

# Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: 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## ***Draft Guidance***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**

**October 2018**

# Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry<sup>1</sup>

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic.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.

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 This draft guidance has been prepared by the Office of Food Safety, Division of Produce Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug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

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## **I. Introduction**

In the *Federal Register* of November 27, 2015, we published a final rule titled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (80 FR 74353) (Produce Safety Rule). The Produce Safety Rule established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption and is part of our implementation of the FDA Food Safety Modernization Act (FSMA). This draft guidance is intended to help the owner, operator, or agent in charge of a covered farm (i.e., “you”) to comply with the requirements of the Produce Safety Rule.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities.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 required.

## **II. Background**

Produce is usually grown outdoors in soil, with influences from weather and other environmental factors, and often does not receive treatment after harvesting that adequately removes pathogens that can cause human illness (referred to in this draft guidance as microorganisms of public health significance). Therefore, we place emphasis on preventive measures throughout growing, harvesting, packing, and holding produce to reduce the incidence of contamination of produce that can lead to foodborne illness.

The Produce Safety Rule established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption. The rule requires covered farms to take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). (21 CFR 112.11). Requirements of the rule focus on major routes of contamination, including: health and hygiene; agricultural water; biological soil amendments of animal origin; domesticated and wild animals; equipment, tools, buildings and sanitation; and related topics that include personnel qualifications and training; growing, harvesting, packing, and holding activities; and sprouts.

This draft guidance relates to compliance and implementation of the following subparts of the Produce Safety Rule:

- Subpart A—General Provisions;
- Subpart C—Personnel Qualifications and Training;
- Subpart D—Health and Hygiene;
- Subpart F—Biological Soil Amendments of Animal Origin and Human Waste;
- Subpart I—Domesticated and Wild Animals;

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- Subpart K—Growing, Harvesting, Packing, and Holding Activities;
- Subpart L—Equipment, Tools, Buildings, and Sanitation;
- Subpart O—Records; and
- Subpart P—Variances.

In the *Federal Register* of January 23, 2017, we published a notification of availability of a draft guidance for industry titled, “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” (82 FR 7751), which focuses on the portion of the Produce Safety Rule (subpart M) that deals with sprouts. Sprout operations should note that this draft guidance addresses aspects of the Produce Safety Rule to which sprout operations may also be subject.

At this time, we are not issuing draft guidance for the following: subpart Q—Compliance and Enforcement; and subpart R—Withdrawal of Qualified Exemption. In the future, we may issue additional draft guidance addressing subpart B—General Requirements related to alternatives, and subpart E—Agricultural Water.

This draft guidance provides our current thinking and recommendations to help you comply with the minimum standards of other subparts of the Produce Safety Rule. In some places, we refer directly to specific requirements from the Produce Safety Rule, which we cite for reference. We also provide recommendations, examples, clarification, and information to help you develop your own procedures, processes, and practices, because the Produce Safety Rule requirements generally include enough flexibility for you to put them in place in a way that best fits your operations. In many instances, there may be several different approaches that all result in compliance with the requirements of the Produce Safety Rule. In some cases, we provide examples to illustrate and describe potential ways to meet the requirements of the Produce Safety Rule. Note that we cannot, nor have we attempted to, describe every possible scenario and solution.

## **Chapter 1: General Provisions (Subpart A)**

This chapter addresses the requirements of Produce Safety Rule Subpart A—General Provisions, which will help you to determine the applicability of the Produce Safety Rule to your farm and your produce. The Produce Safety Rule applies equally to covered produce grown domestically and covered produce imported or offered for import into any state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. (21 CFR 112.1(a)). In other words, covered produce grown internationally and imported is subject to applicable provisions of the Produce Safety Rule.

Generally, the Produce Safety Rule applies when three conditions are present: covered produce, covered farm, and covered activity. If you are a covered farm, you must comply with all applicable requirements of the Produce Safety Rule when conducting a covered activity on covered produce. (21 CFR 112.4(a)).

This chapter is divided into 5 sections:

- Produce;
- Raw agricultural commodity;
- Covered produce;
- Covered farms; and
- Covered activities.

This chapter will discuss each of these terms in sequence, and we recommend that you consider them in the order in which they are presented. Each section is intended to help you determine which provisions of the Produce Safety Rule, if any, apply to you and the food you produce.

In this chapter, we also discuss:

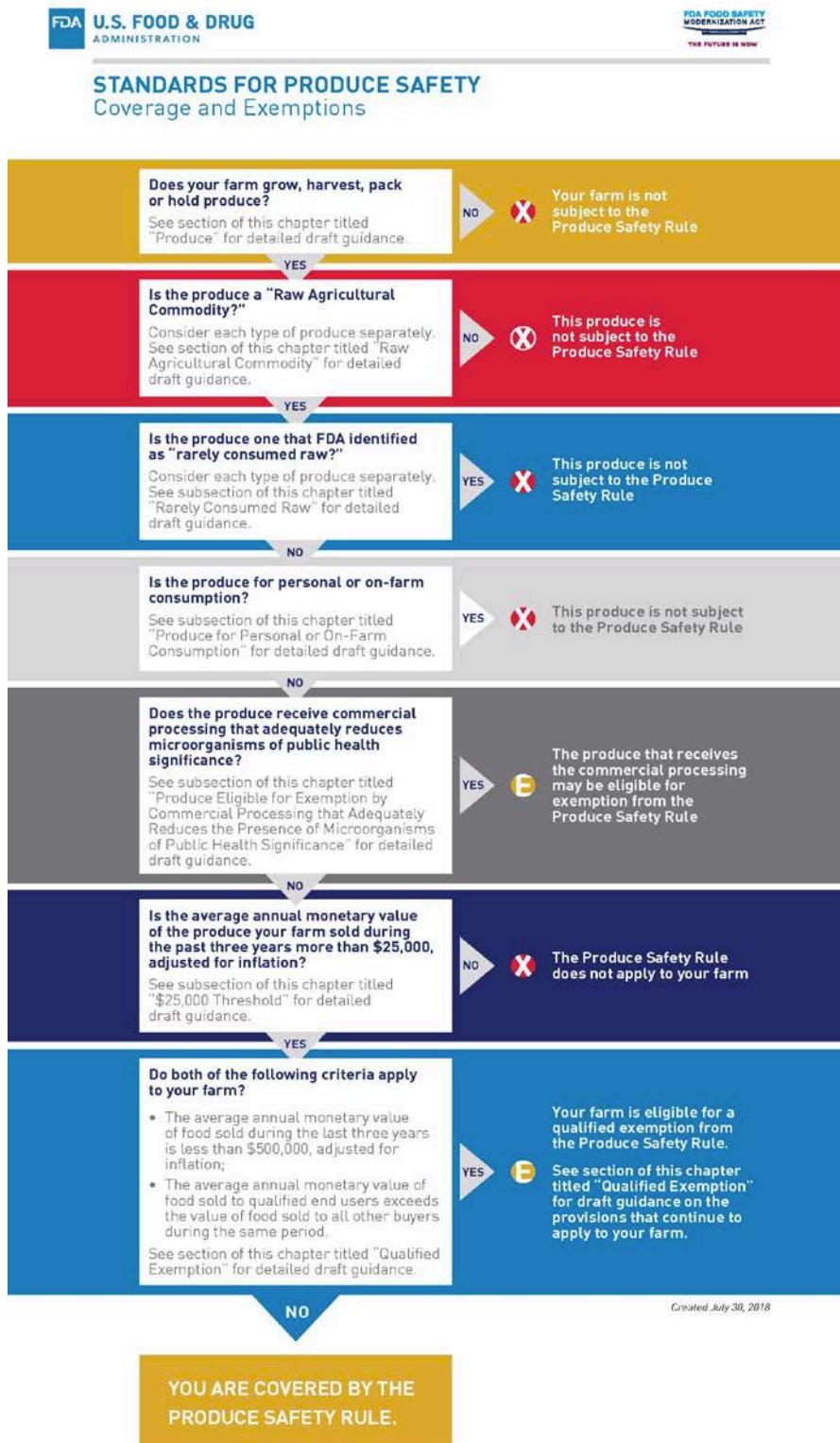
- the threshold for farms not covered by the Produce Safety Rule (average annual value of produce sold during the previous 3-year period of \$25,000 or less);
- produce that is rarely consumed raw and therefore not covered by the Produce Safety Rule;
- farms eligible for a qualified exemption; and
- produce that is eligible for an exemption because it receives commercial processing that adequately reduces the presence of microorganisms of public health significance.

The following is a figure to assist you in determining which provisions of the Produce Safety Rule, if any, apply to you and the food you produce.

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Figure 1a. Standards for Produce Safety: Coverage and Exemptions



## **1. Produce**

In determining whether the Produce Safety Rule applies to your farm and the food you produce on your farm, you should first consider whether the food is “produce.” Under the Produce Safety Rule, “produce” generally means any fruit or vegetable, and includes mushrooms, sprouts, peanuts, tree nuts, and herbs. (See the full definition of “produce” at 21 CFR 112.3). Fruit is further defined as the edible reproductive body of a seed plant or tree nut (such as apple, orange, or almond); stated another way, “fruit” means the harvestable or harvested part of a plant developed from a flower. The Produce Safety Rule defines a vegetable as 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 mushroom) grown for an edible part; in other words, “vegetable” means the harvestable or harvested part of any herbaceous 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. (See 21 CFR 112.3).

Both “produce” and “covered produce” (see the section of this chapter titled “Covered Produce”) refer to the “harvestable or harvested” part of the crop. That means that “produce” could include components of the harvestable or harvested part of the plant that are not edible to humans. For example, based on our current understanding of the crops and practices in the tree nut industry, we consider the entire unit (nut or kernel, hull, and shell), the “harvestable or harvested part” of the crop. The kernels that have been separated from the shell/hull (i.e., nut with no shell/hull) would also be considered “produce.” The shells/hulls that have been separated from the kernel would not be “produce” as defined in 21 CFR 112.3.

Once the harvestable or harvested part of the crop is present, “produce” is present. Ripeness or maturity level does not matter. For example, unripe apples while not normally eaten at that point in their production, are the harvestable and harvested part of the plant and are therefore “produce,” including while they are still growing on the tree.

Produce that is not reasonably expected to be directed to a human food use is not subject to the requirements of the Produce Safety Rule. For example, produce that is reasonably expected to be used for biofuels, clothing, or household products is not subject to the Produce Safety Rule. Produce that is reasonably expected to be used only as animal food is not subject to the requirements of the Produce Safety Rule. Produce that is reasonably expected to be used only for propagation of a crop (e.g., seeds, bulbs) is not subject to the requirements of part 112 (except to the extent the Produce Safety Rule addresses seed for sprouting). If you grow, harvest, pack, or hold produce, some of which is reasonably expected to be directed to a human food use and some of which is not reasonably expected to be directed to a human food use, you could comply with the requirements of the Produce Safety Rule for all of the produce so that you retain the option to direct all of the produce to a human food use.

There are many produce commodities, so we have included in this draft guidance examples in addition to the list provided in 21 CFR 112.1(b)(1): ackee; aronia; arrowhead; arrowroot; atemoya; butterbur; cactus; chipilin; crabapple; dragon fruit; fiddlehead; ginkgo nut; komatsuna;

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longan; loroco; lotus root; microgreens<sup>2</sup>; persimmon; pomegranate; pomelo; ramp; salsify; swamp cabbage; tamarillo; tea; ti plant; and ulluko. Edible flowers such as nasturtiums, lavender, and squash blossoms are also “produce.”

“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, or 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). (21 CFR 112.3). 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).

Saps (e.g., agave, birch, maple, palm) do not fit the definition of “produce” and therefore are not subject to the Produce Safety Rule. Algae (e.g., seaweed) is not produce and therefore also not subject to the Produce Safety Rule.

## **2. Raw Agricultural Commodity**

In determining whether the Produce Safety Rule applies to your farm and the food you produce on your farm, you should next consider whether the food you produce is a raw agricultural commodity. Only food that is both a raw agricultural commodity (“RAC”) and “produce” is subject to the Produce Safety Rule. (See 21 CFR 112.1(a) and 112.2(a)(3)). RAC means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. (Section 201(r) of the FD&C Act (21 U.S.C. 321(r)); (21 CFR 112.3)).

RACs changed into “processed food” are no longer subject to the Produce Safety Rule in their transformed state because they are no longer a RAC. It is important to understand this distinction, which is not always apparent. Changing a RAC into a “processed food” involves changing the general state of the commodity, sometimes referred to as transformation of the RAC into a new or distinct commodity. Processed foods are not subject to the Produce Safety Rule (See 21 CFR 112.2(a)(3)).

As noted earlier, the distinction between a RAC and a processed food is easily apparent in some cases and not in others. Below are examples that help demonstrate the distinction.

Examples of activities that do not change a RAC into a processed food include:

- Hydro-cooling;

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<sup>2</sup> Microgreens and sprouts are distinct commodities. Historically, the primary criterion FDA has used to distinguish between the two product categories has been the growth stage of the leaves (Ref. 221). 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. However, microgreens are considered “covered produce” for the purposes of this rule and, unless exempt or excluded under the provisions in subpart A, microgreens and microgreen farms are subject to all other subparts of part 112. (See 80 FR 74353 at 74497 (Comment/Response 363)).

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- Refrigeration;
- Removal of leaves, stems, and husks;
- Washing; and
- Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant.

Examples of activities that change a RAC into a processed food include:

- Chopping;
- Cooking;
- Cutting;
- Homogenization;
- Irradiation; and
- Pasteurization.

The following are more specific examples of the distinction between RACs and processed foods:

- Whole heads of lettuce are a RAC; however, they are no longer a RAC once they are chopped into smaller pieces; chopped lettuce is a processed food;
- Whole walnuts are a RAC; however, they are no longer RACs once they are ground into walnut butter; walnut butter is a processed food;
- Fresh oranges are a RAC; however, they are no longer RACs once they are processed to produce orange juice; orange juice is a processed food; and
- Fresh papayas are a RAC; however, they are no longer a RAC once they are irradiated, irradiated papayas are a processed food.

The fact that a particular RAC will be made into processed food does not necessarily mean that the RAC is exempt from the Produce Safety Rule. The Produce Safety Rule applies only during the time that the food is a RAC.

### **3. Covered Produce**

Not all produce that is also a raw agricultural commodity is subject to the provisions of the Produce Safety Rule. In determining whether the Produce Safety Rule applies to your farm and the food you produce on your farm, you should next consider whether your produce is “covered produce.” “Covered produce” is produce that is a raw agricultural commodity and within the scope of the Produce Safety Rule. (21 CFR 112.1). “Produce” is subject to the Produce Safety Rule unless it is “not covered” or is eligible for an exemption.

Produce that is not covered under the Produce Safety Rule includes that which is:

- Rarely consumed raw;
- Produced for personal or on-farm consumption; or
- Not a raw agricultural commodity.

Additionally, some produce is eligible for exemption from the Produce Safety Rule under 21 CFR 112.2(b) (i.e., commercial processing that adequately reduces the presence of

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microorganisms of public health significance: “the commercial processing exemption”). We discuss these concepts in the subsequent subsections, except for “Raw Agricultural Commodities” which was covered in a previous section.

**a. Rarely Consumed Raw**

“Rarely consumed raw” (RCR) produce includes those commodities that FDA determined are almost always eaten only after being cooked. The following is a complete list of the produce designated as “rarely consumed raw” in 21 CFR 112.2(a)(1), and thus not subject to the provisions of the Produce Safety Rule:

- Asparagus;
- Black, great Northern, kidney, lima, navy, and pinto beans;
- Garden beet (root and top);
- Sugar beet;
- Cashew;
- Sour cherry;
- Chickpea;
- Cocoa bean;
- Coffee bean;
- Collard;
- Sweet corn;
- Cranberry;
- Date;
- Dill (seed and weed);
- Eggplant;
- Fig;
- Ginger;
- Hazelnut;
- Horseradish;
- Lentil;
- Okra;
- Peanut;
- Pecan;
- Peppermint;
- Potato;
- Pumpkin;
- Winter squash;
- Sweet potato; and
- Water chestnut. (21 CFR 112.2(a)(1)).

For your produce to be RCR, you do not have to have knowledge or confirmation of the cooking process the produce receives, or where, how, or by whom it is performed.

**b. Personal Consumption and On-Farm Consumption**

Produce that is produced by an individual for personal consumption, or produced for consumption on the farm on which it was produced or on another farm under the same management, is not subject to the Produce Safety Rule. (21 CFR 112.2(a)(2)). For example, if a covered farm grows covered produce, and separately grows produce for personal consumption in an owner's personal home garden that is located on the farm's property, the produce for personal consumption would not be covered by the Produce Safety Rule.

**c. Produce Eligible for Exemption by Commercial Processing that Adequately Reduces the Presence of Microorganisms of Public Health Significance**

Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from most provisions of the Produce Safety Rule (commercial processing exemption). To qualify for this exemption, your produce must meet all of the conditions in 21 CFR 112.2(b). (21 CFR 112.2(b)). We discuss each of these conditions in the following subsections:

- Commercial processing;
- Disclosure accompanying produce and affiliated records; and
- Written assurances from your customers and affiliated records.

Subpart A—General Provisions, and subpart Q—Compliance and Enforcement, of the Produce Safety Rule continue to apply to you and your exempt produce even if this commercial processing exemption applies.

**i. Commercial Processing**

It is important to note that the commercial processing exemption is applicable only to the produce that will receive commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of such commercial processing includes: processing in accordance with the requirements of the Low Acid Canned Foods Regulation (21 CFR part 113), the Acidified Foods Regulation (21 CFR part 114), and the Juice HACCP Regulation (21 CFR part 120); treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes); and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer, or similar products. Freezing processes and washing (such as in a flume or dump tank) are commercial processes that generally do not significantly reduce the presence of microorganisms (Ref. 3) (Ref. 8) (Ref. 9) (Ref. 61) (Ref. 90).

In some cases, only a portion of a farm's produce might be eligible for the commercial processing exemption. For example, if you own or operate a covered farm that produces both tomatoes that will be processed into tomato paste, and tomatoes that will be sold into the fresh market (i.e., tomatoes that will not be processed into tomato paste), only the tomatoes that will be processed into tomato paste are eligible for the commercial processing exemption under 21 CFR 112.2(b).

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**ii. Disclosure Accompanying Produce and Affiliated Records**

For your otherwise covered produce to qualify for the commercial processing exemption, you must disclose, in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.” (21 CFR 112.2(b)(2)). Visual examination of the food might not readily reveal whether commercial processing has already been applied, so providing the disclosure through documentation or labeling helps to inform an entity in the supply chain that such a control has not yet been applied.

The requirements for the disclosure statement specify that the disclosure must be made in “documents accompanying the produce, in accordance with the practice of the trade.” (21 CFR 112.2(b)(2); See 21 CFR 112.2(b)(3)(ii)(A) and 112.2(b)(3)(ii)(B)(2)). This allows for the disclosure statement to be provided using a wide variety of documents that accompany the food, such as labels, labeling, bills of lading, freight bills, shipment-specific certificates of analysis, and other documents or papers associated with the shipment that food safety personnel for the customer is likely to read. For purposes of the requirements of the disclosure statement, you could, for example, use labeling that includes a disclosure statement, “not processed to adequately reduce the presence of microorganisms of public health significance,” and then direct the recipient to a website for additional information. However, referencing a website in a document of the trade without including the disclosure statement in the document of the trade would not satisfy the requirement of 21 CFR 112.2(b)(2).

You must maintain documentation of disclosures that you provide to your customers in accordance with the Produce Safety Rule subpart O—Records. (21 CFR 112.2(b)(4)). You could keep the necessary documentation in various forms; for example, you could keep a sample disclosure and a ledger of entries of shipments including the disclosures, or copies of labels with the disclosure for each shipment. We provide additional draft guidance on general records requirements at Chapter 8: Subpart O—Records.

**iii. Written Assurance from your Customers and Affiliated Records**

In the Federal Register of January 5, 2018 (83 FR 598), we published a notification of availability of a guidance document titled “Policy Regarding Certain Entities Subject to the Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs.” In that guidance document, we stated that we intend to exercise enforcement discretion regarding the written assurance requirements of 21 CFR part 112 (the Produce Safety Rule). We intend to exercise such discretion until we can complete a rulemaking process to consider options for the assurance requirements.

## **4. Covered Farms**

With the exception of entities associated with the written assurances described in part 3.c.iii above, only “covered farms” are subject to the requirements of the Produce Safety Rule.<sup>3</sup>

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<sup>3</sup> As noted above, we have stated that we intend to exercise enforcement discretion related to the written assurances associated with the commercial processing exemption.

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“Covered farms” as described in 21 CFR 112.4 are subject to all applicable requirements of the Produce Safety Rule.

Some farms are not covered farms because they are under the \$25,000 threshold that we discuss later in this section. Some farms are eligible for a qualified exemption under 21 CFR 112.5 (21 CFR 112.4(b)), which limits the provisions to which they are subject. Qualified exemptions are explained later in this section.

Covered farms include “farms” and “farm mixed-type facilities” as defined in 21 CFR 112.3. A “farm mixed-type facility” is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered as a food facility under section 415 of the FD&C Act.<sup>4</sup>

Contract harvesters that only perform harvesting operations for a covered farm but do not sell the produce are performing a covered activity on behalf of the covered farm. Those contract harvesters would not be a covered farm; the farm for which they perform the harvesting would be responsible for compliance with the requirements of the Produce Safety Rule with respect to harvesting.

**a. \$25,000 Threshold**

The Produce Safety Rule applies only to those farms or farm mixed-type facilities with more than \$25,000 in average annual value of **produce** sold during the previous 3-year period. (See 21 CFR 112.4(a)). To calculate whether your farm is above or below the \$25,000 threshold:

- Calculate the average annual monetary value of your gross produce sales;
  - Determine which years’ sales need to be considered:
    - For example, if 2018 is the applicable calendar year (i.e., for the year you seek to calculate whether your farm is above or below the \$25,000 threshold), you would need to calculate the average annual value of gross sales for produce that you sold in 2017, 2016, and 2015.
  - Include:
    - All produce sold, not just covered produce—see the section of this chapter titled “Produce”;
    - Produce you purchased or otherwise obtained from another entity and then resold to your customers;
    - Produce you sold at farmer’s markets, to grocery stores, directly to consumers, or online;

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<sup>4</sup> Section 415 of the FD&C Act requires that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Food and Drug Administration. The term “facility” includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include: farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in 21 CFR 123.3(k)).

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- Produce sold by a third party on your behalf (such as when a cooperative that takes possession of your produce without taking ownership sells your produce and returns the proceeds to you after the sale); and
- Retail sales, wholesale sales, intrastate sales, and interstate sales (including produce offered for import to the U.S. or exported from the U.S.).
- Do not include:
  - Produce for which you did not receive payment of money or anything else of value in exchange for the produce (e.g., produce held without sale or produce donated or given away);
  - The value of produce from other entities when a third party sells produce on your behalf along with produce from other entities (for example, if a cooperative sells your produce along with produce for other farms does not take ownership of your produce and returns the proceeds to you after the sale, you should count only the proceeds from your produce, not any proceeds from the sale of produce for other entities).
- Adjust the baseline for inflation.
  - Use a baseline year of 2011 (in other words, \$25,000 in 2011).
    - The U.S. Bureau of Economic Analysis provides the federal calculation for inflation adjustments.
    - We provide and intend to update the current adjusted dollar value for the baseline on our Website (<https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>) as well.
  - Using a baseline year of 2011, \$25,000, adjusted for inflation, is \$26,608 for 2015, \$26,956 for 2016, and \$27,433 for 2017, and the average 3-year value is \$26,999 for 2015-2017 (all figures obtained from the FDA website).

If your average annual value of produce sold during the previous 3-year period is \$25,000 or less, adjusted for inflation with a baseline year of 2011, then your farm is not subject to the requirements of the Produce Safety Rule; you could find it useful to perform the calculation as soon as possible in a given calendar year.

There may be circumstances where a farm does not have 3 calendar years of records, such as for new farms. It would be reasonable for the farm to rely on a projected estimate of revenue (or market value) when it begins operations. We would evaluate the credibility of the projection considering factors such as the farm's number of employees. After the farm has records for one or two preceding calendar years, it would be reasonable for the farm to make the calculation based on records it has (i.e., for one or two preceding calendar years) and we will accept records for the preceding one or two years as adequate in these circumstances.

Following are examples to illustrate how these calculations should be performed:

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Example 1a.

- A farm is performing a calculation in 2018 to determine whether it meets the \$25,000 threshold. The farm would use its sales data for the preceding three years: 2015, 2016, and 2017. In those years, the farm's sales consisted of:
  - 2015: \$100,000 in live cattle; \$50,000 in soybeans; \$20,000 in tomatoes; \$1000 in asparagus;
  - 2016: \$150,000 in live cattle; \$25,000 in soybeans; \$40,000 in tomatoes; \$1500 in asparagus;
  - 2017: \$150,000 in live cattle; \$60,000 in dent-corn; \$10,000 in tomatoes; \$1000 in asparagus;
- The live cattle, soybeans, and dent-corn are not produce<sup>5</sup> (see the section of this chapter titled “Produce” for information on this topic), so sales of these commodities are not included in the calculations;
- The farm sells the tomatoes and asparagus to retail customers through its farm stand and sells some tomatoes to another farmer, who then sells them to a wholesaler. While asparagus is not covered produce (because it is rarely consumed raw), both asparagus and tomatoes are produce, so sales of these commodities are included in the calculations. Retail and wholesale sales count toward the \$25,000 threshold, so all of the farm's tomato and asparagus sales are included in the calculations;
- Total produce sales for each year to be included in the calculations are:
  - 2015: \$21,000;
  - 2016: \$41,500;
  - 2017: \$11,000;
- The three-year average of produce sales is the sum of \$21,000 + \$41,500 + \$11,000, divided by 3 = \$24,500;
- The 2015-2017 three-year average of \$25,000 adjusted for inflation (obtained from the FDA website) is \$26,999;
- \$24,500 is less than \$26,999, so the farm is not subject to the Produce Safety Rule.

Example 1b.

- A new farm began operations in 2016 and is performing a calculation in 2018 to determine whether it meets the \$25,000 threshold. The farm would use its sales data based on the records it has, in this example: 2016 and 2017. In those years, the farm's sales consisted of:
  - 2016: \$13,000 in spinach; \$5,000 in kale;
  - 2017: \$20,000 in spinach; \$10,000 in kale; \$5,000 in basil;
- The farm sells the spinach, kale, and basil to a wholesaler. Spinach, kale, and basil are all produce (see the section of this chapter titled “Produce” for draft guidance on this topic), so sales of these commodities are included in the calculations. The \$20,000 in spinach sales in 2017 included \$10,000 in resale of spinach that the farm purchased

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<sup>5</sup> In these examples, the soybeans are grown for biofuels and are therefore considered food grains rather than produce.

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from other farms in the area. Such sales count toward the \$25,000 threshold, so all the farm's spinach sales are included in the calculations;

- Total produce sales for each year to be included in the calculations are (the farm was not operating in 2015, so this farm has only two years of sales to average):
  - 2016: \$18,000;
  - 2017: \$35,000;
- The two-year average of produce sales is the sum of  $\$18,000 + \$35,000 = \$53,000$ , divided by 2 = \$26,500;
- The two-year average of \$25,000 adjusted for inflation for 2016 and 2017 is  $\$26,956 + \$27,433 = \$54,389$  divided by 2 = \$27,195 (2016 and 2017 inflation-adjusted figures obtained from the FDA website);
- \$26,500 is less than \$27,195, so the farm is not subject to the Produce Safety Rule.

#### **b. Qualified Exemption**

If you exceed the \$25,000 threshold, you could still determine that you are eligible for a qualified exemption. Determination of a qualified exemption is based on **all food<sup>6</sup> sales**, not just produce sales. Examples of food include livestock<sup>7</sup>; meat; dairy products such as milk; hay; grains; and wine; and other food (for humans or other animals).

A farm is eligible for a qualified exemption if it meets the requirements of 21 CFR 112.5:

- 1) the average annual monetary value of the food your farm sold directly to qualified end-users (see criteria section below) must be greater than that sold to all other buyers during the same period; and
- 2) the average annual monetary value of all food your farm sold during the preceding 3-year period must be less than \$500,000, as adjusted for inflation. (See 21 CFR 112.5(a)).

There are examples below that demonstrate how to calculate the criteria for eligibility for a qualified exemption.

If your farm is eligible for a qualified exemption for an applicable calendar year, then modified requirements of the Produce Safety Rule apply (21 CFR 112.6, 112.7); therefore, you could find it useful to perform the calculation as soon as possible in a given calendar year. Draft guidance on modified requirements is provided in the section of this chapter titled "Modified Requirements for a Farm with a Qualified Exemption." You must also analyze your sales every year to verify your continued eligibility for the exemption (21 CFR 112.7(b)).

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<sup>6</sup> Food is defined in 21 CFR 112.3. The qualified exemption is based on sales of all food rather than on produce sales because the exemption is defined in the FSMA statute.

<sup>7</sup> Livestock and meat are both food within the definition of "food" in 21 CFR 112.3. (See U.S. v. Tuente Livestock, 888 F. Supp. 1416 (S.D. Ohio 1995) (FDA may interpret the term "food" to "include live animals raised for food"). There are instances when live animals are sold for purposes other than for food, such as being sold as pets (e.g., dogs). Food held without sale (including live animals raised for food on a farm) need not be counted for purposes of this calculation unless and until it is sold.

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**i. Criteria for Eligibility for a Qualified Exemption**

To be eligible for a qualified exemption in a given calendar year, you must meet both of the criteria below. (21 CFR 112.5(a)).

**A. *Criterion 1: 3-Year Average Annual Food Sales Direct to Qualified End Users is Greater than All Other Buyers***

During the 3-year period preceding the applicable calendar year, your farm's average annual monetary value of food (as defined in 21 CFR 112.3) sold directly to qualified end-users (as defined in 21 CFR 112.3) must exceed the average annual monetary value of food sold to all other buyers during that period in order to be eligible for a qualified exemption. (21 CFR 112.5(a)(1)).

A qualified end-user, with respect to food, is either:

- (1) The consumer of the food (where the term consumer does not include a business);
  - Consumers are qualified end-users, regardless of the consumer's location relative to the farm.
- or
- (2) A restaurant or retail food establishment (as those terms are defined in 21 CFR 1.227) that is located in the same State or the same Indian reservation as the farm that produced the food, or not more than 275 miles away from such farm.
  - A restaurant is a facility that prepares and sells food directly to consumers for immediate consumption. (See 21 CFR 1.227).
  - A retail food establishment's primary function is to sell food directly to consumers. (See 21 CFR 1.227). Examples include roadside farm stands, meal kit services, grocery stores, convenience stores, and farmer's markets that fit the definition.

A sale conducted online or through mail-order can be considered a sale to a qualified end-user if the buyer is a consumer, or is a restaurant or retail food establishment that meets the location requirements. For domestic farms, food sales to a restaurant or retail food establishment in a neighboring country (e.g., Canada, Mexico, or the Bahamas) that is within 275 miles of the farm represent sales to a qualified end-user. The same would also be true for a farm in Mexico selling food to a restaurant or retail food establishment in the United States within 275 miles of the farm.

Criterion 1 involves comparing the value of food "sold directly" to qualified end-users to the value of food sold via all other types of sales during the specified time period. For example, direct sales to a restaurant or retail food establishment at an auction, where the auction serves as a venue for the sale of your produce but does not purchase the produce, can be counted as a sale to a qualified end-user if the restaurant or retail food establishment meets the location requirements.

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The following are examples to illustrate how the calculations for criterion 1 should be performed:

Example 1c (note that this example is a modification of Example 1a above, with some of the factors changed for illustrative purposes).

- A farm is performing a calculation in 2018 to determine whether it meets criterion 1. The farm would use its sales data for the preceding three years: 2015, 2016, and 2017. In those years the farm's sales consisted of:
  - 2015: \$100,000 in live cattle; \$50,000 in soybeans; \$30,000 in tomatoes; \$1000 in asparagus;
  - 2016: \$150,000 in live cattle; \$25,000 in soybeans; \$40,000 in tomatoes; \$1500 in asparagus;
  - 2017: \$150,000 in live cattle; \$60,000 in dent-corn; \$40,000 in tomatoes; \$1000 in asparagus;
- The live cattle, soybeans, dent-corn, tomatoes, and asparagus are all food, as described above, so sales of these commodities are included in the calculations;
- The farm sells the asparagus and some tomatoes to retail customers through its farm stand and also sells some tomatoes to another farmer, who then sells them to a wholesaler. Customers of the farm stand include consumers and the owners of three restaurants located in towns in the same and an adjoining state that are located between two and 15 miles from the farm. Both consumers and the restaurants to which the farm sells meet the definition of "qualified end user," as described above. The farm sells the live cattle, soybeans, and dent-corn to a wholesaler;
- Sales of tomatoes are further divided as follows:
  - 2015: \$20,000 to qualified end users; \$10,000 to wholesaler;
  - 2016: \$20,000 to qualified end users; \$20,000 to wholesaler;
  - 2017: \$20,000 to qualified end users; \$20,000 to wholesaler;
- To facilitate the calculation for criterion 1, the sales data can be displayed as follows:
  - 2015: \$21,000 to qualified end users (\$20,000 tomatoes + \$1000 asparagus); \$160,000 to other buyers (\$10,000 tomatoes + \$100,000 live cattle + \$50,000 soybeans);
  - 2016: \$21,500 to qualified end users (\$20,000 tomatoes + \$1500 asparagus); \$195,000 to other buyers (\$20,000 tomatoes + \$150,000 cattle + \$25,000 soybeans);
  - 2017: \$21,000 to qualified end users (\$20,000 tomatoes + \$1000 asparagus); \$230,000 to other buyers (\$20,000 tomatoes + \$150,000 live cattle + \$60,000 dent-corn);
- The three-year average of food sold to qualified end users is the sum of \$21,000 + \$21,500 + \$21,000, divided by 3 = \$21,167;
- The three-year average of food sold to other buyers is the sum of \$160,000 + \$195,000 + \$230,000, divided by 3 = \$195,000;
- \$21,167 does not exceed \$195,000, so the farm does not qualify for a qualified exemption.

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Example 1d (note that this example is a modification of Example 1b above, with some of the factors changed for illustrative purposes).

- A new farm is performing a calculation in 2018 to determine whether it meets criterion 1. The farm would use its sales data based on the records it has, in this example: 2016, and 2017. In those years, the farm's sales consisted of:
  - 2016: \$40,000 in spinach; \$15,000 in kale;
  - 2017: \$75,000 in spinach; \$12,000 in kale; \$10,000 in basil;
- The farm sells the spinach, kale, and basil at its farm stand and through two regional produce auctions. Spinach, kale, and basil are all food as discussed above, so sales of these commodities are included in the calculations. All the customers of the farm stand are consumers and are, therefore, qualified end users. Sales through the auctions are direct to the customer; that is, the auctions do not take ownership of the food and then resell to the buyer. Some of the buyers at the auctions are restaurants or retail grocers and some are wholesalers. Most of the restaurants and retail grocers meet the criteria for qualified end user (i.e., located within the same state or not more than 275 miles from the farm), but some do not;
- Sales of food are further divided as follows:
  - 2016: \$25,000 at farm stand (to consumers); \$20,000 at auctions to qualified end users; \$10,000 at auctions to other buyers;
  - 2017: \$30,000 at farm stand (to consumers); \$30,000 at auctions to qualified end users; \$37,000 at auctions to other buyers;
- To facilitate the calculation for criteria 1, the sales data can be displayed as follows:
  - 2016: \$45,000 to qualified end users; \$10,000 to other buyers;
  - 2017: \$60,000 to qualified end users; \$37,000 to other buyers;
- The average of food sold to qualified end users is the sum of \$45,000 + \$60,000, divided by 2 = \$52,500;
- The average of food sold to other buyers is the sum of \$10,000 + \$23,500, divided by 2 = \$23,500;
- \$35,000 exceeds \$23,500, so the farm meets criterion 1 for a qualified exemption. The farm would then need to determine whether it meets criterion 2.

***B. Criterion 2: Less than \$500,000 in 3-Year Average Annual Food Sales***

In order to be eligible for a qualified exemption, your farm also must satisfy the requirement in 21 CFR 112.5(a)(2). Under that subsection, your farm's average annual monetary value of all **food** (as defined in 21 CFR 112.3) sold during the 3-year period preceding the applicable calendar year must be less than \$500,000, adjusted for inflation. (21 CFR 112.5(a)(2)). The applicable calendar year for calculating the adjustment for inflation is 2011. (21 CFR 112.5(b)).

Criterion 2 is based on the value of all food "sold." To determine whether your farm's average annual value of food sold is below (i.e., less than) the \$500,000 threshold:

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- Calculate the average annual monetary value of your gross food sales during the three-year period preceding the applicable calendar year (i.e., for the year you seek to calculate whether your farm is eligible for the qualified exemption):
  - Determine which years' sales need to be considered:
    - For example, if 2018 is the applicable calendar year, calculate the average amount of gross sales for all food that you sold in 2015, 2016, and 2017.
  - Include:
    - All food sales, not just produce;
    - Food that you purchased or otherwise obtained from another entity and then resold to your customers;
    - Food that you sold at farmer's markets, to grocery stores, directly to consumers, or online;
    - Food sold by a third party on your behalf; and
    - Retail sales, wholesale sales, interstate sales (including produce offered for import to the U.S. or exported from the U.S.), and intrastate sales.
  - Do not include:
    - Food held without sale (including live animals raised for food on your farm); or
    - Food for which there is no payment of money or anything else of value received in exchange for the food (i.e., produce donated or given away).
- Adjust the baseline for inflation:
  - Use a baseline year of 2011 (in other words, \$500,000 in 2011).
    - The U.S. Bureau of Economic Analysis provides the federal calculation for inflation adjustments.
    - We provide and intend to update the current adjusted dollar value on our website (<https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>) as well.
  - Using a baseline year of 2011, \$500,000, adjusted for inflation is \$532,170 for 2015, \$539,121 for 2016, and \$548,654 for 2017 and the average 3-year value adjusted for inflation for 2015-2017 is \$539,982.

If the average annual value during the previous 3-year period is equal to or less than \$500,000, adjusted for inflation, with a baseline year of 2011, criterion 2 is satisfied. You could find it useful to perform the calculation as early as possible in a given calendar year.

The following are continuations of the above examples, to illustrate how the calculations for criterion 2 should be performed:

Example 1c, continued (note it is included for illustrative purposes only; since this farm already determined that they do not meet criterion 1 for a qualified exemption, there would be no practical need for performing a calculation for criterion 2).

- A farm is performing a calculation in 2018 to determine whether it meets criterion 2. The farm would use its sales data for the preceding three years: 2015, 2016, and 2017. In those years, the farm's sales consisted of:

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- 2015: \$100,000 in live cattle; \$50,000 in soybeans; \$30,000 in tomatoes; \$1000 in asparagus;
    - 2016: \$150,000 in live cattle; \$25,000 in soybeans; \$40,000 in tomatoes; \$1500 in asparagus;
    - 2017: \$150,000 in live cattle; \$60,000 in dent-corn; \$40,000 in tomatoes; \$1000 in asparagus;
  - The live cattle, soybeans, dent-corn, tomatoes, and asparagus are all food, as described above, so sales of these commodities are included in the calculations. Annual sales of food total:
    - 2015: \$181,000;
    - 2016: \$216,500;
    - 2017: \$251,000;
  - The three-year average of food sold is the sum of  $\$181,000 + \$216,500 + \$251,000$ , divided by 3 = \$216,167;
  - The average three-year value adjusted for inflation (obtained from the FDA website) is \$539,982;
  - \$216,167 is less than \$539,982, so the farm meets criterion 2 for a qualified exemption.

Example 1d, continued.

- A farm is performing a calculation in 2018 to determine whether it meets criterion 2. The farm would use its sales data based on the records it has, in this example: 2016, and 2017. In those years, the farm's sales consisted of:
  - 2016: \$40,000 in spinach; \$15,000 in kale;
  - 2017: \$75,000 in spinach; \$12,000 in kale; \$10,000 in basil;
- Spinach, kale, and basil are all food as discussed above, so sales of these commodities are included in the calculations. Annual sales of food total:
  - 2016: \$55,000;
  - 2017: \$97,000;
- The average of food sold is the sum of \$55,000 + \$97,000, divided by 2 = \$76,000;
- The baseline value adjusted for inflation for 2016 is \$539,121 and for 2017 is \$548,654 (obtained from the FDA website) and the two-year average is \$543,888;
- \$76,000 is less than \$543,888, so the farm meets criterion 2 for a qualified exemption. Since this farm also met criterion 1 for a qualified exemption as illustrated above, the farm would qualify for a qualified exemption.

**ii. Records**

If you are eligible for a qualified exemption under 21 CFR 112.5, you must establish and keep adequate records necessary to demonstrate that you satisfy the criteria for a qualified exemption, including a written record reflecting that you have performed an annual review and verification that you continue to meet those criteria. (21 CFR 112.7(b)).

Receipts or ledgers of sales to your customers that show the value of the sale of food items and the location of the customer (for any customers that are restaurants or retail food establishments) are examples of records that could be used to document your eligibility for a qualified

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exemption. In certain situations, such as a farmer's market, if all sales are to consumers, keeping track of daily sales rather than individual sales could be sufficient. If you already keep records for another purpose, you may use those records to document your eligibility for a qualified exemption if they also meet all applicable requirements of the Produce Safety Rule. Records you establish and keep to demonstrate your farm is eligible for a qualified exemption must meet the requirements of 21 CFR 112.7.

To document your annual review and verification of eligibility, you should make and keep a report for each calendar year that includes the following information:

- (1) Your total annual value of sales of food for each of the preceding three calendar years (e.g., \$181,00, \$216,500, \$251,000 for Example 1c; and \$0, \$55,000, \$97,000 for Example 1d);
- (2) The average of the three values from item (1) (e.g., \$216,167 for Example 1c; and \$50,677 for Example 1d);
- (3) The inflation-adjusted value of \$500,000, where the baseline year is 2011, using the applicable calendar year adjustment value (e.g., \$539,982 for Example 1c and 1d). This value should be higher than the value in item (2) for you to be eligible for the qualified exemption;
- (4) Your total annual value of sales of food to qualified end-users for each of the preceding three calendar years (e.g., \$21,000, \$21,500, \$21,000 for Example 1c; and \$0, \$45,000, \$60,000 for Example 1d);
- (5) The average of the three values from item (4) (e.g., \$21,167 for Example 1c; and \$35,000 for Example 1d);
- (6) Your total annual value of sales of food for each of the preceding three years to entities other than qualified end users (e.g., \$160,000, \$195,000, \$230,000 for Example 1c; and \$0, \$10,000, \$37,000 for Example 1d);
- (7) The average of the three values from item (6) (e.g., \$195,000 for Example 1c; and \$15,667 for Example 1d). This value should be lower than the value in item (5) for you to be eligible for the qualified exemption); and
- (8) A statement that, based on this information, you have concluded that you meet or continue to meet the criteria for a qualified exemption.

**iii. Modified Requirements for a Farm with a Qualified Exemption**

If your farm is eligible for a qualified exemption, you are subject to the following modified requirements:

- (1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown (21 CFR 112.6(b)(1)); and
- (2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown on a label, poster, sign, placard, or

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documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice (21 CFR 112.6(b)(2)).

The complete business address must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms. (21 CFR 112.6(b)(3)).

You are also subject to the requirements of the following Produce Safety Rule subparts:

- Subpart A (General Requirements);
- Subpart O (Records);
- Subpart Q (Compliance and Enforcement); and
- Subpart R (Withdrawal of Qualified Exemption).

## **5. Covered Activities**

Covered farms subject to the Produce Safety Rule must comply with all applicable requirements of the Produce Safety Rule when conducting a covered activity on covered produce. (21 CFR 112.4(a)). “Covered activity” is defined at 21 CFR 112.3 and means growing, harvesting, packing, or holding covered produce, as well as certain other types of activities identified in the definition. This means, for example, that if a covered farm grows, harvests, packs, or holds covered produce, it is required to comply with all applicable provisions of the Produce Safety Rule in the process of doing those things.

For example, for a farm that composts biological soil amendments of animal origin to use in growing covered produce, the relevant provisions of the rule related to composting biological soil amendments of animal origin apply. As another example, if a farm packs covered produce on a table, the relevant provisions of the Produce Safety Rule related to cleaning and sanitizing of the table apply.

## **Chapter 2: Personnel Qualifications and Training (Subpart C)**

Personnel can introduce contamination while handling covered produce or food contact surfaces. Some produce-related outbreaks and contamination events identified personnel health and hygiene practices on the farm (Ref. 70) (Ref. 138) and produce handling and storage practices as likely contributing factors to these events (Ref. 32) (Ref. 72). Furthermore, a study of food-related outbreaks found more than 800 instances where personnel practices were reported to be instrumental in or contributory to the outbreak (Ref. 65).

All personnel should be qualified to perform their assigned duties, understand how their actions impact food safety, and understand the regulatory requirements that apply to their assigned duties (See 21 CFR 112.21(b) for specific requirements that apply to some personnel). Training helps provide farm personnel, including supervisors and responsible parties, a knowledge base that promotes safe food handling practices, and should ultimately reduce the likelihood of foodborne illness attributable to food handling practices.

This chapter will help you:

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

Where applicable, we recommend periodically evaluating your relevant personnel, procedures, processes, and practices to ensure that you consider the scope of your relevant activities or operations, your personnel and their assigned duties, and any changes that occurred and how they are affected by and relate to the requirements of the Produce Safety Rule. During such evaluations, you should consider not only typical practices, but also those that occur infrequently or due to unusual circumstances, to account for the breadth of personnel, procedures, processes, and practices associated with a given activity.

### **1. Evaluating Personnel's Assigned Duties**

All personnel who handle covered produce or food contact surfaces, or those who are engaged in the supervision thereof, are subject to specific requirements regarding qualifications and training. (See 21 CFR 112.21). There are specific additional requirements for persons who conduct

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harvest activities for covered produce. (21 CFR 112.22). This includes full-time, permanent, temporary, part-time, seasonal, contracted, and all other relevant personnel.

To identify your personnel subject to the qualifications and training requirements in subpart C, you should review the assigned duties and observe the performance of the duties of all your personnel, including supervisors. All personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must:

- receive adequate training (21 CFR 112.21(a)); and
- have a combination of education, training, and experience necessary to perform their assigned duties in a manner that ensures compliance with the Produce Safety Rule. (21 CFR 112.21(b)).

It is important that you consider the breadth of covered activities on your farm, and how they are performed, to determine whether personnel performing each activity contact covered produce or food contact surfaces. Examples of activities where personnel handle covered produce or food contact surfaces include: harvesting covered produce by hand; sorting, grading, and packing covered produce; handling food contact surfaces of containers used to distribute covered produce; and cleaning and maintaining harvesting and packing equipment that directly contacts covered produce. In some circumstances, activities such as receiving or shipping could also involve contact with covered produce or food contact surfaces, depending on your procedures for such activities. Other personnel could be assigned to duties that do not involve contact with covered produce or food contact surfaces (e.g., removing trash, sweeping floors, maintaining restrooms, maintaining or repairing non-food contact surfaces of equipment, pest control, or operating forklifts and tractors). However, if such personnel are expected to handle covered produce or food contact surfaces, even infrequently, or are engaged in the supervision thereof, they must receive adequate training and have a combination of education, training, and experience necessary to perform their assigned duties in a manner that ensures compliance with the Produce Safety Rule because they are handling covered produce or food contact surfaces. (See 21 CFR 112.21(a) and 21 CFR 112.21(b)).

## **2. Qualifications Necessary to Perform Assigned Duties**

All personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with the Produce Safety Rule. (21 CFR 112.21(b)). You should evaluate the assigned duties of your personnel, identify those who handle covered produce or food contact surfaces and their current level of training, education, and experience, to determine whether they are qualified to perform their assigned duties in a manner that ensures compliance with the Produce Safety Rule. When assigning duties, you must ensure that the assigned personnel have the appropriate combination of education, training, and experience to perform their duties, or that they receive any additional education or training necessary to perform their duties. (See 21 CFR 112.22(b)). Depending on the job duties, this could include training in combination with education, or experience.

An appropriate combination of education, training, and experience prepares these personnel to conduct the assigned duties in a manner that aligns with the requirements of the Produce Safety

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Rule (such as the requirements described in subpart D—Health and Hygiene; subpart K—Growing, Harvesting, Packing, and Holding Activities; and subpart L—Equipment, Tools, Buildings, and Sanitation). These personnel should be able to apply their knowledge to perform their assigned duties. For example, if you assign personnel to pack covered produce by hand, they should have, and be able to apply, knowledge including that related to: health conditions that could result in contamination of covered produce (e.g., their duty to report to a supervisor if they become ill with, for example, diarrhea); the appropriate level of personal cleanliness for their assigned duties; avoiding contact with animals other than working animals; proper hand-washing procedures; using food-packing materials that are adequate for their intended use; proper handling of harvested covered produce; and maintenance of food contact surfaces.

The extent of education, training, and experience necessary is likely to vary among your personnel based on the level of responsibility and range of duties that you assign. Your personnel could already possess valuable education and experience specific to particular assigned duties, which you could consider when evaluating their assigned duties and qualifications. However, some personnel could need additional training or education to ensure they understand your food safety procedures based on the requirements of the Produce Safety Rule. For example, you could assign one of your workers, who has worked on farms for a decade and has a good understanding of horticultural practices for your crops, to several activities that can impact food safety, including harvesting, cleaning packing equipment, and handling raw manure and treated biological soil amendments of animal origin (BSAAOs). If the scope of the worker’s previous assigned duties and farming experience did not provide the worker with the level of food safety knowledge necessary to perform these new activities in a manner that prevents contamination of covered produce, you could determine that the worker needs additional food safety training, such as targeted training about cleaning and sanitizing practices, and provide or otherwise arrange for that training.

You should evaluate your personnel’s current levels of training, education, and experience to determine which personnel you will assign to supervise personnel who handle covered produce or food contact surfaces. Such supervisors should have sufficient knowledge of food safety and hygienic practices to ensure awareness of the requirements of the Produce Safety Rule among personnel and to effectively determine whether other personnel are conducting activities in a manner that complies with the Produce Safety Rule. As an example, one way a farm could implement 21 CFR 112.31 (which requires you to take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition) is by assigning a specific individual to determine daily whether arriving harvest personnel exhibit symptoms of an applicable health condition, and to receive information from personnel about any symptoms or diagnoses of such conditions. In such a circumstance, the assigned individual should have: 1) knowledge of the symptoms of concern (e.g., vomiting, diarrhea); 2) knowledge of your procedure for excluding or reassigning workers with applicable health conditions; and 3) the ability to implement your procedures based on the requirements of the Produce Safety Rule in that area. You should also ensure those who supervise the handling of covered produce and food contact surfaces can recognize whether personnel, individually or collectively, need additional or more frequent training as necessary and appropriate in light of observations or information indicating that

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personnel are not meeting standards established by FDA in subparts C through O of the Produce Safety Rule.

The extent of education, training, and experience needed for personnel who handle covered produce or food contact surfaces, and those engaged in the supervision thereof, could also depend on the specific characteristics or organization of your farm. For example, a farm could have a single worker responsible for completing several diverse activities (such as harvesting produce, evaluating treatment of BSAAOs, and working in the packing area) that involve a broader range of training topics for that worker. Conversely, a farm could have several personnel working together to accomplish the same task, such as harvesting covered produce, that involves focused training specific to that activity. Understanding the extent of your personnel's duties will help you identify and deliver appropriate training so that the personnel who handle covered produce or food contact surfaces, and those engaged in the supervision thereof, have the combination of education, training, and experience necessary to perform assigned duties in compliance with the Produce Safety Rule.

### **3. Training Frequency**

The personnel you identify as those who handle covered produce or food contact surfaces, and those who are engaged in the supervision thereof, must receive adequate training:

- Upon hiring (21 CFR 112.21(a));
- Periodically thereafter, at least once annually (21 CFR 112.21(a)); and
- As necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in the Produce Safety Rule subparts C through O (21 CFR 112.21(d)).

By providing training upon hiring, you introduce personnel to your procedures and the requirements of the Produce Safety Rule applicable to their assigned duties before they handle covered produce or food contact surfaces. Although you may hire personnel at different times throughout the year to perform various activities, training must occur before personnel begin duties that involve handling covered produce or food contact surfaces, regardless of when they are hired (See 21 CFR 112.21(a)). For example, if you hire workers in December whose assigned duties consist of performing clerical work throughout the year, and harvesting covered produce from May to October, then as long as these workers' duties do not entail handling covered produce or food contact surfaces until May, you could choose to delay their initial training until, for example, late April.

You must also provide periodic refresher training at least once annually for personnel who handle covered produce or food contact surfaces, and those who are engaged in the supervision thereof. (See 21 CFR 112.21(a)). Such training helps reinforce your personnel's continued awareness of their responsibility to follow food safety and hygiene principles, and the requirements of the Produce Safety Rule. You have the flexibility to determine the appropriate timing and frequency for periodic refresher training, as long as it occurs at least once per year. Some issues that could influence your decision on timing and frequency include the type, number, and timing of crops, and the timing of hiring and initial training for individual workers. For example, if you use different personnel to grow and harvest covered produce, or if you have

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year-round production, and want to deliver training to smaller groups rather than all personnel at once, then staggered, periodic refresher training could more effectively ensure that all personnel receive the required training. For another example, you could decide to conduct periodic refresher training more frequently than once a year (e.g., bi-annual or quarterly training sessions), before personnel begin certain covered activities, such as before the beginning of the growing season and again before the beginning of covered produce harvesting, particularly if your training focuses on specific topics or activities.

You should provide personnel with the most up-to-date information, to the extent practical, from credible sources. Academia, extension services, industry associations, and government agencies can be useful sources of information. You should keep your procedures and training materials updated and consider conducting periodic refresher training when new or additional information becomes available, such as new information about practices that could contribute to foodborne illness, or new recommendations about minimizing contamination. For example, a multi-state outbreak of *Listeria monocytogenes* associated with cantaloupe led to 143 hospitalizations and 33 deaths in 2011 (Ref. 23). As a result, both FDA and produce industry trade associations updated existing documents to provide information on how to minimize microbial contamination of cantaloupe.

If you change your procedures (for example, as a result of new information about how to best prevent contamination of covered produce you grow), you should update your training materials to reflect your new procedures, and conduct refresher training for affected personnel.

Furthermore, you must repeat training, as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of the Produce Safety Rule. (21 CFR 112.21(d)). Observations and information could be provided by, for example, supervisors, responsible parties, or other personnel. When providing repeat training, you should determine whether certain training content needs to be adapted in order to emphasize the conditions and practices necessary based on the requirements of the Produce Safety Rule. For example, if your harvest crew supervisor reports that harvest personnel are not consistently washing their hands after returning from breaks, you should evaluate the available observations and information related to the harvest personnel's practices. You could determine that training is necessary for those personnel that are not meeting the requirements of subpart D of the Produce Safety Rule; you would then provide refresher training to those personnel. This training should include information about the public health significance of proper hand-washing, your hand-washing procedures, and the requirements of the Produce Safety Rule regarding hand-washing. The training could be coupled with a demonstration of hand-washing technique.

#### **4. Easily Understandable Training**

Training must be conducted in a manner that is easily understood by personnel being trained. (21 CFR 112.21(c)). You should provide training in the language that your personnel customarily speak. Training should also be tailored to the educational level of your personnel, using terminology that is commonly used and avoiding terminology that is unnecessarily complex or easily misinterpreted. Training materials can include easily understood pictorials or graphics of important concepts. You should deliver information in a manner that your personnel

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can relate to their assigned duties and provide examples that are relevant to your farm. You may need to repeat key learning points in successive sessions, such as for complex topics, practices, or procedures.

Training sessions should be designed to effectively deliver the content. Training can include formal, scheduled events or less structured spontaneous sessions (e.g., in response to a real-time observation of poor practices by a supervisor). Training sessions can include several topics or can focus on information related to a specific topic or task. In some cases, longer training sessions could be effective to provide more depth of information or provide personnel with time to focus on complex concepts. Training conducted upon hiring or when introducing concepts to personnel that have limited knowledge or experience with food safety topics could be longer than other training sessions. Furthermore, dedicated training sessions can also emphasize your commitment to implementing food safety procedures based on the requirements of the Produce Safety Rule.

In some cases, training is most effective when it is provided in short sessions, focusing on a specific topic that targets a specific food safety concern among small groups of personnel with the same or similar duties (Ref. 101). When practical, these targeted training sessions should be conducted at or near the applicable work area. For example, you could train personnel that perform cleaning and sanitizing on treatment preparation near the area where these solutions are made. In another example, you could train personnel that perform packing activities about proper handling and cleanliness of food-packing materials, such as fiberboard boxes and plastic totes near their workstation.

Hands-on practice or demonstrations can show your personnel how to perform a specific job task, and provide opportunities for them to practice performing the task under supervision (Ref. 14) (Ref. 57). This allows your trainers to observe, discuss, and correct any poor practices exhibited during training sessions. For example, to train your harvest personnel to recognize covered produce that must not be harvested, as required by 21 CFR 112.22(b)(1), you might provide demonstrations in which you show the personnel examples of covered produce they should not harvest (e.g., covered produce contaminated with animal excreta) to prepare them to look for and recognize certain conditions. As another example, you could train personnel performing packing activities on inspection of food-packing materials (e.g., fiberboard boxes or plastic totes) by showing and discussing the condition of food packing containers and whether they could be contaminated with a known or reasonably foreseeable hazard.

You should consider posting signs or visual aids promoting practices presented in training as an additional reminder for personnel and to reinforce training concepts. You should include, as appropriate, multilingual versions, or pictorials or graphics. If you choose to post signs, you should do so in areas as close as practical to where personnel perform the relevant activities.

## **5. Minimum Training Requirements**

At a minimum, all personnel who handle covered produce or food contact surfaces during covered activities or supervise the conduct of such activities must receive training described in 21 CFR 112.22. (21 CFR 112.22). As stated above, 21 CFR 112.21(a) establishes a training requirement for certain personnel (that is, “all personnel who handle (contact) covered produce

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or food contact surfaces, or who are engaged in the supervision thereof”). The Produce Safety Rule provides the minimum content that must be included in that required training at 21 CFR 112.22. While the section regarding training content (21 CFR 112.22) does not explicitly state that it applies to personnel who contact food contact surfaces, FDA interprets that section to apply to such individuals, and those engaged in the supervision thereof, as provided in the section establishing the training requirement (21 CFR 112.21(a)). You should focus this training on the principles that will help personnel understand how to perform their duties in a way that aligns with the requirements of the Produce Safety Rule and how their actions can affect the safety of covered produce and food contact surfaces. While not required by the Produce Safety Rule, you should train other personnel in the same or similar fashion, as appropriate in light of their duties. An evaluation of assigned duties for all of your personnel who engage in covered activities (even if they do not handle covered produce or food contact surfaces), and their current level of training, education, and experience should help you identify additional personnel for whom it would be prudent to provide training and determine appropriate training for each individual or group.

The topic areas addressed in 21 CFR 112.22(a)(1) and (2)—food hygiene, food safety, and health and personal hygiene, and in 21 CFR 112.22(a)(3)—the standards in subparts C through O of the Produce Safety Rule, represent the minimum topic areas you must cover during training for your personnel who handle covered produce and food contact surfaces during covered activities, and those who are engaged in the supervision thereof.

It is important to provide personnel with an understanding of the potential routes of contamination of covered produce and food contact surfaces so that they can recognize how their own practices have the potential to result in contamination. Your training program should also include your food safety procedures. Your training programs can be designed to supplement your personnel’s prior education, training, and experience. The Produce Safety Rule does not specify who can provide training. You could choose to have qualified farm personnel or a third party conduct your training activities.

**a. Food Hygiene and Food Safety**

Your training must explain the principles of food hygiene and food safety. (21 CFR 112.22(a)(1)). This provides an overall framework for job performance that helps ensure compliance with the requirements of the Produce Safety Rule.

To meet the minimum requirements of food hygiene and food safety training, your training topics should include:

- Relevant sources of foodborne pathogens (e.g., humans and their waste; animals and their waste);
- Routes of contamination (e.g., animals or pests that contaminate covered produce with their excreta; inadequately composted biological soil amendments of animal origin (BSAAOs) handled in a way that results in contact with covered produce during application; a worker with an applicable health condition who handles covered produce; environmental transfer (e.g., contaminated soil or water contacting covered produce); and

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- potential for cross-contamination (e.g., unclean surfaces contacting clean surfaces and transferring contamination));
- Preventive measures (i.e., taking measures to minimize the potential for contamination at those points where potential routes of contamination exist); and
- Corrective measures (e.g., identifying covered produce that has been exposed to the potential for contamination and taking steps reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards and ensure that it is not distributed for consumption, if necessary).

The content of your training should connect these principles to your personnel's specific job duties. If, for example, you are conducting training for personnel whose assigned duties include removing trash from the packing area and infrequent handling of covered produce and food contact surfaces, the training should explain that waste containers could be contaminated (e.g., by pests, animal fecal material tracked onto the floor of the packing area, or in the area of the dumpster) and the potential for cross-contamination when they transition from handling trash and waste containers to handling covered produce and food contact surfaces (e.g., helping other personnel move covered produce, and containers holding covered produce, on packing tables). The training should also explain how to recognize practices (e.g., using packing tables as a break space over lunch) that could result in cross-contamination of covered produce.

**b. Health and Personal Hygiene**

Your training must explain the importance of health and personal hygiene for personnel and visitors; this training must include information on recognizing the symptoms of a health condition (e.g., vomiting, diarrhea, open lesions) that is reasonably likely to result in the contamination of covered produce or food contact surfaces. (21 CFR 112.22(a)(2)). Further, your training should ensure that personnel understand that they have a responsibility to take action to prevent contamination due to their own health (i.e., communicable illness) and hygienic practices. For those who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, your training must also include the requirements of the Produce Safety Rule related to health and personal hygiene that are applicable to their job responsibilities. (21 CFR 112.22(a)(3); see the section of this chapter titled "Standards in Subparts C through O". Training topics for the applicable personnel regarding health and personal hygiene must include:

- Recognizing and reporting, as necessary, applicable health conditions as outlined in 21 CFR 112.31; and
- Hygienic practices to minimize the potential of contamination to covered produce and food contact surfaces, including those outlined in 21 CFR 112.32(b).

Draft guidance on personnel and visitor health and hygiene is provided in Chapter 3: Health and Hygiene (Subpart D).

You should train all personnel who handle covered produce or food contact surfaces to recognize and respond when they encounter situations that present the potential for contamination of covered produce or food contact surfaces. For example, if your worker's assigned duties include handling raw manure as well as harvesting covered produce by hand, you should train them to know how their activities could result in cross-contamination between the raw manure and the

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covered produce. Further, the training should include your procedures regarding personal hygienic practices. Your training should include instructions to report to a supervisor or responsible individual any situations that the worker observes or becomes aware of that could result in contamination of covered produce or food contact surfaces.

#### **c. Standards in Subparts C through O**

Training must cover the standards established by FDA in subparts C through O of the Produce Safety Rule that are applicable to the employee's job responsibilities. (21 CFR 112.22(a)(3)). You should develop or use training programs that ensure that your personnel understand the regulatory requirements that are applicable to their job responsibilities. The standards in subparts C through O often involve action by your personnel that requires a specific understanding of certain practices and their impact on food safety, without which personnel may not meet the standards. Demonstrations are one method to show personnel examples of appropriate or inappropriate practices.

The following are a few examples that connect job responsibilities with job-specific training topics. These examples are intended to illustrate concepts for certain types of job responsibilities and are not intended to be universally applicable. Even if you have personnel with similar job responsibilities to those mentioned here, you should perform your own evaluation based on your farm's specific practices and conditions.

Example 2a. For personnel who sort covered produce by hand after harvest, training:

- must include the requirements of the Produce Safety Rule that are applicable to their duties—including those in subpart D—Health and Hygiene, and subpart K—Growing, Harvesting, Packing, and Holding Activities—that relate to sorting covered produce (See 21 CFR 112.22(a)(3)).
- should include your farm's procedures related to sorting covered produce—including what to do with covered produce that is reasonably likely to be contaminated.
- should include how the personnel's actions while sorting covered produce can lead to contamination of food contact surfaces and covered produce (e.g., situations where cross-contamination could occur).

Example 2b. For personnel who clean and sanitize packing equipment with food contact surfaces, training:

- must include the requirements of subpart L—Equipment, Tools, Buildings, and Sanitation—that relate to equipment cleaning and sanitizing (See 21 CFR 112.22(a)(3)).
- should include your procedures related to equipment cleaning, including how to prepare the cleaning and sanitizing solutions.
- should include how the personnel's actions while cleaning the equipment (e.g., dragging a hose from the floor across a clean food contact surface) can lead to contamination of food contact surfaces.

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Example 2c. For personnel who harvest covered produce by hand, and manage biological soil amendments of animal origin (BSAAOs), including a treatment process and keeping records of process controls, training:

- must include the requirements of the Produce Safety Rule that are applicable to their duties, including those in subpart C–Personnel Qualifications and Training that relate to those who harvest covered produce, subpart D–Health and Hygiene that relate to harvesting covered produce by hand, subpart F–Biological Soil Amendments of Animal Origin and Human Waste that relate to preparing, handling, conveying, and storing BSAAOs and keeping records of the treatment process, subpart K–(Growing, Harvesting, Packing, and Holding Activities that relate to harvesting covered produce, and subpart O–Records that relate to keeping records of process controls.
- should include your procedures related to harvesting activities, managing untreated and treated BSAAOs, including your treatment procedures and recordkeeping system.
- should include how the personnel’s actions while performing certain practices (e.g., handling raw manure and then handling a clean food contact surface) can lead to contamination of covered produce and food contact surfaces.

Example 2d. For personnel who supervise the pest control activities for your farm and do not contact covered produce or food contact surfaces, training:

- should include the requirements of subpart L–Equipment, Tools, Buildings, and Sanitation that relate to pest control.
- should include your procedures related to pest control.
- should include how the personnel’s activities while overseeing the pest control activities (e.g., handling traps and bait stations then contacting a clean food contact surface) can lead to contamination of food contact surfaces and covered produce.
- should include how to recognize signs of pest infestation and animal excreta.
- should include how pests can contaminate covered produce.

## **6. Additional Training for Persons Who Conduct Harvest Activities**

There are specific training requirements for personnel who conduct harvest activities for covered produce (21 CFR 112.21(b)), in addition to the previously discussed training requirements that apply to all personnel who handle covered produce or food contact surfaces.

As part of this training, you should encourage your personnel to communicate with their supervisors or responsible parties, or directly with other personnel, if they observe harvesting practices that do not align with your procedures or the applicable requirements of the Produce Safety Rule. Examples of such observations include harvesting covered produce visibly contaminated with animal excreta, harvesting dropped covered produce, or observing contact between cut surfaces of covered produce and the soil during or after harvest. (Additional information on these observations is found in 21 CFR 112.83, in Chapter 5: Domesticated and Wild Animals (Subpart I), in 21 CFR 112.112 and 112.113, and in Chapter 6: Growing, Harvesting, Packing, and Holding Activities (Subpart K.)).

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You could use contracted or temporary personnel to perform certain activities—for example to perform harvesting activities—but you should ensure that all personnel, including contracted, part-time, and temporary personnel, meet all of the training requirements of subpart C. For example, you could choose to rely on training that the company with whom you contract delivers to their harvesting crews to meet the requirements of subpart C. You should evaluate the training content to ensure that it meets the Produce Safety Rule requirements and aligns with your procedures. You may need to provide additional training to address any topics not covered by the contract company’s training, for example, to ensure the harvest personnel are aware of your specific procedures.

**a. Recognizing When Not to Harvest Covered Produce**

Persons who conduct harvest activities must be trained to recognize covered produce that must not be harvested. (21 CFR 112.22(b)(1)). This includes covered produce that may be contaminated, such as by animal excreta (see also draft guidance in Chapter 6: Growing, Harvesting, Packing, and Holding Activities (Subpart K), titled “Identifying and Not Harvesting Contaminated Covered Produce.” The training should emphasize to personnel that identifying and not harvesting covered produce that may be contaminated is potentially the only opportunity to prevent that covered produce from reaching consumers. Other personnel conducting activities that follow harvesting may not observe or be aware of the signs of possible contamination that harvest personnel are able to observe.

You should evaluate your harvesting activities and add training content specific for harvest personnel, as applicable to your farm’s operations. In particular, you should include the following training topics for personnel conducting harvesting activities:

- Recognizing covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (e.g., excreta, bite marks, crop destruction) immediately prior to and during harvesting (see also discussion of 21 CFR 112.112 and draft guidance in Chapter 6: Growing, Harvesting, Packing, and Holding Activities (Subpart K), titled “Identifying and Not Harvesting Contaminated Covered Produce”); and
- As applicable, recognizing specific growing areas from which covered produce possibly should not be harvested due to significant evidence of potential contamination from animals observed during the growing season (see also discussion of 21 CFR 112.83 and draft guidance in Chapter 5: Domesticated and Wild Animals (Subpart I), titled “Evaluating Significant Evidence of Potential Contamination of Covered Produce by Animals to Determine Whether Harvest Can Occur”).

**b. Harvest Containers and Equipment**

Persons who conduct harvest activities for covered produce must receive training on inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards. (21 CFR 112.22(b)(2)). Such persons must also receive training on correcting problems with harvest containers or equipment, or reporting such problems to a supervisor or other responsible party as appropriate to the person’s job responsibilities. (21 CFR

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112.22(b)(3)). Covered produce is often hand-harvested or hand-packed, sometimes directly into consumer-ready containers, so it is important for personnel to understand the influence of these practices on food safety (Ref. 14) (Ref. 64).

You should train personnel who harvest covered produce to visually assess harvest containers (e.g., food-packing materials, consumer-ready containers, and those from which the covered produce will be repacked) to determine whether they could serve as a source of contamination to the covered produce (see also Chapter 6: Growing, Harvesting, Packing, and Holding Activities (Subpart K), especially the discussion related to food-packing materials).

Training should include:

- Types of handling and practices that can contaminate food contact surfaces of harvesting containers (e.g., illustrations of a worker with an uncovered hand wound touching the food contact surface of a harvest container, or a worker stepping on the food contact surface of a harvest container, or animal excreta present on food contact surfaces);
- How and when personnel should inspect harvest containers;
- Conditions that personnel should look for during their inspections (e.g., visible animal excreta; organic material; residue; debris; evidence of pests or animals; or containers that are cracked, pitted, scored, or otherwise damaged in a way that promotes the growth or transfer of bacteria);
- Conditions that indicate the containers should be discarded; and
- Examples of damaged or unclean harvest containers to help illustrate when cleaning or repair is needed and when the containers should be discarded may be helpful. For example, displays or photos of several harvest containers in different stages of disrepair and an explanation of the expected corrections for each container or examples of harvest containers that should be cleaned prior to use may be helpful.

## **7. Food Safety Training for a Supervisor or Responsible Party**

At a minimum, at least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA. (21 CFR 112.22(c)). The standardized curriculum was developed by the Produce Safety Alliance (PSA), and is offered as one way to meet this requirement. You may use other training programs as long as the training is equivalent to the standardized curriculum. The standardized curriculum covers fundamental food safety topics as they relate to produce and the requirements of the Produce Safety Rule, including an introduction to produce safety, worker health and hygiene, training, wildlife and domesticated animals, land use, agricultural water, produce handling, and sanitation.

You could choose to have additional supervisors, or other personnel, complete this training as well. For example, if your farm has several supervisors who are responsible for ensuring that your operations adhere to the requirements of the Produce Safety Rule, you could direct each of these supervisors to complete the standardized or equivalent training. We also encourage you to

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have those who complete the standardized curriculum training (or equivalent) share what they learned with other personnel on your farm, during your on-farm training or otherwise.

## **8. Supervision to Ensure Compliance**

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of the Produce Safety Rule. (21 CFR 112.23). Such personnel can include full-time, permanent, temporary, part-time, seasonal, contracted, or other personnel you designate as responsible for ensuring that your activities comply with the requirements of the Produce Safety Rule. Oversight by qualified personnel is essential to ensure compliance with the Produce Safety Rule. These supervisors or responsible individuals should be able to evaluate whether other personnel are conducting activities in a manner based on the requirements of the Produce Safety Rule. (See 21 CFR 112.23). You should ensure that your responsible individuals or supervisors are aware of their role in recognizing and ensuring the correction of deviations from your food safety procedures and the requirements of the Produce Safety Rule. They should know that if they notice that a worker is not adhering to a food safety protocol, they should ensure that the worker receives immediate corrective training (e.g., instructions). For example, if a supervisor observes a worker harvesting covered produce with obvious animal excreta, the supervisor should show all harvest personnel the affected produce and remind personnel of why such produce must not be harvested (See 21 CFR 112.112). Your responsible individuals or supervisors also should recognize when individual deviations are recurring, or are more widespread among personnel, as this could signal a need to find a better way to convey the principles of the training materials to the personnel or to provide more frequent periodic refresher training.

You should evaluate your operations and ensure that you have identified personnel to supervise or be responsible for each aspect of your operations that relates to a provision of the Produce Safety Rule. You could find that you will need multiple individuals to fill this role but, in some cases, one individual could be able to perform all of the necessary duties to ensure compliance. These individuals can play an integral role in ensuring food safety and building a culture of food safety on your farm.

## **9. Training Records**

You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the person(s) trained. (21 CFR 112.30(b)). An example of a record that meets the training records requirements is an attendance sheet for a training session that includes the date of training, list of personnel in attendance, and list of topics covered (e.g., proper hand-washing). The records requirement applies regardless of whether you, a supervisor, or a responsible individual, or another entity, provides the training. If you employ contracted personnel, and you choose to rely on the training the contracted company (or a third-party service provider) provides, you should request training documentation from the contracted company or third-party service provider, and maintain the records to demonstrate compliance with the training requirements. (See additional draft guidance related to general recordkeeping requirements provided in Chapter 8: Records (Subpart O)).

## **Chapter 3: Health and Hygiene (Subpart D)**

People can contaminate covered produce and food contact surfaces with pathogens by failing to maintain hygiene practices; thereby potentially impacting the health of those who consume the contaminated produce (Ref. 70) (Ref. 138). Unhygienic practices exhibited by farm personnel have contributed to some produce-related outbreaks (Ref. 70) (Ref. 138). Human skin and clothing can transfer contamination in a variety of ways, including when a person uses the restroom, contacts other parts of the body or contaminated surfaces (e.g., unclean surfaces, soil, floors, trash, animals), and then handles covered produce or food contact surfaces (Ref. 58) (Ref. 81) (Ref. 116). Health and hygiene practices of personnel and visitors are therefore directly relevant to produce safety.

People can carry and transmit pathogens harbored on their skin and in their gastrointestinal and respiratory tracts. Individuals have the potential to spread communicable illnesses even if they do not show symptoms (i.e., asymptomatic carriers) (Ref. 24) (Ref. 131) (Ref. 56).

Asymptomatic carriers do not show symptoms because they either have not yet developed symptoms, symptoms never manifested, or their symptoms have resolved or subsided (Ref. 56) (Ref. 24) (Ref. 131). These individuals might not be aware that they are an asymptomatic carrier with the potential to spread a communicable illness, and may not seek medical examination, receive a diagnosis, or treat their illness. Therefore, hygienic practices are important in protecting covered produce and food contact surfaces from contamination by people who could transmit pathogens.

The requirements of subpart D establish minimum requirements to reduce the likelihood that personnel and visitors will introduce contamination to covered produce or food contact surfaces. The areas of focus include: preventing ill or infected persons from contaminating covered produce; implementing hygienic practices to minimize the risk of contamination by personnel; and minimizing the risk of contamination by visitors. Following these practices will help prevent contamination of covered produce or food contact surfaces from individuals with applicable health conditions (see the section of this chapter titled “Understanding Applicable Health Conditions”) or from unhygienic practices.

Much of the responsibility to prevent contamination of covered produce and food contact surfaces through hygienic practices rests with your personnel; it is important for you to communicate that responsibility to your personnel. The requirements and recommendations discussed in this chapter include not only actions directed at you—the owner, operator, or agent (as defined in 21 CFR 112.3)—but also actions directed at your supervisors or responsible parties, and your personnel. Personnel can include full-time, part-time, contracted, and seasonal personnel; volunteers; and paid or unpaid interns at your facility.

### **1. Measures to Prevent Ill or Infected Persons from Contaminating Covered Produce**

This section contains draft guidance on:

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- Applicable health conditions;
- The responsibility of personnel to recognize and report applicable health conditions to a supervisor or responsible party;
- The role of supervisors and responsible parties in identifying applicable health conditions;
- Addressing reports of applicable health conditions; and
- Responding to potential contamination of covered produce or food contact surfaces.

Among other requirements, 21 CFR 112.31 requires you to:

- Exclude any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health; and
- Instruct personnel to notify their supervisor(s) or a responsible party if they have, or if there is a reasonable possibility that they have, an applicable health condition.

You should also:

- Ensure that you and your supervisors, responsible parties, and personnel can identify applicable health conditions; and
- Ensure that your supervisors and responsible parties are aware of their responsibilities to:
  - Remind personnel to report applicable health conditions;
  - Evaluate whether personnel understand and report applicable health conditions;
  - Understand procedures to address reports of applicable health conditions; and
  - Know how to respond to potential contamination of covered produce or food contact surfaces.

**a. Understanding Applicable Health Conditions**

You must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition. (21 CFR 112.31(a)). This could include, for example, full-time, part-time, contracted, and seasonal personnel; volunteers; unpaid and paid interns; and/or visitors.

Applicable health conditions include communicable illnesses that present a public health risk in the context of normal work duties. The scientific evidence from outbreaks, surveys, and published literature establishes that human pathogens (e.g., *Salmonella*, pathogenic *E. coli*, *Shigella*, and *Cyclospora*) constitute a biological hazard with the potential to cause serious adverse health consequences or death, and result in the vast majority of foodborne illness known to be associated with produce consumption (Ref. 28) (Ref. 121).

Signs and symptoms (Ref. 27) (Ref. 98) (Ref. 115) (Ref. 55) of applicable health conditions can include the following:

- Vomiting;

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- Diarrhea;
- Abdominal cramps;
- Sore throat with fever;
- Jaundice (yellowish discoloration of the skin or of parts of the eyes); and
- Open wounds (e.g. wounds, boils, cuts, or sores).

Keep in mind that in some instances some non-communicable conditions and diseases can cause symptoms (e.g., vomiting, diarrhea) similar to those caused by the communicable illnesses described above. Applicable health conditions do not include conditions such as pregnancy, or non-communicable diseases such as cancer, diabetes, and high blood pressure. You should encourage personnel to report relevant symptoms, such as vomiting or diarrhea, to supervisors or responsible parties, regardless of the underlying condition, and your procedures should specify how to respond to such reports. For further draft guidance, see the section of this chapter titled “Addressing Reports of Applicable Health Conditions.”

**b. Self-identification of Applicable Health Conditions**

You must instruct your personnel to notify their supervisors (or a responsible party) if they have, or if there is a reasonable possibility that they have, an applicable health condition. (21 CFR 112.31(b)(2)). Your personnel could become aware by self-identification or medical examination that they have, or there is a reasonable possibility that they have, an applicable health condition.

You should ensure that personnel who have the potential to contaminate covered produce or food contact surfaces can identify applicable health conditions. Such personnel include those who handle covered produce and food contact surfaces, and those who interact with personnel who handle covered produce and food contact surfaces.

As discussed in this draft guidance at Chapter 2: Personnel Qualifications and Training (Subpart C), personnel who handle covered produce or food contact surfaces must receive training in the importance of health and personal hygiene, including recognizing symptoms of a health condition that is reasonably likely to result in contamination. (21 CFR 112.22(a)(2)). Such personnel also must receive training that includes the requirements established in subpart D of the Produce Safety Rule that are applicable to their job responsibilities. (See 21 CFR 112.22(a)(3)). This training is one way a farm can satisfy its obligation to instruct its personnel to notify their supervisors (or a responsible party) if they have, or if there is a reasonable possibility that they have, an applicable health condition. (21 CFR 112.31(b)(2)). You should, for example, in the training provided for those personnel that you assign to pack covered produce by hand, include training on applicable health conditions and the need to report to a supervisor or other responsible party any applicable health conditions that they might have.

For those personnel not covered by the training requirements in 21 CFR 112.22(a)(2) and (3), you should evaluate their job duties to determine whether you should provide them with training that ensures that they are aware of health and hygiene topics that are applicable to their job duties; depending on the circumstances, these personnel could contaminate covered produce or food contact surfaces if they have an applicable health condition. This includes personnel who do not handle covered produce or food contact surfaces themselves but interact with personnel

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who do. For examples, see the section of this chapter titled “Addressing Reports of Applicable Health Conditions.”

You have the flexibility to determine how to provide awareness of the requirements of 21 CFR 112.31(b)(1) and (2) to your personnel. For example, you could have all personnel attend training on this topic at the same time. You also could, for example, provide separate training on health and hygienic practices for personnel who do not handle covered produce or food contact surfaces and for those who handle covered produce or food contact surfaces.

To promote self-identification of applicable health conditions by personnel, you should:

- Train all personnel who may contaminate covered produce or food contact surfaces (not just those subject to the training requirement in 21 CFR 112.22(a)) on applicable health conditions and how to identify them, including relevant symptoms and communicable illnesses of concern;
- Encourage personnel to be aware of their direct contact with, or exposure to, individuals with symptoms of applicable health conditions (e.g., vomiting, diarrhea), including away from your farm and in their homes.<sup>8</sup> Remind personnel that they could also become ill or could become an asymptomatic carrier (as described in this chapter’s introduction). You should emphasize that if personnel have direct contact with or exposure to symptomatic individuals, they should pay careful attention to their hygienic practices (e.g., frequently wash hands). If personnel do have such contact or exposure, they should carefully monitor their health for potential symptoms of an applicable health condition;
- Provide your personnel with information on which supervisor or responsible party to notify if they have, or if there is a reasonable possibility that they have, an applicable health condition. Remind personnel that if a medical provider diagnoses them with an applicable health condition, information from the medical provider about the time period during which the worker is likely to be contagious could be helpful to you in determining appropriate steps regarding exclusion from duties that involve covered produce or food contact surfaces;
- Encourage personnel to prompt co-workers exhibiting symptoms of applicable health conditions to report their condition to a supervisor or responsible party; and
- Consider using signs or visual aids (e.g., posters) to reinforce important concepts regarding health and hygiene.

***c. Role of Supervisors in Identifying Applicable Health Conditions***

Communication between supervisors or other responsible parties and personnel plays an important role in ensuring that personnel continue to be aware of and report applicable health conditions. You should ensure that supervisors and responsible parties are aware of their responsibilities regarding the health and personal hygiene requirements of the Produce Safety Rule. (See 21 CFR 112.22(a)(2)). For example, if you assign a supervisor to make a daily assessment of whether harvest personnel exhibit symptoms of an applicable health condition and

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<sup>8</sup> An investigation in 2008 of a *Salmonella* outbreak associated with cantaloupe found that farm personnel and their families had recently experienced gastrointestinal illness. (Ref. 32).

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receive information from personnel about their awareness of such conditions (because personnel recognize the condition themselves or are made aware of a condition as a result of a medical examination), you should ensure that the supervisor can recognize applicable health conditions, including the signs and symptoms of concern (e.g., vomiting, diarrhea, frequently visiting the toilet facilities) and knows when and how to exclude or reassign affected workers from operations through which they could contaminate covered produce or food contact surfaces. Supervisors should periodically remind personnel to report any applicable health conditions or symptoms of concern they experience or observe in other personnel.

**d. Addressing Reports of Applicable Health Conditions**

You must exclude any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health. (21 CFR 112.31(b)(1)). You should be aware that the measures to prevent contamination described in 21 CFR 112.31(a) apply to **any person** who is shown to have, or appears to have, an applicable health condition. For example, if a mechanic who is contracted to repair non-food contact equipment located in your farm's packing area, near where covered produce and food contact surfaces are exposed, could contact covered produce or food contact surfaces while repairing equipment, that contact can result in contamination if the mechanic has an applicable health condition. As another example, an unpaid intern who assists personnel packing covered produce could perform tasks that could contaminate covered produce or food contact surfaces, such as bringing food packing materials with food contact surfaces to the packing area.

When presented with a report of a worker with an applicable health condition, you or a supervisor (or a responsible party) should evaluate the worker's applicable health condition and job duties to determine appropriate measures to prevent contamination of covered produce and food contact surfaces. Depending on the worker's specific condition, and the specific operations involved, such measures could include temporarily assigning the worker to other duties, temporarily excusing them from work, or allowing the worker to continue with their job duties after completing certain actions, such as bandaging a wound in a manner that prevents contamination. For example, you must not permit a worker who reports currently experiencing episodes of vomiting to directly handle covered produce or food contact surfaces until their condition no longer presents a risk to public health, and you must exclude that worker from activities where the potential for contamination of covered produce or food contact surfaces exists through indirect contact (e.g., handling shared objects with other personnel who also contact the covered produce or food contact surfaces), until their condition no longer presents a risk to public health. (See 21 CFR 112.31(b)(1)).

The Produce Safety Rule does not require (or authorize) you to obtain medical records of your personnel to determine or verify their applicable health condition. You and your supervisors and other responsible parties should keep worker reports of applicable health conditions confidential and address such reports as necessary to prevent contamination of covered produce or food contact surfaces. Supervisors should not reprimand or otherwise penalize personnel based on a report of an applicable health condition.

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In some cases, it may be possible to temporarily reassign a worker with an applicable health condition to other tasks to prevent contamination of covered produce or food contact surfaces, such as clerical activities in areas away from covered activities or waste removal in areas where covered activities do not occur. If a worker's applicable health condition involves a wound, boil, cut, or sore that can be adequately covered to prevent it from becoming a source of contamination, you could allow the individual to handle covered produce or food contact surfaces after the worker covers the wound, boil, cut, or sore in a manner that prevents contamination. Depending on the location of the wound, boil, cut, or sore, adequate covering could involve the use of an impermeable bandage, finger cot, or glove. A supervisor or other responsible party should assess the covered wound to determine whether it no longer presents a public health risk before allowing a worker to handle covered produce or food contact surfaces. (See 21 CFR 112.31(b)(1)).

You should develop procedures in advance to assist supervisors and other responsible parties in making decisions about excluding or reassigning workers with applicable health conditions and ensure these personnel are aware of your procedures. These procedures could account for specific symptoms associated with applicable health conditions and categories of personnel based on scope of job duties to ensure that any reassignment prevents contamination of covered produce and food contact surfaces. The FDA Food Code is a resource that provides information on potential approaches for addressing situations in which personnel have certain communicable illnesses or conditions that represent a public health risk when handling food (Ref. 55).

**e. Response to Potential Contamination of Covered Produce or Food Contact Surfaces**

You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act because of such hazards. (21 CFR 112.11). For example, if you are aware that a person with an applicable health condition is likely to have contaminated covered produce or food contact surfaces, you must take appropriate measures to ensure that the affected produce is not distributed unless its safety can be reasonably assured, and to prevent contamination of additional covered produce. (See 21 CFR 112.11).

You should train supervisors and personnel who work in areas where covered activities occur on how to respond to situations where a person with an applicable health condition could contaminate covered produce. When such a situation occurs, you should consider taking additional actions such as the following:

- Isolating the areas of potential contamination and ceasing activities in the area until the incident has been addressed;
- Isolating and holding covered produce that could have been contaminated until its safety can be evaluated;
- Disposing of any covered produce that could have been contaminated unless its safety can be assured; and
- Cleaning and sanitizing, or replacing affected surfaces in the area, as appropriate.

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For example, if a worker unexpectedly becomes ill during the work shift and vomits on covered produce on a packing belt, the worker should report the incident to a supervisor or responsible party. The supervisor or responsible party should then ensure that activities in that area cease and must exclude the worker from working in any operations that may result in contamination of covered produce or food contact surfaces until the person's condition no longer presents a risk to public health (See 21 CFR 112.31(b)(1)). A supervisor or other responsible party should also oversee the removal of the affected covered produce, and ensure other appropriate measures are performed, such as cleaning and sanitizing of the affected food contact surfaces.

There could be occasions when you find that the requirements of 21 CFR 112.31 are not being met at your farm. For example, if you learn that a supervisor did not adequately respond to a report of a worker with an applicable health condition and your farm consequently failed to exclude the worker from an operation that may result in contamination of covered produce or food contact surfaces while the worker's condition presented a risk to public health, you should consider taking steps such as retraining that supervisor (or all supervisors) as necessary in accordance with 21 CFR 112.21(d). In addition, under 21 CFR 112.11, you should consider, for example, whether to change your farm's procedures for responding to reports of applicable health conditions.

## **2. Hygienic Practices**

This section contains draft guidance on the following:

- Hygienic practices and the requirements for personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards to use hygienic practices;
- The role of supervisors in ensuring personnel adhere to hygienic practices; and
- Specific hygienic practices required under 21 CFR 112.32(b).

You should take the following steps to ensure your personnel are implementing required hygienic practices (21 CFR 112.32):

- Ensure that applicable personnel are aware of the hygienic practices requirements of the Produce Safety Rule and can identify, and correct or report, unhygienic practices;
- Identify job duties in which personnel are likely to encounter potential sources of contamination (e.g., handling of biological soil amendments of animal origin (BSAAOs), animals, or waste) and, as appropriate, ensure that applicable personnel are aware of hygienic practices;
- Ensure personnel are aware of procedures associated with minimum hygienic requirements of the Produce Safety Rule, including maintaining adequate personal cleanliness, avoiding contact with animals other than working animals, thorough hand-washing, using gloves (if applicable), wearing jewelry, eating, chewing gum, and using tobacco products; and
- Ensure your supervisors and responsible parties observe personnel and communicate with personnel about hygienic practices, and identify unhygienic practices that need to be addressed.

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**a. Personnel and Hygienic Practices**

Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination. (21 CFR 112.32(a)). This requirement is not limited only to personnel who handle covered produce and food contact surfaces, but also applies to others who work in the operation. You should evaluate those covered activities where covered produce or food contact surfaces are at risk of contamination and ensure that your personnel are following hygienic practices to prevent contamination, adjusting your procedures as necessary.

You should ensure that all personnel, including individuals whose job duties may not directly involve covered produce or food contact surfaces—such as office or loading dock staff who occasionally enter a packing area, use hygienic practices while on duty to the extent necessary to protect against contamination and understand how hygienic practices impact the safety of covered produce. For example, at a farm that grows covered produce and raises livestock, even if specific personnel are designated to handle only livestock, if their duties are such that they occasionally enter areas where they could contact covered produce or food contact surfaces with footwear or clothing that contacted animal excreta, their clothing could transfer contamination to covered produce or food contact surfaces if the worker does not follow hygienic practices.

You should identify personnel whose job duties are likely to involve interaction with potential sources of contamination (such as handling trash, raw manure, or animals). You should consider how these personnel interact with or come into proximity with other personnel and with covered produce and food contact surfaces. If you determine that the personnel's interactions create a risk for contamination of covered produce or food contact surfaces, you should ensure that they are aware of (such as through training), and follow, hygienic practices to protect against such contamination.

Personnel should understand the importance of consistently following hygienic practices to prevent contamination, and when hygienic practices are necessary. Personnel should be able to identify and report unhygienic practices that they observe, and you should encourage them to do so. In addition to training, you could use signs, visual aids (e.g., posters), and verbal reminders to re-enforce to personnel the importance of using hygienic practices. For example, you could place signs or visual aids by the entrance to a common area, such as a packing area, reminding personnel to use hygienic practices, including those outlined in 21 CFR 112.32(b).

**b. Role of Supervisors in Ensuring Personnel Follow Hygienic Practices**

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of the Produce Safety Rule. (21 CFR 112.23). The supervisors or other responsible parties you assign should ensure that other personnel consistently follow hygienic practices on your farm. Supervisors or responsible parties should observe and communicate with personnel who have the potential to contaminate covered produce or food contact surfaces about hygienic practices to ensure awareness and implementation. Supervisors and responsible parties should be familiar with the regulatory requirements regarding health and hygienic practices as well as your procedures.

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You should instruct your supervisors and responsible parties to observe personnel when performing their job duties to determine whether personnel are following hygienic practices and to identify and respond to any unhygienic practices. You must perform or assign additional training for the appropriate personnel, as necessary and appropriate, to correct those practices that do not meet the requirements established by FDA in subpart D of the Produce Safety Rule. (See 21 CFR 112.21(d)). In addition, under 21 CFR 112.11, you should consider any other actions you may need to take to ensure compliance with the Produce Safety Rule. For example, consider whether you should change your farm's procedures for responding to reports of unhygienic practices.

You should also ensure that supervisors are aware of your procedures and the applicable requirements of the Produce Safety Rule, which can be achieved as part of required training (See 21 CFR 112.22(a)). For example, if you assign a supervisor to oversee harvest activities in a field where covered produce is handled, the supervisor must receive training including the requirements of subpart D, such as adequate personal cleanliness and thorough hand-washing, that are relevant to the supervisor's job responsibilities. (21 CFR 112.22(a)(3)). The supervisor should also understand your related procedures. For supervisors and responsible parties not subject to the training requirements in 21 CFR 112.22(a), you should nonetheless provide training that ensures that they are aware of the regulatory requirements for health and hygiene that are applicable to their job duties.

**c. Required Hygienic Practices**

Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination. (21 CFR 112.32(a)). The hygienic practices that personnel use to satisfy the requirements of 21 CFR 112.32(a) when handling covered produce or food contact surfaces during a covered activity must include those provided in 21 CFR 112.32(b). (21 CFR 112.32(b)). These represent the minimum requirements for hygienic practices that all operations must apply. In addition, you should evaluate your operations to identify situations, if any, when hygienic practices in addition to those required by 21 CFR 112.32(b) are necessary to protect against contamination, as provided in 21 CFR 112.32(a).

**i. Maintaining Adequate Personal Cleanliness**

Your personnel who handle covered produce or food contact surfaces during a covered activity must maintain adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces. (21 CFR 112.32(b)(1)). Exposed skin, outerwear (e.g., smocks, aprons, coveralls, hair nets, beard guards, and footwear covers), clothing, and footwear should be free of filth, debris, and other material, to the extent practical. Outerwear, clothing, and footwear are likely to accumulate some organic material through the normal course of certain activities for some job duties. You should identify job duties where the accumulation of soil, organic material, filth, or other debris or potential sources of contamination occurs, and ensure your personnel maintain adequate personal cleanliness when later performing other activities where they can transfer contamination to covered produce or food contact surfaces; this could happen, for example, if personnel handle waste and then clean the food contact surfaces of equipment.

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You could, for example, specify certain practices related to outerwear, clothing, and footwear for personnel performing these duties.

There are several strategies that you can use to prevent outerwear, clothing, and footwear from contaminating covered produce and food contact surfaces. Personnel who are wearing soiled clothing upon arrival at the farm could present a source of contamination. Generally, clothing, footwear, and outer garments should be clean when beginning job duties involving covered produce or food contact surfaces. You should instruct personnel to use clean outerwear, clothing, and footwear, and change or remove those items as necessary to prevent contamination of covered produce and food contact surfaces. You could, for example, establish procedures for personnel to wear outer garments while handling covered produce or food contact surfaces and remove them before performing any activities where contamination could occur. You could, for example, establish procedures for personnel to wear aprons while packaging covered produce, then remove and properly store the aprons when taking a break, and put them back on upon returning to packing.

If you establish such procedures, personnel should have access to clean outer garments as needed, and your procedures should ensure that these outer garments are periodically cleaned and replaced when they become damaged or can no longer be cleaned. A suitable schedule for replacing and cleaning outer garments depends on the conditions of their use. You should designate a supervisor or responsible party to periodically assess the condition of outer garments to determine whether cleaning or replacement is warranted; and personnel should store outer garments that are used to prevent contamination of covered produce or food contact surfaces in a location and manner that protects them from contamination. The storage area should be dry and protected from the surrounding environment and pests. For example, if personnel wear different smocks when handling covered produce than those worn when handling waste containers, you should have separate designated areas for storing smocks worn by personnel when handling covered produce and for storing smocks worn by personnel when handling waste containers.

Practices that support maintaining personal cleanliness also include regularly bathing and keeping fingernails trimmed to permit effective removal of material from under and around fingernails. Generally, personnel should bandage all boils, cuts, and other wounds on exposed skin, including the hands and wrists. If a worker has a boil, cut, or other wound on their hands, they should use an impermeable cover, such as a bandage, *and* wear a glove or finger cot as a secondary barrier to protect the covered produce and food contact surfaces (i.e., prevent contamination). We provide additional draft guidance in the section of this chapter titled “Using Gloves.”

**ii. Avoiding Contact with Animals Other Than Working Animals**

Your personnel who handle covered produce or food contact surfaces during a covered activity must avoid contact with animals other than working animals, and take appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals. (21 CFR 112.32(b)(2)). These personnel, while performing covered activities, should also avoid contact with animal fur, feathers, saliva, skin, and excreta, which can harbor pathogens (Ref. 22) (Ref. 33) (Ref. 37) (Ref. 104) (Ref. 111) (Ref. 122). In some cases, proximity to animals can result in the transfer of contamination (Ref. 33) (Ref. 104) (Ref. 111)

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(Ref. 122), which could be without an individual's knowledge or awareness, such as when an animal brushes against a worker's hands or clothing. In the absence of hygienic practices after contact with animals, humans can transfer these pathogens from their hands or clothing to covered produce or food contact surfaces. In some outbreaks, failure to maintain hygienic practices after human contact with animals were identified as likely contributing factors to the outbreaks (Ref. 33) (Ref. 111) (Ref. 122).

Personnel should be aware of their proximity to animals. Personnel must wash their hands as soon as practical after touching animals (21 CFR 112.32(b)(3)(v)), which we discuss in the section of this chapter titled "Thorough Hand-washing." Additionally, personnel should consider the need for other hygienic measures, such as changing clothing or footwear, or using clean outerwear, as discussed in the section of this chapter titled "Maintaining Adequate Personal Cleanliness."

FDA does not expect, suggest, or recommend that you remove animals from your farm. If your farm uses working animals, you should determine which personnel interact with these animals and ensure that those personnel minimize the potential for contamination of covered produce and food contact surfaces. There are several ways that you can minimize the risk of personnel transferring contamination from working animals to covered produce and food contact surfaces. You could, for example, ensure that personnel who have direct contact with working animals are not assigned to duties that involve direct contact with covered produce or food contact surfaces. As an example of this, you could instruct the individual designated to handle a horse pulling a harvest cart not to handle the covered produce or food contact surfaces, and assign other personnel to activities related to loading covered produce in the cart. If you assign personnel to duties in which they contact both covered produce or food contact surfaces and working animals, those personnel must wash and dry their hands thoroughly in accordance with 21 CFR 112.32(b)(3) as soon as practical after touching animals or any waste of animal origin (21 CFR 112.32(b)(3)(iv)). To minimize the potential for contamination, you could, for example, separate such personnel's job duties in a way that they complete those duties that involve handling covered produce or food contact surfaces before those that involve handling animals during a given day. For additional draft guidance on working animals see Chapter 7: Equipment, Tools, Buildings, and Sanitation (Subpart L), and Chapter 5: Domesticated and Wild Animals (Subpart I).

Personnel to whom you assign job duties of handling covered produce or food contact surfaces and working animals should understand your practices and procedures to minimize the potential for contaminating covered produce and food contact surfaces after contact with animals based on the requirements of the Produce Safety Rule. You should instruct your supervisors and other responsible parties on your practices and procedures for personnel to avoid contact with animals other than working animals. You should direct supervisors or responsible parties, as applicable, to ensure that personnel consistently implement practices to avoid contact with animals other than working animals, and minimize the potential for contamination of covered produce after contact with animals.

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**iii. Thorough Hand-washing**

There are specified times when personnel who handle covered produce or food contact surfaces must wash their hands thoroughly, including scrubbing with soap or other effective surfactant and running water, and then thoroughly dry their hands. (21 CFR 112.32(b)(3)). Examples of surfactants include soap and detergents.

You may not use antiseptic hand rubs (i.e., “hand sanitizers”) as a substitute for soap and water. (21 CFR 112.130(d)). The use of soap and water is an effective method to clean hands (Ref. 29) (Ref. 59) (Ref. 100) (Ref. 133). Grease, soil, or other material present on hands in a work environment has been shown to reduce the effectiveness of “hand sanitizers” in eliminating microorganisms (Ref. 59) (Ref. 100). Antiseptic hand rubs may be used **after** proper hand-washing and drying in accordance with 21 CFR 112.32(b)(3), when the antiseptic hand rub serves as an additional measure in reducing the number of bacteria on hands relatively free of grease, soil, and other material.

Personnel should be aware that the greatest concentration of microbes typically exists around and under the fingernails and this is the most difficult area of the hand to clean (Ref. 89) (Ref. 100). Fingernail brushes, if used properly, have been found to be effective tools in cleaning this area of the hand (Ref. 89) (Ref. 100). Adequate hand drying devices include single-service towels (e.g., paper towels that are disposed of after each use), single-use towels provided by a sanitary towel service (i.e., a towel rental service that launders and delivers clean towels), and electric hand dryers. (See 21 CFR 112.32(b)(3)). Personnel should not use common or shared towels for drying hands (Ref. 2) (Ref. 69) (Ref. 133).

Personnel who handle covered produce or food contact surfaces must wash their hands:

- Before starting work. (21 CFR 112.32(b)(3)(i)). Personnel should wash their hands immediately before beginning activities in which they contact covered produce or food contact surfaces. For example, a worker could arrive at work and complete activities that do not involve contact with covered produce or food contact surfaces (e.g., signing in on a timesheet) before handling covered produce or food contact surfaces. They should perform these non-food contact activities and then thoroughly wash and dry their hands before beginning food contact activities.
- Before putting on gloves. (21 CFR 112.32(b)(3)(ii)). Gloves could collect and transfer contamination from unwashed hands to covered produce. Washing hands before putting on gloves could, for example, protect against contamination from one’s hand to the gloves and then to covered produce or food contact surfaces that the gloves contact (Ref. 133). For this reason, the use of gloves is not a substitute for hand-washing as required by 21 CFR 112.32(b)(3). We provide further draft guidance on glove use in the section of this chapter titled “Using Gloves.”
- After using the toilet. (21 CFR 112.32(b)(3)(iii)). Toilet use provides a direct means for hands to become contaminated with pathogens that a worker could shed. Hand-washing after toilet use protects against the transfer of pathogens from hands to other surfaces. You could choose to emphasize the requirement to wash hands after using the toilet by

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placing at toilet facilities and hand-washing facilities signs and visual aids describing hand-washing methods. You could consider placing hand-washing facilities in communal areas immediately outside of each toilet facility. During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands. (21 CFR 112.129(c)).

- Upon return to the work station after any break or other absence from the work station. (21 CFR 112.32(b)(3)(iv)). Absence from the work station includes, for example, taking a break to eat, drink, or use tobacco; leaving the work station to answer the telephone or accept a delivery; using the toilet; or changing job duties. During absences, an individual's hands can become contaminated because they could contact unsanitary surfaces (e.g., surfaces of buildings, equipment, or other objects that are not designed or maintained for food contact; personal food and beverages; toilet facilities; or the worker's mouth, nose, hair, or skin). Hand-washing upon returning to the work station helps to protect against contamination of covered produce and food contact surfaces. For example, if a worker packing chayote fruit stops to take a waste container to a dumpster for disposal, the worker must wash their hands before returning to their work station to continue packing chayote fruit. (See 21 CFR 112.32(b)(3)(iv)).
- As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin. (21 CFR 112.32(b)(3)(v)). For example, if a worker handles a horse pulling a harvest cart, they must wash their hands before handling covered produce. (See 21 CFR 112.32(b)(3)(v)). We discuss contact with animals by personnel who handle covered produce or food contact surfaces in the section of this chapter titled "Avoiding Contact with Animals Other Than Working Animals."
- At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards. (21 CFR 112.32(b)(3)(vi)). Your personnel should recognize situations when their hands may become contaminated and when they are required to wash their hands. Examples of such situations include touching: surfaces of buildings, components of equipment and tools (e.g., control panels, wheels, handles), or other objects that are not designed or maintained for food contact, such as outside walls, the floor, or the ground; objects that have been in contact with the floor; tractors; vehicles; non-food contact tools (e.g., brooms, shovels); trash, dumpsters, or other waste containers; or the worker's nose, mouth, hair, or skin.

Training for your personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must include the hand-washing requirements associated with 21 CFR 112.32(b)(3). (See 21 CFR 112.22(a)(3)). You should emphasize how to recognize potential sources of contamination and the requirement for personnel to wash their hands after handling such objects and before handling covered produce or food contact surfaces. You should also train personnel to be conscientious of contact between their hands and their nose, mouth, hair, skin, and other parts of the body, which increases the potential to transfer contamination.

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You should direct your supervisors and other responsible parties, as applicable, to ensure that personnel consistently follow practices to wash their hands thoroughly. Supervisors and other responsible parties should encourage and remind personnel to thoroughly wash and dry their hands in keeping with your procedures. For example, supervisors or responsible parties could perform demonstrations, or provide verbal reminders, or provide signs and visual aids at hand-washing facilities.

**iv. Using Gloves**

We are not requiring that your personnel use gloves or that gloves, when used, be of a certain type (e.g., disposable, cotton, leather, or other types). However, if you choose to use gloves in handling covered produce or food contact surfaces, the gloves must be maintained in an intact and sanitary condition and replaced when they can no longer be so maintained. (21 CFR 112.32(b)(4)). Gloves with holes, tears, or cracks are not in an intact and sanitary condition. Gloves should be clean when personnel using gloves begin job duties involving covered produce or food contact surfaces.

You should evaluate activities that involve hand contact with covered produce or food contact surfaces, and determine whether personnel should use gloves. Factors to consider in the development of your approach to glove use include: type of activity, glove type, likelihood for contamination of covered produce or food contact surfaces, frequency of glove use, glove storage, frequency of glove cleaning (if appropriate), and glove replacement (e.g., identifying and replacing gloves when they are no longer in an intact and sanitary condition).

We recognize that different types of gloves, or no gloves, may be appropriate depending on the circumstances, and 21 CFR 112.32(b)(4) provides you with the flexibility to choose practices that are appropriate for your operations. Furthermore, if you choose to use gloves for handling covered produce or food contact surfaces during covered activities, your personnel must follow the hand-washing requirements in 21 CFR 112.32(b)(3) before putting on gloves. (See 21 CFR 112.23(b)(3)(ii)).

You should develop procedures for glove storage that personnel should follow when storing reusable gloves while not in use. Gloves used for activities involving contact with covered produce or food contact surfaces should be stored separately from those used for other activities, especially those involving contact with potential sources of contamination (e.g., trash or manure). For both short- and long-term storage, you should provide a clean, dry environment in which it is convenient for your personnel to leave the gloves and where the gloves are protected from contamination. For longer periods of storage, gloves should be stored in a fully or partially-enclosed building, in a designated area that protects the gloves from contamination. For example, a farm could provide a table for short-term storage of gloves near a field that is being harvested so that personnel who temporarily leave the field (e.g., to use the toilet) can place their reusable gloves on the table until they return to work. At the end of the day, the farm could specify that personnel return the gloves to a certain work station in a fully enclosed barn where designated personnel examine, clean, and then store the gloves in a designated cabinet.

You should develop a system to periodically assess the condition of both single-use and reusable gloves to determine when they need to be replaced or, in the case of reusable gloves, cleaned.

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Single-use gloves are intended to be used once and disposed of when removed. They should not be reused. When determining an appropriate frequency for cleaning reusable gloves, you should consider how the gloves will be used and the potential for them to contaminate covered produce or food contact surfaces. For example, reusable gloves that are used daily for harvest activities are likely to need more frequent cleaning than gloves that are used once a month to move pallets.

You should ensure that gloves used for activities that involve handling covered produce or food contact surfaces are immediately replaced or otherwise appropriately addressed when holes, tears, or cracks appear. Single-use gloves should be replaced, and reusable gloves cleaned, when they contact a potential source of contamination, when they are removed from the work station and not stored in an intact or sanitary condition (e.g., when the worker takes a break or uses the toilet without storing the gloves according to your procedures), and when the worker changes job duties. Under some circumstances, it could be appropriate for you to instruct personnel to change gloves when they become visibly soiled or at a predetermined frequency, even if the gloves remain in good condition. The frequency you specify (e.g., every two hours) should be based on the activity in which the gloves are used and the likelihood that they will cause contamination of covered produce or food contact surfaces.

You should identify activities that involve glove use, if any, and the personnel involved in these activities. These personnel should understand your procedures on the use of gloves. Your personnel should understand that hygienic practices involve removing gloves when stopping or completing activities for which the gloves were intended. For example, if personnel wear reusable gloves when handling covered produce or food contact surfaces throughout the day, they should remove those gloves before taking breaks or handling the trash. You should instruct your supervisors and other responsible parties on your practices and procedures for glove use. You should direct your supervisors and other responsible parties, as applicable, to ensure that other personnel follow appropriate practices for glove use. Furthermore, supervisors and responsible parties should emphasize to personnel hygienic practices related to glove use. You could also choose to use signs and visual aids to reinforce your practices.

**v. Hand Jewelry**

Jewelry can serve as a harborage site for contamination (Ref. 46) (Ref. 142). Hand jewelry such as rings, bracelets, and watches could collect soil or other materials and the construction of the jewelry could hinder routine cleaning (Ref. 46) (Ref. 114) (Ref. 133) (Ref. 142). Personnel who handle covered produce or food contact surfaces must remove or cover hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand. (21 CFR 112.32(b)(5)). You should identify the activities on your farm that involve manipulating covered produce by hand, which could include hand harvesting, post-harvest washing, sorting, and packing. For these activities, you should determine an approach to hand jewelry that aligns with the requirements of 21 CFR 112.32(b)(5). You could choose to specify, for example, that personnel remove or cover all hand jewelry when manipulating covered produce by hand, or you could determine, for example, that some hand jewelry can be adequately cleaned and sanitized and allow that type of jewelry to be worn uncovered when your personnel manipulate covered produce by hand.

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Personnel who wear uncovered hand jewelry while manipulating covered produce by hand should clean around and under any hand jewelry to prevent the jewelry from harboring contamination. Jewelry that cannot be cleaned and sanitized can be covered using gloves or sleeve guards, as appropriate. Examples of hand jewelry that is unlikely to be adequately cleaned and sanitized include rings with adornments or embellishments, including stones and carving, as well as bracelets and watches (Ref. 47). Note that tears can occur in gloves or other outer garments, particularly from jewelry with embellishments. Personnel who use gloves should follow your procedures related to glove use, including replacing torn gloves. We provide draft guidance on glove use in the section of this chapter titled “Using Gloves.”

Your personnel, including supervisors and responsible parties, should understand your procedures related to jewelry. You should instruct your supervisors and other responsible parties on your practices and procedures related to hand jewelry, and you should direct them to ensure that other personnel consistently follow your procedures related to hand jewelry. You should instruct your supervisors and responsible parties to observe other personnel when performing their job duties to determine whether they are implementing these hygienic practices, and to identify any practices that need to be addressed.

**vi. Eating, Chewing Gum, and Using Tobacco Products**

Personnel must not eat, chew gum, or use tobacco products in an area used for a covered activity; drinking beverages is permitted in designated areas. (21 CFR 112.32(b)(6)). You should instruct your supervisors or responsible parties to observe personnel when performing their job duties to determine whether they are implementing these hygienic practices, and to identify any unhygienic practices that need to be addressed.

You should visually assess areas where covered activities are performed to determine where to locate areas designated for beverages. You should locate these designated areas at a sufficient distance from covered produce and food contact surfaces so as not to serve as potential sources of contamination to covered produce or food contact surfaces, such as by spillage of partially consumed beverages and by personnel drinking beverages (e.g., through hand to mouth contact or spittle). Locating these designated areas near hand-washing facilities could help to facilitate hand-washing after breaks for beverage drinking. (See 21 CFR 112.32(b)(3)(iv)).

**3. Measures to Prevent Visitors from Contaminating Covered Produce and Food Contact Surfaces**

You must take certain measures to prevent visitors from contaminating your covered produce or food contact surfaces with microorganisms of public health significance. (See 21 CFR 112.33). A visitor is any person (other than personnel) who enters your covered farm with your permission. (21 CFR 112.3). Visitors could include consumers, delivery personnel, vendors, or others who are touring, conducting business, or observing your farm.

Visitors could enter areas where covered produce is grown, harvested, packed, or held, and where food contact surfaces are present. As with personnel, visitors can transmit contamination to covered produce or food contact surfaces. For example, an ill visitor experiencing diarrhea who does not thoroughly wash their hands after using the toilet could unknowingly transfer

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pathogens to covered produce or food contact surfaces when later handling blueberries or harvesting containers during a tour of a blueberry field.

**a. Visitor Awareness of Policies and Procedures**

You must make visitors aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. (21 CFR 112.33(a)). In addition, 21 CFR 112.31(a) requires you to take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition, including visitors.

You should evaluate the different types of visitors on your farm and their interaction with covered produce and food contact surfaces, to determine appropriate approaches based on the requirements of 21 CFR 112.33. You have the flexibility to determine how to make visitors aware of your policies and procedures to protect covered produce and food contact surfaces from contamination by people. Depending on your farm's operations, and the reasons that visitors typically come to your farm, it could be appropriate for you to develop procedures specific to different types of visitor activities. You could, for example, specify in your policies and procedures that visitors or visibly ill visitors cannot access certain areas or operations (e.g., harvesting or packing). You should inform visitors of how their health and hygienic practices while visiting your farm are important to protecting covered produce and food contact surfaces from contamination. You could provide verbal, written, or graphic instructions, or use a combination of these. If you use written or graphic instructions on signs or visual aids, these should be in strategic locations, such as near the entrance or fields designated for visitors at a "pick your own" farm operation. You or your supervisors or other responsible parties should communicate the necessary information to visitors as soon as practical after their arrival at your farm.

There are multiple ways for farms to comply with the requirements of 21 CFR 112.33, including the following examples:

Example 3a: A farm specifies that for visitors that are likely to contact or be in proximity to covered produce or food contact surfaces, a supervisor will explain at the beginning of the visit the importance of health and hygiene, including thorough hand-washing procedures, and the risk from ill or infected visitors with an applicable health condition contaminating covered produce or food contact surfaces; their applicable policies and procedures; and the location of visitor-accessible restrooms and hand-washing facilities.

Example 3b: A farm uses one approach to inform all visitors by placing signs stating their applicable health and hygiene policies and procedures and the location of visitor-accessible restrooms and hand-washing facilities. The farm displays this information where visitors are likely to see and read it at the beginning of a visit, such as near the entrance of the farm, the visitor-accessible restroom, or areas that visitors access.

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Example 3c: A farm provides to all visitors handouts that provide their applicable health and hygiene policies and procedures, and the location of visitor-accessible restrooms and hand-washing facilities.

**b. Toilet and Hand-Washing Facilities**

You must make toilet and hand-washing facilities accessible to visitors. (21 CFR 112.33(b)). You are not required to provide separate toilet and hand-washing facilities for visitors. Toilet facilities can include plumbed facilities or portable facilities. Note, however, that the general requirements that apply to toilet facilities and hand-washing facilities are specified in 21 CFR 112.129 and 112.130, respectively. You should inform visitors of the location of toilet facilities and hand-washing facilities that are accessible to them.

## **Chapter 4:**

### **Biological Soil Amendments of Animal Origin and Human Waste (Subpart F)**

Any biological soil amendment of animal origin (BSAAO) has the potential to be a route of on-farm contamination of produce (Ref. 73) (Ref. 75) (Ref. 74) (Ref. 84) (Ref. 110) (Ref. 117) (Ref. 140) (Ref. 143). The use of unsafe agricultural practices, particularly involving an untreated BSAAO, could lead to foodborne illness from the consumption of contaminated produce.<sup>9</sup>

This chapter provides draft guidance related to Produce Safety Rule subpart F—Biological Soil Amendments of Animal Origin and Human Waste. Subpart F contains minimum standards for BSAAOs, including agricultural teas that are BSAAOs, and human waste to minimize the risk of contamination and help prevent adulteration<sup>10</sup> of your covered produce when you use BSAAOs. You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements. (21 CFR 112.53).

This chapter will help you:

1. Determine whether your soil amendment is a BSAAO;
2. Determine whether your BSAAO is “treated” or “untreated;”
3. Determine the appropriate treatment process and associated microbial standard for your treated BSAAO;
4. Determine how to apply your BSAAO;
5. Determine the requirements for handling, conveying, and storing your BSAAO; and
6. Determine what records to keep related to your treated BSAAO.

Figure 4a is a figure to assist you in determining whether your soil amendment is a BSAAO and Figure 4b provides the application requirements and minimum application intervals to help you understand the applicable requirements for your farm.

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<sup>9</sup> For a more detailed and thorough discussion of the many types, uses, and utility of soil amendments, as well as human pathogens associated with untreated BSAAOs and how certain treatments may reduce their prevalence, please consult FDA’s Qualitative Assessment of Risk (QAR). (Ref. 54).

<sup>10</sup> Under Section 402 of the FD&C Act.

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Figure 4a. Determining Whether Your Soil Amendment is a BSAAO

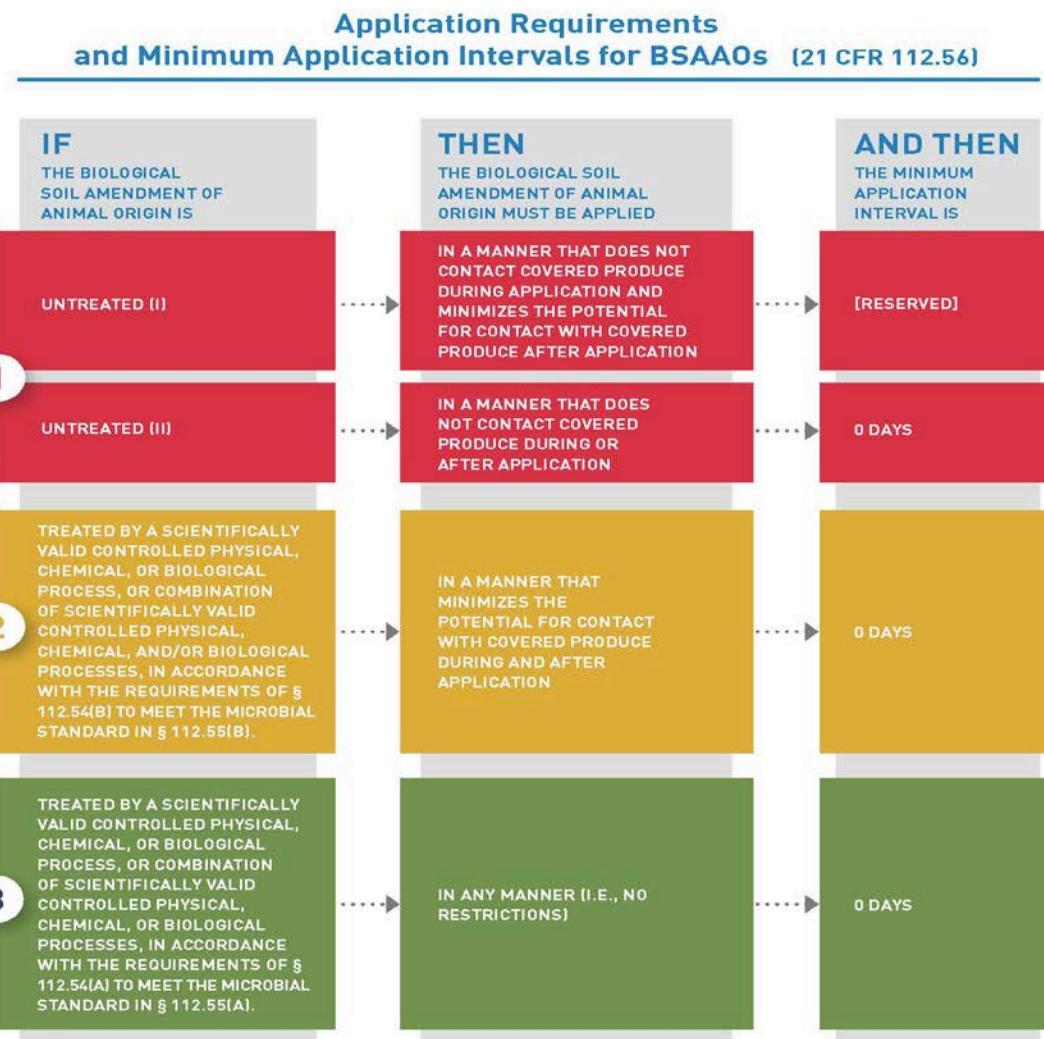


<sup>1</sup> You must handle, convey and store your BSAAO in accordance with the requirements of 21 CFR 112.52. See section "Determine the Requirements for Handling, Conveying, and Storing your BSAAO" for detailed draft guidance.

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Figure 4b. Application Requirements and Minimum Application Intervals (21 CFR 112.56)



## 1. Determine Whether your Soil Amendment is a BSAAO

You should first determine whether your soil amendment, including an agricultural tea, is a BSAAO. You should refer to the definitions listed in the Produce Safety Rule (21 CFR 112.3) that apply to the provisions of subpart F, including the following: soil amendment (SA); biological soil amendment (BSA); biological soil amendment of animal origin (BSAAO); manure; agricultural tea; agricultural tea additive; pre-consumer vegetative waste; non-fecal animal byproduct; stabilized compost; table waste; sewage sludge biosolids; and yard trimmings.

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Understanding the definitions in 21 CFR 112.3 will help you to accurately classify your soil amendment. The following are defined terms from 21 CFR 112.3 that are most frequently used in this draft guidance:

**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).

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

**Biological soil amendment of animal origin** means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term “biological soil amendment of animal origin” does not include any form of human waste.

**Agricultural tea** means a water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for the purposes of the Produce Safety Rule.

You can determine whether a soil amendment, including an agricultural tea, is a BSAAO by determining the nature of the materials (e.g., feedstocks or ingredients) used to prepare them. Examples of BSAAOs include the following:

- Treated, stabilized compost (i.e., finished compost), compost ingredients, or intermediary composting materials that contain materials of animal origin;
- Treated mushroom mulch (i.e., finished mulch), spent (i.e., used previously as a BSAAO) mushroom mulch, mushroom mulch ingredients or intermediary materials that contain materials of animal origin;
- Manure (see 21 CFR 112.3);
- Worm castings;
- Animal bedding material (e.g., straw) that contains animal excreta;
- Grass clippings known to include significant animal excreta;
- Table waste (e.g., post-consumer waste, including components that are animal or plant in origin);

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- Non-fecal animal byproduct (i.e., solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations) (21 CFR 112.3); and
- Agricultural tea containing biological materials of animal origin.

**2. Determine Whether your BSAAO is “Treated” or “Untreated”**

After you have determined that you are using a BSAAO (including an agricultural tea that is a BSAAO), you should determine whether your BSAAO is “treated” or “untreated.” (See 21 CFR 112.51). The treatment status of your BSAAO determines what application restrictions of the Produce Safety Rule apply.

**a. Treated BSAAO**

For BSAAOs, other than agricultural teas, your BSAAO is “treated” if it was processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of 21 CFR 112.54. (21 CFR 112.51(a)). The rule does not require you or your supplier to conduct lot-by-lot microbial testing of treated BSAAOs. If you want to consider a BSAAO to be “treated,” it must be processed to completion using a treatment process described in 21 CFR 112.54 that has been validated to meet the relevant microbial standard in 21 CFR 112.55. See the section of this chapter titled “Determine the Appropriate Treatment Process and Associated Microbial Standard for Your Treated BSAAO” for further draft guidance on treatment processes.

An agricultural tea that is a BSAAO is “treated” if the biological materials of animal origin used to make the tea have been processed to completion in accordance with the requirements of 21 CFR 112.54, and the water used to make the tea is not untreated surface water and has no detectable generic *E. coli* in 100 ml water. (21 CFR 112.51(a)). Agricultural teas cannot contain agricultural tea additives if they are to be considered “treated” for purposes of 21 CFR 112.51. (21 CFR 112.51(b)(5)).

**b. Untreated BSAAO**

If a BSAAO is not “treated” in accordance with the requirements of 21 CFR 112.51(a), it is “untreated.” A BSAAO other than an agricultural tea is untreated if it has not been processed to completion in accordance with the requirements of 21 CFR 112.54. (21 CFR 112.51(b)). An agricultural tea is “untreated” if the biological materials of animal origin used to make it have not been processed to completion in accordance with the requirements of 21 CFR 112.54, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic *E. coli* in 100 mL of water. (21 CFR 112.51(b)). Agricultural tea also is “untreated” if it was made with biological materials of animal origin that contain an agricultural tea additive. (21 CFR 112.51(b)(5)).

In addition, a BSAAO is “untreated” if any of the following conditions apply:

- It is contaminated after treatment;

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- It is combined with an untreated BSAAO component after treatment; or
- It is composed, at least in part, of untreated waste that you know, or have reason to believe, is contaminated with a hazard or has been associated with foodborne illness (See 21 CFR 112.51(b)).

Examples of untreated BSAAOs include:

- Bedding materials (e.g., untreated straw, hay, wood chips) containing horse feces that are not processed to completion in accordance with 21 CFR 112.54 (21 CFR 112.51(b)(1));
- “Stockpiled” or “aged” manure that is not processed to completion in accordance with 21 CFR 112.54 (21 CFR 112.51(b)(1));
- Cow manure, undergoing turned composting, that has been held at an inadequate temperature, for an insufficient number of days, or that has not been turned enough (i.e., that is not processed to completion in accordance with 21 CFR 112.54) (21 CFR 112.51(b)(1));
- Treated BSAAO compost contacted by runoff from a pile of untreated cow manure after treatment was completed on the compost (21 CFR 112.51(b)(2) and 112.52(c));
- Treated BSAAO compost to which bedding materials containing horse feces were added after treatment was completed on the compost (21 CFR 112.51(b)(3));
- Treated BSAAO mushroom mulch collected after use (i.e., spent material) contaminated with animal excreta during storage;
- Agricultural tea made from raw manure (21 CFR 112.51(b)(1));
- Agricultural tea made from “stockpiled” or “aged” manure that was not processed to completion in accordance with 21 CFR 112.54 (21 CFR 112.51(b)(1));
- Agricultural tea made from treated BSAAO compost contacted by runoff from a pile of untreated cow manure after treatment was completed on the compost (21 CFR 112.51(b)(2) and 112.52(c));
- Agricultural tea made from treated BSAAO compost to which bedding materials containing horse feces were added after treatment was completed on the compost (21 CFR 112.51(b)(3));
- Agricultural tea made from treated BSAAO compost and either untreated surface water, or water with detectible generic *E. coli* in 100 ml of water (21 CFR 112.51(b)(1)); and
- Agricultural tea made from treated BSAAO compost to which molasses has been added as an agricultural tea additive (21 CFR 112.51(b)(5)).

You may manage an untreated BSAAO in several ways:

- Using it as an untreated BSAAO to grow covered produce (in accordance with the application restrictions in 21 CFR 112.56(a)(1));
- Treating or re-treating it (in accordance with 21 CFR 112.51 and 21 CFR 112.54) to enable using it as a treated BSAAO to grow covered produce (in accordance with the application restrictions in 21 CFR 112.56(a)(2) or (3));
- Using it in a manner that is not subject to the requirements of 21 CFR Part 112 (e.g., using it to grow produce not covered by the Produce Safety Rule or a non-produce crop); or
- Disposing of it in accordance with local, state, and federal requirements.

### **3. Determine the Appropriate Treatment Process and Associated Microbial Standard for your Treated BSAAO**

The Produce Safety Rule establishes *application restrictions* (application methods and application intervals) for BSAAOs based on whether they are untreated or treated, and for those that are treated, based on the level of treatment. (See 21 CFR 112.56). Thus, the level of treatment you choose for a treated BSAAO will affect the application method you use for the BSAAO in growing covered produce. See the section of this draft guidance titled “Determine How to Apply Your BSAAO.”

There are two different *levels of treatment* (i.e., microbial standards) available for treated BSAAOs; they appear in 21 CFR 112.55(a) and (b). The treatment level in 21 CFR 112.55(a) is more stringent than the treatment level in 21 CFR 112.55(b). The two microbial standards are listed below:

- Figure 4d. 21 CFR 112.55(a) (linked to the treatment processes in 21 CFR 112.54(a)):

<b>For the microorganism -</b>	<b>The microbial standard is -</b>
<i>L. monocytogenes</i>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.
<i>Salmonella</i> species	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
<i>E. coli</i> O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

- Figure 4e. 21 CFR 112.55(b) (linked to the treatment processes in 21 CFR 112.54(b)):

<b>For the microorganism -</b>	<b>The microbial standard is -</b>
<i>Salmonella</i> species	Not detected using a method that can detect three MPN per 4 grams (or milliliter, if liquid is being sampled) of total solids.
Fecal coliforms	Less than 1,000 MPN per gram (or milliliter, if liquid is being sampled) of total solids.

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There are various *processes to treat BSAAOs*. The Produce Safety Rule describes acceptable treatment processes in 21 CFR 112.54(a) and (b) for the treatment of BSAAOs to be used for growing covered produce, provided that the resulting BSAAOs are applied in accordance with the applicable requirements of 21 CFR 112.56 (See 21 CFR 112.54).

You have the flexibility to determine a treatment process for your BSAAO under 21 CFR 112.54. You can use a physical process (e.g., heat), a chemical process (e.g., high alkaline pH), a biological process (e.g., composting), or a combination of processes (Ref. 30) (Ref. 137). A scientifically valid treatment process is an approach based on scientific information, data, or results, published in, for example, scientific journals, references, text books, or peer-reviewed literature, or contained in proprietary research.

**a. Validation Studies**

Validation studies are used to demonstrate that treatment processes meet the applicable microbial standards. A treatment process must be validated to satisfy one of the two microbial standards contained in 21 CFR 112.55. (See 21 CFR 112.54). The validation studies upon which you rely may use any analytical method if the testing methods meet the sensitivity requirements (i.e., detection threshold) specified in 21 CFR 112.55. FDA does not expect farms to perform validation studies related to BSAAO treatment processes; however, farms should ensure that the treatment processes they use have been validated to meet the standards of the Produce Safety Rule. You could, for example, work with technical assistance resources, such as your BSAAO suppliers, academia, extension services, and industry associations to assist you with evaluating validation studies and your practices.

Two examples of scientifically valid, controlled biological (e.g., composting) treatment processes that meet the microbial standard in 21 CFR 112.55(b) are provided in 21 CFR 112.54(b)(1) and (b)(2), so no further validation of these treatments is necessary. Although 21 CFR 112.54(b)(1) and (b)(2) provide two example processes that you may use to satisfy the microbial standard in 21 CFR 112.55(b). These are not the only means of achieving composting treatments that meet the microbial standard in 21 CFR 112.55(b), and we do not discourage you from using other processes that meet the requirements of 21 CFR 112.54.

Validation studies should:

- Adequately examine the treatment process and its ability to consistently and predictably meet the required microbial standard;
- Consider the types of materials that will be used;
- Consider the density of the materials;
- Consider the potential for non-homogeneous material;
- Consider the amount of material to be treated;
- Consider the relevant environmental conditions (e.g., temperature, humidity, and precipitation, as could be impacted by regional or seasonal influences);
- Include multiple repetitions of microbial testing performed using a statistically valid sampling plan to verify that the treatment process will consistently produce a BSAAO that meets the microbial standard; and

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- Outline the parameters (e.g., time, temperature, pH, moisture, number and timing of turnings, carbon:nitrogen ratio) to be controlled, and the acceptable limits or ranges for those parameters, in order to achieve the microbial treatment levels.

The body of validation data used should demonstrate that the selected parameters are likely to be effective under production conditions similar to those used at the treatment site. Materials that are non-homogeneous could contain particles that react differently (e.g., heat at different rates) during the process. Pathogens could be insulated (i.e., protected) within denser BSAAO material, which means that less homogeneous materials could require more intense treatment to meet the microbial standard. In some cases, pilot scale studies may not be indicative of biological responses at a larger production scale. Process validation is critical to ensuring that a treatment process will consistently achieve the specified standards.

**b. Processes to Treat BSAAOs**

You must ensure that the treatment is processed to completion (See 21 CFR 112.51). You should:

- Establish procedures to ensure delivery of the scientifically valid, controlled process throughout the BSAAO;
- Administer the treatment process in a controlled manner to ensure that the treatment parameters (e.g., time, temperature, moisture content, pH) established during validation are achieved throughout the entirety of the BSAAO material;
- Ensure that the BSAAO is sufficiently homogenized during the treatment process, as applicable (e.g., blending or turning a compost pile); and
- Ensure that the treatment parameters are achieved in areas of the material where delivery of the process could be more challenging to achieve, such as the bottom or edges of the pile (e.g., adding a blanket of straw for insulation; appropriate number and placement of thermometers).

With respect to processing the BSAAO to completion using the example of turned composting under 21 CFR 112.54(b)(2), consider that every compost pile has a unique size, shape, and material (i.e., feedstocks or ingredients) composition, all of which affects how the pile will generate and maintain heat. For example, many compost windrows will reach 131°F (55°C) relatively quickly, at which time the operator will begin monitoring the days above this temperature toward meeting the fifteen days of exposure to 131°F (55°C) per 21 CFR 112.54(b)(2). The operator will typically manage both oxygen and nutrients via turning, and, in some situations, moisture, to maintain the 131°F (55°C) temperature for a total of 15 days. Turning the piles also serves the purpose of maximizing exposure of the compost material to the elevated temperatures. To ensure exposure to the 131°F (55°C) temperature, specified in the example treatment provided in 21 CFR 112.54(b)(2), a minimum of 5 turnings are specified, but we do not specify a timeframe for each of the turns. Certain factors, such as windrow size or shape, or material composition or density, could influence the appropriate timing for turning.

The treatment processes provided in 21 CFR 112.54(b)(1) and (b)(2) include adequate curing as the final component. “Curing” is defined at 21 CFR 112.3. Curing is an important and necessary step to produce treated, stabilized compost (Ref. 35) (Ref. 40).

## **4. Determine How to Apply your BSAAO**

The requirements for application of your BSAAO are linked to whether it is treated or untreated, and, when treated, based on the level of treatment it received. (See 21 CFR 112.56). To determine how to apply your BSAAO, you should consider the following factors:

- Whether the BSAAO is treated or untreated;
- If treated, the level of treatment the BSAAO received;
- Based on the BSAAO's treatment status and level of treatment (if applicable), the resulting application restrictions provided by the Produce Safety Rule;
- The application methods that you could use and the likelihood of contact between the BSAAO and the harvestable or harvested part of the crop (e.g., broadcast application usually results in contact with covered produce; some other methods, such as injection or manual application, are less likely to result in contact);
- Practices you could use after application and the likelihood of contact between the BSAAO and the harvestable or harvested part of the crop (e.g., incorporation into the soil or application of plasticulture prior to planting usually reduces the likelihood of contact with covered produce that grows above the ground);
- The type of covered produce (e.g., grows in the ground, grows low to the ground, grows high above the ground);
- The maturity of the covered produce at the time of application (e.g., whether the harvestable or harvested part is present at time of application);
- The location of growing area where the BSAAO is applied with respect to surrounding growing areas (e.g., covered produce in fields adjacent to a field where the BSAAO is applied); and
- The environmental conditions that could impact movement of BSAAO particulates.

We provide examples throughout this section to illustrate potential approaches for the application of BSAAOs given the requirements of 21 CFR 112.56; we also identify specific covered produce in these examples for illustrative purposes. Even if you use similar practices for the specific covered produce mentioned in these examples, you should evaluate your farm's specific conditions and practices, such as through a visual assessment, to determine compliance with the regulatory requirements.

### **a. Untreated BSAAO**

Untreated BSAAOs must be applied in one of two ways:

- Application in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application; or
- Application in a manner that does not contact covered produce during or after application. (21 CFR 112.56(a)).

The two methods of application are the same regarding contact with covered produce **during** application of the BSAAO. These two application methods for untreated BSAAOs are different because the second type of application does not involve contact with covered produce **after**

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application of the BSAAO. The minimum application interval (i.e., interval between application of the BSAAO and harvest) specified for each method of application is discussed in the section of this chapter titled “Minimum Application Interval.”

**i. Contact with Covered Produce During Application**

Untreated BSAAOs must be applied in a manner that does not contact covered produce during application. (See 21 CFR 112.56(a)(1)(i) and 21 CFR 112.56(a)(1)(ii)). This means there is no intended or likely contact between the untreated BSAAO and the harvestable or harvested part of the crop during application. Your evaluation of your farm’s practices should assist you in determining how to apply your BSAAO based on this requirement. You should consider the factors listed in the introduction of this section to determine how to apply your untreated BSAAO.

Some application methods result in BSAAOs contacting the covered produce during application, and therefore cannot be used to apply untreated BSAAOs when the harvestable or harvested part of the crop is present during application. Certain methods, such as broadcast application with any crop or mechanical side-dressing with crops growing on or near the ground, result in contact between the untreated BSAAO and the harvestable or harvested part of the crop during application.

Example 4a: If a farm applies an untreated BSAAO using a broadcast spreader (i.e., application throughout the field) while the harvestable or harvested part of the crop is present, widespread contact between the BSAAO and the crop would occur during application.

You must not place, spread, or spray the untreated BSAAO in such a way that it contacts the harvestable part of your covered produce during application. (See 21 CFR 112.56).

Example 4b: If, for example, a farm manually applies (e.g., with a shovel) an untreated BSAAO to the soil used to grow a crop growing high above the ground (e.g., pistachios) when the harvestable or harvested part is present, the untreated BSAAO would not contact the pistachios during application when properly applied.

**ii. Contact with Covered Produce After Application**

You must apply untreated BSAAOs so that, after application of the BSAAO, either (1) the BSAAO does not contact covered produce, or (2) the potential for contact with covered produce has been minimized. (See 21 CFR 112.56(a)).

As discussed above (regarding contact during application), to meet the requirement that the BSAAO does not contact covered produce after application, there is no intended or likely contact between the BSAAO and covered produce during the relevant time period (in this case, after application). In Example 4b, if the pistachios were harvested without dropping the pistachios to the ground and there was otherwise no contact between the pistachios and the ground during growing or harvesting, then contact between the untreated BSAAO and the harvestable or harvested part of the pistachios after application is not intended or likely (i.e., it meets the

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requirement that the BSAAO does not contact covered produce after application). This is the case even if there was some remote potential for the BSAAO to contact the harvestable or harvested part of the covered produce (e.g., particles to be lifted by the wind to the height of the harvestable or harvested part of the pistachios after applying the BSAAO to the soil). There is always a chance that some soil amendment could be present in dust such that it settles on covered produce; however, we do not believe at this time that this type of potential contact is significant enough to be considered intended or likely for purposes of 21 CFR 112.56.

“Minimize the potential for contact” means there is no intended contact between the BSAAO and covered produce during the relevant time period, but some unintentional contact is likely due to incidental or environmental action.

Example 4c. If a farm applies untreated manure on top of the soil prior to planting a field of green beans, while there would be no intended contact between the untreated BSAAO and the harvestable or harvested part of the crop after application, some unintentional contact between the untreated manure and the harvestable or harvested part of the green beans could occur because the manure could be carried by splash to the green beans during heavy rains. The farm’s procedures include that during growing, the green bean plants will be attached to stakes to assist in minimizing the potential for contact between the harvestable or harvest part of the crop and the BSAAO after application.

Example 4d: There would be no intended contact after application for an untreated agricultural tea applied pre-planting as a drench or spray onto the soil for growing cauliflower; however, some unintentional contact between the untreated BSAAO and the harvestable or harvested part of the cauliflower could occur as a result of splash during heavy rains between the BSAAO and the cauliflower after application. In the farm’s evaluation of factors, the harvestable or harvested part of the cauliflower is not present until several weeks after application, the covered produce grows above the ground with surrounding outer leaves, and the farm determined that rain events are infrequent during the growing and harvesting seasons.

In some cases, contact is both intentional and likely.

Example 4e: If a farm incorporates an untreated BSAAO into the soil immediately prior to planting for the production of a root crop, this would cause the untreated BSAAO to contact the root crop after application (e.g., during growing). In this example, contact between the covered produce and the untreated BSAAO after application is both intentional and likely to occur and its application does not meet the requirements for untreated BSAAO under 21 CFR 112.56(a).

**iii. Minimum Application Interval**

The minimum application interval of an untreated BSAAO that is applied in a manner that does not contact covered produce during or after application is zero days. (21 CFR 112.56(a)(1)(ii)). A minimum application interval of zero days means that harvesting of the covered produce can occur on the same day that the untreated BSAAO is applied.

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FDA has not determined the minimum application interval for untreated BSAAOs that are applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application. FDA reserved the provision that provides the minimum application interval of untreated BSAAO that is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application. (21 CFR 112.56(a)(1)(i)). As a result, the requirements for the minimum application interval for untreated BSAAOs under 21 CFR 112.56(a) do not differ as of the date of publication of this draft guidance. We are deferring action on an application interval until we pursue certain steps, including a risk assessment and further research.

We acknowledge that many organic growers currently employ the National Organic Program (NOP) standard of 90 days or 120 days, as specified in 7 CFR 205.203(c)(1), and we recognize that such growers will likely continue to use this standard for organic crop production. We do not object to growers' use of a 90 or 120 day application interval for untreated BSAAOs subject to 21 CFR 112.56(a)(1)(i). We believe adherence to a 90 or 120 day application interval to be a prudent step toward minimizing the likelihood of contamination while the risk assessment and further research occur.

**b. Treated BSAAO**

For BSAAOs that undergo treatment processes that meet the requirements of 21 CFR 112.54(a) (that is, they meet the more stringent level of treatment in the Produce Safety Rule), you may apply the treated BSAAO in any manner, and the minimum application interval is 0 days. In other words, you do not need to apply the BSAAO in a manner that does not contact covered produce either during or after application of the BSAAO or that minimizes the potential for such contact. Additionally, covered produce can be harvested immediately after application of the BSAAO. (21 CFR 112.56(a)(3)). If you apply your treated BSAAO agricultural tea as a soil amendment in a manner that is intended or likely to contact (e.g. through splash, spray or leeching) your covered produce during or after application, the BSAAO used to prepare it must be treated to meet the requirement of 21 CFR 112.54(a). (See 21 CFR 112.56(a)(3)).

For BSAAOs that undergo treatment processes that meet 21 CFR 112.54(b) (that is, they meet the less stringent level of treatment in the rule), you must apply the treated BSAAO in a manner that minimizes the potential for contact with covered produce during and after application; and the minimum application interval is 0 days, which means covered produce can be harvested immediately after this BSAAO is applied. (21 CFR 112.56(a)(2)).

Example 4f: A farm chooses to side-dress a leafy green crop with a treated BSAAO compost that meets 21 CFR 112.54(b) (a BSAAO treated to meet the less stringent level of treatment in the rule) along the base of planted crop rows, either by manual application or by using specialized equipment to target application to the soil (e.g., at the base of a raised bed), which results in minimizing the potential for contact of the treated compost with the crop. In this example, after application of the treated BSAAO, some limited potential for contact between the untreated BSAAO and the leafy green crop exists due to incidental or environmental action, such as by splash during heavy rains, but such contact, nonetheless, is generally minimized. The farm determines that rain events are

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infrequent during the growing and harvesting seasons, and the farm's procedures include removal of outer leaves during harvest.

Example 4g: For a treated BSAAO agricultural tea that meets 21 CFR 112.51(a) and 112.54(b)) if a farm applies the treated BSAAO agricultural tea by side-dressing the soil (via hand sprayer or soil drench) for broccoli plants prior to flowering, some limited potential for contact exists between the untreated BSAAO and the harvestable or harvested part of the broccoli after application by splash during heavy rains, but such contact, nonetheless, is generally minimized. In the farm's evaluation of factors, the broccoli grows above the ground with surrounding outer leaves, and the farm determines that rain events are infrequent during the growing and harvesting seasons.

Some application methods for BSAAOs do not minimize the potential for contact with covered produce during application and therefore should not be used for BSAAOs unless they have been treated to meet the more stringent standard in the rule. That is, they can be used for BSAAOs that meet 21 CFR 112.54(a) but not for BSAAOs that only meet the treatment requirements of 21 CFR 112.54(b).

Example 4h: If the farm in Example 4f instead applied the treated BSAAO using a broadcast spreader (i.e., application throughout the field) while the harvestable or harvested part of the crop was present, it could be reasonably expected that there would be widespread contact between the BSAAO and the harvestable or harvested part of the leafy greens during application (as well as after application).

The following figure summarizes requirements of 21 CFR 112.55 and 112.56, as applicable, for treated BSAAOs.

Figure 4f. Microbial Standards and Application Requirements for Treated BSAAOs.

BSAAO Treatment Process (§ 112.54)	BSAAO Microbial Standards (§ 112.55) for <i>L. monocytogenes</i>	BSAAO Microbial Standards (§ 112.55) for <i>Salmonella</i>	BSAAO Microbial Standards (§ 112.55) for <i>E. coli</i> O157:H7	BSAAO Microbial Standards (§ 112.55) for Fecal Coliforms	BSAAO Application (§112.56)	BSAAO Application (§112.56) Minimum Interval
§ 112.54(a) – Scientifically Valid Treatment Process to meet § 112.55(a) <sup>5</sup>	Not detected <sup>1</sup>	Not detected <sup>2</sup>	Not detected <sup>3</sup>	Not Applicable	Any manner (no restrictions) (§ 112.56(a)(3))	0 Days
§ 112.54(b) – Scientifically Valid Treatment process to meet § 112.55(b) <sup>6</sup>	Not Applicable	Not detected <sup>2</sup>	Not Applicable	<1,000 MPN per gram (total solids) <sup>4</sup>	Minimizes potential contact during and after application (§ 112.56(a)(2))	0 Days

<sup>1</sup> Using a method that can detect 1 CFU per 5 grams (or milliliter, if liquid is being sampled) analytical portion.

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- <sup>2</sup> Using a method that can detect 3MPN *Salmonella* species per 4 grams (or milliliter, if liquid is being sampled) of total solids.
- <sup>3</sup> Using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion
- <sup>4</sup> Per milliliter (if liquid is being sampled) of total solids (dry weight)
- <sup>5</sup> See figure 4d.
- <sup>6</sup> See figure 4e.

## **5. Determine the Requirements for Handling, Transporting, and Storing your BSAAO**

The requirements of 21 CFR 112.52 state how you must handle, convey, and store BSAAOs. You should carefully evaluate your handling, transport, and storage practices for your BSAAOs (both treated and untreated) for the potential to contaminate your growing areas, water sources, water distribution systems, other soil amendments (including treated BSAAOs), areas used for covered activities, covered produce, and food contact surfaces. (See 21 CFR 112.52(a)). During your evaluation, you should remember that untreated BSAAOs include incomplete or partially treated BSAAOs and re-contaminated BSAAOs.

You should evaluate your storage practices and the location of your BSAAOs to determine whether they are managed in a way that they do not become a potential source of contamination. You should not store these materials in locations where runoff (e.g., from rain or intentionally-added water) could cause contamination of covered produce growing, harvesting, packing, or holding areas, agricultural water sources, or other soil amendments. You, for example, could address this concern through the implementation of runoff controls (e.g., buffer strips or catchment ditches to divert or absorb any runoff) or with physical containment systems (e.g., concrete block walls, soil berms, pits, or lagoons) to prevent runoff.

You must handle, convey, and store any treated BSAAO in a manner and location that minimizes the risk of it becoming contaminated by untreated or in-process BSAAOs. (21 CFR 112.52(b)). You should also take measures to reduce the potential for your stored, treated BSAAO to become contaminated from sources other than BSAAOs, such as from wildlife intrusion and runoff from adjacent land. To minimize the risk of it becoming contaminated, you could consider selecting storage locations where the treated BSAAOs are unlikely to contact untreated BSAAOs, covering the treated BSAAO with a tarp when the location is not subject to runoff, or storing it in an enclosed building. You should ensure that your personnel are aware of potential sources of contamination and periodically assess storage areas for sources of contamination. If your treated BSAAO becomes contaminated, you must handle, convey, and store as if it were untreated. (See 21 CFR 112.52(c)).

You should evaluate how you and your personnel use equipment and tools (e.g. shovels, front end loaders, windrow turners) for handling BSAAOs to minimize the risk of contamination from an untreated BSAAO to a treated BSAAO. You should consider whether the equipment that you use to handle treated BSAAOs (including agricultural teas that are BSAAOs) are also used to handle untreated BSAAOs, which could result in contamination. You should ensure that your personnel use practices that minimize the risk of this contamination. For example, you could use dedicated equipment and tools for activities involving contact with treated BSAAOs, limiting their use only for contact with treated BSAAOs. You also, for example, could clean and sanitize equipment and tools previously used with untreated BSAAOs before use with treated BSAAOs.

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Personnel who handle BSAAOs, supervisors, and responsible parties should understand the potential routes of contamination associated with BSAAOs, your practices and procedures, and how to take appropriate corrective measures when they observe conditions that could lead to contamination. You should direct your supervisors or other responsible parties, as applicable, with ensuring that your personnel consistently implement practices and procedures related to BSAAOs based on the regulatory requirements.

## **6. Determine What Records to Keep for your Treated BSAAO**

For treated BSAAOs that you acquire from a third party, you are required to maintain documentation, at least annually, that (1) the process used by your supplier to treat the BSAAO is a scientifically valid process that has been carried out with appropriate process monitoring (e.g., monitoring of time/temperature, moisture content, and pH); and (2) 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. (See 21 CFR 112.60(b)(1)). One example of such documentation is a Certificate of Conformance, provided at least annually, that certifies that these conditions will be met.

For example, a farm that receives a treated BSAAO from a third party could keep a record that includes a statement such as: “A scientifically valid thermal treatment was applied and carried out with appropriate process monitoring to satisfy the microbial standard in 21 CFR 11.55(a). The BSAAO has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination.” In addition, other information related to producing or managing the BSAAO, such as the BSAAO materials used, process parameters monitored and their results, and any applicable test results could be included.

For a treated BSAAO that you produce for your own covered farm(s), you must establish and keep documentation that the process controls (for example, time, temperature, and turnings) were achieved. (See 21 CFR 112.60(b)(2)). You should evaluate your farm’s specific processes to determine the documentation necessary to comply with the requirements of 21 CFR 112.60(b)(2).

Such documentation for treated, turned compost could include, for example:

- a log book that lists the following: the date that composting began; the nature of the materials(s) (e.g., a compost that contains raw cow manure);
- the carbon:nitrogen ratio of the materials (e.g. 25-30:1); the temperature profile (date, time, and location of each temperature measurement);
- the date and time of each turning event; the date and results of moisture content and pH determinations;
- the date of any addition of water; the date insulation (if any) was added and the means of insulation (e.g., three-inch layer of straw over pile); and
- the end date of the composting and curing processes.

Note that this list is for illustrative purposes only, and would not be applicable in all cases.

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If, for example, a farm receives from a third party a treated BSAAO that will be subject to further treatment processes on the farm, the farm could choose to obtain from the third party documentation about the process used to treat those BSAAOs, and how they were handled, conveyed, and stored. In this example, the farm must keep records for the treated BSAAO produced on their covered farm (21 CFR 112.60(b)(2)). We provide additional draft guidance on general records requirements in Chapter 8: Records (Subpart O).

## **Chapter 5: Domesticated and Wild Animals (Subpart I)**

Domesticated and wild animals are sources of pathogens (Ref. 107) (Ref. 113) (Ref. 139) (Ref. 143) that can transmit foodborne disease through the contamination of produce (Ref. 60) (Ref. 77) (Ref. 86) (Ref. 90) (Ref. 117). Even domesticated companion animals, such as dogs and cats, can carry pathogens that could be transferred to humans (Ref. 31) (Ref. 111), including *Salmonella* spp. (Ref. 6) (Ref. 129) and pathogenic strains of *E. coli* (Ref. 13) (Ref. 103). Furthermore, pathogens associated with animal sources (e.g., animal excreta) (Ref. 110) (Ref. 113) (Ref. 141) can survive for prolonged periods of time in the environment where they are deposited, such as in soil and water (Ref. 109). In this chapter, we use specific animals (e.g., cows, dogs, swine, birds, and deer) as examples to provide draft guidance on protecting covered produce from contamination by animals; the animals used in the examples are not the only animals that can be a potential source of contamination of covered produce.

The Produce Safety Rule does not authorize the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531-1544) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, collect, or to attempt to engage in any such conduct). Further, the Produce Safety Rule does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. (21 CFR 112.84.) We recognize and support the longstanding co-location of animals and plant food production systems in agriculture, and do not prohibit animals from covered farms.

The requirements of subpart I are science-based minimum standards regarding the potential for domesticated or wild animals to contaminate covered produce, and are reasonably necessary to minimize the risk of serious adverse health consequences or death from covered produce. These standards address the potential for biological hazards to be introduced by your own domesticated animals, by domesticated animals from a nearby area, or by wild animals. The requirements of subpart I apply only when covered activities occur in outdoor areas or partially-enclosed buildings and when, under the circumstances, a reasonable probability exists that animals will contaminate covered produce; they do not apply when a covered activity takes place in fully-enclosed buildings or to fish used in aquaculture operations. (See 21 CFR 112.81.)

This chapter will help you:

1. Determine whether, under the circumstances, there is a reasonable probability that animals will contaminate your covered produce;
2. Assess the relevant outdoor areas and partially-enclosed buildings (i.e., relevant areas) on your farm for evidence of potential contamination of covered produce by animals; and
3. Evaluate significant evidence of potential contamination of covered produce by animals to determine whether harvest can occur.

There are other requirements of the Produce Safety Rule that relate to animals. Draft guidance on those requirements can be found in the following chapters and sections of this document:

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- Chapter 3: Health and Hygiene (Subpart D) sections titled “Avoiding Contact with Animals Other Than Working Animals” and “Thorough Hand-washing”;
- Chapter 6: Growing, Harvesting, Packing, and Holding Activities (Subpart K) section titled “Identifying and Not Harvesting Contaminated Covered Produce”; and
- Chapter 7: Equipment, Tools, Buildings, and Sanitation (Subpart L) sections titled “Domesticated Animals”; “Pest Control”; and “Animal Excreta and Litter from Domesticated Animals.”

**1. Determining Reasonable Probability That Animals Will Contaminate Covered Produce**

To determine whether subpart I applies to you, you should:

- Identify outdoor areas and partially-enclosed buildings on your farm where covered activities occur during the growing season; and
- Determine whether, under your specific circumstances, there is a reasonable probability that animals will contaminate covered produce in these identified outdoor areas or partially-enclosed buildings during the growing season. (See 21 CFR 112.81 and 112.83.)

You should evaluate your farm’s covered produce, conditions, and practices when determining the probability that animals will contaminate your covered produce in these areas. This should include an evaluation of the types of animals that could contaminate your covered produce, based on:

- Available historical observations of animals; and
- Other information and factors (e.g., presence of animal attractants or habitats) that could influence animal presence on or near your farm.

Wild and domesticated animals, including your own domesticated animals and those from a nearby area, could be sources of contamination for covered produce and food contact surfaces. Wild and domesticated animals on or near your farm include feral, grazing, and working animals (e.g., guard dogs), livestock, and pets. You should consider the presence of animal attractants or habitats on or near your farm (e.g., water and food sources; discarded produce, brush, or waste piles; wooded areas; areas used for concentrated animal housing or holding, such as animal barns or feeding operations; and potential nesting areas) that influence the presence of animals. You should also consider seasonal presence of animals on your farm, such as areas used for resting or feeding by large numbers of Canada geese or other birds along their migration routes.

In your evaluation, you should also consider land features (e.g., topography), land use, and the presence of existing measures or structures on or near your farm that affect whether animals (or their waste) will be present on your farm. This could include features that control runoff containing animal waste (e.g., ditches, mounds, diversion berms, vegetative buffer strips, or animal waste containment structures) or other structures that impact your relevant areas. For example, if you have well-designed and maintained diversion berms that prevent cattle waste

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runoff from entering your covered produce field, there would not be a reasonable probability that runoff from the diverted animal waste will contaminate your covered produce in that field.

FDA encourages the application of practices that enhance food safety and that are consistent with sustainable conservation. We do not expect, suggest, or recommend that farms eliminate animals from outdoor growing areas. Nor do we require the application of practices that may adversely affect wildlife, such as removal of habitat or wild animals from land adjacent to produce fields. If you determine that there is a reasonable probability that animals will contaminate your covered produce, you must assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season. (See 21 CFR 112.83(b)(1)).

The following examples illustrate how a farm could evaluate their covered produce, conditions, and practices to determine whether there is a reasonable probability that animals will contaminate covered produce. These examples are intended to illustrate concepts and are not intended to be universally applicable. Even if you have circumstances similar to those mentioned here, you should perform your own evaluation based on your farm's specific practices and conditions.

Example 5a: If a farm determines that their growing areas in partially-enclosed shade houses for Swiss chard are not located near animal attractants or habitats, and there have been no observations of animals with the potential to contaminate covered produce in these houses, then there is no reasonable probability that animals will contaminate the Swiss chard.

Example 5b: If a farm determines that their outdoor growing areas for mustard greens are near a pond that is a habitat for water fowl, and the water fowl and their excreta are frequently observed in the outdoor mustard greens growing areas, then there is a reasonable probability that the water fowl will contaminate those mustard greens.

You should periodically re-evaluate your farm's conditions and practices. Changes on or near your farm could impact the probability that animals will contaminate your covered produce. Certain temporary or unusual conditions could influence whether there is a reasonable probability that animals will contaminate your covered produce. Construction or cultivation on or near your farm, or weather events (Ref. 102), such as heavy rains, droughts, or fires (Ref. 91), could alter animal movements or cause atypical or unanticipated animal presence. For example, during a drought, nearby wild animals could be more likely to enter your farm to access areas where you hold water, or animals could change their movements to avoid flooded areas during periods of heavy rainfall. If these events occur, you should determine whether the conditions on or near your farm have changed in a way that affects a previous determination of whether there is a reasonable probability that animals will contaminate your covered produce.

We concluded that it is not necessary for farms to apply the requirements of subpart I to covered produce that grows completely underground because there will not be a reasonable probability of contamination by animals as a general matter because of the growth habit of such produce; however, covered produce that grows completely underground is subject to other requirements of the Produce Safety Rule, as applicable, including 21 CFR 112.112 that requires you to take all

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measures reasonably necessary to identify and, not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

**2. Assessing Relevant Areas for Evidence of Potential Contamination of Covered Produce**

If you determine that there is a reasonable probability that animals will contaminate your covered produce, you must assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season. (See 21 CFR 112.83(b)(1)). You have the flexibility to assess the relevant areas based on your covered produce, your practices and conditions, and your observations and experience. (See 21 CFR 112.83(b)(1)). You should develop an approach that will assist you in assessing relevant areas for evidence of potential contamination of covered produce. Your approach to assessment could vary depending on the types of animals and other factors you identified in determining whether there is a reasonable probability that animals will contaminate your covered produce in each relevant area on your farm.

In your approach to assessment, you should consider the following:

- The personnel who are responsible for monitoring the relevant areas;
- The timing and frequency of monitoring; and
- The reporting of observations of evidence of potential contamination (i.e., how and when reporting occurs and to whom).

The outcome of your monitoring activities will help you determine whether you need to take any additional action with respect to your covered produce. Additional action is discussed in the section of this chapter titled “Evaluating Significant Evidence of Potential Contamination of Covered Produce by Animals to Determine Whether Harvest Can Occur.”

**a. Developing and Modifying Your Approach to Assessment**

You should periodically evaluate your approach to assessment and modify it as needed. There are several factors you should consider in developing and modifying your approach to assessment, including:

- The types of animals that you determined have a reasonable probability of contaminating your covered produce;
- The expected numbers of such animals (i.e., animal populations);
- The expected frequency of animal activity (e.g., monthly, weekly);
- The likely location of animal activity that impacts your relevant areas (e.g., nearby attractants or habitats); and
- The expected time of day of animal activity (e.g., early morning, dusk).

Factors that influence animal presence, such as the presence of animal attractants or habitats (e.g., standing water, discarded produce piles, wooded areas, potential nesting areas, and identified animal pathways) on or near the relevant areas on your farm, should inform where and how often you monitor these areas. For example, if one of the growing areas you plan to monitor

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is directly adjacent to a wooded area, that growing area could be more prone to animal activity, especially along the wood line, and warrant more frequent monitoring than other growing areas that are not near animal attractants.

You should monitor when animals are more likely to be present in your outdoor areas or partially-enclosed buildings, which may vary depending on the type of animal. For example, if your farm is within an animal migratory path (e.g., Canada geese are present during certain times of the year), your monitoring should occur when the migratory animals are present (e.g., the Canada geese).

You should consider the potential impact of weather events and other conditions as you evaluate your monitoring frequency for relevant areas on your farm, and make potential short-term adjustments as needed. As previously noted, weather events, such as heavy rains, droughts, or fires could alter animal movements or cause atypical or unanticipated animal presence (Ref. 91) (Ref. 102). For example, during a drought, if a supervisor observes an increased presence of animals and excreta during monitoring of growing areas near ponds located on the farm, then the farm should more frequently monitor the growing areas near ponds during the drought conditions.

The following examples illustrate how a farm could assess relevant areas for evidence of potential contamination under 21 CFR 112.83(b)(1) after having made a determination that there is a reasonable probability that animals will contaminate covered produce. These examples are intended to illustrate concepts and are not intended to be universally applicable. Even if you have circumstances similar to those mentioned here, you should perform your own evaluation based on your farm's specific practices and conditions.

Example 5c: A farm's outdoor area used for growing basil is near a pond and a wooded area that the farm determines is a habitat for several types of wild animals. The farm personnel observe deer herds and ground squirrels on the farm around the growing areas throughout the growing season (i.e., more than several occasions), and the farm determines the growing areas are within animal movement pathways. The farm must assess these areas for evidence of potential contamination. (See 21 CFR 112.83(b)(1)). The farm should monitor the outdoor basil growing areas at least twice during the growing season.

Example 5d: A farm's outdoor kale growing areas are located near a pond that the farm determines serves as a water source for deer and ducks, and ducks and their excreta are observed in the outdoor growing areas one to two times per month (e.g., less frequently than weekly observations) during the growing season when kale is present. The farm must assess these areas for evidence of potential contamination (See 21 CFR 112.83(b)(1)). The farm should monitor the outdoor kale growing areas at least monthly during the growing season.

Example 5e: A farm's outdoor areas for growing blackberries are located near a barn that the farm determines attracts birds for nesting. Birds are frequently (at least weekly) observed in the outdoor growing areas for blackberries, and personnel observed excreta on blackberries near and during harvesting activities. The farm must assess the

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blackberry growing areas for evidence of potential contamination (See 21 CFR 112.83(b)(1)). The farm should monitor the outdoor blackberry growing areas at least weekly.

**b. Performing Monitoring Activities**

You should determine which personnel will conduct monitoring and how they are to perform monitoring. You could, for example, designate a single individual to perform all monitoring activities, or designate specific individuals to perform these job responsibilities in different areas. Depending upon your situation, you could assign personnel to perform multiple tasks. For example, if you determine that there is a reasonable probability that animals will contaminate your strawberry field and that you need to assess for evidence of potential contamination weekly, you could direct your personnel who perform weekly weeding in a strawberry field to monitor for potential contamination of strawberries while they weed the field. You should also ensure that personnel performing monitoring understand how to identify signs of potential contamination of covered produce by animals.

Monitoring should include a visual examination for evidence of potential contamination of covered produce by animals in your relevant areas. Examples of animal activity to consider when examining for evidence of potential contamination include the presence of significant numbers of animals, animal excreta, nests, and signs of pecking, feeding, rooting, trampling, grazing, or bedding. For example, your personnel performing monitoring of partially-enclosed buildings could look for bird nesting and landing areas in overhead areas, such as the rafters, eaves, or roof.

**3. Evaluating Significant Evidence of Potential Contamination of Covered Produce by Animals to Determine Whether Harvest Can Occur**

If there is significant evidence of potential contamination by animals, you must evaluate whether the covered produce can be harvested in accordance with the requirements of 21 CFR 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. (21 CFR 112.83(b)(2)).

In determining whether evidence of potential contamination is significant, you should consider the extent of the evidence of potential contamination. A single observation of a few animals immediately adjacent to covered produce usually does not represent significant evidence of potential contamination; however, multiple observations of this type reported over time could result in a determination of significant evidence of potential contamination, especially when coupled with observations of excreta on, or damage to, covered produce. On the other hand, a single observation of a large number of animals near covered produce coupled with extensive animal excreta on or near covered produce or crop damage could be sufficient to lead you to determine that there is significant evidence of potential contamination of the affected covered produce.

You must take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be

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contaminated with a known or reasonably foreseeable hazard. (See 21 CFR 112.83(b)(2)). Reasonably necessary measures could include, for example, designating a specific distance around the area where you found significant evidence of potential contamination during the growing season and preventing harvest in that entire area (e.g., a ‘no harvest zone’). In some circumstances, you might identify significant evidence of potential contamination only in a certain portion of an outdoor area (e.g., a portion of a field rather than the entire field). For example, if significant quantities of animal excreta are observed in a portion of a field, you could designate an area around each observation of animal excreta, or block off a single area that includes all observations of animal excreta to prevent transfer to covered produce, such as by runoff or splash. The specific distance around the observations of animal excreta will likely vary by crop, the extent of potential contamination, and other factors. Certain sources, such as academia, extension services, industry associations, and government agencies could provide information on this topic to assist in your determination of an effective ‘no harvest’ perimeter or zone.

The following examples use the principles discussed in this section to illustrate approaches for determining whether significant evidence of potential contamination by animals exists. For illustrative purposes, we selected specific covered produce for these examples. These examples are intended to illustrate concepts, and are not intended to be universally applicable. Even if you have circumstances similar to those mentioned here, you should perform your own evaluation based on your farm’s specific practices and conditions.

#### **Examples of monitoring observations that **likely are** significant evidence of potential contamination:**

##### **Example 5f. Monitoring observations of a flock of geese, crop destruction, and animal excreta.**

A worker observes evidence that a flock of migrating geese has intruded on fields of lettuce. The worker observes extensive crop damage (e.g., evidence of crop consumption and gnaw or bite marks) and extensive goose excreta on and near the lettuce, and reports these observations to a supervisor. The supervisor determines that this represents significant evidence of potential contamination of the affected lettuce fields and determines that the covered produce in the affected fields cannot be harvested, in accordance with 21 CFR 112.112. The farm must take measures reasonably necessary to assist later during harvest so that they can identify and not harvest the affected produce. In this case, the farm’s chosen approach is for the supervisor to mark the affected fields with red flags and to communicate to the appropriate personnel that the affected lettuce fields will not be harvested.

##### **Example 5g. Monitoring observations of animal excreta.**

A worker observes trampled plants, evidence of animal feeding, and animal excreta on green beans in one field. The worker reports to a supervisor this observation. Workers on the farm have previously observed raccoons and animal tracks in the same field. The supervisor determines that these observations are significant evidence of potential contamination for the field of green beans. The farm must take measures reasonably necessary to assist later during harvest so that they can identify and not harvest the affected produce. In this case, the farm’s chosen approach is for the supervisor to mark a

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portion of the field that includes all affected areas with flags to designate the portion of the field that will not be harvested and to communicate to the appropriate personnel that the designated portion of the field will not be harvested. The supervisor also reminds personnel to watch for evidence of potential contamination during the harvesting of covered produce.

Example 5h. Monitoring observations of animal excreta.

A worker identifies and reports several piles of dog excreta observed in several areas during a monthly monitoring event of a zucchini field. The observations indicate that some of the dog excreta is fresh while some appears to have been present in the field for a longer time. Some of the dog excreta contacted the zucchini. The farm owner determines that this observation is significant evidence of potential contamination of a portion of the zucchini in the field. The farm must take measures reasonably necessary to assist later during harvest so that they can identify and not harvest the affected produce. In this case, the farm's chosen approach is for a designated worker to mark an area surrounding each observation of dog excreta with flags and to designate that these areas will not be harvested. The farm owner communicates to the appropriate personnel that the flags identify areas that should not be harvested; a supervisor also reminds the personnel to watch for additional evidence of potential contamination during harvest activities.

**Examples of monitoring observations that **likely are not** significant evidence of potential contamination:**

Example 5i. Observations of animal tracks in an outdoor growing area.

During the growing season, a worker performing monitoring observes a few raccoon tracks in a recently planted field of green beans. This observation was the only observation reported for that field of green beans during the growing season. This contrasts with example 5g where in addition to the observation of animal tracks, there was also evidence of animal feeding, animal excreta, and trampled plants.

Example 5j. Observations of animal excreta.

A worker reports that they saw several small piles of fresh dog excreta in a small area of a blueberry field two weeks prior to harvest. The dog excreta did not directly contact the blueberries. A supervisor confirms that a careful assessment of the entire blueberry field was conducted, but that no other observations of animal excreta or potential contamination of covered produce were observed in the field. A supervisor also confirms that the worker removed the dog excreta from the growing area immediately after the observation occurred.

## **Chapter 6:**

### **Growing, Harvesting, Packing, and Holding Activities (Subpart K)**

Produce is susceptible to contamination during growing, harvesting, packing, and holding activities (Ref. 17) (Ref. 49) (Ref. 67) (Ref. 90). Adhering to food safety practices during the day-to-day operations on your farm is critical to protecting covered produce (Ref. 17) (Ref. 34) (Ref. 67) (Ref. 90) (Ref. 99) (Ref. 121). Where applicable, we recommend evaluating your relevant procedures, processes, and practices periodically to ensure that you consider the scope of your relevant activities or operations and any changes that occurred and how they are affected by and relate to the requirements of the Produce Safety Rule. During such evaluations, you should consider not only typical practices, but also those that occur infrequently or due to unusual circumstances, to account for the breadth of procedures, processes, and practices associated with a given activity.

This chapter provides draft guidance on the requirements of Produce Safety Rule subpart K—Growing, Harvesting, Packing, and Holding Activities. This subpart is applicable to growing, harvesting, packing, and holding activities, including the transition points between those phases. The discussion is divided into: separation of covered and excluded produce; identifying and not harvesting contaminated covered produce; handling harvested covered produce; dropped covered produce; packaging covered produce; and food-packing material.

#### **1. Separation of Covered and Excluded Produce**

We provide draft guidance on the distinction between covered and excluded produce in Chapter 1: General Provisions (Subpart A) in the sections titled “Covered Produce. Depending on your farm layout, planting schedule, and growing and harvesting seasons, there could be times when you grow, harvest, pack, or hold multiple produce crops at the same time and in approximately the same location. You should evaluate your farm’s activities and produce to determine whether you grow, harvest, pack, or hold both covered and excluded produce and how you handle any excluded produce; you should visually assess your farm’s activities to confirm your farm’s practices.

If all of the following conditions are applicable to your farm:

- You grow, harvest, pack, or hold covered produce;
- You grow, harvest, pack, or hold produce that is not covered by the Produce Safety Rule (i.e., excluded produce in accordance with 21 CFR 112.2); and
- The excluded produce is grown, harvested, packed, or held in a manner that is not in accordance with the Produce Safety Rule requirements (21 CFR 112.111);

then you must take measures during covered activities to:

- Keep covered produce separate from excluded produce (except when placed in the same container for distribution) (21 CFR 112.111(a)); and

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- Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce (21 CFR 112.111(b)).

If you do not grow, harvest, pack, or hold both covered and excluded produce, or if you grow, harvest, pack, and hold your excluded produce in accordance with the provisions of the Produce Safety Rule, then the requirements of 21 CFR 112.111 are not applicable to your farm.

Example 6a: A farm grows, harvests, packs, or holds both radishes (covered produce) and beets (excluded produce) at the same time.

- If the farm grows, harvests, packs, or holds both radishes (covered produce) and beets (excluded produce) at the same time, and if the farm grows, harvests, packs, or holds the beets in accordance with the Produce Safety Rule, then 21 CFR 112.111 does not apply and the farm does not need to ensure that the two crops are separated during growing, harvesting, packing, and holding, and that you clean and sanitize, as necessary, any food contact surfaces that contact the beets before they contact the radishes.
- However, if the farm grows, harvests, packs, or holds the beets (excluded produce) in a way that is not in accordance with the Produce Safety Rule requirements for covered produce (e.g., if the farm uses a biological soil amendment of animal origin (BSAAO) and does not follow the applicable requirements related to the BSAAO found in subpart F), then the farm must ensure that the two crops are separated during growing, harvesting, packing, and holding, and that the farm cleans and sanitizes, as necessary, any food contact surfaces that contact the beets before they contact the radishes, as applicable. (See 21 CFR 112.111(a) and (b)).

You are not required to keep covered and excluded produce separate when you place them into the same container for distribution. (21 CFR 112.111(a)). For example, you are not restricted from selling items such as gift baskets or community supported agriculture (CSA) boxes that contain both covered and excluded produce, or other non-produce food items. So, you could put the radishes and beets described in the second bullet of the example above together into a CSA box for distribution to your CSA customers.

If you are subject to the provisions of 21 CFR 112.111, then you should evaluate your farm's practices, including growing, harvesting, packing, and holding activities, to determine how to separate covered produce and excluded produce. This can involve, for example, separation in location (i.e., physical space), separation in time, or a combination of both. You should determine whether activities involving covered and excluded produce occur in the same location or at the same time, use the same equipment and tools, or involve the same personnel, because use of the same location, equipment, or personnel (Ref. 17) (Ref. 134) could necessitate changes to your practices or additional oversight in order to maintain separation.

You should identify the location (i.e., physical space) in which the covered and excluded produce will be grown, harvested, packed, and held. You could, for example, choose to plant

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covered produce in a location that is physically separate from where you plant excluded produce. Similarly, you could, for example, choose to designate and maintain different holding and packing areas or buildings to ensure separation of covered and excluded produce. Depending on your practices, other strategies could be effective in separating covered and excluded produce.

You should also identify equipment and tools used during growing, harvesting, packing, and holding of excluded produce that are also used for covered produce. You should pay particular attention to the food contact surfaces of equipment and tools (e.g., knives and harvest containers) that could contact excluded produce and then contact covered produce. For example, you could assign separate equipment and tools to the growing and harvesting of covered and excluded produce; or you could establish procedures for cleaning and, as necessary, sanitizing equipment and tools used for excluded produce before using them for contact with covered produce (such cleaning, and as necessary, sanitizing, is required by 21 CFR 112.111(b) when the same tools are used in these circumstances, and more generally by 21 CFR 112.123(d)). We provide draft guidance on cleaning and sanitizing in Chapter 7: Equipment, Tools, Buildings, and Sanitation (Subpart L).

For packing and holding activities, you could schedule the packing of covered produce before the packing of excluded produce, using cleaned and, if necessary, sanitized equipment, tools, and containers for the covered produce. Further, if you choose to pack or hold both covered produce and excluded produce (that is not grown, harvested, packed, or held in accordance with the Produce Safety Rule) at the same time, you could consider the following practices to minimize the risk of contamination of the covered produce:

- Providing walls, other barriers, or space to separate covered and excluded produce;
- Clearly marking packing or holding areas for excluded produce or covered produce;
- Clearly marking or color-coding containers to minimize the risk of excluded produce containers being used for covered produce; and
- Establishing procedures for personnel working in the excluded produce packing or holding areas to ensure separation of excluded produce and covered produce.

You should instruct your supervisors and other responsible parties on your procedures for separation of covered and excluded produce. Supervisors and other responsible parties should emphasize and remind personnel to maintain separation of covered and excluded produce based on the regulatory requirements.

Personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive training related to the separation of excluded and covered produce, as applicable. (See 21 CFR 112.22(a)(3)). Personnel who contact food contact surfaces for cleaning and, when necessary, sanitizing activities, or who are engaged in the supervision thereof, must also be trained. (See 21 CFR 112.22(a)(3)). These personnel should understand your practices for maintaining separation of covered and excluded produce, preparing the cleaning and sanitizing solutions, when necessary; and when to perform such activities between handling of excluded and covered produce. We provide further draft guidance on training in Chapter 2: Personnel Qualifications and Training (Subpart C).

## **2. Identifying and Not Harvesting Contaminated Covered Produce**

Immediately prior to and during harvest activities, you must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. (See 21 CFR 112.112). The requirements of 21 CFR 112.112 are intended to be flexible, to allow you to take steps appropriate for your situation based on those requirements. In this section, we specifically discuss animal excreta as a potential source of contamination. (See 21 CFR 112.112). You should consider the possibility of other sources of contamination, such as flooding, that could be relevant to your particular growing and harvesting conditions, and address those as needed.

Animal excreta represent a source of pathogens (Ref. 78) (Ref. 110) (Ref. 143). Environmental investigations for certain outbreaks indicated that wild animal excreta were a source of pathogens linked to the outbreaks, and in some cases were observed in the fields near the time of harvest (Ref. 60) (Ref. 86) (Ref. 85). Animal saliva, skin, fur, and feathers can also be a source of pathogens (Ref. 22) (Ref. 33) (Ref. 37) (Ref. 104) (Ref. 111) (Ref. 122). FDA does not expect, suggest, or recommend that farms eliminate animals from outdoor growing areas. Instead, the Produce Safety Rule requires farms to take measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. This includes taking steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, your efforts must include a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method. (See 21 CFR 112.112).

Signs that covered produce is reasonably likely to be contaminated with a known or reasonably foreseeable hazard include:

- Excreta observed on the covered produce;
- Excreta observed in an area where it is reasonably likely that it has contacted or will contact nearby covered produce during harvest (see also the discussion in Chapter 5: Domesticated and Wild Animals (Subpart I));
- Animal fur, hair, or feathers observed on the covered produce; and
- Crop damage or destruction by animals (e.g., bite/gnaw marks; bent, uprooted, or trampled crops).

The required visual assessment is most effective when it is performed as close in time before beginning harvesting as is practicable, under the circumstances of the farm's operation, or during harvesting itself. A visual assessment should involve designated personnel visually examining the entire designated harvest area, including areas that will be mechanically harvested. For large areas that are mechanically harvested, you should designate personnel to visually assess sections of the growing area shortly before harvesting activities to identify areas where covered produce is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

You must perform visual assessments of the ground above covered produce that is grown completely underground (e.g., carrots, radishes, jicama). (See 21 CFR 112.112). If, during your assessment of the growing area and of the underground covered produce during harvest, you see evidence of animal excreta on or surrounding the covered produce, you must not harvest that

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covered produce. (See 21 CFR 112.112). If animal excreta are present on the ground above such covered produce during harvest and would be likely to contaminate the covered produce or food contact surfaces of harvest equipment, you must not harvest from the affected area. (See 21 CFR 112.112).

Harvest personnel must be trained to recognize covered produce that must not be harvested, including covered produce that may be contaminated with a known or reasonably foreseeable hazard. (See 21 CFR 112.22(b)(1)). You should also instruct your harvest personnel to alert nearby harvest personnel of observations of covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard (e.g., visible animal excreta). You should specify when personnel need to inform a supervisor or other responsible party of observations of covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard so they can determine appropriate steps to ensure that affected covered produce in the surrounding area is also not harvested.

Your procedures should include necessary actions when evidence of contamination, including visible animal excreta, is observed. You should inform your supervisors and other responsible parties of the expected actions and direct them to ensure that these tasks are completed as needed. You should take the following actions in response to observations of animal excreta, or other evidence of contamination: identify areas of covered produce that will not be harvested, such as by cordoning off or otherwise identifying the affected areas; and not harvesting covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. For example, if during a visual assessment, a worker identifies several clusters of blackberries that have visible animal excreta on them, then you could, for example, use a visual marker, such as colored flags, to indicate that they are not to be harvested. You should also assess whether any other blackberries near the blackberries with the visible contamination are reasonably likely to be contaminated and take appropriate steps.

As mentioned in Chapter 5: Domesticated and Wild Animals (Subpart I), during the growing season, you or your personnel could observe significant evidence of potential contamination when you assess relevant areas required by 21 CFR 112.83(b)(2). Based on those observations, you could conclude that some growing areas cannot be safely harvested. If you reach such a conclusion, you must take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. (See 21 CFR 112.112). For example, you could designate a portion of a growing area, so that covered produce in that area is not harvested, as a result of your observations during the growing season. During harvest, you must not harvest such covered produce. (See 21 CFR 112.112).

### **3. Handling Harvested Covered Produce**

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards. (21 CFR 112.113). Harvested covered produce is vulnerable to contamination, and handling practices can protect against contamination (Ref. 36) (Ref. 90).

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You should evaluate your practices during harvesting, packing, and holding, to identify conditions that could increase the likelihood of contamination. You should consider the handling of covered produce by personnel during and after harvest, and the equipment, buildings, and tools used for covered activities during and after harvest. Based on your evaluation, you should adjust existing, or implement new, practices to protect harvested covered produce from contamination during handling, as needed. Practices to consider include: avoiding contact between the cut surfaces of covered produce and soil, and reducing damage to harvested covered produce to the extent practical; and packing and holding covered produce in a manner that minimizes the potential for contamination.

You should establish procedures to ensure that harvesting, packing and holding practices protect against contamination of covered produce. Personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive training related to handling harvested covered produce, as applicable. (See 21 CFR 112.22(a)(3)). These personnel should understand your practices to protect harvested covered produce. Furthermore, personnel you assign to supervise or otherwise be responsible for your operations should ensure that other personnel consistently implement practices to protect harvested covered produce against contamination. We provide further draft guidance on training in Chapter 2: Personnel Qualifications and Training (Subpart C).

Contamination could be transferred to harvested covered produce when contact occurs between the covered produce, especially at cut surfaces, and the soil. Preventing unnecessary contact could reduce the likelihood of pathogen transfer (Ref. 36) (Ref. 90). For example, during lettuce harvest, you should place harvested lettuce heads that have been cut from the root on a clean surface while waiting for trimming, rather than placing them directly on the soil.

Bruises, punctures, or other injuries to harvested covered produce create potential pathways for pathogens to contaminate the covered produce and multiply (Ref. 5) (Ref. 4) (Ref. 67). Personnel should understand which activities will likely result in damage. You could consider practices to protect against contamination of harvested covered produce through damage, such as the following:

- Ensuring harvest containers are free from rough edges or other rigid protrusions;
- Avoiding rough handling when transferring covered produce from one container to another or to a different surface, such as a hopper, table, or belt;
- Avoiding overfilling containers, which can crush or damage covered produce;
- Ensuring that personnel use equipment and tools consistent with your procedures and in a way that minimizes damage to covered produce.

## **4. Dropped Covered Produce**

You must not distribute dropped covered produce. (21 CFR 112.114). Dropped covered produce is produce that drops to the ground before harvest and does not include:

- Root crops that grow underground (such as carrots);
- Crops that grow on the ground (such as cantaloupe); or

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- Produce that is intentionally dropped to the ground as part of harvesting (such as almonds). (21 CFR 112.114).

Covered produce is subject to the requirements in 21 CFR 112.114 unless it is specifically identified as not being included within the meaning of “dropped covered produce” as provided in 21 CFR 112.114. Some covered produce, like almonds, may be intentionally dropped to the ground as part of harvesting (e.g., by shaking the almond tree). This type of harvesting generally occurs with produce that have an inedible, hard outer layer, and an edible, relatively durable inner layer. However, most covered produce, including some with an inedible outer layer or rind and soft-fleshed, inner layer, can be damaged by the force of the impact when dropped to the ground. For covered produce crops that typically are not dropped to the ground during harvest, some could nonetheless fall to the ground, often resulting in damage to or contamination of the covered produce. This damage may not be visible for several days or weeks. The damage could introduce or cause an increase of pathogens (Ref. 5) (Ref. 4). For example, peaches that drop from the tree are likely to impact the ground with a force that can cause damage to the surface of the fruit and allow for the introduction of pathogens into the flesh of the fruit. Produce that grows off the ground, such as peaches or tomatoes, and that drops to the ground before harvest is considered dropped covered produce, even if the produce is still attached to the plant when it contacts the ground. You should establish procedures that ensure that you do not distribute dropped covered produce.

Personnel who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive training related to dropped covered produce, as applicable. (See 21 CFR 112.22(a)(3)). You should train your harvest personnel, and personnel you assign to supervise or otherwise be responsible for your operations, to avoid harvesting dropped covered produce. These personnel should understand your practices related to dropped covered produce. Personnel who supervise harvesting, or other responsible parties, should ensure that personnel who conduct harvesting do not include dropped covered produce with covered produce that will be distributed. Furthermore, personnel you assign to supervise or otherwise be responsible for your operations should ensure that other personnel consistently implement practices to not distribute dropped covered produce. We provide further draft guidance on training in Chapter 2: Personnel Qualifications and Training (Subpart C).

## **5. Packaging Covered Produce**

You must package covered produce in a manner that prevents the formation of *Clostridium botulinum* toxin, if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms). (21 CFR 112.115). Produce containing *C. botulinum* toxin could have no visual indication that toxin is present (i.e., it may not appear contaminated or spoiled), so prevention is essential (Ref. 26) (Ref. 127). Mushrooms develop *C. botulinum* toxin when packaged under certain conditions (Ref. 62) (Ref. 127). Modified atmosphere or other reduced-oxygen packaging of produce other than mushrooms could present a similar risk for botulinum toxin formation depending on factors including produce type and respiration rate, pH, water activity, temperature, oxygen concentrations, initial *Cl. Botulinum* spore levels, and the presence and types of other microflora (Ref. 50) (Ref. 62).

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Most covered produce continues to respire (i.e., breathe) after it is packaged (Ref. 7) (Ref. 120). If the covered produce is packaged in an oxygen-impermeable film, the continued respiration can decrease the level of oxygen and increase the level of carbon dioxide within the package, creating conditions favorable for *C. botulinum* toxin formation (Ref. 67) (Ref. 127). The necessary time for toxin formation varies depending upon the temperature and other conditions. The minimum temperature for *C. botulinum* growth and toxin formation is 38°F (3.3°C) (Ref. 76) (Ref. 118) (Ref. 123).

If *Clostridium botulinum* toxin is a known or reasonably foreseeable hazard, and you package your covered produce, you must do so in a manner that prevents the formation of *C. botulinum* toxin. (21 CFR 112.115)). You should consider your practices and procedures as well as conditions that could occur during distribution, including temperature fluctuation and exceeding set holding temperatures. Some measures for covered produce that could help prevent the formation of *C. botulinum* toxin when identified as a known or reasonably foreseeable hazard include:

- Creating conditions that are less favorable for *C. botulinum* growth and toxin formation, such as using open, perforated, or otherwise oxygen-permeable packaging and packing materials, to allow for gas exchange (i.e., for atmospheric oxygen to replenish the oxygen used by covered produce respiration);
- When conditions are more likely to favor *C. botulinum* growth and toxin formation:
  - Using antimicrobial compounds, or other treatments, that are effective to prevent the growth and toxin formation by *C. botulinum*;
  - Maintaining the temperature of the packaged covered produce below 38°F (3.3°C); and
  - Using time-temperature integrators (trackers) for covered produce to signal when a cumulative time-temperature combination that presents a risk for *C. botulinum* toxin formation is reached.

## **6. Food-Packing Material**

Farms typically place harvested covered produce in containers (i.e., food-packing materials) for various purposes, such as collecting, conveying, or distributing. Some farms use containers to transport harvested covered produce from growing areas to packing areas, where the covered produce is then packed (or repacked) for distribution. For example, food-packing materials include containers used to collect harvested covered produce (e.g., harvest bins, buckets, and totes) in growing areas and transport the covered produce to a packing or holding area. In other instances, harvest containers, such as fiberboard boxes into which the covered produce is placed when harvested, could be the same containers in which covered produce is distributed (e.g., when covered produce is field-packed). Food-packing materials also include “food-packaging materials,” a term that has long been used (such as in FDA’s human food CGMP regulations in 21 CFR part 117, subpart B (previously 21 CFR Part 110)) to generally refer to a container that directly contacts the food.

When you use a food-packing material, it must be adequate for its intended use, which includes being:

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- Cleanable or designed for single use; and
- Unlikely to support growth or transfer of bacteria. (21 CFR 112.116(a)).

You should take the following steps to help you determine whether food-packing material is adequate for its intended use on your farm:

- Identify the types of food-packing materials that you use, and determine whether each type is reusable or for single use;
- Determine whether your food-packing materials are unlikely to support the growth or transfer of bacteria, taking into consideration your handling, maintenance, and storage practices; and
- Determine whether reusable materials can be cleaned, taking into consideration your handling, maintenance, and storage practices.

Food-packing materials (including food packaging materials) are subject to the provisions of both 21 CFR 112.116(a) (subpart K) and 21 CFR 112.123(a) (subpart L). To minimize redundancy and help provide clarity in our draft guidance on food-packing materials, we provide draft guidance on the aspects of the materials themselves in this chapter. We provide draft guidance on other regulatory requirements of the Produce Safety Rule related to food-packing materials, including maintenance, storage, and inspection, in the section of Chapter 7: Equipment, Tools, Buildings, and Sanitation (Subpart L), titled “Equipment and Tools.”

Pathogens can become established in, grow in, or be transferred from materials that have cracks, pits, jagged edges, rough areas, score marks, or other damage; these conditions increase the potential for certain materials to introduce contamination to covered produce (Ref. 128) (Ref. 130) (Ref. 134). Both porous and non-porous materials can facilitate contamination if they are damaged or their surfaces are not intact (Ref. 10) (Ref. 20) (Ref. 83) (Ref. 92) (Ref. 124).

**a. Identifying Single-Use and Reusable Food-Packing Materials**

To ensure that you use a food-packing material that is adequate for its intended use, you should first identify the types of food-packing materials you use and determine whether they are reusable or designed for single use. Generally, single-use packing materials are nondurable (e.g., easily susceptible to damage), or not easily cleaned (e.g., bags that can be torn, fiberboard that loses integrity or disintegrates when contacted by water or cleaning solutions). Examples of single-use food-packing materials include clamshells used for retail packaging of berries, and foam sleeves used to protect Asian pears from bruising during distribution. You should not reuse food-packing materials that are designed for single use. Although some single-use food-packing materials could be sufficiently sturdy for multiple uses, they may not be cleanable after use and, when reused, could then serve as a source of contamination or support bacterial growth or transfer (Ref. 10). Generally, some materials, such as fiberboard or foam, may not be suitable to reuse as packing materials because they are likely to support the growth of bacteria or cannot be adequately cleaned because the structure of the material prevents removal of organic material and bacteria or traps moisture, or the materials could degrade during cleaning (Ref. 10) (Ref. 53) (Ref. 136).

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**b. Evaluating Your Practices and Food-Packing Materials**

You should periodically evaluate your practices, including handling, maintenance, and storage of your food-packing materials, to determine whether, under the conditions, your food-packing materials are adequate for its intended use, including being unlikely to support the growth or transfer of bacteria and whether your reusable packing materials are cleanable. Your practices or use of food packing materials could change over time, and you should account for these changes as appropriate; periodic evaluations can assist you with ensuring that you consider any changes. You should consider several factors that influence whether food-packing materials are adequate for their intended use, including:

- The type of the material (e.g., plastic, metal, wood, foam, cardboard);
  - The nature of the material (e.g., smooth, course, absorbent, porous, non-porous, or); and
  - The durability of the material (e.g., fragile, malleable, firm, sturdy);
- The construction (e.g., solid, stapled, hollow components);
- The food-packing material handling practices (i.e., how carefully they are handled during receiving, storage, and preparation for use);
- The existing condition of the material (e.g., intact, damage, surface abrasions);
- The characteristics of the covered produce for which the packing material is used (e.g., heavy, light, hard shell, soft skin, moist, dry);
- How the covered produce is placed into the food-packing material (e.g., by hand or by machine and how that can impact the potential for damage to the food-packing material);
- Use of single-use, clean liners in otherwise reusable food-packing materials;
- The impact of sanitation procedures (i.e., the cleaning and, when necessary and appropriate, sanitizing process), treatments or chemicals used, and devices used on the food-packing material;
- The storage conditions (e.g., outdoor vs. indoor); and
- The maintenance practices (e.g., approaches to repair or replace worn or damaged components).

The following are examples using the principles and recommendations discussed in this section to illustrate approaches to evaluating food-packing materials and their use based on the requirements of 21 CFR 112.116 and 21 CFR 112.123. To minimize redundancy, concepts related to maintenance, storage, inspection, cleaning, and when necessary and appropriate, sanitizing, are discussed in examples found in the section of Chapter 7: Equipment, Tools, Buildings, and Sanitation (Subpart L), titled “Equipment and Tools”. These examples are intended to illustrate concepts, and are not intended to be universally applicable. For illustrative purposes, we identify specific covered produce in these examples. Even if you use similar materials or practices for the specific covered produce mentioned here, you should perform your own evaluation based on your farm’s specific practices and conditions.

**a. Example 6b: Plastic bags**

A farm uses plastic bags for field packing celery in the growing area for distribution to retail stores. The farm evaluates the plastic bags and their use, and concludes the following:

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- The bag material is primarily polyethylene, which is:
  - smooth and non-absorbent; and
  - fragile (e.g., can be torn) and malleable;
- The bag construction does not include voids or seams that could trap organic material or bacteria;
- The bags are received from the manufacturer in containers that protect them from damage, and the farm's procedures confirm the bags are in sound condition upon receipt;
- The bag handling practices typically do not result in damage prior to use;
- During field packing, each bag's condition is intact and the bags are not reused;
- The celery has a firm surface that is usually dry; and
- The bag is sufficiently durable to withstand the celery being placed by hand into the bag.

The farm determines that the bags are suitable to distribute the celery and are a single-use food-packing material, and continues to periodically evaluate the use and handling of the bags.

b. Example 6c: Wax-impregnated, corrugated fiberboard boxes

A farm places honeydew into wax-impregnated, corrugated fiberboard boxes for distribution. The farm evaluates the waxed, corrugated fiberboard boxes and their use, and concludes the following:

- The box material is wax-impregnated, corrugated fiberboard, which is:
  - smooth and porous, with the wax surfaces having some moisture resistance; and
  - fragile and malleable (e.g., can be bent, dented, or torn);
- The box construction includes open seams that could trap organic material or bacteria;
- The boxes are received from the manufacturer on shrink-wrapped pallets that protect them from damage, and the farm's procedures confirm the boxes are in sound condition upon receipt;
- The box handling practices typically do not result in damage prior to use;
- During packing, each box's condition is intact, and the boxes are not reused;
- The honeydew has a firm surface that is usually dry; and
- The boxes are sufficiently durable to withstand the honeydew being placed by hand into the box.

The farm determines that the boxes are suitable to distribute the honeydew and are a single-use food-packing material, and continues to periodically evaluate the use and handling of the boxes.

## **Chapter 7: Equipment, Tools, Buildings, and Sanitation (Subpart L)**

Maintaining sanitary conditions where covered activities occur is critical to prevent contamination of covered produce from the surrounding environment (including buildings, sanitation systems, equipment, and tools) (Ref. 16). A lack of sanitation can promote harborage of pathogens in the environment, which can increase the likelihood of contamination of covered produce (Ref. 16) (Ref. 52) (Ref. 53) (Ref. 79) (Ref. 108).

This chapter provides draft guidance on the requirements of subpart L—Equipment, Tools, Buildings, and Sanitation. The discussion is divided into sections on: equipment and tools; buildings; other sanitation measures; and records. Where applicable, we recommend evaluating your relevant practices, procedures, and processes periodically to ensure that you consider the scope of your relevant activities or operations and any changes that occurred and how they are affected by and relate to your equipment, tools, buildings, and sanitation and the requirements of the Produce Safety Rule. During such evaluations, you should consider not only typical practices, but also those that occur infrequently or due to unusual circumstances, to account for the breadth of procedures, processes, and practices associated with a given activity.

### **1. Equipment and Tools**

Farms use many types of equipment and tools. Several factors affect the ability of equipment or tools to be adequately cleaned or properly maintained, including: the type of materials; the design, construction, or workmanship; wear or damage; and cleaning practices. This section provides more detailed draft guidance related to these topics.

In this chapter, we provide draft guidance related to equipment and tools 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, as described in 21 CFR 112.121. You should take the following steps based on the requirements of the Produce Safety Rule related to equipment and tools:

- Identify equipment and tools on your farm that are intended to, or likely to, contact covered produce, including instruments and controls used to measure, regulate, or record conditions;
- Evaluate the design, construction, workmanship, installation, and maintenance of these equipment and tools;
- Evaluate your storage and maintenance practices and storage locations for these equipment and tools;
- Establish procedures and schedules for cleaning, and, when necessary and appropriate, sanitizing, food contact surfaces of these equipment and tools;
- Establish procedures and schedules to conduct inspections of these equipment and tools;
- Evaluate your use of transport equipment with covered produce; and
- Evaluate the accuracy, precision, maintenance and numbers of instruments and controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance.

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**a. Identifying Equipment and Tools Intended or Likely to Contact Covered Produce**

You should visually assess your covered activities and your growing, harvesting, packing, and holding areas to identify the equipment and tools that are intended to, or likely to, contact your covered produce. The way you handle covered produce while using equipment or tools, or vice versa, can affect whether contact is likely, as illustrated in the following examples:

Example 7a: If you pack covered produce on a stainless steel table permanently attached to a wall, you could find that the covered produce frequently contacts the surface of the wall. In this case, you should consider both the table and the wall to be pieces of equipment that are intended or likely to contact covered produce.

Example 7b: If separate guards or shields placed near other equipment occasionally contact covered produce or produce rinse water spray routinely rebounds from the guard or shield to a food contact surface, you should identify these guards and shields as pieces of equipment that contact or are likely to contact covered produce.

**b. Design, Construction, and Workmanship**

For equipment and tools subject to this subpart, you must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained. (21 CFR 112.123(a)). The considerations are the same whether you design your own equipment and tools, purchase them prefabricated, or repurpose them.

Food-packing materials (including food packaging materials) are subject to the provisions of 21 CFR 112.116(a) (Subpart K) and 21 CFR 112.123(a). We provide draft guidance on the aspects of the materials themselves in the section of Chapter 6: Growing, Harvesting, Packing, and Holding Activities (Subpart K) titled “Food-Packing Material.” We provide draft guidance on other regulatory requirements of the Produce Safety Rule related to food-packing materials in this section on “Equipment and Tools.”

**i. Evaluating Materials**

You should evaluate the materials used to make your equipment and tools. You should consider whether the materials from which they are constructed will affect whether they can be adequately cleaned or properly maintained under the conditions of their use and throughout the period of their use, considering: stress and strain during use; environmental conditions during use or storage (e.g., wet, humid, dry); and the process of, and treatments used during, cleaning and, when applicable, sanitizing. Equipment and tools made of non-porous materials, such as stainless steel and food-grade plastic (e.g., PVC, nylon), could allow for a wider range of effective cleaning methods; whereas porous material, such as fabric, cardboard, foam, and carpet, can trap moisture, making it difficult to remove organic material and bacteria.

We recommend that you use equipment and tools made from non-porous materials to the extent practical. However, we understand that covered farms sometimes use porous materials such as wood, fabric, or foam when conducting covered activities. If you choose to use equipment and tools made of these materials, the equipment and tools must be of adequate design, construction,

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and workmanship to enable them to be adequately cleaned and properly maintained. (See 21 CFR 112.123(a). We provide further draft guidance on cleaning and sanitizing in of the section of this chapter titled “Cleaning and Sanitizing Equipment and Tools.”

**ii. Evaluating Design, Construction, Workmanship, and Seams**

You should evaluate the design, construction and workmanship of your equipment and tools, including whether the equipment and tools:

- Allow for access to all the components for cleaning, maintenance, and, when appropriate, inspection; and
- Limit the potential for moisture or organic material to accumulate on or within the components of the equipment or tool, and subsequently to drip or drain onto covered produce or spread contamination.

For example, equipment and tools should not have openings to hollow areas that are not otherwise accessible for cleaning and maintenance.

You could choose to seek more information from sources such as equipment manufacturers, academia, extension services, industry associations, and government agencies to assist you with this evaluation.

Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms. (21 CFR 112.123(c)). The materials and surfaces of equipment and tools should not have pits, corrosion, cracks, crevices, partially open seams, poorly bonded welds, rough areas or other damage. Such defects can allow for the accumulation of moisture and organic material and can harbor or transfer bacteria (Ref. 128) (Ref. 130) (Ref. 134).

You should repair or replace any equipment or food contact surface that is damaged in a way that it can no longer be adequately cleaned or properly maintained. (See 21 CFR 112.123(a)).

**c. Installation and Maintenance**

Equipment and tools must be installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces. (21 CFR 112.123(b)(1)). You should evaluate the installation and maintenance of your equipment and tools, and you should visually assess your farm’s activities to confirm your practices. You should consider the potential for installed equipment or tools to accumulate moisture, organic material, or other potential sources of contamination that could contact, drip or drain onto covered produce or food contact surfaces. You should also consider the potential for surrounding surfaces to transfer moisture, organic material, or other potential sources of contamination onto covered produce or food contact surfaces of your equipment and tools.

You should install equipment so that maintenance and cleaning personnel can easily access all food contact surfaces, protective coverings or barriers, equipment framework, any movable parts,

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and other relevant parts. For example, parallel conveyor belt systems should be installed with enough space between the systems to allow personnel to easily access the lines to perform maintenance, cleaning, and production activities. This should include access to the belts, the framework supporting the belts, any enclosed housings for electrical components, and the points at which the framework is secured. Maintenance and cleaning personnel should also have access to adjacent spaces, such as the floors, walls, ceilings, and other equipment and tools in the immediate vicinity. For example, if a conveyor belt system becomes loose and drags on the floor as it rotates, personnel should have access to repair or replace the conveyor belt system. In this example, you or your personnel should also determine whether any damage occurred to the equipment or the floor, any necessary steps to clean and, when necessary and appropriate, sanitize the equipment and floor, and whether any other measures are necessary.

The condition of your equipment and tools, including their surfaces, is likely to degrade over time due to age, wear, or damage. Such degradation could result in cracks, crevices, pits, jagged edges, rough surfaces, score marks, and other conditions or damage that can allow the potential for contamination. You should evaluate your inspection and maintenance practices to ensure that you periodically assess for, and correct, any defects as soon as they are identified. You should repair or replace any equipment or tool that is damaged in a way that it can no longer be adequately cleaned or properly maintained. (See 21 CFR 112.123(a)).

In some instances, maintenance practices could include repair. There are several options to address the condition of equipment and tools, including refinishing, resurfacing, or removing and replacing components to reestablish cleanable surfaces. For example, re-welding or grinding rough seams can smooth the surface and re-establish cleanability. In another example, a scored table top could be resurfaced or replaced.

**d. Storage**

Equipment and tools (including food-packing materials) must be stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting or harboring pests. (21 CFR 112.123(b)(2)). You should evaluate your storage locations periodically to determine the potential for contamination of equipment and tools stored in them, and note their proximity to potential sources of contamination. For example, storage areas or buildings located near tree lines could increase the potential of rodent infestation (Ref. 95) (Ref. 135), which could warrant different procedures to protect covered produce from being contaminated with known or reasonably foreseeable hazards. Storage areas, including outdoor storage areas and storage areas in partially-enclosed buildings, can attract pests and serve as a harborage for pests (Ref. 95) (Ref. 135), especially if equipment and tools are stored for extended periods. See the section of this chapter titled “Pest Control” for further draft guidance on the control of pests.

You should establish procedures to ensure that equipment and tools (including food-packing materials) are stored in a manner based on the requirements of 21 CFR 112.123(b)(2). For example, you could find that sorting equipment used for daily field packing during the season can be protected overnight (after cleaning, and sanitizing as necessary and appropriate, at the end of the production cycle) by storing it in a partially-enclosed building with a clean covering (e.g., a tarp) over the sorting equipment to protect it from pests such as birds, accumulating debris, and

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weather or other conditions. However, you could determine the sorting equipment will not be protected from contamination from pests, such as rodents, if it is stored long-term in a partially-enclosed building. You could determine, for example, that these pieces of equipment should be stored long-term in a fully enclosed building, where rodents can be more easily controlled.

Equipment and tools should be clean and dry before storage to minimize the attraction of pests and protect covered produce from being contaminated. Additionally, you should close or cover any openings into the equipment or tools to reduce the potential for pests to enter (e.g., placing a tarp over food contact surfaces, capping openings of pipes to prevent birds or rodents from nesting) (Ref. 80). You could determine that a deep cleaning, and sanitizing as necessary and appropriate, procedure (i.e., beyond routine procedures) is appropriate when removing certain equipment and tools from storage. See more draft guidance on cleaning and sanitizing in the section of this chapter titled “Cleaning and Sanitizing Equipment and Tools.

Equipment and tools, including food-packing materials, must be protected, including during outdoor storage, from sources of contamination (See 21 CFR 112.123(b)(2), such as dust, dirt, and debris, or cleaned prior to use (See 21 CFR 112.123(d))). You should periodically inspect your storage of equipment and tools, including food-packing materials, that are intended to, or likely to, contact covered produce to ensure they are protected from contamination and do not attract or harbor pests. You should establish procedures for inspection of your storage areas, including the frequency of these inspections, the personnel involved, and conditions that should be reported to you, a supervisor, or responsible party.

**e. Inspection**

You must inspect all food contact surfaces of equipment and tools (including food-packing materials) that are used in covered activities as frequently as reasonably necessary to protect against contamination of your covered produce. (See 21 CFR 112.123(d)(1)). You should also consider inspecting non-food contact surfaces of equipment and tools. You could perform these inspections as independent activities or in conjunction with other activities, such as cleaning, sanitizing, or scheduled maintenance. Periodic inspection of your equipment and tools can help you to identify signs of potential contamination (e.g., visible soil, food residue, grease, or other material) and determine whether maintenance, replacement, or cleaning, or sanitizing is necessary.

You should establish and communicate procedures for inspecting equipment and tools (including food-packing materials), the frequency of these inspections, the personnel involved, and conditions that should be reported to you, a supervisor, or responsible party to determine appropriate steps to protect covered produce. Personnel, to whom you assign the responsibility for the inspection of food contact surfaces of equipment and tools (including transport equipment and instruments and controls, discussed in other sections of this chapter), or who are engaged in the supervision thereof, should understand your procedures for performing inspections. You should direct your supervisors or other responsible parties to ensure that your personnel are consistently inspecting equipment and tools in accordance with your procedures and making corrections as needed. You should also establish procedures to communicate your expected practices when personnel observe unclean, damaged, or worn equipment and tools, including food-packing materials. For example, personnel you assign to inspect food-packing materials

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and those who supervise or are otherwise responsible for your operations involving food-packing materials should recognize food-packing materials that can no longer be cleaned. In this example, supervisors and other responsible parties should ensure that only food-packing materials adequate for their intended use are being used. Your evaluation of your equipment, tools and practices can guide you in developing your inspection procedures.

You should perform inspections after each cleaning activity and before using equipment and tools to ensure that the cleaning activity was effective in removing residue from previous activities and that the equipment and tools remain clean during periods of storage. Inspections should include visually assessing for remaining residues, such as visible soil, food residue, grease, or other material. In some instances, performing inspections on dry equipment and tools can make it easier for personnel to see remaining residues such as visible soil than if the inspection is performed when the surface is wet. The visual assessment should include the entirety of the equipment or tool, including areas that are difficult to access or clean, such as the underside of equipment (which could require the use of lights or other visual aids).

The frequency at which you inspect the condition of your equipment and tools (e.g., for pitting, cracking, damage, partially open seams, excessive wear that provides harborage areas for moisture, organic material, and pathogens) is dependent upon the nature of the equipment or tool and its use. When determining your inspection frequency, you should consider factors including:

- The materials used (e.g., the type, nature, and durability of metal, plastic, wood, or fabric materials);
- The construction technique (e.g., the durability of welded or bolted construction);
- The conditions of use, including impact, abrasion, characteristics of covered produce, such as weight, texture, hardness;
- The cleaning process and treatments used (e.g., reactivity with the materials, abrasion from scrubbing or scraping);
- The storage conditions of the equipment or tool (e.g., potential damage from outdoor or indoor storage);
- The climate (e.g., high humidity could result in more rapid deterioration);
- The age of the equipment and tools (i.e., wear and damage associated with age); and
- How often the equipment and tools are used (i.e., wear and damage associated with use).

Based on your evaluation of these factors, you could, for example, choose to establish different inspection frequencies for different types of equipment and tools. For example, you could determine that you need to implement a more frequent inspection schedule, such as daily or weekly, for equipment or tools that are frequently used or are likely to become worn or damaged relatively quickly (e.g., those with materials such as fabrics or thin blades, or those that are used under intense conditions). Or, for example, you could find that for equipment and tools that are of highly durable construction or receive infrequent or light use, you can inspect them less frequently (e.g., at the beginning of each growing season and monthly thereafter).

You should inspect single-use food-packing materials upon receipt or immediately before use to protect against contamination of your covered produce. Generally, if single-use or reusable food packing materials are stored in a way, or location, where there is a potential for contamination,

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they should be inspected before use. For example, your procedures could specify that your personnel will inspect reusable harvest containers prior to use, identify and set aside unclean or damaged containers, and notify a supervisor or responsible party of any unclean or damaged containers.

The outcomes of your inspections should guide your decisions about continued use of your equipment and tools. You could determine that replacing certain equipment or tools or adjusting equipment or tool placement, storage practices, or maintenance, cleaning, or sanitizing practices is necessary to minimize the potential for contamination of covered produce and food contact surfaces. For inspections performed after each cleaning activity and before using equipment and tools, you could find that additional steps are necessary prior to using the equipment or tools.

**f. Examples**

The following examples use the principles and recommendations discussed so far in this chapter to illustrate how a farm could evaluate their equipment and tools, conditions and practices based on the requirements. The approaches described may not be appropriate for every scenario based on a farm's circumstances. For illustrative purposes, we identified specific covered produce for these examples. Even if you use similar practices for the specific covered produce mentioned here, you should perform your own evaluation based on your farm's specific conditions and practices; there could be circumstances where your practices and conditions would lead you to a different determination than the outcomes in the examples. In these examples the farm visually assesses and evaluates their procedures to determine whether the equipment and tools covered by subpart L that they use are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained based on the requirements of 21 CFR 112.123(a). The farm also determines whether seams on food contact surfaces of these equipment and tools are either smoothly bonded or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms based on the requirements of 21 CFR 112.123(c). Further, in these examples, the farm determines whether the equipment and tools are stored and maintained to protect covered produce from being contaminated and to prevent them from attracting and harboring pests based on the requirements of 21 CFR 112.123(b)(2). Finally, in these examples, the farm determines whether the food contact surfaces of the equipment and tools are inspected and maintained as frequently as reasonably necessary to protect against contamination of covered produce based on the requirements of 21 CFR 112.123(d)(1). We discuss approaches to cleaning, and, when necessary and appropriate, sanitizing equipment and tools in the section of this chapter titled "Cleaning and Sanitizing Equipment and Tools." Your practices or procedures or use of your equipment or tools could change over time, and you should account for these changes as appropriate; periodic evaluations can assist you with ensuring that you consider any changes that occur.

*Examples of farm evaluations that do not lead to a change in equipment or tools, practices or procedures:*

Example 7c. Harvest trailer with a wooden floor for hauling watermelons.

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A farm uses a harvest trailer with a wooden floor to carry watermelons from the field to a packing area. The farm observes that the harvest trailer typically remains dry during use, and that the watermelons remain intact, with very few observations of damage to the watermelons that could result in watermelon residue or liquid from the watermelons leaking onto the trailer. The farm's procedures specify that the harvest trailer is to be kept clean and dry, maintained (e.g., free from splinters and cracks), and stored in a way that protects it from moisture, damage, and contamination, such as in a covered storage shed or garage to minimize the potential for contamination. The farm directs their personnel using the trailer to inspect it for cleanliness and damage both prior to use and after each load, to maintain the trailer, and to clean the trailer by removing organic material, debris, and other material as necessary. Personnel ensure that they do not place moist or damaged watermelons into the trailer. The farm determines that their procedures are consistently followed by personnel, continues to use the harvest trailer, and periodically evaluates their practices and procedures.

**Example 7d. Storage and inspection of plastic bags.**

A farm uses single-use plastic bags for packing celery in the growing area. The farm evaluates their storage, inspection and handling practices for this material from the time of its receipt until it leaves the farm. The farm receives the plastic bags in containers on a pallet. The farm stores and maintains the bags as received from the supplier in a fully enclosed building in a clean, dry environment until ready for use. Any plastic bags that are not used at the completion of field packing are covered, transported and stored in a fully enclosed building on pallets. When the farm is ready to use the material, the pallets are transported to the growing area, and the bags are inspected when they are loaded onto the packing equipment. If they find any signs of potential contamination they do not use the bags and report the conditions to a supervisor or other responsible party. Further, a supervisor or other responsible party inspects the storage area weekly. The farm continues to periodically evaluate their practices and procedures.

**Example 7e. Storage and inspection of wax-impregnated corrugated fiberboard boxes stored in a partially-enclosed building.**

A farm packs honeydew inside a partially-enclosed building and uses single-use, waxed, corrugated fiberboard boxes. The unformed fiberboard boxes are received and stored in shrink-wrap. The farm's procedures specify that the boxes are to be stored indoors in a clean, dry environment. Additionally, they specify that, when in the packing area, the unformed and formed boxes are kept on a pallet in a clean, dry area, away from personnel and equipment traffic, that each pallet is unwrapped on an as-needed basis, and that any unused boxes are to be moved to the indoor storage area daily when packing activities conclude. They also specify that personnel are to inspect the boxes for any signs of potential contamination, damage, or poor condition (e.g., moisture) prior to using them; and that if they find such evidence, they are not to use the boxes and are to report the conditions to a supervisor or other responsible party. Further, they specify that a supervisor or other responsible party is to inspect the location where the boxes are kept in the packing area periodically during the day to ensure that personnel follow these practices, and that a supervisor or other responsible party is to inspect the packaging storage area weekly. The farm continues to periodically evaluate their practices and procedures.

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Example 7f. Storage and inspection of harvest containers stored outdoors.

A farm uses reusable plastic harvest containers to transport and hold pears. The containers are stored outdoors. The farm's procedures specify that the containers are to be cleaned prior to use. They specify that the container storage area is to be inspected by a supervisor or other responsible party twice a week. Also, they specify that personnel are to inspect the containers for cleanliness, damage, and poor condition immediately prior to use to protect the pears that contact them from contamination. Further, they specify that when personnel observe damage to containers to the extent that they can no longer be properly cleaned, the containers should be discarded. The farm continues to periodically evaluate their practices and procedures.

Example 7g. Storage and inspection of harvest containers stored outdoors with temporary storage in the growing area.

A farm uses reusable wood harvest containers to transport cabbage for packing and holding. The containers are removed from an outdoor long-term storage area and temporarily stored outdoors in a growing area for several days prior to harvest. The farm's procedures specify that the long-term container storage area and the storage areas in each growing area are to be inspected by a supervisor or other responsible party twice a week. The farm's procedures specify that personnel are to clean and dry the containers as they are removed from long-term storage for use. They also specify that personnel are to inspect the containers immediately prior to use for cleanliness, damage, and poor condition. Further, they specify that unclean containers are to be set aside for re-cleaning or replacement, and that damaged containers that can no longer be properly cleaned should be repaired or discarded. The farm continues to periodically evaluate their practices and procedures.

*Examples of farm evaluations leading to a change in equipment or tools, practices or procedures:*

Example 7h. Harvest trailer with wooden floor for hauling tomatoes.

A farm uses a harvest trailer with a wooden floor to move tomatoes from the field to a packing area. The farm observes that the tomatoes are frequently damaged during loading and transport such that tomato residue or liquid leaks onto the wooden floor of the trailer. The farm determines that the wooden floor with tomato residue is difficult to clean and is not a suitable food contact surface under the circumstances. The farm changes their procedures to include placing a clean, durable, non-porous, food grade, single-use liner in the harvest trailer to minimize the potential for contamination of the tomatoes from the wooden floor of the trailer. The farm directs their personnel using the trailer to inspect the trailer and liners for cleanliness and damage prior to use, to maintain the trailer and to change the single-use liners between each load. The farm continues to periodically evaluate their practices and procedures.

Example 7i. Harvest trailer with carpeting material on the floor for hauling cantaloupe.

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A farm uses carpeting material on a harvest trailer used to convey cantaloupe. The farm observes that the carpeting material reduces product bruising but it also absorbs moisture and organic material that is difficult to remove. The farm determines that they cannot perform proper cleaning to maintain the carpeting material in a manner that protects against contamination. The farm removes the carpeting and uses materials that are of a design, construction, and workmanship that farm personnel can adequately clean and maintain. Depending on their circumstances, this could include using reusable materials, such as plastic, or single-use materials, such as foam or plastic, or a different vehicle. The farm continues to periodically evaluate their practices and procedures.

Example 7j. Table with a wooden food contact surface used to sort radishes.

A farm sorts radishes using a sorting table with a wooden surface on a metal support system. Farm personnel wash the radishes before sorting. While conducting its evaluation, the farm observes that the wooden surface of the table accumulates soil, residue, and moisture from the radishes during sorting, and the farmer determines that personnel cannot properly clean the wooden surface of the table manner that protects against contamination. The farm replaces the wooden top of the sorting table with a food grade material top that is of adequate design, construction, and workmanship that farm personnel can adequately clean and maintain. Depending on the circumstances, this could include stainless steel, plastic or other materials. The farm continues to periodically evaluate their practices and procedures.

Example 7k. Foam pads on equipment used to convey apples.

A farm uses foam pads on equipment used to convey apples. The foam pads contact the apples. The farm observes that the foam pads are not designed for frequent removal from the equipment which allows for the accumulation of dirt and other organic material, and the porous nature of the material allows for the accumulation of organic material on and underneath the pads. The farm determines that they cannot adequately clean the foam pads in a manner that protects against contamination given their equipment, conditions and practices. The farm evaluates several options, including:

- Replacing the foam pads as frequently as reasonably necessary to protect against contamination;
- Removing the foam pads;
- Adding a removable liner, such as a plastic liner, over the foam with adequate design, construction, and workmanship that personnel can adequately clean and maintain;
- Replacing the foam pads with a food grade material with adequate design, construction, and workmanship that enables personnel to adequately clean and properly maintain, such as a different type of foam, plastic or other material; or
- Replacing the equipment with that which has a design, construction, and workmanship that is more compatible with the farm's operations.

The farm could also choose to take a short-term approach, such as removing or replacing the pads, and develop a long-term plan to replace the equipment with that which has a design, construction, and workmanship that is more compatible with the farm's operations. The farm continues to periodically evaluate their practices and procedures.

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Example 7l. Inspection of harvest containers stored outdoors with evidence of contamination.

A farm uses reusable plastic harvest containers to transport nectarines to a holding area. The containers are stored outdoors. The farm's procedures specify that personnel are to inspect the containers immediately prior to use for cleanliness, damage, and poor condition immediately prior to use to protect the nectarines that contacts them from contamination. The farm determines that the storage area is to be inspected by a supervisor or other responsible party twice a week. A supervisor inspecting the storage area observes rodent excreta in some of the storage containers. Based on the outcome of the supervisor's inspection, the plastic harvest containers located in the area in which evidence of rodent infestation was observed are designated for cleaning and sanitizing or replacement, as appropriate. The farm also determines whether other measures are necessary, such as increasing the frequency of inspection and changes to pest control measures.

Example 7m. Foam pads in plastic bin containers to cushion cherries.

During harvesting, a farm uses foam pads to cushion cherries in plastic containers, and the foam pads contact the cherries. The farm observes that the pads become moist during refrigerated cooling, and the pads remain in place as the packing containers are transported to the packing area. The farm determines they have limited information on the effectiveness of cleaning porous foam materials, and gathers information from the manufacturer of the foam pads and from technical assistance resources to assist in their determination of whether the pads are appropriate for use as a reusable material. If the farm determines the foam pads can be cleaned and that, under their conditions of use, they are unlikely to support the growth of bacteria, then they could reuse the pads with appropriate cleaning. If the farm determines that the foam pads are not cleanable, they must not reuse them. (See 21 CFR 112.123). If the farm determines that single-use of the pads is unlikely to support growth or transfer of bacteria, then they could choose to designate them for single-use.

**g. Cleaning and Sanitizing Equipment and Tools**

Cleaning and sanitizing are different steps that are important to the safety of your covered produce. Unsanitary equipment and tools can serve as a source of contamination for produce (Ref. 8) (Ref. 10) (Ref. 48) (Ref. 108). You must inspect, maintain, clean, and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce. (21 CFR 112.123(d)(1)). You also must maintain and clean all non-food contact surfaces of equipment and tools subject to subpart L used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce. (21 CFR 112.123(d)(2). You should evaluate your equipment and tools by taking the following steps:

- Identify food contact surfaces and non-food-contact surfaces of equipment and tools; and

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- Determine cleaning practices, and, as necessary and appropriate, sanitizing practices for each type of equipment and tool, and the frequency at which you will perform these practices.

**i. Identifying Food Contact Surfaces and Non-Food Contact Surfaces of Equipment and Tools**

In the section of this chapter titled “Equipment and Tools,” we recommend that you identify all equipment and tools on your farm that are intended or likely to contact covered produce. For these equipment and tools, you should also identify their food contact surfaces and non-food contact surfaces.

“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.” (21 CFR 112.3). “Food contact surfaces” also includes food contact surfaces of equipment and tools used in growing covered produce (See 21 CFR 112.123(d)(1)).

You should carefully evaluate your practices during covered activities to identify the food contact surfaces of your equipment and tools. You should visually assess your covered activities to identify food contact surfaces during production activities. Some food contact surfaces could not be easily identified when production activities are not occurring. In particular, you should look for drainage, or other mechanisms of transfer (e.g., water splash) that occur. In some cases, you could have the flexibility to adjust your practices to avoid surfaces being considered food contact surfaces (see Example 7o). The following examples illustrate how a farm could evaluate their equipment and tools, practices and conditions to identify food contact surfaces and non-food contact surfaces. Even if you use similar equipment, tools or practices, you should perform your own evaluation based on your farm’s specific practices and conditions.

Example 7n: A farm observes that the fine mist of water from the nozzles of a spray bar over a conveyor belt containing covered produce contacts the bar itself, resulting in water dripping from the bar onto the covered produce; in this example, the farm should consider the spray bar a food contact surface.

Example 7o: A farm observes parsley protruding through openings in a plastic container that touches the table where the containers were placed, so the farm should consider the table a food contact surface. The farm could start placing a removable plastic surface between the containers and the table so that the table is not the food contact surface.

Example 7p: A farm observes a conveyor belt system used to move turnips and determines that the conveyor belt and some support bars underneath that contact the conveyor belt are food contact surfaces. The farm carefully evaluates the conveyor belt system to determine if other components are food contact surfaces, such as through drainage or other mechanisms of transfer. The farm identifies other components of the system, including the legs of the support structure for the conveyor belt system and the housings for electrical components, are not food contact surfaces.

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**ii. Cleaning and Sanitizing Procedures**

Once you have identified equipment and tools subject to subpart L, and the associated food contact surfaces, you should evaluate and determine appropriate cleaning practices and frequencies for food contact surfaces and non-food contact surfaces. You must inspect, maintain and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities, and maintain and clean all non-food contact surfaces of equipment and tools used during harvesting, packing, and holding, as frequently as reasonably necessary to protect against contamination of covered produce. (21 CFR 112.123(d)(1) and (2)). Cleaning and sanitizing activities should be performed both on a scheduled, periodic basis and in response to identified problems or potential contamination.

Periodically performing cleaning and sanitizing procedures, including deep cleaning and sanitizing procedures, can increase effective soil removal, biofilm prevention and removal, and pathogen inactivation (Ref. 18) (Ref. 38) (Ref. 83) (Ref. 134). You should consider performing deep cleaning and sanitizing, as necessary and appropriate, procedures (i.e., beyond routine procedures) on a scheduled, periodic basis. These procedures can involve additional or different activities, such as disassembling equipment for more targeted cleaning when your routine procedures involve cleaning the assembled equipment (Ref. 66) (Ref. 134). It can also involve using a different sanitizing compound than is typically used during routine procedures, in order to impact a broader range of potential microorganisms (Ref. 15) (Ref. 18) (Ref. 83) (Ref. 93) (Ref. 134).

Your cleaning methods should remove potential sources of contamination, including visible soil, food residue, grease, and other material. Cleaning methods can be broadly divided into wet cleaning and dry cleaning. Generally, wet cleaning is the most effective method to remove organic material (Ref. 15) (Ref. 82), and involves the use of water and cleaning solutions. There are a variety of different cleaning agents you can choose based on your specific needs. You should select a cleaning agent based on, for example, the structure of the items to be cleaned, and the nature of the potential contamination. Some options could include general purpose cleaners, alkaline and chlorinated detergents, or acid and enzyme detergents (Ref. 83) (Ref. 97). You could choose to work with technical assistance resources, such as cleaning and sanitation suppliers, academia, extension services, and industry associations to determine the most appropriate cleaning and sanitizing treatments for your operations.

In some circumstances, dry cleaning could be preferable to wet cleaning, such as when covered produce with dry surfaces are handled in a dry, low moisture environment. In certain situations, the introduction of water into the otherwise low moisture environment can increase the potential for growth of some pathogens that could be present; such pathogens would be unlikely to grow without the addition of water (Ref. 12) (Ref. 11) (Ref. 43). Dry cleaning typically involves mechanical action for the removal of organic material and other residues.

You should evaluate your production environment, covered produce, and equipment and tools you use to determine when you should sanitize and identify sanitizing methods appropriate for food contact surfaces of your equipment and tools. “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,

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but without adversely affecting the product or its safety for the consumer.” (21 CFR 112.3). Sanitizing can include the use of such substances as hypochlorite, chlorine dioxide, iodine, quaternary ammonium compounds, hot water, steam, dry heat, or ultraviolet light (Ref. 15) (Ref. 39) (Ref. 93) (Ref. 119).

You should consider the following list of factors that influence the effectiveness of cleaning procedures:

- *The pressure of water or air used during debris removal (e.g., pre-rinse and post-rinse for wet cleaning).* Overly low pressure could not effectively remove soil or debris from surfaces. However, if you are using high pressure when cleaning, you should take care to not spread contamination from one surface (e.g., floors, floor drains) to another, which can occur through splashing or aerosolizing (Ref. 18) (Ref. 66) (Ref. 134).
- *The material (e.g., plastic, stainless steel, concrete) of the surface to be cleaned and the method of construction of the equipment and tools (e.g., solid welded, bolted for disassembly).* We provide draft guidance on equipment and tool construction and its effect on cleanability in the section of this chapter titled, “Design, Construction, and Workmanship.”
- *The force and duration of physical scrubbing.* Low rates of force applied or short amounts of time spent scrubbing equipment and tools could result in only partial removal of soil and debris. On the other hand, overly aggressive or prolonged cleaning processes could damage equipment and tool surfaces, potentially resulting in surface scratches or other damage, which can serve as harborage sites for pathogens (Ref. 96) (Ref. 97) (Ref. 125).
- *The type and concentration of the cleaning agent or detergent.* You should refer to the label directions and manufacturer instructions for your detergents and other cleaning agents to ensure you use a concentration and method effective for your use, including the type of soil, residue, or material targeted for removal.
- *The contact time of the cleaning solution with the surface being cleaned.* Shortened contact time could result in only partial removal of soil and debris (e.g., the cleaning agent could not be able to fully loosen the debris from the surface or could leave a film or residue on your equipment or tools) (Ref. 38) (Ref. 97) (Ref. 125).
- *The characteristics and quantity of the soil and debris on the surface being cleaned.* Certain types of residues (e.g., oily or high protein) or large quantities of residues can impact the need to modify the other factors described above (e.g., use a highly alkaline detergent or a highly oxidizing cleaner for certain residues or increase contact time and physical scrubbing) (Ref. 97) (Ref. 125).

When choosing a sanitizing treatment, if one is appropriate and necessary, you should consider the following factors that influence their effectiveness, including:

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- *The material of the surface to be sanitized.* Some sanitizers are incompatible with some materials (e.g., products containing chlorine could lead to the degradation of some materials) (Ref. 93) (Ref. 125) (Ref. 105);
- *The type, duration, application method, temperature and concentration of the sanitizing or antimicrobial treatment* (Ref. 15) (Ref. 38). You should refer to the label directions and manufacturer instructions to ensure you use a concentration and method effective for your use;
- *The contact time of the sanitizing or antimicrobial treatment with the surface being treated.* Shortened contact time could cause incomplete treatment and excessive contact time could damage your equipment or tools (Ref. 38) (Ref. 125); and
- *Characteristics of the water you use to prepare the sanitizing agent.* The hardness (i.e., presence of minerals), pH, and temperature of your water could impact the effectiveness of the sanitizing agent and its compatibility with the surface being sanitized (Ref. 38) (Ref. 39) (Ref. 125) (Ref. 126).

The following steps are an example of a typical wet cleaning and sanitizing procedure (Ref. 94) (Ref. 125); some steps could not be applicable to your operation or could be modified (Ref. 38) (Ref. 94):

1. *Pre-Clean:* personnel use tools such as brushes, brooms, scrapers, and collection pans to remove heavy residue, plant material or debris from the equipment or tools.
2. *Initial Rinse:* personnel rinse the equipment or tools with water to remove additional organic material and residue that was loosened during the pre-clean step; scrubbing could be necessary during this step.
3. *Washing with Cleaning Agent and Mechanical Action:* personnel apply a cleaning agent in one of several forms, such as by spray or foam; personnel should ensure full coverage of the relevant surface with the cleaning agent for the time and at the temperature specified by the cleaning agent manufacturer; small equipment or tools or components of these can be washed in sinks or tanks containing a solution of the cleaning agent; mechanical action (e.g. scrubbing) ordinarily should be applied, using tools such as brushes or scouring pads, in order to fully remove organic material and residues.
4. *Post-Rinse:* personnel apply water to remove loosened soil and debris along with the cleaning agent; after the post-rinse the equipment and tools could be allowed to dry prior to further activities.
5. *Inspection:* personnel check the equipment or tools for any remaining soil or residue; additional draft guidance on equipment and tool inspection is found in the section of this chapter titled “Inspection.”
6. *Sanitize:* when necessary and appropriate, personnel apply antimicrobial treatments to clean, rinsed surfaces. Sanitizing is generally not effective unless it is preceded by a

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cleaning step, because residual organic material can protect pathogens from the action of the sanitizing treatment (Ref. 94) (Ref. 38) (Ref. 39) (Ref. 82) (Ref. 93). Antimicrobial treatments should be applied so that the treatment contacts all areas of the food contact surface. Care should be taken to ensure contact of the treatment with hard to reach places (e.g., edges of interlocking conveyor systems, gears and sprockets that contact covered produce, and the undersides of guards, covers, and ceilings, from which moisture could drip or drain onto the covered produce). This could be done by immersion (e.g., for small equipment and tools and their components), spraying, or flushing (e.g., for stationary equipment). You should consult the labeled instructions provided by the supplier. In some instances, antimicrobial treatments should be followed by rinsing.

Dry cleaning typically involves a pre-cleaning step to remove heavy residue, plant material, and debris, followed by a dry-cleaning step using mechanical action to further remove organic material and residue. Tools that are typically used for dry cleaning include vacuum systems, brushes, scrapers, and compressed air. An inspection should also be performed after dry cleaning to evaluate the effectiveness of the cleaning process. Generally, there are fewer options available for routine sanitizing of dry cleaned equipment and tools, and these may not be suitable for all circumstances.

***iii. Frequency of Cleaning and Sanitizing***

You should evaluate and establish cleaning frequencies for both food contact and non-food contact surfaces, as well as sanitizing frequencies for food contact surfaces, as necessary and appropriate. You should schedule cleaning and sanitizing of equipment and tools with food contact surfaces after storage, after relevant production cycles (e.g., daily or between shifts), or as otherwise necessary to protect against contamination of covered produce. In some cases, you could determine that cleaning for both the non-food contact surfaces and the food contact surfaces of equipment and tools should occur at the same frequency.

The following are some factors that you should consider when determining the frequency of cleaning and, when necessary and appropriate, sanitizing:

- Visual observations of the rate of accumulation of soil and debris;
- Whether the surface is a food contact surface;
- Whether the equipment or tools also are used for excluded produce (food contact surfaces of such equipment and tools must be adequately cleaned and sanitized, as necessary, before use on covered produce (21 CFR 112.111(b));
- The potential for contamination of the equipment or tool during use (e.g., more frequent cleaning and sanitizing could be necessary if a field-coring device regularly contacts the soil than if it is held away from the soil);
- The duration of the production cycle (e.g., 8, 12, 16 hours);
- Ambient temperature during use of the equipment and tools (the rate bacterial growth increases as temperature increases) (Ref. 38) (Ref. 126);
- The ability of produce residues to support the growth of pathogens (most support growth, but the rate of growth can be influenced by differences in moisture, water activity, nutrients, and inhibitory substances) (Ref. 38) (Ref. 126);

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- The design, construction, and workmanship of the equipment and tools (Ref. 38) (Ref. 94) (Ref. 125) (Ref. 134) (e.g., more frequent cleaning and sanitizing could be necessary for a conveyor system with interlocking belt pieces compared to a system with a single-piece, smooth belt because there could be a greater potential for accumulation of debris between the interlocking pieces); and
- The results of any testing that you perform (e.g., results showing high levels of microbial indicator organisms could necessitate more frequent cleaning).

You should consider the accumulation of soil, residue, or material during your covered activities and the potential for pathogen growth as you determine appropriate cleaning and sanitizing frequencies. You could find it useful to schedule periodic deep cleaning and sanitizing, as necessary and appropriate, procedures (i.e., beyond routine procedures) at a reduced frequency in comparison to your routine procedures.

You should consider performing a sanitizing step each time that you perform a complete wet cleaning procedure (e.g. steps 1-5 described in the section of this chapter titled “Cleaning and Sanitizing Procedures”) for equipment or tools. The process of cleaning followed by sanitizing enhances microbial removal and inactivation (Ref. 38) (Ref. 83) (Ref. 93) (Ref. 94). Further, depending on your established cleaning process, you could determine that performing a pre-clean step, or some portion of your cleaning procedures, should be performed at an increased frequency compared to that of the entire cleaning process to address heavy accumulation of residue (e.g., leaves, soil and other material) that could build up over the course of use. For example, a farm conveys cucumbers into a packing area; the farm’s procedures could specify that the pre-cleaning step be performed at least twice during a production shift to control accumulation of mud, stems, and other debris, and that a complete wet cleaning cycle, including sanitizing, be performed at the end of each day.

In some limited instances, you could determine that sanitizing food contact surfaces can occur at a reduced frequency compared to cleaning activities, particularly after dry cleaning. For example, if a farm that shells and packs walnuts determines that the shelling area should remain dry, the farm could determine that the shelling equipment should be dry cleaned daily, using brushes and compressed air to remove organic material and residue; this avoids introducing moisture from wet cleaning, which could increase the potential for pathogen growth and transfer. Further, the farm could determine that prior to the beginning of covered activities each season, or at a specified frequency, the shelling equipment should be disassembled, moved to a location outside of the dry production environment, wet cleaned, and the food contact surfaces sanitized; after thorough drying, the equipment would be reassembled in the production area.

You should also determine potential instances when cleaning and sanitizing of equipment or tools should occur outside your scheduled frequency. You should ensure that cleaning and sanitizing of food contact surfaces and non-food contact surfaces of equipment and tools occurs immediately when you discover or suspect that they are potentially contaminated (e.g., after contact with human or animal excreta, contaminated water, contaminated produce, excluded produce, or contaminated hands). For example, your procedures specify that a piece of equipment used for conveying gooseberries is cleaned and sanitized at the end of each production cycle; there could be circumstances where cleaning and, when necessary and appropriate, sanitizing the equipment must be performed before the scheduled time at the end of

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the production cycle, as reasonably necessary to protect against contamination. (See 21 CFR 112.123(d)(1)).

**h. Transport Equipment**

If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. (21 CFR 112.123(e)). Equipment subject to subpart L that you use to transport covered produce must be adequately clean before use in transporting covered produce, and adequate for use in transporting covered produce. (21 CFR 112.125).

You should identify the equipment used to transport covered produce, which could include trucks. If you determine that the transport equipment is not adequately clean, you could, for example, clean the equipment or choose to not use it. You should pay particular attention to the surfaces that contact covered produce.

**i. Instruments and Controls**

Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be: accurate and precise as necessary and appropriate in keeping with their purpose; adequately maintained; and adequate in number for their designated uses. (21 CFR 112.124). Examples of these instruments include pH meters or test strips; iodine test strips; chlorine test strips; oxidation-reduction potential meters; indicating thermometers; recording thermometers; thermocouples, and temperature actuated control valves. These instruments could be used to measure or record such conditions as temperatures in composting piles; pH in composting piles; or the concentration of antimicrobial in a sanitizing solution.

Personnel to whom you assign the responsibility for maintaining these instruments and controls, or who are engaged in the supervision thereof, should understand your procedures. These personnel should understand the importance of accuracy and precision, and should ensure that accurate measurements are collected. You should specify when personnel need to inform a supervisor or other responsible party of certain observations so they can determine appropriate steps. You should direct supervisors or responsible parties, as applicable, to ensure that activities related to instruments and controls are conducted in accordance with your procedures and corrections are made as needed.

**i. Accuracy and Precision**

The accuracy and precision of your instruments and controls help to ensure the efficacy of measures to control or prevent the growth of microorganisms of public health significance on your farm. Accuracy is how close a device's displayed measurement compares to the true value. For example, if your thermometer displays a reading of 75.2°F (24°C) when placed in a container of water and the true temperature of the water is 85.2°F (29°C), your instrument is not very accurate. Precision is the consistency among individual measurements displayed by an

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instrument under the same conditions. For example, if you weighed a single watermelon 5 times on the same scale and the scale read 20.2 lbs., 18.9 lbs., 21.4 lbs., 19.5 lbs., and 22.8 lbs., the scale is not very precise. Continuing with the first example, if your thermometer reads 75.2°F (24°C), 75.2°F (24°C), and 75.2°F (24°C) for three measurements of 84.2°F (29°C) water, the instrument is precise, but not accurate.

You should evaluate your farm's covered activities for which you use instruments or controls to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance. The necessary degree of accuracy and precision for your instruments or controls varies depending on how they are used. For example, an instrument that is both highly accurate and highly precise (e.g., within 2°F (1°C)) should be used when small variations can lead to the growth of pathogens, such as when using a thermometer to measure storage temperature in a cooler that contains mushrooms in oxygen impermeable packages. In this example, the farm should target maintaining temperatures below 36°F (2.2°C) because a temperature above 38°F (3.3°C) during storage can result in the formation of *Clostridium botulinum* toxin (Ref. 76) (Ref. 118) (Ref. 123).

As part of your maintenance activities, you should perform periodic accuracy checks to ensure that your instruments and controls are functioning properly. In some cases, you can check the accuracy and precision of your instruments and controls yourself. Generally, accuracy checks involve comparing an instrument's displayed measurement against at least one true value. In some instances, you could be able to account for minor, consistent deviations in instrument readings. For example, if a farm uses a thermometer to check the temperature of turned compost under a process based on the example provided in 21 CFR 112.54(b)(2) to maintain aerobic conditions at a minimum of 131°F (55°C) for 15 days, and determines that the thermometer consistently reads within 4°F of the true value during accuracy checks; the farm should account for this level of accuracy by targeting a temperature reading that is sufficiently high to ensure that it meets the target (e.g., maintain at least 135°F (57°C)). You should adjust or replace any of your instruments or controls that do not meet your identified level of accuracy or precision.

Documentation or manuals that typically accompany instruments and controls often contain information on the instrument's accuracy. You could, for example, contact the vendor or manufacturer directly to obtain additional information on the accuracy and precision of an instrument or control. You could also choose, for example, to seek further information from technical assistance resources.

You should establish a calibration schedule for all of the instruments and controls that you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy, or other conditions, to control or prevent the growth of microorganisms of public health significance. You should replace instruments or controls that you cannot calibrate to the necessary level of accuracy or precision. Many instrument and control vendors and manufacturers recommend periodically calibrating instruments, and can provide instructions and recommended frequencies for these procedures.

Calibration involves comparing an instrument's displayed measurement against multiple, true values, often using a known reference standard (e.g., National Institute of Science and Technology (NIST) traceable instrument or other recognized reference solutions or instruments)

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and a notation of the extent to which the measurement deviates from the standard. You should use multiple true values, with at least one true value typical of the instrument's use. For example, pH probes are typically calibrated against two reference solutions, using at least one solution that reflects a value typically measured by the instrument when used. As another example, if you are calibrating a thermometer that you typically use to measure temperatures of compost near 131°F, you should use at least one calibration true value near 131°F. Calibration can also involve an adjustment to correct the accuracy deviation, depending on the instrument design. For example, you can check a dial thermometer for accuracy by measuring the temperature it displays when placed in an ice slurry (32°F (0°C)) or boiling water, accounting for your elevation (e.g., 212°F (100°C) at sea level). You could calibrate the thermometer by placing it and a NIST traceable instrument in an ice slurry and boiling water and comparing the temperature displayed by each. You could then adjust your thermometer, if its design allows, to display a reading consistent with that of the NIST instrument. If your thermometer cannot be adjusted, then you should account for the difference between the thermometer and the NIST traceable instrument when you use the thermometer. You can calibrate your instruments and controls yourself or use a third-party, such as a manufacturer or contract laboratory.

Calibration is important to ensure accurate results that are consistent over time. Instrument wear or damage can result in changes in accuracy or precision. The extent to which an instrument or control will maintain its accuracy and precision between calibrations depends on the type of instrument; instrument quality; frequency of use; use and storage environment (e.g., high humidity and temperature can affect some instruments and controls); and the way the instrument is used (e.g., rough handling can affect instruments and controls). In some instances, you should periodically compare results against a more reliable instrument (e.g., periodic checks with a pH probe when typically using pH test strips), especially when there is potential for human error or judgement associated with qualitative results (e.g., color change in a pH test strip).

You should maintain all instruments and controls according to the manufacturer's recommendations. Maintenance could include: performing start-up activities prior to taking measurements; performing instrument or control cleaning steps between measurements, such as flushing residual material from the instrument or control; and confirming expiration dates of the instruments, controls or associated materials. Failure to maintain instruments can lead to inaccurate or imprecise readings. For example, an expired test kit used to measure the concentration of sanitizing solution could provide an inaccurate measurement, possibly impacting the efficacy of your sanitizing procedures. You should perform maintenance activities at appropriate frequencies to ensure that your instruments and controls function in the manner necessary to control or prevent the growth of pathogens. For example, you should instruct your personnel to periodically check expiration dates, and not use expired instruments, test kits, test kit solutions, and instrument and control components.

Storage methods could impact the functionality of some instruments and controls. For example, the probe of a pH meter should not be stored in water, which can damage the probe and result in inaccurate readings. Further, humidity or temperature can impact the accuracy of some test kits and reagents; these types of instruments or controls should be stored under climate-controlled conditions until use.

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**ii. Adequate in Number**

You must have enough instruments on your farm to facilitate measurement (See 21 CFR 112.124) and should have those instruments placed in appropriate locations to ensure control of your processes. You should determine the appropriate number and appropriate placement of instruments and controls given the scale of your farm's activities. You should have sufficient numbers of instruments or controls conveniently located, so they are available when needed. For example, if you perform treatment of biological soil amendments of animal origin (BSAAO), such as composting, at multiple sites of your farm, you should determine the number of thermometers necessary at each site so that your personnel can ensure that the compost meets any relevant temperature standards to comply with 21 CFR 112.54. As another example, if you have multiple growing or packing locations on your farm, you should have enough test kits so that your personnel can check the strength of a sanitizing solution at all of those locations where testing is necessary.

In some cases, you could need multiple instruments in order for them to be adequate in number for their designated uses. For example, if you are composting a small biological soil amendment of animal origin (BSAAO) pile and monitoring the temperature, one thermometer placed near the bottom of the pile where temperature is more challenging to control could be sufficient. However, if you are composting large windrows, you could need multiple thermocouples placed throughout the pile at different depths to evaluate the overall temperature.

## **2. Buildings**

Buildings that are subject to subpart L of the Produce Safety Rule include any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls. (21 CFR 112.122(a)). Buildings that are subject to subpart L also include storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials) (21 CFR 112.122(b)). Such buildings could be permanent or temporary structures. Partially-enclosed buildings typically have a roof, with one or more sides open to the natural environment while fully-enclosed buildings have walls on all sides, a floor, and a roof. You should identify all fully- and partially-enclosed buildings on your farm that you use for a covered activity. Buildings on your farm in which you do not perform covered activities, and which are, therefore, not covered by subpart L could include, for example: personal homes; grain silos; livestock barns; chicken coops; and stables.

### **a. Size, Construction, and Design**

Your buildings that are subject to subpart L must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. (21 CFR 112.126(a)(1)). The buildings must:

- (i) provide sufficient space for placement of equipment and storage of materials; and
- (ii) permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials by effective design

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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. (See 21 CFR 112.126(a)(1)(i) and (ii)).

What constitutes suitable size, construction, and design for a building largely depends on the building's use for covered activities. You should evaluate whether your identified buildings' size, construction, and design are appropriate, considering the covered activities performed and operating conditions in each building. You should consider factors such as drainage, ventilation, facilitation of pest control and whether there is sufficient space for free movement around any equipment. For example, for a partially-enclosed building that a farm uses during the off season to store harvesting equipment that contacts covered produce, the farm should evaluate whether the building provides sufficient space for storage of the equipment and for maintenance of the building (e.g., pest control, removal of debris) to minimize the potential for contamination.

You should ensure that the construction of your buildings facilitates the maintenance of sanitary conditions. Windows, doors, and roofs of fully-enclosed buildings should prevent leaks and the entry of dirt, dust, debris, and pests. Buildings should also allow access for examination and maintenance of equipment contained within the building and the building itself. For example, if you choose to have a drop ceiling in a fully enclosed building used for packing, then the building should be constructed in a way that allows access to the space between the roof and the drop ceiling for maintenance and sanitary operations, such as pest control activities.

Building materials and construction should be durable enough to withstand their use in order to reduce the potential for contamination. You should evaluate your building's materials and construction, and periodically visually assess your buildings. For example, floors should be able to withstand expected foot traffic and movement of equipment and vehicles without becoming damaged and potentially harboring pathogens, and doors and walls should be durable enough to withstand typical impacts by personnel and transport equipment without becoming damaged or permitting pest entry.

To ensure that the size and design of your buildings facilitates maintenance and sanitary operations, you should consider: the activities that occur within the building; the volume and frequency of activity within the building; the number, size, and placement of equipment and tools used or stored within the building; and the number of people (e.g., personnel, supervisors, visitors, contractors) using the building at any given time. For a building to be suitable in size, it should have enough room for covered activities to be conducted without contact between covered produce or food contact surfaces and building materials, non-food contact surfaces, or clothing.

When installing or placing equipment in your buildings, you should be aware of the area surrounding the equipment to ensure that personnel can easily perform inspections, maintenance, and cleaning and sanitizing activities. See the subsection of this chapter titled "Installation and Maintenance" for further draft guidance on equipment placement.

Example 7q: A farm that uses a conveyor belt in a packinghouse should ensure that there is enough space between the conveyor equipment and the wall or adjacent equipment to allow personnel to easily access the entire length of the conveyor belt. This should include access

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to: the conveyor belt; the support frame; the points at which the framework is secured to the floor of the building; and any surfaces that could contact, or from which water could drip or drain onto, covered produce or food contact surfaces.

Example 7r: In a fully enclosed building dedicated to packing covered produce, you should set up operations such that you can efficiently remove the trash without touching food contact surfaces.

Example 7s: If both clean and used harvest containers are stored in a partially-enclosed storage shed, the farm must ensure that there is enough space in the area to separate the containers to reduce the potential for contamination. (See 21 CFR 112.126(a)(1)).

There are multiple ways to ensure that building design separates your operations to reduce the potential for contamination. You can, for example, use careful layout and installation of equipment within buildings to reduce the potential for contamination, such as by installing physical barriers to separate activities, or dedicating areas to specific activities, with sufficient space or barriers between them. For another example, the areas where covered produce are prepared for distribution (i.e., finished product) should not be immediately adjacent to areas where covered produce from the field are washed in a way that water splash could be transferred to the finished product. When you identify the need to separate certain activities, you should ensure that personnel are aware of and understand your procedures that specify the separation to prevent contamination.

**b. Preventing Contamination, Including Floors, Walls, and Ceilings**

You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through floors, walls, ceilings, fixtures, ducts, or pipes; and drip or condensate. (21 CFR 112.126(b)). Surfaces of buildings that are not adequately cleaned have the potential to become a source of contamination (Ref. 51) (Ref. 72). You should evaluate your buildings and their components (e.g., floors, walls, ceilings, ducts, pipes, fixtures, drains), including periodic visual assessments. You should repair or replace damaged or defective building components that have the potential to contaminate covered produce or food contact surfaces.

Examples of measures that you should take, as appropriate, include:

- Repairing piping systems that are leaking onto covered produce or food contact surfaces;
- Repairing roofs, walls or floors with holes or cracks in them;
- Protecting covered produce and food contact surfaces from condensate from ceilings and overhead pipes, or maintaining such surfaces in a sanitary condition if they are subject to the formation of condensation so that they do not serve as a source of contamination;
- Protecting drains from becoming harborage sites for pathogens;
- Cleaning and sanitizing building components as necessary to reduce the potential for contamination; and
- If you use high pressure hoses in your cleaning activities, ensuring that water splash does not spread contaminants from floors, walls, ceilings, fixtures, ducts, or pipes to covered produce or food contact surfaces, or ensuring that maintenance, cleaning and sanitizing, if

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necessary and appropriate, procedures address such surfaces if they are subject to such water splash so that they do not serve as a source of contamination.

Covered produce and food contact surfaces can be protected from dripping condensate using practices such as: routing condensate to drains, drip pans, or areas away from covered produce and food contact surfaces; not storing covered produce or food contact surfaces under or near areas identified as likely condensate areas or “drip zones”; covering covered produce and food contact surfaces to protect them from condensate; and controlling the humidity in your building (e.g., through ventilation) to minimize the formation of condensate.

Ceilings, overhead pipes, walls, floors and drains can be maintained in a sanitary condition by ensuring that their surfaces are of a design, construction and workmanship such that they can be adequately cleaned and properly maintained (see the section of this chapter titled “Design, Construction and Workmanship”) and by cleaning, and, when necessary and appropriate, sanitizing them (see the section of this chapter titled “Cleaning and Sanitizing Equipment and Tools”). In cases where condensate contacts your covered produce or food contact surfaces, you should consider the originating surface of the condensate a food contact surface, and you should evaluate whether measures to address any potentially contaminated covered produce or food contact surfaces are necessary.

Floor drains are known to serve as harborage sites for *Listeria monocytogenes* (Ref. 19) (Ref. 88), likely due to their cool, wet environment and the tendency for drain cleaning and sanitizing to be overlooked or inadequate (Ref. 19) (Ref. 87). You should clean and sanitize drains in a way that prevents harborage of contamination and minimizes the likelihood that water splash or aerosols will contact covered produce or food contact surfaces (e.g., cleaning drains after packing operations end and not using high pressure water rinsing).

**c. Drainage**

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. (21 CFR 112.126(a)(2)). The drainage system, including the drain grate, should accommodate the rate of release or discharge during peak operations. Your buildings could need multiple drains to prevent standing water or slow drainage.

We acknowledge the potential for small pools of water to temporarily form on the floor of buildings used for growing activities, and that pooling of water of this nature, which is temporary and could occur in the normal course of watering practices, is not reasonably likely to contribute to the contamination of covered produce. We are not suggesting that it will always be possible to eliminate pooling. Avoiding pooling by careful control of greenhouse watering practices with consideration to your drainage system is ideal; however, to the extent pooling could be inevitable or could sometimes occur, despite adequate drainage, we expect covered farms to take steps to protect covered produce from any contamination that could build in the pooled water.

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**d. Pest Control**

You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate. (21 CFR 112.128(a)). You should evaluate your buildings in which you perform covered activities to determine what measures are necessary.

For fully-enclosed buildings, you must take measures to exclude pests from your buildings. (21 CFR 112.128(b)). You should prevent pest entry (e.g., cover or repair holes in the building) and reduce pest attractants (e.g., debris for nesting, food scraps, pooled water) in such buildings and their immediately surrounding areas. For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present). (21 CFR 112.128(c)).

You should minimize pest attractants and harborage areas in and around your buildings, including accumulated litter and debris; food scraps; nesting material; unused equipment; waste storage; tall, dense foliage, weeds, and grass; and pooled water (see the section of this chapter titled “Drainage”). You should visually assess potential points of entry and potential routes of pest movement. Your first inspection can be used to guide your monitoring activities. Your monitoring frequency (e.g., weekly, monthly, bi-monthly) should be based on several factors, including the potential for pest activity, environmental conditions, and the level of observed pest activity in or around your buildings. Your monitoring could assist you in identifying areas of concern that you had not previously identified (e.g., you could identify a crack in the foundation, through which insects could enter, that developed after the previous inspection).

During your monitoring activities, assigned personnel should look for pest attractants, points of pest entry, signs of pest activity, both inside and immediately outside of the building and, when found, attempt to identify the type of pest (e.g., bird, rodent, insect), and the extent of the activity. Signs of pest activity might include the presence of the following:

- Animal excreta (e.g., rodent pellets, bird droppings, urine);
- Nests (e.g., bird, rodent);
- Gnaw marks on materials or shredded materials (e.g., produce, packing materials, paper, plastic, wood);
- Burrows, trails, or other evidence of pest movement (e.g., worn paths or grease marks), or tracks outside the building;
- Insects (e.g., flies, larvae, ants) inside the building; and
- Remains of dead pests.

If you observe signs of pest activity, you should identify and address the contributing factors related to the pest activity. You also should evaluate the potential for contamination of covered produce, food contact surfaces, and food-packing materials, and determine whether measures to address any potentially contaminated covered produce or food contact surfaces are necessary.

If you identify pest infestation, 21 CFR 112.128(a) requires that you take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing

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materials from contamination. This can include strategies for their elimination or to prevent them from becoming established, such as installing: indoor rodent traps (e.g., catch-and-release traps, snap traps, glue boards); outdoor rodent traps and bait stations anchored to the perimeter of the building; insect glue boards; light traps; and electronic flying-insect killers. These could be placed in areas of high pest activity, suspected points of entry, and nesting sites, but should be placed away from covered produce, food contact surfaces, and food-packing materials. If you use pest traps or bait stations, you should check them periodically (e.g., weekly) for signs of activity, replace any that become lost or damaged, remove any dead pests, and replace any missing bait. If you use pesticides, you should ensure that you use all pesticides and pesticide devices in accordance with all applicable Federal, state, and local laws.

Personnel to whom you assign the responsibility of pest monitoring, or who are engaged in the supervision thereof, should understand your procedures related to pest control. You should specify when personnel need to inform a supervisor or other responsible party of certain observations so they can determine appropriate steps. You should direct supervisors or responsible parties, as appropriate, to ensure that activities related to pest control are conducted in accordance with your procedures and corrections are made as needed.

**e. Domesticated Animals**

Domesticated animals could be present on your farm for a variety of reasons, including work (e.g., horses, mules), protection (e.g., guard dogs), and personal companionship (e.g., family pet). However, domesticated animals can carry pathogens, such as *Salmonella* spp. (Ref. 6) (Ref. 110) (Ref. 129); and pathogenic strains of *E. coli* (Ref. 13) (Ref. 103) (Ref. 110) (Ref. 143), and serve as sources of contamination of covered produce and food contact surfaces (Ref. 71) (Ref. 77) (Ref. 78) (Ref. 90) (Ref. 117). You must take reasonable precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals (e.g., cats, dogs, horses, chickens) by: (1) excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing materials are exposed; or (2) separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition. (21 CFR 112.127(a)). You should refer to Chapter 5: Domesticated and Wild Animals (Subpart I) of this document for additional draft guidance on domesticated and wild animals related to outdoor areas and partially-enclosed buildings.

You should evaluate the presence and purpose of the domesticated animals on your farm and visually assess their actions when determining reasonable precautions to prevent contamination in your fully enclosed buildings. When excluding domesticated animals from buildings, you should keep all entryways, including windows and doors closed whenever it is not necessary for them to be open. Windows should be screened to help prevent domesticated animal entry. If you choose to satisfy the requirements of 21 CFR 112.127(a) through exclusion and there are times when entryways need to remain open, you should have a system in place to prevent domesticated animal entry. For example, for those times when a loading dock door remains open, you could, for example, designate a worker assigned to that area to monitor and prevent entry of domesticated animals to the area, and to remove any that enter. Alternatively, you

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could, for example, use gates or access limitation devices that domesticated animals are unable to maneuver (e.g., Dutch doors or gates that domesticated animals cannot jump over).

In some instances, exclusion of domesticated animals from an entire, fully-enclosed building could be impractical, such as when the building has multiple rooms, only some of which are used for covered activities. If you do not exclude domesticated animals from the entire building, you must separate them from areas where covered activities are conducted on covered produce by location, time, or partition (21 CFR 112.127 (a)(2)). For example, you could allow animals to visit an administrative office that is separated by a wall that prevents access to the portion of the building in which packing activities occur. For another example, in entryways to areas of the building in which covered activities are conducted on covered produce, self-closing doors can be used to prevent entrance of domesticated animals. You also, for example, could separate portable equipment and tools that contact covered produce or food-packing materials by storing such equipment and tools in closed cabinets in rooms that domesticated animals can access.

Finally, your procedures could permit domesticated animals in areas in which covered activities occur, at times when those activities are not taking place. In these instances, you should clean and, when necessary and appropriate, sanitize, exposed equipment, tools, floors, and walls of the room where the domesticated animals were present, before resuming use of the room for a covered activity. See the section of this chapter titled “Cleaning and Sanitizing Equipment and Tools” for further draft guidance.

Personnel who manage or interact with domesticated animals, or who are engaged in the supervision thereof, should understand your procedures related to reasonable precautions to prevent contamination of covered produce and food contact surfaces from domesticated animals in your fully enclosed buildings. You should direct supervisors or responsible parties, as applicable, to ensure that personnel conduct activities in accordance with your procedures, and corrections are made as needed.

Guard or guide (i.e., service) dogs could be allowed in some areas of a fully-enclosed building if the presence of the dog is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials. (21 CFR 112.127(b)). Guard or guide dogs present in areas where covered produce, food contact surfaces, or food-packing materials are exposed should be under the control of a handler. You should ensure that guard or guide dogs, including their fur, saliva, or skin, do not contact covered produce, food contact surfaces, or food-packing materials. For example, you should not permit guard or guide dogs to: run throughout the building; jump onto equipment or tools that contact covered produce; contact the hands of personnel that contact covered produce; or contact covered produce. You should inform guard and guide dog handlers of the potential for dogs to carry contamination into your buildings and ensure that they minimize the likelihood of the dogs becoming contaminated (e.g., contact with animal excreta) before entering your buildings.

### **3. Other Sanitation Measures**

The other sanitation provisions of the Produce Safety Rule (21 CFR 112.129 - 134) include the management of animal excreta and litter from domesticated animals, toilet facilities; hand-washing facilities; sewage; trash, litter, and waste; and plumbing.

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**a. Animal Excreta and Litter from Domesticated Animals**

If you have domesticated animals, to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must (1) adequately control their excreta and litter; and (2) maintain a system for control of animal excreta and litter. (21 CFR 112.134). For example, you would comply with this provision by not locating manure piles adjacent to packing sheds in which covered produce is exposed.

Draft guidance on related requirements is provided in: this chapter (related to 21 CFR 112.127); Chapter 5: Domesticated and Wild Animals (Subpart I) (related to 21 CFR 112.83); and Chapter 6: Growing, Harvesting, Packing, and Holding Activities (Subpart K) (related to 21 CFR 112.112). Depending on the number and types of domesticated animals on your farm, there are different ways that you can manage the control of their excreta and litter.

For domesticated animals under your control, you should identify the areas in which the animals are likely to produce excreta or litter (e.g., stalls, grazing pastures) and evaluate the potential for contamination, including through runoff and transfer via personnel footwear, of your covered produce, food contact surfaces, areas used for covered activities, agricultural water sources, or agricultural water distribution systems. Additionally, you should evaluate how you store and transport their excreta or litter, and the potential for contamination from these activities. You should house and pasture these animals, and store their excreta or litter downhill and away from areas of concern or by using berms, pits, or grading to contain runoff. For companion or guard animals (e.g., dogs, cats) you could, for example, periodically inspect for excreta in the areas to which they have access, collecting and disposing of it in waste containers.

**b. Toilet Facilities**

Human feces could contain pathogens in relatively high concentrations (Ref. 21) (Ref. 63) (Ref. 40). One of the most basic measures that you can take to prevent the transfer of pathogens from human feces to covered produce and food contact surfaces is to provide toilet facilities to collect and contain human feces and liquid waste. Toilet facilities include portable toilets, outhouses, plumbed facilities, or other enclosed facilities where toilets are located.

**i. Accessibility**

You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities. (21 CFR 112.129(a)). Note that 21 CFR 112.33(b) requires that you also make toilet and hand-washing facilities available to visitors; see Chapter 3: Health and Hygiene (Subpart D) of this document. You should consider personnel and visitor activities and traffic throughout your growing, harvesting, packing, and holding areas to help you determine the appropriate number and locations of toilet facilities to efficiently accommodate the typical numbers of individuals accessing certain areas at the same time, such as at the beginning of work, or after a break. You should evaluate your toilet facilities to determine whether they are easily accessible for personnel working in areas where covered activities occur, including during all harvesting activities. You should ensure that toilet facilities are within a reasonable walking distance from covered activities (e.g., approximately 1/4

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mile or less). You could, for example, consider placing toilet facilities near designated personnel break areas to facilitate their use. You should ensure that personnel are aware of the locations of toilet facilities and know not to relieve themselves in the growing areas or in any area on your farm other than a toilet facility.

**ii. Design, Location, and Maintenance**

Toilet facilities must be designed, located, and maintained to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste. (21 CFR 112.129 (b)(1)). You should evaluate your toilet facilities to ensure that they have proper drainage and that backflow devices do not leak sewage or liquid waste. Toilet facilities, including portable toilet facilities, should securely contain or securely transport all sewage and liquid waste away from locations where covered activities occur. For further draft guidance see the sections of this chapter titled “Sewage Systems” and “Plumbing.”

Within fully or partially-enclosed buildings, your toilet facilities should be located and designed in a way that minimizes the potential for transferring contamination by persons entering and leaving the facilities. For example, in a building used for both packing activities and office work, with the two areas separated, a toilet facility that is typically used by office and delivery personnel and visitors, in addition to packing personnel, ideally could have one entryway from the packing area and a separate entryway from the office area. This arrangement would eliminate the need for office and delivery personnel and visitors to enter the packing area to use the toilet facilities. You should consider toilet facilities as part of the overall size, construction, and design of your buildings. See the subsection of this chapter titled “Buildings – Size, Construction and Design.”

Runoff from toilet facilities has the potential to contaminate covered produce, soil, and irrigation water (Ref. 1) (Ref. 25). The location of your toilet facilities should prevent contamination from human waste and should facilitate containment and cleaning of any accidental spills or leaks. For example, you could locate portable toilet facilities downhill from your growing area and away from your water sources; or, you could, for example, use berms or grades to help protect covered produce, areas where covered activities occur, and water sources and distribution systems from contamination from uphill toilet facilities.

Your toilet facilities must be designed, located, and maintained to be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use, and be kept supplied with toilet paper. (21 CFR 112.129(b)(2)). Sewage transport and other service vehicles should have clear access to your toilet facilities to ensure proper collection and disposal of human waste, minimizing the likelihood of spills or leakage. You should maintain your toilet facilities in a sanitary condition. You should establish monitoring, servicing, and cleaning procedures and schedules for toilet facilities. You should monitor toilet facilities at a frequency that ensures that they remain sanitary and that they are supplied with toilet paper. Your procedures should specify the frequency of these inspections, the personnel involved, and conditions that should be reported to you, a supervisor, or responsible party. You should encourage personnel to report any observed deficiencies of the toilet facilities to their supervisor

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or other responsible party. Tools and equipment used to clean toilet facilities should not be used to clean surfaces where covered activities are performed.

Personnel to whom you assign the responsibility of maintaining toilet facilities, or who are engage in the supervision thereof, should understand your procedures. You should direct the supervisors or other responsible parties, as applicable, to ensure that monitoring and other activities are conducted in accordance with your procedures, and corrections are made as needed.

**iii. Disposal of Waste and Toilet Paper**

Your toilet facilities must be designed, located, and maintained to provide for the sanitary disposal of waste and toilet paper. (21 CFR 112.129(b)(3)). Your toilet facilities should provide for the sanitary collection of human waste, either into a secure sewage collection system that is emptied as needed, or to a sewage transport system that moves it to an individual or municipal treatment system. If your toilet or sewage transport system cannot accommodate toilet paper, you should keep waste containers with self-closing lids immediately adjacent to the toilet, such as receptacles with a sensor operated lid or other hands-free devices. You should monitor these receptacles and empty them as necessary.

**c. Hand-Washing Facilities**

Hand-washing is a key control measure in minimizing the potential for transferring contamination from human hands to covered produce and food contact surfaces (Ref. 100) (Ref. 132). All of the following requirements apply to hand-washing facilities:

- You must provide your personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities. (21 CFR 112.130(a)).
- During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands. (21 CFR 112.129(c)).
- You also must make toilet and hand-washing facilities accessible to visitors. (21 CFR 112.33(b)).

These standards apply to both fully plumbed, stationary hand-washing facilities and portable units.

**i. Adequate and Readily Accessible**

You should consider personnel and visitor activities and traffic throughout your growing, harvesting, packing, and holding areas to help you determine the appropriate number and locations of hand-washing facilities to efficiently accommodate the typical numbers of individuals accessing certain areas at the same time, such as at the beginning of work, or after a break. You should evaluate your hand-washing facilities to determine whether they are easily accessible for personnel working in areas where covered activities occur, including during all harvesting activities and during growing activities that occur in fully-enclosed buildings.

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You should determine whether hand-washing facilities are located close to meal or break areas, or at or near points of entry to areas where covered activities occur. Hand-washing facilities should ideally be available immediately outside or inside the entrance to packing areas. Further, additional hand-washing facilities should be placed near where personnel work (i.e., near a sorting line), to ensure that personnel can easily access it if their hands become soiled or contaminated (e.g., frequent contact with a trash can). The presence of hand-washing facilities at these and similar locations could promote their use by personnel.

You should ensure that hand-washing facilities are in a location where they are accessible for servicing, maintenance or disposal activities. Transport or other servicing vehicles or personnel should have clear access to hand-washing facilities to ensure sanitary collection and disposal of waste, including waste water, or other maintenance activities. For portable hand-washing facilities, you could consider moving hand-washing facilities from areas near where covered activities occur to a more remote location for waste water collection, cleaning, and servicing, rather than have these functions performed when the portable hand-washing facility is near covered activities. You should ensure that whomever performs these activities is aware of your procedures.

You must ensure that your hand-washing facilities are designed, maintained and managed to ensure sanitary conditions (See 21 CFR 112.130(a)). You should establish monitoring, servicing and cleaning and sanitizing procedures and schedules for hand-washing facilities and perform these activities at a frequency that ensures that they remain sanitary. You should consider the frequency of use for your hand-washing facilities to assist you in determining your frequency for cleaning and monitoring. Your procedures should include the frequency of these inspections, the personnel involved, and conditions that should be reported to you, a supervisor, or other responsible party. You should encourage personnel to report any observed deficiencies of the hand-washing facilities to their supervisor or other responsible party to ensure hand-washing facilities are continually maintained.

To assist with maintaining sanitary conditions, you could consider installing hand-washing facility components that are automated or otherwise designed for hands-free use, such as faucets, soap dispensers, and paper towels dispensers that can be activated by motion sensors or by foot pedals. This could help prevent your personnel from re-contaminating their clean hands by touching soiled faucet handles, or soap or paper towel dispensers.

Personnel to whom you assign the responsibility of maintaining hand-washing facilities, or who are engaged in the supervision thereof, should understand your procedures. You should direct the supervisors or other responsible parties, as applicable, to ensure that monitoring and other activities are conducted in accordance with your procedures, and corrections are made as needed.

**ii. Supplies**

Your hand-washing facilities must be supplied with soap (or other effective surfactant). (21 CFR 112.130 (b)(1)). A surfactant is a substance that helps to remove dirt from hands. You could not use an antiseptic hand rub as a substitute for soap (or other surfactant) and water. (21 CFR 112.130(d)). However, you could provide hand sanitizers as an additional bactericidal measure

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for use after hand-washing with soap and water, and drying. See draft guidance in the section of Chapter 3: Health and Hygiene (Subpart D) titled “Thorough Hand-washing”).

You must furnish your hand-washing facilities with running water that satisfies the requirements of 21 CFR 112.44(a) for water used to wash hands (i.e., water must contain no detectable generic *E. coli* per 100 mL of water). (21 CFR 112.130(b)(2)). You could, for example, obtain running water from a fixed plumbing system or a portable unit that supplies and captures running water. Containers used to transport or store water for hand-washing should be emptied and thoroughly cleaned periodically. You should not reuse hand-washing water that has not been treated, nor should you use communal, open containers of water for hand-washing.

You must furnish hand-washing facilities with adequate drying devices. (21 CFR 112.130(b)(3)). Examples of adequate drying devices include single-use disposable towels (e.g., paper towels), electric hand dryers, and cloth towels that are used only once and then laundered (e.g., using your own procedures or use a sanitary towel service). Common or shared towels, or towels intended for multiple uses before laundering are not adequate drying devices for this purpose because repeated use of towels or use by multiple users can increase the potential for contamination.

**iii. Disposal of Waste for Hand-Washing Facilities**

You must provide for appropriate disposal of waste (e.g., waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards. (21 CFR 112.130(c)).

**• Single-Service Towels and Other Solid Hand-Washing Waste**

You should evaluate whether your solid hand-washing waste disposal systems contribute to contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems. Containers used for solid hand-washing waste (e.g., single-service towels) should be intact and free from damage, such as cracks, or should be lined with an intact liner (e.g., garbage bag). You should develop procedures for the frequency that these containers should be emptied (e.g., based on frequency of use) so they do not serve as a source of contamination or pest attractant. These containers should be covered to prevent the solid hand-washing waste from being transported (e.g., by wind, birds) to areas where covered activities occur. You should cover waste containers in a way that also helps prevent potential contamination of hands (e.g., foot-operated or remote sensor-operated lids). Containers used for solid hand-washing waste disposal should be located as close as practical to hand-washing facilities to maximize the likelihood that they will be used.

**• Liquid Hand-Washing Waste**

You should evaluate whether your liquid hand-washing waste disposal systems contribute to contamination of covered produce, food contact surfaces, areas used for covered activities, or agricultural water sources or distribution systems. Your evaluation should include consideration

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of the surrounding area, such as topography and location of nearby water sources and covered activities because of the potential for runoff of liquid waste from hand-washing stations. In plumbed hand-washing facilities, liquid waste typically drains into a plumbed waste system. Piping used to convey hand-washing liquid waste should be intact and free of leaks. See the section of this chapter titled “Plumbing” for further draft guidance on waste water systems.

If you use portable hand-washing facilities, the liquid waste should be collected in a manner that prevents contamination of covered produce, food contact surfaces, areas used for covered activities, or agricultural water sources or distribution systems. For example, if a portable hand-washing facility releases liquid waste onto the ground, the liquid could serve as a source of contamination. Liquid hand-washing waste should be captured in a container that is intact and free from leaks; the container should be covered when it is not in use or when it is collected for disposal. You should empty these containers as necessary (e.g., once they are filled to a certain point or at an established frequency based on use) and periodically clean them (e.g., at an established frequency based on use). Liquid hand-washing waste containers should be emptied in a way that minimizes the potential for spillage. If a third-party entity supplies and services your portable hand-washing facilities, you should ensure that the liquid waste containers are readily accessible to them and that they perform their activities in a manner that prevents contamination. You should not locate portable hand-washing facilities near agricultural water sources or in a location from which spilled liquid hand-washing waste could contaminate areas associated with covered activities.

**d. Sewage Systems**

Sanitary disposal of human waste greatly reduces the likelihood that it will serve as a source of contamination of covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources or distribution systems (Ref. 25) (Ref. 68). Systems used to handle human waste include municipal sewage systems, individual septic systems, self-contained units, which could be portable, and any associated plumbing.

**i. Use and Maintenance**

You must dispose of sewage into an adequate sewage or septic system or through other adequate means. (21 CFR 112.131(a)). You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards. (21 CFR 112.131(b)). You should evaluate your sewage and associated plumbing systems (i.e., collection, containment, transport) based on these requirements. Generally, sewage and septic systems in the U.S. are approved by local health authorities when installed, providing a level of assurance that their design is appropriate (e.g., the volume of water and organic material, including fecal material). However, these systems can degrade over time (e.g., leaks, bypasses, damage, incomplete treatments), presenting the risk for contamination of surrounding soils and waters (Ref. 45) (Ref. 42). Further, for systems that treat the sewage (e.g., septic systems), if your input volume or other characteristics exceed the design capacity, the system could not properly treat the sewage, potentially allowing pathogens to survive in the effluent.

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As part of your maintenance activities, you should periodically inspect your sewage systems, including those used for plumbed (e.g., sewer and septic systems) and non-plumbed (e.g., portable toilets, outhouses) toilet facilities. You should have procedures for the frequency of these inspections, the personnel involved, and conditions that should be reported to you, a supervisor, or other responsible party.

If you use a septic system, the tank should be properly sealed, in good working order, and free from damage. The inlet and outlet plumbing should be in good working order and free from damage, and the drain field should be properly functioning, with no visible leakage at the surface. If you use a septic system, you should have it pumped with sufficient frequency to prevent excess accumulation of solid human waste, which can result in premature septic system or drain field failure (Ref. 41) (Ref. 106).

For portable toilet facilities, the waste retention tank should be structurally sound, not leak, and be constructed to prevent contamination and attraction of flies and other pests. The tanks should remain closed to minimize the potential for contamination. You should store these tanks in a way that protects them from damage that could result in leakage of human waste. Storage containers should be accessible to facilitate collection and transport of sewage and liquid waste or other maintenance and servicing activities. You should dispose of human waste from these tanks periodically (e.g., at an established frequency based on use) to prevent overflow. You should ensure that the collection and disposal of human waste from your portable toilet facilities or outhouses is done in a manner that prevents spills.

**ii. Response to Leaks and Significant Events**

You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems. (21 CFR 112.131(c)).

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

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

Furthermore, if you know or have reason to believe that there is a sewer or septic system failure (e.g., soggy patches of land around your septic tank or drain field, slow draining sinks or drains, sewage odors, gurgling noises from the plumbing drain lines, or effluent backup coming from drains, sinks or toilets) (Ref. 41) (Ref. 44), you should immediately cease any water use that

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drains or transmits waste water into the affected sewage or septic system. You should also determine the cause of the leak or spill and make any necessary repairs. For example, if you find that the sewage system failure is the result of a sewer line that is burst, cracked, or penetrated, such as with tree roots, you should repair or replace the affected section. You should verify that any actions corrected the problem before resuming use of the sewage or septic system. In some instances, this might include having the system professionally inspected by a private firm or your local health authority.

Sewage spills can occur in indoor facilities. For example, if a toilet overflows onto the floor of a toilet facility that is accessed by personnel who work in areas where covered produce is exposed, you should immediately prevent access to the affected area until the spill can be removed and the area thoroughly cleaned and sanitized. If your personnel access the area before it is cleaned, you should visually assess the potential that covered produce or food contact surfaces in adjoining areas have become contaminated. You should ensure that your personnel and supervisors or other responsible parties understand your procedures for responding to a leak or spill of sewage. You should direct your supervisors or other responsible parties, as applicable, to ensure that actions taken to manage and dispose of leakages or spills of sewage are conducted in accordance with your procedures and corrections are made as needed.

In addition, after a significant event, such as flooding or an earthquake, that could negatively impact your sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems. (21 CFR 112.131(d)). After such an event, you should inspect your entire system to the extent that it is accessible to identify and correct any defects with the system. For example, you could find that an earthquake has damaged the intake or output baffles in your septic tanks; you should promptly repair these defects to prevent sewage, incomplete treatments, and premature drain field failure. In another example, if you find that your septic system's drain field is failing due to flooding, you should wait for water levels to recede before resuming use of the system and evaluate the potential for the contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

When your inspection after a significant event indicates defects in your system, you should also consider whether you can continue to perform growing, harvesting, packing, and holding activities in a manner that complies with the Produce Safety Rule. You should consider taking actions such as providing temporary, portable toilet and hand-washing facilities, and you should determine whether such actions would be adequate to prevent contamination (See 21 CFR 112.131(a)). There could be circumstances during which it is unsafe to continue growing, harvesting, packing, and holding covered produce, until the sewage system can be fully repaired (e.g., if water from your production activities and cleaning activities is directed to the sewage system).

**e. Trash, Litter, and Waste**

For the control and disposal of trash, litter, and waste in areas used for covered activities, you must:

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- Convey, store, and dispose of trash, litter, and waste to:
  - Minimize its potential to attract or harbor pests (21 CFR 112.132(a)(1)); and
  - Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards (21 CFR 112.132(a)(2)).
- 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. (21 CFR 112.132(b)).

You should evaluate your waste management system for compliance with these requirements, including:

- Type and location of waste containers for collection or storage;
- Frequency of waste collection and disposal; and
- Maintenance of waste collection and storage areas.

Personnel to whom you assign the responsibility of conveying, storing and disposing of trash, litter and waste, or who are engaged in the supervision thereof, should understand your procedures. You should direct the supervisors or other responsible parties, as applicable, to ensure that activities are conducted in accordance with your procedures, and corrections are made as needed.

You have the flexibility to select waste containers that you determine to be appropriate for your waste collection and storage activities. However, you should ensure that waste containers are not prone to spills, leaks, or overflow. Waste containers should be covered with tight-fitting lids when not in use, especially in outdoor areas or partially-enclosed buildings, to minimize the attraction of pests. You should cover waste containers in a way that also helps prevent potential contamination of hands (e.g., foot-operated or remote sensor-operated lids).

Waste containers should be readily available in areas where waste is typically generated (such as near sorting areas and personnel break areas) and positioned so that they are not likely to be overturned. Their location should minimize the need for personnel who contact covered produce or food contact surfaces to have to adjust or relocate the containers during covered activities. Waste containers should accommodate the typical volumes of waste generated.

You should establish an appropriate frequency for transferring waste from your waste collection containers to waste storage containers (e.g., dumpsters). In establishing the frequency for transfer, you should consider the volume of waste collected and the nature of the waste. Waste removal should be more frequent for waste material that is likely to serve as a source of contamination or attract pests. For example, unlike some dry waste (e.g., damaged boxes or overwrap), discarded produce in areas where covered activities occur could be more likely to attract pests and contribute organic materials that promote bacterial growth, so waste collection in these areas should be more frequent.

You should locate your waste storage containers (e.g., dumpsters) away from areas where covered produce or food contact surfaces are exposed. You should consider the potential for

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runoff from these locations to areas you use for covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems. You could, for example, locate waste storage downhill from these areas or use berms or other grading to prevent runoff. Your waste storage containers should always remain closed when not in immediate use. Waste storage containers should be emptied in a manner and frequency that prevents waste from spilling or leaking.

You should establish periodic cleaning, sanitizing, and maintenance schedules for your waste collection and storage containers, and equipment used to transport these items (e.g., forklifts) to minimize the potential of contamination. Waste containers and equipment used to transport these items should be maintained, free from damage that facilitates leaks, and replaced as necessary. Equipment used for waste disposal (e.g., conveyers) should be separated from covered produce and food contact surfaces and positioned in a way that minimizes the potential for their contamination.

**f. Plumbing**

Plumbing must be of an adequate size and design and be adequately installed and maintained to:

- Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources. (21 CFR 112.133(c));
- Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, hand-washing, or toilet facilities. (21 CFR 112.133(a));
- Properly convey sewage and liquid disposable waste. (21 CFR 112.133(b)); and
- Not allow backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities. (21 CFR 112.133(d)).

Your plumbing system includes water lines and structures (e.g., faucets, toilets, pipes, collection and containment structures), and sewage lines and structures (e.g., pipes, collection and containment structures). You should evaluate the adequacy of your plumbing systems considering such factors as volume of water and frequency of use. You should periodically inspect your plumbing system and identify any conditions that could result in it becoming a source of contamination. Your procedures should include the frequency of these inspections, the personnel involved, and conditions that should be reported to you, a supervisor, or other responsible party. If you observe the potential for contamination, you should take appropriate measures to prevent the plumbing from becoming a source of contamination, as soon as possible. For example, you could remove dead-end piping or periodically flush these lines to remove any residue or other material.

Inadequate water pressure and volume could impact your ability to perform your operations in a sanitary manner. For example, low water pressure could compromise your ability to properly clean your food contact surfaces or to provide water to multiple hand-washing facilities at the same time.

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Plumbing for sewage and liquid disposable waste should be intact and free from leaks to prevent contamination of surrounding areas (e.g., packing area floors, growing area soil, agricultural water sources and distribution systems, such as irrigation systems). For additional draft guidance see the section of this chapter titled “Sewage Systems.”

A cross-connection is a connection between a water source or distribution pipe (e.g., drinking water, water used for hand-washing, water used for cooling covered produce) and a liquid waste pipe (e.g., sink drain, sewage line, floor drain line). Unless it is protected by a backflow prevention device, a cross-connection can result in backflow, the undesirable reversal of the flow against the normal waterline pressure (e.g., from a sewage line to the water line supplying a hand-washing station). You should equip all water supply piping with backflow prevention devices to prevent contamination from cross-connections and backflow.

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

Drainage systems involving water contact with covered produce, such as from flumes or dump tanks, should flow into a floor drain with an air gap or with a backflow or back siphonage prevention device to prevent contamination of the flume system or dump tank if a backup occurs in the drainage system.

#### **4. Records**

You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to subpart L used in (1) growing operations for sprouts; and (2) covered harvesting, packing, or holding activities. (21 CFR 112.140). Examples of such equipment and tools include harvesting tools, knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce). An example of such a record would be a cleaning and sanitizing log for packing equipment that documents the date that cleaning or sanitizing was performed, and the method of cleaning or sanitizing (e.g., “manual scrub with detergent and hot water”). The record should include the concentration of cleaning or sanitizing solutions (e.g., “sanitized with 200 ppm chlorine spray”). You could, for example, develop records for groups of equipment that are cleaned and sanitized in the same way with the same cleaning and sanitizing solutions.

Chapter 8: Records (Subpart O) provides draft guidance on the general records requirements that are applicable to these records.

## **Chapter 8: Records (Subpart O)**

This chapter provides draft guidance on the requirements of subpart O—Records. Records are needed to keep track of measures directed at minimizing the risk of known or reasonably foreseeable hazards, to identify a pattern of problems that increase the risk of such hazards, and to facilitate verification and compliance with regulatory standards. The records requirements will help you to comply with the requirements of the Produce Safety Rule and document, and FDA to determine, your compliance. Additionally, records provide you, and FDA, with a view of the performance of your preventive measures over time.

In this chapter, we provide draft guidance on the requirements of subpart O that apply to all required records under the Produce Safety Rule (21 CFR Part 112). The specific records that your farm must keep depend, in part, on the requirements of the Produce Safety Rule that apply to your farm. The requirements for specific records are listed in the applicable sections of the Produce Safety Rule: subparts A, B, C, E, F, L, and M (i.e., 21 CFR 112.2(b)(4), 112.7, 112.12(c), 112.30, 112.60, 112.140, and 112.150). (See also the subsection of this chapter titled “Specific Records Requirements”). You should consult the chapters of this draft guidance related to subparts A, C, F, and L to ensure that you establish and maintain the specific records that those subparts require; subparts D, I, K, N, P, Q, and R do not require specific records. We separately address specific records requirements for subpart M—Sprouts. We also intend to separately provide draft guidance for the requirements of subparts B—General Requirements (specifically, Alternatives) and E—Agricultural Water; and on specific records for these subparts.

Subpart O describes the requirements for establishing and maintaining records, including: general requirements; records storage; use of existing records; records retention; records format; and records disclosure. With a few exceptions, these requirements apply to all records the Produce Safety Rule requires.

Personnel to whom you assign the responsibility of developing, creating, completing or reviewing records should understand your procedures. You should direct supervisors or responsible parties, as applicable, to ensure that records are created and reviewed in accordance with your procedures and corrections are made as needed. You could access templates for records from sources such as academia, extension services, and industry associations to assist you in creating a consistent approach.

### **1. General Requirements for all Records**

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 farm (21 CFR 112.161(a)(1)(i));
- Actual values and observations obtained during monitoring (21 CFR 112.161(a)(1)(ii));

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- 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 (21 CFR 112.161(a)(1)(iii));
- The location of a growing area or other area (for example, a specific packing shed) applicable to the record (21 CFR 112.161(a)(1)(iv)); and
- The date and time of the activity documented (21 CFR 112.161(a)(1)(v)).

Required records must also:

- Be created at the time an activity is performed or observed (21 CFR 112.161(a)(2));
- Be accurate, legible, and indelible (21 CFR 112.161(a)(3)); and
- Be dated, and signed or initialed by the person who performed the activity documented (21 CFR 112.161(a)(4)).

**a. Farm Name and Location**

Your required records must include, as applicable, the name and location of your farm. (21 CFR 112.161(a)(1)(i)). This requirement ensures that your records are linked to your farm. You should use the postal address or physical location (such as latitude or longitude) of the farm. You may choose to use documents pre-printed with your farm name and location to ensure that this information is captured on each of your records. If your records include written information obtained from a third party (e.g., a report of analysis from a contract laboratory) and the information provided by the third party does not include certain required information (e.g., a customer number instead of your farm's name and location), you can fulfill this requirement by supplementing the record with the additional required information, or including it on a new, attached record. Additional draft guidance is provided in the section of this chapter titled "Use of Existing Records."

**b. Location of Growing or Activity Area**

Your required records must include, as applicable, the location of a growing area or other area applicable to the record. (21 CFR 112.161(a)(1)(iv)). This requirement ensures that your records are linked to the specific growing areas, packing areas, or other areas of your farm that are relevant to the record. Your personnel might create required records relative to several different areas on your farm. You should therefore establish a system to accurately document the location applicable to the record, such as by using specific identifiers (e.g., field names or numbers; building names or numbers; or geographical markers) for the various areas on your farm. For example, if a farm grows carrots in three separate fields and the records do not provide a specific identifier (e.g., name or number) for each field, the record would not be sufficiently specific to link the record to a specific field. You should determine whether areas of your farm have existing specific location identifiers that you can use for your records or whether you need to create new identifiers. If you already have farm maps with specific field, orchard, grove, or vineyard numbers, or other specific identifiers, for each site, you can record those identifiers on your records. You may also choose to use street addresses or specific coordinates using a GPS or other mapping system.

**c. Adequate Description of Covered Produce**

Your required records must include an adequate description of covered produce applicable to the record. (21 CFR 112.161(a)(1)(iii)). Descriptions should include the relevant commodity name, or the variety name or brand name, and any lot number or code that you use to identify the covered produce. For example, if your farm grows different varieties of apples—one variety in each of three orchards—then your records for each orchard should, as appropriate, describe the covered produce grown in the relevant orchard: “apples, Fuji;” “apples, Granny Smith;” or “apples, Golden Delicious.”

**d. Actual Values and Observations**

Your required records must include, as applicable, actual values and observations obtained during monitoring. (21 CFR 112.161(a)(1)(ii)). The records should include accurate values or observations from an instrument or a visual assessment by personnel, as applicable (e.g., a temperature reading of 96.2°F from a thermometer, or a pH meter reading of 4.20). Recording actual values and observations during monitoring is necessary to produce an accurate record. Records stating that monitoring measurements are “satisfactory” or “unsatisfactory,” without recording the actual times and observations (e.g., temperatures and turnings in treating biological soil amendments of animal origin) are vague and subject to varying interpretations and, thus, will not ensure that required measures have been taken or standards have been met. In addition, it is not possible to discern a trend without actual measurement values.

Furthermore, recordings of instrument readings must reflect the actual value displayed by the instrument, without rounding or generalization. (See 21 CFR 112.161(a)(1)(ii)). For example, if personnel conduct a pH measurement of composting manure and the reading is 6.56, the recorded value must be stated as “6.56,” rather than “pass” or “OK,” or rather than being rounded to “7.0” or written as “> 6” (greater than 6.0). (See 21 CFR 112.161(a)(1)(ii)).

**e. Created when Activity is Performed or Observed**

As applicable, your required records must be created at the time an activity is performed or observed. (21 CFR 112.161(a)(2)). This requirement ensures that the accuracy of recorded information is not impacted by human error, such as lapses in memory. If an individual does not create the record at the time an activity is performed or observed, they could create an inaccurate record by forgetting the exact value observed, confusing values for multiple observations, or forgetting to create the record. For example, if a worker is responsible for recording sanitizing activities that occur in a packing area, the worker should record each activity or observation, such as the pieces of equipment sanitized and the compounds and concentrations of treatments used, as it is performed.

**f. Date and Time**

Your required records must include, as applicable, the date and time of the activity documented. (21 CFR 112.161(a)(1)(v)). You should establish a procedure for personnel to use when recording dates to ensure consistency and clarity. For example, you might set a procedure that personnel should record all dates in the format of MM-DD-YYYY. Personnel should record

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times without rounding or generalization. For example, if personnel take a measurement at 1:03pm, they should record that time, not 1:00pm or 1:05pm.

**g. Accurate, Legible, and Indelible**

Your required records must be accurate, legible, and indelible. (21 CFR 112.161(a)(3)). Legibility is particularly important for records involving handwritten entries. Indelibility is important to ensure that the original content has not been altered; therefore, records should not be erasable. For example, an erasable white-board is not indelible. If mistakes are made on a required record, your personnel should correct the original marking in a way that allows both the original content and the updated content to be read. In other words, you should not mark over the original content in a way that prevents a person from reading the original content. For example, if an incorrect value of “6.0” is written in permanent ink, the person who recorded that value should draw a single line through the “6.0,” add the accurate value of “6.1,” and write their initials and the date nearby. For specific records listed in 21 CFR 112.161(b), a supervisor or responsible party reviewing records, when required by 21 CFR 112.161(b), should assess whether the record is legible.

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

The person who performed the activity documented must date, and sign or initial the record. (21 CFR 112.161(a)(4)). This ensures that you can identify the individual who performed the activity recorded as well as the date the record was completed. While this provision allows for the use of initials instead of a signature, there could be circumstances in which initials alone could be confusing. For example, if you have multiple workers with the same initials (e.g., John Dab, Jane Dell, and Jennifer Doe), your procedures should direct those personnel to sign their full name or provide some additional identifier (e.g., “JD1” or “J. Dab” or “JWD”) instead of using only their first and last initials.

**i. Review by a Supervisor or Responsible Party**

A supervisor or responsible party must review, date, and sign the following records within a reasonable time after those records are created:

- As applicable, records demonstrating eligibility for a qualified exemption under 21 CFR 112.7(b);
- As applicable, documentation that process controls were achieved for a treated biological soil amendment of animal origin you produce for your own covered farm(s), as required under 21 CFR 112.60(b)(2);

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- Documentation of cleaning and sanitizing of equipment under 21 CFR 112.140(b)(1) and (2). (21 CFR 112.161(b)).<sup>11</sup>

When reviewing these records, the supervisor or responsible party should determine whether:

- The records are complete, including whether personnel recorded their observations at the appropriate frequency for a given activity;
- If any problems were recorded, those problems were addressed with appropriate corrective measures (for example, if a supervisor reviews a composting record and notices that a given temperature reading was below the necessary temperature for an effective treatment, the supervisor should confirm that the compost was either retreated or handled as untreated); and
- Any necessary corrective measures are taken in a timely manner. For example, if records indicate the need for a corrective measure to prevent distribution of an adulterated product, then a supervisor or other responsible party should confirm that the appropriate measure was performed.

You should also review records to identify trends in recorded values or observations so that you can adjust before it is necessary to take corrective measures. You should review records for any unexpected results. For example, if a supervisor reviews a record of a sanitizer pH value, which they expect to be pH 6-7, and the recorded value is 4.2, the supervisor should follow-up with the worker who made the recording to determine whether there was a malfunction with the monitoring instrument, a difficulty by the worker in reading the instrument, a recording error (i.e., the record is not accurate), or some other problem.

The supervisor or responsible party review must take place within a reasonable time after the records were created. (See 21 CFR 112.161(b)). In most instances, we believe that an appropriate time period for a supervisor or responsible party to review records is approximately one week after the record is created. In some cases, you could find that a shorter or longer timeframe is appropriate. You should adopt procedures regarding records review timeframes to ensure that supervisors and responsible parties consistently perform reviews within a reasonable timeframe to allow for any necessary follow-up actions. For example, a reasonable timeframe should generally allow for covered produce or other items relevant to the record (such as equipment or biological soil amendments of animal origin) to be available so that you can take follow-up actions if needed.

A detailed records review could become tedious, particularly when the various records include similar information. You should ensure that supervisors and responsible parties review records at a time when they can focus on the records.

When the owner or supervisor is both the person who performed the activity and the responsible party who reviews the record, the requirements in both 21 CFR 112.161(a)(4) and 112.161(b) are

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<sup>11</sup> The regulation at 21 CFR 112.161(b) also requires that a supervisor or responsible party review, date, and sign records required by 21 CFR 112.50(b)(2), (4), and (6), and 21 CFR 112.150(b)(1), (4), and (6), which are not addressed in this draft guidance.

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satisfied when that person signs and dates the record. In this situation, the owner or responsible party should perform a thorough record review to evaluate the information in the record **after** the record includes all information required by the Produce Safety Rule (e.g., after that person records information such as the actual values and observations obtained during monitoring).

## **2. Records Storage**

You have the flexibility to store your records in a way that allows you to easily access them as necessary and to organize them consistent with your operating procedures. You should evaluate how frequently you need to access your records and how you use them on your farm, and then develop a records management strategy that best fits your needs. All records required under the Produce Safety Rule must be readily available and accessible to FDA. (21 CFR 112.166).

Required records must be stored either on the farm (i.e., “onsite”) or away from the farm (i.e., “offsite”). (21 CFR 112.162). Electronic records are considered onsite at your farm if they are accessible from an onsite location at your farm. (21 CFR 112.162(b)). If you have multiple growing sites for your farm, you could keep records at each site or consolidate all records from each growing site at a single site on your farm. For example, if a farm has three growing sites and sometimes uses seasonally-rented fields, the farm could choose to store all its records at the farm’s main office, even if some of the records were completed at the three growing sites and the seasonally-rented fields. As another example, the farm could store certain records for each growing site at that growing site while other records are stored at the farm’s main office.

Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. (21 CFR 112.162(a)). For example, your farm could generate some records that you need to easily access for a period of time, such as for one month or for a full growing season. You could choose to transfer the records to a central storage location, which is not part of the farm, for longer-term storage after that initial time period has ended. If those records are in an offsite storage location, they must be able to be retrieved and provided onsite within 24 hours of a request for official review. (21 CFR 112.162(a)).

## **3. Use of Existing Records**

You may use existing records and information (e.g., documents or information that you have already developed and maintained during the normal course of your farm’s business, including records that are kept to comply with other Federal, State, or local regulations, or for any other reason) to comply with subpart O if those records contain all of the required information and satisfy the requirements of the Produce Safety Rule. (See 21 CFR 112.163(a)). It is not necessary for you to keep all of the required information in only one set of records, nor do you need to duplicate existing records, provided that, taken together, your records satisfy all of the applicable requirements of the Produce Safety Rule. (See 21 CFR 112.163). If existing records contain only some of the required information, you may keep additional information required for compliance with the Produce Safety Rule either separately or in combination with the existing records. (21 CFR 112.163(b)). If you maintain records required by another entity, and those records contain some of the information required by the Produce Safety Rule, you are not required to duplicate the overlapping components. For example, your records must contain, as applicable, information such as the name and location of your farm (21 CFR 112.161(a)(1)(i)).

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If your records include written information obtained from a third party (e.g., a report of analysis from a contract laboratory) and the information provided by the third party does not include your farm's name and location, you can fulfill this requirement by keeping your farm's name and location recorded either separately or combined with the existing records.

As another example, if you maintain records of your annual gross food sales as part of your documentation (in addition to your annual review record) to demonstrate that your farm meets the criteria for a qualified exemption from the Produce Safety Rule (21 CFR 112.7(b)), you could find that both your invoices and other financial records kept in the normal course of business provide the necessary information. In this case, you would only need to keep one of these types of records (not both) to satisfy the requirement for documentation that your farm meets the criteria for the exemption (in addition to your annual review record), as long as the records you keep include all of the necessary information.

## **4. Records Retention**

You must keep records required by the Produce Safety Rule for at least 2 years past the date the record was created. (21 CFR 112.164(a)(1)). If you have a record with multiple entries, you should keep the record for 2 years past the date of the last recorded entry. This could include records such as: training records required by 21 CFR 112.30(b); the process used to treat a biological soil amendment of animal origin that you produce, as required by 21 CFR 112.60(b)(2); and the date and method of cleaning and sanitizing of equipment, as required by 21 CFR 112.140(b)(2).

You must also keep records that relate to the general adequacy of your equipment or processes, or records that relate to analyses, sampling, or action plans being used by your farm, including the results of scientific studies, tests, and evaluations, for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued. (21 CFR 112.164(b)). Examples of such records include records that contain annual written assurances from your customers regarding produce that receives commercial processing (21 CFR 112.2(b)(4)), if you keep such records because you rely on the exemption in 21 CFR 112.2.<sup>12</sup>

If you rely on the qualified exemption in 21 CFR 112.5, you must keep records supporting your qualified exemption, in accordance with 21 CFR 112.5 and 112.7, as long as necessary to support your farm's status during the applicable year. (21 CFR 112.164(a)(2)). This period could be as long as four years (i.e., the three previous years of financial records upon which you determined your eligibility for a qualified exemption and the current year for which the determination applies).

## **5. Records Format**

You have the flexibility to maintain your records as original records, true copies, or electronic records. (21 CFR 112.165). “True copies” include, for example, photocopies, pictures, scanned

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<sup>12</sup> As noted above, we have stated that we intend to exercise enforcement discretion related to the written assurances associated with the commercial processing exemption.

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copies, microfilm, microfiche, or any other accurate reproduction of the original record. True copies of records should be of sufficient quality to reveal whether the original record was changed in a manner that obscured an original entry (e.g., by using liquid correction fluid). “Electronic records” are subject to the same requirements as paper records under the Produce Safety Rule. You could use paper or electronic records, or a combination of the two, to satisfy the requirements of the Produce Safety Rule.

## **6. Records Disclosure**

Records obtained by FDA in accordance with the Produce Safety Rule are subject to the disclosure requirements under 21 CFR part 20. (21 CFR 112.167). This includes certain protection for confidential commercial information and trade secrets (See, e.g., 21 CFR 20.61). Our general policies, procedures, and practices relating to the protection of such information also apply to information received under the Produce Safety Rule.

## **7. Specific Records Requirements**

As noted above, subpart O describes how you must establish and maintain records the Produce Safety Rule requires. You should refer to the following specific areas of the Produce Safety Rule and the relevant chapters of this draft guidance to determine what specific records you are required to keep that, with a few exceptions, are subject to the requirements of subpart O:

- Subpart A—General Provisions:
  - Produce eligible for exemption based on receipt of commercial processing that adequately reduces the presence of microorganisms of public health significance (21 CFR 112.2(b)(4));
  - Qualified Exemption (21 CFR 112.7);
- Subpart C—Personnel Qualifications and Training;
- Subpart F—Biological Soil Amendments of Animal Origin and Human Waste; and
- Subpart L—Equipment, Tools, Buildings, and Sanitation.

These specific records represent minimum standards; you could keep additional records related to practices on your farm to support minimizing the risk of contaminating covered produce.

## **Chapter 9: Variances (Subpart P)**

Subpart P of the Produce Safety Rule provides that a State, Federally-recognized tribe (“tribe”), or foreign country from which food is imported into the United States (“foreign country”) may request a variance from one or more requirements of subparts A through O of the rule, where the State, tribe, or foreign country determines that:

- The variance is necessary in light of local growing conditions; and
- The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and to provide the same level of public health protection as the requirements of this part. (21 CFR 112.171).

This chapter provides draft guidance on the requirements of subpart PVariances, and the procedures to request a variance. In addition, this chapter provides draft guidance on how FDA intends to evaluate requests for a variance.

### **1. Entities Eligible to Submit a Variance Request**

The request for a variance must come from the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or foreign country. (See 21 CFR 112.171 and 112.172).

Entities that are not the regulatory authority for food safety, such as a state commodity commission, are not eligible to request a variance. However, as discussed below, such groups (and others) may assist the competent authority in developing supporting information for the variance request.

### **2. Grounds for a Variance**

A competent authority (“CA”) may request a variance from one or more of the provisions of subparts A through O of the Produce Safety Rule. (21 CFR 112.182). Examples of some of the permissible types of variances are provided in 21 CFR 112.182.

To request a variance, a CA must submit a petition under 21 CFR 10.30. (21 CFR 112.172). In addition to the requirements of 21 CFR 10.30, the Statement of Grounds of the CA’s petition requesting a variance must provide a statement that the CA determined that:

- The variance is necessary in light of local growing conditions;
- The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act; and
- The procedures, processes, and practices to be followed under the variance are reasonably likely to provide the same level of public health protection as the relevant requirements of the Produce Safety Rule. (21 CFR 112.173(a)).

The CA also must describe with particularity:

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- The variance requested;
- The persons to whom the variance would apply; and
- The provision(s) of the Produce Safety Rule to which the variance would apply. (21 CFR 112.173(b)).

Further, the CA must present information demonstrating:

- That the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the covered produce is not adulterated under section 402 of the FD&C Act; and
- That the procedures, processes, and practices to be followed under the variance are reasonably likely to provide the same level of public health protection as the requirements of the Produce Safety Rule. (21 CFR 112.173(c)).

In evaluating whether a variance is “necessary in light of local growing conditions,” the CA might consider factors such as climate, soil, and geographical and environmental conditions in its particular region. If particular controls (such as regional-specific practices, processes, or procedures) or oversight (such as regional produce marketing programs) are used, the nature of the oversight established could also be relevant to the CA’s request.

The petition’s Statement of Grounds must describe with particularity the variance requested. (21 CFR 112.173(b)). It must include the persons to whom the variance would apply and the provision(s) of the Produce Safety Rule to which the variance would apply. (21 CFR 112.73(b)). Specifically, this includes what farms would be covered by the variance; the measures that farms covered by the variance would follow; and the provisions of the Produce Safety Rule for which those measures would be substituted. The CA must also indicate the persons to which it requests that the variance apply. (21 CFR 112.173(b)). For example, the requested variance might apply to all persons in the CA’s jurisdiction, or might be limited to a specific group in the jurisdiction. If the CA’s proposed approach is based, at least in part, on climate, soil, or geographical or environmental conditions of a particular region within the CA’s jurisdiction, the petition should describe those conditions and the boundaries of the specific region involved.

### **3. Information to Support a Request for a Variance**

The Statement of Grounds in a petition requesting a variance must present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and to provide the same level of public health protection as the requirements of the Produce Safety Rule. (21 CFR 112.173(c)).

A CA should include relevant and scientifically-valid information or materials specific to the covered produce or covered activity to support the request for a variance from corresponding requirements established in the Produce Safety Rule, in accordance with the requirements of 21 CFR 112.173(c). It is likely that a CA will use several resources to gather the information necessary to support and describe its request for a variance. A CA could develop the information itself, obtain it from scientific literature or a third party (such as a trade association or commodity board), or use some combination of resources to collect the necessary information.

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A CA could, for example, present in its petition information that came from an individual farm or group of farms, an importer or exporter, a trade or other industry association, academia, a private food safety entity, a consultant, or another stakeholder. The scientific support for a variance could be developed, for example, through a broad effort involving farms, academia, extension services, industry associations, and government agencies. Information that a CA uses does not need to be published in a peer-reviewed journal, although we encourage use of peer-reviewed data and information.

Although the types of data or information that a CA should submit in support of its petition for a variance vary widely depending upon the nature of the request, some examples include:

- Information about the specific, local growing conditions, including crop, climate, soil, and geographical and environmental conditions of the region relevant to the request;
- Information about the processes, procedures, or practices followed in the growing, harvesting, packing, or storing of covered produce in the region relevant to the request.

**4. Process for Requesting a Variance**

To request a variance from one or more requirements of subparts A through O of the Produce Safety Rule, a CA must submit a petition to FDA under the procedures contained in 21 CFR 10.30. (21 CFR 112.172). Subpart P—Variances provides additional specific requirements for a petition for a variance. We encourage competent authorities considering requesting a variance to participate in pre-submission consultations with FDA.

A CA could also request that a variance requested by a petition submitted by another competent authority be applied to its similarly situated persons. (See 21 CFR 112.177). Similarly situated persons could include, for example, farms that operate under similar circumstances with similar procedures, processes, and practices as those covered by the other competent authority's request for a variance.

We encourage CAs to collaborate with other entities in the development of their petition requesting a variance, such as industry groups and other relevant stakeholders. These entities could provide the CA with information to support certain aspects of the variance request or they could assist the CA in drafting the petition. Additionally, if a CA is requesting a variance for farms within its jurisdiction that are similarly situated to those covered by a variance requested in a petition submitted by another CA, the requesting CA could find it useful to access scientific data and other information from that petition.

We will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under 21 CFR part 20, and will be made public as part of the docket associated with the request. (21 CFR 112.174).

### **III. References**

We have placed the following references on display in the Dockets Management Staff, 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. As of July 2018, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this draft guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after July 2018.

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