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Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry

Draft Guidance

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

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

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Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

While fruits and vegetables are important to the health and wellbeing of the American consumer, a variety of produce commodities have also been associated with foodborne illness outbreaks. On November 27, 2015, we published in the Federal Register (80 FR 74353) a final rule entitled, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the Produce Safety Rule or the Rule), establishing 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)). Produce that is covered by the rule is referred to as “covered produce.”

The Produce Safety Rule focuses on conditions and practices identified as potential contributing factors for microbial 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 certain common routes of contamination,

¹ This guidance has been prepared by the Office of Food Safety, Division of Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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including: agricultural water; biological soil amendments of animal origin; worker health and hygiene; equipment, tools, buildings and sanitation; domesticated and wild animals; and conditions for growing, harvesting, packing and holding activities.

Sprouts represent a special food safety concern because the conditions under which sprouts are produced (time, temperature, water activity, pH and available nutrients) are also ideal for the growth of pathogens, if present (Ref. 2). Between 1996 and July 2016 in the United States, there were a total of approximately 46 reported outbreaks associated with sprouts, accounting for 2474 illnesses, 187 hospitalizations, and three deaths, including two documented outbreaks of *Listeria monocytogenes* (Ref. 3, Ref. 4, Ref. 5). In foodborne illness outbreaks associated with sprouts, epidemiological investigations often identify the most likely source of contamination as seeds used for sprouting (Ref. 2). However, poor sanitation and unhygienic practices at the sprout operation can also contribute to the contamination of sprouts (Ref. 2).

Because the distinctive practices and conditions for growing sprouts present unique risks, we also established sprout-specific requirements in Subpart M (Sprouts) of the Produce Safety Rule. In general, Subpart M aligns with, and expands upon, the recommendations in our prior guidances on sprouts. However, unlike our sprout guidances, the Rule is binding and has the force and effect of law. 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.

This guidance is intended to assist sprout operations subject to the Produce Safety Rule (80 FR 74353), and primarily focuses on assisting such operations in complying with the sprout-specific requirements in Subpart M. It provides this assistance in part by describing voluntary practices, including some practices that can help operations avoid problems under these requirements. It also includes limited discussion on certain other applicable requirements. In addition, this 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.

Because of the diversity of sprout production practices and types of sprouts, the recommendations in this guidance will be most effective when you adapt these recommendations to the specific practices, processes and procedures at your operation. This guidance focuses primarily on providing recommendations to assist sprout operations covered by Subpart M in complying with the requirements in the Produce Safety Rule applicable to sprouts. It does not describe all aspects of all requirements of the Produce Safety Rule, but rather highlights certain sprout-specific requirements (Subpart M), and briefly discusses certain other Rule requirements from the perspective of a sprout operation (e.g., certain requirements in Subparts E and L of the Rule relating to Agricultural Water, and Equipment, Tools, Buildings, and Sanitation, respectively).

This guidance does not attempt to cover best practices or requirements outside the scope of the Produce Safety Rule. For example, the Produce Safety Rule does not address chemical or physical hazards. 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 in compliance with all applicable laws.

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

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farms that grow, harvest, pack or hold sprouts are referred to in this guidance as “sprout operations.” The Produce Safety Rule and this guidance document are not directed to steps in the seed and sprout supply chain that do not occur at covered farms, such as to operations growing, conditioning, and distributing seed for sprouting provided these operations are not also growing, harvesting, packing, or holding sprouts; 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. 6), everyone in the food supply chain has a responsibility for ensuring food safety. We encourage parties in the sprout supply chain to work together towards this end.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our 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 FDA guidances means that something is suggested or recommended, but not specifically 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 producers) that sprouts have 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 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 industry and academia, to develop an educational video entitled “The Safer Production of Sprouts” (Ref. 7). We have also provided technical assistance to the Illinois Institute of Technology’s Institute for Food Safety and Health (IIT IFSH) Sprout Safety Taskforce in developing their Sprout Grower – Packer Operations Food Safety Standard and an Auditing and Inspection Checklist for Sprouting Facilities (Ref. 8).

We are also working with the Sprout Safety Alliance (SSA), established in 2012, to enhance the industry’s understanding and implementation of best practices for improving sprout safety (Ref. 9, Ref. 10). The SSA has developed a core curriculum and training and outreach programs for stakeholders in the sprout production community. The SSA is composed of the food industry, academia, and members from federal, state, and local food protection agencies. The SSA is funded by a grant from FDA to IIT IFSH.

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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 in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. Covered farms 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 exemptions and limitations on which farms are “covered farms” (see § 112.4).

Sprouts are produce as we defined that term in the Produce Safety Rule (see § 112.3, defining “Produce” in part as “any fruit or vegetable... and includes... sprouts (irrespective of seed source)”). Sprouts are also RACs when they are in their raw or natural state (see § 112.3, defining “Raw agricultural commodity (RAC)” as that term is defined in section 201(r) of the FD&C Act (21 U.S.C. 321(r)): “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)). Processed foods are not subject to the Produce Safety Rule. An example of a processed food made using sprouts is sprouted seed butter. The coverage limitation in § 112.2(a)(3) 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. It means only that the Produce Safety Rule only applies during the time that the sprouts are RACs. Once they are transformed into processed food, other requirements (such as those in 21 CFR Part 117) may apply, depending on the circumstances.

Sprouts do not qualify for the exemption in § 112.2(a)(1) for produce that is rarely consumed raw. This provision contains an exhaustive (all inclusive) list of produce commodities (such as potatoes) that, based on our analysis of dietary consumption patterns, 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) for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance appear in § 112.2(b)(1). This exemption also requires certain documentation and disclosures set forth in § 112.2(b)(2). Sprouts that receive commercial processing to create sprouted seed products (e.g., canned, shelf-stable mung bean sprouts; sprouted seed butters; powdered sprouted seed products; dehydrated 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. We note that simply drying/dehydrating sprouts may not adequately reduce the presence of microorganisms of public health significance (Ref. 11, Ref. 12).

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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 growth media in your operation, you must comply with the applicable requirements in 21 CFR Part 112, Subpart F (Biological Soil Amendments of Animal Origin and Human Waste). We have not included a detailed discussion of the requirements of Subpart F in this guidance, since our understanding of the sprout industry is that the majority of sprouts grown in soil- or substrate are harvested above the soil line and therefore not covered by Subpart M (and this guidance primarily focuses on the requirements in Subpart M).

We recognize that certain soil or substrate grown sprout types, such as wheatgrass, may be sold by sprout operations to retail establishments or other customers in a tray used for growing with the soil/substrate, and roots, intact. In such cases, the farm has harvested the sprouts with the roots and they are subject to Subpart M (see § 112.141). However, we understand that such sprouts may then be cut above the soil and/or substrate line at the retail establishment immediately before use. When a sprout operation sells sprouts with the roots intact in soil or substrate, and the customer 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 customer stating that the sprouts will be cut above the soil or substrate line before use.

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. To the extent production practices for soil- or substrate-grown sprouts that are harvested above the soil or substrate line may present risks similar to those associated with other sprouts, we encourage such operations to consider voluntarily implementing the standards in subpart M, in addition to complying with the required provisions of all other subparts in the Produce Safety Rule.

In addition, 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., the IFSH Sprout Taskforce sprout-specific audit check list (Ref. 8) and the Food Safety Australia New Zealand (FSANZ) standards (Ref. 13) for sprouts. 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 (or 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. Microgreens are also 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. 14). However, microgreens are considered covered produce for the purposes of the Produce Safety Rule and, unless exempt or excluded under

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the provisions in subpart A, microgreens and microgreen farms are subject to all other subparts of the Produce Safety Rule (80 FR 74353 at 74497, comment/response 363).

D. Compliance Dates for Sprouts

The compliance dates for sprouts subject to Subpart M are earlier than the compliance dates for all other covered produce. Sprout operations subject to Subpart M need to be in compliance with all applicable provisions of the Produce Safety Rule with respect to such sprouts by January 28, 2019 (very small businesses); January 26, 2018 (small businesses); or January 26, 2017 (all other businesses). The additional two years beyond other compliance dates provided for some farms to comply with certain provisions related to agricultural water provisions do not apply to sprouts subject to Subpart M. Farms eligible for the qualified exemption from the Produce Safety Rule that grow, harvest, pack, or hold sprouts that would be subject to Subpart M if they did not receive the qualified exemption also have earlier compliance dates for certain modified requirements than other farms covered by the Rule. The same is true for farms relying on the exemption in § 112.2(b) for sprouts that would otherwise be subject to Subpart M that receive commercial processing that adequately reduces microorganisms of public health concern.

The same compliance dates that apply to all other covered produce apply to sprouts that are not subject to subpart M (i.e., soil- or substrate-grown sprouts harvested without their roots).

E. Definitions

The Produce Safety Rule contains definitions of many important terms in § 112.3. We use some of these defined terms in this document. For your convenience, we reproduce some relevant definitions from the Rule here. In addition, the definitions and interpretations of terms in section 201 of the FD&C Act apply to such terms when used in the Produce Safety Rule.

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

Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

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

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of “farm” as defined in [Chapter I of Title 21 of the Code of Federal Regulations]. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. [21 CFR Part 112] does not apply to activities of a facility that are subject to [21 CFR Part 117].

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Covered produce means produce that is subject to the requirements of [21 CFR Part 112] in accordance with §§ 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.

Farm means: (1) *Primary production farm*. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(I) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(I) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) *Secondary activities farm*. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

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

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

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

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

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological agent that has the potential to cause illness or injury in the absence of its control.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/ dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

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

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including

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modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

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

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

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

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

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act.

Pest means any objectionable animals or insects, including birds, rodents, flies, and larvae.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Production batch of sprouts means all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or

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not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

- (1) In the same State or the same Indian reservation as the farm that produced the food; or
- (2) Not more than 275 miles from such farm.

Raw agricultural commodity (RAC) means “raw agricultural commodity” as defined in section 201(r) of the FD&C Act.

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

Small business means a farm that is subject to any of the requirements of [21 CFR Part 112] and, on a rolling basis, the average annual monetary value of produce (as defined in [21 CFR 112.3]) the farm sold during the previous 3-year period is no more than \$500,000; and the farm is not a very small business as defined in [21 CFR 112.3].

Soil amendment means any chemical, biological, or physical material (such as elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

Spent sprout irrigation water means water that has been used in the growing of sprouts.

Surface water means all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.

Very small business means a farm that is subject to any of the requirements of [21 CFR Part 112] and, on a rolling basis, the average annual monetary value of produce (as defined in [21 CFR 112.3]) the farm sold during the previous 3-year period is no more than \$250,000.

Visitor means any person (other than personnel) who enters your covered farm with your permission.

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

We means the U.S. Food and Drug Administration (FDA).

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You, for purposes of [21 CFR Part 112], means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of [21 CFR Part 112].

III. General Sprout Production

This section discusses common production practices for growing, harvesting, packing, packaging and holding of sprouted seeds, and provides a brief overview of some of the most important requirements relevant to your sprout operation that apply at each stage of production. This section does not necessarily cover all relevant requirements but instead provides a high-level overview, and refers in various places to other sections of this guidance that discuss certain practices in greater detail. Although seed is often identified as the most likely source of contamination in many sprout-associated foodborne illness outbreaks, the practices and conditions at your operation may increase or decrease the extent of the microbial hazards (Ref. 2).

Note that throughout this guidance, for the ease of the reader, we often refer collectively to everything sprouted to produce sprouts for human consumption, including beans, 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 not be read to exclude other things that are sprouted to produce sprouts for human consumption, such as beans.

A. Sprout Production

Typically, sprout production consists broadly of the steps depicted in Figure 1. 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. Each stage of typical sprout production is described in more detail below.

Many of the steps in sprout production, such as rinsing and soaking seed, irrigating sprouts and washing finished product, involve the use of water. The Produce Safety Rule establishes certain requirements for water used in covered activities on covered produce where water is intended to or likely to contact food or food contact surfaces (FCSs), or “agricultural water”. Certain uses of “agricultural water” (including sprout irrigation water) are subject to a microbial water quality requirement of no detectable generic *E. coli* per 100 ml (see § 112.44(a)), and all water supplied to hand-washing facilities at sprouting operations is required to meet the same standard (see § 112.130(a) and (b)(2); see also § 112.143(a)). We are not aware of any uses of water common in sprouting operations that are intended to or likely to contact food or FCSs that are not subject to this microbial quality requirement. Agricultural water quality requirements for sprout production operations and how you can meet them are further discussed in Section VI (Agricultural Water in Sprout Operations) of this guidance.

Figure 1. 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 SIW (or in-process sprouts) → Harvest →

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Wash/Drain Sprouts → Bulk Cool/Spin Dry → Pack and/or Package → Cooling & Storage → Distribution

B. Seed Receipt

You must visually examine seeds, and packaging used to ship seeds, for signs of potential contamination with known or reasonably foreseeable hazards (§ 112.142(d)). This visual exam of seeds and their packaging upon receipt is one of the first steps to take at your operation to reduce the chance of seeds serving as a source of contamination in the sprouts you produce (See also Section VII. (Seeds for Sprouting) for more information).

In addition, when receiving seeds used for sprouting, you must take any other measures that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto the seeds during that process (§ 112.142(a)).

C. Seed Storage

When storing seeds used for sprouting, you must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto the seeds (§ 112.142(a)). The measures you take to prevent seeds from being contaminated should vary depending on, for example, the quantity of seeds you order or store at your operation, size and type of storage containers, and how quickly you use them. For example, we recommend you purchase quantities of seed that are based on your short-term production needs, rather than purchasing larger amounts and storing seed at your operation for prolonged periods of time.

Seeds you use for sprouting should be handled and stored in a manner that will prevent any type of damage and contamination. As mentioned in Section I (Introduction) of this guidance, the Produce Safety Rule focuses on microbial contamination, conditions and practices identified as potential contributing factors for microbial contamination of produce, and steps to protect against contamination. The Produce Safety Rule does not address chemical or physical hazards. You have a responsibility to ensure that your sprouts are not adulterated or misbranded under the FD&C Act and are in compliance with all applicable laws.

D. Initial Seed Rinse

Seeds are typically rinsed before treatment. While the Produce Safety Rule does not require pre-treatment rinsing, we recommend that seeds be rinsed thoroughly before treatment to reduce microorganisms of public health significance, to remove dirt, and to increase the efficiency of the treatment. If you do rinse seeds before treatment, you should repeat the rinsing process with new water until most of the dirt is removed and rinse water runs clear. We also recommend that you conduct your rinse in such a way as to maximize seed surface contact with water (e.g., by mixing or agitating).

If you do rinse seeds before treatment, water used to rinse seed must meet the microbial quality criterion in § 112.44(a) (i.e., no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water), and related requirements elsewhere in Subpart E, because such water contacts FCSs (surfaces of the rinse container that also contact seeds used for sprouting) during the covered activity of

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growing covered produce (sprouts) (See § 112.144(a)(3)); see also Section VI. (Agricultural Water in Sprout Operations)).

In addition, if you do rinse seeds before treatment, you must clean and sanitize the FCSs of your tools and equipment that you use for this purpose before they contact the seeds (§ 112.143(b); see also Section V (Cleaning and Sanitizing)). These are FCSs used during the covered activity of growing covered produce (sprouts).

In addition, if you do rinse seeds used for sprouting, you must take any other measures that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto the seeds during that process (§ 112.142(a)).

E. Treating Seeds to Reduce Microorganisms of Public Health Significance

The Produce Safety Rule requires that seeds that will be used to grow sprouts be treated using a scientifically valid method to reduce microorganisms of public health significance (§ 112.142(e)). You have two options for meeting this requirement:

- (1) You may treat the seeds prior to sprouting at your operation, or
- (2) You may rely on prior treatment of seeds conducted by a grower, distributor, or supplier of the seeds (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds at your operation immediately before sprouting).

If you treat seeds at your operation, you must use a scientifically valid method to reduce microorganisms of public health significance (§ 112.142(e)(1)). This includes ensuring that the treatment procedures are followed correctly and taking steps to control all factors that impact the efficacy of the treatment, including, as appropriate:

- treatment time, temperature and pH;
- volume of treatment solution to seeds (if the treatment involves a solution); and
- agitation, as appropriate, to maximize contact between seed and the treatment solution or gas.

The specific factors you will need to monitor and control will depend on the type of treatment you use (e.g., chemical, physical or a combination of treatments) and the procedures for its use. In addition, if you choose to conduct the required seed treatment at your operation, you must take any other measures that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto the seeds during that process (§ 112.142(a)).

If you rely, in whole or in part, on prior treatment by a grower, distributor, or supplier of seeds, you must obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that the prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance, and that the treated seeds were handled and packaged following the treatment in a manner that minimizes the potential for contamination (§ 112.142(e)(2)) (See Section VII (Seeds for Sprouting)).

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F. Pre-germination Seed Soak

Soaking causes seeds to swell and softens hulls to allow the sprout to grow out of the seed. Depending on your production practices and the type of seeds you use, a pre-germination soak may be necessary to improve germination. Pre-germination soaking is not required by the Produce Safety Rule. However, if you soak seeds before germination, FCSs of containers and other tools or equipment used for soaking must be cleaned and sanitized prior to contact with seeds used to grow sprouts (§ 112.143(b)) (See Section IV (Buildings, Tools and Equipment)). These are FCSs used during the covered activity of growing covered produce (sprouts). For both seed soaking and any additional rinses you may conduct after soaking, you must use water that meets the microbial quality criterion in § 112.44(a), and related requirements elsewhere in Subpart E. Such water contacts FCSs (surfaces of the soak/rinse container that also contact seeds used for sprouting) during the covered activity of growing covered produce (sprouts) (See § 112.144(a)(3)); see also Section VI (Agricultural Water in Sprout Operations)).

In addition, if you choose to conduct a pre-germination seed soak you must take any other measures that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds during that process (§ 112.142(a)).

G. Germination and Growth

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” growing units) are those growing units that do not mix 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., “hot spots”) (Ref. 14a). The other category (“mixed” growing units) 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., “hot spots” are less likely, and contamination, if it occurs, is more likely to be widespread) due to the mixing that occurs during growing (Ref. 14a). These differences lead to certain considerations that are specific to the type of growing unit used. For example, collecting a representative spent sprout irrigation water sample can be more challenging from stationary growing units (particularly those with multiple drain points), while mixed growing units present certain unique considerations when determining appropriate corrective actions in response to a positive environmental sample on the growing unit FCS (See Section IX. (Environmental Monitoring)).

Because of the potential for pathogen growth during the sprouting process, it is especially critical that you keep the sprout production area, and the tools and equipment that contact sprouts and FCSs, clean to avoid potential contamination.

You must inspect, maintain, clean, and sanitize all FCSs of tools and equipment as frequently as reasonably necessary to protect against contamination of covered produce, and before they contact sprouts, or seeds used for sprouting (§§ 112.123(d)(1), 112.143(b)). This includes FCSs of growing units (e.g., interior surfaces of rotating drums, bins, and trays). Growing units should be cleaned and

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sanitized before starting to grow each new production batch (see Section V. (Cleaning and Sanitizing)).

Your building must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or FCSs, including by separation of operations in which contamination is likely to occur (§ 112.126(a)(1)(ii)). For example, the germination and growing area (along with harvesting, packing and packaging areas) should be physically separated from the receiving, storage and seed disinfecting areas and should be protected from outside contaminants.

You must also implement measures to prevent contamination of your covered produce 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)). You should consider the placement of tools and equipment with respect to potential routes of contamination, such as splash from the floor or overhead condensate, and take appropriate steps in compliance with § 112.126(b). For example, you might use wall mounted racks and clean pallets to ensure that tools and equipment (such as shovels, stackable bins, and perforated spinning baskets) and product do not contact the floor, especially in areas where water accumulates. If condensation is a problem that you cannot otherwise fix through maintenance (such as roof repair), you might consider installing drip guards to collect and/or divert condensate that might otherwise contact covered produce and food contact surfaces. You should also consider the placement of exposed product and food contact surfaces relative to floors, walls, ceilings, fixtures, ducts, or pipes, and drip or condensate to minimize their potential to serve as a source of contamination. You should also implement measures to ensure that cleaning and sanitizing activities (such as washing floors, walls, and ceilings) are conducted at a time and in a manner so as not to serve as a source of contamination for covered produce and food contact surfaces. As an example, if you wash your floors with high pressure hoses, we recommend you move your in-process and finished sprouts from the area during cleaning to minimize the potential for contamination from water splashing off the floor and on to product.

You must use irrigation water that meets the microbial quality criterion in § 112.44(a), and related requirements elsewhere in Subpart E. (See Section VI. (Agricultural Water in Sprout Operations) for more information).

In addition, you must take any other measures that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds during germination and growth (§ 112.142(a)).

H. Sampling and Testing Spent Sprout Irrigation Water (or In-Process Sprouts) for Pathogens (including *E. coli* O157:H7 and *Salmonella* species)

The Produce Safety Rule requires that you conduct microbial testing of spent sprout irrigation water (SIW) (or in-process sprouts) from each production batch of sprouts to help minimize the likelihood that pathogens are present on sprouts entering the food supply (§ 112.144(b)). Specifically, in accordance with the requirements of § 112.147, you must test spent sprout irrigation water (or in-process sprouts) from each production batch of sprouts during germination and growth for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in § 112.144(c). Testing for additional pathogens (besides *E. coli* O157:H7 and *Salmonella* species) is only required under

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certain, specific circumstances. See Section VIII (Sampling and Testing of Spent Sprout Irrigation Water or In-Process Sprouts) for more detailed information on this topic and for more detailed information on spent sprout irrigation water testing and in-process sprout testing.

I. Harvest

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, and you should not distribute sprouts that may have dropped to the floor during harvest. 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 must ensure all tools and equipment used to transfer sprouts from growing units to harvest containers are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained (§ 112.123(a)).

You must inspect, maintain, clean, and sanitize FCSs of tools and equipment used during harvest as frequently as reasonably necessary to protect against contamination of covered produce, and before they contact sprouts, or seeds used for sprouting (§§ 112.123(d)(1), 112.143(b)). FCSs of tools and equipment used in harvesting sprouts should be cleaned and sanitized at least daily in most circumstances, and before starting to harvest each new production batch of sprouts. (See Section V (Cleaning and Sanitizing)).

J. Wash/Drain and Cool

After sprouts are removed from the growing unit, some sprout operations wash sprouts with cool water to remove hulls and/or to help lower the temperature of the sprouts. Some operations use a bubbling water bath to loosen and float off hulls. Occasionally, sprouts are washed in recirculating water in a flume system. Any agricultural water that is applied in any manner that is intended to or likely to contact covered produce, including sprouts, during or after harvest activities must meet the microbial quality criterion in § 112.44(a), and related requirements elsewhere in Subpart E. This includes water that is applied to sprouts for washing or cooling activities such as those described in this paragraph. There are also additional requirements for maintaining and monitoring the quality of water used during harvest, packing, and holding activities (§ 112.48) (See Section VI (Agricultural Water in Sprout Operations)).

After washing, sprouts are usually spin-dried using a centrifuge. As with all FCSs used in growing, harvesting, packing, and holding sprouts, FCSs of sprout drying equipment must be inspected, maintained, cleaned, and sanitized as frequently as reasonably necessary to protect against contamination of covered produce, and prior to contact with sprouts (§§ 112.123(d)(1), 112.143(b); see also Section V (Cleaning and Sanitizing)). Such equipment must also be of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained (§ 112.123(a)). For example, such equipment should be constructed of food grade materials.

Sprouts are often placed in a cold room between harvest and packing/packaging to remove heat generated during the sprouting process. You must inspect, maintain, clean, and sanitize all FCSs of

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tools and equipment as frequently as reasonably necessary to protect against contamination of covered produce, and before they contact sprouts, or seeds used for sprouting (§§ 112.123(d)(1), 112.143(b); see also Section V (Cleaning and Sanitizing)). This includes FCSs used during cooling harvested sprouts, which should be cleaned and sanitized daily in most circumstances, and before starting to cool each new production batch. You must also implement measures to prevent contamination of your covered produce 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, if you use a cold room for cooling harvested sprouts, you should monitor the cold room for drip or condensate (e.g., from the ceiling over exposed sprouts) and take appropriate steps to minimize the potential for contamination of sprouts and FCSs in compliance with § 112.126(b).

In addition, we recommend that you take steps to minimize the potential for separate production batches of sprouts to be inadvertently mixed during this and other steps in your production process, particularly while you are awaiting test results from spent sprout irrigation water (or in-process sprout) testing. Maintaining the integrity of each production batch will minimize the potential for cross-contamination and the amount of potentially affected product in the event of a positive pathogen finding.

K. Packing/Packaging

Sprouts are usually manually placed into containers, including both “packing” and “packaging.” Typically, finished sprouts are placed into containers at the sprout growing operation but may be occasionally transported in bulk to another location to be packed and/or packaged.

- 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, such as by cleaning food-packing containers or using a clean liner (§ 112.116(b)).
- Food-packing materials 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.
- Your building must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or FCSs, including by separation of operations in which contamination is likely to occur (§ 112.126(a)(1)(ii)). For example, you should pack and/or package finished sprouts in an area separate from areas used for other activities such as seed storage, seed treatment, and sprout production.
- You must handle harvested sprouts in a manner that protects against contamination with known or reasonably foreseeable hazards (§ 112.113).
- You must ensure all tools and equipment used to pack sprouts, including FCSs such as packing tables, are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained (§ 112.123(a)).

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L. Storage and Distribution

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. 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. You should maintain the cold chain as much as possible when staging product to prepare for loading delivery trucks.

Vehicles 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 becomes a potential source of contamination (§ 112.125).

IV. Buildings, Tools and Equipment

Maintaining an environment that promotes the hygienic production of sprouts and minimizes the potential for cross-contamination is essential to food safety. Proper construction of buildings helps protect against potential sources of external contaminants (e.g., airborne contamination and pests) that may compromise the safety of food. Pest control and effective sanitation will help minimize the transfer of microbial hazards within the operation.

Subpart L (Equipment, Tools, Buildings, and Sanitation) of the Produce Safety Rule establishes standards to prevent equipment, tools and buildings, and inadequate sanitation, from contaminating produce. This section of the Rule includes requirements for toilet and hand-washing facilities, and appropriate storage, maintenance, and cleaning of equipment and tools. There are also sprout-specific requirements relating to buildings, tools, and equipment in § 112.143(a) and (b).

A. Requirements for Buildings

Sprout production (growing, harvesting, packing, and holding) must be conducted in a fully enclosed building (§112.143(a)). Such buildings are subject to the requirements of Subpart L (§ 112.122). Sprout operations should take particular note of the following:

- 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)). In addition, for fully-enclosed buildings as required for sprout production, you must take measures to exclude pests from your buildings (§ 112.128(b)).
 - For example, doors of sprout operations should be tight fitting and kept closed when not in use. Windows of sprout operations should be properly fitted and kept closed at all times unless screened. Unprotected openings to the outside should be blocked or repaired to prevent entry of pests.
 - In addition, you should routinely monitor storage areas (e.g., for seed, tools and equipment), sprout production areas, as well as packing, and holding areas for evidence of pests. For example, you should evaluate your operation, focusing on the perimeters of the building, look for unprotected openings through which rodents

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could enter, potential harborage sites as well as other signs of potential contamination (e.g., stains, insects, feces (rodent pellets), urine, or foreign material). You should consider using a black light to examine for signs of rodent urine. We recommend you develop and implement procedures for pest control (e.g., setting traps) and/or work with a private company specializing in pest control.

- 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)).
 - For example, the internal surfaces of buildings and fittings, such as ceilings, walls, floors, cooling units, and light fixtures, should be durable, nonabsorbent, and easily cleanable. The use of wood, sheet rock and other absorbent materials should be minimized, even for non-food-contact surfaces, if these surfaces cannot be adequately maintained, cleaned and sanitized so that they do not become a source of contamination for sprouts or FCSs.
- 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 injury or contamination of product. For example, an area should not be too small to accommodate the tasks being performed. As another 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.
- 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, seed storage, seed treatment, sprout storage and chemical storage each should be located in a separate room or location. In addition, packing and/or packaging activities should be conducted in a separate room or area from where sprout production occurs.
- 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)).
 - Floors should be sloped towards trapped drains with covers to minimize the accumulation of standing water and presence of low spots where water may pool. Stagnant water accumulated on floors can harbor pathogens, especially *Listeria monocytogenes* (Ref. 15). 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, to comply with this provision, you should consider whether the occurrence of drip or condensate in your sprout production building presents a

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potential for contamination of your sprouts or FCSs and take measures to minimize or prevent that potential for contamination. Such measures include:

- Keeping buildings in good repair in order to prevent leakage of rainwater into the walls or ceilings of buildings, and preventing any drip or condensate from overhead pipes or ceilings from dripping onto sprouts or food-contact surfaces.
 - Adequately and regularly cleaning fixtures, ducts or pipes inside the building where covered activities occur.
 - Considering placement of growing units with respect to potential routes of contamination, such as splash from the floor, and taking appropriate steps to minimize the potential for contamination of sprouts and FCSs (as discussed above (see Section III (General Sprout Production))).
 - Monitoring cold rooms used to cool finished sprouts for drip or condensate (e.g., from the ceiling over exposed sprouts) and taking appropriate steps to minimize the potential for contamination of sprouts and FCSs (as discussed above (see Section III (General Sprout Production))).
- We recommend that you consider providing designated areas and/or separate rooms in your building(s) for employees taking breaks. Providing such areas or rooms helps ensure that personnel comply with certain requirements to 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))).

B. 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 covered produce, FCSs, and areas within your operation used for growing, harvesting, packing or holding sprouts, water sources, and 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)).
 - Sprout operations 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 for adequate, readily accessible toilet facilities. This means that sprout operations must provide personnel with adequate, readily accessible toilet facilities during all times in which they are in production (i.e., during all covered activities, including any growing, harvesting, packing, and holding of sprouts). This also means that sprout operations must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands at all times in which sprout operations are in production (§ 112.129(c)).
 - Portable toilets may be used, provided they meet all applicable requirements. In particular, if you use portable toilets, 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 (§

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- 112.129(a)). For example, the service vehicle should be able to enter your property and maneuver as close as necessary to the portable toilet to service the unit.
- Toilets should not leak onto the floor. Clogged, leaking, or broken toilets should be repaired immediately (see §§ 112.129(b)(3) and 112.131(c)).
 - Sprout operations 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)). 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 the operation to facilitate their use at key times, such as when entering sprout production and packaging areas.
 - 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 not use antiseptic hand rubs (i.e., hand sanitizers) as a substitute for soap (or other effective surfactant) and water (§ 112.130(d)).
 - While you must not use hand sanitizers as a substitute for soap (or other effective surfactant) and water, you may consider having hand sanitizer dispensers, aerosol spray devices, or hand-dip bowls of solution available in addition to hand washing stations.

C. Plumbing Systems for Water

The plumbing system within your sprout operation 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)).

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)).

The plumbing system must not allow backflow from or cross-connections between piping systems that discharge wastewater 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)). Practices such as leaving open-ended hoses on the floor of your sprout operation or submerged in tanks of liquid should be avoided because of the potential for water from the floor or tank to back siphon and contaminate your water system. 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.16).

D. 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

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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)). See also §§ 112.129(b)(1) and (3); 112.130(c); and 112.131(c) and (d) regarding disposal of waste from toilet facilities, hand-washing facilities, leakages or spills, and after significant events such as flooding or an earthquake.

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)), and 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)). For example, we recommend that waste be carried out of, but not through, sprout production areas when sprouts are exposed to minimize the risk of contamination of sprouts.

E. 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 include implements, cooling equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce) (§ 112.121).

- 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) and (c)). 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) and (c)).
 - Equipment breakdown and broken or damaged tools and equipment can interfere with the efficient running of your operation and can result in hazards to your employees and food safety risks associated with your products. 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. Damaged or rough surfaces are difficult to adequately clean and sanitize. You should repair or replace any equipment and FCSs that are rusted, pitted or otherwise damaged.
 - Inaccessible or hard-to-clean places may provide harborage or growth sites for microorganisms.
 - Seeds, sprouts, hands, or gloves that come into contact with dirty surfaces can be contaminated with pathogenic microorganisms. Even if tools and equipment are adequately constructed, inadequate cleaning and sanitizing of the tools and equipment can lead to contamination. See also Section V (Cleaning and Sanitizing).
 - Appropriate practices for storing and maintaining equipment and tools can protect against contamination and reduce the potential for attracting or harboring pests, which can carry human pathogens. Pest harborage by equipment not only can contaminate the equipment; it can also increase the prevalence of pests near a

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building, and provide a place for them to live and breed. Sprout operations should store equipment and tools in a fully enclosed building to minimize the potential for contamination.

V. Cleaning and Sanitizing

Cleaning and sanitizing are different, and important steps that are critical to the safety of your finished sprouts. This section discusses cleaning and sanitizing frequencies, recordkeeping and the development of Sanitation Standard Operating Procedures (SSOP), how cleaning and sanitizing differ, verification activities, and corrective actions to take in response to suspected or known contamination.

A. Frequency of Cleaning and Sanitizing

Section 112.123(d)(1) is a general requirement that applies to all covered farms, and requires you to inspect, maintain, clean and, when necessary and appropriate, sanitize all FCSs of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce. For operations growing sprouts covered by Subpart M, we determined that it is “necessary and appropriate” to sanitize all such food contact surfaces used to grow, harvest, pack, or hold sprouts after cleaning them and therefore we specifically require both cleaning and sanitizing for such food contact surfaces prior to contact with sprouts or seeds used to grow sprouts, as reflected in § 112.143(b). “Food contact surfaces” means “those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ‘Food contact surfaces’ includes food contact surfaces of equipment and tools used during harvest, packing, and holding” (§ 112.3). “Food contact surfaces” also includes food contact surfaces of equipment and tools used in growing covered produce, including sprouts (see, e.g., §§ 112.123(d)(1) and 112.143(b)). In a sprouting operation, food contact surfaces include, for example, trays or drums used for sprouting; interior surfaces of containers used for seed rinsing, seed treatment, and pre-germination seed soaking; and counters that come into contact with sprouts during packing and/or packaging (See Section III (General Sprout Production)).

In general, we recommend cleaning and sanitizing of food contact surfaces used in sprout operations at least daily to meet the requirements of §§ 112.123(d)(1) and 112.143(b). For example, you should clean and sanitize all food contact surfaces in the production environment at the end of each production day. Appropriate frequency of cleaning and sanitizing may vary based on specific practices; for example, you should incorporate a cleaning and sanitizing step for food-contact surfaces between each different production batch of sprouts (e.g., when more than one batch will contact the same FCSs on the same day). Cleaning and sanitizing between production batches of sprouts will minimize the potential for cross-contamination, and also facilitate corrective actions in the event that a positive pathogen (or indicator organism) test result is obtained (e.g., from a spent sprout irrigation water, sprouts, and/or environmental sample) (See Section VIII (Sampling and Testing of Spent Sprout Irrigation Water or In-Process Sprouts) and Section IX (Environmental Monitoring)). As another example, you should clean and sanitize FCSs prior to resuming production after more than a day of those food-contact surfaces not being used (in which case your cleaning and

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sanitizing of those surfaces would occur less frequently than daily because they are not being used daily). Surfaces that are used continuously for more than a day, such as bins or drums that contain sprouts during germination and growth periods lasting more than a day, do not need to be cleaned on a daily basis while they continuously contain or otherwise contact only one production batch of growing sprouts. We consider such uses to be a single, continuous instance of contact. The rule requires that the FCSs be cleaned and sanitized “before contact.”

Additionally, you must maintain and clean all non-FCSs of equipment and tools subject to Subpart L and used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of sprouts (§ 112.123(d)(2)). While the rule does not require sanitizing of non-FCSs, we recommend that sprout operations sanitize even non-FCSs on the same schedule as we recommend for cleaning those surfaces because of the particularly high-risk nature of sprout production. We recommend cleaning and sanitizing all non-food-contact surfaces in accordance with the frequencies in Table 1 below. We recommend that initial sanitizing, of any surface, occur immediately following completion of cleaning, and then be repeated as necessary (e.g., re-sanitizing in the morning after cleaning and sanitizing the night before).

The recommendations in the following table are adapted from a 1999 publication by Tompkin et al. (Ref. 17). If the results of environmental monitoring, spent sprout irrigation water, or product testing indicate a food safety concern, you should consider increasing the frequency of cleaning and sanitizing as part of an overall corrective action plan.

Table 1. Recommended Frequency of Cleaning and Sanitizing

| Surface, Area, or Equipment | Frequency of Cleaning and Sanitizing^a |
|---|---|
| Drains and floors | Daily |
| Pallets | Daily |
| Waste containers | Daily |
| Cleaning tools (e.g., mops, brushes) | Daily |
| Surfaces that have a greater potential to become a source of <i>L. monocytogenes</i> contamination (e.g., surfaces likely to be touched by employees who touch product or food-contact surfaces during operations, or areas where there may be a build-up of moisture or product residue) | Daily |
| Condensate drip pans | Monthly |
| Motor housings, external surfaces of enclosed processing systems | Monthly |
| Overhead piping, ceilings and walls ^b | Semi-annually |
| Freezers (e.g., spiral, blast, tunnel) containing exposed RTE foods ^c | Semi-annually |

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| Surface, Area, or Equipment | Frequency of Cleaning and Sanitizing ^a |
|-----------------------------|---|
| Interiors of Ice Makers | Semi-annually |

^a Since production environments vary, it may be appropriate to increase cleaning frequencies depending on the specific circumstances of the product area.

^b We recommend that that you clean and sanitize some walls and ceilings (e.g., those in close proximity to a production line) at the same time as the production equipment (e.g., daily).

^c If the manufacturer of the equipment recommends cleaning on a more frequent basis, we recommend that you increase this frequency to match the recommendations of the manufacturer.

B. Sanitation Standard Operating Procedures (SSOPs) and Recordkeeping

Sprout operations should create and manage one or more Sanitation Standard Operating Procedure(s) (SSOP). A SSOP is a document which describes sanitation procedures, schedules, and needed materials, tools, and chemicals for specific cleaning and sanitizing tasks. Sprout operations may have several SSOPs describing various tasks throughout the production environment. Each piece of equipment as well as the production environment itself should be considered when developing SSOPs. While not required under the Produce Safety Rule, SSOPs promote consistency between applications as well as proper and complete applications of procedures by different workers. The following details should be included in each SSOP and periodically reviewed by management:

- For what piece(s) of equipment or area(s) of the production environment the SSOP was written.
- Who is responsible for the cleaning and sanitizing tasks.
- When each task is to be completed.
- What tools and chemicals (for both cleaning and sanitizing) are needed.
- How the chemicals are to be prepared.
- How the chemicals are to be used and what precautions need to be taken.
- How to properly clean and sanitize the piece(s) of equipment or work area(s).

You must establish and keep records of the date and method of cleaning and sanitizing of equipment used during growing operations for sprouts and all covered harvesting, packing, or holding activities (§ 112.140(b)). If you have an SSOP, these records should document the performance of the steps outlined in the SSOP, for example using a checklist. Maintaining records of the performed activities not only helps a firm ensure activities are appropriately performed, but also serves as documentation to show auditors or inspectors, as necessary, that the activities were properly performed.

C. Cleaning

Cleaning refers to the practice of removing visible organic material and other debris from surfaces. When cleaning and sanitizing is required, you must properly clean surfaces prior to sanitizing because many sanitizers will not be effective unless food and dirt have been removed from the surface first (see definition of “sanitize” in § 112.3, “to adequately treat *cleaned* surfaces ...” (emphasis added)).

Cleaning procedures should have set frequencies established in a sprout operation’s SSOPs (see discussion above). Your cleaning procedures should be established in light of the results of

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sanitation verification activities, environmental monitoring results (see Section IX (Environmental Monitoring)), surface materials (e.g., stainless steel, plastic, concrete), and the general effectiveness of your cleaning agent(s).

To properly clean your equipment, tools, or other surfaces, you should:

1. Prepare the area by removing or appropriately covering food items, electrical equipment, and food-packing materials.
2. If necessary, remove items from the surfaces to be cleaned (including tools, pieces of food, organic material, or other debris) and disassemble equipment to expose surfaces to subsequent cleaning and sanitizing activities.
3. For wet cleaning of food-contact surfaces, rinse the equipment with water that meets the microbial criterion described in § 112.44(a).
4. Wash equipment with an effective cleaning agent/detergent, using concentrations, contact times, and other directions stated on the label.
5. Physically scrub equipment using appropriate tools.
6. Rinse with water if necessary. Water that contacts food-contact surfaces must meet the microbial criterion described in § 112.44(a).

Factors that influence the effectiveness of cleaning procedures include, but are not limited to, the following:

- How well organic matter, sprouts, and other debris is removed from the equipment, through physical removal and/or rinsing.
- The type and strength of the cleaning agent/detergent.
- The surface material (e.g., plastic, stainless steel, concrete, etc.) to be cleaned and its condition. You should consider the surface material to be cleaned when selecting cleaning agents/detergents.
- Contact time of the cleaning agent/detergent with the surface(s) being cleaned.
- The duration and force of physical scrubbing.

Mops, brushes and other equipment used for cleaning and sanitizing should also be durable and replaced immediately if damaged, cracked, or worn, to prevent the colonization of those tools by microorganisms of public health concern. This equipment should also be stored appropriately, and be cleaned and sanitized as needed.

D. Sanitizing

The Produce Safety Rule defines “sanitize” to mean “to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer” (§ 112.3). When cleaning and sanitizing is required, you must properly clean surfaces prior to sanitizing because many sanitizers will not be effective unless food and dirt have been removed from the surface first. Sanitizing surfaces is usually achieved through chemical means.

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The following should be considered when developing your SSOPs and when sanitizing your equipment or production environment:

- The surfaces should be cleaned as described above.
- Verification activities, described below, should be conducted to evaluate the effectiveness of your cleaning and sanitizing activities.
- Sanitizing agents may be harmful to employees. Proper precautions should be taken when such chemicals are used.
- Chemical sanitizing agents must be used according to label directions in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The following should be considered when selecting sanitizing agents:

- Employee safety.
- The material of the surface that is to be sanitized.
- Characteristics of water (e.g., hardness, pH, temperature) used to prepare the sanitizing agent.
- The compatibility of the sanitizing agent with the cleaning chemical(s).
- Possible impact on the sprouts.

Consulting with cleaning and/or sanitizing agent suppliers will help you select the products that are best suited for your operation.

E. Verification of Cleaning and Sanitizing

Effective cleaning and sanitizing is dependent on numerous factors; individuals that are responsible for cleaning and sanitizing should consider what activities can be controlled to reduce sanitation variability. The concentration of the sanitizing agent used is a key factor that directly correlates to its effectiveness. Verification of chemical concentrations should be done with appropriate test kits and, if analytical instruments are used to measure or regulate sanitizer efficacy, they must be accurate and precise as necessary and appropriate in keeping with their purpose (§ 112.124(a)), adequately maintained (§ 112.124(b)), and adequate in number for their designated use (§ 112.124(c)).

We recommend that sprout operations conduct verification sampling of recently cleaned and sanitized surfaces to monitor overall sanitation effectiveness. We recommend that you use at least one, or more, of the various available methods to verify the effectiveness of your cleaning and sanitizing procedures. Some of these tests, which include bioluminescence, adenosine triphosphate (ATP), and protein-based technologies, provide rapid results and allow for follow-up or intensified cleaning and sanitizing activities if results are above established thresholds. Another option is to quantify aerobic plate counts (APC) of a surface to directly monitor viable microbial populations, the results of which could also be used to indicate where to target sampling of *Listeria* spp. or *L. monocytogenes* as part of environmental monitoring. However, it is critical to understand that none of these tests is an appropriate substitute for environmental monitoring of *Listeria* spp. or *L. monocytogenes* as required for sprout operations by § 112.145 (See Section IX (Environmental Monitoring)).

F. Cleaning and Sanitizing Conducted in Response to Suspected or Known Contamination

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Cleaning and sanitizing is required as a corrective action measure if:

1. Sprouts or sprout irrigation water test positive for the pathogens *E. coli* O157:H7, *Salmonella*, or any pathogens meeting the criteria in § 112.144(c). In such a situation, you must clean and sanitize the affected surfaces and surrounding areas (§ 112.148(c)).
2. *Listeria* spp. or *L. monocytogenes* is detected in the growing, harvesting, packing, or holding environment. In such a situation, you must clean and sanitize the affected surfaces and surrounding areas (§ 112.146(b)).

In addition to the cleaning and sanitizing required as corrective action measures in § 112.146(b) and § 112.148(c), we recommend that you undertake intensified cleaning and sanitizing activities in response to any occurrence of known or suspected contamination of your sprouts, seeds used for sprouting, or locations in your operation (e.g., tools, equipment, other surfaces). In such situations (for example, if your environmental monitoring cleaning verification testing yields a second *Listeria* spp. positive result on the same FCS (see Section IX (Environmental Monitoring))), the following actions should be considered as means of performing “intensified” cleaning and sanitizing:

- Dismantling equipment further than described in the SSOP, if you have one, or further than your normal practice.
- Intensified (e.g., more vigorous, longer time) scrubbing of surfaces where positive samples were found (if applicable) or where product residue accumulates.
- Identifying, cleaning, and sanitizing possible harborage sites and evaluating possible cross-contamination routes.
- Removing and soaking of equipment parts in an appropriate sanitizing agent overnight.
- Increased frequency of cleaning and sanitizing activities for all surfaces that are not already cleaned or sanitized daily.
- Heat treatment of equipment or parts.
- Replacement or repair of tools, equipment, or production operation surfaces.

As previously mentioned, the use of an EPA-registered cleaning or sanitizing chemical in any way that is inconsistent with its labeling (e.g., preparing a higher concentration than specified on the label) is a violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Additionally, exposure to these chemicals may be hazardous to employees and may increase the likelihood of damage to the equipment.

Additional information on corrective action measures required and/or recommended in response either to positive pathogen results in spent sprout irrigation water or sprouts (§ 112.148), or to findings of *Listeria* spp. or *Listeria monocytogenes* (§ 112.146) are discussed in Section VIII (Sampling and Testing of Spent Sprout Irrigation Water or In-Process Sprouts) and Section IX (Environmental Monitoring).

In addition to the cleaning and sanitizing specifically required by the Produce Safety Rule, it is important to note that detection of any foodborne pathogens in samples of seed, spent sprout irrigation water or sprouts, or in environmental samples from food- or non-food-contact surfaces in the production operation (e.g., positive pathogen results from voluntary testing conducted in addition to required testing) should also result in previously unscheduled cleaning and sanitizing of affected food- and non-food-contact surfaces. Similarly, involvement of a sprout operation in a foodborne

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illness outbreak, observations of filth, or other signs of possible contamination should result in previously unscheduled cleaning and sanitizing. You should also consider conducting previously unscheduled cleaning and sanitizing activities if you know or have reason to believe that a lot of seeds may be contaminated with a pathogen (in addition to the requirements you must fulfill in such situations, set forth in § 112.142(b))(See Section VII (Seeds for Sprouting)).

VI. Agricultural Water in Sprout Operations

In the Produce Safety Rule, we define “agricultural water” as “water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce)” (§ 112.3).

Several uses of water typical to sprouting operations meet the definition of “agricultural water,” including water used to irrigate sprouts; to prepare ice that will contact sprouts; and to contact food contact surfaces (including water used to prepare seed treatments, or to rinse, wash, or soak seeds prior to sprouting). “Food contact surfaces” means “those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ‘Food contact surfaces’ includes food contact surfaces of equipment and tools used during harvest, packing, and holding” (§ 112.3). “Food contact surfaces” also includes food contact surfaces of equipment and tools used in growing covered produce, including sprouts (see, e.g., §§ 112.123(d)(1) and 112.143(b)). In a sprouting operation, food contact surfaces include, for example, trays or drums used for sprouting; interior surfaces of containers used for seed rinsing, seed treatment, and pre-germination seed soaking; and counters that come into contact with sprouts during packing and/or packaging (See Section III (General Sprout Production)). Therefore, all water used in a sprout operation to contact such surfaces meets the definition of “agricultural water,” including, as mentioned above, water used to prepare seed treatments or to rinse, wash, or soak seeds prior to sprouting.

Not all water uses meet the definition of “agricultural water.” For example, water used to wash the exterior of a sprout operation’s delivery vehicle is not “agricultural water” (assuming that the vehicle exterior is not used in a way that would make it fit the definition of a “food contact surface”).

This section of the guidance is intended to help operations growing sprouts covered under Subpart M comply with the agricultural water requirements of the Produce Safety Rule. Here, we provide a limited discussion of certain provisions of Part 112 related to agricultural water as they relate to sprout production, most notably the requirement that agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41); the numerical microbial quality criterion that is relevant to sprouting operations (§ 112.44(a)); and the related requirements for agricultural water testing frequency (§ 112.46).

A. Numerical Microbial Quality Criterion for Agricultural Water Used in a Sprouting Operation (§ 112.44(a))

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Certain uses of “agricultural water” (including sprout irrigation water) are subject to a microbial water quality requirement of no detectable generic *E. coli* per 100 ml (see § 112.44(a)), and all water supplied to hand-washing facilities at sprouting operations is required to meet the same standard (see § 112.130(a) and (b)(2); see also § 112.143(a)). We are not aware of any uses of water common in sprouting operations that are intended to or likely to contact food or food contact surfaces that are not subject to this microbial quality requirement. The no detectable generic *E. coli* per 100 ml microbial quality criterion applies to water that is:

- Used as sprout irrigation water (§ 112.44(a)(1));
- Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities (§ 112.44(a)(2));
- Used to contact food contact surfaces, or to make ice that will contact food contact surfaces (§ 112.44(a)(3)); and
- Used for washing hands during and after harvest activities (§ 112.44(a)(4)) and all water supplied to hand-washing facilities at sprouting operations, including water used for hand-washing during growing activities (see § 112.130(a) and (b)(2); see also § 112.143(a)).

As discussed above, many uses of agricultural water in sprouting operations contact food contact surfaces, and such uses are subject to this microbial quality criterion (§ 112.44(a)). “Food contact surfaces” as defined in § 112.3 includes (as stated in the definition) food contact surfaces of equipment and tools used in harvesting, packing, and holding covered produce; but it also includes such surfaces of tools and equipment used in growing covered produce, including sprouts (see, e.g., §§ 112.123(d)(1) and 112.143(b)). One important difference between the application of the Produce Safety Rule to sprouts as compared to other types of covered produce are the different microbial water quality requirements that apply to water used during growing. While we apply the most stringent microbial water quality criterion to water used in growing of sprouts (§ 112.44(a)), we apply less stringent microbial water quality criteria to water used during growing of non-sprout covered produce (§ 112.44(b)), and further limit the application of that criteria to only such water applied using a “direct water application method,” as that term is defined in § 112.3. We defined “direct water application method” to include water uses that are intended to, or likely to, contact covered produce or food contact surfaces. Thus, with respect to water used during growing:

- The less stringent microbial water quality criteria in § 112.44(b) apply to water applied to non-sprout covered produce during growing using a “direct water application method,” which includes water applied to food contact surfaces of tools and equipment used on non-sprout covered produce during the growing stage. We do not interpret § 112.44(a)(3) to also apply the more stringent water quality criterion to the same food contact surfaces when they are used in growing non-sprout covered produce, but only to food contact surfaces used during the later stages of harvesting, packing, and holding of non-sprout covered produce.
- On the other hand, the more stringent microbial water quality criterion in § 112.44(a) applies to all agricultural water used to irrigate sprouts (§ 112.44(a)(1)), and to all agricultural water used to contact food contact surfaces of tools and equipment used during growing, harvesting, packing, and holding sprouts (§ 112.44(a)(3)).

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Similarly, the rule applies more stringent requirements for hand-washing water to sprout operations during growing as compared to operations growing covered produce other than sprouts. For sprout operations, § 112.143(a) requires that growing (as well as harvesting, packing, and holding) take place in a fully-enclosed building. Sections 112.130(a) and (b)(2) require that, for growing that takes place in a fully-enclosed building, adequate and readily accessible hand-washing facilities must be provided, furnished with water that satisfies the § 112.44(a) microbial quality criterion.

As discussed above, in a sprouting operation, “food contact surfaces” include, for example, trays or drums used for sprouting; interior surfaces of containers used for seed rinsing, seed treatment, and pre-germination seed soaking; and counters that come into contact with sprouts during packing and/or packaging. While seeds used to grow sprouts are not themselves “covered produce,” seeds for sprouting are considered “food” under Section 201(f) of FD&C Act and as defined in § 112.3. Requirements relating to “food contact surfaces” in Part 112 apply not only to surfaces that contact (or drain onto, or otherwise transfer onto) sprouts themselves but also seeds used to grow sprouts.

Water used to contact seeds prior to sprouting also necessarily contacts food contact surfaces that contact, drain onto, or otherwise transfer onto those seeds, and therefore must meet the § 112.44(a) microbial quality criterion (§ 112.44(a)(3)). For example, this includes water used to rinse seeds to remove dirt or debris, water used to prepare seed treatments, water used for post-treatment rinsing of seeds, and water used for a pre-germination soak of seeds.

B. Agricultural Water Systems and How the Source Type and Treatment Status Affect Relevant Requirements

Sprout operations will need to identify the type(s) of agricultural water source(s) used in their operation (e.g., ground water, water from a public water supply) and are required to inspect and adequately maintain their agricultural water sources and distribution systems (§ 112.42). Under § 112.42(a), sprout operations are required to inspect all of their agricultural water systems to the extent they are under their control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of their covered produce, practices, and conditions. The specific known or potential hazards that may be associated with your operation and food, in relation to your agricultural water, will likely vary dependent on your specific agricultural water source(s), water distribution system(s), practices at your operation, and your covered produce.

In addition, once you identify uses of water in your operation that meet the definition of agricultural water, the water sources you use should be evaluated to determine which requirements of Subpart E are applicable. As explained above, we are not aware of any uses of water common in sprouting operations that are intended to or likely to contact food or food contact surfaces (and therefore, that fit the definition of “agricultural water”) that are not subject to the microbial quality requirement in § 112.44(a). Therefore, we consider it likely that all “agricultural water” uses in a sprouting operation are subject to § 112.44(a), and our discussion below focuses on § 112.44(a) and related provisions.

Untreated surface water may not be used for § 112.44(a) purposes, including for sprout irrigation water (see § 112.44(a)). The definition of “surface water” appears in § 112.3 and includes, for example, water from rivers.

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Untreated ground water may be used for § 112.44(a) purposes. The definition of “ground water” appears in § 112.3 and includes, for example, water from wells that does not meet the definition of “surface water” (e.g., wells that are not influenced by surface water). In addition to all other applicable requirements of Subpart E that apply to agricultural water as a general matter, if you use untreated ground water for § 112.44(a) purposes in a sprouting operation, you must:

- Sample and test water from each untreated ground water source used for such purposes, at the frequency established in the rule (§ 112.46(c); see also Section VI.E. below), and in compliance with the methodology requirements established for both sampling and testing in the rule (§ 112.47(b), 112.151; see also Section VI.E. below);
- If the microbial quality criterion (no detectable generic *E. coli* in 100 mL) is not met, immediately discontinue using water from the affected water source and/or distribution system for any § 112.44(a) purpose, and take appropriate corrective measures before using the affected water source and/or distribution system again for any such purpose (§ 112.45(a));
- Maintain records related to agricultural water testing, corrective actions, and test methodology as required under §§ 112.50(b)(2), (6), and (9).

Treated water (i.e., water that a sprouting operation treats) may be used for §112.44(a) purposes. This is true regardless of the source from which the water was taken. For example, water from a surface water source may be treated in accordance with § 112.43 and used for a § 112.44(a) purpose. Section 112.44(a) says “you must not use untreated surface water for any of these purposes”. If water has been treated in accordance with the requirements of § 112.43, it is “treated” water (not “untreated”). Water that has been treated in accordance with the requirements of § 112.43 is not required to be tested to ensure compliance with the microbial quality criterion (§ 112.46(a)(3)); In addition to all other applicable requirements of Subpart E that apply to agricultural water as a general matter, if you use treated water for § 112.44(a) purposes in a sprouting operation, you must:

- Comply with all applicable requirements for treating water (e.g., the treatment must be effective to make the water meet the no detectable generic *E. coli* per 100 mL microbial quality criterion (§ 112.43(a)(1)), delivered in a manner that ensures it consistently meets that criterion (§ 112.43(a)(2)), and must be monitored at a frequency adequate to ensure it consistently meets that criterion (§ 112.43(b)); and
- Maintain records related to such treatment (§ 112.50(b)(4)).

Water from a public water system or supply, as described in § 112.46(a)(1) and § 112.46(a)(2), may be used for §112.44(a) purposes. Such water is not required to be tested to ensure compliance with the microbial quality criterion (§§ 112.46(a)(1) and (2)). In addition to all other applicable requirements of Subpart E that apply to agricultural water as a general matter, if you use water from a public water system or supply for § 112.44(a) purposes in a sprouting operation, you must:

- Maintain annual documentation of the results or certificates of compliance from the public water system or supply that demonstrate that the water meets the microbial quality criterion of § 112.44(a), i.e., no detectable generic *E. coli* per 100 ml (§ 112.50(b)(7)).

The exceptions from the testing requirements for water received from a public water system (as in § 112.46(a)(1)) or a public water supply (as in § 112.46(a)(2)) apply only when such water is not held under your control in a way that meets the definitions of “ground water” or “surface water” before

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you use it as agricultural water. See the definitions of “ground water” and “surface water” in § 112.3.

If you hold water received from a public water system or public water supply in a surface water capacity (e.g., holding it in an uncovered tank outdoors), then the water is exposed to potential contamination in a manner similar to other surface water sources, such that it becomes a “surface water” source as applicable. The prohibition on using untreated surface water for § 112.44(a) uses prohibits use of such water as agricultural water in a sprouting operation.

If you hold water received from a public water system or public water supply in a ground water capacity (e.g., through recharging a well), the water is exposed to potential contamination in a manner similar to other ground water sources, such that it becomes a “ground water” source, as applicable, and the testing requirements in § 112.46(c) (and related requirements discussed above) applicable to untreated ground water will apply.

C. Safe and of Adequate Sanitary Quality (§ 112.41)

In addition to the specific numerical microbial water quality criterion in § 112.44(a) that applies to sprout operations as discussed above, we have established a general agricultural water quality requirement.

The requirement in § 112.41 (that all agricultural water must be safe and of adequate sanitary quality for its intended use) applies to all agricultural water, including uses for sprout production. The principle of “safe and of adequate sanitary quality for its intended use” contains elements related both to the attributes of the source water used and the activity or practice related to the use of the agricultural water. The way in which agricultural water is used can affect the risk of contamination of produce. This requirement is a general standard of agricultural water quality applicable to all covered activities in which agricultural water is intended to or likely to contact covered produce or food-contact surfaces. For example, where the intended use is sprout irrigation, agricultural water which exceeds the microbial quality criterion of § 112.44(a) would also fail to meet the requirement in § 112.41 that agricultural water must be safe and of adequate sanitary quality for its intended use. Although a test result indicating the agricultural water does not meet the applicable microbial water quality requirement in § 112.44(a) demonstrates that the water is not safe or of adequate sanitary quality for those specified uses, the converse is not necessarily true. That is, agricultural water that meets the § 112.44(a) microbial quality criterion may not be safe or of adequate sanitary quality, for example, if pathogenic organisms are present.

Sprout operations must inspect and adequately maintain the water distribution system and sources of agricultural water used in the operation (see § 112.42). These activities may lead a sprout operation to discover information giving them reason to believe that their agricultural water is not safe or of adequate sanitary quality for its intended use. For example, a sprout operation might inspect a well it uses as a source of untreated ground water for sprout irrigation in compliance with § 112.42 and find a dead animal in the well. The sprout operation in this example now has reason to believe that the agricultural water from that well is not safe or of adequate sanitary quality for its intended use.

If you have determined, or have reason to believe, that your agricultural water source is not safe or of adequate sanitary quality for its intended use as required by § 112.41, you must immediately

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discontinue that use(s), and before you may use the agricultural water source and/or distribution system again for that use(s), you must take appropriate corrective actions as set forth in § 112.45(a).

D. Reuse of Sprout Irrigation Water

We define a “production batch” of sprouts as “all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown within a single growing unit)” (§ 112.3). This definition is intended to treat as a production batch product that is exposed to the same conditions during sprouting, such as multiple seed types grown in a common drum or multiple trays in a single rack that may be exposed to water that has contacted other product in the same growing unit. The example of a “single growing unit” as “a single rack of trays that are connected to each other” refers to a single rack of trays for which irrigation water is shared across the trays, exposing the sprouts grown in that rack of trays to the same conditions (the same irrigation water).

We recommend against using the same water to irrigate multiple production batches of sprouts (e.g., applying spent water from batch 1 to irrigate batch 2) without any form of water management (e.g., treatment) in between batches. The conditions that are used to produce sprouts allow microorganisms, including those of public health significance, to grow. Using spent sprout irrigation water from one production batch of sprouts to irrigate another production batch of sprouts can lead to cross contamination between batches, multiplying the amount of product potentially exposed to any contamination that may be present. Moreover, depending on the circumstances, such water may not be safe and of adequate sanitary quality for its intended use, in which case the use would be prohibited by § 112.41.

Separate from the requirements for agricultural water under Subpart E, we note that the requirements in Subpart M for testing spent sprout irrigation water for *Salmonella* spp., *E. coli* O157:H7 (and any other pathogen meeting the requirements of § 112.144(c)) apply to each individual production batch of sprouts (§ 112.147). Re-using spent sprout irrigation water from one production batch of sprouts to irrigate another production batch of sprouts does not relieve covered sprout operations of the need to conduct required testing under § 112.147 for spent sprout irrigation water from each individual production batch of sprouts (see Section VIII (Sampling and Testing of Spent Sprout Irrigation Water or In-Process Sprouts)).

Similarly, we also recommend that sprout operations not reuse spent sprout irrigation water to irrigate a single production batch of sprouts over time without any form of water management (e.g., treatment) in between uses. Reusing spent sprout irrigation water for subsequent irrigation of the same growing unit on the same production batch of sprouts over time could reintroduce any pathogens present in the water into the growing sprouts. Any pathogens that may be present in the reused spent sprout irrigation water could then multiply to higher numbers during sprouting. For “stationary” growing units in particular, this practice can also spread contamination that might have otherwise been localized to one area of the growing unit (i.e., a “hot spot”) throughout the entire production batch of sprouts. Moreover, depending on the circumstances, such water may not be safe and of adequate sanitary quality for its intended use, in which case the use would be prohibited by § 112.41.

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E. Agricultural Water Testing Frequency, Sampling, and Test Methods

Covered sprout operations are required to test their agricultural water source(s) to ensure compliance with the microbial quality criterion in § 112.44(a) if they use untreated ground water as agricultural water (see Section VI.B above). In this circumstance, sprout operations are initially required to test each such water source a minimum of four times throughout the growing season or over a period of one year (§112.46(c)). If all four of the initial samples tested meet the microbial quality criterion in § 112.44(a), you may test once annually thereafter. You must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criterion in § 112.44(a).

Section 112.46(c) requires that all such samples be collected to be representative of the intended use(s). By “representative of the intended use(s)” we mean collected from a location, and at a time, such that the sample can reasonably be expected to represent the quality of the agricultural water when it is used for the intended use(s).

With respect to timing, the timing of your sample collection should be reasonably related to the timing of your agricultural water use(s) such that the sample can reasonably be expected to represent the quality of the water when it is used. For example, a sprout operation that uses untreated ground water for agricultural water uses only from April through August of each year should take its samples during the part of the year that it is in production (April – August) so that the samples are representative of the intended use(s). A sprout operation should assess its production schedule to determine an appropriate sampling scheme for collecting the four initial samples.

With respect to location, sampling at the point of your actual use is ideal (e.g., sampling where water comes out of a faucet or hose in your building and enters your sprout growing unit to be used for irrigation water). You may also sample at other points along the water distribution system, from the water source itself to the point of use, as long as there is no reasonably likely point of contamination in the water distribution system between your chosen sampling point and the point of use, such that the sample can reasonably be expected to represent the quality of the water when it is used. For example, if untreated ground water is drawn from a well that is not under your control, you might choose to collect samples from a point that is under your control, such as sampling from a valve on a pipe at the edge of your property line. As another example, if the well is under your control, you may choose to collect samples from the well head. In either case, such samples can be considered “representative of the intended use(s)” (with respect to the location of the samples), provided that there is no reasonably likely point of contamination in the water distribution system between your chosen sampling point and the point of use, such that the sample can reasonably be expected to represent the quality of the water when it is used. In compliance with § 112.42(a), you are required to conduct an inspection of the agricultural water system, to the extent under your control, to identify (among other things) reasonably likely points of contamination. This inspection is required at the beginning of a growing season, as appropriate, but at least annually. This inspection should assist you in selecting your sampling points by helping you determine what sampling locations are, or are not, representative of your intended use(s).

Agricultural water samples to be tested for compliance with the § 112.44(a) microbial quality criterion must be collected aseptically in accordance with § 112.47(b). Using the right materials and equipment is particularly important to ensure the sample collection is conducted aseptically as required under § 112.47(b). You must use sterile equipment and tools when collecting samples

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aseptically. Note that cleaning and sanitizing of sampling equipment is not equivalent to sterilization (See Appendix 1 on Aseptic Sampling).

Agricultural water samples must be analyzed for compliance with the § 112.44(a) microbial quality criterion using a method as set forth in § 112.151 (§ 112.47(b)). We reviewed EPA approved test methods for water, and determined that EPA Method 1603 is appropriate for testing water quality for this purpose (§ 112.151(a)).

However, we recognize that other scientifically valid analytical methods may be available or may become available in the future. Therefore, we provide flexibility for covered farms to use any other scientifically valid analytical method that is at least equivalent to the prescribed analytical method (i.e., EPA Method 1603) in accuracy, precision, and sensitivity (§ 112.151(b)(1)). Any scientifically valid method can be used, provided you ensure that the method is at least equivalent to the prescribed analytical method in accuracy, sensitivity, and precision in detecting the relevant organism or indicator (i.e., generic *E. coli*) in the relevant sample matrix (i.e., ground water). Covered farms are not required to notify us or submit information about such methods of analysis for FDA's review or approval prior to use.

You should choose a laboratory that is qualified to test agricultural water for generic *E. coli*. Testing is typically contracted to a third-party testing laboratory. Testing may also be performed by a sprout operation's own laboratory (e.g., an operation's own "in-house" laboratory). You should use a laboratory that employs scientifically valid laboratory methods and procedures that can provide reliable, accurate test results. A laboratory conducting the tests 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 a laboratory will provide reliable, accurate test results. Regardless of which laboratory you use, testing must be done using a method as set forth in § 112.151.

F. Post-Harvest Water Management

Section 112.48(a) requires you to manage the water used during harvest, packing, and holding activities for covered produce, including sprouts, as necessary, including by establishing and following water-change schedules for re-circulated water to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards. Section 112.48(b) requires you to visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material. In addition, under § 112.44(a), agricultural water applied in any manner that directly contacts covered produce during or after harvest activities is required to meet the no detectable generic *E. coli* in 100 mL microbial quality criterion. This requirement applies to the water as it is being added to a dump tank, flume, or wash tank.

- For example, in a sprout operation, these requirements apply to water used for washing and cooling of sprouts. You must visually monitor the quality of water for buildup of organic material (such as hulls and plant debris). If multiple production batches of sprouts use the

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same post-harvest water, we recommend that you visually check the quality of water prior to adding each new production batch of sprouts.

- We recommend that you change water used for post-harvest washes of sprouts as needed to minimize the potential for cross-contamination. Your visual monitoring of the water should provide you with relevant information. For example, you should change the water when you observe buildup of organic material (this is likely to mean that you should change the water multiple times a day), and/or between each production batch of sprouts).
- In addition to changing post-harvest wash water for sprouts as needed, you should also consider using a water treatment system as part of managing your post-harvest water. We also recommend that such treatments, their delivery, and monitoring, follow the provisions in § 112.43.

VII. Seeds for Sprouting

The requirements in § 112.142 are directed at sprout operations to reduce the likelihood that seeds serve as a vehicle for introducing contamination in sprouts. Specifically, under § 112.142(a), you must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds that you will use for sprouting. You must visually examine seeds, and packaging used to ship seeds, for signs of potential contamination with known or reasonably foreseeable hazards (§ 112.142(d)). You must take certain actions if you know or have reason to believe a lot of seeds is contaminated with a pathogen (§§ 112.142(b)(1) and (2) (except in a few specified circumstances as described in § 112.142(c)). Finally, you must use only seeds for sprouting that have been treated using a scientifically valid method to reduce microorganisms of public health significance (§ 112.142(e)). The seed treatment may be applied at your operation and/or you may rely on prior treatment by another party, provided certain requirements are met (§ 112.142(e)(2)).

This section of the guidance provides recommendations to help you comply with these requirements for receiving, storing, and treating seeds for sprouting. As previously mentioned, throughout this guidance, for the ease of the reader, we often refer collectively to everything sprouted to produce sprouts for human consumption, including beans, 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 not be read to exclude other things that are sprouted to produce sprouts for human consumption, such as beans.

A. Seed Receiving, Handling and Storage

Studies indicate that contaminated seed is the likely source of most sprout-related outbreaks (Ref. 2). Seed contamination can occur at the seed farm, seed conditioner, seed supplier, or at the sprout operation. The sprout growing process involves many opportunities for contamination in or on a few seeds to spread through the entire sprout production batch.

Only a small portion of seed produced in the United States is destined for sprouting, while most is used as planting stock to produce forages for livestock or for planting to grow human food (Ref. 2). Although FDA encourages sprout operations to purchase seeds grown under Good Agricultural

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Practices (GAPs), this does not always occur. Therefore, some seeds are grown, milled, and/or stored under conditions where contamination is likely to occur. Seed may become contaminated by potential sources of fecal contamination, such as contaminated water, use of inadequately treated or raw manure as fertilizer, contamination from wild or domesticated animals, or inadequate worker hygiene. These conditions may contribute to the presence of human pathogens on seed for sprouting.

During harvest, seeds may also be exposed to a significant amount of dirt and debris. Localized contamination may be spread throughout the harvested seed lot due to poor equipment sanitation and/or inadequate worker hygiene. The subsequent steps of sorting, cleaning, storing, and packaging of seeds at seed mills may further spread contamination, especially if GAPs are not followed. Damage to the seeds may also contribute to the overall safety of the seeds; such damage may occur inadvertently or deliberately (i.e., scarification). Cracks, crevices, and other types of damage to seeds may facilitate the internalization of pathogens into seeds and aggravate contamination by making it difficult to remove pathogens during subsequent treatment and handling (Ref. 2).

Post-harvest processing, handling, shipping, and storage of seeds also pose unique safety issues. During these steps, seeds from multiple lots of different origins may be mixed together, providing opportunity for cross contamination to occur, and complicating any necessary later traceback (Ref. 2). In many cases, the decision whether to direct seed to cultivation of other crops or to sprouting is not made until after the seeds are harvested. Therefore, the seed grower may not know if the seeds will be sold for sprouting, and may have little incentive to follow GAPs. We are aware that some sprout seed suppliers seek assurances from the seed grower and handler that seeds were produced under GAPs and handled according to food safety best practices throughout harvesting, conditioning, storage, and transportation. Sprout operations can request this information from the entity which sells their seeds. While not requirements of the Produce Safety Rule, we recommend these practices as prudent when sourcing the seeds used for sprouting.

1. Seed receiving by a sprout operation

Because of the role contaminated seeds have played in numerous sprout-associated outbreaks, we recommend that you take all the steps you reasonably can take to ensure you are buying and using quality seeds for the sprouts you grow. As mentioned above, seed can become contaminated at any point along the supply chain. We recommend that seeds for sprouting be grown under GAPs and that they be conditioned and stored under sanitary conditions. Knowing your seed supplier(s) and establishing specifications for the seeds you receive (such as being grown under GAPs and handled under sanitary conditions during storage and distribution or transport) can help improve the safety of the seeds you receive. Specifications also provide standards against which you can assess the acceptability of the seeds you receive for the production of finished sprouts.

Once seeds arrive at your operation, you should verify that the transport vehicle was clean and sanitary. You should also check the seed tag, package labeling and other documentation to ensure the seeds are what you ordered, that they meet any specifications you may have established with your seed supplier (such as microbial testing for pathogens or prior seed treatment if requested), and that any information or documentation that you may plan to keep for your own records (such as documentation of the seed lot number, or of prior treatment of seed) has been provided.

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We recommend you develop a seed receiving program setting out the standard operating procedures (SOPs) you follow to receive and inspect seed upon receipt and the criteria you use in determining whether to accept a shipment. As discussed above, we also recommend you establish specifications in sourcing seeds to ensure only seeds that have been produced and handled in accordance with GAPs are introduced to the sprouting environment. An example of a seed receiving and inspection checklist can be found in the next section (Section VII.A.2. Visual Inspection of Seeds and Their Packaging). Your seed receiving program should include specific procedures to handle any issues identified while inspecting a shipment. Personnel who receive shipments of seeds should be trained to inspect the incoming product and identify any concerns. Before receiving incoming seeds, you should ensure they are from a known supplier and match the information on the purchase order. If a shipment does not meet your pre-specified requirements, you should evaluate the deviation and, based on your criteria for accepting seeds, determine whether the safety of the seed may be compromised and whether the lot should be rejected.

2. Visual inspection of seeds and their packaging

Under the Produce Safety Rule, you must visually examine seeds, and packaging used to ship seeds, for signs of potential contamination with known or reasonably foreseeable hazards (§ 112.142(d)). Each bag should be examined for physical damage (e.g., holes from rodents) and signs of contamination (e.g., stains, insects, feces, urine, or foreign material) upon arrival. This can be as simple as using a black light to examine seed packaging for signs of rodent urine, and using a hand held magnifying glass to examine seeds for small bits of rodent pellets, excessive dirt and debris, or excessive damage. As mentioned above, damage to seeds can provide nooks and crannies for pathogens to lodge in and make any treatment to reduce pathogens less effective.

A seed receiving and inspection checklist should include:

- Verify Shipping information (e.g., truck conditions, shipping protection)
- Verify supplier name and address on packages to see if they match those on purchase order
- Verify date of shipping and amount
- Obtain and verify seed specifications (e.g., seed type, code or lot number, origin, harvest date, and conformance with GAPs)
- Verify lot information (e.g., original lot size, trace-back information)
- Check condition and size of bags
- Inspect for evidence of tampering
- Inspect for evidence of water damage
- Note any strange or foul odor
- Visually inspect for presence of insect, bird, or rodent droppings
- Inspect for vermin urine using a black light
- Check for damaged or moldy packages
- Open one or several bags of seed and inspect for cracked or chipped seeds and the presence of foreign materials in the seeds (e.g., mud balls, sticks, or glass)
- Check seed testing record, if available, including lot number tested, name of laboratory, test results, and details of tests performed (e.g., test method used, information to support scientific validity of test method, date tested)
- Check seed treatment record, if available

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- Check letters of guarantee, certificates of conformance, or certificates of analysis, if applicable (e.g., contractual agreements or statements from your seed supplier attesting to whether the seeds were grown under GAPs, tested for human pathogens, or if a seed treatment was applied)
- Note any lots rejected due to evidence of contamination or for other reasons

This visual exam of seeds and their packaging upon receipt is one of the first steps you should take at your operation to reduce the chance of seeds serving as a source of contamination in the sprouts you produce. If you observe obvious signs of seed damage or contamination upon receipt, you should report the information to the seed grower, distributor, supplier, or other entity from whom you received the seed and return the shipment to the supplier, if you conclude the contamination occurred prior to the seed arriving at your sprout operation. If you have reason to believe the contamination occurred at your own sprout operation, you should evaluate your practices and conditions and consider how best to prevent recurrence of the problem. This evaluation may lead you to identify new measures you should take to prevent the introduction of hazards into seeds at your operation in compliance with § 112.142(a). In both scenarios, you should also discontinue use of the affected part of the seed lot, conduct intensified cleaning and sanitizing of any surfaces that may have become contaminated (see Section V (Cleaning and Sanitizing)), and take any other actions necessary to prevent reoccurrence of contamination.

In the event that your visual examination of seeds identifies contamination, you might consider, in lieu of discontinuing use of the affected part of the seed lot, treating the affected part of the seed lot with a process that is reasonably certain to achieve destruction or elimination of the most resistant microorganisms of public health significance that are likely to occur in the seeds (we understand that some in the industry may refer to such treatments as a “pasteurization step”). However, we note that processes that meet this description are not currently commonly used in the sprouting industry. Such processes are far more robust than seed treatments described in § 112.142(e), which typically only reduce microorganisms of public health significance, rather than eliminate or destroy them. We do not recommend relying on a seed treatment that does not eliminate or destroy pathogens as an appropriate response to visual observations suggesting contamination of seed. For more information, please see the seed treatment section (Section VII.B) of this document below.

3. Seed testing

Because microbial contamination in seeds, if present, is often at low population levels and not uniformly distributed throughout a seed lot, such contamination is often difficult to detect (Ref. 2). If you or your seed supplier tests a lot of seeds for pathogens, you should be aware that the absence of a positive test result for pathogens does not mean that the lot of seeds is necessarily pathogen-free. We consider testing spent sprout irrigation water (or in-process sprouts) from each production batch of sprouts (see discussion in Section VIII. (Sampling and Testing of Spent Sprout Irrigation Water or In-Process Sprouts)) to be a much more reliable indicator than testing seed to determine whether the sprouts, and the seeds used to produce the batch, are contaminated.

The Produce Safety Rule does not require microbial testing of seeds for sprouting by you or your supplier. However, if you choose to conduct seed testing, we recommend that you develop and implement a written sampling plan for collecting a representative sample, collect the sample aseptically, and test the sample using a scientifically valid method. In addition, we recommend you

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develop, as part of such a plan, specific corrective actions that you will take in the event of a positive test result. A positive test result for pathogen indicates that the lot of seeds is contaminated. In such a case, you must take certain actions under § 112.142(b), including discontinuing use of that seed lot for sprout production, except as provided for in certain limited circumstances in § 112.142(c).

One such circumstance is if you treat the lot of seeds with a process that is reasonably certain to achieve destruction or elimination of the most resistant microorganisms of public health significance that are likely to occur in the seeds (§ 112.142(c)(1)). We understand that some in the industry may refer to such treatments as a “pasteurization step.” We note that processes that meet the description in § 112.142(c)(1) are not currently commonly used in the sprouting industry. Such processes are far more robust than seed treatments described in § 112.142(e), which typically only reduce microorganisms of public health significance, rather than eliminate or destroy them. For more information, see the seed treatment section (Section VII.B) of this document below. If you choose to conduct such a treatment on your seed lot so that you may use those seeds for sprouting, we note that you must still comply with the requirement in § 112.142(b)(2) to report the positive test result to your seed grower, distributor, or supplier.

You are not required to take the steps set forth in § 112.142(b)(1) and (2) if you later reasonably determine, through appropriate follow-up actions, that the lot of seeds is not the source of contamination. We consider that there are very few circumstances in which § 112.142(c)(2) would be applicable in the event there has been a positive pathogen test result in an incoming lot of seed, however. It is also important to note that if a positive pathogen test result is obtained from a seed lot, re-testing a new sample from the same seed lot and obtaining a negative result does not negate the previous positive test result. In such a case, required follow-up actions must still be taken. If you choose to test your seeds, or to have them tested, you or your supplier should follow a sampling plan that includes collecting a sufficiently large amount of seeds from throughout the lot to increase the chances of the sample actually reflecting seed throughout the lot and of detecting pathogens if they are present.

4. Seed storage

Seeds can become contaminated during storage. Under the Produce Safety Rule, you must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds that you will use for sprouting (§ 112.142(a)).

Seeds you use for sprouting should be handled and stored in a manner that will prevent damage and contamination. As mentioned in Section I of this guidance (Introduction), 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 FD&C Act and are in compliance with all applicable laws. You should take whatever steps are necessary to also ensure your seeds do not become contaminated with physical or chemical hazards.

Many pests are attracted to seeds, and these pests can serve as a source of, or vector for, spreading contamination, especially when seeds are in storage. In order to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds that will be used for sprouting as required under § 112.142(a), you should store seeds in a protected manner. Your seed storage area should be clean, dry, protected against pests and separate from the rest of your sprout operation. Your seed storage

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area should be an area dedicated for that use, and should not be used for sprout production or to store equipment or other items such as personal items (see also § 112.126(a)(1)(ii), and Section IV (Buildings, Tools and Equipment)). It should be inside a building of sound construction and in good repair (see also §§ 112.143(a), 112.126, and Section IV (Buildings, Tools and Equipment)). You should store seeds off the floor, away from walls and in proper storage conditions to prevent bacterial growth and to facilitate pest control inspection. You should regularly inspect seed packaging, containers, and the surrounding area to monitor for evidence of pests and you should have a pest control program in place (see also § 112.128, and Section IV (Buildings, Tools and Equipment)). You should store seed at an appropriate temperature and take steps to maintain proper humidity levels.

Once the original seed packaging is opened, remaining seed should be stored in closed containers with tight-fitting lids or otherwise protected from contamination. If you use containers other than original packaging to hold seeds, these containers should be emptied, and their food contact surfaces must be cleaned and sanitized prior to use (See § 112.143(b)). We recommend that they also be cleaned and sanitized between uses (See Section IV (Buildings, Tools and Equipment) and Section V (Cleaning and Sanitizing)).

Containers should also be labeled to maintain the identity of the seed lot and to indicate whether the seeds have received prior treatment by a grower, supplier or distributor.

For seeds that have received prior treatment by the seed grower, distributor, or supplier, it is important that you store these seeds under conditions that will prevent them from becoming contaminated in compliance with § 112.142(a), particularly if you do not plan to re-treat the seeds prior to sprouting. We recommend that seeds that received prior treatment be stored separately from untreated seeds, in airtight, containers/packages that are as small as practicable to minimize the number of times any particular container/package is opened and closed to remove seed from that container (because each such event presents the possibility of contamination). If you reuse containers/packaging, you must ensure that food contact surfaces on these containers are cleaned and sanitized before contact with seeds used to grow sprouts (§ 112.143(b)). We recommend that you also clean and sanitize their food contact surfaces in between each use.

B. Seed Treatment

Research indicates that seed contamination, when it occurs, may be at low levels, intermittent, or unequally distributed within seed lots. However, even low levels of human pathogens on seed for sprouting are a concern, due to the ideal growth conditions present during sprouting. There is some evidence that sprout operations associated with outbreaks often did not apply seed treatments correctly, consistently, or at all (Ref. 2). While treating seeds used for sprouting does not guarantee pathogen-free sprouts, seed treatment has been shown to reduce the percentage of contaminated batches (Ref. 18, Ref. 19, Ref. 20, Ref. 21, Ref. 22). Therefore, seed treatment is a critical part of a multi-hurdle approach to reduce the public health risks associated with sprouts.

The Produce Safety Rule requires that the seeds you use to grow sprouts be treated using a scientifically valid method to reduce microorganisms of public health significance (§ 112.142(e)). 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

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research. To meet the seed treatment requirement, you must adopt one of the following two approaches:

- Treat seeds that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance (§ 112.142(e)(1)), or
- Rely on prior treatment of seeds conducted by a grower, distributor, or supplier of the seeds (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds at the covered farm immediately before sprouting), provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that: (i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and (ii) The treated seeds were handled and packaged following the treatment in a manner that minimizes the potential for contamination (§ 112.142(e)(2)).

1. Choosing a seed treatment

A successful seed treatment should reduce microbial pathogens while preserving seed viability, germination, and vigor. Seed types can vary in sensitivity to antimicrobial agents and other types of treatments, which can affect treatment efficacy and how well the seeds germinate and grow after treatment. The varying surface features of different types of seeds can influence how well a treatment can access and inactivate pathogens on or in the seed. Therefore, an antimicrobial treatment that is effective for one type of seed may not be as appropriate for other types.

When reviewing the options available for seed treatment, especially if you plan to treat seeds at your operation (as opposed to, or in addition to, purchasing pre-treated seeds), you should consider the feasibility of correctly applying the treatment at your operation. For example, irradiation² is an option for seed treatment to reduce microorganisms of public health significance that may not be feasible for a sprout operation to apply on-site. In addition, hot water treatments have been demonstrated to reduce pathogens on seeds by more than 5 log CFU/g in one study (Ref. 23) and to undetectable levels in another (Ref. 24). However, these treatments can require use of equipment such as industrial-sized hot water pasteurization machines (Ref. 25) that might be cost prohibitive for a small sprout operation.

Nothing in part 112 requires or authorizes farms to take measures in conflict with existing federal, State, or local regulations. We expect any seed treatment that is used to be applied in accordance with all applicable federal, State, tribal, or local requirements. For example, in compliance with FIFRA, pesticide chemicals used as seed treatments must be registered with the EPA and labeled for

² 21 CFR § 179.26(b)(10) allows seed for sprouting to be treated with ionizing radiation up to a maximum dose of 8 kGy. We note that the codified language in the regulation states “seeds,” but for the purposes of the regulation, the FDA recognizes that beans for sprouting (e.g., mung bean seeds used for sprouting) would also be included. For information about the use of non-ionizing sources of radiation (such as UV light, radio frequency, microwaves, and pulsed light) we refer the reader to 21 CFR Part § 179 more generally. We note that while seeds that have been treated with ionizing radiation must be labeled with a radura symbol along with either the statement “Treated with radiation” or the statement “Treated by irradiation,” sprouts that are grown using irradiated seeds need not be so labeled where the sprouts themselves have not been irradiated (see 21 CFR § 179.26(c)(2); 65 FR 64605, at 64606-7 (Oct. 30, 2000)).

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use to reduce microorganisms of public health significance on seeds for sprouting. Unlike pesticide chemicals, pest control devices that work by physical means (e.g., heat) and are classified by EPA as “pesticide devices” do not require registration by EPA under FIFRA (Ref. 26). Sources of radiation used to treat food are considered food additives under the law and require an authorizing regulation by the FDA. Note also that some States require registration of pesticide devices, and we refer you to the appropriate State pesticide regulatory agency for more information on a particular State’s requirements related to pest control devices (Ref. 27).

Rather than establishing a specific type or method of seed treatment that you must use to treat seeds, the Produce Safety Rule allows the use of any scientifically valid method to reduce microorganisms of public health significance on seeds that you use to grow sprouts (§ 112.142(e)). This approach provides flexibility in choosing a seed treatment. In choosing a treatment(s) appropriate to your operation and sprouts, and in compliance with the Produce Safety Rule, there are a number of things to consider. In this guidance, we highlight certain treatments that have been studied in the literature and discuss important considerations related to using certain treatments.

Known seed treatment methods include those that work by chemical means (liquid or gas), physical means, or a combination of these. Based on a review of available literature, physical and combination style treatments have been reported to be the most effective for removing pathogens from seeds for sprouting. Physical treatments, such as heat (dry heat or hot water), high pressure, and ionizing radiation (herein referred to as “irradiation”) are reported to have better penetration characteristics for reaching bacteria on microscopically rough surfaces as well as the interior of the seed as compared to chemical treatments (Ref. 28). In some studies, physical treatments have been reported to achieve a 5-log or greater reduction in pathogens on seeds (Ref. 25, Ref. 28, Ref. 29, Ref. 30). Combination methods applying two or more methods sequentially or simultaneously may be more effective than using a single treatment alone. Examples of such combination treatments include: Chemical plus heat; irradiation plus dry heat; and high pressure plus dry heat. Literature suggests many combination treatments may be able to achieve 5-log or greater reduction in pathogens on seeds (Ref. 25, Ref. 28, Ref. 29, Ref. 30, Ref. 31, Ref. 32).

As mentioned above, chemical pesticides used as seed treatments must be registered with the EPA and labeled to reduce microorganisms of public health significance on seeds for sprouting in compliance with FIFRA. Previous studies suggest the following chemicals, when used at appropriate concentrations, may be able to achieve at least a 3-log reduction of pathogens. We note, however, that such treatments require EPA approval and registration under FIFRA before they may be used for such purposes: Acidified sodium chlorite (Ref. 33), calcium hydroxide (Ref. 34), calcium hypochlorite³ (Ref. 28), caprylic acid (Ref. 35), gaseous acetic acid (Ref. 36), (Ref. 37), hydrogen peroxide (Ref. 34, Ref. 38), lactic acid (Ref. 32), monocaprylin (Ref. 35), oxalic acid (Ref. 32), and phytic acid (Ref. 32). Moreover, we note that this is not intended to be an exhaustive list.

2. Seed treatment efficacy

³ In our prior sprouts guidances, we cited a 20,000 ppm calcium hypochlorite treatment as an example of a seed treatment. The EPA registration for this treatment has since been updated and we refer readers to EPA for further information.

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Many seed treatments reduce, but do not eliminate or destroy, microorganisms of public health significance that may be present on the seeds. Pathogens that are not eliminated by seed treatment could potentially be amplified during the sprouting process; therefore, seed treatment prior to sprouting is a key component of the multi-hurdle risk reduction framework established in the Produce Safety Rule.

We recommend sprout operations use the most efficacious seed treatment available to reduce the presence of microorganisms of public health significance on seeds for sprouting, with primary consideration given to reduction of *Salmonella* spp. and *E. coli* O157:H7. We are aware of several existing treatments that have been reported to achieve a 4 or 5-log (or greater) reduction of microorganisms of public health significance on seeds for sprouting, when used under the parameters specified in the literature (Ref. 25, Ref. 28, Ref. 29, Ref. 30):

- Heat, including dry heat and hot water (Ref. 39)
- High pressure
- Irradiation + Dry heat

Certain chemical treatments, including gaseous acetic acid, lactic acid, phytic acid, oxalic acid, and sodium hypochlorite have also been reported to achieve a 4 or 5-log (or greater) reduction in microorganisms of public health significance on seeds for sprouting (Ref. 28, Ref. 32); we note, however, that such treatments require EPA approval and registration under FIFRA before they may be used for such purposes. We refer readers to EPA for further information. Information regarding current EPA registered pesticide products is available on EPA's Web site at: <https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1>.

A prudent sprout operation would not rely only on a treatment that achieves a low level of reduction if other, more effective, treatments are available. We understand that a 3-log reduction is the minimum level of reduction of pathogens the EPA will consider to register an antimicrobial treatment that includes a public health claim on seeds. Using the most efficacious seed treatments available is expected to greatly reduce the likelihood of producing contaminated sprouts. As an additional benefit to sprout operations, doing so is also expected to help minimize the time and resources you invest in producing a batch of sprouts that is later determined to be contaminated through routine testing required under § 112.147 (and which must be discarded as a result, as required under § 112.148).

a. Other considerations when evaluating seed treatment efficacy

The validity and efficacy of any treatment is dependent on the specific parameters used, e.g., seed type, treatment concentration, treatment time, temperature, pressure, or radiation dose. Sprout operations should carefully monitor these and other variables that impact the overall efficacy of the treatment, including, for example, for most chemical treatments, the seed-to-treatment solution ratio and pre- and post-treatment rinsing. If you are utilizing a seed treatment described in scientific literature, you should take into account the parameters used in the study and determine whether they are compatible with how you will be applying the treatment at your operation. For example, if the treatment you are considering has only been tested on alfalfa seeds, and you plan to use the treatment on mung beans, you should not assume that the treatment will be equally efficacious at reducing microorganisms of public health significance on mung beans. Additionally, you should pay attention

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to any special equipment that is used to apply the seed treatment as it is described in the literature. For example, hot water seed treatment using a seed pasteurizing system (Ref. 25) would not be equivalent to boiling seeds in hot water on a kitchen stove, because the seed treatment machine has built in temperature control mechanisms that are validated, self-correcting, and time-controlled while a kitchen stove does not.

To ensure seed treatments are consistently applied correctly, if you treat seeds at your sprout operation, you should develop a written seed treatment Standard Operating Procedure (SOP). The SOP should include: objectives, methods used, who is responsible for each task, materials needed, treatment procedures, parameters to be measured or monitored, and relevant records to be made (in compliance with the requirements of § 112.150(b)(1) and otherwise). All plans should be tailored to what is actually done in your operation.

3. Using pre-treated seeds

There are several seed treatment methods that can be effectively applied by a grower, handler, or distributor of seeds such that, when followed by good handling and packaging practices, they can eliminate the need for you to treat seeds at your operations immediately before sprouting. However, using pre-treated seeds does not preclude you from treating the seeds again at your own operation. The availability of various options for seed treatment (e.g., by you, your seed supplier, or both) has several benefits, including increased flexibility for you and increased availability of treatment options that may be cost-prohibitive to some small sprout operations. We encourage sprout operations who choose this option to purchase seeds that have been treated with the most efficacious method available.

We note that sprout operations who choose to purchase seeds that have been pre-treated with ionizing radiation should be aware that if those same seeds are to be treated again with ionizing radiation, the cumulative dose must not exceed the maximum dose as indicated in § 179.26(b)(10).

If you choose to rely, in whole or in part, on using pre-treated seeds, you must obtain documentation from your seed supplier that the treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance (§ 112.142(e)(2)(i)) and that the treated seeds were handled and packaged, following the treatment, in a manner that minimizes the potential for contamination (§ 112.142(e)(2)(ii)). We recommend that you obtain documents of this type from your supplier that are specific to each lot of seeds you receive from that supplier. One such type of document you may obtain is a Certificate of Conformance. Such a certificate (or other forms of documentation used for this purpose) should include documentation of the scientifically valid method used to treat the seeds, the level of log reduction achieved, the type of seeds used for any validation study that may have been done, and the pathogens targeted. We also recommend that if water was used to prepare treatments for the seeds, you should obtain documentation or assurances from your supplier that the water used for treating seeds meets the microbial quality criteria in § 112.44(a) (0 detectible generic *E. Coli* in 100 mL water).

4. Proprietary treatments

The Produce Safety Rule does not prohibit the use of proprietary seed treatments (e.g., treatments developed based on a firm's own scientific research not published in scientific literature). However, we expect any seed treatment that is used to be applied in accordance with all applicable federal,

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State, tribal, or local requirements. If you (or your seed supplier) use a proprietary treatment, then we expect you (or the party who applies the treatment) to take all necessary steps to ensure that it is in compliance with all relevant laws, including the FIFRA, if applicable, and that the treatment is effective in reducing pathogens on seeds. If you rely on treatment conducted by a seed supplier, you must obtain documentation (such as a Certificate of Conformance) from that supplier that the treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance (§§ 112.142(e)(2)(i) and 112.150(b)(1)). We recommend that in such circumstances, you ask your seed supplier for a written explanation of the treatment parameters that were applied, and the basis for the conclusion that the treatment is scientifically valid. In the event of an investigation or inspection of your sprout operation, we may ask to review the science supporting the seed treatment(s) you rely on, including proprietary treatment(s), to ensure it is scientifically valid.

5. Additional considerations for treating seeds for sprouting

If you treat seeds for sprouting at your sprout operation, you should take steps to ensure that the seed treatment(s) is applied correctly and that the treatment of seeds does not result in contamination of food or food contact surfaces.

Seed treatment should take place in a clean location, separate from areas used for storage for seeds and areas used for sprout germination and packing (See also § 112.126(a)(1)(ii) and Section IV (Buildings, Tools and Equipment)). You must visually examine seeds, and packaging used to ship seeds, for signs of potential contamination (§ 112.142(d)). As discussed in Section VII.A.2 above, we recommend that you do this upon the seeds' arrival at your operation. We also recommend that, if you have stored the seeds for any length of time after their arrival at your operation and prior to sprouting, before bringing seeds into the treatment area, you should re-inspect bags of seeds for signs of contamination. Before you treat seeds, any containers or utensils that will come into contact with the seeds as part of the treatment process must be cleaned and sanitized (§ 112.143(b)).

a. Employee practices

Employees who conduct seed treatment at your operation should receive appropriate training for the job, and should be supervised in a manner that ensures that they follow the established treatment procedures (e.g., label instructions, SOPs).

b. Pre-germination seed rinse and soak

Seeds are typically rinsed before treatment. While the Produce Safety Rule does not require pre-treatment rinsing, we recommend that seeds be rinsed thoroughly before treatment to reduce microorganisms of public health significance, to remove dirt, and to increase the efficiency of the treatment. If you do rinse seeds before treatment, you should repeat the rinsing process with new water until most of the dirt is removed and rinse water runs clear. We also recommend that you conduct your rinse in such a way as to maximize seed surface contact with water (e.g., by mixing or agitating). If a surfactant is used to help remove soil and debris during seed rinsing, it should be rinsed out completely before the next step.

Soaking causes seeds to swell and softens hulls to allow the sprout to grow out of the seed. Depending on your production practices and the type of seeds you use, a pre-germination soak may

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be necessary to improve germination. Pre-germination soaking is not required by the Produce Safety Rule.

If you do rinse or soak seeds, water used for these purposes must meet the microbial quality criterion in § 112.44(a) (i.e., no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water), and related requirements elsewhere in Subpart E, because such water contacts FCSs (surfaces of the rinse or soak container that also contact seeds used for sprouting) during the covered activity of growing covered produce (sprouts) (See § 112.44(a)(3)); see also Section VI. (Agricultural Water in Sprout Operations)). This includes water used for any additional post-soaking rinses of seeds that you may conduct, for example, to remove residues generated during soaking.

In addition, if you do rinse or soak seeds, you must clean and sanitize the FCSs of your tools and equipment before they contact the seeds (§ 112.143(b); see also Section V. (Cleaning and Sanitizing)). These are FCSs used during the covered activity of growing covered produce (sprouts).

In addition, if you do rinse or soak seeds, you must take any other measures that are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto the seeds during that process (§ 112.142(a)).

We recommend that sprout operations not rinse or soak large quantities of seed together, but instead, to minimize the possibility of cross-contamination, rinse or soak in a single container only the amount of seed that will be used in a single production batch of sprouts. Containers used to rinse or soak seeds should be large enough to allow thorough mixing without splashing. Personnel should either wear a new pair of disposable or clean reusable gloves, or have clean hands, when pouring seeds into the container. We recommend that you change the water each time you change the seeds you are rinsing or soaking (e.g., for the seeds for each new production batch of sprouts).

c. Chemical seed treatment

If applying a chemical seed treatment, you should use clean, appropriately labeled containers when mixing the treatment chemicals to the desired concentration, and the treatment should be prepared correctly to ensure the chemical is present at the desired concentration. You should determine the volume of chemical needed based on the weight of the seeds to be treated. You should refer to the chemical label instructions to calculate the amount of chemical needed to achieve the desired concentration and volume of the treatment solution. If water is used, you should use a scale to weigh dry chemicals, and then add them to a container that already contains the appropriate amount of water. Water used for mixing such solutions must meet the microbial quality criterion in § 112.44(a) (see Section III.A (General Sprout Production)). The solution should be stirred to mix it completely and dissolve all solids. After mixing, you should verify the treatment solution concentration according to the label directions, since the concentration can impact treatment effectiveness.

Once the chemical treatment is prepared, you should carefully combine it with the seeds. You should agitate the seeds and the chemical treatment at the correct temperature and for the appropriate amount of time according to any seed treatment SOP you may have established, and the chemical's label instructions. It is important to use the correct amount of treatment for a known quantity of seeds; too much seed and/or too little chemical will decrease the effectiveness of the treatment. The same batch of seed treatment solution should not be used on seeds used to produce more than one production batch of sprouts; you should prepare a new treatment before each application. For

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chemical treatments prepared as a solution, you should drain the chemical solution and dispose of it according to label directions and all applicable federal, state, and local requirements after completing the treatment. You should rinse seeds thoroughly to remove any residual treatment if necessary.

C. Corrective Actions for Seeds That May Be Contaminated With a Pathogen

If you learn that a lot of seeds has been associated with foodborne illness, or if you learn that a lot of seeds may be contaminated with a pathogen based on microbial test results (including that required under § 112.144(b)), you have certain duties with respect to that seed lot and sprouts grown from that seed lot under § 112.142(b).

Section 112.142(b) requires that in such circumstances, except as provided in § 112.142(c), you must discontinue use of all seeds from that lot for sprout production (§112.142(b)(1)), must ensure that sprouts grown from that lot of seeds do not enter commerce (§112.142(b)(1)), and must report the information to the seed grower, distributor, supplier, or other entity from whom the seed was purchased (§112.142(b)(2)).

It is important for you to report the findings to the entity (seed grower, distributor, or supplier) that supplied the seeds, so that entity could then take appropriate follow-up actions. These actions include informing other buyers of the suspected lot of seeds regarding the contamination, destroying or diverting any remaining seeds to non-food uses, and/or investigating the potential source of contamination, as necessary. Additionally, the seed grower, distributor, or supplier may be required to submit a report to the Reportable Food Registry (RFR), which requires food facilities to report certain information to the FDA when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

Depending on the circumstances, it may also be appropriate to recall sprouts that have already entered commerce that were produced from the affected seed lot. Any sprouts that are adulterated should be voluntarily recalled.

When your belief that a lot of seeds may be contaminated is based only on microbial test results, you would not have to take the steps described in §112.142(b)(1) (discontinue use of the suspect lot of seeds and ensure sprouts made from them do not enter commerce) if you treat the suspect lot with a process that is reasonably certain to achieve destruction or elimination of the most resistant microorganisms of public health significance that are likely to occur in the seeds (§112.142(c)(1)). This option exists to allow sprout operations flexibility in responding to a finding that would otherwise mean they would have to discontinue use of the seeds and to encourage future innovation in seed treatment processes. Processes that meet the description in §112.142(c)(1) are not, at this time, commonly used in the sprouting industry. Such processes are far more robust than seed treatments described in §112.142(e), which typically only reduce microorganisms of public health significance, rather than eliminate or destroy them. If a sprout operation opts to use irradiation to meet the requirements of § 112.142(c)(1), it is essential to use a level of irradiation that is reasonably certain to achieve destruction or elimination of the most resistant microorganisms of public health significance that are likely to be in the seeds (we note that not all levels of irradiation can achieve this).

Moreover, when the reason for believing the lot of seeds may be contaminated is based only on microbial test results, if you reasonably determine, through appropriate follow-up actions, that the lot

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of seeds is not the source of contamination, you do not have to take the steps in § 112.142(b)(1) or (2). That is, you are not required to discontinue use of that seed lot and ensure that sprouts grown from that lot do not enter commerce (§ 112.142(b)(1)), nor do you need to inform the seed grower, distributor or supplier of the positive test result (§ 112.142(b)(2)). However, we expect that the situations in which you could take follow-up actions that would be adequate to reasonably determine that the lot of seeds was not the source of contamination are not extensive. Two examples of scenarios in which we believe such a determination might be appropriate are described below.

Examples of Possible Scenarios and Follow-Up Corrective Actions

1. Seed lot A is recalled by the seed supplier due to contamination with *Salmonella* while an operation has sprouting in process with that seed lot. The sprout operation immediately stops production of sprouts using seed lot A, disposes of the sprouts and returns unused seed to the distributor. The sprout operation cleans the equipment and starts using the same equipment to grow another batch of sprouts using seed lot B. Seed lot B was purchased from a different seed supplier that sources their seed from a different farm compared to seed lot A. Spent sprout irrigation water from the next production batch of sprouts using seed lot B then tests positive for *Salmonella*, and follow-up sample analysis shows this to be the same *Salmonella* serotype that was identified as contaminating seed lot A. The sprout operation discovers that cleaning and sanitizing protocols were not followed properly following sprout production using seed lot A, and swabs the equipment and finds a matching *Salmonella* serotype on the equipment that had been used to sprout both seed lots A and B. After adequately and thoroughly re-cleaning and sanitizing the equipment and re-testing food contact surfaces for *Salmonella* with negative results, the sprout operation starts a new production batch of sprouts using seed lot B as a follow-up action to the positive test result to determine whether seed lot B may also be contaminated. The second time, all spent sprout irrigation water tests from seed lot B sprouts come back negative. In this circumstance, the sprout operator could reasonably conclude that seed lot A had contaminated the equipment, which was not initially adequately cleaned and sanitized and therefore contaminated the first batch of sprouts produced from seed lot B. If the farm is following appropriate follow-up sanitation procedures, and spent sprout irrigation water from seed lot B is no longer testing positive for *Salmonella*, under these circumstances the farm may reasonably conclude that seed lot B was not the source of contamination that generated the positive test result when testing spent sprout irrigation water from seed lot B sprouts. We note that in general a negative test for seeds or spent sprout irrigation water would not, by itself, be enough evidence that seed lot B was not contaminated. However, in this example, the seed supplier's *Salmonella* serotype result from seed lot A that matches serotype found in the positive spent sprout irrigation water sample and the swab from equipment used to sprout seed lot B, combined with the different supplier and farm source for seed lot B as compared to seed lot A, improper cleaning and sanitizing of equipment, negative subsequent test results, and the intervening improvements in cleaning procedures, supports the conclusion that the positive spent sprout irrigation water sample from sprouts made with seed lot B was most likely due to contamination of shared production equipment with seed lot A.
2. A sprout operation mixes two seed lots (lot A and B) together to result in a mixed sprout product for which the spent sprout irrigation water tests positive for *Salmonella*. The sprout operation could sprout each seed lot individually. If upon follow-up serotype sample

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analysis, spent sprout irrigation water from only one seed lot (lot A) tests positive for *Salmonella* matching the original positive, the sprout operation could reasonably determine that seed lot A was the source of the *Salmonella* positive in spent sprout irrigation water from the mixed seed sprouts. The sprout operation would be required to discontinue use of all seeds from the affected seed lot for sprout production (unless it treats the seed lot in accordance with § 112.142(b)(1)), ensure that sprouts grown from that seed lot do not enter into commerce, and report the information to the grower, distributor, supplier, or other entity from whom the farm received the seeds, in compliance with § 112.142(b). Under § 112.142(c), the sprout operation could continue to use seed lot B, provided there were no subsequent positive test results and no information suggesting association of that seed lot with foodborne illness.

In the event that your sprouts are associated with foodborne illness, you are required to discontinue use of all seeds from the affected lot for sprout production and ensure that sprouts grown from that lot of seeds do not enter commerce (§ 112.142(b)(1)), and you must report the information (i.e., association of the seed lot with illness) to your grower, distributor, supplier, or other entity from whom you received that seed lot (§ 112.142(b)(2)). We are not aware of actions that a sprout operation could take to demonstrate that the lot of seeds was not the source of contamination following an outbreak of foodborne illness. The sprout operation, along with regulators, may make a determination that the farm's seeds were not associated with a foodborne illness outbreak, but it is unlikely that the sprout operation would have adequate information and records (e.g., epidemiological data and traceback information) to make that determination independently. Therefore, the Produce Safety Rule does not provide a similar option to § 112.142(c) applicable in instances where there is knowledge or reason to believe that a lot of seeds has been associated with foodborne illness, and, therefore, in such circumstances you must take the actions required in §§ 112.142(b)(1) and (2).

We restate, as a summary, different scenarios regarding corrective actions for seeds that may be contaminated with a pathogen below.

Scenario 1:

- A lot of seeds is associated with foodborne illness (e.g., you learn that a lot of seeds is implicated in an outbreak); or
- A lot of seeds is recalled by the supplier, grower, distributor, or other entity because of possible contamination with a pathogen (i.e., you learn of a recall of a lot of seeds due to association with foodborne illness or positive microbial test results)

Required Actions:

- Discontinue use of all seeds from that lot for sprout production (§ 112.142(b)(1)).
- Ensure that sprouts grown from that lot of seeds at the sprout operation do not enter commerce (§ 112.142(b)(1)).
- Report the information (association with illness or positive microbial test results) to the seed grower, distributor, supplier, or other entity from whom you received the seeds (§ 112.142(b)(2)).

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- We recommend that you return the affected lot of seeds to the supplier, grower, distributor, or other entity from which they were purchased.
- We recommend that you clean and sanitize the affected surfaces (i.e., those that may have contacted the seeds that were associated with illness) and surrounding areas, and perform any other actions necessary to prevent reoccurrence of the contamination.
- Depending on the circumstances, it may be appropriate to recall sprouts that have already entered commerce that were produced from the affected seed lot. Any sprouts that are adulterated should be voluntarily recalled.

Scenario 2:

- Positive microbial test result finding a pathogen in seeds.

Required Actions:

- Except as provided by § 112.142(c):
 - Discontinue use of all seeds from the affected lot for sprout production (§ 112.142(b)(1));
 - Ensure that sprouts grown from the affected lot of seeds do not enter commerce (§ 112.142(b)(1)); and
 - Report the information (microbial test findings) to the seed grower, distributor, supplier, or other entity from whom you received the seeds (§ 112.142(b)(2)).

Additional Actions:

- We recommend that you return the affected lot of seeds to the supplier, grower, distributor, or other entity from which they were purchased, or, as provided in § 112.142(c)(1), you have the option to treat the lot of seeds with a process that is reasonably certain to achieve destruction or elimination of the most resistant microorganisms of public health significance that are likely to occur in the seeds (may be referred to as a “pasteurization step”). However, we note that processes that meet this description are not currently commonly used in the sprouting industry. Such processes are far more robust than seed treatments described in §112.142(e), which typically only reduce microorganisms of public health significance, rather than eliminate or destroy pathogens. If you treat the affected lot of seeds with a process described in § 112.142(c)(1), you are not required to take the steps described in § 112.142(b)(1). You are still required to report the information about the positive test result to your supplier under § 112.142(b)(2).
- As provided in § 112.142(c)(2), if you reasonably determine, through appropriate follow-up actions, that the lot of seeds was not the source of contamination, you are not required to take the steps described in §§ 112.142(b)(1) and (2). We note, however, that it is unlikely §112.142(c)(2) could be satisfied in the event of a positive seed pathogen test result.
- Depending on the circumstances, it may also be appropriate to recall sprouts that have already entered commerce that were produced from the affected seed lot. Any sprouts that are adulterated should be voluntarily recalled.

Scenario 3:

- Positive microbial test result finding a pathogen in spent sprout irrigation water or sprouts (i.e., positive results from pathogen testing required under § 112.144(b); see also Section VIII (Sampling and Testing of Spent Sprout Irrigation Water or In-Process Sprouts))

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Actions Required:

- Except as provided by § 112.142(c):
 - Discontinue use of all seeds from the affected lot for sprout production (§§ 112.142(b)(1); 112.148(b));
 - Ensure that sprouts grown from the affected lot of seeds do not enter commerce (§§ 112.142(b)(1); 112.148(b)); and
 - Report the information (microbial test findings) to the seed grower, distributor, supplier, or other entity from whom you received the seeds (§§ 112.142(b)(2); 112.148(b)).
- Take appropriate action to prevent any food that is adulterated under section 402 of the FDCA from entering into commerce (§ 112.148(a));
- Clean and sanitize the affected surfaces and surrounding areas (§ 112.148(c)); and
- Perform any other actions necessary to prevent reoccurrence of the contamination (§ 112.148(d)).

Additional Actions:

- We recommend that you return the affected lot of seeds to the supplier, grower, distributor, or other entity from which they were purchased, or, as provided in § 112.142(c)(1), you have the option to treat the lot of seeds with a process that is reasonably certain to achieve destruction or elimination of the most resistant microorganisms of public health significance that are likely to occur in the seeds (may be referred to as a “pasteurization step”). However, we note that processes that meet this description are not currently commonly used in the sprouting industry. Such processes are far more robust than seed treatments described in §112.142(e), which typically only reduce microorganisms of public health significance, rather than eliminate or destroy pathogens. If you treat the affected lot of seeds with a process described in § 112.142(c)(1), you are not required to take the steps described in § 112.142(b)(1). You are still required to report the information about the positive test result to your supplier under § 112.142(b)(2).
- You should also conduct an assessment to determine whether or not the seed lot(s) used was the source of the contamination.
- As provided in § 112.142(c)(2), if you reasonably determine, through appropriate follow-up actions, that the lot of seeds was not the source of contamination, you are not required to take the steps described in §§ 112.142(b)(1) and (2). We expect, however, that the situations in which you could take follow-up actions that would be adequate to make a reasonable determination that the lot of seeds was not the source of the contamination are not extensive. See examples discussed above.
- Depending on the circumstances, it may also be appropriate to recall sprouts that have already entered commerce that were produced from the affected seed lot. Any sprouts that are adulterated should be voluntarily recalled.

D. Recordkeeping

We recommend that you establish and keep sufficient records to allow you to maintain the lot identity of the seeds you receive and the sprouts you produce, by which we mean that you should be able to determine which seed lot was used to grow each production batch of sprouts, and which

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container(s) of seed belong to one lot in the event that corrective actions need to be taken. For each seed lot, your records should allow you to determine the identity of the supplier, variety, date of receipt, batch or lot number of the seed that you received (including all identifying numbers assigned to the seed, both by the supplier and by your operation, if different), and the date(s) that you used the seed from that lot for sprouting. This will facilitate trace back to your seed supplier and (when possible) to the seed grower as needed. Maintaining records that provide traceability by connecting each production batch of sprouts to the lot of seeds used to grow them can help minimize the scope of product potentially affected in the event of a problem with a particular production batch of sprouts or a particular lot of seeds. We recommend that you maintain such records related to each lot of seeds for at least two years after the last use of the seed lot.

When receiving seeds, you should make sure each bag of seeds (or other container) is clearly marked in a way that allows you to maintain the identity of the seed lot, and if received bags or containers are not already so marked, you should mark them as needed.

A seed receiving log documenting seed lot receipt and inspection will help you document your seed receiving procedures and facilitate an effective trace-back if necessary. We recommend you use a seed receiving and inspection checklist (see Section VII.A.2 (Visual Inspection of Seeds and their Packaging)) in part to help you generate useful records such as those described here. We recommend that, for all incoming seed shipments, you record and/or otherwise maintain the information in your seed receiving and inspection checklist in writing.

If the sprout operation is providing the required treatment of seeds used for sprouting (§ 112.142(e)(1)), documentation of this treatment is required (§112.150(b)(1)). Like all records required by the Produce Safety Rule, seed treatment records must comply with all applicable requirements for records in Subpart O of Part 112 (see Section X (Recordkeeping)). For example, they must:

- include actual values and observations obtained during monitoring (§ 112.161(a)(1)(ii)) (i.e., observations of treatment conditions and key parameters monitored during preparation and application of treatments (e.g., chemical composition, heating temperature, equipment used, concentration or strength of treatment, treatment time, pH of the treatment solution, agitation));
- include the date and time of the activity documented (§ 112.161(a)(1)(v)) (i.e., the date and time the treatment was applied);
- be created at the time an activity is performed or observed (§112.161(a)(2)) (i.e., they must be created at the time of the treatment, not before or afterward);
- be dated, and signed or initialed, by the person who performed the activity documented (§ 112.161(a)(4)) (i.e., by the person applying the treatment); and
- be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party (§ 112.161(b)).

The following information should also be maintained in seed treatment records:

- Type of seeds treated
- Seed lot number
- Type of treatment (i.e., chemical, heat)

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- References to the scientific data supporting the method
- Printed name of person applying treatment
- Printed name of reviewing supervisor or responsible party

If you are relying on prior treatment of seeds by someone in the supply chain prior to your operation (e.g., a grower, distributor, or supplier of seeds) (§ 112.142(e)(2)), whether to fulfill the treatment requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment at your operation, you must obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier seeds that the treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance (§ 112.142(e)(2)(i)) and that the treated seeds were handled and packaged, following the treatment, in a manner that minimizes the potential for contamination (§ 112.142(e)(2)(ii)) (See also § 112.150(b)(1)). We recommend that you obtain documents of this type from your supplier that are specific to each lot of seeds you receive from that supplier. Certificates of Conformance (or other forms of documentation used for this purpose) should include documentation of the scientifically valid method used to treat the seeds, the level of log reduction achieved, the type of seeds used for any validation study that may have been done, and the pathogens targeted. We also recommend that if water was used to treat the seeds, you should obtain documentation or assurances from your supplier that the water used for treatment meets the microbial quality criteria in § 112.44(a) (0 detectible generic *E. Coli* in 100 mL water).

Sprout operations also must maintain documentation of certain corrective actions (see § 112.150(b)(6)). Required corrective actions that relate particularly to seeds (the topic of this section), as discussed in Section VII.C. (Corrective Actions for Seeds that May be Contaminated with a Pathogen), include those taken in accordance with §§ 112.142(b) and (c) (i.e., required actions if you know or have reason to believe that a lot of seeds may be contaminated with a pathogen), and 112.148 (i.e., additional required actions where your knowledge or reason to believe that the lot of seeds is contaminated came from required spent sprout irrigation water or sprout pathogen testing pursuant to § 112.144(b)). With respect to records you keep to document any of these corrective actions:

- You must make a record of the date and time at which you performed each activity (e.g., returning the affected seed lot to a supplier, destroying sprouts grown from the affected seed lot, reporting information to your seed supplier, treating seeds with a process reasonably certain to achieve destruction or elimination in seeds of the most resistant microorganisms of public health significance, or conducting follow up actions to investigate the potential source of the contamination) (§ 112.161(a)(1)(v)).
- You must make such records of each such activity at the time the activity is performed (§ 112.161(a)(2)).
- Such records must be dated, and signed or initialed, by the person who performed the activity documented (§ 112.161(a)(4))
- Such records must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party (§ 112.161(b)).

Specifically, if you treat the affected lot of seeds with a process that is reasonably certain to achieve destruction or elimination in seeds of the most resistant microorganisms of public health significance, the records you keep to document this action for purposes of §§ 112.142(c)(1) and 112.150(b)(6)

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must include the same content required for records documenting routine seed treatment under §§ 112.142(e)(1) and 112.150(b)(1) (see above in this same section). We also recommend that such records also include the same additional content that we recommend for records documenting routine seed treatment (see above in this same section).

With respect to records you keep to document follow up actions taken in accordance with § 112.142(c)(2), we recommend including as much detail as practical in your records (e.g., regarding the scope of your evaluation, any deficiencies found, and all relevant actions taken).

VIII. 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. Under § 112.144(b), you must 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 for hydroponically grown sprouts that use very little water), you must test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing).

Under § 112.144(c) the Produce Safety Rule requires testing of other pathogens in addition to *E. coli* O157:H7 and *Salmonella* 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). If both conditions are met for a particular pathogen such that testing would be required, we intend to issue additional guidance to inform stakeholders.

This section of the guidance provides recommendations to help you comply with the requirements related to sampling and testing spent sprout irrigation water (or in-process sprouts), including establishing and implementing a written sampling plan (§ 112.147), collecting samples using an aseptic technique (§ 112.147(b)), preventing each production batch of sprouts from entering commerce until test results are received (§ 112.147(b)), testing samples in accordance with required methods (§§ 112.147(b) and 112.153), and developing and implementing corrective actions to be followed in the event that the sample(s) of spent sprout irrigation water or sprouts test positive for a pathogen (§ 112.147(c)). Recommendations related to recordkeeping requirements for sampling and testing of spent sprout irrigation water (or in-process sprouts) are also discussed (§ 112.150).

A. Developing a Sampling Plan

Under § 112.147(a), you must 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, under § 112.147(b), in accordance with the written sampling plan, you must aseptically collect samples of spent sprout

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irrigation water or sprouts, and test the collected samples for pathogens using a method as set forth in § 112.153. You must not allow the production batch of sprouts to enter into commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* species, and, if applicable, a pathogen meeting the criteria in § 112.144(c). Also, under § 112.147(c), your written sampling plan must 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:

1. Should specify whether you are testing spent sprout irrigation water or, alternatively, in-process sprouts (i.e., while the sprouts are still growing). If the latter, you should explain why testing spent sprout irrigation water is not practicable. For example, we recognize testing spent sprout irrigation water is not practicable for soil-grown sprouts harvested with roots and for hydroponically grown sprouts that use very little water;
2. Should 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));
3. Should identify the specific test method by which collected samples will be tested for relevant pathogens (you are required to use a method as set forth in § 112.153);
4. Should indicate the person(nel) (name or title) in your sprout operation who is (are) responsible for sample collection, as well as any specific training and/or qualifications that the sample collector(s) should possess;
5. Must specify the specific 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. We also recommend including a diagram of the different growing units at your operation, and indicating the points of sample collection in your sampling plan;
6. Should 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.
7. Must 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)). You should also note any differences in the number of samples based on the type of growing unit or irrigation practices, as well as the number of sub-samples, as applicable;
8. Should indicate the volume of spent sprout irrigation water (or in-process sprouts) to be collected for each sample;
9. Should 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. You may need to describe more than one procedure for aseptic sample collection, depending on the types of sprouts you grow and the growing practices in your operation;
10. Should 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;
11. Should 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

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- specific laboratory(ies) that you use (e.g., name, address, contact information), any forms that should be completed, sample labeling procedures, and storage considerations;
12. Should 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)) (§ 112.147(b)). The sampling plan should also describe your specific procedure(s) for ensuring that this requirement is satisfied for each production batch of sprouts;
 13. Must include a corrective action plan, as required under § 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 either include your cleaning and sanitizing procedures, or reference your SSOP, in your corrective action plan to describe how you will accomplish the required cleaning and sanitizing corrective actions (§ 112.148(c));
 14. Should indicate the person(nel) (name or title) in your sprout operation who is (are) responsible for implementing the corrective action plan in response to a positive test result;
 15. Should describe the records that you will make and maintain for each sample of spent sprout irrigation water or sprouts, and identify the person(nel) (name or title) in your sprout operation who is (are) responsible for completing and maintaining the records; and
 16. Should indicate any additional considerations for spent sprout irrigation (or in-process sprouts) sampling and testing as appropriate for your operation (e.g., growing unit type, irrigation practices, and sprouting cycle).

We recommend you develop your written sampling plan taking into account the specific growing and irrigation practices at your operation. 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

In the following section, we provide additional recommendations on how to develop and implement your written sampling plan in six key areas: (1) Collecting and shipping samples, (2) Preventing a production batch of sprouts from entering commerce while test results are pending, 3) Choosing a laboratory and test method, (4) Interpreting results, (5) Developing a corrective action plan (and taking relevant corrective actions), and (6) Preparing and keeping records. We also provide certain recommendations regarding other pathogen testing you may choose to do on spent sprout irrigation water, in-process sprouts, or finished sprouts in addition to the required testing discussed elsewhere in this section.

B. Collecting and Shipping Samples

1. Preparing for sample collection

You should assess the configuration of your growing units, water outlets, and product distribution within the growing unit 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 allow ready access for representative sampling.

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The person(s) that perform sample collection of spent sprout irrigation water (or in-process sprouts) should be identified in your written sampling plan, at least by title. Sample collection may be performed by, for example, employees or contracted personnel. If you determine that training is needed to perform sample collection, then this should be specified in the sampling plan and records should indicate that training was successfully completed. Samples must be collected aseptically in accordance with § 112.147(b) and, therefore, training in aseptic techniques may be useful.

- Sterile sample containers, labeled with relevant information, including production batch number and identifying information for your sprouts and your sprouting operation
 - For spent sprout irrigation water samples, 1-liter sterile containers (e.g., plastic cups) should be used instead of bags, because bags can leak or spill liquid samples;
 - For in-process sprout samples, individual containers (e.g., cups or bags) should be used for each sub-sample;
- Sterile sampling equipment (e.g., cups or tongs);
- Single-use gloves;
- Cleaned countertop or other surface;
- Clean cooler with ice packs dedicated to sample storage;
- Neutralizing agent (if collecting samples of spent sprout irrigation water that is chlorinated, see below); and
- Any forms or records to be completed.

If your sprout operation uses chlorinated water for irrigation, there is likely to be residual chlorine in the spent sprout irrigation water. To neutralize the effect of any residual chlorine on test results, you should add an appropriate amount of neutralizing agent (e.g., 100 mg/L of sodium thiosulphate) in the sampling bottle prior to collecting the sample in that bottle.

Using the right materials and equipment is particularly important to ensure the sample collection is conducted aseptically as required under § 112.147(b). You must use sterile equipment and tools to collect samples aseptically. Cleaning and sanitizing is not equivalent to sterilization (See Appendix 1 on Aseptic Sampling).

2. Collecting the sample

If samples are improperly collected or mishandled, or collected in a manner such that samples are not representative, the test results may not accurately reflect the potential for contamination in that production batch of sprouts. Therefore, it is important to establish sample collection procedures and implement them uniformly.

a. Identifying the production batch of sprouts

Under § 112.144(b), you must sample and test spent sprout irrigation water (or sprouts) from each “production batch of sprouts” at your operation. 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). 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

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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 started at the same time in way that exposes sprouts in some trays to water that has contacted sprouts in other trays (for example, if the water drips through upper trays of sprouts on the rack down into lower trays of sprouts on the rack), the sprouts in the rack of connected trays (the growing unit) are a single production batch of sprouts. If, however, the connected trays of sprouts in such a rack were started at two different time points, there would be two different production batches of sprouts in that single growing unit, based on the two different start times, for which two samples and tests (one from each production batch of sprouts) would be required. As another example, two separate growing units of sprouts would be two production batches of sprouts, even if the sprouts in them were started at the same time, because a “production batch of sprouts” is limited to a single growing unit. If you have two drums of sprouts, these are two separate growing units, even if they contain sprouts started at the same time. You must not pool samples from multiple growing units for purposes of testing spent sprout irrigation water (or in-process sprouts). “Pooling” 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.

If you start growing sprouts in one growing unit and then transfer them to different growing units during sprouting, multiplying 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 VIII.B.2.b.ii 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 into sprouting, and you should sample and test growing units B and C separately, as two production batches. On the other hand, if your predetermined sampling time is 24 hours into sprouting, sample collection should occur from growing unit A, which you should treat 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 is not be confused with a lot of seeds. 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 the sprout operation to track seeds, and we recommend that sprout operations keep sufficient records to connect their test results and corrective actions to specific seed lots whenever possible. 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.

b. Collecting a representative sample

As provided in § 112.147, you must 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

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samples, to the extent possible, accurately reflect the potential for contamination in the larger production batch of sprouts. One indicator of the extent to which the samples of spent sprout irrigation water or in-process sprouts are representative of the production batch is the degree to which the samples “cover” the production batch, i.e., the proportion of the batch of sprouts that has come into contact with the spent sprout irrigation water from which the sample is taken, or the degree to which the sample of in-process sprouts has been collected from different physical locations across the production batch. The greater the coverage of the production batch of sprouts, the more representative the sample. In order to collect a representative sample of spent sprout irrigation water or sprouts, you may need to, for example, increase the number of sub-samples or the total amount of sample you collect. Below, we discuss certain growing conditions and irrigation practices, their potential impact on sample collection, and recommendations for obtaining a representative sample.

i. 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, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water, you must test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) under § 112.144(b)(2). This does not preclude, however, additional voluntary testing (e.g., testing finished product sprouts for specific pathogens) you may choose to do in addition to the required sampling and testing under § 112.144(b).

ii. 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. The optimal time for sample collection may vary depending on the type of sprouts you produce, or 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. 40). 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 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. If the complete sprouting process for a given sprout type takes fewer than 48 hours, we recommend you collect samples as close to 48 hours as practicable even if that is towards the end of the growing cycle. If you pre-soak 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-soak time in your calculations.

If you wish to explore the optimal timing for sample collection in your sprouting operation (e.g., unique considerations based on sprout types, 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

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microorganisms in a sample, and can help determine the point in the sprouting process at which the highest levels of bacteria (including pathogens) are detected (Ref. 41).

We also recommend that, to the extent possible, you collect samples of spent sprout irrigation water at the start of your irrigation cycle rather than towards the end of the cycle. Pathogens that may be present in the production batch of sprouts are likely to be at their highest levels at the beginning of the irrigation cycle and will continue to decrease through the end of the irrigation cycle. Therefore, collecting samples at the start of irrigation is likely to maximize the probability of detecting pathogens if they are present.

In instances where irrigation cycles are not frequent (e.g., many hours pass between each irrigation cycle) or where irrigation is not otherwise occurring at the optimal sampling time, irrigation water may be added specifically for sample collection to facilitate collecting your sample at the optimal time. If adding irrigation water specifically for sample collection, you should do this as close to the start of the next regular irrigation cycle as possible to allow time for pathogens that may be present in the production batch of sprouts to grow after the end of your last irrigation cycle. If it is impracticable to add irrigation water for collecting a sample of spent sprout irrigation water (e.g., for sprouts grown using very little water), you may instead sample in-process sprouts before the start of the next irrigation cycle (§ 112.144(b)(2)).

iii. 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 quart) from each production batch of sprouts. It may be advisable for this sample to be made up of multiple subsamples, depending on whether your growing unit has a single drainage point or multiple drainage points (see VIII.B.2.b.iv, “Where to Collect Sample,” below). As a general matter, when sub-sampling is advisable, we recommend that you collect at least 30 subsamples (Ref. 41a, Ref. 41b).

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.

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 representative of the production batch of sprouts. The number of different microorganisms for which you are testing can also affect the volume of sample necessary for testing.

(1) Large production batches of sprouts

If the level (percentage) of contamination with pathogens and the sample size tested are held constant, the amount of potentially contaminated finished product that may escape detection through sampling and testing increases with the size of the production batch (Ref. 42). In addition, the fact that distribution of contamination in any given production batch is likely to be heterogeneous makes it difficult to ensure that your test results accurately represent the potential for contamination in the production batch, especially for production batches that are particularly large (Ref. 42a). Because of these concerns, we recommend that you collect additional samples of spent sprout irrigation water (or in-process sprouts) from particularly large production batches, and test those samples separately, to

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provide a comparable level of control over the volume of potentially contaminated product that may escape detection during production of large production batches as compared to small production batches. We developed these recommendations by establishing a threshold amount of potentially contaminated product that might escape detection at a level that is three times the amount that might escape detection for a batch of typical size with a single sample and test. We recommend additional samples and tests for batch sizes where that threshold amount would otherwise be exceeded because of the large size of the batch (Ref. 42). For example, if your single production batch will consist 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 collected) of spent sprout irrigation water from that production batch and test each sample separately. If sampling in-process sprouts from a production batch of the same size, we recommend that you collect two samples (each totaling at least 1500 g, each made up of 30 (50 g) subsamples, for a total of 3000 g and 60 (50 g) subsamples collected), and test each sample separately (Ref. 42). 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 collected) of spent sprout irrigation water from that production batch and test each sample separately. Similarly if sampling in-process sprouts from a production batch of the same size, you should collect a total of 3 samples (each at least 1500 g, each made up of 30 (50 g) subsamples for a total of 4500 g and 90 (50 g) subsamples collected) (Ref. 42).

(2) High volumes of irrigation water/high flow rates

Larger volumes of irrigation water and/or higher rates of irrigation flow (e.g., as often used for mung bean sprouts grown in bins, such that a 1.5 liter container is likely to overflow immediately at the normal flow rate) can dilute any pathogen that may be present in the water, making collecting a representative sample of spent sprout irrigation water more difficult and therefore making it less likely that a pathogen that is present will be detected. We recommend that sprout operations using large volumes of water and/or high rates of flow either temporarily decrease the volume of water and/or flow rate through a growing unit during spent sprout irrigation water sampling; or add water to the growing unit at a lower volume/flow rate between regular irrigation cycles for the specific purpose of collecting a sample.

(3) Low volumes of irrigation water/low flow rates

Conversely, operations using lower volumes of irrigation water and/or rates of irrigation flow, such as misting, may find collecting a sufficient amount of irrigation as a sample water (e.g., collecting at least the recommended 1.5 liter) more challenging. We recommend that such operations, to the extent possible, either temporarily increase the volume of water and/or flow rate through a 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. We recommend that you consider whether either of these options is practicable for your operation before deciding to sample in-process sprouts rather than spent sprout irrigation water. If, however, sampling spent sprout irrigation water is not practicable under the circumstances, you may instead sample in-process sprouts (§ 112.144(b)(2)).

iv. Where to collect sample

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For samples of spent sprout irrigation water, you should assess the configuration of your growing units, the flow of irrigation water, outlets of water exiting the growing unit, and product distribution within the growing unit to determine how and where to best collect a representative sample. Sprouts that are not mixed during growing (e.g., in racks of trays, bins, or tanks) can result in a more heterogeneous (i.e., uneven) spread of pathogens in spent sprout irrigation water than sprouts that are mixed during growing (e.g., in a rotating drum). A growing unit may have a single or multiple points for collection of spent sprout irrigation water dependent on the type of the growing unit. 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 (we recommend at least 1.5 liter) at that point. Because this spent sprout irrigation water has flowed through the entire growing unit of sprouts, collection at this point is likely to be representative, even if your sprouts are not mixed during growing. 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 (sub-samples) from 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 a minimum of 30 sub-samples of approximately equal volume from various drainage points (e.g., by moving your sample container around to different drainage locations). The 30 sub-samples should, together, comprise your sample of at least 1.5 liter (total) of spent sprout irrigation water.

To collect samples of in-process sprouts, we recommend that you collect at least thirty (30) 50-gram sub-samples from multiple locations in the growing unit, for a total of at least 1,500 grams from each production batch.

v. How to collect your sample

You must collect samples aseptically, as required under § 112.147(b). In Appendix 1 of this document, we provide specific recommendations on aseptic sampling procedures.

3. Preparing the sample for shipping, and shipping the sample for testing

Prior to and during delivery or shipping to a laboratory, samples should be held at an appropriate temperature, preferably between 0 and 4.4 °C (between 32 and 40 °F). Sealed coolant packs should be used in lieu of ice, as needed during delivery or shipment, to avoid the possibility of melting ice contaminating the sample. Samples should not be frozen. The samples should be shipped to 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. 43).

Prior to sending the samples to a laboratory for testing, you should check to verify that your samples are clearly identified with the production batch number and other identifying information for your sprouts and your sprouting operation. You should specify the microorganisms for testing on any laboratory forms.

C. Preventing Production Batches of Sprouts from Entering Commerce

Under § 112.147(b), you must not allow the 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*

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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 do not enter commerce until negative test results are obtained for all required pathogen tests.

Establishing and using unique production batch numbers or other identifiers can help ensure implementation of these procedures. For example, the production batch number or other identifier should be written clearly and prominently on the sample(s) sent to the testing laboratory and on containers used for the sprouts at your operation (or otherwise displayed on or in association with the sprouts while at your operation).

D. Choosing a Test Method

In accordance with § 112.153(a), spent sprout irrigation water (or in-process sprouts) from each production batch must be tested 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 <http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM467055.pdf>)⁴ (§ 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)). For any other pathogen(s) meeting the criteria in § 112.144(c), you are required to use a scientifically valid method (§ 112.153(b)).

If you use a method to test for *E. coli* O157:H7 and/or *Salmonella* species other than the one in § 112.153(a)(1), it must be a scientifically valid method that is at least equivalent to the method in § 112.153(a)(1) in accuracy, precision, and sensitivity, as required under § 112.153(a)(2). 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, text books, or proprietary research. Although you are not required to notify or submit information to FDA prior to using such alternate method, you must establish and keep records of any such alternate methods that you use (§ 112.150(b)(5)). Such records should include detailed analytical procedures, results and/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.

We recommend use of methods validated through a collaborative study (currently available at <http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM298730.pdf>)⁵, for example per

⁴ 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 <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm>, <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/default.htm>, and <http://www.fda.gov/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 <http://www.fda.gov>, or using a generally available search engine.

⁵ Alternative websites where you can currently access this document include: <http://www.fda.gov/ScienceResearch/FieldScience/ucm273423.htm> and <http://www.fda.gov/fsma>. Alternatively,

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AOAC Appendix J or ISO 16140:2016. Alternate methods should be validated for *E. coli* O157:H7 or *Salmonella* spp. against FDA's reference method (§ 112.153(a)(1)) in spent sprout irrigation water and/or sprouts, as applicable, and demonstrated to meet the requirements for alternate methods 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, and AFNOR (Association Française de Normalisation) 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. Information on alternate methods reviewed by FDA and found to be equivalent will be made available on our website, such as at <http://www.fda.gov/fsma>, <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm>, and <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/default.htm>.

E. Interpreting Test Results

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 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 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 cannot “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 does not negate a previous positive test result. 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 the inaccuracy of the first test result (e.g., reported issue at the laboratory, such as cross-contamination).

Sprouts must not be allowed to enter commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* spp., and, if applicable, any additional pathogens meeting the criteria in § 112.144(c) (§ 112.147(b)). If you obtain a negative result (of either type described above) for all relevant pathogens, your obligation under §

you can search on part or all of the title of the method, in the search box on FDA's Web site at <http://www.fda.gov>, or using a generally available search engine.

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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 (e.g., there is no concern about potential contamination of your production environment with *L. monocytogenes* based on which you should continue to prevent the batch from entering commerce; see Section IX (Environmental Monitoring)).

F. 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). Testing is typically contracted to a third-party testing laboratory. Testing may also be performed by a sprout operation's own laboratory (e.g., an operation's own "in-house" laboratory). You should use a laboratory that employs scientifically valid laboratory methods and procedures that can provide reliable, accurate test results. A laboratory conducting the tests 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 a laboratory will provide reliable, accurate test results. Regardless of which laboratory you use, testing must be done using a method as set forth in § 112.153.

G. Developing a Corrective Action Plan and Taking Corrective Actions

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), and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c) (§ 112.147(c)). Under § 112.148, you must, at a minimum, take these actions if your 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 VII.C (Corrective Actions for Seeds that May be Contaminated with a Pathogen) of this document);
- Clean and sanitize the affected surfaces and surrounding areas (§ 112.148(c));
- 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. Having a correction action plan in place at your operation will help ensure that corrective actions are taken quickly in response to positive findings of pathogens in spent sprout irrigation water or sprouts. The plan should include:

- procedures for identifying the contaminated production batch of sprouts (for example, using the production batch number information associated with the positive test results), and

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destroying the contaminated production batch of sprouts; as well as steps necessary to ensure any contaminated food does not enter commerce;

- procedures for identifying affected food contact surfaces and surrounding areas, and for cleaning and sanitizing affected surfaces and areas;
- procedures for appropriate handling of the lot of seeds corresponding to the contaminated production batch of sprouts (i.e., procedures for discontinuing the use of that lot of seeds, ensuring that sprouts grown from that lot 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 as provided 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 VII.C (Corrective Actions for Seeds that May be Contaminated with a Pathogen) of this document for additional information on these provisions); and
- any specific steps that are necessary to prevent recurrence of the contamination, considering the conditions and practices in your sprout operation.

One required corrective action is to take appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering into commerce (§ 112.148(a)). This requires you to prevent the contaminated production batch of sprouts from entering commerce (see also § 112.147(b)). In addition, you should also 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). 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 food-contact surface as the contaminated production batch of sprouts without intervening cleaning and sanitizing and the food has therefore become adulterated, § 112.148(a) requires that you take appropriate action to prevent that food from entering commerce. For example, you could destroy that food. You should take special care when handling contaminated sprouts (or other food), water, and equipment to avoid accidental exposure of other food, food contact surfaces, and other parts of the production environment to pathogen(s).

Another required corrective action is to clean and sanitize the affected surfaces and surrounding areas (§ 112.148(c)). You should evaluate your operation for the potential for the affected production batch of sprouts to have contaminated other objects and production areas (both food and non-food contact surfaces). Anything in your sprout operation that has come into contact with the contaminated sprout production batch (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 treated as an affected surface. These surfaces, and the areas surrounding them, could potentially contaminate other food, including subsequent batches of sprouts at your operation, without effective cleaning and sanitizing. As part of your evaluation, you should review your production records to identify both food-contact and non-food contact surfaces that may have come in 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

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sanitized. We recommend you conduct intensified cleaning and sanitizing of affected surfaces and areas surrounding them (see Section V (Cleaning and Sanitizing)) in response to the known contamination event.

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 accurate and proper implementation of your seed treatment protocol, seed handling procedures, visual examination of seed and packaging, and any other relevant controls. For example, if you have repeated positive pathogen test results in spent sprout irrigation water or in-process sprouts, we recommend that you observe your employees as they implement your sprout production process (and/or specific procedures, such as those related to seed receipt or seed treatment) to determine if there are any deficiencies;
- Re-evaluating your seed sourcing. For example, if you have multiple positive pathogen test results in spent sprout irrigation water or in-process sprouts that are associated with different lots of seeds obtained from the same seed supplier, we recommend that you re-evaluate whether you should continue using that seed supplier; and
- Re-evaluating your cleaning and sanitizing procedures and, as needed, retraining employees on appropriate practices. For example, if you obtain 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 food contact surface, you should re-evaluate your cleaning and sanitizing procedures and the manner in which your employees are implementing those procedures.

H. Recordkeeping

You must establish and keep certain records to satisfy the requirements of the Produce Safety Rule. For more information on the recordkeeping requirements, see the Recordkeeping Section of this Guidance. Section 112.150(b)(3) to (b)(6) describe records that you must establish and maintain related to sampling and testing of spent sprout irrigation water (or in-process sprouts) and corresponding corrective actions. Specifically, you must prepare and keep these records:

1. Your written sampling plan, which includes your corrective action plan, for each production batch of sprouts (§ 112.150(b)(3)).
2. Records of any analytical methods you use in lieu of the methods that are incorporated by reference in § 112.153(a)(1) to test for *E. coli* O157:H7 or *Salmonella* species (§ 112.150(b)(5)). Such records should include analytical procedures, as well as information relevant to the determination of the scientific validity of the alternate method; If you use the method listed in § 112.153(a)(1), keeping records of your use of this test method, although not required, would be helpful to demonstrate compliance. 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.

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3. Documentation of the results of all required analytical tests (§ 112.150(b)(4)).

The results of all required analytical tests conducted either by a third-party or in-house laboratory must be documented. Records of required pathogen test results for spent sprout irrigation water (or sprouts) must include the following information, in accordance with § 112.161(a)(1):

- The name and location of your operation;
- Actual values and observations obtained (e.g., test results);
- An adequate description of covered produce applicable to the record (e.g., production batch number);
- Location of the growing area from which the sample was collected (e.g., growing unit information); and
- Date and time of activity documented (e.g., information about date and time of sample collection, and sample receipt and analysis by the testing lab).

In addition, such records must be dated, and signed or initialed by the person who performed the activity documented (e.g., the individual who conducted sample analysis) as required under § 112.161(a)(4). Also, as required under § 112.161(b), these records must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

4. Records of procedures for preventing production batches of sprouts from entering commerce. We also recommend that you maintain records of your procedures for preventing production batches of sprouts from entering commerce unless required spent sprout irrigation water (or in-process sprout) pathogen test results are negative. For example, in conjunction with your test results, you should document the date you received each test result and either the date the sprouts were released into commerce following a negative test result, or the date of your corrective actions with respect to the contaminated batch following a positive result (see also § 112.150(b)(6), discussed below).

5. Records of corrective actions (§ 112.150(b)(6)). You must maintain documentation of corrective actions taken in accordance with § 112.148, which requires you to take certain follow-up actions if samples of spent sprout irrigation water (or sprouts) test positive for pathogens. To implement this requirement you should establish a system that allows you to accurately identify a production batch of sprouts and associated seed lot number with the results of spent sprout irrigation water (or sprouts) testing samples, and corresponding corrective actions taken for a positive test result. In addition to the required corrective action records, we recommend that you also document additional information describing the event, such as the results of any evaluation or comprehensive investigation you may conduct, and identification of food and food contact surfaces potentially affected by the contamination.

Corrective action records must include documentation of the following:

- Documentation of your disposition of contaminated production batches of sprouts (i.e., the manner in which you chose to prevent them from entering into commerce), 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, in accordance with § 112.142(b) (except as

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allowed under §112.142(c) (§ 112.148(b)). (For more information about these records, see Section VII.D (Seeds for Sprouting – Recordkeeping) of this document.)

- Documentation of cleaning and sanitizing of the affected surfaces and surrounding areas (we recommend that you include your cleaning and sanitizing procedures and any verification of cleaning and sanitizing you may perform) (§ 112.148(c)).
- Documentation of any other actions you took to prevent reoccurrence of the contamination (e.g., re-training of your employees, re-evaluating your cleaning and sanitizing procedures; re-evaluating your seed treatment protocol; and/or re-evaluating your seed sourcing, as applicable) (§ 112.148(d)).

Records of corrective actions must include the following information, in accordance with § 112.161(a)(1):

- The name and location of your operation;
- Actual values and observations obtained, when applicable (e.g., values and observations obtained in any verification of cleaning and sanitizing you may conduct such as post-cleaning and sanitizing ATP test results);
- An adequate description of covered produce applicable to the record (e.g., affected sprout production batch number);
- The location of a specific growing area or other area applicable to the record, when applicable (e.g., location or other identifiers for growing units and other surfaces cleaned and sanitized as corrective actions); and
- Date and time of the activity documented (e.g., information about when and where cleaning and sanitizing corrective actions were performed; information about when any employee re-training corrective action was conducted).

In addition, such records must be dated, and signed or initialed by the person who performed the activity documented (e.g., the individual who reported positive test findings to the seed supplier; the individual who took steps to ensure contaminated production batch of sprouts did not enter commerce) as required under § 112.161(a)(4). Also, as required under § 112.161(b), these records must be reviewed, dated, and signed within a reasonable time after the records are made, by a supervisor or responsible party.

I. Additional Voluntary Testing

We understand that some sprout operations may voluntarily conduct additional 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, we recommend that you 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). We recommend that you establish a recordkeeping 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 test result. Note that specific recommendations on testing of finished product for *L. monocytogenes* are described in Section IX. (Environmental Monitoring).

IX. Environmental Monitoring

This section of the guidance is intended to help sprout operations comply with the requirements of the Produce Safety Rule for environmental monitoring of the sprout growing, harvesting, packing, and holding environment by sampling and testing environmental samples for *Listeria* species (spp.) or *Listeria monocytogenes* (*L. monocytogenes*). For the purposes of this guidance, environmental samples are samples collected from a surface or area of the growing, harvesting, packing, and holding environment in an operation for the purpose of testing the surface or area for the presence of *Listeria* spp. or *L. monocytogenes* in accordance with the requirements of §§ 112.144(a) and 112.145. To accomplish this, you must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment (§ 112.145(a)). As part of your environmental monitoring plan, you must also develop a sampling plan (§ 112.145(c)) that includes how often, when, and where you will sample the environment and the test microorganism (*Listeria* spp. or *L. monocytogenes*). Environmental samples must be collected aseptically and tested using a method as set forth in § 112.152 (§ 112.145(d)).

The written environmental monitoring plan must also include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* spp. or *L. monocytogenes* (§ 112.145(e)). Section 112.146 describes the corrective actions that you must take if the growing, harvesting, packing, or holding environment tests positive for *Listeria* spp. or *L. monocytogenes*, which include:

- Conducting additional testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem (§ 112.146(a)) (we refer to this type of testing in this document as “exploratory testing”),
- Cleaning and sanitizing the affected surfaces and surrounding areas (§ 112.146(b)),
- Conducting additional sampling and testing to determine whether the *Listeria* spp. or *L. monocytogenes* has been eliminated (§ 112.146(c)) (we refer to this type of testing in this document as “cleaning verification testing”),
- Conducting finished product testing when appropriate (§ 112.146(d)),
- Performing any other actions necessary to prevent recurrence of the contamination (§ 112.146(e)), and
- Taking appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering into commerce (§ 112.146(f)).

A. Principles for Developing an Environmental Monitoring Plan

L. monocytogenes has been identified as the target pathogenic microorganism of concern for environmental monitoring in a sprout operation. There are several species of *Listeria* but *L. monocytogenes* is the primary species known to cause disease in humans. This pathogen is among the leading causes of death from foodborne illness in the United States, and predominantly affects the most susceptible populations, including older adults, pregnant women, newborns and those with weakened immune systems (Ref. 44, Ref. 45, Ref. 46, Ref. 47). Once *L. monocytogenes* becomes established in an operation, it can serve as a source of repeated product contamination and potentially

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lead to foodborne illness outbreaks (Ref. 48). A number of outbreaks and recalls involving sprouts have occurred due to contamination with *L. monocytogenes* (Ref. 3, Ref. 4, Ref. 49).

L. monocytogenes is widespread in the environment. It is found in soil, water, sewage, and decaying vegetation (Ref. 50, Ref. 51, Ref. 52, Ref. 53). It can be readily isolated from humans, domestic animals, raw agricultural commodities, and food processing environments (particularly cool, damp areas). *L. monocytogenes* can multiply slowly at refrigeration temperatures, thereby challenging an important defense against proliferation of foodborne pathogens, refrigeration (Ref. 54, Ref. 55, Ref. 56, Ref. 57, Ref. 58). *L. monocytogenes* will grow faster at warmer temperatures. While *L. monocytogenes* may occasionally be found almost anywhere in a sprout production environment, it is most likely to become established in areas and on surfaces that are not only wet, but are relatively undisturbed and that may trap organic material. These include drains, cooling units, drip pans, condensation on walls or ceilings, and areas that are difficult to access or difficult to clean (e.g., weld seams, metal cracks, and rollers). *L. monocytogenes* is known to form biofilms (i.e., communities of microbes embedded in an organic polymer matrix, adhering to a surface) on food contact surfaces (FCSs) and non-food contact surfaces and, as a result, persists on these surfaces despite aggressive cleaning and sanitizing (Ref. 59). “Food contact surfaces” as defined in § 112.3 includes (as stated in the definition) food contact surfaces of equipment and tools used in harvesting, packing, and holding covered produce; but it also includes such surfaces of tools and equipment used in growing covered produce, including sprouts (see, e.g., §§ 112.123(d)(1) and 112.143(b)). The term “non-food contact surfaces” (Non-FCSs) refers to any surfaces that, under normal operating procedures, do not contact either food or food-contact surfaces. Non-FCSs may include equipment, vents, fixtures, drains, walls, floors, and employee clothing, shoes, and accessories. Once *L. monocytogenes* has established a niche, it may persist in the environment for long periods of time, serving as a potential source of repeated contamination, until and unless the niche is identified and eliminated (Ref. 58, Ref. 60).

The goals of an environmental monitoring program should be to:

- Find *L. monocytogenes* and harborage sites if present in your operation;
- Ensure that corrective actions have eliminated *L. monocytogenes* and harborage sites when found in your operation; and
- Verify the effectiveness of your control programs for *L. monocytogenes*.

B. The Written Environmental Monitoring Plan

Section 112.144(a) requires you to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* in accordance with the requirements of § 112.145. Section 112.145(a) requires that you develop a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing or holding environment. In order to identify *L. monocytogenes* if it is present, § 112.145(b) requires that you direct your plan to sampling and testing for *L. monocytogenes* or *Listeria* species. Your written environmental monitoring plan must also include a sampling plan (§ 112.145(c)). You must collect samples aseptically and test them using a method as set forth in § 112.152 (§ 112.145(d)). Finally, your environmental monitoring plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes* (§ 112.145(e)).

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We recommend that you periodically review and assess your written environmental monitoring plan and update the plan as needed in response to new information or corrective actions that have been taken (e.g., if new equipment has been purchased, new product lines have been added, significant changes have been made to production flow, or new sampling locations have been identified).

In the sections below, we describe in more detail the components of the environmental monitoring plan.

C. Developing a Sampling Plan

As part of your environmental monitoring plan, you must have a written sampling plan. Your written sampling plan:

- Must specify what you will test collected samples for (i.e., *Listeria* species or *L. monocytogenes*) (§ 112.145(c)(1)) (we refer to this microorganism as the “test microorganism” in the remainder of this document);
- Should identify the specific test method by which collected samples will be tested for the test microorganism (you are required to use a method as set forth in § 112.152);
- Should identify the person(s) responsible for sample collection in your operation and any specific training that the person(s) should have;
- Must specify the number and location of sample collection sites, which must include appropriate FCS sites and non-FCS sites of equipment and other surfaces within the growing, harvesting, packing, and holding environment (§ 112.145(c)(3)). You should include a list of all identified FCS and non-FCS sites in your plan, along with a description of whether the number and location of your sample collection sites will result in sampling from all identified sites within a specified time period or a representative subset of all identified sites;
- Must specify the frequency of sample collection, which must be no less than monthly (§ 112.145(c)(2));
- Must specify at what point during production you will collect the samples (§ 112.145(c)(2));
- Should specify the requirement of § 112.145(d) that samples must be collected aseptically. Your plan should include procedures for aseptic sample collection, including appropriate materials and steps to prepare for sample collection.
- Should specify the sample collection method used (e.g., sponge v. swab sampling, whether any samples will be composited) and sample sizes to be collected at the various sample collection sites;
- Should identify the laboratory you are using to conduct the testing; and
- Should identify the records you will keep for each sample collected, including the documentation of the results of your analytical tests and actions you take in accordance with § 112.146.

D. Testing for *Listeria* spp. or *L. monocytogenes*

Your sampling plan must specify what you will test collected samples for (i.e., *Listeria* spp. or *L. monocytogenes*) (§ 112.145(c)(1)). The purpose of environmental monitoring is to verify the adequacy, or lack thereof, of cleaning and sanitizing practices through monitoring for the presence of pathogens in the environment and, if pathogens are present, to eliminate or minimize their presence and prevent transfer of pathogens to food-contact surfaces or to sprouts where they might cause

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illness. Testing for either the pathogen directly (*L. monocytogenes*) or an indicator organism (*Listeria* spp.) facilitates accomplishing these objectives. An indicator organism is indicative that the food has been exposed to conditions that pose an increased risk for contamination of the food with a pathogen or that the food has been exposed to conditions under which a pathogen can increase (Ref. 61). Therefore, if you test for *Listeria* spp., you should eliminate *Listeria* spp. regardless of whether it is *L. monocytogenes*, and except in certain circumstances described further below (such as when product testing of sprouts is appropriate as a corrective action), this guidance does not recommend determining whether identified *Listeria* spp. is *L. monocytogenes*. For these reasons, we recommend that you primarily test your production environment for *Listeria* spp. rather than *L. monocytogenes*, except in certain circumstances described further below.

Testing for *Listeria* spp. will detect multiple species of *Listeria*, including *L. monocytogenes*. A positive test result for the presence of *Listeria* spp. on an FCS or non-FCS indicates the potential for contamination of that surface with *L. monocytogenes* and suggests that conditions are suitable for survival and/or growth of *L. monocytogenes*. A positive test result for the presence of *Listeria* spp. on an FCS or a non-FCS does not establish the presence of *L. monocytogenes* on that surface.

When testing product (e.g., as part of corrective actions), we recommend testing for *L. monocytogenes* rather than for *Listeria* spp. because of the risk to public health from *L. monocytogenes* in food. If you choose to test food for *Listeria* spp. and find it to be positive, we recommend you determine whether the *Listeria* spp. is *L. monocytogenes* or treat the food as if it were contaminated with *L. monocytogenes*.

E. Person(s) Collecting Samples

The person(s) that perform sample collection should be identified in your sampling plan, at least by title. Sample collection may be performed by, for example, employees or contracted personnel. For a larger operation, we recommend you assemble a trained Sampling Team to undertake this activity. If you determine that training is needed to perform sample collection, then this should be specified in the sampling plan and records should indicate that training was successfully completed. Samples must be collected aseptically in accordance with § 112.145(d) and, therefore, training in aseptic techniques may be useful.

F. Establishing Sample Collection Locations and Frequency

1. Identifying sample collection locations

You should take a risk-based approach in determining where to sample and test the environment for the presence of *Listeria* spp. or *L. monocytogenes*. This can be accomplished by characterizing the areas in your operation according to the potential for product contamination. One way of doing this is to characterize your operation in terms of a zone system. Zone designations for surfaces or areas reflect how close those surfaces or areas are to a ready-to-eat food (such as sprouts), and the risk the surfaces or areas pose to food if the surfaces or areas are contaminated with *L. monocytogenes*. For example, you could characterize your operation with four zones as shown in Table 2.

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Table 2. Example of Four Sampling Zones in a Sprout Operation

| Zones | Description | Examples |
|--------|--|--|
| Zone 1 | Food-Contact Surfaces | Utensils, table surfaces, rotary drums, growing bins or trays, washing tubs, spinner/dryer, packaging and conveyors, hoppers |
| Zone 2 | Non-food-contact surfaces in close proximity to food and food-contact surfaces | Equipment housing or framework, and some walls, floors, ceilings or drains in the immediate vicinity of FCSs |
| Zone 3 | More remote non-food-contact surfaces that are in or near the production areas and could lead to contamination of zones 1 and 2 | Forklifts, hand trucks and carts that move within the operation, and some walls, floors or drains not in the immediate vicinity of FCSs |
| Zone 4 | Non-food-contact surfaces, remote areas outside of the production area, from which environmental pathogens can be introduced into the production environment | Locker rooms, cafeterias, and hallways outside the production area or outside areas where raw materials or finished products are stored or transported |

Establishing a zone system is not a requirement under the Produce Safety Rule, but doing so is helpful in designing an environmental monitoring plan and determining frequency for sampling different surfaces in different areas. If you do not establish a zone-based system, you should otherwise characterize areas where you will collect environmental samples according to potential for contamination and, at a minimum, you should distinguish between FCSs and non-FCSs.

2. Number of food contact surface and non-food contact surface sampling sites

You must specify sample collection sites in your sampling plan, and this must include both FCS and non-FCS sites (§ 112.145(c)(3)). You should make an extensive list of FCS and non-FCS sites for potential sampling and include this list as part of your sampling plan. For examples of FCS and non-FCS sampling sites, see Appendix 3 – Potential Sources of *L. monocytogenes* for Sampling in a Sprout Operation.

We also recommend that you describe or assign identifiers to each of your sample sites in your sampling plan, particularly if your operation has more than one possible location that could meet a site description. For example, if you have three rotary drum growing units, you should consider assigning unique identifiers (e.g., Growing Unit A, Growing Unit B) to facilitate sample collection and to be able to associate test results with the correct sample site in order to take appropriate corrective actions. In addition, you should consider developing a diagram of your operation which identifies the FCSs and non-FCSs that have been identified as sampling sites.

To determine the appropriate number of FCS and non-FCS sites to sample, you should consider the size of your operation (e.g., square footage), operation features, equipment design, product flow, the production methods used to produce the sprouts, and previous sampling results (if any). The number

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of sampling sites must be sufficient to determine whether measures are effective (i.e., to verify the implementation and effectiveness of sanitation measures for controlling the presence of *L. monocytogenes* in the sprout production environment by finding *Listeria spp.* or *L. monocytogenes* if it remains in the sprouting operation after routine cleaning and sanitizing procedures) (§ 112.145(c)(3)). We recommend you select a number of sampling locations from the list of FCS and non-FCS sampling sites to sample at a specified frequency, so that the plan rotates through different sites over time and all sites get tested within a defined time period. If you are using a zone system, we recommend that the number of sampling sites be higher in zones 1 and 2 because of the greater risk of sprout contamination if *L. monocytogenes* is present in these zones.

While larger sprout operations will likely have more sampling sites than smaller operations, even the smallest sprout growers should collect samples from at least 5 sites of FCS and 5 sites of non-FCS from each production area (e.g., each growing room) per sampling event.

As discussed in Section IX.A, *L. monocytogenes* is widespread in the environment, has been isolated from sprout production environments, and has been shown to persist in equipment and the production environment in harborage sites. As a result, even when an operation is cleaning and sanitizing effectively, you should expect that there will be occasional positives in environmental samples collected from your operation. As also discussed in Section IX.A, the goals of an environmental monitoring program should be to find *L. monocytogenes* and harborage sites if present in your operation; ensure that corrective actions have eliminated *L. monocytogenes* and harborage sites when found in your operation; and verify the effectiveness of your control programs for *L. monocytogenes*. If you consistently see negative test results on the sites you are sampling, we recommend that you revise your environmental monitoring procedures to add, substitute, or both add and substitute other sites in your plan for sample collection and testing to ensure you are not missing a possible source of contamination.

3. Identifying sampling frequency

Your sampling plan must specify how often you will collect environmental samples, which must be no less than monthly (§ 112.145(c)(2)). Frequency of sampling should be based on risk and depends on the size and complexity of your operation. Your sampling plan should describe whether you will collect samples from all sample sites identified as part of the extensive list of potential sampling sites or from a representative subset of FCS and non-FCS during each sampling event. If you sample and test a representative set of sites (rather than all sites) each month, we recommend that your written sampling plan be designed so that all sites that you have identified in your extensive list of potential sampling sites are tested within a predetermined interval appropriate to your operation (e.g., quarterly).

If you are testing a representative subset of FCS and non-FCS sites during each sampling event, different surfaces should be assigned different frequencies/priorities for sampling based on risk, with FCSs and certain non-FCSs (i.e., zone 2) being most frequently tested and non-FCSs further from the production area being least frequently tested (the zone system helps with this type of planning).

Sampling Frequency Example #1:

You evaluate your operation and identify 90 potential sites for sampling (30 FCS, 60 non-FCS), of which a representative number will be sampled monthly. There are various ways to achieve this.

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- You might determine, for example, that all FCS sites will be tested at least bi-monthly and all non-FCS sites will be tested at least quarterly.
- In such a case you could choose to, for example, collect 35 monthly samples (from 15 FCS and 20 non-FCS sites) at one sampling event (e.g., first of every month).
- Alternatively, for example, you could choose to collect a certain proportion of those samples every week, for a total of 35 samples collected over the course of the month (e.g., 5-10 samples each week).
- You could not wait, however, for the end of each quarter to collect all 90 samples (e.g., sampling January 1 and then waiting until April 1 to sample all 90 sites again) as this practice would not meet the monthly minimum sampling frequency requirement (§ 112.145(c)(2)).

Sampling Frequency Example #2:

You establish a 4-zone system that prioritizes sampling from Zones 1 and 2. There are various ways to achieve this.

- You might determine, for example, that all FCS sites will be tested at least once a month and all non-FCS sites will be tested at least quarterly.
- In such a case you could choose to, for example, specify sample collection from specific FCS sites at least once every week, such that all FCS sites in the operation are tested at least once each month.
- As part of such an approach, you might choose to, for example, specify sample collection from representative sets of non-FCS sites every two weeks for zone 2 sites and monthly for zone 3 and 4 sites, such that all non-FCS sites identified in your monitoring plan are tested at least once each quarter.

G. Timing of Sample Collection

Your sampling plan must specify the point(s) during production at which environmental samples will be collected (§ 112.145(c)(2)). We recommend you collect environmental samples several hours into production (e.g., 3 to 4 hours), and preferably towards the end of production, just prior to cleanup. Collecting your samples toward the end of production allows *L. monocytogenes* (if present) to work its way out of harborage sites and into the environment where it can more easily be detected.

Environmental samples should not be taken immediately after surfaces have been sanitized, as the sanitizer may affect the test results. In addition, environmental samples for identifying *L. monocytogenes* should not be confused with other types of samples collected for verification of cleaning and sanitizing, which are typically collected immediately after sanitizing (e.g., ATP hygiene monitoring involves the use of a device called a luminometer to measure the combined total ATP of organic material (food residues and microbial populations) collected from a swabbed surface). See discussion on verification of cleaning and sanitizing in Section V (Cleaning and Sanitizing) of this guidance for more information.

H. Sample Collection and Shipping

Your sampling plan should specify the sampling method you will use and details of your sample collection procedures. Use of appropriate materials and equipment is particularly important to ensure

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the sample collection is conducted aseptically, as required under § 112.145(d). For more details on Aseptic Sampling, see Appendix 1. Information on sampling methods and sample collection can be found in Appendix 2 (Recommended Procedures for Collecting Environmental Samples).

Prior to and during delivery or shipping to a laboratory, samples should be kept refrigerated. Sealed coolant packs should be used in lieu of ice, as needed during delivery or shipment, to avoid the possibility of melting ice contaminating the sample. Samples should not be frozen. Samples should be shipped to the laboratory within 24 hours after sample collection. We recommend that the maximum timeframe between environmental sampling and analysis of the sample at an external or internal pathogen testing laboratory be 48 hours.

Prior to sending the samples to a laboratory for testing, you should check to verify that your samples are clearly identified with all necessary information about the samples and your sprouting operation. You should specify the microorganism for testing on any laboratory forms.

I. Testing

1. Test methods for *Listeria* spp. or *L. monocytogenes*

In accordance with § 112.152, the growing, harvesting, packing, and holding environment must be tested for *Listeria* spp. or *L. monocytogenes* using “Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples” (currently available at <http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM467056.pdf>⁶ (§ 112.152(a))) or a scientifically valid method that is at least equivalent to FDA’s method in accuracy, precision, and sensitivity (§ 112.152(b)).

A common technique is to combine several samples and analyze the mixture (which is referred to as a “composite”). We do not recommend compositing samples from FCS sites.

If you test sprouts for *Listeria monocytogenes* as part of your Corrective Actions, we recommend that you use the procedures described in FDA’s Bacteriological Analytical Manual Online (BAM), Chapter 10 – “*Listeria monocytogenes*,” “Detection and Enumeration of *Listeria monocytogenes* in Foods” (currently available at: <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071400.htm>)⁷ for preparing food samples and testing them for the presence of *L. monocytogenes*.

⁶ 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 <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm>, <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/default.htm>, and <http://www.fda.gov/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 <http://www.fda.gov>, or using a generally available search engine.

⁷ 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 <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm>, <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/default.htm>, and <http://www.fda.gov/fsma>. Alternatively, you can search on

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2. Alternate methods under § 112.152(b)

If you plan to use a test method other than the one in § 112.152(a) to test the growing, harvesting, packing, and holding environment for *Listeria* spp. or *L. monocytogenes*, it must be a scientifically valid method that is at least equivalent to the method in § 112.152(a) in accuracy, precision, and sensitivity, as required under § 112.152(b). 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, text books, or proprietary research. Although you are not required to notify or submit information to FDA prior to using such alternate method, you must establish and keep records of any such alternate methods that you use (§ 112.150(b)(5)). Such records should include detailed analytical procedures, results and/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.

We recommend use of methods validated through a collaborative study, (currently available at <http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM298730.pdf>)⁸, for example per AOAC Appendix J or ISO 16140:2016. Alternate methods should be validated for *Listeria* spp. or *L. monocytogenes* against FDA’s reference method (§ 112.152(a)) in environmental samples, and demonstrated to meet the requirements for alternate methods in § 112.152(b) (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, and AFNOR (Association Française de Normalisation) may meet the requirements in § 112.152(b); however, FDA does not automatically consider methods validated by third party organizations such as the listed organizations to be equivalent. Information on alternate methods reviewed by FDA and found to be equivalent will be made available on our website, such as at such as at <http://www.fda.gov/fsma>, <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm>, and <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/default.htm>.

3. Interpreting test results

Testing for *Listeria* spp. or *L. monocytogenes* in environmental samples using the FDA reference method (§ 112.152(a)) can yield one of the following results:

- A positive result for *Listeria* spp., which for purposes of the FDA reference method, means finding the presence of typical colonies on a *Listeria* specific agar (i.e., completing Steps I.A-I.F in the FDA reference method with respect to *Listeria*)⁹.

part or all of the title of the method, in the search box on FDA’s Web site at <http://www.fda.gov>, or using a generally available search engine.

⁸ Alternative websites where you can currently access this document include: <http://www.fda.gov/ScienceResearch/FieldScience/ucm273423.htm> and <http://www.fda.gov/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 <http://www.fda.gov>, or using a generally available search engine.

⁹ The FDA reference method provides options for testing for both *Listeria* spp. and *L. monocytogenes*. They are described in the reference method in parallel, such that, for example, step I.E.1 describes part of the procedure for testing for *L. monocytogenes* while step I.E.2 describes part of the procedure for testing for *Listeria* spp. Thus, a

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- A positive result for *L. monocytogenes*, which can be obtained if a positive result for *Listeria* spp., or a presumptive positive result for *L. monocytogenes*, is followed by confirmatory steps that result in a confirmed *L. monocytogenes* cultural isolate (i.e., completing Step I.I in the FDA reference method).
- Two types of negative results can be obtained:
 - *Listeria* specific agars do not yield a positive result for *Listeria* spp., indicating a negative finding for *Listeria* spp.; or
 - Additional confirmatory steps after a positive result for *Listeria* spp. or a presumptive positive result for *L. monocytogenes* does not result in confirmation of the presence of *L. monocytogenes*, indicating that while *Listeria* spp. were found, *L. monocytogenes* was not found.

You are required to specify the test microorganism (*Listeria* spp. or *L. monocytogenes*) in your sampling plan (§ 112.145(c)(1)). If you choose to establish a sampling plan that specifies testing for *Listeria* spp. as we recommend, you are not required to perform confirmatory testing for *L. monocytogenes* after obtaining a positive test result for *Listeria* spp., although you may voluntarily choose to do so.

If your plan specifies that you will test for *Listeria* spp. and you conduct testing using the FDA reference method (Recommended approach):

- a positive result for *Listeria* spp. triggers the requirement to take corrective actions under § 112.146;
- a negative result for *Listeria* spp. does not trigger the requirement to take corrective actions under § 112.146;
- if you voluntarily choose to perform confirmatory testing for *L. monocytogenes* on an environmental sample that yields a positive result for *Listeria* spp., a positive result for *L. monocytogenes* also triggers the requirement to take corrective actions under § 112.146; and
- if you voluntarily choose to perform confirmatory testing for *L. monocytogenes* on an environmental sample that yields a positive result for *Listeria* spp., a negative result for *L. monocytogenes* does not trigger the requirement to take corrective actions under § 112.146, but your positive result for *Listeria* spp. already triggered that requirement and the *L. monocytogenes* negative does not affect that outcome.

If your plan specifies that you will test for *L. monocytogenes* and you conduct testing using the FDA reference method:

- a positive result for *Listeria* spp. triggers the requirement to take corrective actions under § 112.146, and you must continue with confirmatory testing to identify *L. monocytogenes* as provided in your sampling plan;
- a negative result for *Listeria* spp. does not trigger the requirement to take corrective actions under § 112.146;

“positive result for *Listeria* spp.” refers to completion of the reference method up to step I.F (or G, if applicable) including all steps relevant to *Listeria* spp.

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- a positive result for *L. monocytogenes* triggers the requirement to take corrective actions under § 112.146; and
- a negative result for *L. monocytogenes* does not trigger the requirement to take corrective actions under § 112.146, but your positive result for *Listeria* spp. already triggered that requirement and the *L. monocytogenes* negative does not affect that outcome.

4. Laboratory that conducts testing

You should choose a laboratory that is qualified to test environmental samples for *Listeria* spp. or *L. monocytogenes* (whichever you are testing for). Testing is typically contracted to a third-party testing laboratory. Testing may also be performed by a sprout operation's own laboratory (e.g., an operation's own "in-house" laboratory). You should use a laboratory that employs scientifically valid laboratory methods and procedures that can provide reliable, accurate test results. A laboratory conducting the tests 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 a laboratory will provide reliable, accurate test results. Regardless of which laboratory you use, testing must be done using a method as set forth in § 112.152.

J. Developing a Corrective Action Plan and Taking Corrective Actions

Your written environmental monitoring plan must also include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* spp. or *L. monocytogenes* (§ 112.145(e)). Section 112.146 describes the corrective actions that you must take if the growing, harvesting, packing, or holding environment tests positive for *Listeria* spp. or *L. monocytogenes*.

1. Corrective action plan

Your corrective action plan must detail when and how you will accomplish the actions in § 112.146 when required. Having a corrective action plan in place at your operation will help ensure that corrective actions are taken quickly in response to a finding of *Listeria* spp. or *L. monocytogenes* in the environment. Your corrective action plan:

- Must specify how and when you will conduct additional testing of surfaces and areas surrounding the area where the positive test result was detected to evaluate the extent of the problem, including the potential for *Listeria* spp. or *L. monocytogenes* to have become established in a niche (§ 112.146(a)) ("exploratory testing");
- Must specify how and when you will clean and sanitize the affected surfaces and surrounding areas (§ 112.146(b));
- Must specify how and when you will conduct additional sampling and testing to determine whether the *Listeria* spp. or *L. monocytogenes* has been eliminated (§ 112.146(c)) ("cleaning verification testing");
- Must specify when and how you will conduct finished product testing when appropriate (§ 112.146(d));

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- Must indicate that you will perform any other actions necessary to prevent recurrence of the contamination (§ 112.146(e)) and should specify what some of those actions may be. For example, you should specify additional steps you will take to determine the source and route of contamination if your cleaning verification testing yields positive results for *Listeria* spp. or *L. monocytogenes*;
- Must specify when and how you will take appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering into commerce (§ 112.146(f)); and
- Should identify the person(s) responsible for corrective actions in your operation and any specific training that the person(s) should have.

2. Implementing corrective actions

We recommend that you consider your corrective actions based on whether or not you detected *Listeria* spp. or *L. monocytogenes* and whether or not you detected the organism on an FCS or a non-FCS site (see Table 3 - Corrective Actions when *Listeria* species is found in an environmental sample). In the sections below and in Figure 2 (Examples of Non-FCS* testing and follow-up activities for zone 2) and Figure 3 (Example of FCS* testing and follow-up activities), we describe corrective action steps based on the combination of organism and location.

a. Corrective actions if you detect *Listeria* spp. on a non-food-contact surface

We describe appropriate corrective actions for a positive test result for *Listeria* spp. from an environmental sample collected during your routine sampling of a non-FCS site in this section. These steps are also summarized in Figure 2 (Examples of Non-FCS* testing and follow up activities for Zone 2). We focus on corrective actions for positives in zone 2, which are in close proximity to food and food contact surfaces. You must also take corrective actions as required by § 112.146 if a positive result(s) is obtained in Zones 3 or 4. Corrective actions for non-FCS positives in Zones 3 and 4 may be less rigorous than those for non-FCS positives in Zone 2 provided that all relevant requirements are met. For example, after obtaining a positive test result in Zone 3 or 4, you must conduct additional testing (referred to below as “exploratory testing,” see Section IX.J.2.a.i) of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected (§ 112.146(a)). However, it would be reasonable to take fewer exploratory samples after a positive in Zone 3 or 4 compared to a positive test result in Zone 2, especially for Zone 4 positives, as these have a lower potential to contaminate food or food contact surfaces. You must clean and sanitize the affected surfaces and surrounding areas (§ 112.146(b)), however the cleaning and sanitizing conducted might be less aggressive for a positive in Zone 3 or 4 compared to cleaning and sanitizing for a positive in Zone 2. You must then conduct additional sampling and testing (referred to below as “cleaning verification testing,” see section IX.J.2.a.i) to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated (§ 112.146(c)), however it would be reasonable to take fewer samples as a follow-up for a positive in Zone 3 or 4 compared to Zone 2. Finished product testing is less likely to be necessary in response to a positive in Zone 3 or 4 compared to a positive in Zone 2. Recommendations in section IX.J.2.a.i below regarding 112.146(e) would still apply to a Zone 3 or 4 positive, and would depend on the number of positives identified during follow up testing.

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The discussion in this section relates only to positive environmental samples on non-FCSs. If you obtain a positive environmental sample (e.g., *Listeria* spp.) on an FCS during any of the various types of follow-up testing to an original positive on a non-FCS (i.e., exploratory testing, cleaning verification testing, or intensified testing), you should immediately switch to taking corrective actions appropriate to finding positives on FCSs in section IX.J.2.b. below.

i. Non-FCS *Listeria* spp. positive (1st positive)

You should examine the area surrounding the site of the positive test result in all directions for potential sources of *Listeria* spp. as described in Appendix 3 (Potential Sources of *L. monocytogenes* for Sampling in a Sprout Operation) of this guidance. You should pay particular attention to possible niches that allow harborage of *L. monocytogenes*.

Exploratory testing: You must conduct additional testing of surfaces and areas surrounding the area where *Listeria* spp. was detected to evaluate the extent of the problem, including the potential for *Listeria* spp. or *L. monocytogenes* to have become established in a niche (§ 112.146(a)).

- Exploratory testing provides you with information about the extent of the problem represented by the initial positive test result (e.g., whether the presence of *Listeria* spp. or *L. monocytogenes* is isolated or more extensive). The results of exploratory testing should be used to inform your cleaning and sanitizing (see below, § 112.146(b)). In addition, if you receive any positive results from your exploratory testing, you should consider conducting intensified cleaning and sanitizing and intensified sampling and testing (discussed below as a recommended response to a 2nd positive).
- If the original positive test result is from a composite sample, you should either first conduct additional follow-up testing to identify the specific non-FCS that is contaminated with *Listeria* spp. or, alternatively, conduct your exploratory testing as if each non-FCS site represented by the composite is positive (i.e., conduct exploratory testing of surfaces and areas surrounding all of the sites represented by the composite).
- The exploratory testing samples should include at least 3 to 5 samples from surrounding FCS and non-FCS sites in close proximity to the positive site.
- Exploratory Testing While in Production: If you receive a positive result for a routine individual sample for a non-FCS site while you are in production (e.g., you are either still growing the production batch of sprouts that was growing when you took your routine samples, or you have started another production batch of sprouts), you should conduct exploratory sampling and testing during that production cycle, provided that you are at least 3 hours into the production cycle.
- Exploratory Testing When Not in Production: If you receive a positive result for a routine sample for a non-FCS site when you are not in production (e.g., the growing unit has already been cleaned and sanitized from the prior production batch of sprouts and you have not started the next production batch), you should conduct exploratory sampling and testing at least 3 hours into the production of the next batch.

Cleaning and sanitizing: You must clean and sanitize the affected surfaces and surrounding areas (§ 112.146(b)).

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- You must conduct additional cleaning and sanitizing of the site from which the positive sample was taken, as well as from the surrounding areas, including both FCS and non-FCS (whether or not you have already conducted routine cleaning and sanitizing of these surfaces). You should consider the results of your exploratory testing in determining what locations should be cleaned and sanitized, and how the cleaning and sanitizing should be conducted. The site of the initial positive result and the sites of any additional positive results found during exploratory testing should all be cleaned and sanitized.
- You should also consider verifying the efficacy of your cleaning and sanitizing using additional methods beyond the required testing (§ 112.146(c)) before your next production run (e.g., ATP testing). See Section V (Cleaning and Sanitizing).

Cleaning verification testing: You must conduct additional sampling and testing to determine whether the *Listeria* species has been eliminated (§ 112.146(c)).

- Timing: You may conduct your cleaning verification testing at the same time as your next regularly scheduled environmental sampling event.
- If all your cleaning verification tests are negative, you should resume routine environmental monitoring. We recommend that you target these surfaces where positives have previously been found for sampling and testing during your next routine environmental sampling event.
- If your cleaning verification tests identify another positive result at the site of the initial positive or in any of that site’s surrounding areas, this should lead you to take further steps (see below).

ii. Non-FCS *Listeria* spp. positive from cleaning verification testing
(2nd positive)

Intensified cleaning and sanitizing: If any of the cleaning verification samples from the initial positive site or areas around it are positive for *Listeria* spp., we recommend that, as an action to prevent recurrence of the contamination (§ 112.146(e)), you perform intensified cleaning and sanitizing in the affected areas. Intensified cleaning and sanitizing includes sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continued findings of positive samples. Intensified cleaning and sanitizing can include increasing the frequency of cleaning and sanitizing for certain pieces of equipment and breaking down the equipment into its parts for further cleaning. (See Section V (Cleaning and Sanitizing)).

- We also recommend that you conduct another round of sampling and testing at this stage, both to verify the effectiveness of your intensified cleaning and sanitizing, and to look for possible harborage sites in the affected area (see below). Thus, to look for possible harborage sites, you should sample and test areas of the equipment exposed by disassembly prior to cleaning and sanitizing the equipment.

Intensified testing: If any of the cleaning verification samples from the initial positive site or areas around it are positive for *Listeria* spp., we also recommend that, as an action to prevent recurrence of the contamination (§ 112.146(e)), you conduct another round of sampling and testing at this stage (“intensified testing”), both to verify the effectiveness of your intensified cleaning and sanitizing, and to look for possible harborage sites in the affected area.

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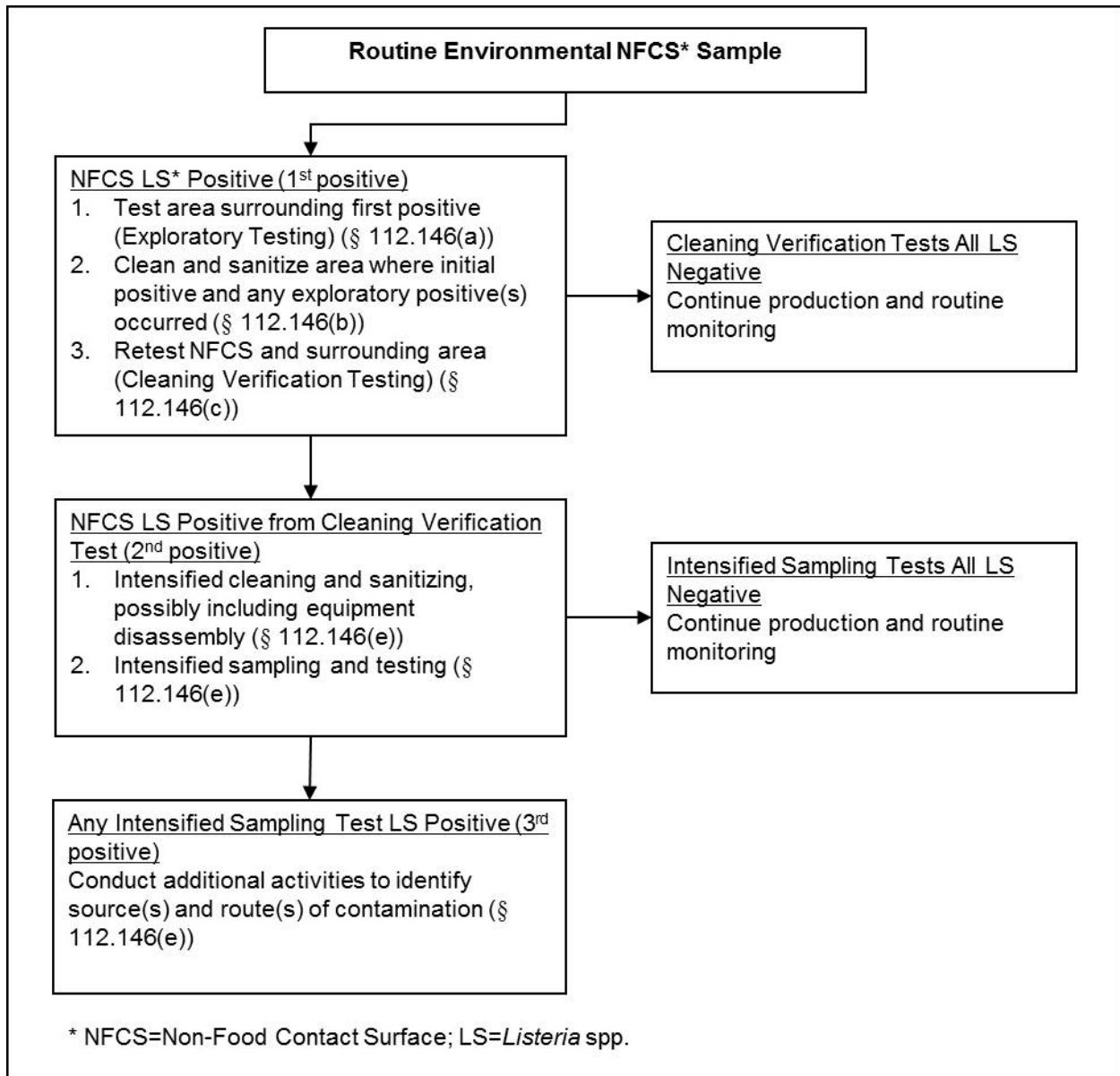
- The follow-up samples should include at least 3 to 5 samples including the initial positive site, surrounding positive sites identified in cleaning verification testing, and surrounding FCS and non-FCS sites in close proximity to any positive sites. As appropriate, equipment should be disassembled during follow-up testing and exposed areas should be sampled and tested, ideally before such areas are cleaned and sanitized (see above) to help identify possible harborage sites.
- If your intensified sampling and testing results are all negative, you should return to routine environmental monitoring. We recommend that you target these surfaces where positives have previously been found for sampling and testing during your next routine environmental sampling event. If you find another positive result at the site of the initial positive or in any of that site's surrounding areas, this should lead you to take further steps (see below).
 - iii. Any intensified sampling test *Listeria* spp. positive (3rd or subsequent positive)

Additional activities/Comprehensive investigation: If your intensified sampling and testing results in an additional positive sample(s), as an action to prevent recurrence of the contamination (§ 112.146(e)) we recommend that, you conduct additional activities to determine the source and route of contamination, including activities involved in a comprehensive investigation as discussed in section IX.J.2.b.i. These actions could vary depending on the risk that an FCS or food could become contaminated from the positive non-FCS site. Examples of such actions include escalating mitigation efforts to identify and eliminate the *Listeria* spp. source, and considering consultation with a *Listeria* control expert.

The example in Figure 2 addresses testing and follow-up actions for specific positive finding of *Listeria* spp. on a Zone 2 non-FCS during one sampling period. Detecting *Listeria* spp. at several non-FCS sampling locations during the same sampling period could indicate that your routine sanitation procedures are inadequate, and could indicate that the *Listeria* spp. has become established in one or more harborages in Zone 2. In such situations, the risk associated with cross contamination from a contaminated a Zone 2 non-FCS site to FCS (Zone 1) or food increases as the number of contaminated Zone 2 non-FCS sites increases. When several Zone 2 non-FCS site positives are detected during one sampling period, we recommend that you review your written sanitation procedures to identify and implement more effective routine sanitation procedures and escalate your corrective actions until the situation is resolved.

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Figure 2. Example of Non-FCS* Testing and Follow-Up Activities for Zone 2.



b. Corrective actions if you detect *Listeria* spp. on a food-contact surface

We describe appropriate corrective actions for a positive test result for *Listeria* spp. from an environmental sample collected during your routine sampling of an FCS site in this section. These steps are also summarized in Figure 3 (Example of FCS* testing and follow-up activities).

i. FCS *Listeria* spp. positive (1st positive)

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You should examine the area surrounding the site of the positive test result in all directions for potential sources of *Listeria* spp. as described in Appendix 2 (Potential Sources of *L. monocytogenes* for Sampling in a Sprout Operation) of this guidance. You should pay particular attention to possible niches that allow harborage of *L. monocytogenes*.

Exploratory testing: You must conduct additional testing of surfaces and areas surrounding the area where *Listeria* species was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in a niche (§ 112.146(a)).

- Exploratory testing provides you with information about the extent of the problem represented by the initial positive test result (e.g., whether the presence of *Listeria* spp. or *L. monocytogenes* is isolated or more extensive). The results of exploratory testing should be used to inform your cleaning and sanitizing (see below, § 112.146(b)). In addition, if you receive any positive results from your exploratory testing, you should consider conducting intensified cleaning and sanitizing and intensified sampling and testing (discussed below as a recommended response to a 2nd positive).
- You should conduct exploratory sampling and testing of sites that represent a potential source of the FCS contamination identified by your initial positive FCS result. Conduct exploratory sampling and testing upstream (i.e., locations in the operation that the product contacts earlier in the product flow) from the positive FCS in the production area to help identify a source of contamination.
- While in Production: If you receive a positive result for a routine individual sample for an FCS site while you are in production (e.g., you are either still growing the production batch of sprouts that was growing when you took your routine samples, or you have started another production batch of sprouts), you should conduct exploratory sampling and testing during that production cycle, provided that you are at least 3 hours into the production cycle.
- When Not in Production: If you receive a positive result for a routine sample for an FCS site when you are not in production (e.g., the growing unit has already been cleaned and sanitized from the prior production batch of sprouts and you have not started the next production batch), you should conduct exploratory sampling and testing at least 3 hours into the production of the next batch.

Cleaning and sanitizing: You must clean and sanitize the affected surfaces and surrounding areas (§ 112.146(b)).

- You must conduct additional cleaning and sanitizing of the site where the positive sample was taken, as well as from the surrounding areas, including both FCSs and non-FCSs (whether or not you have already conducted routine cleaning and sanitizing of these surfaces). You should consider the results of your exploratory testing in determining what locations should be cleaned and sanitized, and how the cleaning and sanitizing should be conducted. The site of the initial positive result and the sites of any additional positive results found during exploratory testing should all be cleaned and sanitized.
- You should also consider verifying the efficacy of your cleaning and sanitizing using additional methods beyond the required testing (§ 112.146(c)) before your next production run (e.g., ATP testing); See Section V (Cleaning and Sanitizing).

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Cleaning verification testing: You must conduct additional sampling and testing to determine whether the *Listeria spp.* has been eliminated (§ 112.146(c)).

- Timing: You may conduct your cleaning verification testing at the same time as your next regularly scheduled environmental sampling event.
- If all your cleaning verification tests are negative, you should resume routine environmental monitoring. We recommend that you target these surfaces where positives have previously been found for sampling and testing during your next routine environmental sampling event.
- If your cleaning verification tests identify another positive result at the site of the initial positive or in any of that site's surrounding areas, this should lead you to take further steps (see below for 2nd Positive).

Comprehensive investigation: Following a positive finding of *Listeria spp.* on an FCS, as an action to prevent recurrence of the contamination (§ 112.146(e)), you should conduct a comprehensive investigation to identify and mitigate *Listeria* sources, and modify procedures where appropriate. You may need to stop production at your sprout operation in order to conduct the comprehensive investigation. Such an investigation could involve:

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

Based on the comprehensive investigation described above, you may find there are additional actions you need to take to prevent recurrence of the contamination (§ 112.146(e)). The following are examples of potential actions you should consider:

- Check maintenance records for modifications or repairs to major equipment or any other significant changes in production practices; and
- Correct any identified problems (e.g., re-train personnel, revise sanitation procedures, repair equipment, update maintenance program).

ii. FCS *Listeria spp.* positive from cleaning verification test (2nd positive)

Three production days of intensified cleaning and sanitizing: If any of the cleaning verification samples from the initial positive site or areas around it are positive for *Listeria spp.*, we recommend that, as an action to prevent recurrence of the contamination (§ 112.146(e)), you perform intensified cleaning and sanitizing in the affected areas for the next three production days. Intensified cleaning and sanitizing includes sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continued findings of positive samples. Intensified cleaning and sanitizing can include increasing the frequency of cleaning and sanitizing for certain

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pieces of equipment and breaking down the equipment into its parts for further cleaning. (See Section V (Cleaning and Sanitizing)).

- We also recommend that you conduct three additional rounds of sampling and testing at this stage, both to verify the effectiveness of your intensified cleaning and sanitizing, and to look for possible harborage sites in the affected area (see below). Thus, to look for possible harborage sites, you should sample and test areas of the equipment exposed by disassembly prior to cleaning and sanitizing the equipment.

Three production days of intensified testing: If any of the cleaning verification samples from the initial positive site or areas around it are positive for *Listeria* spp., we also recommend that, as an action to prevent recurrence of the contamination (§ 112.146(e)), you conduct three additional rounds of sampling and testing at this stage (“intensified testing”), for the next three production days both to verify the effectiveness of your intensified cleaning and sanitizing, and to look for possible harborage sites in the affected area.

- Each round of follow-up samples should include at least 3 to 5 samples including the initial positive site, surrounding positive sites identified in cleaning verification testing, and surrounding FCS and non-FCS sites in close proximity to any positive sites. As appropriate, equipment should be disassembled during follow-up testing and exposed areas should be sampled and tested, ideally before such areas are cleaned and sanitized (see above) to help identify possible harborage sites.

Finished product testing and other product actions: You must conduct finished product testing when appropriate (§ 112.146(d)). In the circumstances described here, where you have identified a second FCS positive result:

- You should test the production batch of sprouts from the production day associated with the second positive for *Listeria* spp. on the FCS. You should test the sprouts for *L. monocytogenes* using a statistically-based sampling protocol and analytical methods that will provide an appropriate level of confidence in these results (e.g., 95% confidence that you will detect *L. monocytogenes* in the sample if present). While these test results are pending, and while you are taking the other steps recommended in this section (i.e., three production days of intensified cleaning and sanitizing, three production days of intensified sampling and testing, receiving results from such testing, conducting a comprehensive investigation), you should not allow the production batch of sprouts to enter commerce.
- You should also prevent the production batches of sprouts from the second and third production days from entering commerce while you are taking the other steps recommended in this section (three production days of intensified cleaning and sanitizing, three production days of intensified sampling and testing, receiving results from such testing, and conducting a comprehensive investigation).

Comprehensive investigation: Following a positive finding of *Listeria* spp. on an FCS, as an action to prevent recurrence of the contamination (§ 112.146(e)), you should conduct a comprehensive investigation to identify and mitigate *Listeria* sources, and modify procedures where appropriate. You may need to stop production at your sprout operation in order to conduct the comprehensive investigation. For more information on comprehensive investigations, see section IX.J.2.b.i above.

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Negative Results from Intensified Testing and Finished Product Testing: If all results from your three production days of intensified testing are negative, and your finished product testing is also negative, you should return to routine environmental monitoring. It would be reasonable to allow all three production days' worth of sprouts to enter commerce at this point, provided there is no other reason for concern (e.g., other testing requirements in § 112.147 have been satisfied for these batches). We recommend that you target these surfaces where positives have previously been found for sampling and testing during your next routine environmental sampling event.

Positive Results from Intensified Testing and/or Finished Product Testing: If any of the intensified testing results, or product testing results, are positive, this should lead you to take further steps (see below).

- iii. Product *L. monocytogenes* positive and/or any intensified sampling test *Listeria* spp. positive (3rd or subsequent positive)

Stop production and investigate: If your intensified sampling and testing again detects *Listeria* spp. on an FCS and/or a non-FCS site, and/or you detect *L. monocytogenes* in your product (third or subsequent positive), you should assume that you have a harborage site. As an action to prevent recurrence of the contamination (§ 112.146(e)), you should stop production, destroy and/or consider recalling any potentially contaminated sprouts (or other food) (see “Product Actions” below) and consult food safety experts familiar with troubleshooting *L. monocytogenes* contamination problems in operations to conduct a comprehensive investigation and make recommendations for appropriate actions to take based upon that investigation.

Product Actions: You must take appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering into commerce (§ 112.146(f)).

- If your production batch of sprouts tests positive for *L. monocytogenes*, § 112.146(f) requires you to prevent it from entering into commerce. We recommend that you destroy any such production batch. If you have held batches of sprouts from your two subsequent production days, you should consider the possibility that those production batches may also be adulterated, depending on the circumstances. If those batches are adulterated, § 112.146(f) requires you to prevent them from entering into commerce. Moreover, we recommend that you destroy any such batches in light of the positive finding of *L. monocytogenes* in the first batch, combined with the earlier positive findings in your environment.
- If any of the samples from the three production days of intensified sampling and testing of FCS and non-FCS sites for *Listeria* spp. is positive, you should consider the possibility that the production batches representing all three of those days of production may also be adulterated, depending on the circumstances. If the batches are adulterated, § 112.146(f) requires you to prevent them from entering into commerce. Moreover, we recommend that you destroy any such batches in light of all of the positive findings in your environment.
- In both of these circumstances, you should also evaluate whether any other production batches of sprouts (either at your operation or in distribution) should be recalled or destroyed.

Returning to production: After all of these corrective actions have been taken and production begins again, you should take action to prevent your new production batches of sprouts from entering commerce until further steps are taken. We recommend that you test each production batch of

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sprouts, and conduct intensified sampling and testing on each production day, until you have three consecutive days of negative test results for FCSs, non-FCSs, and sprouts.

- c. Additional considerations for if you detect *Listeria* spp. on a food-contact surface with continuous contact with sprouts that are being mixed (e.g., rotary drum growing units)

If you obtain a positive for *Listeria* spp. from an FCS with continuous contact with sprouts that are also being mixed (e.g., FCS from a rotary drum growing unit), there is a heightened risk that your sprouts may be contaminated with *L. monocytogenes* (as compared to finding *Listeria* spp. on FCSs that do not continuously contact sprouts while they are also being mixed, such as surfaces of stationary tray growing units). As a result, we recommend that you take additional corrective actions in response to such a finding, beyond those already discussed above.

If you receive notification of a positive test result for *Listeria* spp. from an environmental sample from an FCS collected during your routine sampling (i.e., a first environmental positive from such a site), you should take all corrective actions described above and should also take action to prevent the production batch of sprouts associated with the positive sample site (i.e., the production batch of sprouts that was grown in the rotary drum where the positive *Listeria* spp. was identified and any other potentially affected product) from entering commerce while you take the following steps:

- Conduct exploratory testing as described above (§ 112.146(a)). If your exploratory testing yields additional positives for *Listeria* spp., you should conduct intensified cleaning and sanitizing, and intensified testing, for three consecutive production days (as described above as a recommended response to a 2nd positive on an FCS site). If any of your intensified testing yields a positive result, you should proceed to the corrective actions recommended above for a 3rd positive on an FCS site.
- Further analyze the sample that was positive for *Listeria* spp. to determine whether the *Listeria* identified is *L. monocytogenes*. If you determine the sample is positive for *L. monocytogenes*, § 112.146(f) requires you to take appropriate action to prevent the production batch of sprouts grown in the affected rotary drum from entering commerce. We recommend that you destroy any such product.
- If all of your intensified testing of the environment for *Listeria* spp. for 3 consecutive production days, and *L. monocytogenes* finished product testing is negative, it would be reasonable at that time to allow the production batch of sprouts grown in the rotary drum at issue to enter commerce, and to return to routine sampling and testing.

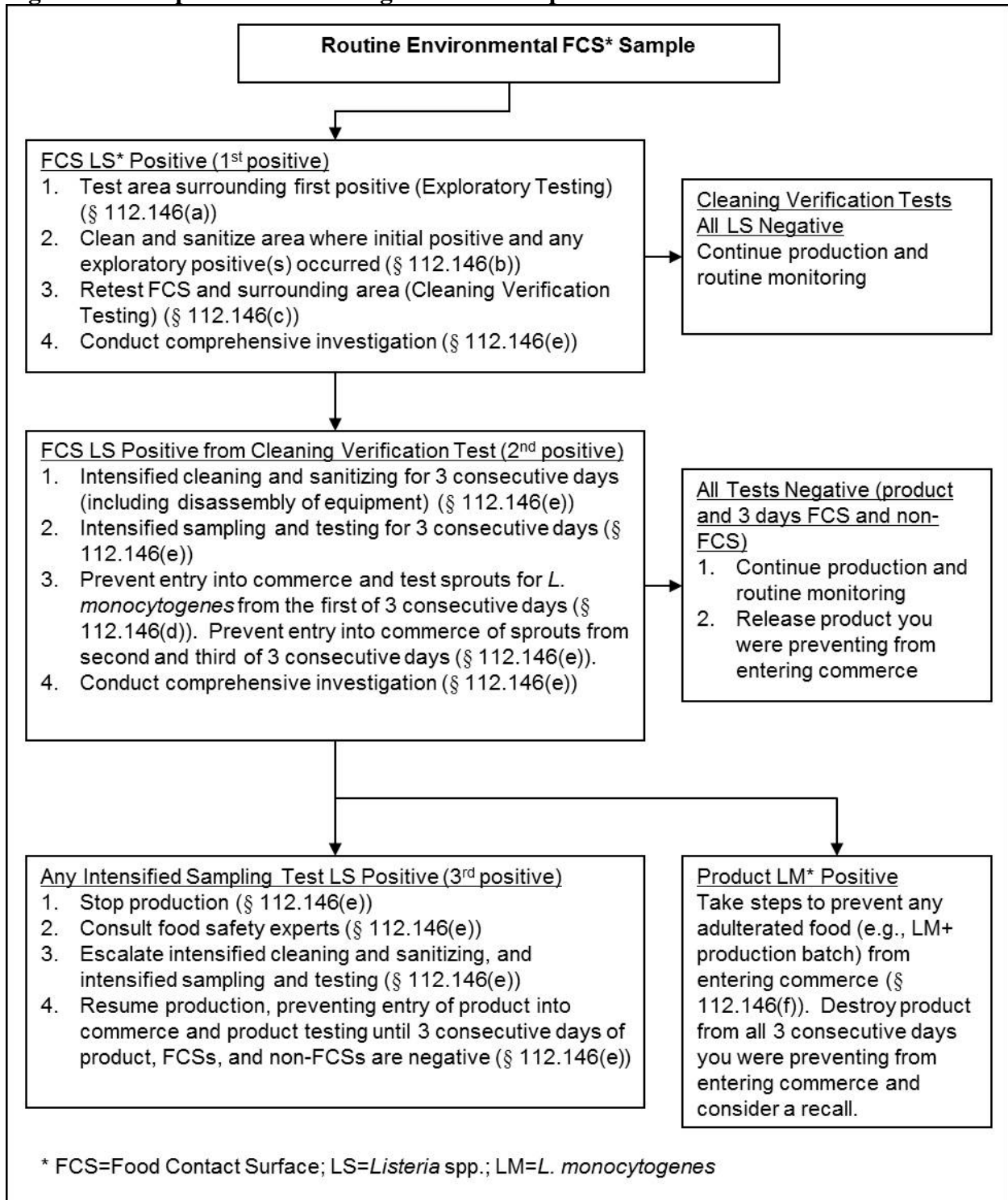
The example in Figure 3 addresses testing and follow-up actions for specific positive finding of *Listeria* spp. on an FCS during one sampling period. Detecting *Listeria* spp. at several FCS sampling locations during the same sampling period could indicate that your routine sanitation procedures are inadequate, and could indicate that the *Listeria* spp. has become established in one or more harborage sites. In such situations, the risk associated with cross contamination from contaminated FCS sites to food increases as the number of contaminated FCS sites increases. When several FCS site positives are detected during one sampling period, we recommend that you immediately review your written sanitation procedures to identify and implement more effective routine sanitation procedures, escalate your corrective actions, and identify and eliminate the *Listeria* spp. source(s).

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If you find *Listeria* spp. on FCS sites in the same general area on multiple occasions, we recommend that you evaluate why this area continues to be a source of positive results and take actions to eliminate the contamination, such as by determining the efficacy of your sanitation procedures and modifying them as necessary.

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Figure 3. Example of FCS* Testing and Follow-Up Activities



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Table 3. Corrective Actions when *Listeria* Species is Found in an Environmental Sample

| | Non-FCS | FCS |
|--|---|--|
| Routine sampling positive #1 | <ul style="list-style-type: none"> • Exploratory testing (§ 112.146(a)) • Clean and sanitize area of positive(s) (§ 112.146(b)) • Cleaning verification testing (may be during next routine sampling event) (§ 112.146(c)) • *If exploratory testing yields positives, consider moving to recommended corrective actions for positive #2 below. | <ul style="list-style-type: none"> • Exploratory testing (§ 112.146(a)) • Clean and sanitize area of positive(s) (§ 112.146(b)) • Cleaning verification testing (may be during next routine sampling event) (§ 112.146(c)) • Comprehensive investigation (§ 112.146(e)) • *If exploratory testing yields positives, consider moving to recommended corrective actions for positive #2 below. • *For continuous contact/mixing FCS positives, see additional recommendations in J.2.c of this document. |
| Cleaning verification sampling positive #2 | <ul style="list-style-type: none"> • Intensified cleaning and sanitizing (including disassembly of equipment) (§ 112.146(e)) • Intensified sampling and testing (§ 112.146(e)) | <ul style="list-style-type: none"> • Intensified cleaning and sanitizing (including disassembly of equipment) (§ 112.146(e)) • Intensified sampling and testing (§ 112.146(e)) • Test product and prevent it from entering commerce (§ 112.146(d)) • Comprehensive investigation (§ 112.146(e)) |

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| | Non-FCS | FCS |
|----------------------------------|---|--|
| Intensified sampling positive #3 | <ul style="list-style-type: none"> • Additional activities to determine source(s) and route(s) of contamination (§ 112.146(e)) | <ul style="list-style-type: none"> • Stop production and consult experts for comprehensive investigation (§ 112.146(e)) • Intensified cleaning and sanitizing (escalated, e.g., steam equipment) (§ 112.146(e)) • Intensified sampling and testing (§ 112.146(e)) • Resume production, preventing entry of product into commerce and product testing until 3 consecutive days of product, FCSs, and non-FCSs are negative (§ 112.146(e)) |

d. Corrective actions if you detect *Listeria monocytogenes* on a food-contact or non-food contact surface

In general, we expect that sprout operations will test FCS and non-FCS sites for *Listeria* spp. rather than *L. monocytogenes*. There is likely minimal value in determining whether *Listeria* spp. is *L. monocytogenes* because, typically, you should focus on eliminating the *Listeria* spp. regardless of whether it is *L. monocytogenes*. However, in certain cases you should consider conducting further tests to determine whether the *Listeria* spp. positive in your environmental samples is *L. monocytogenes*. One example of such a situation is described above in section IX.J.2.c for continuous contact/mixing FCS positives.

If you detect *L. monocytogenes* on an FCS, § 112.146(f) requires to you take appropriate action to prevent any food that is adulterated under section 402 of the FD&C Act from entering into commerce. Depending on the circumstances, you may have production batches of sprouts that are adulterated under section 402(a)(4) of the FD&C Act because of their association with the affected FCS location. We recommend that you destroy any potentially affected production batch of sprouts (or other food) associated with the contaminated FCS (as part of a recall, if applicable) and follow procedures outlined above (see “returning to production” in discussion of recommended corrective actions for a 3rd positive on an FCS).

K. Voluntary Periodic Sampling and Testing of Sprouts

Periodic sampling and testing of sprouts that you produce can provide a historical reference of baseline performance for your operation and verify the adequacy of your control of *L. monocytogenes* over time. We recommend that you establish and implement written procedures for periodic sampling and testing finished sprouts for the presence of *L. monocytogenes*. We recommend that you test food products for *L. monocytogenes* rather than for *Listeria* spp. because of the risk to public health from *L. monocytogenes* in food. If you choose to test food for *Listeria* spp. and find it to be positive, we recommend you determine whether the *Listeria* spp. is *L.*

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monocytogenes or treat the food as if it were contaminated with *L. monocytogenes*. We recommend that you take action to prevent all product that is represented by the sprouts you test from entering commerce while results are pending (e.g., the full production batch and any other food produced during the same period from cleanup to cleanup). We recommend that your written procedures include the frequency of this sampling (e.g., monthly, quarterly) and the sampling plan to ensure the sample collected is representative of the production batch of sprouts. The ideal frequency of sampling and sampling plan should also reflect factors such as any relevant customer requirements and the frequency of detection of *Listeria* spp. in your environmental samples. Note that recommendations pertaining to voluntary testing for other pathogens besides *L. monocytogenes* (in addition to the required testing in § 112.144(b)) in spent sprout irrigation water, in-process sprouts, or finished sprouts are discussed in Section VIII (Sampling and Testing of Spent Sprout Irrigation Water or In-Process Sprouts).

L. Analysis of Data for Trends

To make the best use of the data that you collect through your environmental monitoring program, we recommend that you analyze the data (e.g., sample results, corrective actions, findings from comprehensive investigations) from your environmental monitoring program over time for trends that can help you to continuously improve sanitation conditions in your operation by reducing the percentage of overall positive environmental samples in your operation. This trend analysis could provide evidence that *L. monocytogenes* in your operation is not being controlled (e.g., if a resident strain has become established in a niche environment) so that you can take steps to control it. Examples of trends that could indicate that *L. monocytogenes* in your plant is not being controlled are:

- Finding *Listeria* in the same area on multiple but non-consecutive sampling occasions (e.g., positive one week and negative the next, appearing to be isolated positives);
- An increase in the percentage of overall positives in the establishment; and
- Increases in positive environmental samples in particular sites or areas.

Even if you have taken appropriate corrective actions for individual positive results from a particular area, the continued finding of *Listeria* spp. positives in that area over time may indicate a continuing problem such as an unidentified harborage site. If your analysis of data indicates a potential problem, such as an increased incidence of *Listeria* species in your operation, you should conduct a more complete investigation to determine if further actions are warranted and take appropriate corrective actions to reduce the incidence of *Listeria* species in your operation. We recommend that you establish and maintain a record of any trend analysis that you conduct. The trend analysis may also lead you to update your written environmental monitoring plan.

M. Recordkeeping

Section 112.150 describes records that you must establish and maintain related to sprouts. For more information on the recordkeeping requirements, see the Section X (Recordkeeping). Specifically, you must establish and maintain the following records related to environmental monitoring:

- Your written environmental monitoring plan, including your sampling plan and corrective action plan, in accordance with the requirements of § 112.145 (§ 112.150(b)(2));

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- Documentation of the results of all analytical tests (§ 112.150(b)(4)). The results of all analytical tests must be documented, regardless of whether they were conducted by your own (e.g., in-house) laboratories or third-party laboratories. Records of environmental monitoring tests must include the following information, in accordance with § 112.161(a)(1):
 - The name and location of your operation;
 - Actual values and observations obtained;
 - An adequate description of covered produce applicable to the record (e.g., production batch number of sprouts in production at the time of the environmental sample);
 - Location of the growing area or other area(s) applicable to the record (e.g., identification of each sampling site, including whether it is an FCS or non-FCS site); and
 - Date and time of the activity documented (e.g., date/time of sample collection, and sample receipt and analysis by the testing lab).

In addition, such records must be dated, and signed or initialed by the person who performed the activity documented (e.g., the individual who conducted sample analysis) as required under § 112.161(a)(4). Also, as required under § 112.161(b), these records must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

- Records of any analytical methods you use in lieu of the methods that are incorporated by reference in § 112.152(a) (§ 112.150(b)(5)). Such records should include analytical procedures, as well as information relevant to the determination of the scientific validity of the alternate method. If you use the method listed in § 112.152(a), keeping records of your use of this test method, although not required, would be helpful to demonstrate compliance; and
- Documentation of corrective actions you take in accordance with § 112.146 (§ 112.150(b)(6)). Records of corrective actions must include the following information, in accordance with § 112.161(a)(1):
 - The name and location of your operation;
 - Actual values and observations obtained (e.g., observations and information related to a comprehensive investigation following repeated *Listeria spp.* positives on an FCS, such as the food and food contact surfaces potentially affected by the contamination event);
 - An adequate description of covered produce applicable to the record (e.g., production batch number of sprouts in production at the time of the corrective action);
 - Location of a growing area or other area(s) applicable to the record (e.g., identification of locations sampled for follow-up testing or intensified cleaning and sanitizing); and
 - Date and time of the activity documented (e.g., date/time of follow-up testing or intensified cleaning and sanitizing).

In addition, such records must be dated, and signed or initialed by the person who performed the activity documented (e.g., the individual who performed the corrective action) as required under § 112.161(a)(4). Also, as required under § 112.161(b), these records must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

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X. Recordkeeping

Records are an essential component of safely growing, harvesting, packing, and holding food, including sprouts. Records can be used to ascertain safety of products, monitor storage conditions, document good agricultural practices, and track receipt and distribution of product(s). Records also offer written evidence that operational processes are being properly followed and are under control. They may also be used to help determine the cause of underlying problems in the event of an outbreak or recall.

In this section, we provide a brief overview of certain aspects of the recordkeeping requirements in the Produce Safety Rule for sprout operations covered by Subpart M.

A. Recordkeeping Overview

1. General requirements

Except as otherwise specified, the requirements of Subpart O apply to all records that are required under the Produce Safety Rule. All required records must include, as applicable and unless otherwise specified:

- The name and location of your sprout operation (§ 112.161(a)(1)(i));
- Actual values and observations obtained during monitoring (§ 112.161(a)(1)(ii));
- An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record (§ 112.161(a)(1)(iii));
- The location of a growing area or other area (for example, a specific packing shed) applicable to the record (§ 112.161(a)(1)(iv)); and
- The date and time of the activity documented (§ 112.161(a)(1)(v)).

Required records must also:

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

Actual Values and Observations

Section 112.161(a)(1)(ii) requires records to include, as applicable, the actual values and observations obtained during monitoring. “Actual values and observations” means: (a) the value or observation, as applicable, itself is written, e.g., 96°F; and (b) truthful information is recorded. For example, if a batch of sprouts tests positive for *Salmonella*, a person must not write on the test results that the sample of spent sprout irrigation water was negative for *Salmonella*. Observation records can take many forms, including photographs. For example, if you are documenting a repair you are conducting, we recommend taking pictures before and after the repair.

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Date and Time

As applicable, the date and time of the documented activity must be written on the records as required under § 112.161(a)(1)(v). This information not only shows when something happened, it can also help demonstrate that an operation consistently followed its written plans and procedures. Records must also be created at the time that an activity is performed or observed under § 112.161(a)(2). You must not pre-fill records, nor rely on your memory to write down the information later.

Adequate Description of Covered Produce Applicable to the Record

An adequate description of covered produce applicable to the record is required under § 112.161(a)(1)(iii). For sprouts, an adequate description of covered produce should include the product name (including the commodity/product name, or the specific variety or brand name) and any number or other identifier that your operation uses to identify the product. We recommend that you assign a unique identifier for each individual production batch of sprouts (as that term is defined in § 112.3 and relates to various requirements in Subpart M, such as the spent sprout irrigation water or sprout testing required for each production batch of sprouts under § 112.144(b)). Using unique production batch numbers and including them on all applicable records helps enable a sprout operation to track any production batch internally and through distribution in the event there is a problem with a production batch of sprouts. If you use additional identification systems (e.g., for product that has been packaged for sale), then you should be able to link the information used in those additional identification systems to each associated production batch of sprouts. For example, you may combine product from Production Batch “A” with Production Batch “B” during packaging, and assign an additional identifier (e.g., #1234) to the final packaged product. In this example, you should be able to (e.g., through records or a coding scheme) use the additional identifier (#1234) to identify each production batch that is a component of the final product (i.e., Production Batches A and B).

For each production batch of sprouts, we also recommend that you keep records of the following information, as applicable:

- The seed lot number(s) for the seeds used to grow the production batch of sprouts (so that the seeds that were used to grow each production batch of sprouts can be easily and reliably identified in the event of a problem);
- Container size/type;
- Date packaged;
- Number of units packaged;
- Holding area; and
- Any other comments and information that may be useful in the event of a problem.

We also recommend that, for records of seed treatments that you perform at your operation to reduce microorganisms of public health significance (§§ 112.142(e)(1) and 112.150(b)(1)), you include a description of the seeds to which the record relates. Such a description should include the type of seeds treated, and the seed lot number (see also Section VII.D (Seeds for Sprouting – Recordkeeping) of this guidance for more information on seed treatment records).

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Location of growing area or other area applicable to the record

As applicable, the location of the growing area or other area applicable to the record must be included in the record under § 112.161(a)(1)(iv). For example, a sprout operation's growing area could be the specific sprouting room in which a batch of sprouts is grown. Other areas applicable to the batch record could include the designated seed treatment area, or a particular packing line used for that batch of sprouts. If you have diagrams of your sprout operation, it is desirable for the locations on the records to match the descriptions in your diagrams, as appropriate.

Accuracy, Legibility, Indelibility

Required records must be accurate, legible, and indelible under § 112.161(a)(3). If mistakes are made on a record, they should be marked through with a single line and initialed and dated by the person making the correction. The correct information should be written adjacent to it. The person correcting the record should not write over existing information, obscure it by scratching it out, or use liquid correction fluid. While handwriting styles may vary, the information on a required record must be legible so that company officials and regulatory agencies, as appropriate, can review it. Information must be written in an indelible manner, e.g., written in ink, so that it cannot be erased.

Dated, and Signed or Initialed by the Person Who Performed the Activity

The individual who performed the activity documented is required to date, and sign or initial the required record under § 112.161(a)(4). Examples of individuals who perform the activity requiring a record include the person inspecting the agricultural water system (for records required under § 112.50(b)(1)), a worker sanitizing equipment used for growing sprouts (for records required under § 112.140(b)(1)), or a laboratory analyst testing sprout spent sprout irrigation water samples for microbiological contamination (for records required under § 112.150(b)(4)).

2. Duplication not required

Section 112.163(a) provides that you are not required to duplicate any existing records if those records contain all of the required information and satisfy the requirements of the Produce Safety Rule. Similarly, if you have records containing some but not all of the required information, § 112.163(b) provides you the flexibility to keep any new information required either separately or combined with your existing records, even where the formats for each record may not be the same.

3. Record retention and availability

Required records must be kept for at least 2 years past the date the record was created (§ 112.164(a)(1)).

Records that relate to the general adequacy of equipment or processes or records that relate to analyses, sampling or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the sprout operation for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued (§ 112.164(b)). Examples of such records for a sprout operation include: the written sampling plan for spent sprout irrigation water or sprouts including the corrective action plan (§§

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112.147(a) and (c); 112.150(b)(3)), and the written environmental monitoring plan including the corrective action plan (§§ 112.145(a) and (e); 112.150(b)(2)).

For sprout operations that are eligible for the qualified exemption in accordance with § 112.5, records that you rely on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained as long as necessary to support your exemption status during the applicable calendar year (§ 112.164(a)(2)).

In addition, you must have all required records readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to us for inspection and copying (§ 112.166(a)). Offsite storage of required records is permissible, provided such records can be retrieved and provided onsite within 24 hours of request for official review (§ 112.162(a)). Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm (§ 112.162(b)).

4. Format

As required by § 112.165, you must keep records as: (1) original records; (2) true copies; or (3) electronic records. “True copies” include, for example, photocopies, pictures, scanned copies, microfilm, microfiche or other accurate reproductions of the original records. True copies of records should be of sufficient quality to detect whether the original record was changed in a manner that obscured the original entry (e.g., through the use of liquid correction fluid). “Electronic records” are subject to the same requirements under the Produce Safety Rule as paper records. We are not requiring electronic records, nor are we specifying the form or format of the records that must be established and maintained except as otherwise set forth in Subpart O (e.g., certain content is required when applicable as discussed in Section X.A.1 above). To satisfy the requirements of the produce safety regulation, paper or electronic records or a combination of the two may be used.

Records that are established or maintained to satisfy the requirements of part 112 and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11 (Electronic Records; Electronic Signatures). Records that satisfy the requirements of part 112, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 (§ 112.165(c)).

Although part 11 does not apply, except for records otherwise subject to part 11 (as provided in § 112.165(c)), covered sprout operations should take appropriate measures to ensure that electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. Also, as noted above, electronic records are subject to the same requirements in part 112 as paper records, including requirements for making records available and accessible to FDA (§ 112.166) and retention requirements (§ 112.164).

B. Sprouts-Specific Record Requirements

The following recordkeeping requirements apply to growing, harvesting, packing, and holding of sprouts covered by Subpart M.

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- **Records related to seed treatment:** Section 112.150(b)(1) requires that you establish and keep documentation of your treatment of seeds to reduce microorganisms of public health significance in the seeds, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e).
 - See section VII.D of this guidance for discussion of required and recommended content for these records.
- **Written environmental monitoring plan, including corrective action plan:** Section 112.150(b)(2) requires sprout operations to establish and keep a written environmental monitoring plan, in accordance with § 112.145, which is designed to identify *Listeria monocytogenes* if it is present in the growing, harvesting, packing, or holding environment. Your environmental monitoring plan must be directed to sampling and testing for either *Listeria* species or *L. monocytogenes* and your written environmental monitoring plan must include a sampling plan and a corrective action plan, including actions described in § 112.146.
 - See Section IX (Environmental Monitoring) of this guidance for discussion of required and recommended content for these records.
- **Written sampling plan for testing spent sprout irrigation water (or, where that is not practicable, sprouts) from each production batch of sprouts, including corrective action plan:** Section 112.150(b)(3) requires that you establish and keep a written sampling plan for each production batch of sprouts, in accordance with § 112.147(a) and (c). Your corrective action plan must, at a minimum, require you to take the actions in § 112.148, and detail 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* spp., or a pathogen meeting the criteria in § 112.144(c).
 - See Section VIII (Sampling and Testing of Spent Sprout Irrigation Water or In-Process Sprouts) of this guidance for discussion of required and recommended content for these records.
- **Documentation of analytical test results for all testing done under Subpart M:** Section 112.150(b)(4) requires records of all analytical tests conducted for purposes of compliance with subpart M. This includes, e.g., records of test results from:
 - Environmental testing for *Listeria* spp. or *L. monocytogenes* under §§ 112.144(a) and 112.145;
 - Testing spent sprout irrigation water (or sprouts) from each production batch of sprouts for *E. coli* O157:H7, *Salmonella* spp., and any pathogen meeting the criteria in § 112.144(c) under §§ 112.144(b) and 112.147;
 - Any additional testing conducted if you detect *Listeria* spp. or *L. monocytogenes* in the environment under § 112.146 (a), (c), (d), and (e) (see also § 112.150(b)(6) below);
 - Any additional testing conducted if you detect *E. coli* O157:H7, *Salmonella* spp., or any pathogen meeting the criteria in § 112.144(c) in spent sprout irrigation water or sprouts under § 112.148(d) (see also § 112.150(b)(6) below); and
 - Any testing conducted as part of follow-up actions related to suspected contamination of a seed lot with a pathogen under § 112.142(c)(2) (see also § 112.150(b)(6) below).

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- **Documentation of analytical methods used in lieu of those incorporated by reference in the rule for sprout-specific testing requirements:** Section 112.150(b)(5) requires sprout operations to establish and keep documentation of any analytical methods used in lieu of the methods for both environmental testing and sprout production batch testing that are incorporated by reference in §§ 112.152 and 112.153.
 - In the event that other pathogens meet the criteria in § 112.144(c), thereby requiring you to test spent sprout irrigation water or sprouts for such pathogens using a scientifically valid method (§§ 112.144(b) and 112.153(b)), we recommend that you establish and maintain a record of the method used for such testing.
- **Corrective action records:** Section 112.150(b)(6) requires records of corrective actions conducted in accordance with the requirements of §§ 112.142(b) and (c), 112.146, and 112.148:
 - See Section VII.D (Seeds for Sprouting – Recordkeeping) of this guidance for discussion of required and recommended content for records related to corrective actions for possible contamination of a seed lot (§§ 112.142(b) and (c))
 - See Section IX (Environmental Monitoring) of this guidance for discussion of required and recommended content for records related to corrective actions if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes* (§ 112.146).
 - See Section VIII (Sampling and Testing of Spent Sprout Irrigation Water or In-Process Sprouts) of this guidance for discussion of required and recommended content for records related to corrective actions if samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* spp., or a pathogen meeting the criteria in § 112.144(c) (§ 112.148).

C. Other Required Records

The records required under the Produce Safety Rule are dependent, in part, on the nature of practices and procedures related to the covered activities in your operation, and are listed under the applicable sections of part 112, including in Subparts A, C, E, F, L, and M (i.e., §§ 112.2(b)(4), 112.7, 112.30, 112.50, 112.60, 112.140, and 112.150). Required records that are specific to sprout operations are discussed above in Section X.B (records required under § 112.150 for sprouts subject to subpart M). Records required under other subparts of the Produce Safety Rule that may be relevant to sprout operations are identified briefly below.

- **Records relating to commercial processing exemption:** Section 112.2 requires farms relying on the exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance to establish and maintain documentation of their required disclosures to customers and annual written assurances obtained from customers.
- **Records relating to eligibility for qualified exemption:** Section 112.7 requires farms eligible for the qualified exemption in accordance with § 112.5 to establish and keep adequate records necessary to demonstrate that the farm 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 farm has performed an annual review and verification of the farm's continued eligibility for the qualified exemption.

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- **Training records:** Section 112.30 requires you to establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.
- **Records related to agricultural water:**
 - Section 112.50(b)(1) requires you to establish and keep records of your agricultural water system inspection findings in accordance with the requirements of § 112.42(a).
 - Section 112.50(b)(2) requires documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with Subpart E.
 - Section 112.50(b)(3) requires documentation of scientific data or information relied on to support the adequacy of a method used to satisfy the requirements of §§ 112.43(a)(1) and (a)(2) for treating agricultural water. All covered farms that treat their water to achieve a water quality requirement in the Produce Safety Rule are required to keep these records of the science supporting their agricultural water treatment method(s).
 - Section 112.50(b)(4) requires documentation of results of monitoring water treatment under § 112.43(b). All covered farms that treat their water to achieve a water quality requirement in the Produce Safety Rule are required to keep these records of the results of their water treatment monitoring.
 - Section 112.50(b)(6) requires you to establish and keep documentation of actions you take when your agricultural water does not meet the water quality requirements in the Produce Safety Rule in accordance with § 112.45. For example, if you determine that water you use for a purpose listed in § 112.44(a) does not meet the microbial quality criterion established in that section, § 112.45(a) provides that you must take certain steps as a result, and § 112.50(b)(6) requires you to keep records documenting the steps that you took.
 - Section 112.50(b)(7) requires annual documentation of the results or certificates of compliance from a Public Water System required under § 112.46(a)(1) or (a)(2), if applicable. All covered farms that rely on the exemption from agricultural water testing requirements for water furnished by a public water system or public water supply are required to keep these records demonstrating that the water supplied by the public entities meets relevant requirements.
 - Section 112.50(b)(9) requires you to establish and keep documentation of any analytical methods that you choose to use for agricultural water testing in lieu of the method that is incorporated by reference in § 112.151(a).
- **Records related to biological soil amendments of animal origin:** Section 112.60 requires you to establish and keep certain documentation relating to any treated biological soil amendments of animal origin (BSAAO) you use (e.g., substrates). The required records differ based on whether treatment was conducted by the sprout operation or by a third party. For a treated BSAAO supplied by a third party, you are required to establish and keep documentation (such as a Certificate of Conformance) at least annually that the process used to treat the BSAAO is a scientifically valid process that has been carried out with appropriate process monitoring, and that the BSAAO has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination by an untreated or in process BSAAO (§ 112.60(b)(1)). For a treated BSAAO you produce for your own covered farm(s), you are required to establish and keep documentation that process controls were achieved (§ 112.60(b)(2)).

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- **Records of cleaning and sanitizing:** Section 112.140 requires you to establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to subpart L used in growing, harvesting, packing, or holding sprouts.

D. Supervisory Review of Records

Certain required records must be reviewed, dated, and signed by a supervisor or a responsible party within a reasonable time after the records are created (§ 112.161(b)). These records include:

- As applicable, records related to eligibility for the qualified exemption (§ 112.7(b));
- Records related to required training of personnel (§ 112.30(b)(2));
- As applicable, documentation of the results of all agricultural water testing (§ 112.50(b)(2));
- As applicable, documentation of the results of water treatment monitoring (§ 112.50(b)(4));
- As applicable, documentation of actions you take in when your agricultural water does not meet the water quality requirements in the Produce Safety Rule (§112.50(b)(6));
- As applicable, for a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls were achieved (§ 112.60(b)(2));
- Documentation of cleaning and sanitizing of equipment (§§ 112.140(b)(1) and (2));
- Records related to seed treatment (§ 112.150(b)(1)).
- Documentation of analytical test results for all sprout-specific testing done under Subpart M (§ 112.150(b)(4));
- As applicable, documentation of sprout-specific corrective actions you take under Subpart M (§ 112.150(b)(6)).

The person reviewing records should ensure that they were completed accurately and in a timely manner, consider whether the records suggest any problems that need to be corrected, and institute any corresponding corrective actions as necessary. The person reviewing records should also look for any trend that could lead to problems in the future if not adequately addressed, and institute preventive measures as necessary.

Reviewing records can be tedious, particularly since a reviewer may be looking at similar records day after day. It can be a challenge to remain focused when reviewing records and not to skim over them with a quick glance. We recommend that you select a time to review records when you are able to focus without interruption. If more than one supervisor or responsible person is qualified to review records, you may find it helpful to rotate the review of different types of records among these reviewers, or to rotate review shifts, so that reviewers do not have to review the same records repeatedly or for long time periods. This rotation may help in reviewing records with a “fresh” pair of eyes.

XI. Appendices

A. Appendix 1. Aseptic Sampling

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You must aseptically collect environmental samples (§ 112.145(d)) and samples of spent sprout irrigation water or sprouts (§ 112.147(b)). If you are required to test your agricultural water (§§ 112.44(a), 112.46(c)), you must aseptically collect water samples as well (§ 112.47(b)). Aseptic sampling is a sampling technique used to assure that the microbial load of a sample is not affected by the sampling method and/or the sample collector does not contaminate the source from which the sample is collected (including cross-contamination between sample sites). The use of sterile sampling implements and containers and a prescribed sampling method defines aseptic sampling (See 80 FR 74450 and references cited therein). Collected samples should also be handled in a manner to ensure samples are not contaminated during storage or during transportation to the laboratory.

Sterile Equipment

The requirements in §§ 112.47(b), 112.145(d) and 112.147(b) to collect samples “aseptically” mean that you must use sterile sampling equipment to collect the required samples. Note that “sterile” is not equivalent to “clean and sanitized.” Sterilization achieves a higher standard than cleaning and sanitizing. “Sterilization” refers to a validated process used to render a product free of all forms of viable microorganisms. In many cases, thermal methods, such as steam, are used to achieve sterilization (See Liquid Chemical Sterilization)(Ref. 62). “Sterile” refers to the end point achieved by a sterilizing process. You may purchase pre-packaged sterilized tools/equipment to use in sampling, or you may use (and re-use) tools and equipment for sampling that have been properly sterilized, such as in an autoclave or a dry heat oven. An autoclave machine is a device that sterilizes laboratory instruments and equipment by using highly pressurized saturated steam to effectively kill microorganisms. If you decide to use an autoclave, any responsible personnel should receive adequate training prior to the use of the autoclave. When used properly, autoclaves are safe and highly effective to sterilize sample containers or sampling equipment (e.g., cups or tongs) and can be cost-effective. Sampling equipment, such as one-piece stainless steel, forceps, spatulas, and sample containers, may be sterilized using an autoclave (steam heat), for example, at 121 °C (250 °F) for 30 minutes at 15 psi, or for heat-resistant, dry materials in a dry-heat oven, for example, at 140 °C (284 °F) for 3 hours (Ref. 63). If you choose to use an autoclave, you should follow the instructions provided by the manufacturer to ensure that sterilizing of sampling tools and equipment is effective. If you choose to sterilize your own sampling tools and equipment, you should package them after sterilization in a manner to prevent contamination post-sterilization (e.g., wrap them with aluminum foil), and should only open their packaging immediately prior to use.

We recommend that you include your plans regarding use of sterilized sampling equipment in your written sampling plan for spent sprout irrigation water (or sprouts) (see Section VIII (Spent Sprout Irrigation Water or In-Process Sprouts)) and your written environmental monitoring plan (see Section IX (Environmental Monitoring)).

General Aseptic Sample Collection Procedures

The requirements in §§ 112.47(b), 112.145(d), and 112.147(b) to collect samples “aseptically” also mean that, in addition to using sterile equipment for sampling, you must use a sampling method that does not affect the microbial load of the sample collected and does not contaminate the source from which the sample is collected. We recommend that you include your procedures for aseptic technique in your written sampling plan for spent sprout irrigation water (or sprouts) (see Section

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VIII (Spent Sprout Irrigation Water or In-Process Sprouts)) and your written environmental monitoring plan (see Section IX (Environmental Monitoring)). We recommend the following aseptic techniques, which are generally applicable to any kind of sampling:

1. For activities in fully enclosed buildings, a sample collector should wear a clean lab coat, single-use gloves, and a hair net to ensure he or she does not contaminate the samples.
2. Hands should be washed immediately before sampling, and prior to putting on disposable clean gloves. Gloves should be put on in a manner that does not contaminate the outside of the glove. Gloves should be properly disposed of after use.
3. To prevent cross contamination, gloves should be changed between samples. In addition, you should change gloves if you touch any surfaces other than the sample sites such as garbage, drains, or the floor.
4. Hands should be kept away from mouth, nose, eyes, and face while collecting samples. Try not to cough or sneeze into the samples, and if you do, discard the affected sample(s).
5. Sampling instruments should be protected from contamination at all times before and during use. Either use them only once or sterilize them in between uses, so each sample will be taken by fresh and sterile utensils. Sampling equipment and samples moving between the sampling site and the sample container should not be passed over the remaining pre-sterilized instruments.
6. The type of sample containers used (e.g., bags, tubes, cups, flasks) should depend on the type of sample collected. You should use containers that are dry, leak-proof, wide-mouthed, and of a size suitable for the type of sample collected.
 - The container should be properly labeled, such as with a marked strip of masking tape, prior to sampling to identify the sample information, such as the sample production batch, time, and the date of sampling. You should not use a felt pen directly on plastic containers because the ink might penetrate the container. The container should be opened only sufficiently to collect the sample directly in the container, and then immediately closed and sealed.
 - Containers such as plastic jars or metal cans that are leak-proof may be hermetically sealed.
 - If collecting samples in a container with a lid, the lid should not be placed on a counter.
 - Whenever possible, avoid using glass containers, which may break and contaminate the sample, the source from which the sample was taken, and/or covered produce, including sprouts.
7. Sample containers for water samples (i.e., agricultural water and spent sprout irrigation water) should not be overfilled, and you should leave an air space of 1 to 2 inches at the top to prevent overflow.
8. For samples collected indoors, samples and sampling equipment should not be exposed to unfiltered air currents. When opening sterile sampling containers, you should work rapidly, open sterile sampling containers only to admit the sample and close it immediately.
9. You should not touch inside the sterile sample container, lip or lid. You should not allow fingers or anything except the sample to contact the inside of the sample container.
10. You should not use a sample container that has fallen on the floor.
11. You should not expose covered produce, including sprouts or food contact surfaces to samples or hands after sampling. You must wash hands with soap and water following

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sample collection, because sampling is a time when hands may have become contaminated in manner reasonably likely to lead to contamination of covered produce (§ 112.32(b)(3)(vi)).

12. Samples should be delivered to the laboratory promptly.
13. Spent sprout irrigation water (or in-process sprouts) should be kept at an appropriate temperature, preferably at 0 to 4.4 °C (32 to 40 °F). Sealed coolant packs, rather than ice, should be used to avoid contamination from melting ice.

Collection Procedures – Environmental Sampling

For environmental sampling of food and non-food contact surfaces for *Listeria* spp. or *Listeria monocytogenes*, more specifically, we recommend the following aseptic techniques in addition to the general techniques (discussed in Section XI.A immediately above).

1. You should wash and sanitize hands to the mid-forearm. Aseptically place a glove on the hand used for swabbing.

If sponge sampling:

2. Using the ungloved hand, open the bag containing the sponge on a stick by pulling off the clear perforated strip at the top of the bag.
3. Pull apart the white tabs to open the mouth of the bag.
4. Aseptically pour 9-10 ml of sterile Dey-Engley (D/E) or other neutralizing broth into the bag to hydrate the sponge, being careful not to contaminate the broth or sponge during the transfer.
5. Close the bag and evenly moisten sponges by hand massage.
6. Position the sponge so that the handle is sticking out of the bag and close the bag around the stick.
7. Through the bag, squeeze the excess broth gently out of the sponge. Do not let your hand go past the thumb stop on the stick.
8. Carefully take the sponge-stick out of the bag by grasping the stick and swab the area selected using firm and even pressure. Be careful to maintain sanitary conditions when sampling. Do not let your hand go past the thumb stop on the handle.
9. Swab between 4 inches by 4 inches up to 12 inches by 12 inches square of food contact or environmental surface area. If collecting from surfaces with visible residue (e.g., dust, dirt, buildup of organic material), we recommend increasing the number of sponges and collecting from a smaller surface area for each sponge to improve the likelihood of detection.
10. Swab the chosen area using firm and even pressure:
 - Sponge vertically (approximately 10 times); then
 - Flip the sponge and use the other side to swab horizontally (approximately 10 times);
 - Then move the sponge diagonally, using the same surface side as you used for horizontal (approximately 10 times).
11. Open the bag and insert the sponge portion into the bag.
12. Grip the sponge through the bag and bend the stick of the sponge back and forth with slight force, while gripping the sponge through the bag. The stick should break easily within the sponge (do not break the stick at the thumb stop). Discard the broken stick. If the stick is sticking out above the sponge, discard this sample.

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13. Squeeze as much air out of the bag as possible and fold the top of the bag down at least 3 times until it is folded all the way down to the sponge. Fold in the tabs to lock the fold in place.
14. Label the bag with the date and location of the sample.
15. Take each new sample following the same steps in 1) – 14), starting by changing the glove on the gloved hand between samples.
16. When all samples have been taken and prepared for shipping or delivery, ship the samples or deliver them to the laboratory as soon as possible for analysis. Keep the samples in a refrigerator if not ready to be shipped to the lab.

If swab sampling:

2. Using the ungloved hand, open the tube containing the swab.
3. Aseptically pour 9-10 ml of sterile D/E or other neutralizing broth into the tube to hydrate the swab or use sampling swabs that are already pre-moistened in 9-10 ml of D/E broth. If the D/E broth is not purple, discard the tube.
4. Close the cap of the tube and wait until the swab is moistened.
5. Carefully take the swab out of the tube and swab the area selected using firm and even pressure. Be careful to maintain sanitary conditions when sampling.
6. Swab at least 1 inch by 1 inch square of food contact or environmental surface area.
7. Swab the chosen area using firm and even pressure:
 - Sponge vertically (approximately 10 times); then
 - Flip the sponge and use the other side to swab horizontally (approximately 10 times);
 - Then move the sponge diagonally, using the same surface side as you used for horizontal (approximately 10 times).
8. Do not touch the outside of the opening and insert the swab portion into the tube.
9. Close the cap of the tube.
10. Label the bag with the date and location of the sample.
11. Take each new sample following the same steps in 1) – 10), starting by changing the glove on the gloved hand between samples.
12. When all samples have been taken and prepared for shipping or delivery, ship the sample or deliver it to the laboratory as soon as possible for analysis. Keep the sample in a refrigerator if not ready to be shipped to the lab.

B. Appendix 2. Recommended Procedures for Collecting Environmental Samples

Laboratory analysis of samples should only be conducted by persons with appropriate microbiological training or experience. *Listeria monocytogenes* infection can cause serious illness and death, including fetal death. We recommend that pregnant women and persons who are immunocompromised because of illness, medication, or advanced age avoid working with this organism. Contaminated equipment and media should be sterilized before disposal or reuse.

Preparing for Sample Collection

You should assess the configuration of your sprout growing, harvesting, packing and holding environment, to determine how best to collect environmental samples. Based on your assessment,

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you may determine that it is necessary to make changes to your sprout production area; for example, relocating growing units to gain easier access to surfaces for sampling.

To prepare for sample collection, you should assemble the materials necessary for aseptic sample collection and shipping, which may include:

- Gloves
- Sponges (non-microbiocidal, sterile)
- Plastic bags (sterile) to hold sponges (e.g., lab blender bag)
- Swabs (cotton tipped applicators; non-microbiocidal and sterile)
- Sterile containers (with lids) to hold swabs (e.g., screw-capped or snap-capped plastic tubes), or sterile commercial swab-container devices with neutralizing broth
- Scissors (sterile)
- Plastic container to hold 100 ml (sterile)
- Bottles (with lids) to hold 100 ml (sterile)
- Dey-Engley (D/E) neutralizing broth (commercially available, or prepared according to a formula) (sterile)
- Cleaned working surface (e.g. counter top or rolling cart)
- Cooler with ice packs
- Any forms or records that need to be completed

See Appendix 1: Aseptic Sampling for specific information on aseptic techniques. Aseptic sampling technique, including use of sterile equipment and media, is required under § 112.145(d).

Collecting Samples from Surfaces (Including Both Food-Contact Surfaces and Non-Food-Contact Surfaces)

The two most common methods to collect samples are “surface sponging” and “swabbing.” Another method used for sampling difficult to clean areas is liquid rinse samples. In general, the preferred method of sampling is surface sponging, but swabs may be more appropriate for small or hard-to-access surfaces.

In general, the preferred method of sampling is surface sponging, but certain areas could be more appropriately sampled using a swab (e.g., head screws, small water collection points, screw holes, threaded surfaces or interior corners of equipment) or rinse method. The sample size of each site should be consistent with the testing methodology and the sample collection method being used. The recommended sample size for swabs is generally smaller (e.g., 1 inch by 1 inch) compared to sponges (e.g., 4 inches by 4 inches up to 12 inches by 12 inches). However, if collecting from surfaces with visible residue (e.g., dust, dirt, buildup of organic material), we recommend increasing the number of sponges and collecting from a smaller surface area for each sponge to improve the likelihood of detection.

We recommend that you wear sterile gloves. For wet surfaces, you should wipe and absorb moisture and wet product and residue with the sponge. For dry surfaces, you should wipe the sample site area with a sponge or swab moistened with D/E broth. You should use a systematic technique that swabs in multiple directions as also described in “Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples” (currently available at

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<http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM467056.pdf>)¹⁰. You should add more buffer if necessary.

Samples should be properly identified, packaged with ice packs and shipped refrigerated within 24 hours after sampling. We recommend that the maximum time frame between shipping and receipt at an external or internal pathogen testing laboratory be within 48 hours. Samples should not be frozen.

Collecting Rinse Samples

To collect samples using a rinse technique, you should add small pieces from equipment (such as screws, nuts or gaskets) directly to the bag containing D/E broth and hand massage the bag for sufficient time to remove soil and residues (approximately 1 minute). Then you must aseptically remove the items from the bag and subject the broth to analysis.

In some situations involving small cracks and crevices, it may help to use a plastic bulb transfer pipette. You should use tubes containing 10 mL sterile D/E broth in this procedure. You should pull the D/E broth into the pipette bulb and transfer the D/E broth to the crack or crevice, and then you should pull it back into the bulb. You should repeat this several times to thoroughly rinse the crack or crevice. Then you must use aseptic procedures when transferring the D/E broth to a sterile container for further analysis (§ 112.145(d)).

Collecting Liquid Samples (Including Floor Drain Effluents)

We recommend that you use a sterile beaker or similar container to collect 110 ± 5 ml of liquids, where possible, such as drainage effluents, standing water, melt water from thawed processing ice, and vacuum or drip pan condensate. We recommend that you immediately transfer the collected sample into a sterile screw-capped bottle and then chill and store the bottle at 5 degrees C (41 degrees F), including during transport to the testing laboratory.

Compositing Samples Collected from Sponges or Swabs

A common technique is to combine analytical portions from several samples and analyze the mixture of the portions (which is referred to as a “composite”). A typical composite scheme is to composite up to 5 sponges or swabs. We do not recommend compositing more than 5 sponges or swabs, and we do not recommend compositing samples from FCSs.

Preparing Samples Collected from Liquids

For larger samples (e.g., 100 mL or greater), we recommend that you filter 100 ml of the collected liquid through one or more sterile 0.45 micron pore-diameter filters as soon as possible after sample collection. If particulate content is high (e.g., judging from the sample turbidity), we recommend

¹⁰ 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 <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm>, <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/default.htm>, and <http://www.fda.gov/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 <http://www.fda.gov>, or using a generally available search engine.

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that you pass the liquid through a sterile glass pre-filter before the 0.45 micron filter. You should rinse the retentate on the filter plus any pre-filter with 5-10 ml of D/E broth to remove any residual inhibitory substances. If necessary, you should excise the filters from the funnel devices, using sterile scalpels. You should put each filter and the pre-filter, if any, in a sterile bag (if you will use a Stomacher) or in a sterile container (such as a blender jar, if you use a blender). You should add 225 mL of UVM broth, and follow procedures in “Testing Methodology for *Listeria* species of *L. monocytogenes* in Environmental Samples” (version 1, Oct 2015) (currently available at: <http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM467056.pdf>¹¹) beginning with incubation of the primary enrichment.

For small volumes of liquid samples, we recommend that you add the liquid sample to 225 mL of UVM broth, and follow procedures in “Testing Methodology for *Listeria* species of *L. monocytogenes* in Environmental Samples” (version 1, Oct 2015) beginning with incubation of the primary enrichment.

Note: If composites are made from the filters, you should cut the filter and any pre-filter in half using sterile instruments. You should use one half of each filter to form a composite and retain the other half at 5 degrees C (41 degrees F) as a reserve for analysis if the composite is positive for *Listeria* spp.

Sample Analysis

See “Testing Methodology for *Listeria* species of *L. monocytogenes* in Environmental Samples” (version 1, Oct 2015) for testing the samples.

C. Appendix 3. Potential Sources of *L. monocytogenes* for Sampling in a Sprout Operation

This table provides examples of possible food contact and non-food contact surfaces for use in developing a *Listeria* environmental monitoring program. The list is not all-inclusive. This list could be further sub-divided to establish a four zone system for an operation.

Table 4. Potential Sources of *L. monocytogenes* in a Sprout Operation

| Category | Potential Sources of <i>L. monocytogenes</i> |
|---------------------------------|---|
| A. Contact surfaces for sprouts | <ul style="list-style-type: none">• Fibrous and porous-type conveyor belts• Interior of drums, carts, crates, containers, bins, tubs and baskets• Utensils• Gloves |

¹¹ 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 <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm>, <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/default.htm>, and <http://www.fda.gov/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 <http://www.fda.gov>, or using a generally available search engine.

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| Category | Potential Sources of <i>L. monocytogenes</i> |
|---|---|
| B. Surfaces that generally do not contact sprouts | <ul style="list-style-type: none"> • Cracked hoses • Hollow rollers for conveyances • Equipment framework • Wet, rusting, or hollow framework • Open bearings within equipment • Condensate drip pans • Motor housings • Maintenance tools (e.g., wrenches and screw drivers) • Forklifts, hand trucks, trolleys, and racks • On/off switches • Vacuum cleaners and floor scrubbers • Trash cans and other such ancillary items • Tools for cleaning equipment (e.g., brushes and scouring pads) • Aprons |
| C. Sprout Operation Environment | <ul style="list-style-type: none"> • Floors, walls and drains • Ceilings, overhead structures, and catwalks • Wash areas (e.g., sinks), condensate, and standing water • Wet insulation in walls or around pipes and cooling units • Rubber seals around doors, especially in coolers • Contents of vacuum cleaners |

XII. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. We have verified the website addresses, but we are not responsible for any subsequent changes to websites after this document publishes in the **Federal Register**.

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