearly labeled chemicals should be stored in a designated chemical storage area away from sprout production.

9.3.2 Personal Protective Equipment (PPE)

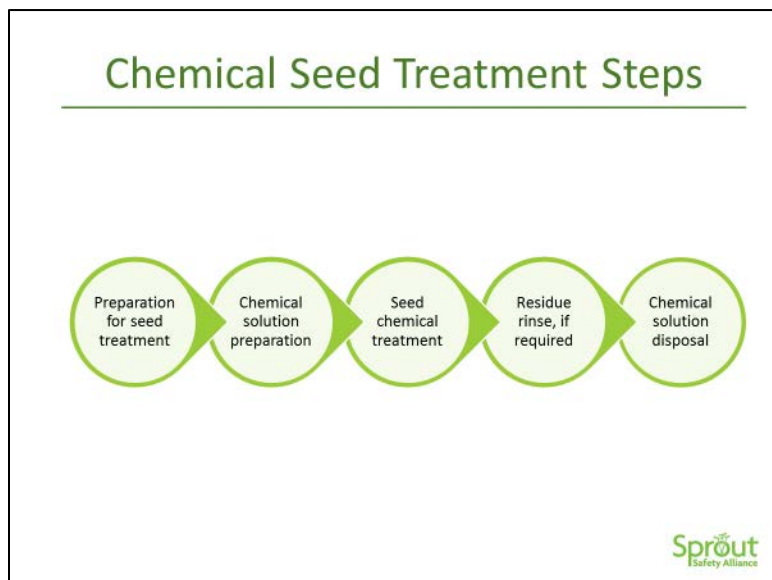
Personal Protective Equipment Examples

- Consult product label and Safety Data Sheet
- Strong chemicals PPE examples may include:
 - Coveralls over long-sleeved shirt and long pants
 - Waterproof gloves
 - Chemical-resistant footwear plus socks
 - Protective eyewear
 - Chemical-resistant headgear for overhead exposure
 - Chemical-resistant apron
 - Dust/mist filtering respirator



As previously mentioned, appropriate PPE is critical for workers who handle chemicals. Handlers of a concentrated chemicals, such as high levels of chlorine, may be required to use all or some of the PPE listed above. Handlers of diluted or less irritating solutions may not need some of these PPE examples. Consult the chemical label and Safety Data Sheets for safe handling requirements.

9.4 CHEMICAL SEED TREATMENT PROCEDURE



9.4.1 Preparation for Seed Treatment

Preparation for Seed Treatment

- Sanitary seed treatment area
- § Cleaned and sanitized containers and utensils
- § Agriculture water (no detectable *E. coli*/100 mL)
- Seed pre-rinse

See Appendix 9.1 for a seed treatment SOP example

Sprouters should inspect seed bags for contamination before bringing them into a seed treatment area. Details of seed inspection are described in Module 8: Seed Purchasing, Receiving and Storage.

Seed treatment should be conducted in a sanitary area separate from seed and chemical storage areas, and away from germination and packaging activities. Before treating any batch of seed, all food contact surfaces of tools and equipment must be thoroughly cleaned and sanitized (§112.143(b)). The container should be large enough to allow thorough mixing without splashing. **Agricultural water** (§112.44(a)(3)) must be used for this procedure and is added to the

Ag water for sprouts

“When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic *E. coli* in 100 mL of agricultural water, and you must not use untreated surface water for any of these purposes...”

- 21 CFR 112.44(a)

container first. When pouring seed into a container, the operator should wear a pair of clean gloves and not touch the seed with bare hands.

Some seed treatment processes recommend or require pre-rinsing the seed to remove surface organic matter, such as dirt, to maximize the chemical treatment efficacy. An example of pre-rinsing seed before treatment is presented in Appendix 9.1.

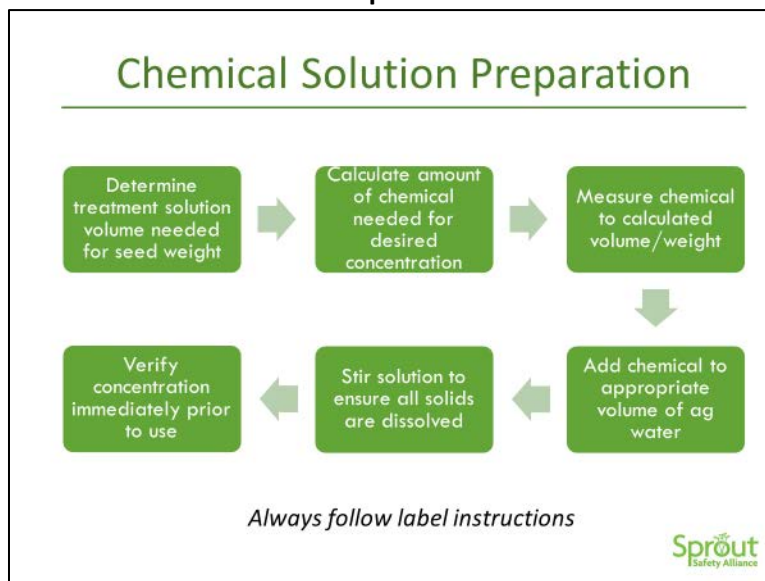
Seed from a seed bag or other container should be carefully poured into the rinse container. The seed/water mixture should be stirred or agitated to ensure all seeds are wetted and to facilitate removal of dirt and debris. Damaged seeds and debris that float to the surface should be skimmed with a sanitary utensil before draining water from the seed. The seed can be rinsed repeatedly with fresh agricultural water until the wash water drains clear. A **surfactant** or detergent can be added to help remove soil and debris from seed. If a surfactant is used, it should be rinsed out completely before the next step.

Definition

Surfactant: A surface-active substance (e.g., a detergent) that reduces the surface tension of a liquid to increase wetting and surface penetration.

- SSA

9.4.2 Chemical Solution Preparation

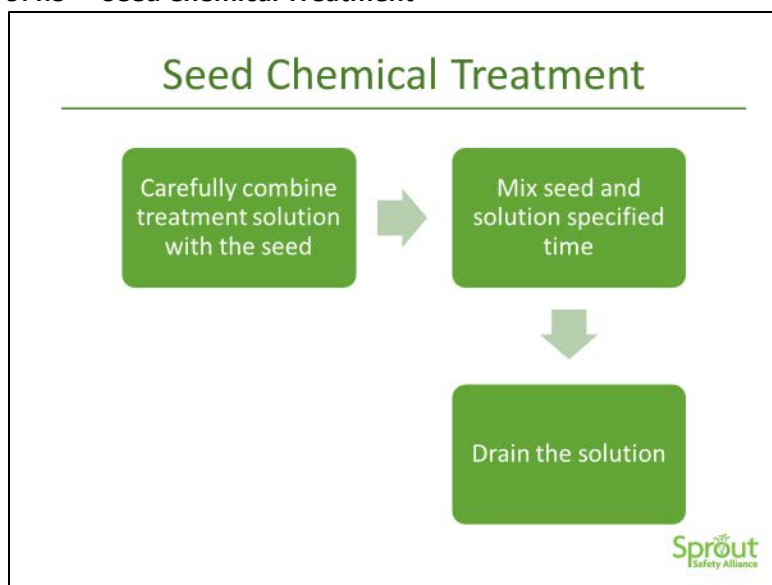


The first step in applying a chemical seed treatment is to ensure the chemical is present at the appropriate concentration. Always follow the label instructions for the use of any chemical. General steps for preparing a chemical solution are:

- 1) Determine the volume of treatment solution based on the seed weight and label information
- 2) Calculate the amount of chemical needed for the desired concentration and volume based on the chemical's label use instructions

- 3) Measure the chemical to the calculated volume of solution per weight of seed
- 4) Add the chemical into a container that contains the appropriate amount of agricultural water
- 5) Stir solution well to ensure it is mixed and all solids are dissolved
- 6) Verify concentration of treatment solution immediately prior to (and in some operations immediately after) treatment following instructions on test strips or kit.

9.4.3 Seed Chemical Treatment



The personal protective equipment (PPE) used during chemical solution preparation is also important during seed chemical treatments to protect worker safety. When conducting seed treatments, sprouters should ensure that the treatment is effective by paying close attention to the concentration of the treatment chemical immediately before (and in some operations after) treatment. The ratio of seed to chemical solution previously determined is important to ensure an effective treatment. Agitation during treatment for a specified treatment time, as applicable, helps to ensure uniform contact between the seed and the solution. Drain the solution when the process is complete.

Considerations for Seed Treatment

- Maintain a written seed treatment SOP
- Standardize the ratio of seed to chemical solution and treatment time
- Apply agitation during treatment
- Verify solution concentration for each batch
 - A fresh solution may be needed for each production batch of sprouts
- Verify each SOP step by initials on a checklist



Having an SOP for seed treatment can help ensure seed treatments are applied consistently and correctly. It is important to have the information or data supporting the scientific validity of the treatment available for inspectors or auditors as evidence that the treatment complies with the requirements in the *Produce Safety Rule*, government standards, and any 3rd party specifications. This is especially important when using a new or novel seed treatment method.

9.4.4 Residue Rinse if Required

Post-treatment Residue Rinse

When required:

- Use agricultural water for rinsing treated seeds
 - Rinse treated seeds thoroughly
 - Repeat the rinse until chemical residue is at safe levels per instructions for chemical use, and government or 3rd party requirements
- § Treated seeds must be protected from re-contamination!



After treatment, treated seed should be rinsed according to instructions, if required, until the treatment chemical is removed from seed. To rinse the seed, agricultural water (no detectable *E.*

coli/100mL) may be added to the container in a sufficient volume to ensure full contact with every seed. The seed may also be rinsed in running water.

After treatment, seed should be protected from contamination through contact with contaminated containers, workers, dust or water before and during sprouting.

9.4.5 Chemical Solution Disposal

Disposal of Seed Treatment Solutions

- Follow federal, state and local agency requirements
- Follow disposal information on the chemical label
- Dilute or neutralize the chemical prior to disposal if needed



Sprouters should follow disposal procedures specific to the chemical used for seed treatment. Federal, state and local regulations, including National Organics Programs and any 3rd party regulatory requirements on chemical discharge, should be followed. Do not dispose of higher than approved levels of solution into storm sewers, streams or rivers where chemicals can be toxic to aquatic life.

For more information on disposal of seed treatment solutions, sprouters can watch the video *Safer Processing of Sprouts*, Module 3C: Seed Treatment (See References) jointly developed by the California Department of Public Health's Food and Drug Branch and FDA's Center for Food Safety and Applied Nutrition in cooperation with the Centers for Disease Control and Prevention, university researchers and industry representatives.

9.5 RECORDS

Seed Treatment Records

§ Sprouters must establish and keep documentation of their treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans

- May document this in two separate records
 1. Seed treatment method – **What to do**
 2. Seed treatment log sheet – **What was done**



When the sprouter is treating seed, records of seed treatment must be maintained for every treatment batch (§112.150(b)(1)). The information can be documented in two separate files, such as a Seed Treatment Method, that describes the procedure to follow and scientific basis for the method, and a Seed Treatment Log Sheet, which serves as a monitoring record of what was actually done for each batch. The seed treatment method record must be updated when the method is modified or a new method is used. Information for the seed treatment log must be recorded for *every* batch of treated seed (§112.161(a)). Sample documents are in the Appendix 9.

§ Seed Treatment Records Must...

- Comply with applicable requirements for records in Subpart O
 - Discussed in Module 12: Recordkeeping
- Include actual values and observations obtained during monitoring, for example:
 - Observations of treatment conditions
 - Key parameters monitored



Seed treatment records must comply with the requirements for records in Subpart O discussed in Module 12: Recordkeeping. The actual values and observations made during monitoring activities (§112.161(a)(1)(ii)), such as chemical concentrations, must be recorded.

Seed Treatment Method Records

- Describe **what to do**; e.g.,
 - Treatment parameters such as:
 - Type of seed to treat
 - Chemical concentration/time
 - Temperature/time
 - Chemical handling
 - Rinse procedures
 - Monitoring procedures
 - Scientific basis for method



Information that is likely to be required in seed treatment records that address what to do during the sprouting process are listed above. Specific requirements depend on the operation, the different types of sprouts produced, and potentially other factors. The scientific basis for the method used to reduce pathogens should be stated in seed treatment records. FDA stated in the preamble of the final *Produce Safety Rule* that 20,000ppm calcium hypochlorite treatment is an example of a treatment that has been shown to be effective for the reduction of pathogens. However, § 112.142(e) allows any scientifically valid method to treat seeds or beans that are used to grow sprouts, including proprietary seed treatments. FDA expects an operation using a proprietary seed treatment to ensure that its treatment is effective in reducing pathogens on seed. In the event of an inspection or investigation of a sprout operation, FDA may ask to review the science supporting the use of the proprietary treatment to ensure the scientific validity of the treatment.

Seed Treatment Method – Example

SOP# XYZ	Seed Treatment Method for Alfalfa Sprouts	Page x of y
OPERATION NAME: XYZ Sprout Company		Issue Date: 03/03/2017
ADDRESS: 123 Sprouter Road, Yourtown, USA		Supersedes: 02//17/2017

Objectives

- Reduce pathogen levels that may be present on seed
- Reduce the risk of seed being a source of contamination in the sprouting process
- Meet regulatory requirements


Responsible Party

- Production manager responsibilities include supervising, conducting or verifying seed treatment procedure, and training new employees

Materials Needed

- Personal protective equipment (see PPE listing below)
- Seed Treatment chemical [specific name]
-

See example in Appendix 9.1




Appendix 9.1 has an example of a seed treatment method that could be modified by a facility to create a record for how seed treatment is done.

§ Seed Treatment Records Must Include What Was Done

Required, as applicable, to the process

<ul style="list-style-type: none"> • Seed type • Seed lot number • Treatment date • Treatment method, e.g., whether seeds where: <ul style="list-style-type: none"> - Rinsed before treatment - Agitated during treatment - Rinsed after treatment 	<ul style="list-style-type: none"> • Applicable treatment parameters, e.g.: <ul style="list-style-type: none"> - Soak or other - Concentration - Duration - Temperature • Signature (or initials) and date for: <ul style="list-style-type: none"> - Operator - Reviewer
--	--




The information that must be recorded depends on the specific seed treatment method used. The slide above identifies several parameters that must be recorded when they are used in a seed treatment procedure. Certain information, such as seed type, lot number, treatment date and signatures are required on all records. Applicable parameters and method considerations will vary based on the treatment method used.

Seed Treatment Log Form – Example

XXX Sprout Company Name 123 Sprouter Road, Yourtown USA									
Seed Treatment Log									
Day & Date:							Corrective Action (if any)		
Seed type	Harvest Code	Lbs	Chemical	Concentration (ppm)	Time	Operator Initials	Chemical	Time	Concentration (ppm)
Alfalfa									
Org. Alfalfa									
Clover									
Bean Sprouts									
etc.									
* If initial chemical reading is not at the right concentration, take corrective action to achieve the right concentration									
Reviewed by Signature:						Date:			

See example in Appendix 9.3




An example of a seed treatment log record is illustrated above. This example should be tailored to the specific products and seed treatment processes used in an individual sprout operation. All parameters that are relevant to the treatment used must be documented. These may include temperature, pre- and post-rinse performance and potentially other factors.

When Seed Suppliers Treated Seeds...

§ Obtain documents from the supplier, for each seed lot, showing that:

- The treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance
- The treated seeds were handled and packaged following the treatment in a manner that minimizes the potential for contamination



If the seed is treated by a seed supplier or other vendor, documentation from the supplier must be kept for each lot of seed (§112.150(b)(1)). Documentation, such as a Certificate of Conformance, must specify that the prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance (§112.142(e)(2)(i)), and that following the

treatment the treated seed was handled and packaged in a manner that minimizes the potential for contamination (§112.142(e)(2)(ii)).

Certain suppliers may include information on the seed treatment applied, length of treatment and any parameters that were monitored to assure the effectiveness of the treatment, as well as packaging and handling practices after the seed treatment was applied. However, other suppliers may not share treatment information with the sprouter or may share only limited information if proprietary treatment was used.

While detailed information on the seed treatment is not required for the Certificate of Conformance (or other documentation), this information could help the sprouter determine whether the seed can be used for sprouting without an additional treatment step. If a seed supplier uses a proprietary treatment, they must take all necessary steps to ensure that the treatment complies with all relevant laws, including FIFRA, if applicable, and that the treatment is effective in reducing pathogens on seed.

It is recommended that sprouters ask the seed supplier for a written explanation of the treatment parameters applied and the basis for the conclusion that the treatment is scientifically valid. In the event of an investigation or inspection of a sprout operation, FDA may ask to review the science supporting the seed treatments sprouters rely on, including proprietary treatments, to ensure treatments are scientifically valid.

Seed Treatment Summary

- Effective seed treatment prior to sprouting reduces the risk of seed being a source of sprout contamination
- § A scientifically valid treatment method must be used
- § Records required include:
 - A written seed treatment (e.g., an SOP)
 - Monitoring records for critical parameters in the SOP



In summary, effective seed treatment prior to sprouting helps to reduce the risk of seed being a source of contamination of sprout products. Sprouters must apply a scientifically valid method for their seed treatment. The written seed treatment procedure document, such as an SOP or seed treatment log, is required by the *Produce*

Safety Rule if seed treatment is conducted in a sprout operation. Suppliers that treat seed must also use scientifically valid treatments and should provide documentation supporting the validity of their treatment as well as conformance with practices to prevent contamination after treatment. The sprouting operation must also document monitoring activities for each seed treatment.

9.6 REFERENCES AND SAMPLE DOCUMENTS

- California Department of Public Health, Food and Drug Branch and US FDA Center for Food Safety and Applied Nutrition, 2000. *Safer Processing of Sprouts*
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- FDA, 2017. Draft Guidance for Industry: Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations.
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- FDA, 2015. *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*.
<https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption>.
- FDA, 1999. Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds. <https://www.gpo.gov/fdsys/granule/FR-1999-10-27/99-28016>
- Fransisca, L, and Feng H. 2012. Effect of surface roughness on inactivation of *Escherichia coli* O157:H7 87-23 by new organic-surfactant combinations on alfalfa, broccoli, and radish seeds, *Journal of Food Protection*, 75: 261-269.
- Ontario Department of Public Health. Guideline for Sprout Production. (Available on the SSA website).

Appendix 9: Seed Treatment Supplemental Information

- A9.1 Seed Treatment Method (Standard Operating Procedure Example)
- A9.2 Seed Treatment Procedure – Alternate Format for Chemical Treatment
- A9.3 Seed Treatment Log Example

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Module 10. Sampling and Testing Spent Sprout Irrigation Water (or In-process Sprouts)

10.1 INTRODUCTION

Learning Objectives

- In this module, you will learn:
 - The purpose of sampling and testing of spent sprout irrigation water (or in-process sprouts)
 - Key components of a sampling plan
 - What, when, how and where to sample and test
 - How to interpret results and determine corrective actions
 - Types of records to be maintained



This module discusses sampling and testing of spent sprout irrigation water and sprouts. The key components of a sprout and spent sprout irrigation water sampling plan include what, when, how and where to sample. Results interpretation and determination of corrective action, as well as records for sampling and testing of sprouts and irrigation water are also addressed in this module.

Why Test Spent Sprout Irrigation Water or In-process Sprouts?

- Current seed treatments cannot guarantee total elimination of pathogens
- Surviving pathogens can grow during sprouting and contaminate the production batch
- § Testing spent sprout irrigation water (or in-process sprouts if water is limited) is required



Although use of a scientifically valid seed treatment can reduce the number of pathogens present in or on seed, seed treatments cannot guarantee total elimination of pathogens. Under the warm, wet conditions of sprout growth, bacterial pathogens can proliferate. Even if only a few pathogenic cells survive the seed treatment, they can grow to large numbers during sprouting and contaminate the production batch. Therefore, testing spent sprout irrigation water or in-process sprouts is an additional hurdle to help ensure that pathogens are not present before sprouts enter the food supply.

Under §112.144(b) of the *Produce Safety Rule*, sprouters must test **spent sprout irrigation water** (or in-process sprouts when testing the water is not practical) from each production batch for *E. coli* O157:H7 and *Salmonella*. Testing for other pathogens is also required when it is reasonably necessary to minimize the public health risk *and* when scientifically valid test methods for sprouts or spent sprout irrigation water are available (§112.144(c)). This is discussed later in this module.

Definition

Spent sprout irrigation water: Water that has flowed over and through the growing sprouts.

- 21 CFR 112.3

Testing Spent Sprout Irrigation Water vs. In-process Sprouts

- Bacteria are more uniformly distributed in spent sprout irrigation water
 - Easier to sample water
 - In-process sprout sampling may miss a small area of contamination in the batch
 - No additional sample preparation steps for water
- § When sampling sprout irrigation water is **not feasible**, testing in-process sprouts is required



Testing spent sprout irrigation water is required unless it isn't practical. For example, soil-grown sprouts or hydroponically grown sprouts may not have enough water to meet volume requirements.

Spent sprout irrigation water that flows over and through sprouts is a good indicator of the types of **microorganisms** present on the sprouts. Testing spent sprout irrigation water for pathogens has several significant advantages.

- Bacteria are distributed more uniformly in spent sprout irrigation water.
- Collecting a representative sample of spent sprout irrigation water is easier than collecting in-process sprouts from the growing unit.
- Testing spent sprout irrigation water is likely to be more effective than testing sprouts. Depending on the growing practice, water may bathe the entire production batch and can pick up bacteria from even a small area of contamination. Conversely, sampling in-process sprouts may miss a small area of contamination in the production batch.
- Testing spent sprout irrigation water does not require additional sample preparation steps, such as weighing and mixing sprouts samples.

It is recognized that sampling spent sprout irrigation water has some disadvantages.

- Sometimes sampling spent sprout irrigation water is not practical, such as production conditions that do not use enough irrigation water to collect a sample.
- The level of microorganisms in spent sprout irrigation water can be about 1-log (or 1/10) less than the level in sprouts. If pathogens are present in sprouts at very low levels, they may be missed in the spent sprout irrigation water.

Definition

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

- 21 CFR 112.3

If testing spent sprout irrigation water is not practical, each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) must be tested (112.144(b)(2)).

Goals

- The goals of spent sprout irrigation water (or in-process sprouts) testing are to:
 - Detect presence of pathogens
 - Reduce likelihood of contaminated product entering the food supply
 - Verify adequacy of control measures (e.g., seed sourcing, seed treatment, sanitation etc.)



The goals of spent sprout irrigation water testing, or in-process sprout testing when water testing is not feasible, are to detect the presence of pathogens before a production batch is released to the public. This protects not only public health, but also the business. This testing also verifies the adequacy of control measures that a business has in place, such as seed sourcing, seed treatment, sanitation practices and other programs previously discussed.

10.2 SPROUT GROWERS' RESPONSIBILITIES

Sprout Growers' Responsibilities

- § Develop and follow a written sampling plan for testing *E. coli* O157:H7 and *Salmonella*
- § Aseptically collect samples of spent sprout irrigation water (or in-process sprouts)
 - Use sterile sampling equipment and supplies
 - Select a qualified laboratory
- § Hold product unless pathogen results are negative
- § Maintain records



Sprouters must have *written* sampling plans in place to ensure the collected samples represent the production batch when testing for contamination (§112.147(a)).

Sampling personnel must aseptically collect samples of spent sprout irrigation water (or in-process sprouts) (§112.147(b)). It is important to train personnel on **aseptic** sampling procedures and how to collect a representative sample in accordance with the written sampling plan. During sampling, sprout growers must use **sterile** equipment and tools to collect samples aseptically.

Sample collection should be done on site, either by employees or contract personnel (e.g., from a 3rd party laboratory). Sprout growers should select a qualified laboratory for testing. A production batch must not enter commerce unless testing results for spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* spp., and any additional pathogen tests (§112.147(b)). All related records must be maintained (§112.150(b)).

Definitions

Aseptic procedure:
Practices and procedures applied to prevent microbiological contamination of samples.

Sterile: Free from viable microorganisms.

10.3 SAMPLING

What to Include in a Sampling Plan

§ A written plan is required

• Include procedures such as:

- When to take samples
- What to sample (spent sprout irrigation water or in-process sprouts)
- How to take samples (aseptic sampling)

§ Number and location(s) of samples to represent batch

- Where and how to send samples for analysis
- Hold and release procedures

§ Corrective action plan

See Appendix 10.1 for a sampling plan example



A written sampling plan is required by the *Produce Safety Rule*, and should include step-by-step procedures of when, what and how to sample. It must include the number and location of samples (spent sprout irrigation water or in-process sprouts) collected to represent the production batch (§112.147(a)). Procedures for sending samples to the laboratory for analysis are usually included. A sampling plan must also include a corrective action plan (§112.147(c)) for responding to positive test results. Procedures for holding production batches until results demonstrating the absence of pathogens in the test samples are received from the lab are also useful and can be included in the sampling plan.

The key elements of a written sampling plan are discussed in the sections below. An example of a written sampling plan is in Appendix 10.1. An example of a hold and release procedure is in Appendix 10.2: Sprout Product Hold and Release Procedure - Example.


10.3.1 Preparation for Sampling

Preparation for Sampling


§ Samples must be collected in an aseptic manner

§ Equipment and tools for sample collection must be sterile

- Sample containers should be dry, leak-proof, wide mouthed, of a suitable size and properly labeled
- Personnel should be trained in aseptic sampling techniques

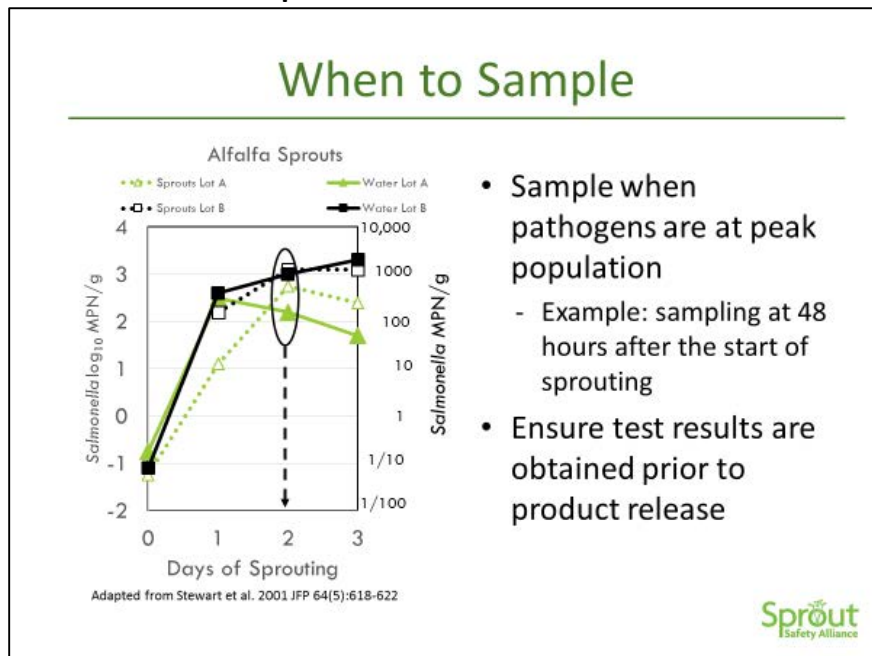


Source: Sprouter provided



Spent sprout irrigation water (or in-process sprout) samples must be collected in an aseptic manner to ensure that the sample collection process does not accidentally contaminate an otherwise clean sample (§112.147(b)). **Aseptic** procedures are also critical to avoid contaminating the sample(s) during storage and transportation to the lab. Sample containers, equipment and tools used for sample collection must be **sterile** in order to collect samples aseptically (§112.147(b)). If re-usable tools, including sample containers, are used, they should be sterilized by heat treatment at 284°F (140°C) for 3 hours in a dry-heat oven. Aseptic sampling procedures should be part of the written sampling plan. An example of aseptic sampling procedures is included in Appendix 7.1: Aseptic Sampling Procedures – Example.

10.3.2 When to Sample



- Sample when pathogens are at peak population
 - Example: sampling at 48 hours after the start of sprouting
- Ensure test results are obtained prior to product release

Samples should be collected when pathogen levels are likely to be at their highest, to maximize the likelihood of detecting pathogens. The optimal time for sample collection may vary depending on the type of sprouts produced, or on sprouting practices.

For alfalfa sprouts, pathogen levels peak approximately 48 hours from the start of the sprouting process. Pathogen levels will not necessarily increase after 48 hours and may decline slightly. In general, FDA recommends that sprouters collect samples as close to 48 hours from the start of sprouting as practicable. Sprouting seeds that have a longer growth cycle compared to alfalfa sprouts may take longer to reach the conditions that encourage the growth of pathogens, if present. In addition, sample collection may be sooner for sprouts that have a shorter growth cycle compared to alfalfa sprouts. If the operation pre-soaks the seeds (i.e., soaking them in water for a short time before transferring them to growing units for sprouting), the pre-soak time should be included in this time frame.

If you wish to explore the optimal timing for sample collection in your sprouting operation when growing sprout types with shorter or longer sprouting cycles, sprouters may collect the spent sprout irrigation water at, e.g., 24 hour-intervals and send samples to a laboratory for aerobic plate count (APC, also known as total plate count, TPC) testing. The appropriate time to sample for pathogen testing may be when maximum bacterial populations are observed.


Samples may be collected later than 48 hours after the start of sprouting while allowing time for test results to come back before product release. If a corrective action plan includes running

confirmatory tests on a presumptive positive, testing earlier (i.e., at 48 hours) rather than later allows more time to run additional tests.

10.3.3 What to Sample

Produce Safety Rule Definition
“Production Batch of Sprouts”

“All sprouts that are **started at the same time** in a **single growing unit**
 (e.g., a single drum or bin, or a single rack of trays that are connected to each other),
 whether or not the sprouts are grown from a single lot of seed
 (including, for example, when multiple types of seeds are grown in a single growing unit).”
 – 21 CFR 112.3
Definition applies for purposes of sampling and testing.




For the purposes of sampling and testing spent sprout irrigation water, FDA defined a **production batch of sprouts** as all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown within a single growing unit).

What to Sample

§ Sample **every** production batch

- Product exposed to the same conditions during sprouting is treated as one batch per definition
- Pooling samples is not permitted



Sprouters must test for pathogens by collecting a sample of spent sprout irrigation water (or in-process sprouts) from *each* production

batch of sprouts (§112.147(a)). The definition of a “production batch of sprouts” is intended to treat as one batch product that is exposed to the same conditions during sprouting. For example:



- When multiple seed types are started at one time and used to grow sprouts in a common drum, the mixed sprouts grown together in the drum are a single production batch of sprouts.

Page 65 of FDA’s draft *Sprout Hazards Guidance* has more examples related to the definition of a “production batch of sprouts.”



- When a rack of connected trays is used to grow sprouts started at the same time in way that exposes sprouts in some trays to water that has contacted sprouts in other trays (for example, if the water drips through upper trays of sprouts on the rack down into lower trays of sprouts on the rack), the sprouts in the rack of connected trays (the growing unit) are

a single production batch of sprouts. If, however, the connected trays of sprouts in such a rack were started at two different time points, there would be two different production batches of sprouts in that single growing unit, based on the two different start times, for which two samples and tests (one from each production batch of sprouts) would be required.

- Two separate growing units of sprouts are *two* production batches of sprouts, even if the sprouts in them were started at the same time, because a “production batch of sprouts” is limited to a single growing unit. If you have two drums of sprouts, these are two separate growing units.

A sprouter may define a production batch of sprouts for other purposes in other ways, e.g., a lot code for product tracking might be assigned to sprouts harvested from multiple growing units on a single day. However, for the purposes of sampling and testing spent sprout irrigation water or sprouts required by the *Produce Safety Rule*, one production batch of sprouts is limited to a single growing unit. If the growing unit is very large, e.g., to the extent that it is difficult to collect a sample that would be representative of the entire production batch, sprouters should consider a sampling plan that includes collecting more than one sample from that production batch and test each sample separately.

Please note that pooling samples from different production batches is *not permitted* under the *Produce Safety Rule* because this practice may decrease the sensitivity of the tests by diluting the level of pathogens in a contaminated sample with samples that are not contaminated. “Pooling” refers to the practice of combining samples from multiple production batches of sprouts to create one sample for testing.

10.3.4 How to Sample

How to Sample

- Wear clean garments, wash hands and wear gloves to avoid contaminating samples
- Follow aseptic procedures during sample collection
- Make sure samples are packaged and shipped to the lab in an appropriate and timely manner

See Appendix 10.1 for procedure examples



Use aseptic sampling procedures for sample collection. This involves wearing clean garments and washing hands before putting on clean, preferably single-use gloves. Collect samples in sterile containers that can be sealed to prevent leakage prior to analysis. Samples should be held and shipped at temperatures that prevent growth of bacteria ($\leq 41^{\circ}\text{F}$ (5°C)), such as in a cooler with ice packs. Sprouters should communicate with their laboratory to assure that samples are collected and shipped in an appropriate and timely manner.

Water Sampling - Examples

Appendix 10. Sampling and Testing Spent Sprout Irrigation Water or In-process Sprouts Supplemental Information

Sampling procedures for spent sprout irrigation water from drums

1. Open the sterile sample container immediately before collecting a 1.5 L or more sample
2. Close sampling container and seal immediately after collecting the sample.
3. If collecting samples in a container with a lid, hold the lid in one hand while collecting the sample with another hand. Do not place the lid on a counter.

Sampling procedure for collecting spent sprout irrigation water samples from bean sprout bins

1. Adjust irrigation water flow rate to approximately 1 gallon/minute so the water will percolate through the sprouts and collect bacteria on its way down through the bottom of the growth bin.
2. Wash hands and put on a pair of sterile gloves.
3. Open a 2L sterile wide-mouth sampling bottle. Hold the lid with one hand and the jar in the other.¹
4. Collect a separate water sample from the bottom of each growing bin
5. Before sampling the next bin, close the bottle immediately, and put in cooler per aseptic sampling procedures above.



Appendix 10.1 provides an example of aseptic sampling and shipping procedures for different sprout types, including drum-grown sprouts, bean sprouts and green sprouts grown in trays. For bean sprouts, a representative sample of spent sprout irrigation water can

be collected by moving a sterile wide-mouth sampling jar or bottle under the growing bin. Sample collection should be done at the beginning of an irrigation cycle when pathogens are at their highest levels. Because bean sprouts grown in bins are frequently irrigated with a large volume of water, pathogens that may be present in the bin can be diluted by irrigation water that passes through the sprouts in the bin. Thus, reducing the irrigation water flow rate through a growing unit during spent sprout irrigation water sampling may be appropriate. This is described in the Appendix 10.1 example.

10.3.5 How Much Spent Sprout Irrigation Water to Collect

§ How Much Water to Sample

- Collect 1.5L of spent sprout irrigation water for analysis
 - For drum-grown sprouts – 1.5L from each drum
 - For tray-grown sprouts, 1.5L:
 - from the common trough or
 - if there is no common trough, collect water from individual trays within a rack of trays and pool these samples
 - For bean sprouts – 1.5L from each bin
- FDA recommends testing more samples/batch for batches > 2400 lbs (1100 kg)



Samples should be collected directly into a clean, sterile, pre-labeled container. The sample volumes provided below are sufficient to allow sprouters to obtain samples representative of the production batch of sprouts and to test for both *Salmonella* and *E. coli* O157:H7. A larger volume may be needed if additional pathogen tests are conducted.

A 1.5L sample of water (about 3 pints) should be collected from each production batch of sprouts.

- If sprouts are grown in a rotating drum, the entire spent sprout irrigation water sample (at least 1.5L) may be collected through a trough or other common point where water drains from the growing unit.
- If sprouts are grown in trays, and all trays in a production batch have a common trough for collecting spent sprout irrigation water, a 1.5L sample may be collected from that trough. If the growing unit has multiple points of drainage and sprouts are not mixed during growing (e.g., a single rack of connected trays or a large bin for growing mung bean

sprouts), sprouters should collect sub-samples from these different points of drainage to ensure the combined sample represents the batch. In such cases, sprouters should collect portions of their sample by moving a sample container around to different drainage locations to obtain a spent sprout irrigation water sample of at least 1.5L.

10.3.5.1 Large production batches of sprouts

When production batches are particularly large, FDA recommends collection of more spent sprout irrigation water samples and testing them separately. For example, if a single production batch is greater than 2400 lbs. (about 1100 kg) of finished sprouts, FDA recommends collecting two 1.5L spent sprout irrigation water samples (for a total of 3L) from that production batch and testing each 1.5L sample separately. For production batches that are larger than 10,500 lbs. (about 4,800kg), collecting three 1.5L samples (for a total of 4.5 L) from the production batch and test each sample separately is recommended.

10.3.6 In-Process Sprout Sampling

Sampling Sprouts: Considerations

- Similar to spent sprout irrigation water sampling
 - Aseptic techniques
 - Appropriate sampling time
 - When pathogens are predicted to reach peak population
 - Test results are obtained prior to product release
 - Definition of production batch
- § Must collect multiple samples from different locations to be representative of the batch



When sampling spent sprout irrigation water is not practical, sampling and testing in-process sprouts is required. The principles that apply to sampling spent sprout irrigation water, e.g., aseptic techniques, proper sampling time, and definition of a production batch, also apply to sampling sprouts.

In designing procedures for sampling in-process sprouts, sprouters should take into account the technical challenges involved in sampling and testing sprouts. First, multiple sprout samples must be collected from different locations in one growing unit to make sure that samples collected represent the production batch (§112.147(a)). Second, the number of sub-samples collected should

be appropriate, which is discussed later. The personnel who perform these procedures should be trained to strictly follow aseptic techniques. Using sterile equipment and tools for sampling is very important to avoid contamination.

As with the timing for spent sprout irrigation water sampling, in-process sprout samples are taken when pathogens are at peak populations. This is typically during the most rapid growth of sprouts. Ensure that test results are obtained prior to product release.

10.3.6.1 How to Collect Sprout Samples

How to Sample Sprouts

- Collect 30 sub-samples (50 g each) from different locations throughout production batch
 - Top to bottom, side to side, front to back
- Clearly label each sample unit
- Keep samples in refrigerator before delivery to lab for testing




Aseptic sampling procedures, as described above for spent sprout irrigation water, must be followed for collecting sprout samples (§112.147(b)). According to FDA (2017) Draft Guidance, at least thirty (30) sub-samples should be aseptically collected, approximately 50g each, from multiple locations in the growing unit (e.g., from top to bottom, side to side, and front to back of the growing unit). The total sprout sample will be at least 1,500g (about 53 oz or 3.3 lbs from each production batch). Weigh the sub-samples in individual clean, sterile, pre-labeled containers. Each sub-sample should be clearly labeled with its weight and kept in a cooler or refrigerator before sending for testing. Keeping the 30 sub-samples separate makes it easier for the lab to take representative analytical units (25g from each sub-sample) for microbial analysis compared to pulling analytical units from a single 1,500g mass of sprouts.

10.4 MICROBIOLOGICAL TESTING CONSIDERATIONS

10.4.1 What to Test For

§ **What to Test For**

- The presence or absence of two major pathogens
 - *E. coli* O157:H7
 - *Salmonella* species
- Other pathogens of concern as directed by FDA when:
 - There is evidence that testing will reduce risks of illness
 - There is a scientifically valid test available for the pathogen




Testing for two major pathogens, *Salmonella* and *E. coli* O157:H7, is required by the *Produce Safety Rule* (§112.144(b)). In the future, FDA may require testing for additional pathogens (§112.144(c)), when 1) there is evidence that testing will reduce risk of illnesses and that 2) there is a scientifically valid test method available to detect the pathogen in spent sprout irrigation water (or in-process sprouts). FDA will issue guidance regarding testing for any additional pathogens when these two criteria are met.

10.4.2 Where to Test

Criteria for a Testing Lab

- A qualified laboratory should be used to test for pathogens
 - Examples of accredited labs for microbiological testing
 - Meets ISO 17025:2005 standards or
 - Accredited by state or national authority




Laboratory considerations for testing spent sprout irrigation water (or in-process sprouts) are similar to those for testing agricultural water and environmental samples. As discussed in Module 7: Environmental Monitoring for *Listeria* Species or *L. monocytogenes* in a Sprout Operation, a qualified laboratory should test for pathogens using scientifically valid methods. *Salmonella* and *E. coli* O157:H7 can cause serious adverse health consequences or death, thus culturing and handling potential human pathogens in proximity to a sprout facility is inherently risky.

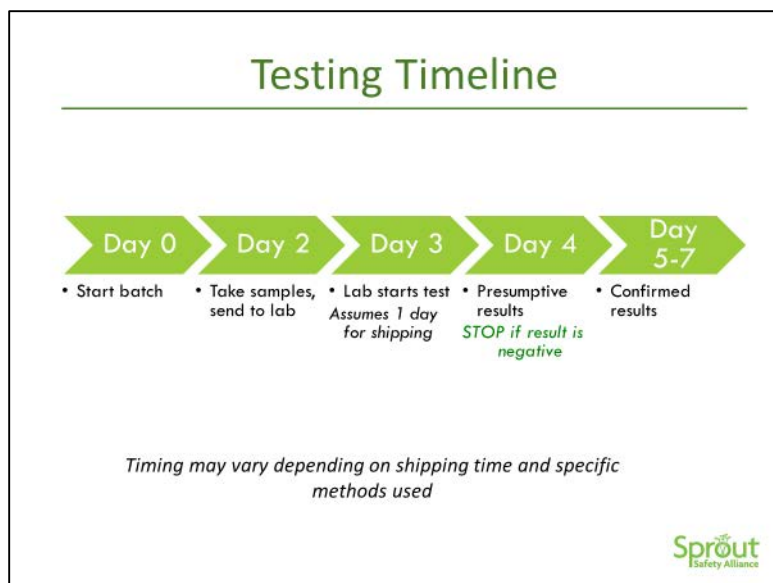
10.4.3 Test Methods

§ Testing Methods

- FDA reference methods:
 - *Testing Methodologies for E. coli O157:H7 and Salmonella species in Spent Sprout Irrigation Water (or Sprouts)*
 - See references for link
- Scientifically valid methods equivalent to the FDA methods in accuracy, precision, and sensitivity



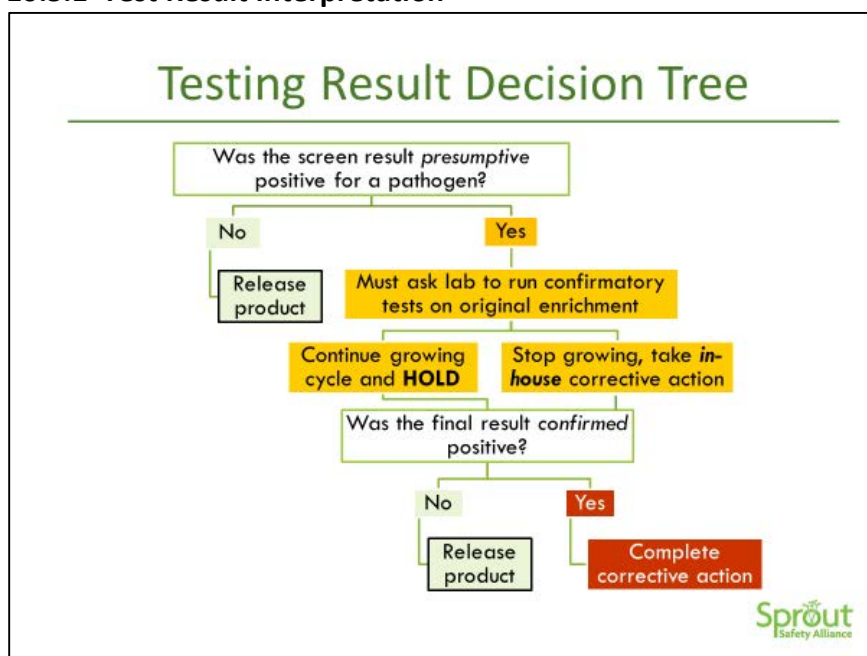
FDA published reference methods for testing *E. coli* O157:H7 and *Salmonella* in spent sprout irrigation water (or in-process sprouts) (FDA, 2015). Sprouters should verify that the methods used by the laboratory analyzing samples are either the FDA prescribed methods (§112.153(a)(1)) or an alternate method that is scientifically valid and at least equivalent to the FDA prescribed methods in accuracy, precision and sensitivity for detection of *E. coli* O157:H7 or *Salmonella*, as appropriate, in spent sprout irrigation water or sprouts (§112.153(a)(2)). For example, alternative methods (e.g., screening test kits) used should be scientifically validated by formal collaborative studies or by comparative studies with the standard FDA methods to ensure they are appropriate for use with spent sprout irrigation water and/or sprouts before they are used for these purposes.



An idealized timeline for testing is presented above to illustrate how long testing may take. Samples are taken and sent to the lab on the same day. The lab starts testing the day after sampling and presumptive results are ready the next day. If presumptive results are negative, then testing ends on Day 2. However, if presumptive results are positive, additional confirmation testing can take a few more days.

10.5 INTERPRETATION OF RESULTS AND CORRECTIVE ACTIONS

10.5.1 Test Result Interpretation



When the initial screening test provides negative results for all pathogens tested, product can be released. However, when the initial screening test result for either *E. coli* O157:H7 or *Salmonella* in spent sprout irrigation water (or in-process sprouts) is a presumptive positive, further confirmation is required to verify that the pathogen of concern is truly present. In other words, sprouters *may not stop the analysis at the presumptive positive result*. Keep in mind that sprouters must notify their seed supplier if they know or have reason to believe that a lot of seeds or beans may be contaminated with a pathogen (§112.142(b)(2)). Thus, sprouters have two major decisions to make when a presumptive positive result is received: 1) what to do about the presumptively positive batch and 2) when to tell the seed supplier.

10.5.1.1 What to do with a presumptively positive production batch

Sprouters must not allow the sprout production batch to enter commerce unless the results of spent sprout irrigation water (or sprouts) tested are negative for *Salmonella*, *E. coli* O157:H7 or other pathogens of concern (§112.147(b)). When sprouters are notified that a batch is presumptively positive, they may:

- 1) continue the growing cycle, pending results of confirmatory testing, or
- 2) take immediate *in-house* corrective action, such as discarding that production batch of sprouts and cleaning and sanitizing affected equipment and the surrounding area (discussed later in the module) to prevent potential spread of contamination and reduce disruption of supply to customers.

If a sprouter decides to take the first option (i.e., continue the growing cycle), the associated production batch of sprouts must be put on hold until the confirmatory testing results are obtained. Sprouts from this production batch must not enter commerce until they test negative for the pathogens for which the firm is testing. The sprouter should also put the seed lot(s) associated with that production batch of sprouts on-hold pending results of confirmatory testing for spent sprout irrigation water (or in-process sprouts).

If a sprouter decides to take the second option (i.e., take immediate *in-house* corrective action based on a presumptive positive), confirmatory testing must still be performed. The sprouter may decide to voluntarily take some or all required corrective actions prior to receiving the confirmed test result. The sprouter should put the associated seed lot on hold during confirmatory testing.

In either case, if the sprouter receives a positive confirmatory testing result, the sprouter must discontinue the use of the associated seed lot for sprouting, notify the seed supplier as described below and take all other required corrective actions. Communication and

coordination between staff involved in production, testing and product distribution are needed. Verification of the hold and release program needs to be conducted on a regular basis.

10.5.1.2 When to notify the seed supplier

Confirmatory testing of presumptive positive batches is performed to verify that the presumptive positive test is indeed the pathogen of concern and not a similar but non-pathogenic organism. Notifying the seed supplier of a presumptive positive result is not required but may be appropriate. Early notification would allow a seed supplier to put the associated seed lot on-hold while waiting for the confirmatory test result. Sprouters must notify the seed supplier when confirmatory testing yields a confirmed positive result.

Additional Test Results Interpretation Considerations

- Confirmatory testing should be performed using the enrichment sample from the original test
- Screening test kits cannot be used for confirmation
- § Product can be released:
 - When the original screening test is negative, or
 - The confirmation test is negative
- A confirmed positive result stands even if additional tests on new samples test negative



Confirmatory testing of presumptive positive batches should be performed using the same enrichment sample from the original screening test regardless if it is performed in-house or by an outside laboratory.

Confirmatory testing of *E. coli* O157:H7 and *Salmonella* should be conducted using procedures published by FDA (2015) or alternate methods that are scientifically valid as previously discussed. Screening test kits may not be used or repeated for confirmatory testing.

A confirmed positive result is obtained when screening tests yielding a presumptive positive result are followed by confirmatory steps that demonstrate the presence of *E. coli* O157:H7 or *Salmonella*; or other pathogen of concern. When presumptive positive results are confirmed, sprouters must take immediate corrective actions discussed below. Product can be released only when the screening test is negative or when confirmation tests results are negative. If additional spent sprout irrigation water (or in-process sprouts)


samples taken from the same production batch test negative, that does not negate the initial positive result. Keep in mind that a positive test result stands, even if tests of additional samples are negative. A negative test does not undo a positive test. In other words, you cannot test your way to safety.

10.5.2 Corrective Actions

Corrective Action Plan

§ A written sampling plan must include a corrective action plan


- What actions will be taken after positive findings
- Details on when and how these actions will be accomplished



Each operation must have a written corrective action plan in place (§112.147(c)) before a positive sample is found so that, if one does occur, corrective actions can be taken quickly. A corrective action plan must be included in the written sampling plan (§112.147(c)). The corrective action plan must describe the actions to take after positive findings and must provide details on when and how those actions will be accomplished (§112.147(c)).

§ Corrective Actions

- Discard all contaminated products
- Evaluate products that may have contacted contaminated tools or equipment for potential contamination and disposition
- Clean and sanitize anything that contacted the contaminated production batch or its water
 - Equipment, tools and other food contact surfaces
 - Floor, drains, walls and other production areas



If samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella*, or other pathogens identified by FDA, sprouters must take appropriate action to prevent any food that is adulterated under section 402 of the *Federal Food, Drug, and Cosmetic Act* from entering commerce (§112.148(a)). Any sprout production batch that tests positive for pathogens must be discarded. In addition, contaminated sprouts or spent sprout irrigation water, equipment and test materials should be handled with care to avoid accidental exposure of other sprouts, food contact surfaces or other parts of the production environment to the pathogen(s). Products that have contacted tools or equipment shared with contaminated product should be evaluated for potential contamination and disposition. The need for a recall of other production batches should be considered. Recall considerations are discussed in Module 11: Additional Control Programs.

In addition, anything in the sprouting operation that came into contact with the contaminated production batch or its spent sprout irrigation water (e.g., drums, trays, bins, buckets, tools and other sprouting equipment, testing equipment, and other possible surfaces, such as floors, drains, walls, and tables) must be thoroughly cleaned and then sanitized (§112.148(c)) to avoid contamination of subsequent sprout production batches.

§ Corrective Actions (cont.)

- Discard or return contaminated seeds, unless:
 - Sprouter treated the seed lot and is certain that pathogens are eliminated or destroyed, or
 - Sprouter later determined that the lot was not the source of contamination
- Notify seed suppliers regarding positive sample findings



Seed is suspected to be the likely source of contamination in most sprout-associated foodborne illness outbreaks. Testing spent sprout irrigation water facilitates detection of pathogen contamination from seeds on growing sprouts. Outbreak investigations have shown that a single contaminated seed lot can contaminate multiple sprout production batches. Therefore, when a production batch of sprouts is demonstrated to be contaminated with a pathogen through testing, any other sprout production batches that were made from

the same seed lot and are still under the sprouter's control should be discarded. Unless there is clear evidence that the seed was not the source of contamination, the seed lot used to produce the sprouts must be discarded or returned to the supplier to be diverted to agricultural use (§112.142(b)).

The sprouter must also notify their seed supplier (seed grower, distributor or other entity from whom they received the seeds) about positive sample findings associated with their seed lot. If the sprouter becomes aware of contaminated seeds or beans based only on microbial test results, the *Produce Safety Rule* provides two additional options:

- 1) Sprouters do not need to discard or return the contaminated seeds or beans if they treat their lot of seeds or beans with a process that is reasonably certain to destroy or eliminate the most resistant pathogens that are likely to occur in the seeds or beans (§112.142(c)(1)). Keep in mind that processes that meet this requirement are far more robust than the seed treatment processes typically applied (and described in §112.142(d)), because those treatments only reduce the levels of pathogens but do not eliminate them.
- 2) Sprouters are also not required to discontinue use of seed or beans, or to notify the seed supplier if they determine, through appropriate follow-up actions, that the lot of seed or beans is not the source of the pathogen found in spent sprout irrigation water or sprouts (§112.142(c)(2)).

Corrective Actions (cont.)

§ Perform other necessary actions to prevent recurrence of contamination

- Re-evaluate control procedures
 - o Seed treatment methods or procedures used
 - o Seed sourcing program
 - o Sanitation procedures
- Add verification steps to the control procedures
- Re-train employees




The sprout operation must also perform any other actions necessary to prevent reoccurrence of the contamination (§112.148(d)). For example, a sprout grower may consider re-evaluating their seed treatment protocol and procedures against current scientific

information, consider re-evaluating their seed supplier and seed sourcing specifications, or cleaning and sanitizing procedures and, as needed, retraining employees on appropriate practices, such as proper implementation of the seed treatment protocol, seed handling procedures, visual examination of seed and packaging, and any other relevant controls. Adding verification steps to ensure practices and procedures are appropriately and consistently implemented may also be helpful.

10.6 ADDITIONAL VOLUNTARY TESTING

Voluntary Testing

- Sprouters may conduct other pathogen tests, if desired
- If voluntary testing identifies pathogens, sprouters should:
 - Take the same corrective actions required for *E. coli* O157:H7 and *Salmonella*
 - Establish records to associate voluntary test results with production batches, seed lots, etc.



In addition to required tests, some sprout operations may voluntarily conduct additional pathogen tests on seed, spent sprout irrigation water, in-process sprouts or finished sprouts. If voluntary test results identify pathogens, sprouters should take the same correct actions as those required for a positive test result for *E. coli* O157:H7 or *Salmonella* in spent sprout irrigation water (or in-process sprouts). Also, sprouters should establish a recordkeeping system that allows them to associate their voluntary pathogen test results with the related production batch of sprouts, the related seed lot number(s) and any corrective actions taken in response to a positive test result.

10.7 RECORDS

§ Recordkeeping Requirements

- Written sampling plan and corrective action plan
- All test results and methods used
 - includes documentation of alternative methods
 - organized by batch of sprouts
- All positive sample findings
- Corrective actions taken
- Records must be kept for two years



The *Produce Safety Rule* §112.150(b)(3) through (b)(6) describes records that must be established and maintained related to sampling and testing of spent sprout irrigation water (or in-process sprouts) and corresponding corrective actions conducted by sprouters. Sprouters must keep records of the written sampling plan, which includes corrective action, for each production batch of sprouts (§112.150(b)(3)). Sprouters must keep records of any analytical methods used instead of the FDA (2015) prescribed method for *E. coli* O157:H7 and *Salmonella* (§112.150(b)(5)). Also, the result of all required analytical tests conducted either by a third-party or in-house laboratory must be documented (§112.150(b)(4)). Laboratory records should identify the test method used to generate the results.

An example of a testing record for sprouter use is in Appendix 10.3: Spent Sprout Irrigation Water Sampling and Testing Record – Example. Sprouters must also maintain documentation of corrective actions taken (§112.150(b)(6)). These records should identify the production batch of sprouts and the seed lot(s) used to produce the production batch of sprouts. An example of a corrective action form is in Appendix 10.4 Corrective Actions Records - Example.

Records must be maintained for two years past the date the record was created (§112.164(a)(1)).

Spent Sprout Irrigation Water (or In-process Sprout) Testing Summary

- The purpose of spent sprout irrigation water (or in-process sprout) testing is to:
 - Detect the presence of pathogens
 - Reduce the likelihood of contaminated sprouts entering commerce
- A written plan for *Salmonella* and *E. coli* O157:H7 testing is required
- Corrective action is required when pathogens are detected
- Records must be maintained for 2 years



In summary, the purpose of spent sprout irrigation water or sprout testing is to detect the presence of pathogens in sprout products and reduce the likelihood of contaminated sprout products entering into commerce. It is also a verification step to ensure the prior control procedures are effective. Developing and implementing a written sampling plan of spent sprout irrigation water or sprout testing are required by the *Produce Safety Rule*. Corrective action is required when pathogens are detected. All records must be maintained for 2 years.

10.8 REFERENCES

- FDA, 2017. Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry. <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM537031.pdf>
- FDA, 2015. *Testing Methodologies for E. coli O157:H7 and Salmonella species in Spent Sprout Irrigation Water (or Sprouts)*. <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm>

Appendix 10: Spent Sprout Irrigation Water Supplemental Information

- A10.1. Spent Sprout Irrigation Water Sampling Plan – Example
- A10.2. Sprout Product Hold and Release Procedure – Example
- A10.3 Spent Sprout Irrigation Water Sampling and Testing Record – Example

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Module 11. Additional Control Programs

11.1 INTRODUCTION

Learning Objectives

- In this module, you will learn about:
 - Management responsibility
 - Sprout safety training requirements
 - Supplier verification programs
 - Product labeling, tracing and recall procedures
 - Sanitary transportation
 - Allergen controls
 - Food defense



Previous modules presented general information related to building and equipment design and maintenance, operational programs and requirements for safe sprout production (e.g., seed treatment, spent sprout irrigation water testing, environmental monitoring, etc.). The focus of this module is on additional implementation and control programs that can help sprout operations ensure food safety, including management responsibility; employee training; supplier verification; product labeling, tracing, and recall procedures; sanitary transportation, allergen controls; and basic elements of food defense.

Goal of the Additional Programs

- Establish a solid foundation to support effective food safety program implementation



The goal of these additional programs is to establish a solid foundation for an overall food safety program. Some of these programs, such as food allergen controls, apply only to those operations that produce sprouts or other products that are food allergens. Others, such as management responsibility and employee training, apply to all firms as appropriate to the operation.

11.2 MANAGEMENT RESPONSIBILITY

Management Responsibility

- Make food safety a top priority
- Establish clear food safety policies and programs
- Communicate food safety policies to employees
- § Designate individual(s) to supervise and ensure compliance with the rule
- Provide adequate resources to implement and execute food safety programs



It is important for sprout safety programs to have the support and commitment of the company's senior management (e.g., owner, president, CEO) to ensure effective and consistent implementation. If the owner and senior management do not demonstrate commitment

to food safety or provide resources necessary to meet food safety objectives, it is difficult to implement effective food safety programs. Senior management can make food safety a priority through their attitudes and actions, such as including food safety in the company's mission statement and incorporating food safety awareness into every aspect of the company's operation. This tangible leadership is central to the proper functioning and effectiveness of any food safety program.

Management should be intimately familiar with how food safety programs operate, and should establish clear food safety policies. Clear communication of these policies to all employees and visitors, as appropriate, is essential. Management should participate in regular meetings with the food safety staff and periodically attend training sessions to demonstrate commitment. Employees also need to be aware of the potential risk that each policy is intended to address and the importance of consistent implementation of these policies to the company and its customers. Management must designate individual(s) to supervise (or otherwise be responsible for) the operation to ensure compliance with the *Produce Safety Rule* (§112.23).

Management should provide sufficient resources for food safety programs, including required training of supervisors and food handlers. For very small companies, although resources may not be available to send staff to training courses, it is important that individuals with food safety responsibilities have management support to learn and continuously expand their knowledge of food safety practices.

Management Responsibility (cont.)

- Develop organizational chart indicating
 - reporting structure
 - contact information of food safety team
 - notification procedures when food safety deviation occurs



No matter the size of the operation, an organizational chart should be developed and indicate the reporting structure by function

and/or title. The chart may include the names and contact information of the food safety team and should be updated regularly. The chart should be readily accessible and should include notification procedures to be followed in situations when food safety policy or procedure deviations are evident or may have been compromised. Notification procedures should include both internal and external sources of possible deviations.

Management Responsibility (cont.)

- § Must provide training for personnel as appropriate to the person's duties
- Establish disciplinary and re-training procedures for food safety violations
 - Establish recognition and rewards for employees contributing to food safety improvements



Management must provide food safety training to personnel who handle sprout products or food contact surfaces, as well as those who supervise these activities (§112.21(a)). There should also be written worker disciplinary and/or re-training procedures for food safety deviations. In addition, providing periodic recognition and simple rewards for people “doing it right” can help build a positive food safety culture.

11.3 EMPLOYEE TRAINING

11.3.1 General Food Safety Training

§ General Training Requirements

- **All** personnel who handle sprouts or food contact surfaces:
 - Must receive training appropriate to their duties
 - Must have appropriate education, training and experience
- One responsible party must successfully complete training equivalent to the standardized curriculum recognized by FDA



Training is an important element in developing and implementing an effective food safety program. The *Produce Safety Rule* requires all personnel (including temporary, part time, seasonal, and contracted personnel) who handle sprouts or food contact surfaces, or supervisors of these activities, to receive adequate training appropriate to the person's duties, upon hiring and at least once annually (§112.21(a)). At least one responsible party must successfully complete food safety training that is at least equivalent to the standardized curriculum recognized as adequate by FDA (§112.22(c)), which is this *Safer Sprout Production for Produce Safety Rule Compliance* course.

All employees must be trained to understand the company's food safety policies and to respond to the potential hazards that are reasonably likely to occur during sprout production (§112.21 and 112.22).

General Training Topics

- | | |
|---|---|
| <ul style="list-style-type: none"> § Employee health § Employee hygiene (e.g., hand-washing policy) § Food safety policies for <i>Produce Safety Rule</i> compliance § Principles of food hygiene and food safety | <ul style="list-style-type: none"> • Clothing/footwear/headwear policy • Storing clothing/utensils/equipment • Chemical inventory and use policies • Visitor policy |
|---|---|



General topics to include in personnel training are listed above. The importance of health and personal hygiene for all personnel and visitors (§112.22(a)(2)) was discussed in Module 5: Employee Health and Hygiene Practice. Management and employees must understand how to implement, the company's food safety policies and programs developed to meet *Produce Safety Rule* requirements (§112.22).

All employees should be able to identify the known or reasonably foreseeable hazards in a sprout operation, as discussed in Module 3: Sprout Safety Hazards.

General food safety training should also include:

- Clothing/footwear/headwear policies (Refer to Module 5: Employee Health and Hygiene Practices).
- Storage of clothing/utensils/equipment in a manner that prevents contamination.
- Chemical inventory, use and storage in a manner that ensures worker safety and complies with prevailing regulations. Refer to Module 6: Cleaning and Sanitizing Buildings and Equipment and Module 9: Seed Treatment for more discussion.
- **Visitor** policies to ensure that employees understand that visitors are required to follow policies to prevent contamination. Refer to Module 5: Employee Health and Hygiene Practices and Appendix 5.3 for a Visitor Policy example.

Definition

Visitor: Any person (other than personnel) who enters your covered farm with your permission.

- 21 CFR 112.3

11.3.2 Specific Training

§ **Specific Training**

- Additional food safety training for employees performing specific tasks:
 - Seed receiving
 - Seed treatment
 - Sprout growing
 - Spent sprout irrigation water (or sprouts) sampling
 - Environmental sampling
 - Cleaning and sanitizing
 - Product transportation and delivery
 - Preparation and maintenance of records



Personnel who handle sprouts or food contact surfaces must receive training on the *Produce Safety Rule* requirements that are applicable to their job responsibilities (§112.21(a) and §112.22). These responsibilities may include seed receiving, seed treatment, spent sprout irrigation water (or in-process sprouts) sample collection, environmental monitoring, cleaning and sanitizing, preparation and maintenance of records or sprout transportation/delivery. Previous modules addressed requirements and best practices for these tasks. These individuals must also have a combination of education, training and experience necessary to perform their assigned duties in compliance with the *Produce Safety Rule* (§112.21(b)). Employees must also be trained in preparation and maintenance of records. Training must be repeated as necessary when observations or information indicates that personnel are not meeting *Produce Safety Rule* compliance (§112.21(d)).

11.3.3 Additional Requirements for Training

§ Training - Additional Requirements

- Conduct training in a language and manner to promote understanding by all levels
- Document all training (e.g., a training attendance log signed by trainer and trainees)
 - including date of training, topics covered, and persons trained
- Conduct refresher training at least annually
- Re-train employees after a food safety infraction or changes to procedures



Training must be provided in a manner that is easily understood by trainees (§112.21(c)). For example, training should be conducted in the language(s) spoken by the operation's employees. All training activity must be documented (§112.30(a)). A simple and effective way to meet this documentation requirement is to require the trainer and trainees to sign a training attendance log after each training course. Companies must maintain records of all employee-training activities, including the topics covered at each training session, date of training, and persons trained (§112.30(b)). Refresher training must be provided to employees at least annually (§112.21(a)), and re-training must be provided if there is a food safety deviation (§112.21(d)) or a change to procedures.

The video *Safer Processing of Sprouts* (California Department of Health et al., 2000) and the "Personnel Practices" section of the "Ontario Sprout Safety Guidelines" (see References) are excellent English language resources for employee training.

11.4 SUPPLIER APPROVAL AND VERIFICATION

Supplier Approval and Verification

- Goal: To ensure only safe and approved materials and ingredients are received

§ Requirements for food packaging materials

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

Also see Module 8: Seed Purchasing, Receiving and Storage for seed supplier discussion



The safety of finished sprout products depends not only on seed safety (covered in Module 8: Seed Purchasing, Receiving and Storage), but also on the food contact materials (e.g., equipment, tools and packaging materials) used throughout production. Having an effective supplier approval and verification program can help to ensure only safe and approved materials and ingredients are introduced into the operation. The *Produce Safety Rule* specifies that food packaging materials must be cleanable or designed for single use and they must not support growth or transfer of bacteria (§112.116). Lubricants for machinery that could drip onto food should be food-grade quality.

Supplier Program Implementation

- Establish written criteria for approving suppliers
- Confirm food safety procedures and programs implemented by suppliers
- Have a receiving program for incoming materials
- Keep records of each supplier



To develop a supplier approval and verification program, sprouters should understand potential hazards associated with incoming materials and establish written criteria for approving suppliers. Questions for suppliers should be designed to confirm that effective food safety procedures and programs have been implemented. Questions to ask suppliers may include those listed below. Questions may be different for vendors supplying different materials.

- Are the materials that you supply for food contact uses made of food grade materials?
- Do you have a food safety plan and have you performed a systematic hazard analysis?
 - What are the principal food safety hazards that were identified?
 - What controls have been implemented to address those hazards?
- Do you have a product traceability program?
 - Where are the lot codes located on your materials?
 - Are lot codes included on each unit or only the master carton or unitizing shipping container?
 - Do you have a recall process?
 - When was your most recent mock recall?
- Do you undergo third party food safety audits?
 - What types of audits have you had and what are the key food safety principles or standards that those audits are based on?
 - Which company performed the audits?
 - When was your most recent audit?
 - Can we review your audit report?
 - When is your next audit?
- Do you have a corrective action process?
- Do you have written specifications for your products or materials? Can you supply us with those specification sheets?
- Are all ingredients and processing aids approved for their intended use?
- Can you supply us with a Certificate of Conformance (CoC), or Certificate of Analysis (CoA), as appropriate, with each lot of materials?
 - Where applicable, include test results
- Can you supply us with a Letter of Continuing Guarantee? (See example in Appendix 11.1).
- Will you notify us if there are any changes to your products or materials? (This is to avoid food safety or potentially disruptive supply chain issues).

A receiving program for incoming materials may also be implemented and it may include inspection of a sample of each of the products received. All supplier information should be documented. Alternate approved suppliers can be used if a primary supplier is not

available. It is critical to keep records on the approval status of every supplier.


As discussed in Module 8: Seed Purchasing, Receiving and Storage, if a sprouter purchases seeds or other food materials originating from countries outside of the U.S., the importer must comply with *Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals* regulations. Refer to Module 8 for more information.

11.5 PRODUCT CODING, TRACING AND RECALL PROCEDURES

11.5.1 Product Coding

Product Coding

- Goal: Facilitate tracking and locating individual lots in the event of a consumer complaint, foodborne illness outbreak or recall
- § Sprouts must be clearly and correctly labeled with a lot code or production identifier



A product coding and recall system is needed to facilitate efficient, rapid and complete traceability and recall when product retrieval is necessary. Each company should have written procedures to ensure proper labeling and coding of finished products. Labels must meet the requirements of all appropriate federal, state and local food labeling and weights and measures regulations. General food labeling guidance can be found in *Guidance for Industry: A Food Labeling Guide (General Food Labeling Requirements)* (FDA, 2013).

Sprouts stored within or shipped from the sprout operation should be clearly and correctly labeled with a lot code or production identifier. Product coding allows for specific lots of sprouts to be located and identified in the event of a recall, consumer complaint or foodborne illness outbreak. If the sprouts in question do not have a unique identifying code, they cannot be distinguished or separated from other similar products; thus, corrective actions would encompass all similar products produced or distributed within the applicable timeframe.

Product Coding Criteria

- “Lot” definition
 - Sprouts produced under similar conditions and in a similar timeframe
 - May be different from the batch defined for microbial testing
- Lot code
 - Should identify all seed lots used
 - Can be based on the date of packing or sell-by date
 - Can include more information to make product tracking easier



Product coding can be as simple or as complex as the producer needs it to be. For purposes of production, a **lot** can be defined as “sprout products produced under similar conditions (e.g., in a definable location or uniquely identifiable equipment) and in a similar timeframe.” A lot *may be different* from the “production batch” defined for microbial testing purposes described in Module 10: Sampling and Testing of Spent Sprout Irrigation Water or In-process Sprouts.

The timeframe for a production lot should not exceed one day. For example, all the packages of one specific sprout product, consisting of sprouts harvested on the same day could have the same lot or code number. Those harvested the following day would have a different lot/code number. A record should be kept indicating the specific seed lot used for each sprout lot produced each day. Sprouts germinated from different seed lots should have different product lot codes, even if harvested on the same day. If seeds from different seed lots are mixed during the germination process, then the product lot code should identify the different seed lots used in that lot of sprouts.

For example, a simple lot code may be the date packed (e.g., 070917 or JUL0917). The code may also contain a production line designation and time stamp, as appropriate. Alternatively, the code could be a sell-by date. Some sprout producers may include more information in their lot numbers/codes in order to quickly trace the sprout’s history. For example, if seed lot H1003 was used, germination took place in room “B”, and sprouts were packed on July 9, 2017, this information may produce a code number H1003B070917. More detailed lot codes can facilitate trace back and recall.

Product Codes and Records

- Records should contain information necessary for tracing the sprout's history
 - seed lot, production date and spent sprout irrigation water testing
- Product codes should be permanent, legible and distinguishable from all lots
- Lot code format should be explained in writing and be readily available



It is important that product coding be permanent, legible and able to distinguish a lot from all others. The format of the code should be explained in writing and be readily available so that others can determine what the elements of the code mean. All production records for each lot must be kept for at least two years (§112.164(a)(1)). The records for each production lot should clearly identify the seed lot, when production was started, and when spent sprout irrigation water was collected during sprouting and tested. No matter how simple or complex the code, a thorough production record will make product tracking easier.

11.5.2 Product Traceability Programs

Product Traceability Program

- Facilitates an effective market withdrawal or recall
- Limits scope and cost of recall
- Provides accurate lot identification, product description and documentation



An effective product traceability program provides the tools to protect the public through effective recall or withdrawal from the market of problematic products. Accurate lot identification, product description, documentation (e.g., product distribution records) and a product tracing system can substantially narrow the scope and reduce the cost of a recall by limiting the recall or market withdraw to only the affected product.

Product Tracing System

- Maintain a list of customers
- Have shipping documents for all sprout products
- Sprouter, customer and delivery truck driver each keeps a copy of the packing slip
- Maintain shipping records and documents



An effective product tracing system includes:

- Keeping a customer list, including name, address, contact information (phone and e-mail) and, if applicable, a special contact person for recalls.
- Having a shipping document for all sprout products. This can be in the form of a bill of lading, invoice, shipping slip or packing slip.
- Making sure the sprouter, the customer and the delivery truck driver each keep a copy of the shipping documents.
- Maintaining shipping records and documents for an appropriate period of time, usually two years.

Information on a Shipping Document

- Product name
 - As specific as possible
- Shipping date
- Lot number
- Quantity shipped to each account
- Transport broker information, if applicable
- Cleanliness and temperature set-point of transport vehicle
- Who received the sprouts (customer)
- Record completed by (name or initials)
- Comments and observations section



The information listed above is useful to include on a shipping document.

11.5.3 Recall Program

Product Recall

- Actions taken by a company to remove a violative product from the market
- Initiated by the sprout producer or by federal or state agencies
- Initiated because of consumer complaints or illness, test results, incorrect labeling, etc.
- *Effective product coding, tracking and recall systems help ensure rapid and complete recall of affected products*



Recalls are actions taken by a company to remove a product from the market when the product violates a law and presents a risk of illness, injury or is otherwise defective. A recall may be initiated either by the sprout producer or by federal or state agencies. A recall may be initiated in response to customer complaints or illness, laboratory test results, incorrect labeling, etc. Any product for which FDA or a state could take legal action against the company would be subject to recall. If a company withdraws a product for quality issues that do not violate food law, this is typically considered a market

withdrawal and not a recall. All sprout products should be lot-coded and a recall system should be established so that a rapid and complete recall of all affected products can be conducted.

How to Prepare for a Product Recall

- Have a written recall plan
- Assemble a recall team and assign recall responsibilities to each member
- Review recall procedures
- Conduct mock recalls



Product recalls are resource intensive events that can significantly damage a business, especially when a company is not prepared. Having a written recall plan that identifies specific functions for recall team members is important for a rapid response and to protect the business. The team should be familiar with recall procedures and conduct mock recalls to prepare them in the event of a real recall situation. Each of these topics are discussed below.

Useful FDA Websites

FDA provides contact information for recall coordinators on the web. <https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>

Include information for your district coordinator in your Recall Plan and consider getting to know them prior to a recall situation. For example, several states have Food Safety Task Force meetings that provide access to regulatory officials in an open forum.

Recall Plan Contents – Key People

- Define a recall team
 - Important for rapid communication
 - Include specific names and contact information
- Describe duties and roles for each
- FDA and state recall coordinators
- Recall functions may include:
 - Recall coordinator
 - Operations manager
 - Public relations
 - Logistics and receiving
 - Quality assurance
 - Accountant
 - Attorney
 - Administrative support



It is important to identify key people *before* a recall situation occurs and document their function and contact information in a recall plan.

Some of the functions that should be included are listed above and in Appendix 11.6: Recall Plan template.

An individual should be assigned responsibility for coordinating and implementing a recall. A recall team to support the recall coordination is important for an efficient recall process, recognizing that the size of the team depends on the resources available within the specific operation. For example, the recall coordinator may also lead communications, such as contacting newspapers and preparing a speech on behalf of the sprout operation, or another team member may lead this effort. An individual may cover more than one function on the list above, depending on the size of the operation. Backups should be designated in case the primary person is unavailable. Ensuring that each individual understands their role can avoid overlap or miscommunication.

The plan should also have the contact information of local offices of FDA and state, and other regulatory authorities, if appropriate for the location.

Recall Plan Contents – Key Information

- Procedures to determine if recall action is necessary
- Information to assemble for regulatory consideration
- Templates to capture volume and distribution of product
- Lists of customers and others who receive product
- Procedures to rapidly inform customers
- Product disposition procedures
- A Recall Notification template



Appendix 11.2 is a recall plan template that can help a sprouter develop a company specific recall plan, such as information that can help a sprouter to determine if a recall is actually necessary, as well as the information that a company should assemble for regulators when a recall is needed. A Recall Notification Letter template should also be included in the plan. Keep in mind that when considering the need for a recall, it is important to engage with appropriate regulatory authorities to ensure that the extent of the recall is appropriately defined and communicated to customers and the public, if needed. A procedure to rapidly inform customers, regulators and general public about the recall should be clearly written in the plan. Detailed information (e.g., customers to be

contacted and product disposition) to be recorded during the recall should also be included. A corrective action plan including product disposition procedures should also be established.

Information to Communicate to Customers

- Product identification
 - Codes/Lot numbers, sizes, brand names involved, image of labeling, invoice number and date of shipment
- Nature of the defect requiring the recall
- Instructions on notifying others involved in the distribution chain
- Instructions on returning or handling disposition of the product
- A completed Recall Notification Letter



Sprouters should contact customers at all points in the distribution chain. Details of the recall should be communicated by telephone, email, mail, and/or facsimile with the information listed above. A Recall Notification Letter can be sent to the customers to initiate the recall process. Customers should be directed to return or destroy the recalled products. A verbal or written confirmation of product disposition should be obtained and documented. Sprouters may wish to provide customers with a form the customer can use to document details of the product disposition. The completed form can be returned to the sprouter as evidence of product disposition.

Recall Procedures – Internal Investigation

- Convene the Product Recall Team
- Identify known or implicated products
- Collect pertinent data including records and product information
- Examine inventory record of each lot of affected product
- Identify the date of production in inventory record
- List all sale orders by date of the product
- Identify the products sold within 3-4 days of the production date



The initial key steps in conducting a product recall are listed above. The investigation begins within the company to identify the specific lot or lots of product involved in the recall. It is important to take the time needed to identify the lot code or codes involved to avoid an expanded recall. Example of product recall worksheets and procedures can be found in Appendix 11.3 and 11.4.

Recall Procedures – Recall Execution

- Notify FDA and local agency
- Contact customers for recall
- Identify seed lot(s) used for affected products
- Include all sprouts grown from the suspect seed lot
- § Advise seed suppliers of suspected contamination
- § Record all information
- Confirm disposition of the products



Frequently, FDA or local regulatory agencies notify a sprouter that a recall is needed in response to a foodborne illness investigation. If a sprouter becomes aware of a situation that requires product recall, they should notify the appropriate regulatory authority. As previously mentioned, contaminated seed is frequently the source of pathogens in sprout-associated outbreaks, and the *Produce Safety Rule* requires notification of seed suppliers of suspected contamination (§ 112.142(b)(2)). Detailed records are required on the process (§ 112.150 (b)(6)).

Information to be Documented

- Where the product went and how much went there
- How much product was returned
- Who was contacted in receiving companies
- Amounts of the recalled product shipped; produced; and still in inventory
- Confirmation of disposition of all recalled products



Details on all steps of the recall should be documented, including where product went and how much went there; how much product was returned to the sprout operation; who was contacted in the receiving companies; the amount sent, the amount produced and the amount still in inventory to ensure that all affected products are accounted for. Disposition of returned products or confirmation of product disposition by customers should also be documented.

Mock Recall

- Tests the effectiveness of a written recall plan
- Should be conducted at least once a year
- Should be completed within 2 hours
 - 100% stock identification and customer notification contact
- Conduct review with recall team after a mock recall
- Correct and improve recall processes if necessary
- Update the recall plan and contact information
- Re-train personnel



Mock recalls test the effectiveness of the written recall plan and the product tracing system, including the preparedness of the relevant staff, the ability to access records and documents, the accuracy of documentation and records (e.g., product codes, quantity of lots produced, locations shipped), and the efficiency of contacting customers, distributors and seed suppliers.

A mock recall should be conducted at least once a year. Sprouters should be able to complete all parts of the mock recall within two hours. The first part is to identify 1) how much product is still in-house and 2) how much product was shipped and to whom. A sprouter should be able to account for 100% of the product using inventory and shipping records during the mock recall.

The second part of the mock recall is to verify that current contact information is available if the event were real. Keep in mind that retailers handle many true recalls on a weekly basis. A simple call to a customer or an email asking for verification that their contact information is current is sufficient for a mock recall. Avoid asking them to trace your product during a mock recall.

Once the mock recall is completed, a review should be carried out with the relevant recall personnel to correct and improve the process, where necessary. Contact information should be updated after the mock recall. If the mock recall does not go smoothly, more frequent mock recalls may be appropriate to train relevant personnel and to confirm that the recall system actually works in a timely manner.

FDA (2003) *Guidance for Industry: Product Recalls, Including Removals and Corrections* has more details on this topic. Additionally, the previously mentioned FSPCA recall plan template (FSPCA, 2017) was based on FDA's guidance on recalls.

11.6 SANITARY TRANSPORTATION

Sanitary Transportation

- Goal: To prevent cross-contamination during transportation and distribution of sprouts
- § Equipment must be clean before use
- § Equipment must be adequate to transport sprouts
- Ensure vehicles are equipped to maintain an appropriate temperature
- Examine vehicles for cleanliness and odors
- Keep shipping, cleaning and sanitizing records



A primary goal of sanitary transportation is to prevent cross-contamination during delivery of finished sprout products. Equipment used to transport sprouts must be adequately clean before use (§112.125(a)). Practices such as inadequate cleaning or

Raw sprouts are considered a time/temperature control for safety food and therefore, require refrigeration per the FDA Food Code 2013 (<http://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm374275.htm>)

sanitizing of vehicles or failure to properly protect food during transportation can create food safety risks. Thus, vehicles and transportation equipment must be maintained in a sanitary condition; e.g., by cleaning between loads and periodically sanitizing after shipping other freight, especially raw meat, fish, poultry, farm-fresh products, other animal products or products containing allergens. Drivers should be trained in sanitary transportation basics and job responsibilities, and insanitary vehicles should be rejected. An easy-to-use sample truck inspection document is in Appendix 11.5.

Equipment used to transport sprouts must also be adequate for use ((§112.125(a)). Holding sprouts at $\leq 41^{\circ}\text{F}$ (5°C)) at retail is required in the *FDA Food Code* (FDA, 2013b; and see text box) and thus by many state or local jurisdictions and customers. Sprouters should ensure that trucks are equipped to maintain an appropriate temperature for transport of products.

11.7 FOOD ALLERGEN CONTROL PROGRAMS

Major Food Allergens (The Big 8)

<ul style="list-style-type: none"> • Milk • Egg • Peanut • Tree nuts 	<ul style="list-style-type: none"> • Fish • Crustacean Shellfish • Wheat • Soy
--	--

➔ 90% of U.S. food allergic reactions are caused by these allergens






Photo Sources: Microsoft Clip Art and KMJ Swanson (soybeans)

As discussed in Module 3: Food Safety Hazards, food allergies are an important public health concern. Many foods can cause an allergic reaction in people, but eight foods listed above are responsible for over 90% of the food allergic reactions in the U.S. Strict avoidance of the offending food remains the only effective means to prevent an allergic reaction. Successful avoidance requires that food producers use preventive controls to ensure allergens that are intended to be present in a food are declared on the label and no unintended allergens are present.

In the U.S., the Food Allergen Labeling and Consumer Protection Act (FALCPA) requires manufacturers to clearly list ingredients derived

from eight allergenic foods (milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans). Federal law considers sprouts as raw agricultural commodities; therefore, sprouts are exempt from allergen labeling requirements. However, allergen labeling may be required by individual state laws or by customers. Even if not required by law, if one of your sprout products is allergenic, having an allergen control plan is a good food safety practice. Examples of allergenic products that may be found in a sprout operation include soybean sprouts, wheat grass and potentially others like nuts.

Food Allergen Control

- Developing an Allergen Control Plan
 - Preventing allergen cross-contact with any food allergens in the facility
 - Ensuring accurate and clear disclosure of allergen information on product labels
- Allergen Control Plan and associated activities should be actively managed, frequently checked, and kept up to date



If allergenic and non-allergenic products are produced in the same operation, an Allergen Control Plan should be developed. The plan should document controls used to prevent allergen cross-contact in various parts of the operation and ensure that the allergenic sprout products are clearly labelled. The Allergen Control Plan and associated activities should be actively managed and frequently checked by the individuals in charge. The information should be up to date and used for effective communication with sprout production workers, seed suppliers and sprout customers.

11.7.1 Allergen Cross-contact Control

Allergen Cross-Contact Controls

- Dedicated tools, equipment and food contact surfaces for specific allergens
- Segregation of allergenic products and ingredients
 - Product containment
 - Physical barrier
 - Additional space
- Production scheduling
- Allergen cleaning
 - Visibly clean
 - Verified with allergen detection kits



Allergen cross-contact can occur during receiving, handling, processing, packing and storage of ingredients and foods, through improper handling and cleaning of equipment, utensils, facilities, and through improper facility design. When designing a sprout operation that contains both allergenic and non-allergenic products, consider the use of physical containment, barriers or additional space to minimize allergen cross-contact. Different allergens should be separated from each other so that they are not mixed.

If the production area includes both allergen-containing and non-allergen-containing sprout products, the processing schedule should be designed so that allergen-containing products are run at the end of the production shift. For example, if different sprouts are washed in the same tank, to prevent allergen cross contact the non-allergenic sprouts should be washed first and allergenic sprouts should be handled last. Wash tanks should always be thoroughly cleaned after handling allergenic sprouts. Developing a scheduling table for processing different sprouts is recommended.

It is important that sprout contact surfaces be easy to clean. Because very small amounts of allergenic proteins can induce reactions in sensitive individuals, effective cleaning is an essential element in an allergen management program. Surfaces should be visibly clean. If possible, tools, food contact surfaces and other equipment should be dedicated for use with specific allergens (e.g., soy sprouts). If dedicated tools and equipment are not an option, tools and surfaces must be thoroughly cleaned and inspected prior to producing or handling another sprout product. Allergen cleaning validation may be appropriate when a new variety of allergenic seeds or sprouts is introduced into production, or if production creates accumulation of

different types of residues that require different cleaning procedures. Commercially available allergen testing methods and kits may be used to validate and verify the effectiveness of cleaning and sanitation processes for surfaces that carry allergens.

11.7.2 Food Allergen Label Control

Food Allergen Label Control

- Possible labeling errors
 - Failure to list allergenic ingredients
 - Errors on labels
 - Wrong label on a package
- How to avoid errors
 - Identify allergenic seeds, sprouts, and ingredients used in the operation
 - Label allergens in consistent with FALCPA requirements
 - Proofread label copy
 - Separate labels for allergenic products from other labels
 - Train personnel in correct application of allergen labels



Ensuring that a sprout product has the correct label is a key measure to protect allergic consumers. Undeclared allergens can lead to illness and even death. A labeling error can cause allergen-related recalls, which can cause brand damage, regulatory inquiry and potential liability. For operations that produce sprouts from peanut, soy, wheat, almond and other tree nuts, allergen labeling should be clear and accurate. The presence of allergens should be declared in plain English using the common or usual name of the major food allergen either as part of the ingredient declaration, or in a “contains” statement adjacent to the ingredient declaration (403(w)(1)). FALCPA does not address advisory statements such as “may contain” or “manufactured on equipment that also processes allergen.” Advisory statements should be truthful and not misleading and should not be used as a preventive control or as a substitute for current good manufacturing practices (cGMPs).

Labeling errors are the primary cause of allergen recalls. Errors may include failure to list allergenic ingredients on a printed label, incorrect allergen information on the label, label printing errors, and placing the wrong label on a package. Proofreading label copy can prevent errors. Storing labels for allergenic products separate from labels for non-allergen products is another way to minimize errors. The most important label check is the one that occurs when the label is being placed on the finished sprout product. General labeling errors should be caught with an inspection of packages during

production by a trained employee using a check list to check and ensure appropriate labels are placed on the packages.

Food Allergen Control Training

- An essential part of an Allergen Control Plan
- Allergen awareness and control training at all levels of the company is critical
 - What allergenic sprout products are present in the operation?
 - Where and when are the allergenic products handled and held?
 - How are allergens labeled?
 - What are the procedures for allergen cleaning?



Training is an essential part of an Allergen Control Plan. Workers handling food allergens or contacting surfaces that contact allergens should be trained on the importance of allergens in consumer health, the importance of not comingling allergenic and non-allergenic ingredients or sprout products, and the procedures for effective cleaning of food contact surfaces and how to properly label products containing allergens.

11.8 FOOD DEFENSE

Food Defense

- Goal: To protect food against intentional adulteration
- Develop a food defense program
- Train personnel assigned to the vulnerable areas
- Maintain records for food defense monitoring, corrective actions, and verification activities



Deliberate tampering with or adulteration of food can have devastating and long-lasting effects not only on the health of consumers but also on the company's image and future business. FDA's (2016) *FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration* is aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply. Such acts could cause illness, death, economic disruption of the food supply absent mitigation strategies. The rule covers domestic and foreign companies that are required to register with the FDA as food facilities. Sprout operations are considered "farms" per the *Produce Safety Rule*, and therefore are not subjected to the food defense rule. However, following the basic requirements of this rule helps ensure a secure sprout production environment and protects the food products against intentional adulteration.

Though not required by the *Produce Safety Rule*, sprouters should consider developing a food defense plan to identify vulnerabilities and actionable process steps, mitigation strategies and procedures for food defense monitoring, corrective actions and verification. Management should train personnel assigned to the vulnerable areas. Records for food defense monitoring, corrective actions, and verification activities should be maintained.

11.8.1 Food Defense Plan

Elements of a Food Defense Plan

- Vulnerability assessment
 - Severity and scale of potential impact on public health
 - Degree of physical access to the product
 - Ability to successfully contaminate the product
- Mitigation strategy management components
 - Monitoring
 - Corrective actions
 - Verification



A written Food Defense Plan for a sprout operation should outline vulnerability assessment and mitigation strategies. Vulnerability assessment evaluates the severity and scale of the potential impact on public health, the degree of physical access to the product and the ability to successfully contaminate the product.

A written Food Defense Plan should also include actionable process steps, mitigation strategies and procedures for food defense monitoring, corrective actions and verification. Examples of mitigation approaches can include control of chemicals and hazardous materials; restricting entry with locks, sign-in procedures, visitor policies, systems to prevent access of unauthorized personnel; and implement inspection procedures for arriving materials.

Sprouters should consider the likelihood of a person or persons deliberately contaminating products to cause harm to the firm or to consumers. While food security threats may originate outside the facility, do not overlook the potential for angry or disaffected workers or former workers to contaminate food. The best defense is not to make it easy or convenient for them to contaminate the products. Securing chemicals, maintaining a current list of chemicals and excluding or discarding unnecessary chemicals, and installing surveillance systems can all act as effective deterrents.

The following questions can be used in developing mitigation strategies:

- Does the operation need some form of identification for employees, such as nametags, or does everyone know each other?
- Does the operation restrict entry to the establishment with locks, doorbells, sign-in procedures, visitor nametags and/or signs indicating areas for authorized personnel only?
- Does the operation protect perimeter access with fencing or other deterrents?
- Does the operation minimize the number of entrances to restricted areas?
- Are arriving materials and items received and inspected by designated personnel?
- Do arriving materials come from pre-approved suppliers?
- Are all chemicals locked when not being used, with access granted only to authorized personnel?
- Does the operation have an evacuation plan in case of emergency, including an evacuation procedure and escape route assignment?
- Has the emergency plan ever been tested?

A reanalysis of the written plan is recommended every three years or when certain criteria are not met, including mitigation strategies that are determined to be improperly implemented. FDA (2016b) has an Food Defense Plan Builder that can be used to develop a facility specific Food Defense Plan.

For more details, please refer to *FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration* (FDA, 2016a).

§ Additional Control Programs Summary

- All employees must be trained to follow food safety policies and procedures
- Only safe food contact materials are used for sprout production
- All sprout products must be clearly labeled
- Sanitary transportation requirement must be followed



Among the control programs covered in this module, sprouters must develop and implement those required by the *Produce Safety Rule*. They include that all employees must be trained to follow food safety policies and procedures (§112.21); only safe food contact materials are used for sprout production (§112.116); all sprout products must be clearly labeled; and transport equipment must be clean and adequate (§112.125).

11.9 REFERENCES AND SAMPLE DOCUMENTS

- FDA, 2016a. Food Defense Plan Builder
<https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm>
- FDA, 2016b. FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration <http://www.regulations.gov/document?D=FDA-2013-N-1425-0146>
- FDA, 2013a. Guidance for Industry: A Food Labeling Guide (3. General Food Labeling Requirements
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064866.htm>
- FDA, 2013b. Definition for Time/temperature control for safety food. FDA Food Code 2013.
<https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf>
- FDA, 2003. Guidance for Industry: Product Recalls, Including Removals and Corrections
<http://www.fda.gov/safety/recalls/industryguidance/ucm129259.htm>
- FSPCA, 2017. Recall Plan template, which is based on FDA Guidance is available at:
<https://www.ifsh.iit.edu/fspca/fspca-materials>

Appendix 11: Additional Control Programs Supplemental Information

A11.1 Recall Plan Template

A11.2: Recall Worksheet – Example

A11.3: Recall Procedure – Example

A11.4: Truck Inspection Form – Example

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Module 12. Recordkeeping

12.1 INTRODUCTION

Learning Objectives

- In this module, you will learn:
 - The importance of recordkeeping
 - Types of records that are required
 - Procedures for completing, reviewing, and storing records
 - Example records for sprout operations



Records are an essential component of safely growing, packing, transporting and storing sprouts. They are used to track the safety of products, monitor storage conditions, document adherence to good handling practices and Good Agricultural Practices (GAPs), track receipt of raw materials and product distribution, document employee training in performing assigned tasks, and provide evidence of adherence to food safety programs for customers, auditors and regulatory agencies. Sprouters should keep records of the operation and actions taken if something has gone wrong. Records also offer written evidence that operational processes are properly followed and are under control. They may be used to help determine the cause of safety problems during an outbreak or recall. Most records are completed voluntarily in the normal course of business. Some records are mandated by federal, state or local laws.

The *Produce Safety Rule* requires certain records to be established and kept. Records related to particular procedures and practices are discussed in previous modules, however some of this information is repeated in this module as a review. General requirements for records are also covered in this module.

Goals

- Provide evidence that operational processes are properly followed and are under control
- Help determine the cause of safety problems and appropriate actions
- Demonstrate adherence to food safety standards for customers, auditors and regulatory agencies



The ultimate goal of recordkeeping is to provide evidence of what was done in the past. Records provide evidence that an operation follows food safety requirements and that processes were under control. In the event of an incident, records help to determine what was done and to demonstrate that appropriate actions were taken to resolve issues. Finally, records provide evidence to customers, auditors and regulatory agencies that food safety practices are implemented not only when they are there to observe, but also as a routine practice.

12.2 REQUIRED RECORDS

§ Required Records

- Training of personnel
- Scientific data or results relating to agricultural water testing or treatment
- Records for any biological soil amendment of animal origin
- Date and method of cleaning and sanitizing equipment



Under the *Produce Safety Rule*, there are certain broad areas where specific records are required. For example:

- Sprout operations must maintain records documenting required training of personnel, including the date of training, topics covered, and the persons(s) trained. See section 11.3.3 of this manual and §112.30 for more details.
- Sprout operations must keep documents related to agricultural water used in the operation. This was previously discussed in Module 4: Sprout Production Environment. See section 4.3.6 in this manual and §112.50 (b) for more details.
- Sprout operations must maintain records for any biological soil amendments of animal origin that they use, including documentation of scientifically valid processes applied to the material. See section 4.5.1 of this manual and §112.60 for more details.
- Sprout operations must establish and maintain documentation of the date and method of cleaning and sanitizing of equipment used in growing operations and other covered harvesting, packing or holding activities (§112.140). Cleaning and sanitizing records were discussed in section 6.7 of Module 6: Cleaning and Sanitizing Buildings and Equipment.

§

Exemption Records

- Proof of eligibility for qualified exemptions
- Written assurance that sprouts will receive further processing



If a sprout operation is eligible for a qualified exemption from certain *Produce Safety Rule* requirements, it must keep records to demonstrate that its operation satisfies the criteria for a qualified exemption as described in §112.5. This includes a written record reflecting that it has performed an annual review and verification of its operation's continued eligibility for the qualified exemption (see §112.7 for more details).

If sprout products are going to receive further processing that adequately reduces pathogens (§112.2(b)), a written assurance from the company who process the products is required (§112.2(b)(3)).

§ Sprout-specific Required Records

- Seed treatment documentation
- Written plans for:
 - Environmental monitoring
 - Spent sprout irrigation water (or in-process sprouts)
- Results of analytical tests
- Analytical methods used
- Corrective actions related to:
 - Contaminated seed lot
 - Spent sprout irrigation water (or in-process sprouts) tests
 - Environmental test results



For sprout operations that do not have exemptions, records related to sprouting practices include the following:

- Sprout operations must maintain documentation of their seed or bean treatment to reduce **microorganisms** of public health significance. This may be documentation of treatments applied at their operation. As discussed in Module 8: Seed Purchasing, Receiving and Storage, this may also be documentation (such as a Certificate of Conformance) from their seed supplier that seeds or beans have been treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment (§112.150(b)(1)).
- A written environmental *Listeria* monitoring plan (§112.150(b)(2)) must be maintained. These plans were discussed in Module 7: Environmental Monitoring.
- Sprout operations must also keep a written sampling plan to collect and test spent sprout irrigation water (or in-process sprouts) for pathogens in accordance with §112.147, for each production batch of sprouts (§112.150(b)(3)). Examples of these records were discussed in Module 10: Sampling and Testing Spent Sprout Irrigation Water (or In-process Sprouts).
- Documentation of the results of all analytical tests conducted for purposes of compliance with Subpart M of the *Produce Safety Rule* (§112.150(b)(4)) must be maintained. This

Definition

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

- 21 CFR 112.3

would include, for example, *Listeria* environmental testing results and pathogen testing results for spent sprout irrigation water or in-process sprouts.

- Sprout operations must keep records of any analytical methods they use in place of the FDA methods cited in the *Produce Safety Rule* for environmental and sprout production batch testing (§112.150(b)(5)).
- Records of corrective action taken in response to the use of contaminated seed lot(s) or positive test results from testing of spent sprout irrigation water (or in-process sprouts) or the growing, harvesting, packing and holding environment (§112.150(b)(6)).

12.3 PROCEDURES FOR COMPLETING, REVIEWING AND STORING RECORDS

12.3.1 What Is Required in Records

§ Information Included in Records

- Name and location of the operation
- Actual values and observations obtained during monitoring
- Adequate description of the sprouts covered in the record
- Location of growing area or other area applicable to the record
- Date and time of the activity documented



The *Produce Safety Rule* requires that records include (§112.161(a)(1)):

- The name and location of the operation
- Actual values and observations obtained during monitoring
- An adequate description (e.g., the specific variety or brand name, and, when available, any lot number or other identifier) of sprouts applicable to the record
- The location of a growing area or other area applicable to the record; and
- The date and time of the activity documented.

12.3.1.1 *Actual values and observations*

Actual Value and Observation

- § The value itself must be written
- § Truthful information must be recorded
- § It is a violation of Federal law to falsify records required by law
 - Pictures can be helpful (e.g., before/after a repair, locations where samples are taken)



The actual values and observations obtained during monitoring and testing must be entered on the record (112.161(a)(iii)). “Actual values and observations” means: the value itself is written (e.g., a specific temperature, chemical concentration, pH, etc.) and truthful information is recorded. Regulatory agencies, third-party auditors and others expect that records be truthful and accurate. It is a serious violation of Federal law to falsify records that are required by law.

Documentation can take many forms, including photographs. For example, it is helpful to take a photograph of the location where spent sprout irrigation water or environmental samples are taken. If any repair is conducted, it is useful to take pictures before and after the repair.

12.3.1.2 Adequate Description of Sprouts Covered in Records

Adequate Description of Sprouts Covered in Record

§ Information needed

- Type of sprouts
- Batch code or lot number of sprouts
- Accurate product code important for:
 - Quick and easy identification of records corresponding to a specific lot
 - Tracking a product lot internally and through distribution



When available, information such as sprout types, growing units, location or product must be included in records (§112.161). An adequate description of sprouts covered in a record allows the operation to identify specific types of sprouts or production areas that may be associated with food safety problems, to track and verify control measures, to take appropriate actions to correct problems, and to facilitate regulatory inspections or third party audits.

Writing the batch or lot code on records for a particular batch of sprouts is important. It allows the grower and regulatory agencies to quickly and easily identify which records correspond to which sprout batches. It also enables the grower to track the batch internally and through distribution in case there is a problem with a batch of sprouts. For example, if a batch of sprouts tests positive for *Salmonella*, then the sprouts in that particular batch can be identified and segregated from other “clean” batches. In the event of a product recall, having the batch code on records makes it easier to identify which sprouts to recall. Without batch codes on records, a grower may have to expand the recall to cover all sprouts distributed within a certain time period. This is more costly and disruptive than a recall of one batch of sprouts.


12.3.1.3 Date and Time

Date and Time of Activity

§ Include date and time on required records

- Including the date and time provides evidence that:
 - Something happened
 - It was done consistently

§ Records **must** be created at the time when an activity is performed or observed



The date and time of the documented activity must be written on the record (§ 112.161(a)(1)(v)). It not only shows when something happened, it also shows that the operation consistently followed its written plans and procedures.

Records must be created at the time that an activity is performed or observed (§ 112.161(a)(2)). Monitoring information should not be written down later, based on one's memory. Conversely, monitoring results cannot be pre-filled either. Regulatory agencies sometimes find records that contain monitoring "results" before the operator has even performed the documented activity. A reason given for this practice is that, since the results are always the same, it saves time to complete the records before the activity occurs. If an operation fills in documents prematurely, it risks losing the trust of auditors and regulatory officials. Records filled out before an operation takes place or completed later are inappropriate and may lead to legal action, particularly if actual conditions or values observed do not match what was written on the record.

12.3.2 Requirements for Completing Records

Requirements for Completing Records

- § Accurate
- § Legible; i.e., clear enough to read
- § Indelible; i.e., permanent (e.g., written in ink)
 - Correcting mistakes
 - Mark through with a *single* line, initial and date by the person making the correction
 - Writing-over, obscuring and using correction fluid is not allowed



Records must be accurate, legible and indelible, and be dated and signed or initialed by the person who performed the documented activity (§ 112.161(a)(3)(4)). Remember that company officials, regulatory agencies and third-party auditors, as appropriate, will review records.

Information should be written in ink so that it cannot be erased. If mistakes are made, they should be marked through with a single line and initialed and dated by the person making the correction. The correct information should be written adjacent to it. The person correcting the record should not write over existing information, obscure it by scratching it out, or use liquid correction fluid (i.e., “white-out”).

§ Generating the Records

- Generated by the person who performed the task, e.g.:
 - Monitoring the water system
 - Sanitizing equipment
 - Collecting spent irrigation water samples
- What should they do?
 - Accurately enter the information
 - Record the time and date
 - Sign or initial the record




Person(s) performing the activities or making the observations should complete the records. For example, this could be the person monitoring the water system, a worker sanitizing equipment used for growing sprouts, trained staff treating seeds prior to sprouting or a lab analyst testing spent sprout irrigation water samples for microbial contamination. They must sign or initial the record when they complete the task and write the date when the activity occurred (§112.161(a)(4)). This ensures responsibility and accountability, and, if there is a question about the record, a signature or initials ensures that the source of the record will be known.

12.3.3 Reviewing Records

§ Record Review

- Records must be reviewed, dated and signed by a supervisor or responsible party within a reasonable time include:
 - Eligibility for qualified exemption
 - Personnel training
 - Testing and treating agricultural water
 - Seed treatment
 - Analytical tests
 - Cleaning and sanitizing
 - Corrective actions related to contaminated seeds or positive test results



Certain records required by the *Produce Safety Rule* must be reviewed, dated and signed by a supervisor or responsible party within a reasonable time after the records are completed (§112.161(b)). Examples of these records include those related to a sprout operation’s eligibility for receiving a qualified exemption, training of personnel, certain records related to testing and treating of agricultural water, treatment of seeds or beans, analytical testing, cleaning and sanitizing of equipment and certain corrective action activities relating to contaminated seed lot, spent sprout irrigation water and environmental testing results.

Rationale for Record Review

- Ensures records are accurate and completed in a timely manner
- Review can identify potential problems
- Best practices
 - Review records when able to focus without interruptions
 - Rotate the review of different types of records among different reviewers and among shifts



The purpose of reviewing records is to ensure that they were completed accurately and in a timely manner, and to identify if the records document any existing problems that need to be corrected. Requiring a signature from a supervisor or responsible party for these records emphasizes the importance of such a review.

Occasionally, supervisory review identifies a specific problem not identified by an operator or detects a trend that could lead to significant problems. For example, ATP levels trending upward may indicate problems with the sanitation procedures, environmental conditions within the sprout operation, improper employee practices or other potential issues that need to be investigated and corrected.

Reviewing records can be tedious, particularly since a reviewer often looks at the same record forms day after day. It is a challenge to remain focused when reviewing records, and not just skim over them with a quick glance. Reviewers may select a time to review records when they are able to focus without interruptions. If more than one supervisor or responsible person is qualified to review records, it may be a good idea to rotate different types of records among these reviewers, or to rotate review shifts, so that these individuals do not have to review the same records repeatedly or for long periods. This rotation may help them review records with a fresh pair of eyes.

12.3.4 Records Retention and Availability

§ Record Retention and Availability

- Must keep for at least two years past the date that the record was created
- All required records must be readily available and accessible for inspection by the FDA upon request
- Offsite storage is permitted if records can be retrieved and provided onsite within 24 hours of a request for official review by FDA



Records required by the *Produce Safety Rule* must be kept for at least two years past the date when the record was created (§112.164(a)(1)). Records to support a qualified exemption must be retained as long as necessary to support the exemption during the applicable calendar year (i.e., the 3-years preceding the applicable calendar year, §112.164(a)(2)). Records that relate to the general adequacy of equipment or processes, or records that relate to analyses, sampling or action plans being used, including the results of scientific studies, tests and evaluations, must be retained at the sprout operation for at least two years after use of the equipment or processes is discontinued (§112.164(b)). For example, a process validation document can be created more than two years before its information is applied to a process.


A sprout operation should have all records required by the *Produce Safety Rule* readily available and accessible during the retention period for inspection and copying by FDA or their designee upon oral or written request. Records obtained in accordance with the *Produce Safety Rule* are subject to the disclosure requirements under 21 CFR part 20 (§112.167).

Offsite storage of records is permitted if they can be retrieved and provided onsite within 24 hours of a request for official review (§112.162(a)). If electronic techniques are used to keep records or true copies of records, or if reduction techniques such as microfilm are used to keep true copies of records, sprouters must provide the records in a format is accessible and legible (§112.166(b)). If an operation is closed for a prolonged period, the records may be transferred to another reasonably accessible location but must be returned to the operation within 24 hours for official review upon request (§112.166(c)).

12.3.5 Record Formats

§ Record Formats

- Original records
 - Records completed at the time when the activity is performed with date and the operator's original signature or initials on them
- True copies
 - Photocopies, pictures, scanned copies, microfilm, microfiche or any other accurate reproduction of the original record
- Electronic records




Records required by the *Produce Safety Rule* must be kept as original records, true copies or electronic records (§112.165). *Original* records are completed at the time when the activity is performed, are dated, and have the operator's original signature or initials on them.

True copies are photocopies, pictures, scanned copies, microfilm, microfiche or any other accurate reproduction of the original record. True copies of records should be of sufficient quality to detect whether the original record was changed in a manner that obscured the original entry, such as using liquid correction fluid.

Electronic Records

§ If used, must be established and maintained to satisfy the requirements of the Rule

- Electronic signatures need to be equivalent to traditional handwritten signatures
- Should have a secure audit trail indicating
 - Who created the record
 - Alterations made and when, and who, made the changes



Generally, electronic or computerized records are acceptable if they are equivalent to paper records and if the electronic signatures are equivalent to traditional handwritten signatures (§112.165(c)). The system should provide a secure audit trail for the records, including for any signature. Such an audit trail would allow the electronic record to be tracked to the date/time when it was first created. An audit trail would indicate who created the electronic record, any alterations that were made to the record and when, and who made any changes. It would provide a retrievable electronic history of the record.

Electronic Records (cont.)

- Controls are necessary to ensure that records are authentic, accurate and protected from unauthorized changes
- Electronic recordkeeping systems should be validated to ensure performance
- Electronic records are subject to same review and storage requirements as paper records
- Electronic records are considered “onsite” records if accessible at the operation



Controls are necessary to ensure that electronic records are authentic, accurate, and protected from unauthorized changes. It is very important that an electronic record system has protections in place to prevent alterations of original data. Typically, an electronic record system allows an operator to input data into the system, but does not allow the operator or unauthorized persons to alter the data unless it can also track changes and allow input of reason(s) why data were altered.

Usually, electronic record systems are “closed,” meaning that access is controlled by the persons who are responsible for the content of the electronic records. If a sprout operation decides to use an electronic recordkeeping system, then the system should be validated to ensure that it works properly, and that it securely protects and stores the data.

Electronic records are subject to the same review and retention requirements as paper records. Therefore, a means should be available for a reviewer to sign and date such records electronically. The system should ensure that records are protected for later retrieval. It should be possible for complete copies of records to be generated for review upon request by regulatory agencies, as

appropriate. The *Produce Safety Rule* considers electronic records to be onsite at a sprout operation if they are accessible from a location at the operation (§112.162(b)).

12.3.6 Existing Records

§ Existing Records

- No need to duplicate the records if existing records are available
- Be supplemented to include required information and satisfy the rule requirements
- New information required by the rule may be kept separately or combined with existing records



If a sprout operation already has existing records (e.g., to comply with customer requirements or other Federal, State or local regulations) that contain all of the required information, these can be used to comply with the *Produce Safety Rule*. Existing records may also be supplemented as necessary to include all of the required information and satisfy the requirements of the rule (§112.163 (a)). If existing records contain some of the required information, any new information required by the rule may be kept either separately or combined with the existing records (§112.163 (b)).

12.4 EXAMPLE RECORDS FOR SPROUT OPERATIONS

12.4.1 Production-related Records

Examples of Production-related Activities

- Seed receiving
- § Seed inspection and treatment
- § Spent irrigation water and sprout product sampling and testing
- Sprout packaging/holding
- Sprout distribution
- § Sprout recall




Production records typically maintained by sprouters are listed above. Some of these records can be used to meet requirements of the *Produce Safety Rule* while others are maintained as routine business practice. These records can be organized chronologically based on the sprout production. Sprout growers should maintain records of the seed supplier(s), seed quantity received, lot number, seed inspections and any seed testing. Copies of these records, together with Certificates of Analysis and Letters of Guarantee, are often attached to the bill of lading if requested. More details can be found in Module 8: Seed Purchasing, Receiving and Storage.

A sprout operation must keep records documenting their treatment of seed or beans to reduce pathogens (§112.150(b)(1)). For example, if a chemical antimicrobial treatment is applied to seeds used to grow sprouts, the records should include the type of seed, the lot number, the date of the treatment, the concentration of antimicrobial treatment solution, the duration of treatment, and the person(s) responsible for administering the treatment (see Module 9: Seed Treatment for details). Alternatively, documentation (such as a Certificate of Conformance) from the seed supplier stating that seeds or beans have been treated to reduce pathogens and are appropriately handled and packaged following the treatment is acceptable. If a sprout product recall is conducted, its record must be documented as a part of the corrective actions (§112.150(b)(6)).

Product Distribution Sheet – Example

XXX Sprout Company, 123 Sprouter Road, Yourtown USA	
Product Distribution Sheet	
Shipping date	3/28/2017
Product Name	Alfalfa sprouts
Lot code	03282017-1
Quantity Shipped	10 X 50lb bags
Transporter	XYZ Company
Customer	A3B Supermarket
Record completed by	John Shipper, 3-28-12:53 pm
Comments and observation	None
Reviewer Signature: <i>J.M. Supervision</i>	Date: 4-5-2017



In the previous modules, records associated with different control programs were included as sample documents. The above form is an example of a production record. The format will vary at different operations. Examples of a materials receiving log, a product packing and holding log, product distribution sheet, a product return record and a corrective action record are in the Appendix 12: Recordkeeping Supplemental Information.

Distribution records play an important role in sprout operations. In the event of a recall, accurate distribution records enable the producer or shipper to trace and recall any lot of sprouts in a timely fashion. The records should contain sufficient information to permit traceability to a specific batch or lot number. Good distribution records identify the product, package type and size, batch or lot number, quantity distributed and customer's name and contact information. It also is helpful to indicate the type of customer (e.g., wholesale distributor, retailer) and method of distribution (e.g., commercial carrier, sprout operation's own company delivery truck, customer pick-up). Sprout growers should retain seed lot delivery receipts and link seed lots they use with specific lots of finished sprouts. As previously discussed, this is crucial information in the event of a recall. All required information, such as company name, location, date and time, etc., must be included in the document (§112.161(a)(1)).

§ Water Testing Record

- May be from a municipality for potable water
- May be from a laboratory, e.g. for well water



The actual test result record from the lab would also be required and typically would be attached to the company's record. Information on the sprout company name and address should also be included on such a form. Examples of these types of records can also be found in the Appendix.

12.4.3 Corrective Action Records

Corrective Action Records

- § Required for:
- Notifying seed supplier if seed is contaminated
 - *Listeria* positive results for environmental sampling
 - Pathogen positive results for spent sprout irrigation water testing
- A corrective actions record should include:
 - Cause of the problem
 - Affected products or procedure
 - What was done
 - Date/signature of operators
 - Date/signature of reviewers
 - How corrective actions prevent reoccurrence




Sprout operations must establish and keep documentation of actions taken when a standard is not met. §112.150(b)(6) specifically requires documentation of actions taken when a sprouter has reason to believe that seed is contaminated, when environmental tests are positive for *Listeria* and when pathogens are detected in spent sprout irrigation water. This documentation is often referred to as

“corrective action records”. Generally, a corrective action record documents the cause(s) of the deviation, the affected product (type, batch/lot number, amount) if applicable, the actions taken regarding the product, procedures to prevent a future recurrence, any results of testing and evaluation of affected product, and names and signatures (or initials) of the persons performing the corrective action and reviewing the related records.

Corrective Actions Record Sheet Example

Company Name and Address: XYZ Sprouts, Inc., 315 N. Star St., Sun City, AS 76543

FOOD SAFETY CONCERN <i>Specific environmental condition or operating practice that does not meet expected/ required food safety standard</i>	CORRECTIVE ACTIONS <i>Specific actions taken to eliminate the food safety concern and to prevent its recurrence</i>	COMPLETION DATE	ACTION STATUS <i>Complete, In Progress, Not Complete</i>	OPERATOR <i>Signature/Date</i>
1. ATP reading of bin #1 interior was higher than 110.	1. Re-clean and re-sanitize the bin. 2. Took another ATP swab 3. ATP reading after re-cleaning was 102.	12/2/2016	complete	Bill W.; 12/2/16
2				
Reviewed by: John S.		Date: 12/5/2016		



The example can be used to document corrective actions taken after an ATP result higher than the threshold is obtained. While this example does not represent one of the situations that requires formal documentation of corrective action, recording information like actions taken for verification of cleaning procedures on one form can be useful to identify trends.

Corrective Action Record – Example

Corrective Action Form	
Date of Record:	Seed Lot Number(s):
Date and Time of Deviation:	Production batch:
Description of Issue:	
Actions Taken to Restore Order:	
Person (name and signature) of Person Taking Action:	
Amount of Product Involved in Deviation:	
Evaluation of Product Involved with Deviation:	
Final Disposition of Product:	
Reviewed by (Name and Signature):	Date of Review:




A more detailed form may be useful to document situations that are less routine, such as detecting pathogens in spent sprout irrigation water or *Listeria* in an environmental sample. Situations like these frequently require time to investigate and report conclusions, which can be accommodated on a form such as the one above. It includes the date the record was created, as well as the date and time that the incident was first identified. Seed lot and batch lot information is recorded, as well as a description of the issue, action taken in response to the issue, as well as implications for product involved. An example of this form is included in Appendix 12.5: Corrective Action Form – Example.

12.4.4 Other Records

Other Record Examples

§ Personnel Training

- Training dates, topics covered, and the persons trained
- Visitor Sign-in/Sign-out
 - Date, visitor’s name and company, host name, time in/out, initials of visitor, initials of security manager



Definition


Visitor: Any person (other than personnel) who enters your covered farm with your permission.

- 21 CFR 112.3

Other records required by the *Produce Safety Rule* include personnel training records (§112.30(b)(1)). Sprout operations must have records that document required training of personnel, including the dates of training, the topics covered, and the persons trained. In addition, it is recommended to keep records of **visitors** in and out of the operation to ensure food safety and security.

Employee Training Record – Example

Company Name and Address: XYZ Sprouts, Inc., 315 N. Star St., Sun City, USA 12345		
Employee Name	Bill Trainee	
Hiring Date	1-1-2008	
Training Course	Location	Completion Date
SSA training	IFSH-IIT Bedford Park IL	12-2-2015
Reviewed by: John S.	Date: 12/21/2016	



An example of personnel training record is illustrated above. This Sprout Safety Alliance course is an example of employee training that could be documented. For individuals with many food safety duties, a training record such as this for an individual may be useful. Another approach, for example for an internal training session for employees, is a simple sign-in sheet for all attendees of the course. A

similar approach can be used for visitors using a visitor log-sheet, and example of which is in Appendix 12.6.

§ Recordkeeping Summary

- Records must be established and kept in accordance with the *Produce Safety Rule*
- Records must be clear, accurate, permanent, signed and dated by the person performed the activity
- Certain records must be reviewed, signed and dated within reasonable time
- All records associated with sprout safety must be available for inspection



In summary, records are essential components of food safety programs in a sprout operation. Sprouters must establish and keep records in accordance with the requirement of the *Produce Safety Rule* (§112.150(a)). The records must be clear, accurate, permanent, signed and dated (§112.161(a)). Certain records must be reviewed, signed and dated within reasonable time after they are made (§112.61(b)). Good records should be timely, consistent, reliable and complete. All records must be made available for inspection by FDA or their designee.

As a principle, good records should truthfully reflect what took place and should document the methods and results of any testing and any corrective actions. They are evidence of a sprouter's due diligence and help to protect the operation.

12.5 REFERENCES AND SAMPLE DOCUMENTS

FDA, 2017. Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry. <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM537031.pdf>

FDA, 2015. FSMA Final Rule on Produce Safety. <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

Appendix 12: Recordkeeping Supplemental Information

A12.1: Materials Receiving Log Sheet – Example

A12.2: Product Packaging/Holding Log Sheet – Example

A12.3: Product Distribution Sheet – Example

A12.4: Product Return Record – Example

A12.5: Corrective Action Form – Example

A12.6: Visitor Record – Example

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Appendix 1. Glossary – Definitions and Acronyms

Note: Terms as Defined in this Glossary Are for Purposes of the SSA Training ONLY

- Adequate¹:** Means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- Adulteration:** Addition of foreign or inferior substances to a product, thereby reducing its quality.
- Aerobic plate count (APC):** Plating technique used to determine the numbers of aerobic bacteria present in food. It is used as an indicator of bacterial populations in a sample. It is also called the Standard Plate Count or Total Plate Count.
- Aerosols:** Tiny airborne droplets of water or other liquid.
- Agricultural water¹:** Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).
- Allergen cross-contact²:** that which is needed to accomplish the intended purpose in keeping with good public health practice.
- Aseptic procedure:** Practices and procedures applied to prevent microbiological contamination of samples
- ATP:** Adenosine triphosphate (ATP) is an energy molecule found in all organic substances. ATP tests provide an indication of the amount of biological residue on a surface.
- Audit trail:** Refers to the list of actions and documents taken at any time during specific operation, procedure, or event.
- Audit²:** means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an entity's food safety processes and procedures.
- Back siphonage:** The reverse flow of fluid caused by reduced pressure in a piping system
- Bill of Lading:** A document issued by a carrier or by a shipper's agent that identifies the goods for shipment, where the goods are to be delivered, and who is entitled to receive the shipment.
- Biological soil amendment¹:** Any soil amendments containing biological materials such as stabilized compost, manure, non-fecal animal by-products, peat moss, pre-consumer vegetative waste, sewage sludge bio-solids, table waste, agricultural tea, or yard trimmings, alone or in combination.
- Certificate of Conformance (CoC):** A document certified by a competent authority that the supplied good or service meets the required specifications, also called Certificate of Compliance.
- Certificate of Analysis (CoA):** A document provided by a supplier of an ingredient prior to or upon receipt of the ingredient that confirms conformance with its product specification. The certificate usually includes the actual test results performed on the product batch.
- Cleaning⁴:** The removal of soil, food residue, dirt, grease or other objectionable matter.
- Code of Federal Regulations (CFR):** An annual codification of the general and permanent rules and regulations published in the Federal Register by the executive departments and agencies of the Federal Government of the United States.
- Compost:** A mixture of organic matters used to improve soil structure and to provide nutrients.
- Composting¹:** A process to produce stabilized compost in which organic material is decomposed by the action of microorganisms under thermophilic conditions of designated period of time at a designated temperature, followed by a curing stage under cooler conditions.

Condensate: Water droplets that form or condense when warm humid air comes in contact with cooler surfaces such as ceilings, walls, overhead fixtures, pipes, and refrigeration units.

Correction²: means an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Corrective action: An action of identification and elimination of the causes of a problem, thus preventing their recurrence. It takes place when results of monitoring indicate a loss of control of a process or identification of an infraction.

Cross-Contamination²: The unintentional transfer of a foodborne pathogen from a food (where it may occur naturally) or insanitary object to another food (where it may present a hazard).

Enteric pathogen: Harmful microorganism that is naturally occurring in the digestive tract or intestine of humans, animals or birds.

Environmental Protection Agency (EPA): An independent US government agency with jurisdiction over existing and under-development chemicals (such as pesticides) that affect the environment. It regulates their manufacture, processing, distribution and use, and sets tolerance levels for their presence in food and feed. It aims at reducing pollution and protecting the environment.

Facility²: A domestic facility or foreign facility that is required to register under section 415 of the Federal Food Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR Part 1, subpart H.

Farm¹:

(1) *Primary production farm.* A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

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

(2) *Secondary activities farm.* A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

FDA Food Safety Modernization Act (FSMA): Act which aims to integrate the nation’s food safety system into one that is based on the prevention of foodborne illnesses. It is a set of regulations directing the food

industry to systematically put in place measures proven effective in preventing contamination.

Food¹: Means food as defined in section 201(f) of the Federal Food Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

Food allergen⁵: Any of the following: (1) Milk, egg, fish (e.g., bass, flounder or cod), Crustacean shellfish (e.g., crab, lobster or shrimp), tree nuts (e.g., almonds, pecans or walnuts), wheat, peanuts and soybeans. (2) A food ingredient that contains protein derived from a food specified in paragraph (1), except any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

Food and Drug Administration (FDA): A National government agency responsible for regulating the manufacture and sale of most foods sold in the United States.

Food contact surfaces¹: Those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food contact surfaces" include food contact surfaces of equipment and tools used during harvest, packing and holding.

Food defense: Protection of food products from intentional contamination or adulteration by biological, chemical, physical, or radiological agents. It addresses additional concerns including physical, personnel and operational security of foods.

Food grade: Refers to the minimum standards required for substances to qualify as fit for human consumption or permitted to come into contact with food.

Food safety hazard: A biological, chemical or physical agent, or condition of food, with the potential to cause harm or an adverse health effect when eaten.

Foodborne illness: Illnesses which result from the intake of contaminating microorganisms, chemicals, parasites, viruses or from naturally occurring toxins or poisons in foods.

Foodborne pathogens: Harmful microorganisms that are transmitted by food.

Food-grade lubricants: Lubricants used for equipment or machinery that may contact food must meet defined standards of suitability for human consumption. Food grade lubricants are potentially indirect food additives.

Foreign Supplier Verification Program (FSVP): Program that requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not, among other things, adulterated and that it was produced in compliance with FDA's preventive controls requirements and produce safety standards, where applicable.

Good Agricultural Practices (GAPs): Voluntary practices or guidelines to minimize contamination of agricultural foods and food products in the field.

Good Manufacturing Practices (GMPs): The Federal regulation (§117 Subpart B) that outlines the conditions and practices the food industry must follow for processing safe food under sanitary conditions including personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, and defect action level considerations.

HACCP²: Hazard Analysis and Critical Control Point – A system which identifies, evaluates, and controls hazards which are significant for food safety.

Harvesting¹: Applies to farm and farm mixed-type facilities and means activities that are traditionally performed on the farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/ dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug and Cosmetic Act. An example of harvesting includes cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming the raw agricultural commodity (e.g. foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from shelling, sifting, threshing, trimming of outer of leaves of, and washing raw agricultural commodities grown on a farm.

Hazard¹: Any biological agent that has the potential to cause illness or injury in the absence of its control.

Holding¹: Storage of food and includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and dehydrating raw agricultural commodities when drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201 (gg) of the Federal Food, Drug and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Indicator organisms: Organisms, species or communities whose characteristics reflect the presence of specific environmental conditions.

Known or reasonably foreseeable hazard¹: means a biological hazard that is known to be, or has the potential to be, associated with the farm or the food.

Letter of Guarantee: A document from a supplier of raw materials or ingredients that indicates that their product meets certain safety or quality requirements and/or was manufactured under appropriate sanitary conditions.

Listeriosis: The disorders caused by the bacterium *Listeria monocytogenes*.

Luciferin: Compound which produces light on oxidation.

Manure¹: Animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

Microgreens - difference from sprouts: According to 21 CFR SUPPLEMENTARY INFORMATION XVIII. Subpart M- Comments on Sprouts, “Historically, the primary criterion FDA has used to distinguish between the two product categories has been the growth stage of the leaves. Sprouts are usually harvested when the cotyledons (or seed leaves) are still un-developed or under-developed and true leaves have not begun to emerge. In contrast, microgreens reach a later stage of growth, typically associated with the emergence of “true” leaves. Microgreens are also typically grown in soil or substrate and harvested above the soil or substrate line. However, microgreens are considered “covered produce” for the purposes of this rule and, unless exempt or excluded under the provisions in subpart A, microgreens and microgreen farms are subject to all other subparts of part 112”.

Material Safety Data Sheet (MSDS): See Safety Data Sheet

Microorganisms¹: Yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites including species having public health significance. The term “Undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth or that otherwise may cause food to be adulterated.

Mixed-type facility²: An establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor¹: To conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and when required, to generate an accurate record of the observation or requirement.

National Organic Program (NOP): A regulatory program, administered by the USDA, responsible for developing national standards for organically produced agricultural products. These standards assure consumers that products with the USDA organic seal meet consistent, uniform standards. However, the regulation does not address food safety or nutrition.

Occupational Safety and Health Administration (OSHA): A federal agency created under the US Department of Labor to establish and enforce standards and laws for working conditions in commercial and industrial sectors.

Outbreak: An incident in which two or more people experience the same illness after eating the same food.

Packing¹: Placing food into a container other than packaging food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food such as sorting, culling, grading, and weighing, or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug and Cosmetic Act.

Pathogen²: Any microorganism of public health significance.

Pest¹: Any objectionable animals or insects, including birds, rodents, flies, and larvae.

pH: Measure of the concentration of hydronium ions (H⁺) present in a solution and, therefore, its acidity or alkalinity.

Potable water: Water that meets the standards for drinking purposes of the State or local authority having jurisdiction, or water that meets the standards prescribed by the U.S. Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR 141).

Prerequisite programs: Procedures, including Good Manufacturing Practices (GMPs), that provide the basic environmental and operating conditions necessary to support the Food Safety Plan.

Produce¹: Any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed, plant or tree (such as an apple, orange or almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of a herbaceous plant (such as cabbage and potato) or fleshy fruity body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and include mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption such as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent - or flint -corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Production batch of sprouts¹: All sprouts that are started at the same time in a single growing unit (e.g. single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Raw Agricultural Commodity (RAC)¹: "Raw Agricultural Commodity" as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Recall: Action taken by a food company to remove a product from the market.

Recordkeeping: Activity of maintaining the records of events and related data.

Salmonellosis: An infection with certain species of the genus *Salmonella*, usually caused by ingestion of food containing salmonellae or their products, also known as *Salmonella* gastroenteritis or *Salmonella* food poisoning.

Sanitation Standard Operating Procedures (SSOP): Written procedures describing a sanitation process or activity that an establishment develops and implements to achieve a hygienic environment.

Sanitize¹: To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of the microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for its consumer.

Safety Data Sheet (SDS): Formal document containing important information about the characteristics and actual or potential hazards of a substance. Sometimes called a Material Safety Data Sheet (MSDS).

SDS: (see Safety Data Sheet)

Shelf life: The period of time during which a commodity, as food, remains effective, useful, or suitable for

consumption.

Should²: Used to state recommended or advisory procedures or identify recommended equipment.

Soil amendments¹: Any chemical, biological, or physical material (such as elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge bio solids, table waste, agricultural tea, and yard trimming) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of the covered produce (such as mushrooms and some sprouts).

SOP: See Standard operating procedure

Spent sprout irrigation water¹: Water that has been used in the growing of sprouts.

Sprouter: a person who owns a sprout operation and grows sprouts.

Standard operating procedure (SOP): A written procedure or set of procedures that describes how to perform a given operation. SOPs should indicate the procedure, who has responsibility for carrying it out, and what actions should be taken if the procedures are not performed according to the written protocol or if the procedures do not have the expected outcome.

Sterile: Free from viable microorganisms

Suppliers²: The establishment that manufactures/processes the food or ingredients, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment; except for further manufacturing/processing that consists solely of labeling or similar activity of a *de minimis* nature.

Swabbing: Technique used to collect samples for microbial analysis

Validation²: That element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards.

Verification²: Those activities other than monitoring, that establish the validity of the Food Safety Plan and that the system is operating according to the plan.

Visitor¹: Any person (other than personnel) who enters your covered farm with your permission.

Definition sources

¹ Food and Drug Administration (FDA), *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*. 21 CFR 112.3 Definitions.

² Food and Drug Administration (FDA), *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food*. 21 CFR 117.3 Definitions

³ FDA, Section 201 (f) of the Federal Food, Drug and Cosmetic Act

⁴ FAO/WHO, 2003. *General Principles on Food Hygiene*. CAC/RCP 1-1969. Rev.4-2003

⁵ FDA, Section 201(qq)- Based on requirements in that section

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Appendix 2. FDA Regulation on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

NOTE: NOT an official version. Provided for reference only.

TITLE 21 OF THE CODE OF FEDERAL REGULATION PART 112— STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

Subpart A—General Provisions

§ 112.1 What food is covered by this part?

- (a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.
- (b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:
- (1) Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and
 - (2) Mixes of intact fruits and vegetables (such as fruit baskets).

§ 112.2 What produce is not covered by this part?

- (a) The following produce is not covered by this part:
- (1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.
 - (2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and
 - (3) Produce that is not a raw agricultural commodity.
- (b) Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (2), and (3) of this section) under the following conditions:
- (1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products; and
 - (2) You must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;” and

- (3) You must either:
- (i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or
 - (ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:
 - (A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and
 - (B) Will only sell to another entity that agrees, in writing, it will either:
 - (1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or
 - (2) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and
- (4) You must establish and maintain documentation of your compliance with applicable requirements in paragraphs (b)(2) and (3) in accordance with the requirements of subpart O of this part, including:
- (i) Documents containing disclosures required under paragraph (b)(2) of this section; and
 - (ii) Annual written assurances obtained from customers required under paragraph (b)(3) of this section; and
- (5) The requirements of this subpart and subpart Q of this part apply to such produce; and
- (6) An entity that provides a written assurance under § 112.2(b)(3)(i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 112.3 What definitions apply to this part?

- (a) The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part.
- (b) For the purpose of this part, the following definitions of very small business and small business also apply:
- (1) Very small business. For the purpose of this part, your farm is a very small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$250,000.
 - (2) Small business. For the purpose of this part, your farm is a small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.
- (c) For the purpose of this part, the following definitions also apply:
- Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.
- Agricultural tea means a water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for the purposes of this rule.
- Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.
- Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).
- Animal excreta means solid or liquid animal waste.
- Application interval means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.
- Biological soil amendment means any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological soil amendment of animal origin means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term “biological soil amendment of animal origin” does not include any form of human waste.

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

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of “farm” as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

Curing means the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation, depending on environmental conditions.

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

Farm means:

- (i) **Primary Production Farm.** A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:
- (A) Pack or hold raw agricultural commodities;
 - (B) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (i)(C)(2)(i) of this definition; and
 - (C) Manufacture/process food, provided that:
 - (1) All food used in such activities is consumed on that farm or another farm under the same management; or
 - (2) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
 - (i) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
 - (ii) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and
 - (iii) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or
- (ii) **Secondary Activities Farm.** A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm in paragraphs (i)(B) and (C) of this definition.

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

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

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

Growth media means material that acts as a substrate during the growth of covered produce (such as mushrooms and some sprouts) that contains, may contain, or consists of components that may include any animal waste (such as stabilized compost, manure, non-fecal animal byproducts or table waste).

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

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

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

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

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

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

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

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered.

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

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

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

Pest means any objectionable animals or insects, including birds, rodents, flies, and larvae.

Pre-consumer vegetative waste means solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Production batch of sprouts means all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

- (i) In the same State or the same Indian reservation as the farm that produced the food; or
- (ii) Not more than 275 miles from such farm.

Raw agricultural commodity (RAC) means “raw agricultural commodity” as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

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

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

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

Spent sprout irrigation water means water that has been used in the growing of sprouts.

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

Static composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure).

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

Table waste means any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.

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

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

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

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

Yard trimmings means purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

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

§ 112.4 Which farms are subject to the requirements of this part?

- (a) Except as provided in paragraph (b) of this section, a farm or farm mixed-type facility with an average annual monetary value of produce (as “produce” is defined in § 112.3(c)) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a “covered farm” subject to this part. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.
- (b) A farm is not a covered farm if it satisfies the requirements in § 112.5 and we have not withdrawn the farm's exemption in accordance with the requirements of subpart R of this part.

§ 112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

- (a) A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:
 - (1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3(c)) the farm sold directly to qualified end-users (as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and
 - (2) The average annual monetary value of all food (as defined in § 112.3(c)) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.
- (b) For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

§ 112.6 What modified requirements apply to me if my farm is eligible for a qualified exemption in accordance with § 112.5?

- (a) If your farm is eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:
 - (1) This subpart (General Provisions);
 - (2) Subpart O of this part (Records);
 - (3) Subpart Q of this part (Compliance and Enforcement); and
 - (4) Subpart R of this part (Withdrawal of Qualified Exemption).
- (b) In addition, you are subject to the following modified requirements:
 - (1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.
 - (2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.
 - (3) The complete business address that you must include in accordance with the requirements of paragraph (b)(1) or (2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

§ 112.7 What records must I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5?

If your farm is eligible for a qualified exemption in accordance with § 112.5:

- (a) You must establish and keep records required under this provision in accordance with the requirements of subpart O of this part, except that the requirement in § 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Such receipts must be dated as required under § 112.161(a)(4).
- (b) You must establish and keep adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption that are described in § 112.5, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption.

Subpart B—General Requirements

§ 112.11 What general requirements apply to persons who are subject to this part?

You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards.

§ 112.12 Are there any alternatives to the requirements established in this part?

- (a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.
- (b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.
- (c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of this part. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.

Subpart C—Personnel Qualifications and Training**§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?**

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:

- (a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.
- (b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part.
- (c) Training must be conducted in a manner that is easily understood by personnel being trained.
- (d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.

§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity?

- (a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:
 - (1) Principles of food hygiene and food safety;
 - (2) 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 covered produce or food contact surfaces with microorganisms of public health significance; and
 - (3) The standards established by FDA in subparts C through O of this part that are applicable to the employee's job responsibilities.
- (b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:
 - (1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;
 - (2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and
 - (3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.
- (c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.

§ 112.23 What requirements apply regarding supervisors?

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part.

§ 112.30 Under this subpart, what requirements apply regarding records?

- (a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.
- (b) You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.

Subpart D—Health and Hygiene

§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?

- (a) You must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person 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).
- (b) The measures you must take to satisfy the requirements of paragraph (a) of this section must include all of the following measures:
 - (1) Excluding any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health; and
 - (2) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.

§ 112.32 What hygienic practices must personnel use?

- (a) Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination.
- (b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices:
 - (1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;
 - (2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;
 - (3) Washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:
 - (i) Before starting work;
 - (ii) Before putting on gloves;
 - (iii) After using the toilet;
 - (iv) Upon return to the work station after any break or other absence from the work station;
 - (v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and
 - (vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards;
 - (4) If you choose to use gloves in handling covered produce or food contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so;
 - (5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and
 - (6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).

§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?

- (a) You must make visitors aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.
- (b) You must make toilet and hand-washing facilities accessible to visitors.

Subpart E—Agricultural Water

§ 112.41 What requirements apply to the quality of agricultural water?

All agricultural water must be safe and of adequate sanitary quality for its intended use.

§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

- (a) At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably

foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:

- (1) The nature of each agricultural water source (for example, ground water or surface water);
 - (2) The extent of your control over each agricultural water source;
 - (3) The degree of protection of each agricultural water source;
 - (4) Use of adjacent and nearby land; and
 - (5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.
- (b) You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.
- (c) You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.
- (d) As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.

§ 112.43 What requirements apply to treating agricultural water?

- (a) When agricultural water is treated in accordance with § 112.45:
- (1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable.
 - (2) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.
- (b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

§ 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

- (a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:
- (1) Used as sprout irrigation water;
 - (2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, 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;
 - (3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and
 - (4) Used for washing hands during and after harvest activities.
- (b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):
- (1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and
 - (2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

§ 112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

- (a) If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44(a), you must immediately discontinue that

use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either:

- (1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or
- (2) Treat the water in accordance with the requirements of § 112.43.
- (b) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either:
 - (1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:
 - (i) Applying a time interval between last irrigation and harvest using either:
 - (A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or
 - (B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or
 - (ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data and information;
 - (2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or
 - (3) Treat the water in accordance with the requirements of § 112.43.

§ 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

- (a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:
 - (1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;
 - (2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or
 - (3) You treat water in accordance with the requirements of § 112.43.
- (b) Except as provided in paragraph (a) of this section, you must take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b):
 - (1) Conduct an initial survey to develop a microbial water quality profile of the agricultural water source.
 - (i) The initial survey must be conducted:
 - (A) For an untreated surface water source, by taking a minimum total of 20 samples of agricultural water (or an alternative testing frequency that you establish and use, in accordance with § 112.49) over a minimum period of 2 years, but not greater than 4 years.
 - (B) For an untreated ground water source, by taking a minimum total of four samples of agricultural water during the growing season or over a period of 1 year.
 - (ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile initially consists of the geometric mean (GM) and the statistical threshold value (STV) of generic *Escherichia coli* (*E. coli*) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You must determine the appropriate way(s) in which the water may be used based on your microbial water quality profile in accordance with § 112.45(b).
 - (iii) You must update the microbial water quality profile annually as required under paragraph (b)(2) of this section, and otherwise required under paragraph (b)(3) of this section.
 - (2) Conduct an annual survey to update the microbial water quality profile of your agricultural water.

- (i) After the initial survey described in paragraph (b)(1)(i) of this section, you must test the water annually to update your existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze:
 - (A) For an untreated surface water source, a minimum number of five samples per year (or an alternative testing frequency that you establish and use, in accordance with § 112.49).
 - (B) For an untreated ground water source, a minimum of one sample per year.
 - (ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest.
 - (iii) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from within the previous 4 years, to make up a rolling data set of:
 - (A) At least 20 samples for untreated surface water sources; and
 - (B) At least 4 samples for untreated ground water sources.
 - (iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with § 112.45(b).
- (3) If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed.
- (i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of:
 - (A) At least 20 samples for untreated surface water sources; and
 - (B) At least 4 samples for untreated ground water sources.
 - (ii) You must modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b).
- (c) If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected to be representative of the intended use(s). Based on these results, you must determine whether the water can be used for that purpose, in accordance with § 112.45(a). If your four initial sample results meet the microbial quality criteria of § 112.44(a), you may test once annually thereafter, using a minimum of one sample collected to be representative of the intended use(s). You must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criteria in § 112.44(a).

§ 112.47 Who must perform the tests required under § 112.46 and what methods must be used?

- (a) You may meet the requirements related to agricultural water testing required under § 112.46 using:
 - (1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or
 - (2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.
- (b) Agricultural water samples must be aseptically collected and tested using a method as set forth in § 112.151.

§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

- (a) You must manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).
- (b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).
- (c) You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

§ 112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

Provided you satisfy the requirements of § 112.12, you may establish and use one or more of the following alternatives:

- (a) An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b);
- (b) An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i);

- (c) An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A); and
- (d) An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A).

§ 112.50 Under this subpart, what requirements apply regarding records?

- (a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.
- (b) You must establish and keep the following records:
 - (1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a);
 - (2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart;
 - (3) Scientific data or information you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(a)(1) and (2);
 - (4) Documentation of the results of water treatment monitoring under § 112.43(b);
 - (5) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that you used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *Escherichia coli* (*E. coli*), in accordance with § 112.45(b)(1)(ii);
 - (6) Documentation of actions you take in accordance with § 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (ii), such documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing);
 - (7) Annual documentation of the results or certificates of compliance from a public water system required under § 112.46(a)(1) or (2), if applicable;
 - (8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and
 - (9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).

Subpart F—Biological Soil Amendments of Animal Origin and Human Waste

§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

- (a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.
- (b) A biological soil amendment of animal origin is untreated if it:
 - (1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic *E. coli* in 100 mL of water;
 - (2) Has become contaminated after treatment;
 - (3) Has been recombined with an untreated biological soil amendment of animal origin;
 - (4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or
 - (5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?

- (a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.
- (b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.
- (c) You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.

§ 112.53 What prohibitions apply regarding use of human waste?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:

- (a) A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical and/or biological processes that has been validated to satisfy the microbial standard in § 112.55(a) for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157:H7; or
- (b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for *Salmonella* species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:
 - (1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and
 - (2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

§ 112.55 What microbial standards apply to the treatment processes in § 112.54?

The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.

- (a) For *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7, the relevant standards in the table in this paragraph (a); or

For the microorganism -	The microbial standard is -
(1) <i>L. monocytogenes</i>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.
(2) <i>Salmonella</i> species	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
(3) <i>E. coli</i> O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

- (b) *Salmonella* species are not detected using a method that can detect three MPN *Salmonella* species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

- (a) You must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph (a) in accordance with the application requirements specified in the second column of the table in this paragraph (a) and the minimum application intervals specified in the third column of the table in this paragraph (a).

If the biological soil amendment of animal origin is-	Then the biological soil amendment of animal origin must be applied-	And then the minimum application interval is-
(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application	[Reserved].
(ii) Untreated	In a manner that does not contact covered produce during or after application	0 days.
(2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b)	In a manner that minimizes the potential for contact with covered produce during and after application	0 days.
(3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a)	In any manner (i.e., no restrictions)	0 days.

(b) [Reserved]

§ 112.60 Under this subpart, what requirements apply regarding records?

- (a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.
- (b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:
- (1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that:
 - (i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and
 - (ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and
 - (2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.

Subpart G-H [Reserved]

Subpart I—Domesticated and Wild Animals

§ 112.81 How do the requirements of this subpart apply to areas where covered activities take place?

- (a) The requirements of this subpart apply when a covered activity takes place in an outdoor area or a partially-enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.
- (b) The requirements of this subpart do not apply:
- (1) When a covered activity takes place in a fully-enclosed building; or
 - (2) To fish used in aquaculture operations.

§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

- (a) You must take the steps set forth in paragraph (b) of this section if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.
- (b) You must:
- (1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and
 - (2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

§ 112.84 Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

No. Nothing in this regulation authorizes the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531-1544) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Subpart J—[Reserved]

Subpart K—Growing, Harvesting, Packing, and Holding Activities

§ 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

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

- (a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and
- (b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.

§ 112.112 What measures must I take immediately prior to and during harvest activities?

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used.

§ 112.113 How must I handle harvested covered produce during covered activities?

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

§ 112.114 What requirements apply to dropped covered produce?

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

§ 112.115 What measures must I take when packaging covered produce?

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

§ 112.116 What measures must I take when using food-packing (including food packaging) material?

- (a) You must use food-packing material that is adequate for its intended use, which includes being:
 - (1) Cleanable or designed for single use; and
 - (2) Unlikely to support growth or transfer of bacteria.
- (b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

Subpart L—Equipment, Tools, Buildings, and Sanitation**§ 112.121 What equipment and tools are subject to the requirements of this subpart?**

Equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

§ 112.122 What buildings are subject to the requirements of this subpart?

Buildings subject to the requirements of this subpart include:

- (a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and
- (b) Storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).

§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?

All of the following requirements apply regarding equipment and tools subject to this subpart:

- (a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and
- (b) Equipment and tools must be:
 - (1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and
 - (2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.
- (c) Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.
- (d)(1) You must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

- (2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.
- (e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.

§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?

Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:

- (a) Accurate and precise as necessary and appropriate in keeping with their purpose;
- (b) Adequately maintained; and
- (c) Adequate in number for their designated uses.

§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?

Equipment that is subject to this subpart that you use to transport covered produce must be:

- (a) Adequately clean before use in transporting covered produce; and
- (b) Adequate for use in transporting covered produce.

§ 112.126 What requirements apply to my buildings?

- (a) All of the following requirements apply regarding buildings:
- (1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must:
- (i) Provide sufficient space for placement of equipment and storage of materials;
- (ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and
- (2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.
- (b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through:
- (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and
- (2) Drip or condensate.

§ 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?

- (a) You must take reasonable precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:
- (1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or
- (2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.
- (b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials.

§ 112.128 What requirements apply regarding pest control in buildings?

- (a) You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.
- (b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.
- (c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).

§ 112.129 What requirements apply to toilet facilities?

All of the following requirements apply to toilet facilities:

- (a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.
- (b) Your toilet facilities must be designed, located, and maintained to:

- (1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;
 - (2) Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use, and be kept supplied with toilet paper; and
 - (3) Provide for the sanitary disposal of waste and toilet paper.
- (c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.

§ 112.130 What requirements apply for hand-washing facilities?

All of the following requirements apply to hand-washing facilities:

- (a) You must provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities.
- (b) Your hand-washing facilities must be furnished with:
 - (1) Soap (or other effective surfactant);
 - (2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and
 - (3) Adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).
- (c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.
- (d) You may not use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.

§ 112.131 What must I do to control and dispose of sewage?

All of the following requirements apply for the control and disposal of sewage:

- (a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.
- (b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.
- (c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.
- (d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?

All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:

- (a) You must convey, store, and dispose of trash, litter and waste to:
 - (1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and
 - (2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.
- (b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.

§ 112.133 What requirements apply to plumbing?

The plumbing must be of an adequate size and design and be adequately installed and maintained to:

- (a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand-washing and toilet facilities;
- (b) Properly convey sewage and liquid disposable waste;
- (c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources; and
- (d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.

§ 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?

- (a) If you have domesticated animals, to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must:
 - (1) Adequately control their excreta and litter; and

(2) Maintain a system for control of animal excreta and litter.

(b) [Reserved]

§ 112.140 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:

- (1) Growing operations for sprouts; and
- (2) Covered harvesting, packing, or holding activities.

Subpart M—Sprouts

§ 112.141 What commodities are subject to this subpart?

The requirements of this subpart apply to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots.

§ 112.142 What requirements apply to seeds or beans used to grow sprouts?

In addition to the requirements of this part, all of the following requirements apply to seeds or beans used to grow sprouts.

- (a) You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.
- (b) Except as provided in paragraph (c) of this section, if you know or have reason to believe that a lot of seeds or beans may be contaminated with a pathogen (either because it has been associated with foodborne illness; or based on microbial test results, including a positive finding of a pathogen in tests required under § 112.144(b)), you must:
 - (1) Discontinue use of all seeds or beans from that lot for sprout production and ensure that sprouts grown from that lot of seeds or beans do not enter commerce; and
 - (2) Report the information (association with illness and/or findings of microbial testing) to the seed grower, distributor, supplier, or other entity from whom you received the seeds or beans.
- (c) If your reason to believe that a lot of seeds or beans may be contaminated was based only on microbial test results:
 - (1) You are not required to take the steps set forth in paragraph (b)(1) of this section if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans; or
 - (2) You are not required to take the steps set forth in paragraphs (b)(1) and (2) of this section if you later reasonably determine, through appropriate followup actions, that the lot of seeds or beans is not the source of contamination (e.g., the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts).
- (d) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards.
- (e) You must either:
 - (1) Treat seeds or beans that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance; or
 - (2) Rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds or beans at the covered farm immediately before sprouting), provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that:
 - (i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and
 - (ii) The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination.

§ 112.143 What measures must I take for growing, harvesting, packing, and holding sprouts?

You must take all of the following measures for growing, harvesting, packing, and holding sprouts:

- (a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building.
- (b) Any food contact surfaces you use to grow, harvest, pack, or hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts.
- (c) You must conduct testing during growing, harvesting, packing, and holding sprouts, as specified in § 112.144.
- (d) You must establish and implement a written environmental monitoring plan as specified in § 112.145.
- (e) You must take certain actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment, as specified in § 112.146.
- (f) You must establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens as specified in § 112.147.

- (g) You must take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen as specified in § 112.148.

§ 112.144 What testing must I do during growing, harvesting, packing, and holding sprouts?

All of the following testing must be done during growing, harvesting, packing, and holding sprouts:

- (a) You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* in accordance with the requirements of § 112.145.
- (b) You must either:
- (1) Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147; or
 - (2) If testing spent sprout irrigation water is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147.
- (c) In addition to *E. coli* O157:H7 and *Salmonella* species, you must conduct tests as provided in paragraph (b) of this section for additional pathogens when the following conditions are met:
- (1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and
 - (2) A scientifically valid test method for the pathogen is available to detect the pathogen in spent sprout irrigation water (or sprouts).

§ 112.145 What requirements apply to testing the environment for *Listeria* species or *L. monocytogenes*?

All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes*.

- (a) You must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment.
- (b) Your written environmental monitoring plan must be directed to sampling and testing for either *Listeria* species or *L. monocytogenes*.
- (c) Your written environmental monitoring plan must include a sampling plan that specifies:
- (1) What you will test collected samples for (i.e., *Listeria* species or *L. monocytogenes*);
 - (2) How often you will collect environmental samples, which must be no less than monthly, and at what point during production you will collect the samples; and
 - (3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment.
- (d) You must aseptically collect environmental samples and test them for *Listeria* species or *L. monocytogenes* using a method as set forth in § 112.152.
- (e) Your written environmental monitoring plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*.

§ 112.146 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*?

You must, at a minimum, take the following actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment:

- (a) Conduct additional testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in a niche;
- (b) Clean and sanitize the affected surfaces and surrounding areas;
- (c) Conduct additional sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated;
- (d) Conduct finished product testing when appropriate;
- (e) Perform any other actions necessary to prevent recurrence of the contamination; and
- (f) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce.

§ 112.147 What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens?

All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for pathogens as required in § 112.144(b):

- (a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.
- (b) In accordance with the written sampling plan required under paragraph (a) of this section, you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens using a method as set forth in § 112.153. You must not allow the production batch of sprouts to enter into commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* species, and, if applicable, a pathogen meeting the criteria in § 112.144(c).
- (c) Your written sampling plan must include a corrective action plan that at a minimum, requires you to take the actions in § 112.148, and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c).

§ 112.148 What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen?

You must, at a minimum, take the following actions if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c):

- (a) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce;
- (b) Take the steps required in § 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under § 112.142(c));
- (c) Clean and sanitize the affected surfaces and surrounding areas; and
- (d) Perform any other actions necessary to prevent reoccurrence of the contamination.

§ 112.150 Under this subpart, what requirements apply regarding records?

- (a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.
- (b) You must establish and keep the following records:
 - (1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e);
 - (2) Your written environmental monitoring plan in accordance with the requirements of § 112.145;
 - (3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of § 112.147(a) and (c);
 - (4) Documentation of the results of all analytical tests conducted for purposes of compliance with this subpart;
 - (5) Any analytical methods you use in lieu of the methods that are incorporated by reference in §§ 112.152 and 112.153; and
 - (6) Documentation of actions you take in accordance with §§ 112.142(b) and (c), 112.146, and 112.148.

Subpart N—Analytical Methods

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?

You must test the quality of water using:

- (a) The method of analysis published by the U.S. Environmental Protection Agency (EPA), “Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC), EPA-821-R-09-007,” December, 2009. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from EPA, Office of Water (4303T), 1200 Pennsylvania Avenue NW., Washington, DC 20460. You may inspect a copy at FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html; or
- (b)(1) A scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity; or
- (2) For any other indicator of fecal contamination you may test for pursuant to § 112.49(a), a scientifically valid method.

§ 112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.144(a)?

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

- (a) The method of analysis described in “Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples,” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves

this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; <http://www.fda.gov/fsma>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

- (b) A scientifically valid method that is at least equivalent to the method of analysis in § 112.152(a) in accuracy, precision, and sensitivity.

§ 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?

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

- (a) For *E. coli* O157:H7, *Salmonella* species:

(1) The method of analysis described in “Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts),” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; <http://www.fda.gov/fsma>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(2) A scientifically valid method that is at least equivalent to the method of analysis in § 112.153(a)(1) in accuracy, precision, and sensitivity; and

- (b) For any other pathogen(s) meeting the criteria in § 112.144(c), a scientifically valid method.

Subpart O—Records

§ 112.161 What general requirements apply to records required under this part?

- (a) Except as otherwise specified, all records required under this part must:

(1) Include, as applicable:

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

(2) Be created at the time an activity is performed or observed

(3) Be accurate, legible, and indelible; and

(4) Be dated, and signed or initialed by the person who performed the activity documented.

- (b) Records required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

§ 112.162 Where must I store records?

- (a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.

- (b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.

§ 112.163 May I use existing records to satisfy the requirements of this part?

- (a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part.

- (b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 112.164 How long must I keep records?

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

- (2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year.
- (b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

§ 112.165 What formats are acceptable for the records I keep?

You must keep records as:

- (a) Original records;
- (b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or
- (c) Electronic records. Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 112.166 What requirements apply for making records available and accessible to FDA?

- (a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.
- (b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.
- (c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.

§ 112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

Subpart P—Variances

§ 112.171 Who may request a variance from the requirements of this part?

A State, Federally-recognized tribe (or “tribe”), or a foreign country from which food is imported into the United States may request a variance from one or more requirements of this part, where the State, tribe, or foreign country determines that:

- (a) The variance is necessary in light of local growing conditions; and
- (b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.172 How may a State, tribe, or foreign country request a variance from one or more requirements of this part?

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

§ 112.173 What must be included in the Statement of Grounds in a petition requesting a variance?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must:

- (a) Provide a statement that the applicable State, tribe, or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part;
- (b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of this part to which the variance would apply;
- (c) Present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?

We will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information

exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with this request.

§ 112.175 Who responds to a petition requesting a variance?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance.

§ 112.176 What process applies to a petition requesting a variance?

- (a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a variance.
- (b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the Federal Register, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (e.g., because their farm is covered by the petition or as a person similarly situated to persons covered by the petition).
- (c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing and will also make public a notice on FDA's Web site announcing our decision to either grant or deny the petition.
 - (1) If we grant the petition, either in whole or in part, we will specify the persons to whom the variance applies and the provision(s) of this part to which the variance applies.
 - (2) If we deny the petition (including partial denials), our written response to the petitioner and our public notice announcing our decision to deny the petition will explain the reason(s) for the denial.
- (d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied).

§ 112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?

- (a) A State, tribe, or a foreign country that believes that a variance requested by a petition submitted by another State, tribe, or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with § 10.30 of this chapter. These comments must include the information required in § 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State, tribe, or foreign country that submitted these comments that a separate request must be submitted in accordance with §§ 112.172 and 112.173.
- (b) If we grant a petition requesting a variance, in whole or in part, we may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition.
- (c) If we specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, we will inform the applicable State, tribe, or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our Web site announcing our decision to apply the variance to similarly situated persons in that particular location.

§ 112.178 Under what circumstances may FDA deny a petition requesting a variance?

We may deny a variance request if it does not provide the information required under § 112.173 (including the requirements of § 10.30 of this chapter), or if we determine that the variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.179 When does a variance approved by FDA become effective?

A variance approved by FDA becomes effective on the date of our written decision on the petition.

§ 112.180 Under what circumstances may FDA modify or revoke an approved variance?

We may modify or revoke a variance if we determine that such variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?

- (a) We will provide the following notifications:
 - (1) We will notify a State, tribe, or a foreign country directly, in writing at the address identified in its petition, if we determine that a variance granted in response to its petition should be modified or revoked. Our direct, written notification will provide the State, tribe, or foreign country with an opportunity to request an informal hearing under part 16 of this chapter.
 - (2) We will publish a notice of our determination that a variance should be modified or revoked in the Federal Register. This notice will establish a public docket so that interested parties may submit written comments on our determination.
 - (3) When applicable, we will:
 - (i) Notify in writing any States, tribes, or foreign countries where a variance applies to similarly situated persons of our determination that the variance should be modified or revoked;
 - (ii) Provide those States, tribes, or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and

- (iii) Include in the Federal Register notice described in paragraph (a)(2) of this section public notification of our decision to modify or revoke the variance granted to States, tribes, or foreign countries in which similarly situated persons are located.
- (b) We will consider submissions from affected States, tribes, or foreign countries and from other interested parties as follows:
 - (1) We will consider requests for hearings by affected States, tribes, or foreign countries under part 16 of this chapter.
 - (i) If FDA grants a hearing, we will provide the State, tribe, or foreign country with an opportunity to make an oral submission. We will provide notice on our Web site of the hearing, including the time, date, and place of the hearing.
 - (ii) If more than one State, tribe, or foreign country requests an informal hearing under part 16 of this chapter about our determination that a particular variance should be modified or revoked, we may consolidate such requests (for example, into a single hearing).
 - (2) We will consider written submissions submitted to the public docket from interested parties.
- (c) We will provide notice of our final decision as follows:
 - (1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter.
 - (2) We will publish a notice of our decision in the Federal Register. The effective date of the decision will be the date of publication of the notice.

§ 112.182 What are the permissible types of variances that may be granted?

A variance(s) may be requested for one or more requirements in subparts A through O of this part. Examples of permissible types of variances include:

- (a) Variance from the microbial quality criteria when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, established in § 112.44(b);
- (b) Variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in § 112.45(b)(1)(i); and
- (c) Variance from the approach or frequency for testing water used for purposes that are subject to the requirements of § 112.44(b), established in § 112.46(b).

Subpart Q—Compliance and Enforcement

§ 112.192 What is the applicability and status of this part?

- (a) The failure to comply with the requirements of this part, issued under section 419 of the Federal Food, Drug, and Cosmetic Act, is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act.
- (b) The criteria and definitions in this part apply in determining whether a food is:
 - (1) Adulterated within the meaning of:
 - (i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or
 - (ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;
 - or
 - (2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

§ 112.193 What are the provisions for coordination of education and enforcement?

Under section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act, FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches.

Subpart R—Withdrawal of Qualified Exemption

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

- (a) We may withdraw your qualified exemption under § 112.5:
 - (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or
 - (2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.
- (b) Before FDA issues an order to withdraw your qualified exemption, FDA:
 - (1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction;

- (2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and
- (3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption.

§ 112.202 What procedure will FDA use to withdraw an exemption?

- (a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.
- (b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.
- (c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.
- (d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 must include the following information:

- (a) The date of the order;
- (b) The name, address and location of the farm;
- (c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:
 - (1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or
 - (2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm.
- (d) A statement that the farm must either:
 - (1) Comply with subparts B through O of this part on the date that is 120 calendar days from the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or
 - (2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.
- (e) A statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 112.213;
- (f) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act and of this subpart;
- (g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.208;
- (h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and
- (i) The name and the title of the FDA representative who approved the order.

§ 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under § 112.5 must either:

- (a) Comply with applicable requirements of this part within 120 calendar days of the date from receipt of the order or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or
- (b) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.

§ 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?

- (a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.
- (b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order:
 - (1) The owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 120 calendar days from the date of receipt of the order, or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

- (2) The owner, operator, or agent in charge of the farm is no longer subject to the modified requirements in §§ 112.6 and 112.7.

§ 112.206 What is the procedure for submitting an appeal?

- (a) To appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must:
- (1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of the order; and
 - (2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies.
- (b) In a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207.

§ 112.207 What is the procedure for requesting an informal hearing?

- (a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:
- (1) May request an informal hearing; and
 - (2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 15 calendar days of the date of receipt of the order.
- (b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial.

§ 112.208 What requirements are applicable to an informal hearing?

If the owner, operator, or agent in charge of the farm requests an informal hearing, and FDA grants the request:

- (a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.
- (b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.
- (c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:
- (1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of the opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.
 - (2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.
 - (3) Section 112.209, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.
 - (4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.
 - (5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.
 - (6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.
 - (7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (2), (3), and (5) of this chapter and 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 112.209 Who is the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 112.210 What is the timeframe for issuing a decision on an appeal?

- (a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.
- (b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing:
 - (1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or
 - (2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

- (a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or
- (b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or
- (c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.
- (d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702.

§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

- (a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that the farm has adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or at the request of a farm, reinstate the qualified exemption.
- (b) You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of this subpart as follows:
 - (1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and
 - (2) Present, in writing, data and information to demonstrate that you have adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.
- (c) If your qualified exemption was withdrawn under § 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.
- (d) If your qualified exemption was withdrawn under § 112.201(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section.

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## Appendix 3. Reserved

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No appendix material is available for Module 3: Sprout Safety Hazards





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## Appendix 4. Reserved

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No appendix material is available for Module 4: Sprout Production Environment



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# Appendix 5. Employee Health and Hygiene Practices Supplemental Information

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## A5.1 INFECTIOUS DISEASE POLICY EXAMPLE

This model Infectious Disease Policy is offered to facilitate creating a company policy. No specific format or content is required by the *Produce Safety Rule*. This example can be edited to develop an operation specific policy.

|                                                  |                    |             |
|--------------------------------------------------|--------------------|-------------|
| <b>INFECTIOUS DISEASE POLICY -EXAMPLE</b>        |                    | Page X of Y |
| <b>OPERATION NAME:</b> XXX Sprout Company        | <b>ISSUE DATE:</b> | 02/10/2017  |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA | <b>SUPERSEDES:</b> | 01/17/2017  |

XXX Sprouting Company is committed to food safety and maintains the following policy regarding employees and all visitors with infectious diseases.

1. All employees are required to notify XXX (**phone # xxx-xx-xxxx**) if diagnosed with an infectious disease such as but not limited to: *Salmonella*, *E. coli* O157:H7 or other pathogenic strains, *Giardia*, *Cryptosporidium parvum*, norovirus, hepatitis and other enteric viruses. Visitors must also notify the company if they are diagnosed with an infectious disease within a few weeks of visiting.
2. Employees or visitors who experience sudden, bloody or extreme diarrhea, vomiting, jaundice, sore throat with fever, or uncovered infected cuts or burns on hands or wrists are excluded from direct contact with food or food contact surfaces by the supervisor and may not return to those positions until the symptoms resolve or the employee or visitor is released by a physician, as appropriate to the symptoms.
3. If any product or food contact surface is accidentally contaminated with blood or other bodily fluid the supervisor is notified immediately so the product can be disposed of and affected surfaces cleaned and sanitized before re-use.

## A5.2 SANITARY PRACTICE EXAMPLES

Good sanitary practices must be applied to sprout production operations. Visitors and service personnel must follow the Visitor Policy (see next document). This example includes information that is offered to facilitate effective implementation of such a policy. The *Produce Safety Rule* does not require any specific format. This example may be used to develop an operation-specific procedure. **Details are provided for illustrative purposes and are not necessarily required by the rule.**

### Example Procedures:

- Remove earrings, watches, necklaces, bracelets or any piercings on the face, tongue or other exposed parts of the body. Plain wedding bands may be worn. No other rings are allowed.
- Hairnets (and beard guard if needed) are worn. Hairnets must cover all hair including the temple area and will be worn while working except in management offices. This includes the cooler and all storage areas.
- A lab coat or apron is worn to protect product. No tank tops or sleeveless shirts may be worn. Coats must be worn and snapped to the top to cover body hair and clothing with buttons or other objects that may come loose. Clothing with glitter is not allowed, even under a lab coat. If necessary, a lab coat will be worn under an apron. Personal items may not be kept in lab coat pockets.
- Gloves must be worn in production area. Gloves are discarded if contaminated with trash or floor contact; when switching between raw material and finished product; after handling allergens and as necessary to prevent cross-contamination. Hands/gloves are not sanitized in chlorine solutions intended for equipment washing. Gloves are discarded upon leaving the production area. Employees getting seed for soaks put on clean gloves and use sanitizer before handling seed. Gloves are discarded before re-entry into production.
- Change or cover shoes before entering the production area. Non-skid footwear is required in production areas. No sandals, thongs or clog type shoes are allowed. The company supplies non-skid rubber boots to employees. If an employee is unable to wear them, they may supply their own footwear and provide documentation that the footwear is non-skid. This footwear, along with the company supplied footwear, must be dedicated for use at this facility and may not be removed from the property.
- Visitors and contractors wear shoe covers, which are put on in the changing room, worn only in production areas and discarded in the waste basket before leaving the production area.
- Sanitize hands before opening door to production area.
- After entering the packaging room, wash hands using soap and water then put on gloves, as appropriate. Working production personnel must put on clean gloves.
- All production footwear, aprons and lab coats are removed when leaving the production area for breaks, bathroom or supplies.
- Production personnel must wash after using the bathroom, after handling garbage or pallets or picking anything up off the floor; after touching the face or hair; before work,



after break and after lunch; and as necessary to prevent contamination or cross-contamination.

- Protective clothing such as lab coats and aprons are changed/sanitized if contaminated with trash or floor contact; when switching between raw material and finished product; after handling allergens and as necessary to prevent cross-contamination. Lab coats and aprons are hung on a hook at the entrance when not being worn in the production area. Aprons other than disposable are washed in the designated area at the end of each day.
- Kleenex or handkerchief use is not allowed in the production areas.
- Band-Aids on exposed areas are blue and covered by plastic gloves or other covering.
- Workers must arrive at work clean and free of body odor. Facial hair must be covered with a beard guard.
- Workers' fingernails are trimmed and clean. No fingernail polish or false fingernails are allowed.
- There is no smoking, drinking, eating (including product) or gum chewing in packaging/growing areas or in any other common work area. This includes cough drops and candy.
- Medicines/drugs may not be taken into any production area. This includes prescription and over the counter pills, liquids, creams, etc. Drugs are securely locked in a locker if required by an employee during working hours and the Line Supervisor is notified.

**A5.3 VISITOR POLICY EXAMPLE<sup>1</sup>**

This model Visitor Policy is offered to facilitate creating a company policy. The *Produce Safety Rule* does not require any specific format or content. This example can be edited to develop an operation specific policy.

|                                                  |                    |             |
|--------------------------------------------------|--------------------|-------------|
| <b>VISITOR POLICY –EXAMPLE</b>                   |                    | Page X of Y |
| <b>OPERATION NAME:</b> XXX Sprout Company        | <b>ISSUE DATE:</b> | 02/10/2017  |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA | <b>SUPERSEDES:</b> | 01/17/2017  |

All visitors must agree to abide by Federal Regulations governing the operation.

1. Visitors must wear clean garments. Extra clothing must be left in the office and not taken into the production areas.
2. Visitors must wear aprons or lab coat before entering the production area. No personal items should be kept in them.
3. Shoes must be in good repair. Boots or shoe covers can be used as per company policy. No open toes.
4. All visitors must wash hands with soap and warm water and sanitize their hands prior to handling sprouts or entering sprout production area.
5. Visitors and service personnel also must wash hands after using the bathroom and as necessary to prevent contamination or cross-contamination.
6. All visitors must wear effective hair restraints including hairnets, beard and mustache covers where applicable.
7. All jewelry, including watches, must be removed when entering the production area.
8. No food items, drugs or medicines of any kind are permitted in the production areas. Food may only be consumed in designated eating areas or outside the building.
9. No smoking, drinking, chewing gum is allowed in the production areas. Tobacco is not permitted in the plant. Smoking is restricted to designated smoking areas.
10. No visitors infected with any infectious or communicable disease, including boils, sores, infected wounds or any other affliction which may spread disease, may be in contact with sprouts.

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<sup>1</sup> Adapted from *Rules for Plant Visitors Sample Form* of Almond Board of California

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# Appendix 6. Cleaning and Sanitizing

## Supplemental Information

### A6.1 GENERAL CHARACTERISTICS OF SOME FOOD CONTACT SURFACES

| Surface Material          | Concerns                                                                                                                                                                                | Recommendations                                                                                                                                                                                                                                            |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Aluminum                  | Readily attacked by acidic and highly alkaline cleaners.                                                                                                                                | Use only soft metal-safe, moderately alkaline cleaners                                                                                                                                                                                                     |
| Black iron or cast iron   | Acid or chlorinated detergents can cause rust. Lacks strength                                                                                                                           | Not recommended in food processing. If present in drains, use moderately alkaline cleaners.                                                                                                                                                                |
| Brass, copper, mild steel | All less corrosion resistant than stainless steel.                                                                                                                                      | Acidic cleaners encourage steel rusting; use moderately alkaline cleaners with corrosion inhibitors.                                                                                                                                                       |
| Concrete                  | Often etched by acidic products and cleaning compounds. Can crack                                                                                                                       | Concrete should be dense and acid resistant. Materials should not loosen from surface. Use alkaline cleaners.                                                                                                                                              |
| Galvanized metals         | Tend to rust leaving a white powder by-product due to zinc corrosion that could cause product adulteration.                                                                             | Avoid use as food contact surface. Should not be used with acidic foods                                                                                                                                                                                    |
| Glass                     | Strong caustic cleaning compounds can etch.                                                                                                                                             | Clean with moderately alkaline or neutral detergents.                                                                                                                                                                                                      |
| Lead                      | Solder and flux containing more than 0.2% lead may not be used as a food contact surface                                                                                                | Try to eliminate use in food processing plant.                                                                                                                                                                                                             |
| Nylon                     | Sensitive to acidic cleaners                                                                                                                                                            | Do not use acidic cleaners                                                                                                                                                                                                                                 |
| Paint and sealants        | Chemical leaching, flaking and peeling.                                                                                                                                                 | Generally, not recommended for direct contact surfaces, especially those subject to abrasion. Use only approved substances. Use moderately alkaline cleaners.                                                                                              |
| Plastics                  | Some stain easily. Some cannot be used at very low or high processing temperatures. May crack or cloud from prolonged exposure to strong acidic or alkaline cleaners; easily scratched. | More corrosion resistant than stainless steel; resistant to chlorine. Useful to color coordinate items for intended use (e.g., treated seeds vs. untreated seeds) and select plastics that will not deform or crack when exposed to processing conditions. |
| Rubber                    | Damaged by certain solvents. Deteriorates with constant chlorine use. Trimming boards can warp and their surface can dull knife blades.                                                 | Avoid porous or spongy types that hold water or food debris. Use alkaline cleaners                                                                                                                                                                         |
| Stainless steel           | Expensive, certain grades are pitted by chlorine or other oxidizers.                                                                                                                    | Best metal surfaces for food processing. Consider 300 level series. Use non-abrasive acidic and alkaline cleaners; do not use hydrochloric acid or chlorides.                                                                                              |
| Wood                      | Pervious to moisture and oils/fats. Softened by alkali and other caustics. Often difficult to clean.                                                                                    | Should not be used in food applications. Where used, clean with detergents containing surfactants. Treated woods must meet criteria for wood preservatives in 21 CFR 178.380. Limit use as food contact surface.                                           |

Adapted from National Seafood HACCP Alliance, 2000. *Sanitation Control Procedures for Processing Fish and Fishery Products*, pp. 2-8, and Ontario Ministry of Agriculture, Food and Rural Affairs, 2006.

## A6.2 TYPES OF SANITIZERS

| Sanitizer                           | Forms/<br>Description                                                                         | Advantages                                                                                                                                                                                                                                                                                                                                                                               | Disadvantages                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------|-----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chlorine                            | Hypochlorite<br>Chlorine gas<br>Organic<br>chlorine, e.g.,<br>chloramines                     | <ul style="list-style-type: none"> <li>- Kills most types of microorganisms</li> <li>- Less affected by hard water than some</li> <li>- Does not form films</li> <li>- Effective at low temperatures</li> <li>- Relatively inexpensive</li> <li>- Concentration determined by test strips</li> </ul>                                                                                     | <ul style="list-style-type: none"> <li>- May corrode metals and weaken rubber</li> <li>- Irritating to skin, eyes and throat</li> <li>- Unstable, dissipates quickly</li> <li>- Liquid chlorine loses strength in storage</li> <li>- pH sensitive</li> </ul>                                                                                       |
| Iodophors                           | Iodine<br>dissolved in<br>surfactant and<br>acid                                              | <ul style="list-style-type: none"> <li>- Kills most types of microorganisms</li> <li>- Less affected by organic matter than some</li> <li>- Less pH sensitive than chlorine</li> <li>- Concentration determined by test strips</li> <li>- Solution color indicates active sanitizer</li> </ul>                                                                                           | <ul style="list-style-type: none"> <li>- May stain plastics and porous materials</li> <li>- Inactivated above 120°F (48.9°C)</li> <li>- Reduced effectiveness at alkaline pH</li> <li>- More expensive than hypochlorites</li> <li>- May be unsuitable for CIP due to foaming</li> </ul>                                                           |
| Quaternary<br>Ammonium<br>Compounds | Benzalkonium<br>chloride and<br>related<br>compounds,<br>sometimes<br>called quats or<br>QACs | <ul style="list-style-type: none"> <li>- Non-corrosive</li> <li>- Less affected by organic matter than some</li> <li>- Residual antimicrobial activity if not rinsed</li> <li>- Can be applied as foam for visual control</li> <li>- Effective against <i>Listeria monocytogenes</i></li> <li>- Effective for odor control</li> <li>- Concentration determined by test strips</li> </ul> | <ul style="list-style-type: none"> <li>- Inactivated by most detergents</li> <li>- May be ineffective against certain organisms</li> <li>- May be inactivated by hard water</li> <li>- Effectiveness varies with formulation</li> <li>- Not as effective at low temperature as some</li> <li>- May be unsuitable for CIP due to foaming</li> </ul> |
| Acid-<br>Anionic                    | Combination of<br>certain<br>surfactants and<br>acids                                         | <ul style="list-style-type: none"> <li>- Sanitize and acid rinse in one step</li> <li>- Very stable</li> <li>- Less affected by organic matter than some</li> <li>- Can be applied at high temperature</li> <li>- Not affected by hard water</li> </ul>                                                                                                                                  | <ul style="list-style-type: none"> <li>- Effectiveness varies with microorganism</li> <li>- More expensive than some</li> <li>- pH sensitive (use below pH 3.0)</li> <li>- Corrodes some metals</li> <li>- May be unsuitable for CIP due to foaming</li> </ul>                                                                                     |
| Peroxy<br>Compounds                 | Acetic acid and<br>hydrogen<br>peroxide<br>combine to<br>form<br>peroxyacetic<br>acid         | <ul style="list-style-type: none"> <li>- Best against bacteria in biofilm</li> <li>- Kills most types of microorganisms</li> <li>- Relatively stable in use</li> <li>- Effective at low temperatures</li> <li>- Meets most discharge requirements</li> <li>- Low foaming; suitable for CIP</li> </ul>                                                                                    | <ul style="list-style-type: none"> <li>- More expensive than some</li> <li>- Inactivated by some metals/organics</li> <li>- May corrode some metals</li> <li>- Not as effective as some against yeast and molds</li> </ul>                                                                                                                         |
| <i>continued</i>                    |                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                    |

| Sanitizer                                                                                                                                      | Forms/Description                                                                                 | Advantages                                                                                                                                                                                                                                                                        | Disadvantages                                                                                                                                                                                                                                                                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Carboxylic Acid                                                                                                                                | Fatty acids combined with other acids; sometimes called fatty acid sanitizers                     | <ul style="list-style-type: none"> <li>- Kills most types of bacteria</li> <li>- Sanitize and acid rinse in one step</li> <li>- Low foaming, suitable for CIP</li> <li>- Stable in presence of organic matter</li> <li>- Less affected by hard water than some</li> </ul>         | <ul style="list-style-type: none"> <li>- Inactivated by some detergents</li> <li>- pH sensitive (use below pH 3.5)</li> <li>- Less effective than chlorine at low temperatures</li> <li>- May damage non-stainless steel materials</li> <li>- Less effective against yeasts and molds than some</li> </ul> |
| Chlorine Dioxide                                                                                                                               | A gas formed on-site and dissolved in solution or by acidification of chlorite and chlorate salts | <ul style="list-style-type: none"> <li>- Kills most types of microorganisms</li> <li>- Stronger oxidizer (sanitizer) than chlorine</li> <li>- Less affected by organic matter than some</li> <li>- Less corrosive than chlorine</li> <li>- Less pH sensitive than some</li> </ul> | <ul style="list-style-type: none"> <li>- Unstable and cannot be stored</li> <li>- Potentially explosive and toxic</li> <li>- Relatively high initial equipment cost</li> </ul>                                                                                                                             |
| Ozone                                                                                                                                          | A gas formed on-site and dissolved in solution                                                    | <ul style="list-style-type: none"> <li>- Kills most types of microorganisms</li> <li>- Stronger oxidizer (sanitizer) than chlorine and chlorine dioxide</li> </ul>                                                                                                                | <ul style="list-style-type: none"> <li>- Unstable and cannot be stored</li> <li>- May corrode metals and weaken rubber</li> <li>- Potentially toxic</li> <li>- Inactivated by organic matter (similar to chlorine) pH sensitive</li> <li>- More expensive than most</li> </ul>                             |
| Hot Water/Heated Solutions                                                                                                                     | Water at 170 – 190°F (76.7 –87.8°C)                                                               | <ul style="list-style-type: none"> <li>- Kills most types of microorganisms</li> <li>- Penetrates irregular surfaces</li> <li>- Suitable for CIP</li> <li>- Relatively inexpensive</li> </ul>                                                                                     | <ul style="list-style-type: none"> <li>- May form films or scale on equipment</li> <li>- Burn hazard</li> <li>- Contact time sensitive; inappropriate for general sanitation</li> </ul>                                                                                                                    |
| From National Seafood HACCP Alliance, 2000. <i>Sanitation Control Procedures for Processing Fish and Fishery Products</i> , pp. 2-22 and 2-23. |                                                                                                   |                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                            |

### A6.3 SANITATION STANDARD OPERATING PROCEDURES (SSOP) - EXAMPLE

This model is offered to facilitate creating a company specific SSOP. The *Produce Safety Rule* does not require any specific format. This example can be edited to develop an operation specific SSOP.

|                                                  |                                                         |                               |
|--------------------------------------------------|---------------------------------------------------------|-------------------------------|
| <b>SOP# XYZ</b>                                  | <b>Cleaning and Sanitizing of Food Contact Surfaces</b> | Page X of Y                   |
| <b>OPERATION NAME:</b> XXX Sprout Company        |                                                         | <b>ISSUE DATE:</b> 02/10/2017 |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA |                                                         | <b>SUPERSEDES:</b> 01/17/2017 |

**Purpose:** An effective sanitation program prevents the contamination or re-contamination of sprouts, which may impact the quality, safety and shelf life.

**Frequency:** Before the beginning of every operation, after the end of production cycle of each types of sprout, and at the end of daily overall production.

**Who:** Sanitation team member

**Cleaning and Sanitizing Procedure:**

1. Remove/cover food items, sensitive electrical equipment/ motor and packaging materials to prepare the area.
2. Remove items on the surface to be cleaned.
3. Disassemble, if needed to facilitate cleaning.
4. Pre-rinse the equipment with warm potable<sup>1</sup> water from top down.
5. Foam and scrub the equipment with XYZ<sup>2</sup> cleaner and scrub using dedicated food contact surface brushes (blue).
6. Rinse the equipment, floors and drains thoroughly with potable water using a low-pressure hose.
7. Remove excess water from floors.
8. Sanitize the equipment.

**Monitoring and Verification:**

- Inspect all food contact surfaces for residual material. Record any findings on Cleaning and Sanitizing Log Sheet.
- Use test strips to confirm appropriate sanitizer concentration BEFORE each application. Record concentration on Cleaning and Sanitizing Log Sheet
- Conduct ATP test and record on Cleaning and Sanitizing Log Sheet.<sup>3</sup>

**Corrective Actions:**

- If residual material is observed on any food contact surface, re-clean and sanitize.
- If ATP results exceed standard values, repeat the cleaning and sanitation procedures.
- Replace any equipment that cannot be reliably cleaned and sanitized.

**Records:**

- Cleaning and Sanitizing Log Sheet (*see example in A6.5*)
- ATP Verification Record

**Verification:** Supervisor reviews and signs records.

---

<sup>1</sup> This hypothetical facility uses city water, which meets agricultural water standard. They use the term “potable” in this procedure to facilitate communication with their workers.

<sup>2</sup> A sprouter should enter the name of the cleaner and a reference to the appropriate concentration to use.

<sup>3</sup> ATP testing is an optional verification activity performed by this hypothetical company.



**A6.4 CLEANING AND SANITATION SELF-ASSESSMENT – EXAMPLE**

|                                                                                                                                                                                                                                    |                                                      |                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|----------------------------|
| <b>XXX Sprout Company Name</b>                                                                                                                                                                                                     |                                                      |                            |
| <b>123 Sprouter Road, Yourtown USA</b>                                                                                                                                                                                             |                                                      |                            |
| <b>Date/Time</b>                                                                                                                                                                                                                   |                                                      |                            |
| <b>Cleaning and Sanitation Assessment</b><br><small>(5 = full compliance; 1 = non-compliance; N/A = not applicable)</small>                                                                                                        | <b>Rating</b><br><small>(5, 4, 3, 2, 1, N/A)</small> | <b>Comments</b>            |
| SSOPs are in place to identify areas, equipment and utensils to be cleaned, the frequency of cleaning, the procedures and chemicals to be used, those responsible, the procedure to verify effectiveness and the records required. |                                                      |                            |
| Cleanliness is evident throughout the facility in both production and non-production areas.                                                                                                                                        |                                                      |                            |
| Food contact surfaces are clean.                                                                                                                                                                                                   |                                                      |                            |
| There are no buildups or accumulations of food products or soil.                                                                                                                                                                   |                                                      |                            |
| Spills are cleaned up promptly and floors are free of standing water.                                                                                                                                                              |                                                      |                            |
| Utensils used during processing are cleaned and sanitized regularly.                                                                                                                                                               |                                                      |                            |
| Hoses are neatly stored off the floor.                                                                                                                                                                                             |                                                      |                            |
| No cleaning practices are observed during operations that could potentially cause product contamination. For example, food and packaging are protected from contamination during cleanup.                                          |                                                      |                            |
| Water and air pressure is used in a way that does not create water droplets or aerosols that could potentially contaminate food, packaging or food contact surfaces.                                                               |                                                      |                            |
| Cleaning/sanitizing containers, brushes, applicators, etc. are labelled or color-coded to prevent inadvertent use in unintended areas where there is potential for cross-contamination.                                            |                                                      |                            |
| There is evidence that materials/systems for checking sanitizer concentration levels are in place and used at appropriate intervals.                                                                                               |                                                      |                            |
| Overall good housekeeping practices are observed.                                                                                                                                                                                  |                                                      |                            |
| <b>Pre-operational Assessment</b>                                                                                                                                                                                                  |                                                      |                            |
| A designated individual(s) other than the individual(s) who performed the cleaning/sanitizing operations routinely performs a sanitation assessment before operations begin or resume.                                             |                                                      |                            |
| Operations do not start until sanitation standards meet SSOP requirements.                                                                                                                                                         |                                                      |                            |
| <b>Possible Points</b>                                                                                                                                                                                                             | 70                                                   | <b>Additional Comments</b> |
| <b>Actual Points</b>                                                                                                                                                                                                               |                                                      |                            |
| <b>Percentage (%)</b>                                                                                                                                                                                                              |                                                      |                            |

**Operator's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
**Reviewer's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Form Effective date: 3/27/2017  
 Supersedes: 11/20/2016

**A6.5 CLEANING AND SANITIZING LOG SHEET – EXAMPLE**

|                                                                                                                                                                                                                                                                                  |                     |                    |                          |                      |                                     |                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------------|----------------------|-------------------------------------|--------------------------|
| <b>XXX Sprout Company Name</b>                                                                                                                                                                                                                                                   |                     |                    |                          |                      |                                     |                          |
| <b>123 Sprouter Road, Yourtown USA</b>                                                                                                                                                                                                                                           |                     |                    |                          |                      |                                     |                          |
| <b>Area Cleaned</b>                                                                                                                                                                                                                                                              |                     |                    |                          |                      |                                     |                          |
| <b>Date</b>                                                                                                                                                                                                                                                                      |                     |                    |                          |                      |                                     |                          |
|                                                                                                                                                                                                                                                                                  | <b>Pre-Op Time:</b> | <b>Start Time:</b> | <b>Lunch Break Time:</b> | <b>Post-Op Time:</b> | <b>Comments/ Corrective Actions</b> | <b>Operator Initials</b> |
| <b>Sanitation Area and Goal</b>                                                                                                                                                                                                                                                  |                     |                    |                          |                      |                                     |                          |
| <b>SSOP XYZ: Condition &amp; Cleanliness of Food Contact Surfaces</b><br><ul style="list-style-type: none"> <li>• Equipment cleaned and sanitized (S/U) *</li> <li>• Sanitizer type: _____</li> <li>• Sanitizer concentration<sup>†</sup>: _____</li> </ul>                      |                     |                    |                          |                      |                                     |                          |
| <b>SSOP ABC: Condition &amp; Cleanliness of Non-food Contact Surfaces</b><br><ul style="list-style-type: none"> <li>• Floors and wall splash zones cleaned and sanitized (S/U)</li> <li>• Sanitizer type: _____</li> <li>• Sanitizer concentration<sup>†</sup>: _____</li> </ul> |                     |                    |                          |                      |                                     |                          |
| * S = Satisfactory, U = Unsatisfactory                                                                                                                                                                                                                                           |                     |                    |                          |                      |                                     |                          |
| † Enter ppm measured per test strip                                                                                                                                                                                                                                              |                     |                    |                          |                      |                                     |                          |
| Reviewer signature:                                                                                                                                                                                                                                                              |                     |                    |                          | Date:                |                                     |                          |

Form Effective date: 3/27/2017  
Supersedes: 11/20/2016

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# Appendix 7. Environmental Monitoring for *Listeria* spp. or *L. monocytogenes* in a Sprout Operation

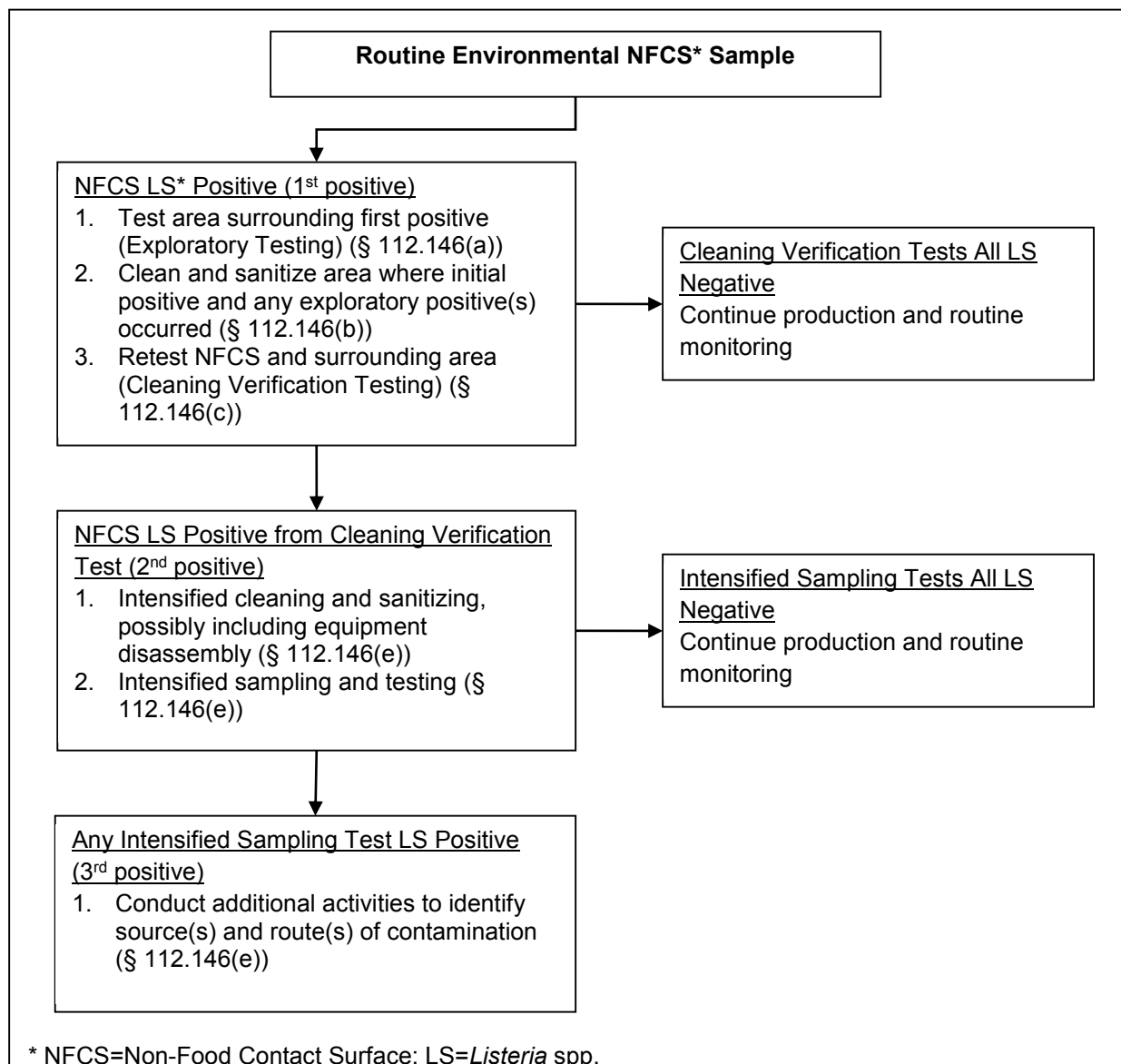
---

## A7.1 ASEPTIC PROCEDURE FOR SAMPLING

Aseptic procedures are critical to avoid contaminating the sample during sample collection, storing the sample(s), and transporting the sample(s) to the lab and are required for collecting environmental samples (§112.145(d) and for sampling spent irrigation water or sprouts (§112.147(b)). Aseptic sampling procedures, as described below, should be part of a firm's plan for sample collection.

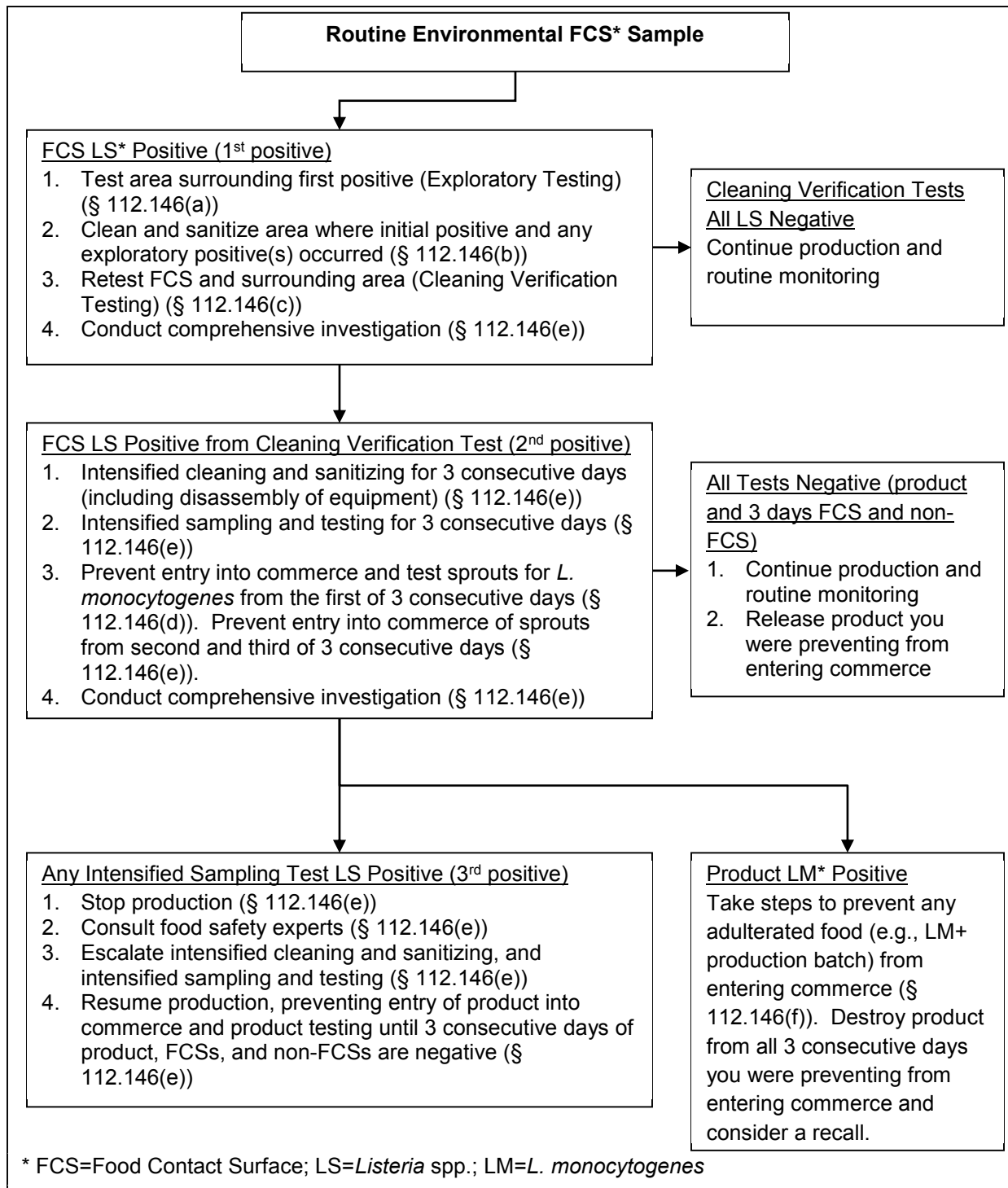
- Equipment used to collect samples should be clean and sterile. Sampling tools and sample containers may be purchased pre-sterilized. Alternatively, tools and containers may be sterilized at 121°C (250°F) for 30 minutes in an autoclave prior to use. Heat-resistant, dry materials may be sterilized in a dry-heat oven at 140°C (284°F) for 3 hours.
- The type of sample containers used depends on the type of samples collected but may include pre-sterilized plastic bags, tubes, cups and flasks. Containers should be dry, leak-proof, wide mouthed and of a size suitable for the samples. Sample containers should be properly labeled prior to starting sample collection.
- Sample collectors should wear a clean lab coat, single-use gloves and a hair net to ensure they do not contaminate the samples. Hands should be washed immediately before sampling, and prior to putting on gloves. Gloves should be put on in a manner that does not contaminate the outside of the glove. Gloves should be properly disposed of after use.
- Hands should be kept away from mouth, nose, eyes and face while collecting samples.
- Sampling instruments should be protected from contamination at all times before and during use. Sampling instruments and samples moving between the sampling site and the sample container should not be passed over the remaining pre-sterilized instruments.
- The sterile sample container should be opened only sufficiently to admit the sample, place the sample directly in the container, then immediately closed and sealed. If collecting samples in a container with a lid, the lid should be held in a hand and not be placed on a counter.
- The sample container should be filled no more than ¾ full to prevent overflow. Samples or sampling equipment should not be exposed to unfiltered air currents.
- Samples should be delivered to the laboratory promptly. Perishable material should be kept at an appropriate temperature, preferably at 0 to 4.4°C (32 to 40°F). Sealed coolant packs should be used to avoid contamination from melting ice.

**A7.2 NON-FOOD CONTACT SURFACE TESTING AND FOLLOW-UP ACTIVITIES FOR ZONE 2 – EXAMPLE**



Source: FDA, 2017. *Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry.*

**A7.3 FOOD CONTACT SURFACE TESTING AND FOLLOW-UP ACTIONS FOR ZONE 1 – EXAMPLE**



Source: FDA, 2017. *Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry.*

#### A7.4 ENVIRONMENTAL MONITORING FOR *Listeria* SPP. - EXAMPLE

Examples are offered to facilitate creating a company specific Sampling Plan. The *Produce Safety Rule* does not require any specific format. Examples should be edited to develop an operation specific Plan.

|                                                  |                                                          |                               |
|--------------------------------------------------|----------------------------------------------------------|-------------------------------|
| <b>SOP# WXY</b>                                  | <b>Environmental Monitoring for <i>Listeria</i> spp.</b> | Page 1 of 5                   |
| <b>OPERATION NAME:</b> XXX Sprout Company        |                                                          | <b>ISSUE DATE:</b> 03/22/2017 |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA |                                                          | <b>SUPERSEDES:</b> 02/17/2017 |

##### Objectives

- Testing for presence of *Listeria* spp. within the production environment
- Tracking the monitoring data to identify trend of *Listeria* contamination in the production environment if the microorganism is found
- Taking appropriate corrective actions in response to positive sample findings to eliminate *Listeria* from its harborage sites
- Meeting regulatory requirements (§112.145 and §112.150(b)(2))

##### Responsible Person

- Safety manager or trained Food Safety Team responsible for supervising, conducting or verifying sampling and testing procedures, associated documents, and training new operators

##### Materials Needed

- Sampling kit (including labeled sterile sample bags; sterile sponges or swabs; and neutralizing broth)
- Disposable gloves
- Cooler with ice packs
- Clean working surface
- Blank sample submission forms

##### Sampling Time

- Must perform environmental sampling *during* production (e.g. 3-4 hours into production)
- During routine sampling, DO NOT perform environmental sampling after the environment has been cleaned and sanitized.

##### Sampling Procedure

Follow aseptic techniques for collecting environmental monitoring samples:

- Wear clean clothing, new gloves and a hair net so as to not contaminate the samples.
- Wash hands immediately before sampling and prior to putting on new gloves.
- Keep hands away from mouth, nose, eyes and face while collecting samples. Try not to cough or sneeze into the samples.
- Protect sampling instruments from contamination before and during use.
- Open the sterile sample container (e.g. a sterile Whirl-Pak bag) only immediately before collecting a sample, and close and seal immediately after collecting the sample.



|                                                  |                                                          |                               |
|--------------------------------------------------|----------------------------------------------------------|-------------------------------|
| <b>SOP# WXY</b>                                  | <b>Environmental Monitoring for <i>Listeria</i> spp.</b> | Page 2 of 5                   |
| <b>OPERATION NAME:</b> XXX Sprout Company        |                                                          | <b>ISSUE DATE:</b> 03/24/2017 |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA |                                                          | <b>SUPERSEDES:</b> 02/17/2017 |

**Sampling Protocols**

A sampling kit recommended by a qualified testing lab should be used. Manufacturer’s instructions of the sampling kit should be followed. The following is an example protocol.

*Environmental Sampling Using a Prehydrated Swab (EXAMPLE)*

Swabs are pre-hydrated with a D/E neutralizing broth. These swabs should be used for sampling of small areas that cannot be accessed any other way. Examples include a hole in the floor, cracks or insides of tubular equipment mounts.

- a) Loosen cap of swab tube and remove the swab. Do not touch any portion of the swab except the cap.
- b) Collect an environmental sample by using even, firm pressure to glide the swab 10 times vertically, 10 times horizontally and 10 times diagonally over the designated sample area.
- c) Each time you change the swabbing direction, re-insert the tip of the swab into the tube and broth to rehydrate. If visible soil or residue is present, vigorously rub the swab over the designated area until the soil or residue is removed.
- d) Return the swab to its tube.
- e) Close the tube tightly and place it in a labeled sample bag that identifies each specific sample collected (e.g., sampling location, sample number and date/time of sample collection). Place the samples in the cooler with ice packs to keep samples cold but not frozen.
- f) Fill out a sample submission form.
- g) Submit the samples to the laboratory ASAP, no later than 24 hours from the time of collection.

|                                                  |                                                          |                               |
|--------------------------------------------------|----------------------------------------------------------|-------------------------------|
| <b>SOP# WXY</b>                                  | <b>Environmental Monitoring for <i>Listeria</i> spp.</b> | Page 3 of 5                   |
| <b>OPERATION NAME:</b> XXX Sprout Company        |                                                          | <b>ISSUE DATE:</b> 03/24/2017 |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA |                                                          | <b>SUPERSEDES:</b> 02/17/2017 |

### Sampling Frequency

- Monthly - the maximum acceptable time between sampling and should be used only for operations with a robust monitoring program showing control of *Listeria* over time.
- More frequently - When starting an operation and trying to establish an environmental monitoring profile, until monitoring shows no *Listeria* (+) result.
- Upon finding a positive result, frequent cleaning and re-testing until eliminated.
- An example of monthly sampling site rotation schedule is listed below.

| Date    | Sample Group    |
|---------|-----------------|
| Date 1  | A               |
| Date 2  | B               |
| Date 3  | C               |
| Date 4  | D               |
| Date 5  | E               |
| Date 6  | F               |
| Date 7  | G               |
| Date 8  | H               |
| Date 9  | I               |
| Date 10 | J               |
| Date 11 | K               |
| Date 12 | L               |
| Etc.    | Repeat sequence |

|                                                  |                                                          |                               |
|--------------------------------------------------|----------------------------------------------------------|-------------------------------|
| <b>SOP# WXY</b>                                  | <b>Environmental Monitoring for <i>Listeria</i> spp.</b> | Page 4 of 5                   |
| <b>OPERATION NAME:</b> XXX Sprout Company        |                                                          | <b>ISSUE DATE:</b> 03/24/2017 |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA |                                                          | <b>SUPERSEDES:</b> 02/17/2017 |

**Sampling Locations**

*(Some possible sampling sites are listed here. Note: The zone identification here is an example ONLY. Actual zones should be defined based on your sprout operation.)*

| Sample Group | Sample # | Zone | Sampling Locations              | Sample Group | Sample # | Zone | Sampling Locations             |
|--------------|----------|------|---------------------------------|--------------|----------|------|--------------------------------|
| Group A      | 1        | 1    | Work table-a                    | Group G      | 1        | 1    | Irrigation sprinkler nozzles-c |
|              | 2        | 1    | Sprout washing tub interior -a  |              | 2        | 1    | Reusable apron on worker -b    |
|              | 3        | 1    | Growing surface -a              |              | 3        | 1    | Spin dryer interior -c         |
|              | 4        | 1    | Spin Dryer Interior -a          |              | 4        | 1    | Sprout harvest container -b    |
|              | 5        | 2    | Transportation racks -a         |              | 5        | 2    | Ceiling in growing room -b     |
|              | 6        | 2    | Floor drain in grow room -a     |              | 6        | 4    | Floor in break room            |
| Group B      | 1        | 1    | Sprout conveyor belt -a         | Group H      | 1        | 1    | Work table-d                   |
|              | 2        | 1    | Sprout transportation tub -a    |              | 2        | 1    | Sprout transportation tub -b   |
|              | 3        | 1    | Irrigation sprinkler nozzles -a |              | 3        | 1    | Growing surface g              |
|              | 4        | 1    | Growing surface -b              |              | 4        | 1    | Sprout conveyor belt -d        |
|              | 5        | 2    | Ceiling in growing room -a      |              | 5        | 1    | Reusable apron on worker -c    |
|              | 6        | 2    | Floor drain in grow room -b     |              | 6        | 2    | Work table legs                |
| Group C      | 1        | 1    | Work table-b                    | Group I      | 1        | 1    | Growing surface h              |
|              | 2        | 1    | Growing surface -c              |              | 2        | 1    | Irrigation sprinkler nozzles-d |
|              | 3        | 2    | Sprout Conveyor frame -a        |              | 3        | 1    | Spin Dryer interior -d         |
|              | 4        | 1    | Reusable apron on worker -a     |              | 4        | 1    | Sprout washing tub interior -c |
|              | 5        | 2    | Sprout washing tub exterior -a  |              | 5        | 3    | Cooler condensate drip pan     |
|              | 6        | 2    | Floor drain in grow room -c     |              | 6        | 4    | Floor in changing area         |
| Group D      | 1        | 1    | Growing surface -d              | Group J      | 1        | 1    | Work table-e                   |
|              | 2        | 1    | Irrigation sprinkler nozzles -b |              | 2        | 2    | Spin Dryer exterior            |
|              | 3        | 1    | Sprout conveyor belt -b         |              | 3        | 2    | Floor drain in packaging room  |
|              | 4        | 2    | Wall behind grow equipment      |              | 4        | 2    | Sink in production room        |
|              | 5        | 3    | Floor leading to production     |              | 5        | 3    | Wall in packaging room         |
|              | 6        | 3    | Floor drain in cooler -a        |              | 6        | 3    | Floor in packaging room        |
| Group E      | 1        | 1    | Work table-c                    | Group K      | 1        | 1    | Sprout transportation tub -c   |
|              | 2        | 1    | Growing surface -e              |              | 2        | 1    | Cleanup hose nozzle -b         |
|              | 3        | 1    | Sprout harvest container -a     |              | 3        | 1    | Irrigation sprinkler nozzles-e |
|              | 4        | 1    | Spin Dryer interior -b          |              | 4        | 1    | Spin Dryer interior -e         |
|              | 5        | 2    | Floor drain in grow room -d     |              | 5        | 4    | Employee break room            |
|              | 6        | 3    | Floor in seed storage area      |              | 6        | 4    | Floor in changing area         |
| Group F      | 1        | 1    | Growing surface -f              | Group L      | 1        | 1    | Work table-f                   |
|              | 2        | 1    | Sprout conveyor belt -c         |              | 2        | 1    | Growing surface -i             |
|              | 3        | 1    | Cleanup hose nozzle -a          |              | 3        | 1    | Sprout conveyor belt -e        |
|              | 4        | 1    | Sprout washing tub interior -b  |              | 4        | 1    | Sprout harvest container -c    |
|              | 5        | 3    | Floor in cooler walk area       |              | 5        | 4    | Sink in break/bathroom         |

|                                                  |                                                          |                    |            |
|--------------------------------------------------|----------------------------------------------------------|--------------------|------------|
| <b>SOP# WXY</b>                                  | <b>Environmental Monitoring for <i>Listeria</i> spp.</b> | Page 5 of 5        |            |
| <b>OPERATION NAME:</b> XXX Sprout Company        |                                                          | <b>ISSUE DATE:</b> | 03/24/2017 |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA |                                                          | <b>SUPERSEDES:</b> | 02/17/2017 |

**Records**

See Appendix 12: Recordkeeping for a corrective action record example

*Sampling and testing record sheet (Can be used as a template.)*

| <b>XXX Sprout Company Name</b>            |                   |                                         |               |                               |                                          |             |
|-------------------------------------------|-------------------|-----------------------------------------|---------------|-------------------------------|------------------------------------------|-------------|
| <b>123 Sprouter Road, Yourtown USA</b>    |                   |                                         |               |                               |                                          |             |
| <b>Testing Laboratory Name</b>            |                   | 123 Testing Company                     |               |                               |                                          |             |
| <b>Address</b>                            |                   | 456 Analytical Lane, Nexttown USA 23456 |               |                               |                                          |             |
| <b>Phone and Fax</b>                      |                   | XXX-XXX-XXXX                            |               |                               |                                          |             |
| <b>E-mail</b>                             |                   | 123Test@xxx.com                         |               |                               |                                          |             |
| <b>Primary Contact Person</b>             |                   | Bugs Hunter                             |               |                               |                                          |             |
| <b>Environmental Monitoring Test Form</b> |                   |                                         |               |                               |                                          |             |
| <b>Swabbed by</b>                         |                   |                                         |               |                               |                                          |             |
| <b>Date of Sampling</b>                   |                   |                                         |               |                               |                                          |             |
| <b>Date of Sample Submission</b>          |                   |                                         |               |                               |                                          |             |
| Sample Number                             | Sampling Location |                                         | Swab Kit Used | Surface Type*<br>(circle one) | Test for<br>(circle one)                 | Test Result |
|                                           | General Location  | Specific Location                       |               |                               |                                          |             |
| A-1                                       |                   |                                         |               | FC NFC                        | <i>Listeria</i> spp.<br><i>/L. mono.</i> |             |
| A-2                                       |                   |                                         |               | FC NFC                        | <i>Listeria</i> spp.<br><i>/L. mono.</i> |             |
| A-3                                       |                   |                                         |               | FC NFC                        | <i>Listeria</i> spp.<br><i>/L. mono.</i> |             |
| A-4                                       |                   |                                         |               | FC NFC                        | <i>Listeria</i> spp.<br><i>/L. mono.</i> |             |
| A-5                                       |                   |                                         |               | FC NFC                        | <i>Listeria</i> spp.<br><i>/L. mono.</i> |             |
| A-6                                       |                   |                                         |               | FC NFC                        | <i>Listeria</i> spp.<br><i>/L. mono.</i> |             |

\*FC - Food Contact Surface, NFC – Non-food Contact Surface

**(Attach ALL testing results from the lab prior to filing)**

**Reviewer’s Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Form Effective date: 3/24/2017  
Supersedes: 11/20/2016

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# Appendix 8. Seed Purchasing, Receiving and Storage Supplemental Information

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## A8.1 EXAMPLE QUESTIONS FOR SEED GROWERS

1. Are the seeds grown only on a well-drained field? Are you aware of any improperly designed or malfunctioning septic systems and sewage treatment facility discharge?
2. Are seeds grown in the fields away from animal activities?
3. Do feedlots, animal pastures, and dairy operations in the region use fences or other barriers to minimize animal access to shared water sources?
4. Are controls generally in place to minimize contamination of agricultural waters from other farm or animal operations?
5. Do you test the irrigation water on a periodic basis? Are testing results available?
6. Have the seed fields been treated with raw manure? If so, has sufficient time passed between application of manure and harvest of the seeds?
7. Are measures in place to exclude domestic animals from the seed fields during growing season?
8. Is any unapproved chemical and/or fertilizer used in the seed field?
9. Are personal health and hygiene training programs for your employees and visitors implemented?
10. Are the harvest/packing equipment and containers cleaned and sanitized between uses?
11. Are the storage facilities cleaned prior to harvest season?
12. Is a chemical drying agent used for desiccating harvested crop?
13. Is the harvest equipment adjusted to minimize soil uptake during harvesting? Do you notice any mechanical damage on the seeds by harvest equipment?
14. Has a pest control/inspection system been established in all of your facilities in which seed for sprouting is held, stored, or conditioned?
15. Are trucks or transport cartons inspected for cleanliness and free from odors, obvious dirt or debris before beginning the loading process?
16. Are the seed bags protected from weather during storage and shipping?
17. Are the records of the seeds planted and harvested available? Is there an effective seed tracing system including field and date of harvest; farm identification; and who handled the seeds from grower to receiver?

## A8.2 EXAMPLE QUESTIONS FOR SEED SUPPLIERS

1. Do you purchase your seeds from a grower following GAPs? Do you request the GAPs status documentation from the grower?
2. For any imported seed, do you know the precise origin of where the seed was grown?
3. Can you provide the documentation of good handling practices and sanitation procedures for the seed conditioning facility: either copies of programs or a copy of 3<sup>rd</sup> party or government food safety audit and score? If so, please list the total possible audit score on and the score achieved in the most recent audit.
4. *If relevant:* Have the seeds been scarified through an intentional scarification process? What was the purpose of scarification? Could you provide the scarification procedure that you used?
5. Do you have a trace-back record for each bag/lot of seed? Do you perform at least one mock recall annually?
6. If you condition seeds in your facility, do you follow a regular, documented program to clean and sanitize the seed conditioning equipment between lots?
7. Do you sample every bag in each lot of seed you sell for possible microbial contamination? If so, what is it tested for? *E. coli* O157:H7 and *Salmonella*? Non-O157 STECs? *Listeria*? Are the test results available?
8. Do you perform a risk reduction step (such as irradiation, heat, high pressure, etc.) on your seeds before selling them to a sprout producer? Do you do the microbiological seed test before the procedure? If so, do you divert the seed from sale to sprouters if it tests positive?
9. Are the trucks inspected for cleanliness prior to transporting seed bags?
10. Do you keep temperature and humidity records for seed storage?



### A8.3 EXAMPLE CHECKLISTS FOR SEED RECEIVING AND SAMPLING

#### *QA/Receiver Checklist:*

- ✓ Notify QA that seed has arrived
- ✓ Get paperwork from Receiving Board
- ✓ Fill out Incoming Materials Log
- ✓ QA and Receiver inspect truck
- ✓ Make sure seed is protected before removing from the truck
- ✓ Check seed and photograph issues
- ✓ Note issues on Bill of Lading: which seed and how many bags are affected by problems
- ✓ Break down pallets, if necessary, to count damage
- ✓ Delivery driver signs record of issues
- ✓ Verify lot number on seed tag matches COA
- ✓ Complete Seed Receiving Log
- ✓ QA tags seed with Hold notice
- ✓ QA segregates and tags damaged seed with Hold notice
- ✓ QA completes Hold Log

#### *Sampler Checklist:*

- ✓ Wash/sanitize hands and equipment, as necessary, to prevent contamination
- ✓ Review receiving paperwork
- ✓ Assign your company's Lot #, if necessary
- ✓ Black light at least the top layer of bags on each pallet
- ✓ Print one label and place on storage bucket
- ✓ Sift one bag of seed into labeled storage bucket (NOTE: sift more than one if issues are noted)
- ✓ If ok, print rest of labels and label collection bucket
- ✓ Collect seed
- ✓ Place hold tag or quarantine tape on each lot of seed
- ✓ Complete paperwork
- ✓ Put pallets of seed in appropriate area and cover with plastic

### A8.4 EXAMPLE PATHOGEN TESTING USING A SEED SPROUTING PROCEDURE

- Collect at least 6 lbs. of seed from each seed lot.
- If the seed lot is 100 lbs. or less, take multiple samples from each bag to total 1 lb.

#### Protocol

1. Using a seed sampling tool (commonly called a “trier”) collect sufficient amount of seed samples from each seed bag to total sample size of at least 6 lbs.
2. Put the seed in a designated bucket, one sample lot per bucket (large lot may require more than one bucket – or you may wish to divide lot into sub samples to test each sub sample separately).
3. Fill the bucket(s) with room temperature water and soak for several hours to initiate seed germination.
4. Drain the soak water and rinse again with room temperature water and drain. Allow the seed to grow for 48 hours while rinsing and draining 2 or 3 times;
5. After 48 hours, collect 2L of the water in a cleaned and sanitized container as you drain the bucket. Keep the water collected from this product isolated from all crops and seeds.
6. Divide the water into two 1L Whirl-pak™ bags for duplicate lab testing)
7. Submit the duplicate water samples to be tested for pathogens of concern.

## A8.5 EXAMPLE SEED RECEIVING LOG SHEET

This example is offered to facilitate creating a company specific form. The *Produce Safety Rule* does not require any specific format. This example can be edited to develop an operation specific.

|                                                                                                              |                    |                              |
|--------------------------------------------------------------------------------------------------------------|--------------------|------------------------------|
| <b>XXX Sprout Company Name</b>                                                                               |                    |                              |
| <b>123 Sprouter Road, Yourtown USA</b>                                                                       |                    |                              |
| <b>Seed Receiving Log</b>                                                                                    |                    |                              |
| <b>Supplier Name</b>                                                                                         |                    |                              |
| <b>Order Date</b>                                                                                            |                    |                              |
| <b>Arrival Date</b>                                                                                          |                    |                              |
| <b>QA/Receiving (Visual Inspection)</b>                                                                      | <b>Observation</b> | <b>Operator Initial/Date</b> |
| Number of torn or dirty bags                                                                                 |                    |                              |
| Any evidence of insects or rodents                                                                           |                    |                              |
| Are bags labeled with seed type, weight and lot number?                                                      |                    |                              |
| Do lot numbers on bags match COA's?                                                                          |                    |                              |
| <b>Seed Sampling</b>                                                                                         |                    |                              |
| Physical contaminant Inspection                                                                              |                    |                              |
| Black-light results                                                                                          |                    |                              |
| Sifting results                                                                                              |                    |                              |
| <i>Complete information below for each lot received. Use additional sheet for more than 3 lots/shipment.</i> |                    |                              |
| Supplier Lot No.                                                                                             |                    |                              |
| Our Lot No.                                                                                                  |                    |                              |
| Seed                                                                                                         |                    |                              |
| Weight                                                                                                       |                    |                              |
| Bag count                                                                                                    |                    |                              |
| Origin                                                                                                       |                    |                              |
| Sampling weight                                                                                              |                    |                              |
| Sampling date                                                                                                |                    |                              |
| Date started                                                                                                 |                    |                              |
| Lab results                                                                                                  |                    |                              |
| <b>Reviewer's Signature</b>                                                                                  | <b>Date</b>        |                              |

Form Effective date: 3/27/2017  
Supersedes: 11/20/2016

Notes:

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# Appendix 9. Seed Treatment Supplemental Information

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## A9.1 SEED TREATMENT METHOD (STANDARD OPERATING PROCEDURE EXAMPLE)

This model is offered to facilitate creating a company specific SOP. The *Produce Safety Rule* does not require any specific format. This example can be edited to develop an operation specific SOP.

|                                                  |                                                              |                               |
|--------------------------------------------------|--------------------------------------------------------------|-------------------------------|
| <b>SOP# XYZ</b>                                  | <b>Seed Treatment Method for Alfalfa Sprouts<sup>1</sup></b> | Page X of Y                   |
| <b>OPERATION NAME:</b> XXX Sprout Company        |                                                              | <b>ISSUE DATE:</b> 03/03/2017 |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA |                                                              | <b>SUPERSEDES:</b> 02/17/2017 |

### Objectives

- Reduce pathogen levels that may be present on seed
- Reduce the risk of seed being a source of contamination in the sprouting process
- Meeting the regulatory requirements (§112.142(e) and 112.150(b)(1))

### Responsible Party

- Production manager responsibilities include supervising, conducting or verifying seed treatment procedure, and training new employees

### Materials Needed

- Personal protective equipment (see PPE listing below)
- Seed treatment process materials [specific names]
- Potable<sup>2</sup> city water (certificate on file) or agricultural water
- Adequate location to perform process
- Container to hold seeds
- List of tools required to perform procedure

### Personal Protective Equipment (PPE) required for process (for chemical example, see below)

- Coveralls over long-sleeved shirt and long pants
- Waterproof gloves
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant headgear for overhead exposure
- Chemical-resistant apron
- Dust/mist filtering respirator (MSHA/NIOSH-D/M approval # prefix TC-21C)

### Chemical Handling

- Seed is treated in the designated seed treatment room
- All handlers must:
  - Read and understand Safety Data Sheets (SDS) of the chemicals
  - Wear proper PPE for procedure

<sup>1</sup> This alfalfa example may not be appropriate for other types of sprouts

<sup>2</sup> This hypothetical facility uses city water, which meets agricultural water standard. They use the term “potable” in this procedure to facilitate communication with their workers.

- Carefully follow manufacturer's instructions to prepare, use and dispose of any chemicals
- Store the chemicals in a designated chemical storage area away from sprout production

### Seed Treatment Protocol

#### 1. Seed pre-wash (if required by process)

- a. Choose a container large enough to allow thorough mixing without splashing
- b. Label the containers with seed lot # and treatment time if more than one seed lot are being treated consecutively
- c. Clean and sanitize the container(s) and tools
- d. Pour seeds from a seed receptacle into a clean container that contains a large volume of agricultural water
- e. Stir or agitate the seed/water mixture to ensure all seeds are wetted
- f. Add surfactant or other cleaning agent and Stir or agitate the seed/water mixture for at least [X] minutes
- g. Skim damaged seed and debris that float to the surface with a sanitary utensil
- h. Drain the water from the seed
- i. Rinse the seed with water until the wash water drains clear

#### 2. Sample preparation of chemical solution

- a. Determine the volume of [name of chemical] solution based on the seed weight
- b. Calculate the amount of chemical needed for the desired concentration and volume of water based on the chemical use instructions
- c. Weigh out dry chemicals on a scale
- d. Add the chemical into a container that already contains the appropriate amount of agricultural water
- e. Stir solution well to ensure it is mixed and all solids have dissolved
- f. Verify concentration of treatment solution as described in the chemical instruction or research protocol

#### 3. Sample seed treatment procedure (for chemical treatment)

- a. Carefully combine the freshly prepared treatment solution with the seed
- b. Mix/agitate seed and solution for the time and at the temperature appropriate for the method used
- c. Drain the solution

#### 4. Chemical residue rinse

- a. Rinse the seed with sufficient water to ensure full contact with every seed; until sanitizer is removed from seed, per the label instructions;
- b. Protect the seeds from re-contamination after treatment by covering containers for transport to sprouting room.

#### 5. Chemical solution disposal

- a. Follow federal, state and local requirements and manufacturer's label information.

#### 6. Records

- a. Complete a Seed Treatment Log for each batch of seeds treated
- b. Scientific basis for treatment conditions is documented in [day month year] report from ABC University (on file in QA office)



## A9.2 SEED TREATMENT PROCEDURE – ALTERNATE FORMAT FOR CHEMICAL TREATMENT

Some operations may use an employee focused seed treatment procedure in place of an SOP. A seed treatment procedure may be useful when different treatments are used for different seed types. This example is offered to illustrate a different approach to document a seed treatment procedure. The *Produce Safety Rule* does not require any specific format.

|                                                  |  |                               |
|--------------------------------------------------|--|-------------------------------|
| <b>Seed Treatment Procedure</b>                  |  | Page X of Y                   |
| <b>OPERATION NAME:</b> XXX Sprout Company        |  | <b>ISSUE DATE:</b> 03/27/2017 |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA |  | <b>SUPERSEDES:</b> 02/17/2017 |

Use the chart below as a guideline for each specific seed. Use brand name sanitizer (XX %).

Using the Seed Sanitation Log (*see example in A9.3*), record the chemical concentration verification test reading. If the reading is less than required add XX cup more chemical, stir and check again. Record second reading.

Once the reading is acceptable, stir measured seed in the treated water with dedicated tool until all seeds are wet. Record the time seeds are added. Wait XX minutes, stir with paddle and check with a test kit again. Record the time and the test kit reading.

Drain tub, rinse seeds with agricultural water per manufacturer's instructions, remove seeds, wipe out vat and prepare for the next batch.

Until further notice, alfalfa seed is to be soaked 20 lb or less at a time.

| Seed                           | PPM | Chemical to add | Max lbs/ tub | Where            | Specific instructions                                                                                                                                                                      |
|--------------------------------|-----|-----------------|--------------|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Alfalfa                        | XX  | XX cup          | up to 20     | Cradle or Bucket | Cold water and chemical to just cover seeds, stir every X minutes for XX minutes.                                                                                                          |
| Clover                         | XX  | XX cup          | 15 - 40      | Cradle           | Cold water and chemical to just cover seeds, stir every X minutes for XX minutes.                                                                                                          |
| Beans                          | XX  | XX cup          | 210          | Large soak vat   | Chlorinate beans when instructed by QA. Wash seed, cover w/hot water, leave 1 hour, fill tub with 70°F (21°C) water, add XX chemical, stir every X minutes for XX minutes; leave overnight |
| Radish, Clover Kale & Broccoli | XX  | XX cup          | 12           | Radish Cradle    | Cold water and chemical to just cover seeds, stir every X minutes for XX minutes.                                                                                                          |
| etc.                           |     |                 |              |                  |                                                                                                                                                                                            |



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# Appendix 10. Sampling and Testing Spent Sprout Irrigation Water or In-process Sprouts Supplemental Information

Examples are offered to facilitate creating a company specific Sampling Plan. The *Produce Safety Rule* does not require any specific format. Examples should be edited to develop an operation specific Plan.

## A10.1. SPENT SPROUT IRRIGATION WATER SAMPLING PLAN – EXAMPLE

|                                           |                                             |             |
|-------------------------------------------|---------------------------------------------|-------------|
| SOP# XYZ                                  | Spent Sprout Irrigation Water Sampling Plan | Page 1 of 2 |
| OPERATION NAME: XXX Sprout Company        | ISSUE DATE:                                 | 03/27/2017  |
| ADDRESS: 123 Sprouter Road, Yourtown, USA | SUPERSEDES:                                 | 01/17/2017  |

### Objectives

- Reduce the likelihood of contaminated product entering the food supply through detection of *Salmonella*, *E. coli* O157:H7<sup>1</sup> prior to shipment
- Verify the effectiveness of seed treatments and other controls
- Meeting regulatory requirements (§ 112.144(b)(1) and § 112.150(b)(3))

### Responsible Person

- Safety manager or trained Food Safety Team responsible for supervising, conducting or verifying spent sprout irrigation water sampling and testing; and training new operators

### Sample Type

- Spent sprout irrigation water

### Materials Needed

- Labeled, sterile widemouthed 2L non-glass jars
- Disposable gloves
- Cooler with ice packs
- Cleaned working surface
- Blank testing forms

### Sampling Time

- Approximately 48 hours after the start of sprouting
  - Record sampling time on the record sheet [Example in Appendix 10.4]

### What to Sample

- Every production batch<sup>2</sup>
  - Sprouts – every drum
  - Bean sprouts – every bin started at the same time
- Record sampling location and sample size on the record sheet

<sup>1</sup> Other pathogens may be added if they present a concern and methods are available

<sup>2</sup> It may be useful to prepare a separate sheet that describes a “batch” for the specific operation.

|                                           |                                                            |             |
|-------------------------------------------|------------------------------------------------------------|-------------|
| SOP# XYZ                                  | Spent Sprout Irrigation Water and In-Process Sampling Plan | Page 2 of 2 |
| OPERATION NAME: XXX Sprout Company        | ISSUE DATE:                                                | 03/09/2017  |
| ADDRESS: 123 Sprouter Road, Yourtown, USA | SUPERSEDES:                                                | 01/17/2017  |

### Sampling Procedure for Spent Sprout Irrigation Water

*Aseptic sampling procedures for **all** spent sprout irrigation water samples*

1. Wear clean clothing, sterile gloves and a hair net so as to not contaminate the samples.
2. Wash hands immediately before sampling, and prior to putting on sterile gloves.
3. Keep hands away from mouth, nose, eyes, and face while collecting samples. Do not cough or sneeze into the samples.
4. Protect sampling instruments from contamination before and during use.
5. Collect sample per procedure below.
6. After sampling, put samples in a cooler with ice packs.
7. Discard used gloves.
8. Fill out Water Testing Submission Form.
9. Submit water samples to the testing lab within 24 hours of sampling.

*Sampling procedures for spent sprout irrigation water from **drums***

1. Open the sterile sample container *immediately before* collecting a 1.5 L or more sample
2. Close sampling container and seal immediately after collecting the sample.
3. If collecting samples in a container with a lid, hold the lid in one hand while collecting the sample with another hand. Do not place the lid on a counter.

*Sampling procedure for collecting spent sprout irrigation water samples from **bean sprout bins***

1. Adjust irrigation water flow rate to approximately 1 gallon/ minute so the water will percolate through the sprouts and collect bacteria on its way down through the bottom of the growth bin.
2. Wash hands and put on a pair of sterile gloves.
3. Open a 2L sterile wide-mouth sampling bottle. Hold the lid with one hand and the jar in the other.<sup>3</sup>
4. Collect a separate water sample from the bottom of each growing bin
5. Before sampling the next bin, close the bottle immediately, and put in cooler per aseptic sampling procedures above.

### Hold and Release Program

All product is held until results are received from the laboratory and released or subjected to the Corrective Action Plan [see example in A10.2 Hold and Release Procedure - Example for details]

<sup>3</sup> Alternatively, you may attach the end of a long stick to the bottle and maneuver the bottle underneath the entire bottom of the growing bin to collect a representative sample of the lot.

**A10.2. SPROUT PRODUCT HOLD AND RELEASE PROCEDURE – EXAMPLE**

|                                                  |                                                  |                               |
|--------------------------------------------------|--------------------------------------------------|-------------------------------|
| <b>SOP# XYZ</b>                                  | <b>Sprout Product Hold and Release Procedure</b> | Page 1 of 2                   |
| <b>OPERATION NAME:</b> XXX Sprout Company        |                                                  | <b>ISSUE DATE:</b> 03/02/2017 |
| <b>ADDRESS:</b> 123 Sprouter Road, Yourtown, USA |                                                  | <b>SUPERSEDES:</b> 01/17/2017 |

**Responsible Person:**

QA or a trained employee

**Procedure**

The lab must contact at least one agreed upon responsible person at company by phone as soon as they are aware of any presumptive or positive results in company’s Spent Sprout Irrigation Water samples.

1. When preparing Spent Sprout Irrigation Water (SSIW) samples for the lab, record all samples on a “Lab Sample Tracking & Product Release Sheet”.
2. Schedule (An example)

| SSIW Collection | Product | Result Receiving |
|-----------------|---------|------------------|
| Monday          |         | Tuesday          |
| Sample 1        |         |                  |
| Sample 2        |         |                  |
| Other           |         |                  |

3. Use a separate sheet for each day for samples sent to lab.
4. Upon receiving a lab result, match the lot numbers on the result with the ones on the “Lab Sample Tracking & Product Release Sheet”.
5. Contact supervisors immediately if there is any positive result, the results must be “negative” for *Salmonella*, *E. coli* O157:H7 (and other tested pathogens).
6. Initial each negative result in the “Lab Sample Tracking & Product Release Sheet” and record the date.
7. Responsible person must initial and date the completed “Lab Sample Tracking & Product Release Sheet” to verify the product being shipped has been cleared. No product will leave company’s control until a negative lab result is received and recorded.

**A10.3. SPENT SPROUT IRRIGATION WATER SAMPLING AND TESTING RECORD – EXAMPLE**

(The following table can be used as a template, recognizing that many different formats are appropriate)

| <b>XXX Sprout Company Name</b>                 |                                               |                  |                        |                        |              |                   |
|------------------------------------------------|-----------------------------------------------|------------------|------------------------|------------------------|--------------|-------------------|
| <b>123 Sprouter Road, Yourtown USA</b>         |                                               |                  |                        |                        |              |                   |
| <b>Testing Laboratory Name</b>                 | 123 Testing Company                           |                  |                        |                        |              |                   |
| <b>Address</b>                                 | 456 Analytical Lane, Nextown USA 23456        |                  |                        |                        |              |                   |
| <b>Phone and Fax</b>                           | XXX-XXX-XXXX                                  |                  |                        |                        |              |                   |
| <b>E-mail</b>                                  | 123Test@xxx.com                               |                  |                        |                        |              |                   |
| <b>Primary Contact Person</b>                  | Bugs Hunter                                   |                  |                        |                        |              |                   |
| <b>Spent Sprout Irrigation Water Test Form</b> |                                               |                  |                        |                        |              |                   |
| <b>Sample Description</b>                      | EXAMPLE 48-hour spent sprout irrigation water |                  |                        |                        |              |                   |
| <b>Tests run</b>                               | <i>E. coli</i> O157:H7 and <i>Salmonella</i>  |                  |                        |                        |              |                   |
| <b>Sampled by</b>                              |                                               |                  |                        |                        |              |                   |
| <b>Date of Sampling</b>                        |                                               |                  |                        |                        |              |                   |
| <b>Date of Sample Submission</b>               |                                               |                  |                        |                        |              |                   |
| Sprout type                                    | Batch #                                       | Trace back Lot # | Results                |                        | Release Date | Operator Initials |
|                                                |                                               |                  | <i>E. coli</i> O157:H7 | <i>Salmonella</i> spp. |              |                   |
| Mung beans                                     |                                               |                  |                        |                        |              |                   |
| Mung beans                                     |                                               |                  |                        |                        |              |                   |
| Organic alfalfa                                |                                               |                  |                        |                        |              |                   |
| Clover                                         |                                               |                  |                        |                        |              |                   |
| Alfalfa                                        |                                               |                  |                        |                        |              |                   |
| Alfalfa                                        |                                               |                  |                        |                        |              |                   |
| Etc.                                           |                                               |                  |                        |                        |              |                   |

(Attach **all** testing results from the lab.)

**Reviewer’s Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Form Effective date: 3/27/2017  
Supersedes: 11/20/2016



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# Appendix 11. Additional Control Programs Supplemental Information

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## A11.1 RECALL PLAN – EXAMPLE

### [Company Name] Recall Plan

Reviewed by: *Signature*, Title

Date:

This model Recall Plan identifies information that is either required or recommended to facilitate an effective and efficient recall. No specific format or content is specified. This model contains questions and templates that can be used to develop an individualized Recall Plan.

Refer to FDA's website for guidance on recalls and recall plans.

<http://www.fda.gov/safety/recalls/industryguidance/ucm129259.htm>

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**Recall Team**

[Add, combine or delete rows to accommodate your operation]

| Assignment                                   | Person | Contact Information                                                |
|----------------------------------------------|--------|--------------------------------------------------------------------|
| Senior Operations Manager<br>Alternate:      |        | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxxx<br>Home: xxx-xxx-xxxx |
| Publicity and Public Relations<br>Alternate: |        | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxxx<br>Home: xxx-xxx-xxxx |
| Sales & Marketing<br>Alternate:              |        | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxxx<br>Home: xxx-xxx-xxxx |
| Scientific Advisor<br>Alternate:             |        | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxxx<br>Home: xxx-xxx-xxxx |
| Logistics and Receiving<br>Alternate:        |        | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxxx<br>Home: xxx-xxx-xxxx |
| Quality Assurance<br>Alternate:              |        | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxxx<br>Home: xxx-xxx-xxxx |
| Accountant<br>Alternate:                     |        | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxxx<br>Home: xxx-xxx-xxxx |
| Attorney<br>Alternate:                       |        | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxxx<br>Home: xxx-xxx-xxxx |
| Administrative Support                       |        | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxxx<br>Home: xxx-xxx-xxxx |
| FDA Recall Coordinator <sup>1</sup>          |        | Office: xxx-xxx-xxxx                                               |
| State Recall Coordinator                     |        | Office: xxx-xxx-xxxx                                               |

<sup>1</sup> FDA maintains a list of recall coordinators. Try this link or search for "ORA District and Headquarters Recall Coordinators" <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>

## Appendix 11

Recall Plan Example (continued)

### Determining if a Recall Action Necessary

| Problem reported by                                             | Initial Action                                               | Decisions                                                          | Actions                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Regulatory Agency believe your product is causing illness       | Assemble recall team and ask agency if recall is recommended | Evaluate situation; decide if, what and how much product to recall | <b>If no recall is needed:</b><br><br>Document why not and action.                                                                                                                                                                                                                                                                            |
| News media story on problem with a type of food you produce     | Assemble recall team, review internal records                |                                                                    | <b>If recall is needed:</b>                                                                                                                                                                                                                                                                                                                   |
| Internal QC or customer information suggest a potential problem | Assemble recall team and review internal records             |                                                                    | <ul style="list-style-type: none"> <li>• Assign responsibilities</li> <li>• Gather evidence</li> <li>• Analyze evidence</li> <li>• Get word out</li> <li>• Monitor recall</li> <li>• Dispose of product</li> <li>• Apply for termination of recall</li> <li>• Assemble recall team and debrief</li> <li>• Prepare for legal issues</li> </ul> |
| Health Department believes your produce is causing illness      | Assemble recall team, contact appropriate regulatory agency  |                                                                    |                                                                                                                                                                                                                                                                                                                                               |

**Information Templates for FDA Communication**

*Product Information:*

Modify the “Product Description, Distribution, Consumers and Intended Use” form as needed to reflect only the product involved, including:

- Product name (including brand name and generic name)
- Product number/UPC or product identification
- Remove any names of products that are not involved in the recall

Assemble TWO COMPLETE SETS OF ALL labeling to the Local FDA District Recall Coordinator.

Include:

- Product labeling (including ALL private labels)
- Individual package label
- Case label (photocopy acceptable)
- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

*Codes (Lot Identification Numbers):*

- UPC code(s) involved: \_\_\_\_\_
- Lot number(s) involved: \_\_\_\_\_
- Lot numbers coding system: *Describe how to read your product code:* -  
\_\_\_\_\_  
\_\_\_\_\_
- Expected shelf life of product: \_\_\_\_\_

## Appendix 11

Recall Plan Example (continued)

### Recalling Firm Contacts

Provide this information to FDA for clear communication:

**Manufacturer name:** [Name and address]

| Position                    | Name, Title                                                                                                                                                                                 | Contact Information                                                                     |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| RECALL coordinator          |                                                                                                                                                                                             | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxx<br>Fax: xxx-xxx-xxxx<br>email: xxxxxxxxxxxx |
| Most responsible individual |                                                                                                                                                                                             | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxx<br>Fax: xxx-xxx-xxxx<br>email: xxxxxxxxxxxx |
| Public contact:             | <i>May be one of the above or another individual. If possible, it is useful to name a different individual to allow the coordinator focus on retrieving product and resolving the issue</i> | Office: xxx-xxx-xxxx<br>Mobile: xxx-xxx-xxx<br>Fax: xxx-xxx-xxxx<br>email: xxxxxxxxxxxx |



**Reason for the Recall**

|                                                                                                                                                                                                                                                                    |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Explain in detail how product is defective or violative                                                                                                                                                                                                            |  |
| Explain how the defect affects the performance and safety of the product, including an assessment of a health risk associated with the deficiency, if any.                                                                                                         |  |
| If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.                                                                                                                                |  |
| If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant.                    |  |
| If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.                                                                                      |  |
| If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).                                                                                                                     |  |
| Explain how the problem occurred and the date(s) it occurred.                                                                                                                                                                                                      |  |
| Explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.                                                                                                                                   |  |
| Explain why this problem affects only those products/lots subject to recall.                                                                                                                                                                                       |  |
| Provide detailed information on complaints associated with the product/problem: <ul style="list-style-type: none"> <li>• Date of complaint</li> <li>• Description of complaint -include details of any injury or illness</li> <li>• Lot Number involved</li> </ul> |  |
| If a State agency is involved in this recall, identify Agency and contact.                                                                                                                                                                                         |  |

## Appendix 11

Recall Plan Example (continued)

### Volume of Recalled Product

|                                                                                                                                       |  |
|---------------------------------------------------------------------------------------------------------------------------------------|--|
| Total quantity produced                                                                                                               |  |
| Date(s) produced                                                                                                                      |  |
| Quantity distributed                                                                                                                  |  |
| Date(s) distributed                                                                                                                   |  |
| Quantity on HOLD                                                                                                                      |  |
| Indicate how the product is being quarantined                                                                                         |  |
| Estimate amount remaining in marketplace <ul style="list-style-type: none"><li>• distributor level</li><li>• customer level</li></ul> |  |
| Provide the status/disposition of marketed product, if known, (e.g. used, used in further manufacturing, or destroyed).               |  |

### Distribution Pattern

Number of DIRECT accounts (customers you sell directly to) by type

| Type                                                                                       | Number |
|--------------------------------------------------------------------------------------------|--------|
| ▪ wholesalers/distributors                                                                 |        |
| ▪ repackers                                                                                |        |
| ▪ manufacturers                                                                            |        |
| ▪ retail                                                                                   |        |
| ▪ consumers (internet or catalog sales)                                                    |        |
| ▪ federal government consignees                                                            |        |
| ▪ foreign consignees (specify whether they are wholesale distributors, retailers or users) |        |
| ▪ Geographic areas of distribution, including foreign countries                            |        |

**CONSIGNEE LIST**

*Provide this list to the local District Recall Coordinator. Include US customers, foreign customers and federal government consignees (e.g., USDA, Veterans Affairs, Department of Defense)*

**Commercial customers**

| <i>Name</i> | <i>Street Address</i> | <i>City</i> | <i>State</i> | <i>Recall contact name</i> | <i>Contact phone number</i> | <i>Recalled product was shipped?</i> | <i>Recalled product was sold?</i> | <i>Recalled product may have been shipped or sold</i> |
|-------------|-----------------------|-------------|--------------|----------------------------|-----------------------------|--------------------------------------|-----------------------------------|-------------------------------------------------------|
|             |                       |             |              |                            |                             |                                      |                                   |                                                       |
|             |                       |             |              |                            |                             |                                      |                                   |                                                       |

***Was product sold under Government Contract?***

Yes \_\_\_\_\_ No \_\_\_\_\_

*If yes, include contact name and information above AND complete information below.*

| <i>Contracting Agency</i> | <i>Contract Number</i> | <i>Contract date</i> | <i>Implementation date</i> |
|---------------------------|------------------------|----------------------|----------------------------|
|                           |                        |                      |                            |
|                           |                        |                      |                            |

***School Lunch Program:***

If product was sold to federal, state or local agency for the school lunch program, complete table and notify “ship to” (so they can retrieve product) and “bill to” customers (so they can initiate the sub-recall).

| <i>Consignee</i> | <i>Quantity</i> | <i>Sale date</i> | <i>Shipment date</i> |
|------------------|-----------------|------------------|----------------------|
|                  |                 |                  |                      |
|                  |                 |                  |                      |

**Appendix 11**

Recall Plan Example (continued)

**Recall Strategy**

*Level in the distribution chain*

| Level                 | Included |    | Rationale if “No” |
|-----------------------|----------|----|-------------------|
|                       | Yes      | No |                   |
| Wholesale/distributor |          |    |                   |
| Retail                |          |    |                   |

*Instructions for Consignee Notification*

Write instructions on how consignees will be notified (i.e. by mail, phone, facsimile, e-mail). NOTE: It is advisable to include a written notification so customers will have a record of the recall and your instructions. Include instructions such as:

- How letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)
- Draft phone script, if you decide to use phone. NOTE: If initial notification is by phone, be prepared to provide a copy of the phone script to FDA.
- Draft recall notification (see example on last page) for website and instructions for posting it, if applicable. NOTE: The web is not recommended as a sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. If there is a recall, FDA will want a copy of final instructions.
- Consider what to do for out-of-business distributors.

**Effectiveness Checks**

**Effectiveness checks by account** – Consider filling in the Consignee’s recall contact name and information to make it easier to contact them in the event of a recall.

| Consignee | Recall contact |              | Date contacted | Method of contact |       |     |        | Date if response | Number of products returned or corrected |
|-----------|----------------|--------------|----------------|-------------------|-------|-----|--------|------------------|------------------------------------------|
|           | Name           | Contact info |                | Phone             | Email | Fax | Letter |                  |                                          |
|           |                |              |                |                   |       |     |        |                  |                                          |
|           |                |              |                |                   |       |     |        |                  |                                          |
|           |                |              |                |                   |       |     |        |                  |                                          |

**Effectiveness check summary – to be provided to FDA periodically**

| Date of notification | Method of notification | Number of consignees notified | Number of consignees responding | Quantity of product on hand when notification received | Number of consignees not responding and action taken | Quantity accounted for | Estimated completion date |
|----------------------|------------------------|-------------------------------|---------------------------------|--------------------------------------------------------|------------------------------------------------------|------------------------|---------------------------|
|                      |                        |                               |                                 |                                                        |                                                      |                        |                           |
|                      |                        |                               |                                 |                                                        |                                                      |                        |                           |
|                      |                        |                               |                                 |                                                        |                                                      |                        |                           |
|                      |                        |                               |                                 |                                                        |                                                      |                        |                           |

**Product destruction/ reconditioning**

- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. It is recommended that you provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable GMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
- It is recommended that you contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- You and your customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, like product relabeling, be performed by recalling firm representatives, or under their supervision and control. Contact your local FDA District Recall Coordinator prior to release of reconditioned goods.

## Appendix 11

Recall Plan Example (continued)

### DRAFT Recall Notice

***[Company Name] Voluntarily Recalls [insert summary info] Representing [X quantity]  
[--No Other Products Affected--]***

#### Contact

Consumer:

1-xxx-xxx-xxx

Media Contact:

xxx-xxx-xxxx

**FOR IMMEDIATE RELEASE** – [date] – [Company name] is voluntarily recalling [X] Lot Codes of [COMPANY/BRAND name] [insert specific product name and description], representing [insert quantity]. [Insert reason for recall].

**This action relates only to [COMPANY NAME] products with any of these Lot Codes printed on the package:**

- [insert lot codes]

**No other Lot Codes, or any other [COMPANY NAME] products, are involved in this action.**

Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

#### PRODUCT

#### LOT CODE

#### ITEM NO.

[Company Name] [insert product name(s)] [insert product codes(s)] [insert item number(s)]

[Company Name] is conducting this voluntary recall because [insert product name(s)] [modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.]

For more information or assistance, please contact us at 1-xxx-xxx-xxxx (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at [www.xxx.com](http://www.xxx.com)

A11.2 RECALL WORKSHEET - EXAMPLE

| <b>XXX Sprout Company Name</b>         |             |                         |                     |             |                        |                     |               |
|----------------------------------------|-------------|-------------------------|---------------------|-------------|------------------------|---------------------|---------------|
| <b>123 Sprouter Road, Yourtown USA</b> |             |                         |                     |             |                        |                     |               |
| <b>Recall Worksheet</b>                |             |                         |                     |             |                        |                     |               |
| <b>Date</b>                            |             |                         |                     |             |                        |                     |               |
| <b>Start time</b>                      |             |                         |                     |             |                        |                     |               |
| <b>Finish time</b>                     |             |                         |                     |             |                        |                     |               |
| <b>Seeds recognized by the Seed ID</b> |             |                         |                     |             |                        |                     |               |
| <b>Seed ID</b>                         | <b>Seed</b> | <b># of lbs. Soaked</b> | <b>Harvest Date</b> | <b>Code</b> | <b>Estimated Yield</b> | <b>Sell by date</b> | <b>Tossed</b> |
|                                        |             |                         |                     |             |                        |                     |               |

|               |                     |  |  |  |  |  |  |
|---------------|---------------------|--|--|--|--|--|--|
| <b>Packed</b> | <b>Product</b>      |  |  |  |  |  |  |
|               | <b>Quantity</b>     |  |  |  |  |  |  |
|               | <b>Quantity</b>     |  |  |  |  |  |  |
|               | <b>Total Packed</b> |  |  |  |  |  |  |

|                   |                 |                               |  |                               |  |                               |  |
|-------------------|-----------------|-------------------------------|--|-------------------------------|--|-------------------------------|--|
| <b>Shipped To</b> | <b>Customer</b> | <b>Product Name/ Quantity</b> |  | <b>Product Name/ Quantity</b> |  | <b>Product Name/ Quantity</b> |  |
|                   |                 |                               |  |                               |  |                               |  |
|                   |                 |                               |  |                               |  |                               |  |
|                   |                 |                               |  |                               |  |                               |  |
|                   |                 |                               |  |                               |  |                               |  |

\*Packed must equal shipped, inventory and discarded

\*\*Explanation for less than 100% recovery

**Reviewer's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Form Effective date: 3/24/2017  
Supersedes: 11/20/2016

**A11.3 RECALL PROCEDURE - EXAMPLE**

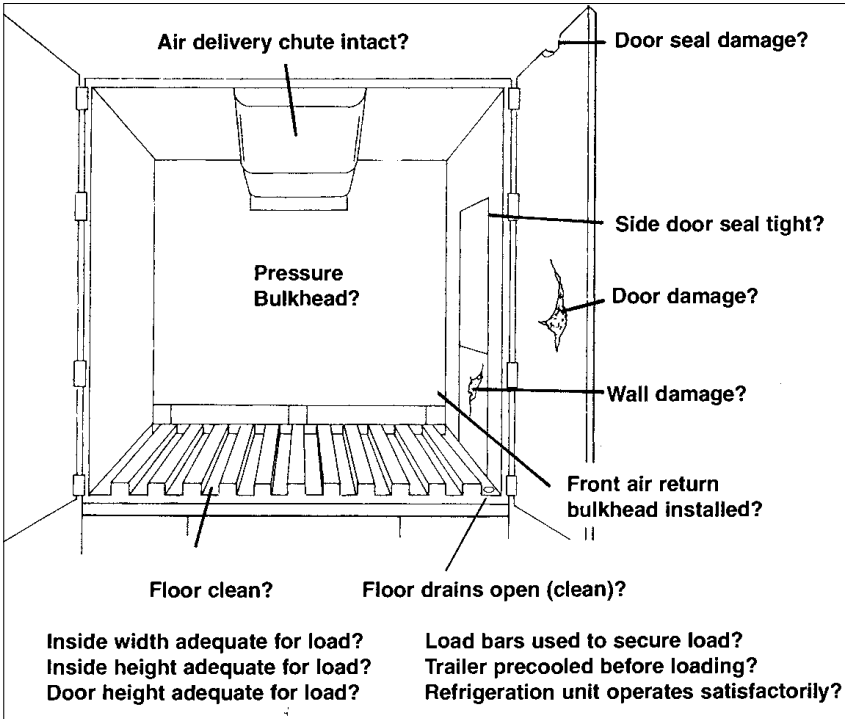
| <b>XXX Sprout Company Name</b><br><b>123 Sprouter Road, Yourtown USA</b> |                                                                                                                                                                                                                                                |                                                                                    |                    |           |
|--------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------------|-----------|
| <b>Recall Worksheet</b>                                                  |                                                                                                                                                                                                                                                |                                                                                    |                    |           |
| Step                                                                     | Action                                                                                                                                                                                                                                         | Information needed                                                                 | Person Responsible | Date/Time |
| 1.                                                                       | Convene the Product Recall Team                                                                                                                                                                                                                | Team member names                                                                  |                    |           |
| 2.                                                                       | Identify and locate suspect products                                                                                                                                                                                                           | Product name; Product description; Package size; Use-By date; Lot number; Quantity |                    |           |
| 3.                                                                       | Collect product information                                                                                                                                                                                                                    | Production records; packing slips                                                  |                    |           |
| 4.                                                                       | Examine inventory records for each lot of the affected products                                                                                                                                                                                | Inventory record, production date; Lot number, quantity on hand                    |                    |           |
| 5.                                                                       | Identify seed lot(s) used for affected products                                                                                                                                                                                                | Production records, seed lot identifiers                                           |                    |           |
| 6.                                                                       | If the recall is due to detection or suspicion of a pathogen on the sprouts consider including all sprouts grown from the suspect seed lot                                                                                                     | Seed lot identifiers                                                               |                    |           |
| 7.                                                                       | List all sales by date of the product and customer sold to.                                                                                                                                                                                    | Sales orders and or shipping slips with lot numbers                                |                    |           |
| 8.                                                                       | Identify the products sold within 3-4 days of the production date, if appropriate                                                                                                                                                              | Information gathered from above.                                                   |                    |           |
| 9.                                                                       | Contact customers for recall and inform them of the codes on the affected products                                                                                                                                                             | Customers contact information                                                      |                    |           |
| 10.                                                                      | If product has left the plant, but is still within control of the company or independent distribution system, instruct the distributor to place the shipment <i>ON HOLD</i> and to refrain from performing any further deliveries until notice |                                                                                    |                    |           |
| 11.                                                                      | Confirm disposition of the products                                                                                                                                                                                                            | Confirmation form from contacted customers                                         |                    |           |
| 12.                                                                      | Cross reference Seed Receiving Log, if appropriate.                                                                                                                                                                                            | Seed Receiving records                                                             |                    |           |
| 13.                                                                      | Advise seed suppliers of suspected contamination                                                                                                                                                                                               | Seed suppliers contact information                                                 |                    |           |
| 14.                                                                      | Record all information in a Recall Log Sheet (aka Recall Worksheet)                                                                                                                                                                            | Recall Log Sheet (A sample document can be found in the appendices)                |                    |           |

**Reviewer's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Form Effective date: 3/24/2017  
 Supersedes: 11/20/2016



A11.4 TRUCK INSPECTION FORM - EXAMPLE

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>XXX Sprout Company Name</b><br><b>123 Sprouter Road, Yourtown USA</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                     |
| <b>Truck Inspection Form</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                     |
| <b>Driver's Name</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                     |
| <b>Trucking Company or Affiliation</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                     |
| <b>Date</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                     |
| <b>Time</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                     |
| <b>Destination</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                     |
| <p><b>Circle any problem area and report them to your supervisor BEFORE loading</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |
| <p><b>ALSO Check the following:</b></p> <ol style="list-style-type: none"> <li>1) Trailer has not been previously used to transport livestock or unpackaged animal products or feed.             <ul style="list-style-type: none"> <li>• IF NO: DO NOT LOAD. Call for another Trailer</li> </ul> </li> <li>2) Inside of trailer is clean and odor free.             <ul style="list-style-type: none"> <li>• IF NO: Have Trailer Cleaned BEFORE Loading</li> </ul> </li> <li>3) Product Temperature at loading _____ °F; Trailer Temperature at loading _____ °F</li> </ol> |                                                                                     |
| <p><b>Approved for Loading by:</b> _____</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                     |
| <p><b>Reviewer's Signature:</b> _____ <b>Date:</b> _____</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                     |
| <p>Form Effective date: 3/24/2017<br/>Supersedes: 11/20/2016</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                     |



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# Appendix 12. Recordkeeping Supplemental Information

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## A12.1 MATERIALS RECEIVING LOG SHEET – EXAMPLE

|                                                                          |  |       |  |
|--------------------------------------------------------------------------|--|-------|--|
| <b>XXX Sprout Company Name</b><br><b>123 Sprouter Road, Yourtown USA</b> |  |       |  |
| <h3>Materials Receiving Log</h3>                                         |  |       |  |
| Date received                                                            |  |       |  |
| Supplier Name                                                            |  |       |  |
| Name of the product received                                             |  |       |  |
| Quantity received                                                        |  |       |  |
| Invoice or Reference Number                                              |  |       |  |
| Lot Number #                                                             |  |       |  |
| Name of Transporter (carrier)                                            |  |       |  |
| Seal Number (if applicable)                                              |  |       |  |
| Temperature during transport                                             |  |       |  |
| Storage Location                                                         |  |       |  |
| Comments                                                                 |  |       |  |
| Corrective Action(s)                                                     |  |       |  |
| Received by                                                              |  |       |  |
| Reviewer Signature:                                                      |  | Date: |  |

## A12.2 PRODUCT PACKAGING / HOLDING LOG SHEET – EXAMPLE

|                                        |              |
|----------------------------------------|--------------|
| <b>XXX Sprout Company Name</b>         |              |
| <b>123 Sprouter Road, Yourtown USA</b> |              |
| <b>Product Packaging / Holding Log</b> |              |
| <b>Product Name</b>                    |              |
| <b>Container size/type</b>             |              |
| <b>Date packed</b>                     |              |
| <b>Sprout Batch #</b>                  |              |
| <b>Seed lot #</b>                      |              |
| <b>Number of unit packed</b>           |              |
| <b>Holding area / Cooler</b>           |              |
| <b>Cooler temperature/time</b>         |              |
| <b>Product Temperature</b>             |              |
| <b>Record completed by</b>             |              |
| <b>Comment and observation</b>         |              |
| <b>Corrective Action(s) if any</b>     |              |
| <b>Received by</b>                     |              |
| <b>Reviewer Signature:</b>             | <b>Date:</b> |

## A12.3 PRODUCT DISTRIBUTION SHEET – EXAMPLE

|                                                                          |              |
|--------------------------------------------------------------------------|--------------|
| <b>XXX Sprout Company Name</b><br><b>123 Sprouter Road, Yourtown USA</b> |              |
| <b>Product Distribution Sheet</b>                                        |              |
| <b>Shipping date</b>                                                     |              |
| <b>Product Name</b>                                                      |              |
| <b>Lot code</b>                                                          |              |
| <b>Quantity Shipped</b>                                                  |              |
| <b>Transporter</b>                                                       |              |
| <b>Customer</b>                                                          |              |
| <b>Record completed by</b>                                               |              |
| <b>Comments and observation</b>                                          |              |
| <b>Reviewer Signature:</b>                                               | <b>Date:</b> |

## A12.4 PRODUCT RETURN SHEET – EXAMPLE

|                                                                          |              |
|--------------------------------------------------------------------------|--------------|
| <b>XXX Sprout Company Name</b><br><b>123 Sprouter Road, Yourtown USA</b> |              |
| <b>Product Return Sheet</b>                                              |              |
| <b>Customer Name</b>                                                     |              |
| <b>Date Product Was Returned</b>                                         |              |
| <b>Description of Product</b>                                            |              |
| <b>Amount of Product Returned</b>                                        |              |
| <b>Lot Number</b>                                                        |              |
| <b>Reason for Product Return</b>                                         |              |
| <b>Person at Sprout Firm who Received the Returned Product</b>           |              |
| <b>Disposition of the Returned Product</b>                               |              |
| <b>Person Who Destroyed the Produce</b>                                  |              |
| <b>Comment and observation</b>                                           |              |
| <b>Reviewer Signature:</b>                                               | <b>Date:</b> |



## A12.5 CORRECTIVE ACTION RECORD – EXAMPLE

|                                                    |                     |
|----------------------------------------------------|---------------------|
| <b>XXX Sprout Company Name</b>                     |                     |
| <b>123 Sprouter Road, Yourtown USA</b>             |                     |
| <b>Corrective Action Form</b>                      |                     |
| Date of Record:                                    | Seed Lot Number(s): |
| Date and Time of Deviation:                        | Production batch    |
| Description of Issue:                              |                     |
| Actions Taken to Restore Order:                    |                     |
| Person (name & signature) of Person Taking Action: |                     |
| Amount of Product Involved in Deviation:           |                     |
| Evaluation of Product Involved with Deviation:     |                     |
| Final Disposition of Product:                      |                     |
| Reviewed by (Name and Signature):                  | Date of Review:     |





