Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption

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U.S. Department of Health and Human Services
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I. Introduction

This draft guidance is intended for those persons ("you") who grow, harvest, pack and/or hold sprouts covered by Subpart M of our final rule, published in the Federal Register (80 FR 74353) on November 27, 2015, entitled, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (the Produce Safety Rule or the Rule).

The Produce Safety Rule established for the first time U.S. Federal requirements for the growing, harvesting, packing, and holding of produce for human consumption, including sprouts (Title 21 Code of Federal Regulations part 112 (21 CFR part 112)). The Rule focuses on certain conditions and practices identified as common routes of contamination of produce (similar to the areas covered by the 1998 Guidance, "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (GAPs Guide)) (Ref. 1). The Rule establishes requirements addressing common routes of microbial contamination, including: agricultural water; biological soil amendments of animal origin; worker health and hygiene; equipment, tools, buildings and sanitation; and domesticated and wild animals.

Sprouts represent a distinct food safety concern because the conditions under which sprouts are produced (i.e., temperature, water activity, pH and available nutrients) are also ideal for the growth of pathogens, if present (Ref. 2). Between 1996 and 2020 in the United States, FDA observed 52 reported outbreaks of foodborne illness associated with sprouts. Together, it is estimated that these outbreaks resulted in at least 2700 cases of illness, 200 hospitalizations, and three deaths (Ref. 3, Ref. 4, Ref. 5, Ref. 6, Ref. 7, and Ref. 8). During this timeframe, sprouts have been associated with outbreaks of several different pathogens, including *Salmonella* spp., *Listeria monocytogenes*, *E. coli* O157:H7, and several types of non-O157:H7 pathogenic *E. coli* (i.e., *E. coli* O157:NM (H-), *E. coli* O104:H4, *E. coli* O26, *E. coli* O121, *E. coli* O103) (Ref. 9 and

Ref. 10). In foodborne illness outbreaks associated with sprouts where the source of contamination was identified, epidemiological investigations often identify the most likely source of contamination as seeds used for sprouting (Ref. 2 and Ref. 11). However, poor sanitation and unhygienic practices at the sprout operation have also contributed to the contamination of sprouts (Ref. 2, Ref. 6, Ref. 12, Ref. 13, and Ref. 14).

Because the distinctive practices and conditions for growing sprouts present unique risks, we established sprout-specific requirements in Subpart M (Sprouts) of the Produce Safety Rule. Subpart M of the Rule builds on sprout production practices similar to areas covered in our 1999 Sprout Guidances (discussed further below, now withdrawn). Sprout operations subject to the Produce Safety Rule must comply with all applicable requirements in the Rule, including, but not limited to, all applicable requirements in Subpart M.

The requirements in the Produce Safety Rule are directed specifically to covered farms (as that term is defined in the Rule) that grow, harvest, pack or hold covered produce, including sprouts. Covered farms that grow, harvest, pack or hold sprouts are referred to in this guidance as "sprout operations," or "you." Produce that is covered by the Rule is referred to as "covered produce."

Neither the Produce Safety Rule nor this draft guidance document is directed to growing, conditioning, or distributing seed for sprouting or to the handling of sprouts at a retail food establishment. However, as noted in our prior Sprout Guidances and our May 2009 letter to suppliers and distributors of seed for sprouting and sprout operations (Ref. 15 and Ref. 16), everyone in the sprout supply chain has a responsibility to help ensure food safety. FDA has also issued the final guidance document regarding good agricultural practices for seed for sprouting, entitled "Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Guidance for Industry" (Ref. 17). The Produce Safety Rule does not address chemical or physical hazards. However, you have a responsibility to ensure that your sprouts are not adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §§ 301 *et seq.*) and are produced in compliance with all applicable laws and regulations. Under section 402(a)(1) of the FD&C Act, a food is adulterated if it bears or contains any added poisonous or deleterious substance which may render it injurious to health, and such substances may include or otherwise result from physical and chemical (including radiological) contamination.

This draft guidance provides our current thinking and recommendations to assist sprout operations subject to the Produce Safety Rule primarily in complying with the sprout-specific requirements in Subpart M, specifically the requirements related to sampling and testing spent sprout irrigation water or in-process sprouts. This draft guidance accompanies the final guidance, *Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption* (Ref. 18), which discusses other requirements of Subpart M (e.g., seed treatment, environmental monitoring), which are covered in the finalized sections (Ref. 18). FDA is issuing this draft guidance to receive comments on revised sections of a currently issued draft guidance entitled "Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations" (January 23, 2017). After reviewing comments and incorporating any changes, FDA will combine the subjects discussed into this guidance into a single final guidance, as appropriate. This draft guidance also briefly discusses certain requirements (in Subpart L of the Rule relating to Equipment, Tools, Buildings, and Sanitation) of particular relevance to a sprout operation. In

addition, this draft guidance may also be useful to sprout operations that are not subject to the Produce Safety Rule that voluntarily choose to follow the standards established in the Rule. In the development of this draft guidance, we particularly considered industry and international documents related to food safety and hygienic production of sprouts (Ref. 19, Ref. 20, and Ref. 21). We have incorporated aspects of these documents that are consistent with our laws, regulations, and existing policies.

Some of the material in this draft guidance relates to regulatory requirements of the Produce Safety Rule that are also covered in the draft "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry" (general produce compliance and implementation draft guidance (83 FR 53196) issued in October 2018) (Ref. 22). At the present time, the material on these overlapping topics (e.g., training, equipment, tools, and buildings) is consistent between these two draft guidance documents. This draft guidance focuses specifically on insights drawn from FDA's experience with sprout operations, such as from inspections and sprout-associated foodborne illness outbreak investigations, and elaborates on how the broader training, equipment, tools, and buildings standards in part 112 could apply to and be implemented in a sprout operation.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. Background

A. Other FDA Efforts Related to Sprouts

On October 27, 1999, we published a notice of availability in the Federal Register (64 FR 57893) for two guidance documents to inform all parties involved in the production of sprouts (i.e., producers, conditioners, and distributors of seeds used for sprouting, and sprout operations) that sprouts had been recognized as an important cause of foodborne illness and to provide recommendations for preventive controls that we believed should be taken immediately to reduce the likelihood of sprouts serving as a vehicle for foodborne illness. We refer to these prior (now withdrawn) guidance documents collectively as the 1999 Sprout Guidances.

FDA and our food safety partners in the public and private sectors have engaged in education and outreach to the sprout industry to promote adoption of our recommendations. We have also worked with the sprout industry to advance the scientific knowledge applicable to enhancing the safety of sprouts. For example, in 2000, we collaborated with the California Department of Public Health, in cooperation with the sprout industry and academia, to develop an educational video series entitled, "Safer Processing of Sprouts" (Ref. 23). In addition, we have provided technical assistance to the Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH) Sprout Safety Taskforce in developing their US Sprout Industry Production Best Practices (Ref. 20).

We also have been working with the Sprout Safety Alliance (SSA), a public-private partnership, since 2012 to develop a standardized curriculum and training and outreach programs for stakeholders in the sprout industry to enhance the industry's understanding and implementation of the requirements of the Produce Safety Rule, and of best practices for improving sprout safety (Ref. 24, Ref. 25, and Ref. 26). The SSA is composed of representatives from the sprout industry, retailers, academia, and federal, state, and local food safety agencies. The SSA is funded by a grant from FDA to IIT IFSH.

B. Coverage of the Produce Safety Rule

Under § 112.1 of the Produce Safety Rule, unless specifically excluded under § 112.2, food that is produce (as that term is defined in the Rule), and that is a raw agricultural commodity (RAC), is covered by the Rule. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import into any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. Covered farms (i.e., those subject to the Produce Safety Rule) must comply with all applicable requirements of the Rule when conducting a covered activity on covered produce (see § 112.4). There are certain exclusions, exemptions and limitations on which farms are "covered farms" (see § 112.4). For example, sprout operations, for which, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period, adjusted for inflation, is less than or equal to $25,000 are not covered by this regulation (§ 112.4(a)). See https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs for information on FDA Food Safety Modernization Act (FSMA) inflation adjusted cut-offs. See also "Standards for Produce Safety, Coverage and Exemptions/Exclusions for 21 Part 112", available at https://www.fda.gov/media/94332/download to assist you in determining which provisions of the Produce Safety Rule, if any, apply to you.

Sprouts are produce as we defined that term in the Produce Safety Rule (see § 112.3). Sprouts are also RACs when they are in their raw or natural state (see § 112.3 and section 201(r) of the FD&C Act, defining "raw agricultural commodity" as "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."). Therefore, sprouts in their raw or natural state are covered produce, except as otherwise provided in § 112.2.

If sprouts are made into processed food(s), those processed foods are not covered by the Produce Safety Rule (see § 112.2(a)(3)). An example of a processed food made using sprouts is sprouted seed butter. This does not mean that sprout RACs that will be made into processed food are themselves exempt from the Produce Safety Rule simply because those RACs will later be transformed into processed food. Rather, it means that the Produce Safety Rule only applies during the time that the sprouts are RACs. Other requirements, such as those in 21 CFR Part 117, may apply to any manufacturing/processing of the sprout RACs into processed food, depending on the circumstances.

Sprouts do not qualify for the exemption from the Produce Safety Rule in § 112.2(a)(1) for produce that is rarely consumed raw. This provision contains a list of produce commodities (such as potatoes) for which we have analyzed dietary consumption patterns and determined such

commodities are rarely consumed raw. This exemption applies only to the commodities identified in § 112.2(a)(1), none of which are sprouts.

Some sprouts may be eligible for exemption from the Produce Safety Rule under § 112.2(b), if they will receive 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 appear in § 112.2(b)(1). This exemption requires covered farms to establish and maintain certain documentation and disclosures set forth in § 112.2(b)(2)-(3): 1) disclosures to customers; and 2) annual written assurances obtained from customers. Sprouts that receive commercial processing (e.g., canned, shelf-stable mung bean sprouts) could potentially qualify for this exemption from the Produce Safety Rule, but only if the commercial processing adequately reduces the presence of microorganisms of public health significance and all documentation and disclosure requirements are met.[1] We note that simply drying/dehydrating sprouts may not adequately reduce the presence of microorganisms of public health significance (Ref. 27 and Ref. 28) and therefore would not make them eligible to receive the commercial processing exemption from the Rule.

Some sprout operations may be eligible for a qualified exemption and associated modified requirements in a calendar year if, during the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3) the sprout operation sold directly to qualified end-users (as defined in § 112.3) during such period exceeded the average annual monetary value of the food the sprout operation sold to all other buyers during that period; and the average annual monetary value of all food (as defined in § 112.3) the sprout operation sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation. (FDA makes available the updated inflation-adjusted figures at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs.) Section 112.6(b) describes the modified requirements applicable to a qualified exempt operation (e.g., labeling). Section 112.7 requires the sprout operation eligible for the qualified exemption, provided for in § 112.5, to establish and keep adequate records necessary to demonstrate that the sprout operation satisfies the criteria for a qualified exemption (e.g., dated sales receipts), including a written record reflecting that the owner, operator, or agent in charge of the sprout

[1] In the *Federal Register* of January 5, 2018 (83 FR 598), we published a notification of availability of a guidance document titled "Policy Regarding Certain Entities Subject to the Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs." In that guidance document, we stated that we intend to exercise enforcement discretion regarding certain written assurance requirements, including those in 21 CFR part 112 (the Produce Safety Rule). We intend to exercise such discretion until we can complete a rulemaking process to consider options for the assurance requirements. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-policy-regarding-certain-entities-subject-current-good-manufacturing-practice-and. See also the Federal Register of March 14, 2022 (87 FR 14169), in which we published a notification of availability of a guidance document titled "Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions." In that guidance document, we restated our intent to exercise enforcement discretion with respect to the Produce Safety Rule assurance requirements, as previously indicated in the 2018 guidance document described immediately above. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-current-good-manufacturing-practice-and-preventive-controls-foreign-supplier.

operation has performed an annual review and verification of the sprout operation's continued eligibility for the qualified exemption.

C. Coverage of Subpart M

The requirements in 21 CFR part 112, Subpart M apply to the growing, harvesting, packing and holding of all sprouts except sprouts that are grown in soil or non-soil substrates (e.g., mats, perlite or other growth media) and that are harvested above the soil or substrate line without their roots (see § 112.141). We determined that soil- or substrate-grown sprouts that are harvested above the soil or substrate line, such that their roots are not harvested for human consumption, do not present the same risks as other types of sprouts and, therefore, we excluded them from the sprout-specific requirements in Subpart M (80 FR 74353 at 74497). However, the requirements of Subpart M do apply to soil- or substrate-grown sprouts that are harvested with the roots. If you use soil or substrate as a growth medium in your operation, in addition to all other relevant requirements of the Produce Safety Rule, you must comply with the applicable requirements in 21 CFR part 112, Subpart F (Biological Soil Amendments of Animal Origin and Human Waste). We discuss the requirements of Subpart F in the draft compliance and implementation guidance (Ref. 22). We recognize that sprout operations may sell certain soil- or substrate-grown sprout types, such as wheatgrass, in a tray used for growing, with the soil/substrate and root intact, to commercial entities, including facilities that are required to register with FDA under section 415 of the FD&C Act, restaurants, retail food establishments, and non-profit food establishments. In such cases, the operation that has harvested the sprouts with the roots and these sprouts are ordinarily subject to Subpart M (see § 112.141). However, we understand that, in some cases, such sprouts may then be cut above the soil and/or substrate line at the commercial entity immediately before use or sale to the consumer. When a sprout operation sells sprouts with the roots intact in soil or substrate, and the commercial entity that receives them will cut the sprouts above the soil or substrate line before use, we intend to exercise enforcement discretion for the requirements of Subpart M if the sprout operation annually collects written assurances from the commercial entity stating that the sprouts will be cut above the soil or substrate line before use (see also Section VII.C.1 in the finalized sections (Ref. 18)).

Note that soil- or substrate-grown sprouts harvested above the soil line are still considered covered produce and, unless exempt or excluded under the provisions of 21 CFR part 112, Subpart A, are subject to all other applicable requirements of the Produce Safety Rule. The standards in Subpart M may be useful to sprout operations that produce soil- or substrate-grown sprouts that are harvested above the soil or substrate line that voluntarily choose to follow these standards, in addition to complying with the required provisions of all other subparts in the Produce Safety Rule.

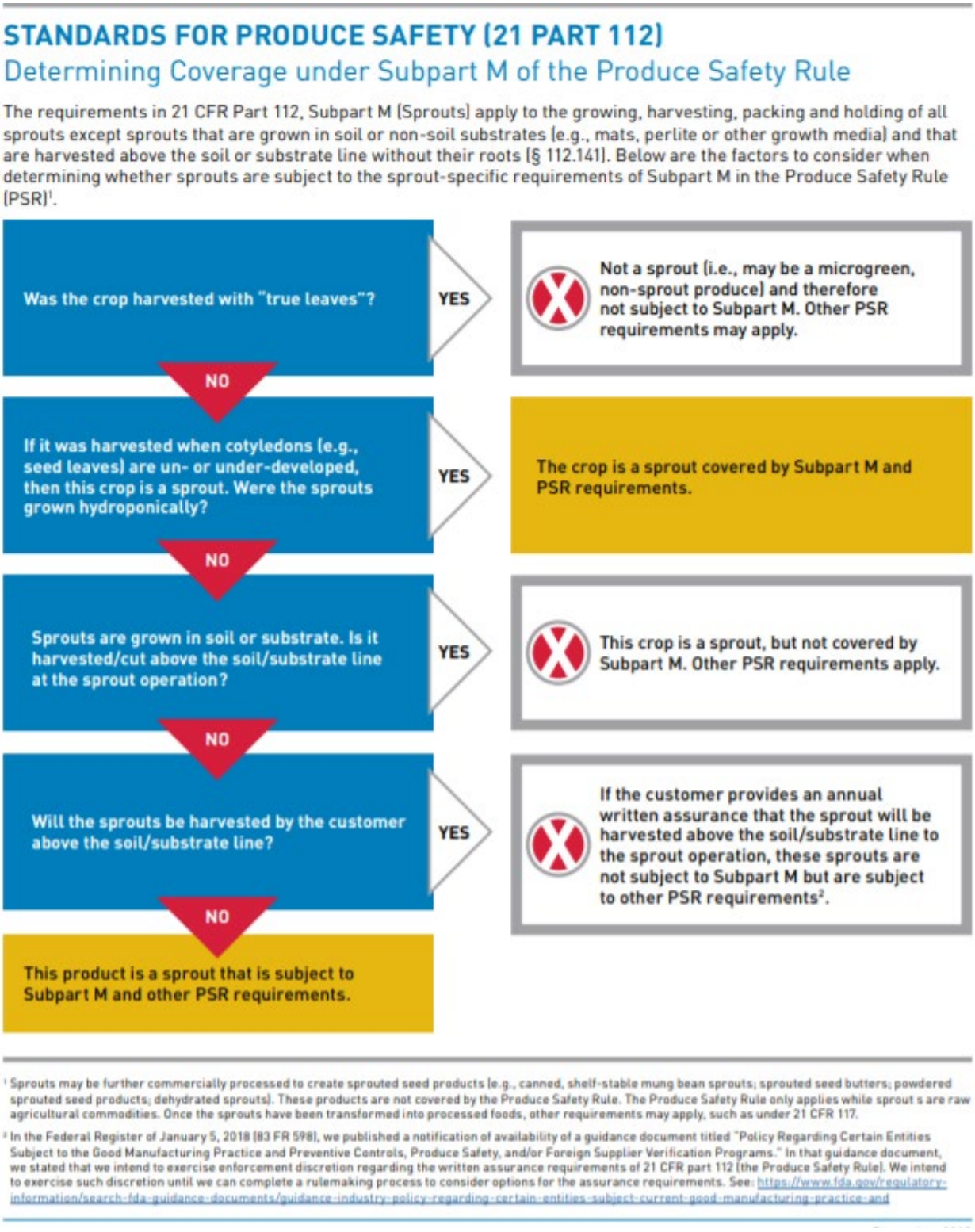
We are aware that certain sprouts are grown hydroponically in trays, and then harvested without the root at either the sprout operation or by the customer. As we previously stated in the preamble to the final rule (80 FR 74353 at 74497, comment/response 364), all hydroponically grown sprouts are subject to the requirements of Subpart M. Under typical conditions for growing hydroponic sprouts, water circulates between sprouts in the same growing unit, such that any pathogens present in the seed or introduced during sprouting can spread throughout the production lot of sprouts (Ref. 2, Ref. 29, and Ref. 30) .

We are also aware of certain products marketed using descriptions such as activated seeds, sprouted seeds/briefly sprouted seeds, or sprouted nuts/briefly sprouted nuts (e.g., sprouted almonds, sprouted cashews, sprouted chia seeds, and sprouted pumpkin seeds). They are produced by soaking seeds, beans, or nuts in water for a brief period of time (e.g., 4-48 hours) to induce nutritional and textural changes in the seed, bean, or nut (e.g., to break down antinutrients that reduce the bioavailability of vitamins, minerals and other nutrients) and then drying the seeds, beans, or nuts (Ref. 31 and Ref. 32). Although soaking could begin the germination process, soaking would stop before the cotyledons (i.e., seed leaves) and roots are visible (Ref. 31). Because the seeds, beans, or nuts are no longer in their raw or natural state, and because the intent of the soaking is to induce nutritional and textural changes in the seed rather than to grow a produce RAC, we consider these products to be processed food rather than RACs. (See the definition of RAC in section 201(r) of the FD&C Act.) Foods described using terms such as activated seeds, sprouted seeds/briefly seeds/briefly sprouted seeds, or sprouted nuts/briefly sprouted nuts that were subsequently dried and used in manufactured foods without a process that adequately reduces microorganisms of public health significance have been involved in recent foodborne illness outbreaks and other contamination events (Ref. 33 and Ref. 34). We consider that such products typically are subject to the requirements of the Preventive Controls for Human Food Rule (21 CFR part 117). The controls such as those described in Subpart M of the Produce Safety Rule may be an effective option to control the food safety hazards introduced by the soaking step and may be appropriate for the product, depending upon the specific circumstances (e.g., the availability of other controls, the nature of subsequent manufacturing steps) as the soaking step associated with these products likely presents a similar risk to the soaking and irrigation steps associated with traditional sprouts (Ref. 35), and, as previously stated, simply drying/dehydrating the soaked sprouts may not adequately reduce the presence of microorganisms of public health significance (Ref. 27 and Ref. 28). However, we acknowledge that certain seeds or nuts may be sprouted into a traditional sprout which would then be subject to the requirements of the Produce Safety Rule.

We note that microgreens and sprouts are different products. This interpretation is consistent with our prior Sprout Guidances and with other public and private standards (e.g., IIT IFSH Sprout Taskforce US Sprout Industry Production Best Practices document (Ref. 20), Food Safety Australia New Zealand (FSANZ) standards for sprouts (Ref. 36). Historically, the primary criterion we have used to distinguish between the two product categories has been the growth stage of the leaves. Sprouts are usually harvested when the cotyledons (i.e., seed leaves) are still un- 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. Unlike sprouts covered by Subpart M, microgreens are typically grown in soil or substrate and harvested above the soil or substrate line. Because microgreens are not sprouts, they are not subject to the requirements in Subpart M (Ref. 37). However, microgreens are considered covered produce for the purposes of the Produce Safety Rule and, unless exempt or excluded under the provisions in Subpart A, microgreens are subject to the other subparts of the Produce Safety Rule (80 FR 74353 at 74497, comment/response 363).

The following figure provides factors to consider when determining whether sprouts are subject to the sprout-specific requirements of Subpart M of the Produce Safety Rule.

Figure 1. Determining Coverage under Subpart M of the Produce Safety Rule



Note that throughout this guidance, for the ease of the reader, we often refer collectively to everything, including beans, sprouted to produce sprouts for human consumption simply as "seeds." In the Rule, we used the phrase "seeds or beans" to remove any potential confusion as to whether beans for sprouting were included. References to "seeds" in this guidance should be read to include things other than seeds that are sprouted to produce sprouts for human consumption, such as beans.

In addition, the definition of "produce" includes sprouts irrespective of seed source (see § 112.3). We consider sprouts to be a distinct category of produce that includes many different varieties (e.g., alfalfa, mung). Sprouts (i.e., alfalfa, mung and soybean sprouts) were evaluated to determine whether they are rarely consumed raw, and therefore exempt from the Produce Safety Rule (see 80 FR 74353 at 74392, comment/response 68). Sprouts did not meet the threshold criteria for the rarely consumed raw exemption and are therefore considered covered produce. The mature plant and/or the seeds used to grow sprouts may or may not fall under the definition of "produce." For example, wheatgrass sprouts and soybean sprouts have long been considered sprouts by the food industry and FDA and are covered produce under the Produce Safety Rule. However, for both wheat and soybeans, the mature crops are considered food grains, which do not fall under the definition of "produce," and are not subject to the Produce Safety Rule. Sprouts may also be produced from seeds of produce that is considered to be rarely consumed raw, such as beet or pumpkin sprouts. While the mature produce may be rarely consumed raw, and therefore exempt from the Produce Safety Rule, the sprouts produced from the seeds of these crops are still covered produce under the Produce Safety Rule because we consider sprouts to be a distinct commodity from the mature form, and sprouts have not met the threshold criteria for the rarely consumed raw exemption.

D. Compliance Dates for Sprouts

Sprout operations covered by the Produce Safety Rule and subject to Subpart M must be in compliance with all applicable provisions of the Produce Safety Rule at this time. The extended compliance dates provided for covered farms producing other produce commodities to comply with the agricultural water requirements of Subpart E do not apply to the production of sprouts subject to Subpart M. Sprout operations eligible for the qualified exemption from the Produce Safety Rule are also expected to be in compliance with the applicable modified requirements at this time.

The same compliance dates that apply to all other covered produce apply to sprouts that are not subject to Subpart M but are otherwise subject to the Produce Safety Rule (i.e., soil- or substrate-grown sprouts harvested without their roots).

E. General Sprout Production

This section discusses common production practices for growing, harvesting, packing, packaging and holding of sprouted seeds. Later sections of this guidance describe the requirements of the Produce Safety Rule and provide recommendations for sprout operations in conducting the different steps in sprout production.

Typically, sprout production consists broadly of the steps depicted in Figure 2. Your operation may add to or omit some of these practices (or do them in a different order) depending on a number of factors, including: the type of seeds you sprout; whether the required seed treatment is applied by you, your seed supplier, or both; and the size and resources of your operation.

Figure 2. Typical Sprout Production Processes (Adapted from Ref. 2)

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

III. Personnel Qualifications, Training, and Hygienic Practices

This section will help you understand qualifications and training requirements related to Subpart M and introduces concepts related to health and hygiene.

We provide additional guidance on training and health and hygiene in the draft guidance titled, "Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (Ref. 38), including recommendations to help you:

- Evaluate personnel's assigned duties and identify personnel subject to the qualifications and training requirements;
- Evaluate whether personnel have the necessary qualifications to perform their assigned duties;
- Provide training at frequencies necessary to comply with Produce Safety Rule Requirements;
- Determine how to provide easily understandable training;
- Understand minimum training content for required training;
- Understand additional training for persons who conduct harvest activities;
- Understand training requirements for supervisors and responsible parties;
- Understand requirements for supervision to ensure compliance; and
- Determine required records for training.

Subpart C of the Produce Safety Rule includes requirements for qualifications and training directed at personnel who handle or contact covered produce, including sprouts, or food contact surfaces (FCSs). While § 112.22(a) does not explicitly state that it applies to personnel who contact FCSs, FDA interprets that section to apply to such individuals, in part because such personnel are specifically included in § 112.21 (Ref. 38).

Employees who handle (contact) covered produce or FCSs during covered activities, or who supervise the conduct of such activities, at your operation must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with the Produce Safety Rule (§ 112.21(b)). All personnel who handle covered produce or FCSs, or those who are engaged in the supervision thereof (including temporary, part time, seasonal and contracted) must receive adequate training as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually (§ 112.21(a)). In addition, training must be conducted in a manner that is easily understood by personnel being trained (§ 112.21(c)). For example, if English is not the primary language for personnel in your operation, you should provide training in the language they customarily speak. Training should be provided at the appropriate educational level. Training must be repeated as necessary and appropriate in light of observations or information indicating the personnel are not meeting standards established by FDA in Subparts C through O of the Produce Safety Rule (§ 112.21(d)). For example, if a supervisor observes that an employee is not collecting spent sprout irrigation water in accordance with your written sampling plan, the supervisor must retrain the employee on spent sprout irrigation water sample collection.

To identify which of your personnel, including supervisors, are subject to the qualifications and training requirements, you should review the assigned duties of your personnel, and observe how they perform those duties (i.e., whether they handle or contact covered produce, including sprouts, or FCSs, or are engaged in the supervision thereof). It is important that you consider the breadth of activities at your operation that are covered by the Produce Safety Rule, and how they are performed. This will enable you to identify which personnel contact covered produce or FCSs.

Examples of activities in which personnel likely handle covered produce or FCSs include:

- Applying seed treatment (since the container in which the seeds are treated is an FCS);
- Soaking seeds (since the container in which the seeds are soaked is an FCS);
- Collecting spent sprout irrigation water, in-process sprouts, agricultural water or environmental monitoring samples;
- Placing seeds into the growing unit;
- Harvesting and washing sprouts;
- Packing sprouts;
- Receiving seed and performing a visual inspection for signs of contamination;
- Handling containers used to pack and distribute sprouts or tools and equipment that contact sprouts;
- Cleaning and maintaining equipment and tools that contact sprouts; and

- Performing corrective actions in response to a positive sample finding or outbreak of foodborne illness, for example, recognizing sprouts that may be adulterated or conducting intensified cleaning and sanitizing in response to a contamination event.

Subpart C of the Produce Safety Rule also describes the minimum training requirements for personnel. All personnel who handle or contact covered produce, including sprouts, or FCSs during covered activities or supervise the conduct of such activities must receive training that includes all of the following (§ 112.22(a)):

- Principles of food hygiene and food safety;

- The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or FCSs with microorganisms of public health significance; and

- The standards as established by FDA in Subparts C through O of part 112 that are applicable to the employee's job responsibilities.

Persons who conduct harvest activities for covered produce must receive additional training that includes the following (§ 112.22(b)):

- Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;

- 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

- 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.

For example, harvest personnel must be trained to inspect bins that are used to hold harvested sprouts and to understand the requirement that bins must be cleaned and sanitized prior to contact with sprouts ((§§ 112.22(a)(3), 112.22(b)(2)), 112.143(b)). Harvest personnel should be trained to be aware of actions during harvesting that can lead to contamination of FCSs and covered produce (e.g., stepping on the FCSs of a growing bin to harvest sprouts, or reaching an arm with a visibly soiled sleeve into a rotating drum to harvest sprouts).

In addition, at a minimum, at least one supervisor or responsible party for your sprout operation must have successfully completed food safety training at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA (§ 112.22(c)). Attending training based on the standardized sprout curriculum developed by the Sprouts Safety Alliance (SSA) is one way to meet this requirement. We recommend that at least one supervisor or responsible party take the SSA course to meet the requirement in § 112.22(c). You may use other training programs, provided the training is equivalent to the standardized sprout curriculum. The

standardized sprout curriculum covers fundamental food safety topics as they relate to sprouts and the requirements of the Produce Safety Rule, including an introduction to produce safety, sprouts specific requirements (e.g., spent irrigation water testing and seed treatment), worker health and hygiene, worker training, agricultural water, sanitation and recordkeeping.

You could choose to have more than one supervisor, or other personnel, complete this training. For example, if your sprout operation has several supervisors who are responsible for ensuring that your operations adhere to the requirements of the Produce Safety Rule (see § 112.23), you could charge each of these supervisors with completing the standardized curriculum or equivalent training. We also encourage you to have those who complete the standardized curriculum training (or equivalent) share what they learned with other personnel at your sprout operation.

If you also conduct covered activities on non-sprout covered produce, at least one supervisor or responsible party for your sprout operation must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA for produce other than sprouts (§ 112.22(c)). The Produce Safety Alliance (PSA) developed the standardized curriculum, which covers additional topics relevant to non-sprout produce operations, such as wildlife, domesticated animals, produce handling, and land use. We have recognized the standardized curriculum developed by the PSA as the standardized curriculum referenced in § 112.22(c). If you also conduct activities that are subject to the "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" requirements in 21 CFR part 117, for example, if you conduct manufacturing and processing of food in addition to growing sprouts, additional qualifications and training requirements may apply. See 21 CFR 117.4 for additional information on these requirements.

Subpart D includes the specific requirements for Health and Hygiene, including measures that must be taken to prevent ill workers from contaminating sprouts with microorganisms of public health significance, hygienic practices that must be used, and measures you must take to prevent visitors from contaminating sprouts and FCSs. We provide additional guidance on training, health and hygiene in the guidance titled, "Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (Ref. 38). Training which covers the requirements of Subpart D must be provided to all personnel who handle or contact covered produce, including sprouts, or FCSs, during covered activities or supervise such activities (§ 112.22(a)(3)). Furthermore, § 112.32(a) specifically requires all personnel who work in a sprout operation to use hygienic practices while on duty to the extent necessary to protect against contamination. In a sprout operation, this requirement applies to personnel who handle sprouts, seeds for sprouting or FCSs, including personnel who enter, but may not be assigned to, production or storage areas, such as personnel with shipping, delivery or other duties.

A. Training Conducted to Implement Subpart M

All personnel who handle (contact) covered produce or FCSs, or who supervise those personnel, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with the Produce Safety Rule (see § 112.21(b)). Additionally, all personnel who handle (contact) covered produce or FCSs during covered activities, or who supervise the conduct of such activities, must receive training on food

safety, personal hygiene, and the standards of the Produce Safety Rule (subparts C through O of part 112), as applicable to their job responsibilities (see §112.22).

1. Training and supervision of personnel who conduct cleaning and sanitizing activities

At your sprout operation, employee(s) responsible for cleaning and sanitizing, as well as their supervisors, must receive training on the following topics, as applicable to their job responsibilities:

- Cleaning and sanitizing of FCSs used to grow, harvest, pack, or hold sprouts before contact with sprouts or seeds or beans used to grow sprouts (§ 112.143(b)). The following topics may be required for training, for example:
    - How to properly clean and sanitize (e.g., steps involved, what tools and chemicals are needed, how to prepare chemicals);
    - Considerations unique to individual pieces of equipment (e.g., if disassembly is necessary);
    - How to identify an FCS and the frequency of cleaning and sanitizing for FCS;
    - Activities to verify effectiveness of cleaning and sanitizing; and
    - How employee actions while cleaning and sanitizing equipment (e.g., dragging a hose from the floor across an FCS, or using a high-pressure hose on the floor next to an FCS) can lead to contamination of FCSs and covered produce.
- Maintaining and cleaning all non-FCSs of equipment and tools used during harvesting, packing, and holding of sprouts (§ 112.123(d)(2)). The following topics may be required for training, for example:
    - How to properly clean and maintain non-FCS (e.g., steps involved, what tools and chemicals are needed, how to prepare chemicals);
    - Considerations unique to individual pieces of equipment (e.g., if disassembly is necessary); and
    - How to identify a non-FCS, and frequency of cleaning and maintenance for non-FCS.
- Ensuring equipment and tools are installed and maintained to facilitate cleaning of the equipment and of all adjacent spaces (§ 112.123(b)(1));
- Managing the quality of water used in cleaning and sanitizing activities (§ 112.44(a)(3);
- Performing intensified cleaning and sanitizing in response to suspected or known contamination (§§ 112.146(b) and 112.148(c)); and

- Establishing and maintaining records that relate to cleaning and sanitizing (§§ 112.22(a)(3) and 112.140(b)(1)).

You must assign or identify personnel to supervise (or otherwise be responsible for) your operation to ensure compliance with the requirements of the Produce Safety Rule (§ 112.23), including those related to cleaning and sanitizing. For more information about cleaning and sanitizing, see also Section III (Cleaning and Sanitizing) in the finalized sections (Ref. 18).

2. Training and supervision of personnel who handle seed

At your sprout operation, employee(s) responsible for handling seed, as well as their supervisors, must receive training on the following topics, as applicable to their job responsibilities:

- Preventing contamination in seeds (§ 112.142(a)) (e.g., during storage; while rinsing, soaking or growing; and preventing recontamination of seed that has been treated). The following topic may be required for training, for example:
    - Seed sourcing considerations, for example the conditions that could result in seed becoming contaminated with pathogens prior to it arriving at your operation.
- Seed receiving and performing a visual inspection for signs of contamination (§ 112.142(d));
- Applying seed treatment (§ 112.142(e)(1)) and/or ensuring prior treatment by another entity meets the Produce Safety Rule requirements (§ 112.142(e)(2));
- If applying seed treatment at your sprout operation, personnel must be trained on how to apply seed treatment correctly (e.g., according to the label instructions at appropriate concentrations), how to monitor seed treatment, and materials needed (§ 112.142(e)(1));
- Managing the quality of water used to contact seeds (§ 112.44(a));
- The cleaning and sanitizing requirements for FCS that contact seeds or sprouts (§ 112.143(b));
- Performing corrective actions in response to seed that is known or believed to be contaminated as required under § 112.142 (discontinuing use of seed lot and contacting seed supplier, or treating seed to comply with § 112.142(c)(1)); and
- Establishing and maintaining records that relate to seed, and records related to corrective actions (§§ 112.22(a)(3); 112.150(b)(1) and (b)(6)). The following topic may be required for training, for example:
    - Maintaining the identity of a seed lot during rinses, treatment, and growing.

You must assign or identify personnel to supervise (or otherwise be responsible for) your operation to ensure compliance with the requirements of the Produce Safety Rule (§ 112.23),

including those related to handling seed. For more information about handling seeds for sprouting, see also Section V (Seeds for Sprouting) in the finalized sections (Ref. 18).

3. Training and supervision of personnel who conduct testing of spent sprout irrigation water or sprouts

At your sprout operation, employee(s) responsible for spent sprout irrigation water (or in-process sprouts) testing, as well as their supervisors, must receive training on the following topics, as applicable to their job responsibilities:

- Definition of "production batch of sprouts" (§112.3);
- Implementing the written sampling plan (§ 112.147(a)), specifically how to collect a representative sample (location for collecting a sample, number of samples). The following topic may be required for training, for example:
    - Reviewing and updating the written sampling plan (e.g., after changes to the operation).
- Aseptic sample collection (§ 112.147(b)). The following topics may be required for training, for example:
    - Gathering materials and tools necessary for sample collection;
    - Understanding the sample volume to be collected and timing of sample collection; and
    - Preparing samples for shipment (if conducted by a third-party laboratory).
- Not allowing a production batch of sprouts to enter commerce until test results are received (§ 112.147(b)). The following topic may be required for training, for example:
    - Maintaining the identity of the seed lot and production batch during growing, sample collection, interpreting results, and taking corrective actions.
- Methods to test samples for pathogens (if testing in-house) in compliance with § 112.153;
- Performing corrective actions in response to a positive sample finding (i.e., taking action to prevent adulterated food from entering commerce, discontinuing use of seed, contacting the seed supplier, cleaning and sanitizing the affected areas (§ 112.148)). The following topic may be required for training, for example:
    - Interpreting test results.
- Establishing and maintaining records related to testing spent sprout irrigation water or in-process sprouts, and records related to corrective actions (§§ 112.22(a)(3); 112.150(b)(4) and (b)(6)).

You must assign or identify personnel to supervise (or otherwise be responsible for) your operation to ensure compliance with the requirements of the Produce Safety Rule (§ 112.23), including those related to spent sprout irrigation water or sprouts sampling and testing activities. For more information about spent sprout irrigation water or in-process sprouts testing, see also Section V (Sampling and Testing of Spent Sprout Irrigation Water (or In-Process Sprouts)) in this document.

4. Training and supervision of personnel who conduct environmental monitoring

At your sprout operation, employee(s) responsible for implementing your environmental monitoring plan, as well as their supervisors, must receive training on the following topics, as applicable to their job responsibilities:

- Implementing the environmental monitoring plan (§ 112.145(a)), specifically, the microorganisms for which samples will be tested (Listeria spp. or L. monocytogenes), number and location of sample collection sites, frequency of sample collection, point in production for sample collection. The following topics may be required for training, for example:
    - Reviewing/updating the written sampling plan (e.g., after changes to the operation); and
    - How to identify an FCS and non-FCS, as well as Zone 1, 2, 3 or 4 if you use the zone concept.
- Aseptic sample collection (§ 112.145(d)). The following topics may be required for training, for example:
    - Gathering materials and tools necessary for sample collection;
    - Understanding how to collect a sample (e.g., sponge or swab sampling) and sample sizes to be collected at the various sample collection sites;
    - Understanding how to conduct composite sampling (if applicable); and
    - Preparing samples for shipment (if conducted by a third-party laboratory).
- Methods to test samples for pathogens or indicator organisms (if testing in-house) in compliance with § 112.152;
- Performing corrective actions in response to a positive sample finding (i.e., conducting additional testing of nearby surfaces, cleaning and sanitizing the affected and surrounding areas, conducting additional sampling and testing, conducting finished product testing when appropriate, conducting intensified cleaning and sanitizing if that is part of your corrective actions, and taking action to prevent adulterated food from entering commerce (§ 112.146)). The following topic may be required for training, for example:

  - Interpreting test results.

- Establishing and maintaining records related to testing, and records related to corrective actions (§§ 112.22(a)(3); 112.150(b)(4) and (b)(6)).

You must assign or identify personnel to supervise (or otherwise be responsible for) your operation to ensure compliance with the requirements of the Produce Safety Rule (§ 112.23), including those related to environmental monitoring. For more information about environmental monitoring, see also Section VI (Environmental Monitoring) in the finalized sections (Ref. 18).

IV. Equipment, Tools, and Buildings

Maintaining an environment that promotes the hygienic production of sprouts and minimizes the potential for cross-contamination is essential to food safety. Proper design, size, and construction of buildings 1) help protect against potential sources of external contaminants (e.g., airborne contamination and pests) that may compromise the safety of your sprouts and 2) facilitate maintenance and sanitary operations to minimize the potential for cross-contamination. Proper design, construction, installation, storage and maintenance of equipment and tools is necessary to facilitate their cleaning and sanitizing, as well as to minimize the potential for harborage and growth of pathogens on equipment and tools. Effective pest control and properly constructed and maintained sanitary facilities (e.g., properly functioning toilets, waste systems, and handwashing facilities) will help minimize the introduction and transfer of microbial hazards within your operation.

Subpart L (Equipment, Tools, Buildings, and Sanitation) of the Produce Safety Rule establishes standards to prevent equipment, tools and buildings from contaminating produce, including sprouts. This subpart of the Rule includes requirements for building design and construction, pest control, toilet and hand-washing facilities, plumbing systems, waste management, and design, construction, storage, maintenance, and cleaning of equipment and tools. There are also sprout-specific requirements within Subpart M relating to buildings, tools, and equipment, in § 112.143(a) and (b). The following section provides guidance on these topics for sprout operations, except that the cleaning and sanitizing provisions of Subpart L and Subpart M (§ 112.143(b)) are discussed separately, in Section III (Cleaning and Sanitizing) in the finalized sections (Ref. 18).

A. Requirements for Buildings

You must conduct sprout production (growing, harvesting, packing, and holding) in a fully-enclosed building (§112.143(a)). Such buildings are subject to the requirements of Subpart L (§ 112.122). The activities that must occur in a fully-enclosed building include seed storage and treatment. Storage sheds, buildings, or other structures used to store food contact surfaces (FCSs) (such as harvest containers and food-packing materials) are also subject to the requirements of Subpart L (§112.122(b)). Sprout operations should take particular note of the following:

- Fully-enclosed building means a structure confined with walls and a ceiling, and may have openings such as windows, doors (including warehouse doors), or air intake vents. All covered activities related to sprout production (e.g., seed storage, treatment, growing, and holding of sprouts) must occur within a fully-enclosed building. To ensure your

building is fully-enclosed:

  - Doors should be tight fitting and kept closed when not in use. Weather stripping around the doors should not contain gaps that show entry of light when the door is closed.

  - Windows should be properly fitted and kept closed at all times, unless screened. Air intake vents should be equipped with close-fitting screens or filters. Screens should not be damaged, ripped or torn. Unprotected (e.g., unscreened) openings to the outside should be blocked or repaired.

- Building size, construction, and design must be suitable to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of sprouts or FCSs with known or reasonably foreseeable hazards (§ 112.126(a)(1)). Specifically, your building must provide sufficient space for placement of equipment and storage of materials (§ 112.126(a)(1)(i)). For example, you should ensure enough space is available to allow easy access to equipment, such as sprout growing units, for cleaning, sanitizing and maintenance activities. Sufficient space should exist for employees to perform their job tasks in a way that does not result in contamination of product. For example, spare equipment or food-packing material should not block easy access to facilities that employees need to do their jobs adequately, such as hand washing sinks or sinks used to wash tools and equipment. This situation could result in contamination of food or FCSs.

  - To assess whether a building is suitable in size, you should consider:

    - The types of activities that occur within the building;

    - The volume and frequency of activity within the building;

    - The number, size and placement of equipment and tools used or stored within the building; and

    - The number of people (e.g., personnel, supervisors, contractors, visitors) using the building at any given time.

  - Buildings should have enough space for covered activities to be conducted without contact between non-FCSs and either seeds, sprouts or FCSs; such non-FCSs include the floor, waste or other potential sources of contamination. For example:

    - There should be adequate space to store bins or other equipment that contact sprouts off the floor, particularly for bins that are FCSs and have been cleaned and sanitized;

      There should be sufficient space between sprout growing units to avoid water from cleaning of one growing unit to splash onto sprouts or FCSs of another growing unit; and

There should be enough space available to allow easy access to equipment, such as sprout growing units, for cleaning, sanitizing and maintenance activities.

- The internal surfaces (e.g., ceilings, walls, floors) of buildings and the surfaces of fittings (including cooling units, light fixtures), even if non-FCSs, should be durable, nonabsorbent, and easily cleanable, to the extent necessary to minimize the potential for contamination of sprouts and FCSs, giving consideration to the way in which these surfaces will be cleaned (e.g., wet cleaning, dry cleaning, see Section III (Cleaning and Sanitizing) in the finalized sections (Ref. 18)). Any cracks or damage to ceilings, walls, and floors should be repaired to facilitate cleaning of those surfaces and to minimize the potential for harborage of environmental pathogens. For example:
    - The use of wood, sheetrock, and other absorbent materials should be minimized, even for non-FCSs, if these surfaces cannot be adequately maintained for their intended use, or if use of these materials will interfere with appropriate cleaning and, when necessary and appropriate, sanitizing, so that they do not become a source of contamination for sprouts or FCSs. For example, we do not recommend the floors, walls or ceilings be made of wood or sheetrock in a wet environment, such as the sprout germinating and growing room;
    - Where catwalks are installed over sprouts, FCSs or seeds for sprouting, they should be constructed of solid surface materials with kick plates, they should have catch trays installed beneath them, or the product should be protected from drippage by covers or other barriers. Personnel should not walk above unprotected product and FCSs;
    - If you have a drop ceiling in a fully-enclosed building, the building should be constructed in a way that allows access to the space between the roof and the drop ceiling for maintenance and sanitary operations, such as pest control activities; and
    - Air intakes should be designed to be adequately maintained and cleaned, and not be located near potential sources of contamination.

- 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 (§ 112.126(a)(1)(ii)). For example:
    - The following areas should be separated from each other unless the potential for cross-contamination between them has been otherwise adequately addressed: 1) seed receiving and storage; 2) seed treatment; 3) seed soaking, sprout germination, and growing; 4) sprout packing, packaging, cooling, and storage; and 5) microbiological analysis (i.e., for samples analyzed at an in-house

laboratory) (Ref. 39);

  - You should consider providing designated areas and/or separate rooms in your building(s) for employees to take breaks. Providing such areas or rooms helps ensure that personnel comply with requirements that they use hygienic practices while on duty (e.g., not eating, chewing gum, or using tobacco products in an area used for a covered activity (§§ 112.32(a) and (b)(6))).

- 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 (§ 112.126(a)(2)). For example:

  - Any rooms where activities involving water, such as cleaning and sanitizing, are conducted should be appropriately drained and graded, e.g., cold storage rooms, seed treatment areas, seed soaking, sprout germinating and growing rooms, bathrooms, and post-harvest washing areas;

  - Such floors should be sloped towards trapped drains with covers to minimize the accumulation of standing water. The presence of low spots, where water may pool, should be minimized. Stagnant water accumulated on floors can harbor pathogens, especially Listeria monocytogenes (Ref. 40). Minimizing the accumulation of standing water is particularly important for sprout operations where large quantities of water are used during production.

- You must implement measures to prevent contamination of sprouts and FCSs in your buildings, as appropriate, considering the potential for such contamination through floors, walls, ceilings, fixtures, ducts, or pipes; and drip or condensate (§ 112.126(b)). For example:

  - You should keep buildings (e.g., roofs, walls) in good repair in order to prevent leakage of rainwater into production areas, which can bring with it contaminants from outside the building;

  - You must handle harvested sprouts in a manner that protects against contamination with known or reasonably foreseeable hazards (§ 112.113). For example, you should avoid contact between sprouts and the floor (or other potentially contaminated surfaces) during harvest. You should not distribute for human consumption any sprouts that have dropped to the floor, as the floor can serve as a source of contaminants such as Listeria monocytogenes. As another example, if harvested sprouts are placed in perforated containers, you should handle these containers in a way that minimizes the potential for contamination of the sprouts, such as placing them on clean pallets, off the floor;

  - You should consider whether the occurrence of drip or condensate in your sprout production building presents a potential for contamination of your sprouts or FCSs and take measures to minimize or prevent that potential from occurring. Such measures include:

- Installing and maintaining fixtures, ducts, pipes, and overhead structures to prevent or minimize drips and condensate onto product, seed for sprouting, or FCSs, and adequately and regularly cleaning these fixtures;

- Utilizing refrigeration drip pans so that water is drained and disposed of away from sprouts and FCSs;

- Monitoring sprout germinating and growing rooms, cold rooms used to cool or hold finished sprouts, and other rooms susceptible to accumulation of condensate, for drips and condensate (e.g., from the ceiling over exposed sprouts), taking appropriate steps to protect the product when drips or condensate are found, and taking corrective action to ensure that any contaminated sprouts are not distributed; and

- If condensation is a problem that you cannot otherwise correct in your sprout operation, you might consider installing drip guards to collect and/or divert condensate that might otherwise contact sprouts, seeds for sprouting or FCSs.

B. Pest Control

You must take those measures reasonably necessary to protect covered produce, FCSs, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate (§ 112.128(a)). Further, for fully-enclosed buildings, you must take measures to exclude pests from your buildings (§ 112.128(b)).

You are required to conduct all covered activities related to sprout production within a fully-enclosed building (see section above on §§ 112.143(a)) and 112.122 on fully-enclosed buildings). Conducting your sprout operation within a fully-enclosed building helps ensure that pests are excluded.

- As part of a pest control program, you should:

    - Inspect for and remove any potential harborage sites and food or water sources (e.g., spilled seed);

    - Inspect for potential entry points for pests. You should look for unprotected openings through doors or windows as well as elsewhere around the perimeter of your buildings, through which rodents, birds, insects and other pests can enter. You should take measures to close any unprotected openings;

    - Implement procedures on a routine schedule to eliminate the presence of pests (e.g., setting traps) and/or work with a private company specializing in pest control; and

    - Routinely monitor storage areas (e.g., storage of seeds, packaging materials, tools, and equipment), sprout production areas, waste storage areas, and packing and holding areas for evidence of pests and other signs of vermin activity that could

lead to contamination of sprouts (e.g., stains, insects, feces (e.g., rodent pellets), urine, or foreign material). You should consider using a black light to examine for signs of rodent urine as part of routine monitoring.

In addition, you must properly store and maintain equipment and tools to prevent them from attracting and harboring pests (see discussion below on storage of equipment and tools) (§112.123(b)(2)).

C. Toilet and Hand-Washing Facilities

You must provide personnel with adequate, readily-accessible toilet facilities that are designed, located, and maintained to prevent contamination of sprouts, FCSs, and areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with human waste (§§ 112.129(a) and (b)(1)). Toilet facilities must be directly accessible for servicing, must be serviced and cleaned at a frequency sufficient to ensure suitability of use, must be kept supplied with toilet paper, and must provide for the sanitary disposal of waste and toilet paper (§§ 112.129(b)(2) and (3)).

You are required to grow, harvest, pack, and hold sprouts in a fully-enclosed building (§ 112.143(a)), and such buildings are subject to Subpart L, including the requirement in § 112.129.

- Portable toilets may be used, provided they meet all applicable requirements. You should consider their location with respect to meeting relevant requirements for accessibility for servicing (§ 112.129(b)(2)) and being readily accessible to personnel when they are conducting covered activities (§112.129(a)). Service vehicles should be able to enter your property and maneuver as close as necessary to the portable toilet to service the unit, to prevent spillage of sewage during servicing;

- Toilets must not leak onto the floor because, for example, personnel movement can result in transfer of contaminants to production areas of your operation. Clogged, leaking, or broken toilets should be repaired immediately (see §§ 112.129(b)(3) and 112.131(c));

- You must provide a hand-washing station that is in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands (§ 112.129(c)). Toilet use provides a direct means for hands to become contaminated with pathogens. Hand-washing after toilet use protects against the transfer of pathogens from hands to sprouts, seeds for sprouting, and FCSs;

- Hand-washing stations must also be adequate and readily accessible to workers during sprout growing, harvesting, packing, and holding (§ 112.130(a)). Hand-washing stations should be strategically located within your operation to facilitate their use at key times for employees, such as when they enter sprout production and packaging areas, after their breaks, when their hands become soiled after contact with insanitary objects, and after bathroom use;

- Your hand-washing facilities must be furnished with: soap (or other effective surfactant); running water that satisfies the requirements of § 112.44(a) for water used to wash hands;

and adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers) (§112.130(b));

- 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 handwashing facility from contaminating covered produce, FCSs, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards (§ 112.130(c)); and

- You must not use antiseptic hand rubs (i.e., hand sanitizers) as a substitute for soap (or other effective surfactant) and water (§ 112.130(d)). Antiseptic hand rubs may be used after proper hand-washing and drying in accordance with §112.32(b)(3), as the antiseptic hand rub can serve as an additional measure in reducing the number of bacteria on hands relatively free of grease, soil, and other material.

D. Plumbing Systems

Your plumbing system must be of an adequate size and design and be adequately installed and maintained to 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 (§ 112.133(a)). Inadequate water pressure and volume could impact your ability to perform your operations in a sanitary manner. For example, low water pressure could compromise your ability to properly clean your FCSs or to provide water to multiple handwashing facilities at the same time. You should evaluate the adequacy of your plumbing systems, considering such factors as volume and frequency of water use.

In addition, the plumbing must be of an adequate size and design and be adequately installed and maintained to properly convey sewage and liquid disposable waste and avoid being a source of contamination to covered produce, FCSs, areas used for a covered activity, or agricultural water sources (§§ 112.133(b) and (c)). You should establish procedures on how to inspect your plumbing system periodically and identify any conditions that could result in it becoming a source of contamination. Your procedures should include the frequency of these inspections, the personnel involved, and those conditions that should be reported to you, a supervisor, or other responsible party for corrective action. If you observe the potential for contamination, you should take appropriate measures to prevent the plumbing from becoming a source of contamination, as soon as possible. For example, you could remove dead-end piping when it is detected or periodically flush these lines to remove any residue.

The plumbing system must not allow backflow from, or cross-connections between, piping systems that discharge waste water or sewage and piping systems that carry water used for sprout production, for sanitary operations or for use in hand-washing facilities (§ 112.133(d)). A cross-connection is a connection between a water source or distribution pipe (e.g., drinking water, water used for hand-washing, water used for cooling sprouts) and a liquid waste pipe (e.g., sink drain, sewage line, floor drain line). Unless adequate backflow prevention is implemented (e.g., air gap, installation/maintenance of an adequate backflow prevention device), a cross-connection can result in backflow, the undesirable reversal of the flow against the normal waterline pressure (e.g.,

from a sewage line to the water line supplying a hand-washing station). To avoid such conditions, you should, for example:

- Inspect all water supply piping to determine where appropriate backflow prevention devices are needed, whether they have been installed, and if absent, install such devices. The appropriate device for any cross-connections in your operation is dependent on your plumbing system, how the water is used, and the level of risk associated with contamination;

- Use hoses in a manner that prevents backflow. Hoses that are connected to water lines under pressure could become sources of contamination to the water supply if an unintentional, temporary cross-connection is created. For example, if you leave an open-ended hose on the floor in pooled water or submerged in a tank of water, backflow can occur if a pressure differential develops, reversing the flow of water in the hose. This backflow could result in contamination of the water supply. Hoses should be stored off the floor on a designated holder and should have an adequate backflow prevention device installed upstream; and

- We recommend that you refer to the U.S. Environmental Protection Agency's (EPA's) Cross-Connection Control Manual regarding situations that may lead to contamination through cross-connections and backflow, and the devices and procedures you can use to prevent such contamination (Ref. 41).

E. Sewage and Waste Management

You must dispose of sewage into an adequate sewage or septic system, or through other adequate means (§ 112.131(a)). You must maintain sewage and septic systems in a manner that prevents contamination of sprouts, FCSs, areas used for a covered activity, agricultural water sources and agricultural water distribution systems with known or reasonably foreseeable hazards (§ 112.131(b)). For example:

- Your sewage system, including a system that services portable toilets, should securely contain or securely transport sewage and liquid waste away from locations where you conduct covered activities; and

- If you use a septic system, the tank should be properly sealed, in good working order, and free from damage. The inlet and outlet plumbing also should be in good working order and free from damage, and the drain field should be properly functioning, with no visible leakage at the surface.

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 FCSs, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems. (§ 112.131(c)).

In the event of a sewage spill or leak, you should contact your local public health or waste management authorities for assistance in complying with their regulations for sewage disposal. Management of a human waste spill or leak should include:

- Containing the spill or leak;
- Preventing your personnel from entering the affected area;
- Evaluating any potential impacts to covered produce, FCSs, covered activity areas, or agricultural water sources or distribution systems;
- Removing and disposing of the spill or leakage contents;
- Disposing of any contaminated sprouts;
- Cleaning and sanitizing any contaminated FCSs; and
- Repairing or replacing any faulty sewage system components.

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, FCSs, areas used for a covered activity, agricultural water sources or agricultural water systems (§ 112.131(d)).

You must convey, store, and dispose of trash, litter and waste in a way that minimizes the potential for trash, litter, or waste to attract or harbor pests and protects against contamination of sprouts, FCSs, areas used for sprout production, agricultural water sources, and agricultural water distribution systems (§ 112.132(a)). For example:

- Waste should be carried out of, but not through, sprout production areas to minimize the risk of contamination of sprouts and FCSs. Your operation should be arranged so that waste from other areas is not conveyed through sprout growing/production areas;
- We recommend that waste containers be kept closed with tight fitting lids to minimize the attraction of pests. In addition, waste containers should be routinely monitored and emptied, and storage areas for waste should be monitored for pests as part of your pest control program; and
- Storage of waste should be in areas that are easily accessible, but at the same time will not serve as a source of contamination for workers, production areas, seeds and sprouts, and FCSs.

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 (§ 112.132(b)). You should establish frequencies to collect waste (including sprouts that drop on the floor during harvesting or packing activities). You should be aware of containers, equipment and personnel involved in transferring waste from sprout production areas to waste storage and treatment areas and implement practices to prevent contamination of sprouts, seeds for sprouting and food contact

surfaces by these objects and personnel. You should maintain outdoor waste storage containers, such as dumpsters, and areas near these containers to minimize the potential for their serving as a source of contamination.

If you treat plant-based biological material (e.g., waste sprouts) by composting prior to disposal, you should do so in a manner that minimizes contamination of sprouts, seeds, and FCSs and does not attract pests (e.g., consider the placement of the compost pile and the process of aerating the pile and checking temperatures). If you use such biological material in the production of soil-grown sprouts or non-sprout produce, you must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards (see § 112.11). If your compost that is used in the production of sprouts or other covered produce includes materials of animal origin, it is considered a biological soil amendment of animal origins (BSAAO) and the requirements of Subpart F apply.

F. Equipment and Tools

Equipment and tools subject to the requirements of Subpart L 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 of equipment include growing units, irrigation systems, cooling equipment, equipment used to store or convey harvested sprouts (such as containers, bins, food-packing material), wash tanks, balances, packing tables, forklifts, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce (§ 112.121). Further examples of tools used at a sprout operation include harvesting rakes, shovels, thermometers, or instruments to measure sanitizer concentration.

You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained (§ 112.123(a). Seams on FCSs 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 (§112.123(c)).

- Areas that commonly need attention in a sprout operation are cracked or worn belts and conveyors, chipped or cracked guards, and cracked, chipped or worn equipment, including growing units. You should properly repair (e.g., such that it can be adequately cleaned) or replace tools or equipment that is rusted, pitted, or otherwise damaged;

- Inaccessible or hard-to-clean components of equipment may provide harborage sites for pathogens that can lead to contamination of your sprouts. You should evaluate equipment to identify any areas that may be inaccessible or hard-to-clean. If any such areas are identified, you should evaluate the potential risk associated with the areas that are inaccessible for cleaning and sanitizing, and consider:

    - Moving the equipment to a new location that allows easier access;

    - Purchasing cleaning tools and products to facilitate access to those hard-to-clean areas (e.g., extendable brushes);

- Reassembling equipment in a new layout that facilitates access for cleaning and sanitizing; and

- Replacing that equipment entirely.

You must install, store, and maintain equipment and tools in a way that will facilitate cleaning of the equipment and all adjacent spaces, protect against contamination, and prevent attraction and harborage of pests (§ 112.123(b)). For example:

- When installing equipment, you should elevate growing units (e.g., trays) or other containers used to hold sprouts (e.g., dewatering centrifuge) off the floor at a sufficient height to ensure that splash off the floor (e.g., from production, cleaning) does not contaminate the sprouts or FCSs of the equipment;

- Equipment should not be installed or stored so close to a wall that employees cannot clean the equipment and the wall, perform environmental monitoring between the equipment and the wall, or monitor for pests between the equipment and the wall;

- All sprout production equipment and tools must be stored within a fully-enclosed building, even when not in use (e.g., long-term storage);

- You should consider the storage of tools and equipment (such as shovels, stackable bins, and perforated spinning baskets) with respect to potential routes of contamination, such as splash from the floor or overhead condensate. For example, you might use wall mounted racks or clean pallets for short-term storage (e.g., during employee break times), especially in areas where water accumulates, to ensure that FCSs of tools and equipment do not contact the floor;

- Pest harborage in stored equipment can lead to contamination of FCSs and give pests ready access to sprout production areas and exposed product. You should thoroughly clean and dry any equipment before storage and remove any pieces of food or other organic material to minimize attraction of pests. You should also ensure storage areas for equipment are covered as part of your pest control program (e.g., monitored for pests). See section IV.B. (Pest Control) for more information.

If you use equipment such as pallets, forklifts, tractors, and vehicles, such that they are intended to, or likely to, contact sprouts, you must do so in a manner that minimizes the potential for contamination of sprouts or FCSs with known or reasonably foreseeable hazards (§ 112.123(e)).

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 accurate and precise as necessary and appropriate in keeping with their purpose; adequately maintained; and adequate in number for their designated uses (§ 112.124). Examples of such instruments in a sprout operation include thermometers (e.g., to record the temperature of sprouts, cold storage rooms) and meters for measuring pH or sanitizer concentration (e.g., to monitor seed treatment or sanitizer efficacy).

You should follow the manufacturer's instructions on proper care, calibration, and maintenance of these instruments to ensure the instrument is providing accurate and precise readings.

Sprouts are usually manually placed into containers, including in the process of both "packing" and "packaging." Typically, finished sprouts are placed into finished product containers at the sprout growing operation, but occasionally may be transported in bulk to another location. To minimize the risk that such containers will serve as a source of contamination:

- 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 (§ 112.116(a));

- If you reuse food-packing material (e.g., for bulk delivery of sprouts), you must take adequate steps to ensure that FCSs are clean and sanitized (§§ 112.116(b) and 112.143(b));

- Equipment and tools, including food-packing material, must be stored and maintained to protect sprouts from being contaminated with known or reasonably foreseeable hazards and to prevent those materials from attracting and harboring pests (§ 112.123(b)(2)). For example, food-packing materials should be stored in a clean, dry area, separate from seeds used for sprouting; and

- When you store finished sprouts, you should arrange product to allow good air circulation and rapid cooling. Because sprouts are still respiring, they can generate heat, even in a cold room. Hot spots can facilitate the growth of any pathogens present in the sprouts. Small containers and good air circulation help prevent "hot spots" in a batch of sprouts that may result due to heat generated by the still-living sprouts. Vehicles/equipment that you use to transport sprouts must be adequately clean before use and adequate for use in transporting sprouts to minimize the risk that vehicles/equipment used during transportation become a potential source of contamination (§ 112.125)

You should maintain the cold chain as much as possible when staging product to prepare for loading to delivery trucks. State and local regulations may require temperature control upon receipt by a retail establishment for the safety of the sprouts.

V. Sampling and Testing of Spent Sprout Irrigation Water (or In-Process Sprouts)

Microbial testing of spent sprout irrigation water (or in-process sprouts) is an important part of a multi-hurdle approach to ensure contaminated sprouts do not enter the marketplace. Section 112.144(b) requires that you either test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7 and *Salmonella* species and any pathogens meeting the criteria in § 112.144(c) or, if testing spent sprout irrigation water is not practicable (for example, soil-grown sprouts harvested with roots or 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).

Section 112.144(c) requires testing of other pathogens in addition to *E. coli* O157:H7 and *Salmonella* species 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 the 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). We intend to issue additional guidance to inform you if both conditions are met for a particular pathogen such that testing would be required (80 FR 74353 at 74504, comment/response 375).

In this section of the guidance we provide recommendations to help you comply with the requirements related to sampling and testing spent sprout irrigation water (or in-process sprouts), including developing a sampling plan (§ 112.147), collecting and shipping samples (§ 112.147(b)), preventing a production batch of sprouts from entering commerce while the results of the testing are pending (§ 112.147(b)), choosing a test method (§§ 112.147(b) and 112.153), interpreting test results, choosing a laboratory, and developing a corrective action plan and implementing corrective actions (§ 112.147(c)). Section III (Personnel Qualifications, Training, and Hygienic Practices) of this guidance above also provides recommendation to help you comply with the requirements on training and supervision of personnel who conduct testing of spent sprout irrigation water (or in-process sprouts) (§ 112.21(b)). We also discuss additional voluntary testing you may choose to conduct.

A. Developing a Sampling Plan

Section 112.147(a) requires that you establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or in-process 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. In addition, § 112.147(b) requires that, in accordance with your written sampling plan, you aseptically collect samples of spent sprout irrigation water or sprouts and test the collected samples for pathogens using a method set forth in § 112.153. You must not allow the production batch of sprouts to enter 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). Also, § 112.147(c) requires that your written sampling plan include a corrective action plan that at a minimum, describes the actions you are required to take under § 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).

The written sampling plan must:

- Specify whether you are testing spent sprout irrigation water or, alternatively, in-process sprouts (i.e., while the sprouts are still growing). For example, we recognize testing spent sprout irrigation water may not be practicable for soil-grown sprouts harvested with roots and for hydroponically grown sprouts that use very little water;

- Specify the location(s) in your sprout operation where samples are to be collected (§ 112.147(a)). If your sample collection location differs, for example, depending on the type of growing unit or irrigation practices used, you should describe any such

differences. You may find it useful to include a diagram of the different growing units at your operation, and indicate the points of sample collection in the diagram;

- Specify the number of samples of spent sprout irrigation water (or in-process sprouts) to be collected from each production batch of sprouts (§ 112.147(a)); and

- Include a corrective action plan, as required by § 112.147(c), which describes the specific corrective actions you must take in response to a positive test result (§112.148) and provides details of how and when you will accomplish those actions. You should reference or include your cleaning and sanitizing policies and procedures in your corrective action plan to describe how you will accomplish the required cleaning and sanitizing corrective actions (§ 112.148 (c)).

While not required by the Produce Safety Rule, we further recommend that the written sampling plan:

- Specify that the collected samples are to be tested for *Salmonella* spp. and *E. coli* O157:H7 (as well any other pathogens, if applicable, in accordance with § 112.144(c));

- Identify the specific test method by which collected samples will be tested for relevant pathogens. (You are required to use a scientifically valid method that conforms to the requirements in § 112.153);

- Indicate the person(s) (name or title) in your sprout operation (or contracted personnel, including from a laboratory) who is (are) responsible for sample collection, as well as any specific training and/or qualifications that the sample collector(s) should possess (see discussion on § 112.22(a)(3) in Section III. A. 3 (Training and Supervision of Personnel Who Conduct Testing of Spent Sprout Irrigation Water or Sprouts));

- Indicate the timing during the growth cycle of sprouts when samples of spent sprout irrigation water (or in-process sprouts) are to be collected and any differences in sampling time for specific sprout types or growing practices;

- Indicate the volume of spent sprout irrigation water (or in-process sprouts) to be collected for each sample;

- Specify that samples must be collected aseptically (§ 112.147(b)). The sampling plan should also describe your procedure(s) for aseptic collection of spent sprout irrigation water or in-process sprout samples (see Appendix 1 (Aseptic Sampling) in the finalized sections (Ref. 18));

- Include information about sampling tools and materials necessary for aseptic sample collection following your procedures, as well as any other instructions necessary to ensure that samples adequately represent each production batch of sprouts;

- Indicate your procedures for delivering or shipping collected samples to the testing laboratory (and if applicable, how to schedule sample pick-up), including identifying the

specific laboratory(ies) that you use (e.g., name, address, contact information), any forms that should be completed, sample labeling procedures, and storage and transport considerations (e.g., holding samples at 4°C);

- Specify that the production batch of sprouts must not enter into commerce until results of the testing are obtained and those results are negative for *E. coli* O157:H7 and *Salmonella* spp. (as well as, if applicable, any other pathogens in accordance with § 112.144(c)), as required by § 112.147(b). The sampling plan should also describe your specific procedure(s) for ensuring that § 112.147(b) is satisfied for each production batch of sprouts;

- Indicate the person(s) (name or title) in your sprout operation who is (are) responsible for implementing the corrective action plan in response to a positive test result; and

- Indicate any additional considerations for spent sprout irrigation (or in-process sprouts) sampling and testing appropriate for your operation (e.g., growing unit type, irrigation practices, and sprouting cycle).

You should develop your written sampling plan taking into account the specific growing and irrigation practices at your operation. For example, you should note any differences in your sampling practices based on the type of sprouts, growing unit or irrigation practices, as applicable. We recommend that you periodically review your written sampling plan, particularly in light of any changes in production practices or conditions that may impact your sample collection procedures.

B. Collecting and Shipping Samples

1. Preparing for sample collection

You should assess the configuration of your growing units, their water outlets, and product distribution and placement within the growing units to determine how to collect a sample that adequately represents the production batch of sprouts. Your assessment may lead you to make changes to your sprout production area, for example relocating growing units to provide ready access for representative sampling.

Sample collection may be performed by employees or contracted personnel. Samples must be collected aseptically, in accordance with § 112.147(b), and, therefore, training in aseptic techniques is recommended for the sample collector(s) (see discussion on § 112.22(a)(3) in Section III. A. 3 (Training and Supervision of Personnel Who Conduct Testing of Spent Sprout Irrigation Water or Sprouts).

The following materials and practices are recommended for aseptic sampling of spent sprout irrigation water or in-process sprouts:

- Sterile sample containers, labeled with relevant information, including the production batch number and name of your sprouting operation:

  - For spent sprout irrigation water samples, sterile containers (e.g., sterile plastic cups intended for sample collection) should be used. We note that bags can leak or spill liquid samples;

  - For in-process sprout samples, individual containers (e.g., cups or bags) should be used for each subsample;

- Sterile sampling equipment (e.g., tongs);

- Single-use gloves;

- Cleaning and sanitizing of the countertop or other work surface used for holding the sampling supplies and packaging the sample;

- Clean cooler and ice packs dedicated to sample storage;

- A neutralizing agent (if collecting samples of spent sprout irrigation water that is chlorinated, see discussion below); and

- Preparation of appropriate forms or records that include information about the samples being collected (i.e., spent sprout irrigation water or in-process sprouts), production batch number, date and time of collection, person collecting the sample etc. (Although not required by the Produce Safety Rule, we recommend preparation of such forms to effectively manage and document your spent irrigation water and sprout testing activities.)

If you use chlorinated water for irrigation, there is likely to be residual chlorine in the spent sprout irrigation water. Residual free chlorine in a water sample can inactivate pathogens that may be present (Ref. 42 and Ref. 43) and therefore impact your ability to detect pathogens in spent sprout irrigation water if they are present. If there could be any detectable residual chlorine in your spent sprout irrigation water, you should add an appropriate amount of neutralizing agent to the sampling bottle prior to collecting the sample to neutralize the residual chlorine's effect on the test results. For example, if you use chlorinated irrigation water from a municipal water source and choose not to test for residual free chlorine in the municipal water or spent sprout irrigation water, you should add a neutralizing agent (e.g., 100 mg sodium thiosulphate per L of spent sprout irrigation water) to the sampling bottle. However, the method of neutralizing the treatment may be different depending on treatments applied.

Using appropriate materials and equipment is particularly important to ensure that the sample is collected aseptically, as required by § 112.147(b). You must use sterile equipment and tools to collect samples aseptically. Cleaning and sanitizing are not equivalent to sterilization (See Appendix 1 on Aseptic Sampling in the finalized sections (Ref. 18)).

2. Collecting the sample

If samples are collected improperly or in a manner such that they are not representative, or if the samples are mishandled (e.g., during storage or transport), then the test results may not accurately

reflect the potential for contamination in the related production batch of sprouts. Therefore, it is important to establish appropriate sample collection procedures and implement them uniformly.

a. Identifying the production batch of sprouts

Section 112.144(b) requires you to sample and test spent sprout irrigation water (or sprouts) from each "production batch of sprouts". A production batch of sprouts is defined 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 in a single growing unit)" (§ 112.3). We note that this definition links a production batch of sprouts to a single growing unit, not a single irrigation line. This 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. As another example, when a rack of connected trays is used to grow sprouts that are started at the same time in such a way that exposes some sprouts 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 times, they would be two different production batches of sprouts in that single growing unit, for which two samples and tests (one from each production batch of sprouts) would be required. As another example, sprouts in two separate growing units (e.g., drums) of sprouts would be separate 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.

You must not pool samples from multiple growing units for purposes of testing spent sprout irrigation water (or in-process sprouts). "Pooling" in this context refers to the practice of combining samples from multiple growing units to create one sample for testing. You must separately sample and test each production batch of sprouts (§ 112.144(b)).

If you start growing sprouts in one growing unit and then transfer them to different growing units during sprouting, thereby increasing the number of growing units, you should collect your samples (of spent sprout irrigation water, or in-process sprouts) from the growing unit(s) where the sprouts are held at your predetermined time of sample collection (see Section V. B. 2. d below (When to Collect the Sample)). In this scenario, the production batches should be determined based on the growing unit(s) that contain the sprouts at the pre-determined time of sample collection. For example, if alfalfa sprouts started together in growing unit A are transferred to growing units B and C after 36 hours of sprouting, and your predetermined sampling time is 48 hours into sprouting, sample collection should occur from growing units B and C since that is where the sprouts will be contained at 48 hours after the start of sprouting, and you should sample and test growing units B and C separately, as two separate production batches. On the other hand, if your predetermined sampling time is 24 hours after the start of sprouting, sample collection should occur from growing unit A, and you should treat the sprouts in growing units B and C as a single production batch. In some cases, collecting a representative sample of spent sprout irrigation water may be more challenging after the transfer (e.g., collecting necessary volume), which may lead you to adjust your production practices (e.g., delaying transfer).

A production batch of sprouts does not usually correlate with a lot of seeds. It is typical for a single seed lot to be used to produce multiple production batches of sprouts. In addition, it is also common for multiple seed lots to be mixed to produce a single production batch of sprouts.

Seed lot numbers are typically assigned by seed suppliers. The seed lot number may appear on seed packages, or on seed shipment records. The seed lot number allows both the seed supplier and you to track seeds. Although not required by the Produce Safety Rule we recommend that you keep sufficient records to connect your test results and corrective actions to specific seed lots whenever possible. In addition, FDA published a rule to establish additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List. The rule will affect some sprout operations. For further information, see "Food Traceability List" at https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list.

b. Collecting a representative sample

Section 112.147 requires that you establish and implement a written sampling plan to ensure that the collected samples are representative of the production batch when testing for contamination.

Collecting samples that are "representative," in the context of microbiological testing, means that the samples, to the extent possible, accurately reflect the potential for contamination in the entire production batch of sprouts.

Sprout operations use different types of growing units. Some examples of typical growing units include rotating drums, bins, and racks of trays. In terms of potential for contamination, we consider that there are two categories of growing units, "stationary" and "mixed". The first category ("stationary") are those growing units that do not mix, or agitate, sprouts during growing (e.g., bins and racks of trays). We expect these types of growing units to produce sprouts that are less homogenous with regard to contamination, meaning that they are somewhat more likely to keep contamination of the production batch of sprouts, if it occurs, localized to particular area(s) of the growing unit (i.e., "contamination hot spots") (Ref. 30). The other category ("mixed") are those growing units that mix sprouts during growing (e.g., rotary drums). We expect the sprouts from this type of growing unit to be more homogenous with respect to contamination (i.e., "contamination hot spots" are less likely, and contamination, if it occurs, is more likely to be widespread throughout the production batch of sprouts) due to the mixing that occurs during growing (Ref. 30). For these reasons, collecting a representative spent sprout irrigation water sample can be more challenging from stationary growing units (particularly those with multiple drain points) than from mixed growing units. For a stationary growing unit, you may need to take multiple subsamples from various locations (e.g., drains for spent sprout irrigation water) in the growing unit for the sample to be representative.

The effectiveness of spent sprout irrigation water (or in-process sprouts) testing depends on having a sample that represents the entire production batch. For example, if you are testing the sprouts themselves, this means collecting subsamples from different physical locations across the production batch. When you are testing spent sprout irrigation water, the greater the degree to which the sample is taken from spent irrigation water that has covered (i.e., passed over,

interacted with) the entire batch of sprouts, the more representative the sample. To come as close as possible to achieving complete coverage (i.e., 100% representative of the production batch), you may need to increase the number of subsamples you collect.

A 2018 quantitative risk assessment conducted by the FDA (Ref. 44) describes the importance of collecting a representative sample. The researchers assessed the risk of salmonellosis associated with the consumption of alfalfa sprouts and evaluated the public health impact of seed treatment and spent sprout irrigation water testing for *Salmonella* cells during production. Given the model parameters, data, and assumptions, if there were not any interventions, the assessment estimates that there would be 76,000 (95% confidence interval (CI) 15,400-248,000) cases of salmonellosis every year tied to the consumption of contaminated sprouts.

The risk assessment looked at the impact of mitigation strategies, such as spent sprout irrigation water testing, on the predicted numbers of cases of salmonellosis. The predicted effectiveness of testing was highly influenced by the degree to which the sampled spent sprout irrigation water covered the production batch. For example, FDA researchers estimated that if the coverage was complete (100% representative of the production batch), spent sprout irrigation water testing would detect 86% of the contaminated production batches, assuming that spent sprout irrigation water from every production batch was sampled for testing. By contrast, if the sampled spent sprout irrigation water contacted 20% of the production batch, FDA researchers estimated that only 43% of the contaminated batches would be detected.

It is important to recognize that even with proper spent sprout irrigation water testing (100% coverage), you may miss 14% of the contaminated production batches of sprouts. Because only a proportion of the cells present in a contaminated production batch of sprouts are transferred to irrigation water during sampling and only 1.5 liters is tested, it is possible that spent sprout irrigation water testing will not detect all the contaminated production batches (Ref. 44). Nonetheless, we consider microbial testing of spent sprout irrigation water to be a critical part of the multi-hurdle approach, combined with seed treatment, to ensure contaminated sprouts do not enter the marketplace.

Among the interventions the researchers evaluated, the model predicted to have the greatest public health impact was a 5-log seed treatment combined with spent sprout irrigation water testing with 100% coverage. Together, they would result in an estimated 99.9994% reduction in the number of salmonellosis cases per year – essentially 1 case every two to three years (0.45 (95% CI 0.10-1.5)) (see Section V.B (Seed Treatment) of the finalized sections (Ref. 18)).

Below, we discuss certain growing conditions and irrigation practices, their potential impact on the representativeness of a sample, and recommendations for obtaining a representative sample.

c. What to sample

You must collect a sample of spent sprout irrigation water or sprouts from each production batch of sprouts (§ 112.144(b)). Only when testing spent sprout irrigation water is not practicable, for example, with soil-grown sprouts harvested with roots or hydroponically grown sprouts that use very little water, are you permitted to instead test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) (§ 112.144(b)(2)). This does not prevent you

from performing additional voluntary testing (e.g., testing finished product sprouts for specific pathogens) in addition to the sampling and testing required by § 112.144(b).

d. When to collect the sample

The optimal time for sample collection is when pathogen levels are likely to be at their highest, to maximize the likelihood of detecting pathogens if they are present. The optimal time for sample collection may vary depending on the type of sprouts you produce, and on your sprouting practices.

Current research indicates that 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 (Ref. 45). However, if you are sprouting seeds that have a longer growth cycle compared to alfalfa sprouts, it may take longer for the germinating seeds to reach the conditions that will encourage the growth of pathogens, if present. Optimal timing of sample collection may be sooner than 48 hours for sprouts that have a shorter growth cycle compared to alfalfa sprouts.

Based on the available science, as a general matter we recommend that you collect samples as close to 48 hours from the start of sprouting as practicable, even if that is towards the end of the growing cycle. If you conduct a pre-germination soak of the seeds (i.e., soaking them in water for a short time before transferring them to growing units for sprouting), we recommend that you include the pre-germination soak time in your calculations related to timing of sample collection.

If you wish to explore the optimal timing for sample collection in your sprouting operation (e.g., unique considerations based on sprout type, seed treatment, and/or production practices at your operation), we recommend collecting the spent sprout irrigation water (or in-process sprouts) at 24 hour-intervals and sending the samples to a laboratory to test the Aerobic Plate Count (APC) (also known as Total Plate Count, TPC). The Aerobic Plate Count is used to measure populations of microorganisms in a sample and can help determine the point in the sprouting process at which the highest levels of bacteria (including pathogens) are present (Ref. 46). You would then identify the point during growing at which the populations of microorganisms are highest, and sample spent sprout irrigation water at this time.

In instances in which irrigation cycles are infrequent (e.g., many hours pass between each irrigation cycle) or in which irrigation otherwise does not occur at the optimal sampling time, you may add irrigation water specifically to facilitate sample collection so that you can collect your sample at the optimal time.

e. How much and how many samples to collect

If testing spent sprout irrigation water, you should collect at least one sample of 1.5 liters of water (about 3 pints or 1.6 quarts) from each production batch of sprouts. It may be advisable for this sample to be made up of multiple subsamples, which are subsequently combined (i.e., combined volume of 1.5 liters), depending on whether your growing unit has a single drainage point or multiple drainage points (see Section V. B. 2. f (Where to Collect Samples) below). As a general matter, we recommend that you collect a subsample from every drainage point, up to 30 subsamples (Ref. 47 and Ref. 48).

If testing in-process sprouts, we recommend that you collect at least thirty (30) 50-gram sub-samples of sprouts for a total of at least 1500 grams (about 52.91 ounces or 3.31 pounds) from each production batch of sprouts. You should collect one sample of 1.5 liters of spent sprout irrigation water (or 1500 g of in-process sprouts) per production batch of sprouts irrespective of whether you are using the method in § 112.153(a)(1) or using an alternate method as permitted under §112.153(a)(2).

However, you should also consider circumstances specific to your sprout operation or production practices and adjust your sampling as needed to ensure you obtain samples that are representative of the entire production batch of sprouts. The number of different microorganisms for which you are testing can also affect the volume of sample necessary for testing. If additional pathogen testing is required under § 112.144(c), sample volume of spent sprout irrigation water or in-process sprouts may need to be increased.

Recent scientific advancements have also shown improvements in the ability to detect low levels of pathogens in water samples when using a concentration or filtration step (e.g., Moore Swab) (Ref. 49, Ref. 50, and Ref. 51). It may be worth considering the applicability of these methods for testing spent sprout irrigation water.

i. Large production batches of sprouts

Even with the same level of contamination (i.e., percent of sprouts that are contaminated) and the same sample size, the potential for illness is greater from a larger production batch of sprouts than a smaller one (Ref. 52). This is true because the quantity (e.g., pounds) of contaminated product that can be missed with that sampling is larger with a larger lot, and because contamination is likely to be unevenly spread throughout the batch, particularly in "stationary" growing units, and even more so with larger production batches (Ref. 53). Because of these concerns, we recommend that you collect additional samples (beyond those recommended above) of spent sprout irrigation water (or in-process sprouts) from particularly large production batches and test those samples separately.

Increasing the volume of spent sprout irrigation water tested increases the likelihood of detecting a pathogen (Ref. 44). For example, if your production batch consists of greater than 2400 lbs. of finished sprouts, we recommend that you collect two samples (of at least 1.5 liters each, for a total of 3 liters) of spent sprout irrigation water from that production batch and test each sample separately. If you are instead sampling in-process sprouts from that production batch, we recommend that you collect two samples (each totaling at least 1500 g, each made up of thirty 50 g subsamples, for a total of 3000 g and sixty 50 g subsamples) and test each sample separately (Ref. 52).

If your production batch is greater than 10,500 lbs. of finished sprouts, we recommend that you collect three samples (of at least 1.5 liters each, for a total of 4.5 liters) of spent sprout irrigation water from that production batch and test each sample separately. Similarly, if you are instead sampling in-process sprouts from that production batch, you should collect a total of three samples (each at least 1500 g, each made up of thirty 50 g subsamples, for a total of 4500 g and ninety 50 g subsamples) (Ref. 52).

ii. High volumes of irrigation water/high flow rates

Use of large volumes of irrigation water and/or high rates of irrigation flow (e.g., as is often used for mung bean sprouts grown in bins), such that a sampling container is likely to overflow almost immediately at the normal flow rate can dilute any pathogens that may be present on the sprouts. That makes collecting a representative sample of spent sprout irrigation water more difficult, and therefore makes it less likely that any pathogens that are present will be detected. We recommend that if your irrigation system normally uses large volumes of water and/or high rates of flow, you temporarily decrease the volume of water and/or flow rate through the growing unit during spent sprout irrigation water sampling.

iii. Low volumes of irrigation water/low flow rates

Conversely, if you use low volumes of irrigation water and/or rates of irrigation flow, such as in a misting system, you may find collecting a sufficient amount of irrigation water (e.g., collecting at least the recommended 1.5 liter) more challenging. In this case, we recommend that you, to the extent possible, either temporarily increase the volume of water and/or flow rate through the growing unit during spent sprout irrigation water sampling; or add water to the growing unit at a higher volume/flow rate immediately prior to the regular irrigation cycle for the specific purpose of collecting a sample. You should consider whether either of these options is practicable for your operation before determining that you may instead sample in-process sprouts in accordance with § 112.144(b)(2).

f. Where to collect samples

You should assess the configuration of your growing units, the flow of irrigation water, the location of water outlets from the growing unit, and product distribution and placement within the growing unit to determine how and where to best collect representative samples. Growing sprouts in a growing unit in which they are not mixed during growing (e.g., grown in racks of trays, bins, or tanks) can result in a more uneven distribution of pathogens in spent sprout irrigation water than growing sprouts in a growing unit that is mixed during growing (e.g., in a rotating drum).

If your sprout growing unit has a trough or other common point where water drains from the growing unit (e.g., the low point of the front of a rotating drum), you should collect the entire spent sprout irrigation water sample at that point. Because water at this point represents spent sprout irrigation water that has flowed through the entire growing unit of sprouts, collection at this point is likely to be representative. If the growing unit has multiple points of drainage (e.g., a single rack of connected trays or a large bin for growing mung bean sprouts), you should collect partial samples (subsamples) from each of these different points of drainage to ensure the combined sample is representative, especially if your sprouts are not mixed during growing. In such cases, you should collect up to 30 subsamples of approximately equal volume from the various drainage points (e.g., by moving your sample container around to different drainage locations). The subsamples may be combined and should, together, comprise your sample of at least 1.5 liter of spent sprout irrigation water.

g. How to collect your sample

You must collect samples aseptically (§ 112.147(b)). In Appendix 1 of the finalized sections (Ref. 18), we provide specific recommendations on aseptic sampling procedures.

3. Preparing and shipping the sample

You should ship one sample of 1.5 liters of spent sprout irrigation water (or 1500 in-process sprouts) per production batch of sprouts to a laboratory for analysis, irrespective of whether you are using the method specified in the rule (§ 112.153(a)(1)) or using an alternate method as permitted under § 112.153(a)(2). Prior to and during delivery or shipment to a laboratory, you should hold your samples at an appropriate temperature, preferably between 0 and 4.4 ºC (between 32 and 40 ºF). You should use sealed coolant packs in lieu of ice, as needed during delivery or shipment, to avoid the possibility of melting ice contaminating the sample. You should not freeze the samples. You should ship the samples so that they are received by the laboratory within 24 hours from the time of sample collection and analyzed promptly. A delay of more than 24 hours between sample collection and the lab's receipt of spent sprout irrigation water or sprout samples may make the test results inaccurate (Ref. 54).

Prior to sending the samples to a laboratory for testing, you should check to verify that your samples are clearly identified with the sprout production batch number and the name of your sprouting operation. You should specify the microorganisms for which the samples will be tested on any laboratory forms.

C. Preventing a Production Batch of Sprouts from Entering Commerce while Test Results are Pending

Section 112.147(b) requires that you not allow a production batch of sprouts to enter commerce unless the results of the testing of the spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* spp., and, if applicable, any additional pathogen test required under § 112.144(c).

While awaiting test results, you may move the production batch of sprouts from the growing area to another physical location, such as a holding or storage area in your sprouting operation, or an off-site storage location. However, you may not sell it or offer it for sale to another entity during this time. You should establish and implement procedures to ensure that production batches of sprouts do not enter commerce until negative pathogen test results are obtained for all required pathogen tests. Establishing and using unique production batch numbers or other identifiers that can be linked to samples that are being tested can help ensure implementation of these procedures.

D. Additional Voluntary Testing

We understand that some sprout operations may voluntarily conduct other pathogen tests on spent sprout irrigation water, in-process sprouts, or finished sprouts in addition to the required testing discussed elsewhere in this section.

For any such voluntary testing, if test results identify pathogens, you should take the same corrective actions as those required for a positive test result for *E. coli* O157:H7 or *Salmonella* species in spent sprout irrigation water (or in-process sprouts) (see Section V.G. (Developing a

Corrective Action Plan and Implementing Corrective Actions)). We recommend that you establish a system that allows you to associate such 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 pathogen test result.

E. Choosing a Laboratory

You should choose a laboratory that is qualified to test spent sprout irrigation water (and/or in-process sprouts, as applicable) for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in § 112.144(c) using methods that meet the requirements of § 112.153. Testing is typically contracted to a third-party testing laboratory, but you may perform the testing in your own "in-house" laboratory. If using a third-party testing laboratory, you should use a laboratory that employs scientifically valid laboratory methods and procedures that can provide reliable, accurate test results. If you use an "in-house" laboratory, you may be able to complete the screening step of the test method but may need to send the enrichment broth out to a third-party testing laboratory for confirmatory testing (if it cannot be conducted "in-house"). (§§ 112.144(b), 112.147, and 112.153).

If your laboratory utilizes a different method from the method listed in § 112.153 (or an alternate method found to be equivalent by FDA available on our website) to test your samples of spent sprout irrigation water or in-process sprouts, we recommend you use the questions included in the decision tree for test methods requirements for *Salmonella* and *E. coli* O157:H7 in spent sprout irrigation water (or sprouts) (available at https://www.fda.gov/media/132369/download) to assist you in determining whether the method meets the requirements of § 112.153. You should discuss the method with the laboratory to ensure the necessary sample volume will be tested for each pathogen. We recommend testing 750-mL of spent sprout irrigation water (or 750-g of in-process sprouts) for *Salmonella* spp., and 200-mL of spent sprout irrigation water (or 50-g of in-process sprouts) for *E. coli* O157:H7, irrespective of whether you are using the method described in § 112.153(a)(1) or an alternate method as permitted under § 112.153(a)(2). The number of tests for each pathogen will depend on the test method being used. For example, if you use an alternate method to test for *E. coli* O157:H7 that has been validated for 25-mL, the lab should conduct 8 tests (i.e., one test per 25-mL subsample, for a total sample volume of 200-mL). If the alternate method for *E. coli* O157:H7 has been validated for a higher sample volume (e.g., 100-mL of spent sprout irrigation water), you may be able to use a reduced number of tests (e.g., one test per 100-mL subsample, or two tests total per 200-mL).

If you conclude the laboratory's test methods do not meet the requirements of § 112.153, you may consider requesting that the laboratory utilize a different method or select another laboratory to analyze your samples (see the next section, V. F. Choosing a Test Method, for more information).

A laboratory conducting the tests required by§ 112.144(b) on which you rely might be, but is not required to be, accredited. Using an accredited laboratory (e.g., a laboratory accredited to

International Organization for Standardization (ISO) Standard 17025) is one way to have confidence that it will provide reliable, accurate test results.[2]

F. Choosing a Test Method

Section 112.153(a) requires that you test spent sprout irrigation water (or in-process sprouts) from each production batch of sprouts for *E. coli* O157:H7 and *Salmonella* species using either: the method of analysis described in "Testing methodologies for *E. coli* O157:H7 and *Salmonella* species in spent sprout irrigation water (or sprouts)" (currently available at https://www.fda.gov/media/94349/download)[3] (§ 112.153(a)(1)); or a scientifically valid method that is at least equivalent to this method in accuracy, precision, and sensitivity (§ 112.153(a)(2)). A decision tree for test methods requirements for *Salmonella* and *E. coli* O157:H7 in spent sprout irrigation water (or sprouts) is available at https://www.fda.gov/media/132369/download. For any other pathogen(s) meeting the criteria in § 112.144(c), you are required to use a scientifically valid method (§ 112.153(b)).

We recommend that you have a discussion with your laboratory to select a method that meets the requirements of § 112.153 to test your spent sprout irrigation water or in-process sprouts. It is the responsibility of the sprout operation (not the laboratory) to ensure that the appropriate test method is used.

We use the term "scientifically valid" to mean an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, textbooks, or proprietary research. Although you are not required to notify or submit information to FDA prior to using such an alternate method, you must establish and keep records of any such alternate methods that you use (§ 112.150(b)(5)) to test for *E. coli* O157:H7 or *Salmonella* species. Such records should include the 1) name and identification number of the method validated by a third-party methods validation organization, or 2) the detailed analytical procedures, and results or data from validation studies showing equivalence of the alternate method to the reference method, and any other relevant information supporting the use of the alternate method. In addition, if you test spent sprout irrigation water (or in-process sprouts) for any other pathogen(s) meeting the criteria in § 112.144(c), you should keep records of the scientifically valid test method you used for such testing (see § 112.153(b)) (see Section VII.C.3 (Required Records for Spent Sprout Irrigation Water) in the finalized sections (Ref. 18)).

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[2] By contrast, sprout operations must use a laboratory participating in the laboratory accreditation for analyses of foods (LAAF) program, as required by FSMA, for corrective action testing of environmental samples (§ 112.146(a) and (c)) and finished product (§ 112.146(d)). See https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-laboratory-accreditation-analyses-foods-laaf for more information.

[3] Because websites are subject to change, it is possible that this specific website address will change. If you cannot access this document at that website, alternative websites where you currently can access this document include https://www.fda.gov/food/science-research-food/laboratory-methods-food and https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma. Alternatively, you can search on part or all of the title of the method, in the search box on FDA's Web site at https://www.fda.gov/ or using a generally available search engine.

We recommend use of methods validated through a collaborative study (such methods are currently available at https://www.fda.gov/media/83812/download)[4], for example per AOAC Appendix J or ISO 16140-2:2016. Alternate methods should be validated for *E. coli* O157:H7 in spent sprout irrigation water and/or sprouts, as applicable, against FDA's reference method (§ 112.153(a)(1)). Alternate methods should be validated for *Salmonella* spp. in sprouts against FDA's reference method (§ 112.153(a)(1)). We recommend that alternate methods for *Salmonella* spp. in spent sprout irrigation water be validated against FDA's Bacteriological Analytical Manual (BAM) (Chapter 5, Section C.29: *Salmonella*), a method that was updated after the development of FDA's reference method and which is scientifically valid and at least equivalent to the method of analysis in § 112.153(a)(1) in accuracy, precision, and sensitivity for this application. All alternate methods must meet the requirements in § 112.153(a)(2) (i.e., demonstrated to be at least equivalent to the reference method in accuracy, precision, and sensitivity). Methods validated by third-party methods validation organizations, such as AOAC Official Methods of Analysis (OMA), MicroVal, or Association Française de Normalisation (AFNOR), may meet the requirements in § 112.153(a)(2). However, FDA does not automatically consider methods validated by third-party organizations, such as the listed organizations, to be equivalent to our reference methods. Information on alternate methods reviewed by FDA and found to be equivalent will be made available on our website, such as at https://www.fda.gov/ and https://www.fda.gov/food/science-research-food/laboratory-methods-food.

Section §112.150(b)(4) requires that you establish and keep records of all analytical tests conducted on spent sprout irrigation water or in-process sprouts for *Salmonella* spp., *E. coli* O157:H7, and any additional pathogen required under § 112.144(c). The results must be documented whether they were conducted by a third-party or your own (e.g., in-house) laboratory.

Testing for *E. coli* O157:H7 and *Salmonella* species in spent sprout irrigation water or sprouts using the FDA reference method (§ 112.153(a)(1)) can yield one of two results:

- A confirmed positive result, which is obtained when screening procedures yield a presumptive positive result that is followed by confirmatory steps demonstrating the presence of *E. coli* O157:H7 or *Salmonella* species; or
- A negative result, which can be obtained if either:
- Screening procedures do not yield a presumptive positive result; or
- Confirmatory steps after a presumptive positive result do not result in confirmation of the presence of *E. coli* O157:H7 or *Salmonella* species.

Confirmatory steps that are part of FDA's reference method are conducted on the same culture enrichment as the screening procedures used at the beginning of the analysis. To comply with the requirements of §§ 112.144(b), 112.147, and 112.153 for testing spent sprout irrigation water or

[4] Alternative websites where you can currently access this document include: https://www.fda.gov/science-research/field-science-and-laboratories/method-validation-guidelines and https://www.fda.gov/. Alternatively, you can search on part or all of the title of the method, in the search box on FDA's Web site at https://www.fda.gov/, or using a generally available search engine.

in-process sprouts, if you receive a presumptive positive result from screening procedures, you must conduct confirmatory steps and may not stop the analysis at the presumptive positive result.

You should not attempt to "test your way to safety" by collecting and testing additional samples of spent sprout irrigation water or sprouts from the same production batch if your first test yields a confirmed positive result. A negative test result in additional samples from the same production batch of sprouts does not negate a previous positive test result. You should consider any confirmed positive result to be valid (even if subsequent tests on the original sample or other samples collected from the production batch of sprouts are negative), absent other circumstances clearly demonstrating that the first test result was inaccurate (e.g., a reported issue at the laboratory, such as cross-contamination). If one test on a sample is confirmed positive, and then another test from that sample is negative, that may be because pathogens may not be evenly distributed within the sample.

If you obtain a negative result (of either type described above) for all relevant pathogens, your obligation under § 112.147(b) to prevent the batch from entering commerce has been satisfied. Once you have all such negative test results for a given production batch of sprouts, it would be reasonable to allow that production batch to enter commerce, provided there is no other reason for concern.

G. Developing a Corrective Action Plan and Implementing Corrective Actions

1. Developing a corrective action plan

As required by § 112.147(c), your written sampling plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.148 (listed below), if 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):

- 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 (§ 112.148(a));
- Take the steps required in § 112.142(b) with respect to the lot of seeds used to grow the affected production batch of sprouts (except as allowed under § 112.142(c)) (§ 112.148(b)) (see Section V. C of the finalized sections (Corrective Actions for Seeds that May be Contaminated with a Pathogen) (Ref. 18));
- Clean and sanitize the affected surfaces and surrounding areas (§ 112.148(c)); and
- Perform any other actions necessary to prevent recurrence of the contamination (§ 112.148(d)).

Your corrective action plan must detail when and how you will accomplish these actions (§ 112.147(c)). Having a corrective action plan in place at your operation will help ensure that you take corrective actions quickly and consistently in response to positive findings of pathogens in spent sprout irrigation water or sprouts. The plan should include:

- Procedures for identifying a contaminated production batch of sprouts (for example, using the production batch number information associated with the positive test results), destroying the contaminated production batch of sprouts or diverting it to a non-food use, and ensuring any contaminated food does not enter commerce;

- Procedures for identifying affected food contact surfaces (FCSs) and surrounding areas, and for cleaning and sanitizing those surfaces and areas;

- Procedures for appropriate handling of the lot(s) of seeds corresponding to the contaminated production batch of sprouts (i.e., procedures for discontinuing the use of that (those) lot(s) of seeds, ensuring that sprouts grown from that (those) lot(s) of seeds do not enter commerce, and reporting positive test findings to the seed grower, distributor, supplier, or other relevant entity, as required in § 112.142(b)). Alternatively, procedures for any follow-up actions you intend to take if that lot of seeds is not the source of contamination (e.g., the lot of seeds is not the source of the pathogen found in spent sprout irrigation water or sprouts), as required in § 112.142(c)(2); and/or if you decide to treat that lot of seeds as provided in § 112.142(c)(1), procedures for appropriate handling of the lot of seeds prior to, during, and after treatment) (see Section V. C of the finalized sections (Corrective Actions for Seeds that May be Contaminated with a Pathogen) for additional information on these provisions (Ref. 18));

- Procedures for understanding the underlying cause of contamination (e.g., sources and routes of contamination) and/or contributing factors; and

- Procedures for any specific steps that are necessary to address the underlying cause of contamination in order to prevent recurrence of the contamination, considering the conditions and practices in your sprout operation.

2. Taking corrective actions

You should take special care when handling contaminated sprouts (or other food), water, and/or equipment to avoid accidental exposure of other food, FCSs, and other parts of the production environment to pathogen(s).

You are required to prevent the contaminated production batch of sprouts from entering commerce (see §§ 112.147(b) and 112.148(a)). You should determine (for example, through review of your production and sanitation records) the potential for other foods produced at your operation to have become adulterated due to cross-contamination from the contaminated production batch of sprouts, its spent sprout irrigation water, or its associated seed lot(s). A food will be deemed to be adulterated 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(a)(4) of the FD&C Act). It is a prohibited act to introduce or deliver for introduction into interstate commerce any food that is adulterated (section 301(a) of the FD&C Act). If any other food has become adulterated, you must take appropriate action to prevent it from entering into commerce. For example, if you packaged another food item (e.g., tofu) on the same FCS as was used for the contaminated production batch of sprouts without intervening cleaning and sanitizing, the food is adulterated and § 112.148(a) requires that you take

appropriate action to prevent that food from entering commerce. One option would be to destroy the tofu.

You should evaluate your operation for the potential for the affected production batch of sprouts to have contaminated other objects and production areas (both FCS and non-FCSs). Any surface in your sprout operation that has come into contact with the contaminated production batch of sprouts (e.g., packaging areas, cold storage, or harvest containers), its spent sprout irrigation water (e.g., drums, trays, bins, buckets, tools and other sprouting equipment, sampling/testing equipment, and other surfaces, such as floors, drains, walls, and tables), or the associated lot(s) of seeds (e.g., containers used to store and treat seeds) should be considered an affected surface. These surfaces, and the areas surrounding them, could potentially contaminate other food, including subsequent batches of sprouts, at your operation, if they are not effectively cleaned and sanitized. You should conduct intensified cleaning and sanitizing of all affected surfaces and areas surrounding them (see Section III (Cleaning and Sanitizing) in the finalized sections (Ref. 18)) in response to the known contamination event. As part of your evaluation, you should review your production records to identify FCS and non-FCSs that may have come into contact with the contaminated production batch of sprouts, its spent sprout irrigation water, or its associated seed lot(s), and review your cleaning and sanitation records to determine when those surfaces were last cleaned and sanitized.

In addition, you must take any other actions necessary to prevent recurrence of contamination (§ 112.148(d)). Examples of such corrective actions that may be appropriate include:

- Re-evaluating your seed treatment protocol and procedures against current scientific information;

- Retraining your employees to ensure consistent implementation of your seed treatment protocol, visual examination of seeds, seed handling procedures, and any other relevant controls. For example, you should observe your employees to determine if they are properly implementing your procedures and the requirements of the Produce Safety Rule. Section 112.21(d) requires that you repeat training as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established in the Produce Safety Rule;

- Re-evaluating your seed sourcing. For example, you should re-evaluate whether you should continue using your current seed supplier; and

- Re-evaluating your cleaning and sanitizing procedures and, as needed, retraining employees on appropriate cleaning and sanitizing practices. For example, repeated positive pathogen test results from spent sprout irrigation water or in-process sprouts from different production batches grown from different seed lots that shared the same growing unit or FCS could indicate a deficiency in your cleaning and sanitizing procedures and/or in the degree to which your employees are implementing those procedures.

3. Documenting your corrective actions

Section § 112.150(b)(6) requires that you establish and keep records of actions you take in accordance with §§ 112.142(b) and (c) and 112.148. These records of corrective actions should include information describing the event, such as the results of any evaluation or comprehensive investigation you may conduct, and identification of the food and FCSs potentially affected by the contamination. They must include the following information:

- Documentation of your disposition of contaminated production batches of sprouts, as well as the disposition of any other adulterated food (§ 112.148(a));
- Documentation of steps you took with respect to the lot of seeds associated with the affected production batch of sprouts (§§ 112.142(b) or (c) and 112.148(b));
- Documentation of cleaning and sanitizing of the affected surfaces and surrounding areas (§ 112.148(c)); and
- Documentation of any other actions you took to prevent reoccurrence of the contamination (§ 112.148(d)) (e.g., retraining of your employees (see § 112.21(d)), re-evaluating your cleaning and sanitizing procedures; re-evaluating your seed treatment protocol; and/or re-evaluating your seed sourcing, as applicable).

VI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the Federal Register, but websites are subject to change over time.

Ref. 1. Food and Drug Administration. 1998. "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." Accessed September 20, 2023. (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm064574.htm)*

Ref. 2. National Advisory Committee on Microbiological Criteria for Foods. 1999. "Microbiological Safety Evaluations and Recommendations on Sprouted Seeds." *International Journal of Food Microbiology* 52(3):123-153.

Ref. 3. D'Lima, C., et al. "Memorandum to the File: Produce Related Outbreaks and Illnesses, December 2011." Food and Drug Administration.*

Ref. 4. Merriweather, S., et al. "Memorandum to the File: 2011-2014 Produce Related Outbreaks and Illnesses, May 2015." Food and Drug Administration.*

Ref. 5. Gubernot, D., et al. "Memorandum to the File: 2015-2016 Sprout and Sprout-Derived Product Related Outbreak Data, July 2016." Food and Drug Administration.*

Ref. 6. Obenhuber, D., et al. "Memorandum to the File: August 2018-August 2020 Sprout Related Outbreak Data, October 13, 2020." Food and Drug Administration.*

Ref. 7. Fatica, Marianne K., et al. "Memorandum to the File: July-December 2016 Sprout Related Outbreak Data, February 16, 2017." Food and Drug Administration.*

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Ref. 10. Foley, Catherine, et al. 2013. "Outbreak of *Escherichia coli* O104: H4 Infections Associated with Sprout Consumption—Europe and North America, May–July 2011." *Morbidity and Mortality Weekly Report* 62(50):1029-1031.

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Ref. 14. Food and Drug Administration. 2020. "Waning letter: Chicago Indoor Garden, Inc." Accessed September 20, 2023. (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/chicago-indoor-garden-inc-606992-07302020)*

Ref. 15. Food and Drug Administration. 2009. "Letter from FDA to Seed Suppliers, Distributors, and Sprouters." Accessed September 20, 2023. (http://wayback.archive-it.org/7993/20180908120136/https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm078778.htm)*

Ref. 16. Food and Drug Administration, 1999. "Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Operation." (withdrawn) Accessed September 20, 2023. (https://www.ifsh.iit.edu/sites/ifsh/files/departments/ssa/pdfs/fda1999_spent_irrigation_water.pdf)*

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