

AT A GLANCE: KEY POINTS IN THE PRODUCE SAFETY RULE DRAFT GUIDANCE

CHAPTER 7: EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION (SUBPART L)

What is the goal of this chapter?

To help farmers comply with the requirements covering equipment and tools, buildings, and sanitation in the Produce Safety Rule. Maintaining sanitary conditions is critical to preventing the contamination of produce from the surrounding environment.

References to “you” in this document (as well as in the Produce Safety Rule and draft guidance) mean the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of the rule. In addition, unless otherwise specified, we’re only talking about produce covered by the rule.

■ EQUIPMENT AND TOOLS

What kinds of equipment and tools are covered by the requirements, and what are some of the recommendations?

Farmers use many different types of equipment and tools during the growing, harvesting, packing and storing of their crops. The rule covers equipment and tools that are intended to, or likely to, contact produce. It also covers equipment and tools used to transport produce and those instruments or controls used to measure, regulate or record conditions in the interest of preventing the growth of microorganisms that could contaminate them.

As a starting point, you should take a look at your operation to identify the equipment and tools on your farm that are intended, or likely to, contact produce, including all the uses mentioned above.

For more information and examples, see the “Equipment and Tools” section in Chapter 7 of the draft guidance, specifically the subsection on identifying equipment and tools intended or likely to contact covered produce.

Examples of covered equipment and tools include knives, implements (i.e. tools or utensils), mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or transport harvested covered produce (such as containers, bins, food-packing materials, dump tanks, flumes, and vehicles). Those that measure and record conditions include thermometers.

The draft guidance recommends that you distinguish between food contact surfaces and non-food contact surfaces. There are requirements for each, although they are more stringent



for the surfaces that contact food. For example, the blades and conveyors on a harvesting machine come in direct contact with produce, while the portion of the machine that holds boxes containing harvested produce does not. You may have to clean and sanitize the former, but just clean the latter. Cleaning and, when necessary and appropriate, sanitizing are required for food contact surfaces. For non-food contact surfaces, cleaning is required.

For more information and examples, see the “Equipment and Tools” section in Chapter 7 of the draft guidance, specifically the subsection on identifying food contact surfaces and non-food contact surfaces.

What are the recommendations for equipment and tools?

After you identify the equipment and tools that are intended to, or likely to, contact produce and determine which are food contact and non-food contact surfaces, there is a series of steps to follow:

- **Evaluate the design, construction, workmanship, installation, and maintenance of these equipment and tools.** What materials are they made of? Are any seams smooth? Can they be adequately cleaned and properly maintained? Do they allow access for cleaning and maintenance activities? Do they limit potential for moisture or organic material to accumulate? Look for signs of damage or other wear-and-tear such as pits, cracks, corrosion, crevices, score marks, jagged edges, and partially opened space that could create an environment in which bacteria can thrive. Is equipment installed so cleaning and maintenance personnel have space to easily access all relevant parts? Do maintenance procedures ensure that any identified defects or damage is repaired or replaced?
- **Evaluate your storage and maintenance practices and storage locations.** Are equipment and tools stored in a location and manner that will protect produce from contamination, including measures taken to avoid attracting or harboring pests? Have you considered both short-term (such as between shifts or overnight) and long-term (such as during the off-season) storage? Look for signs of moisture or other potential sources of contamination.
- **Establish procedures and schedules for cleaning, and, when necessary, sanitizing food contact surfaces.** This must take place as often as reasonably necessary to protect against contamination. And non-food contact surfaces must also be maintained and cleaned as often as necessary. The cleaning and, when necessary, sanitizing methods you choose should be based on your production environment, the produce handled, and the equipment and tools used. The draft guidance gives examples of wet (using water and cleaning solutions) and dry (mechanical or other means without using liquids) cleaning methods and the factors to consider when choosing the best methods for your farm.

For more information and examples, see the “Equipment and Tools” section in Chapter 7 of the draft guidance, specifically the subsections on cleaning and sanitizing procedures and frequency of cleaning and sanitizing.

- **Establish procedures and schedules to conduct inspections.** Periodic inspections can help you identify signs of potential contamination. Inspections can be conducted independent of, or in conjunction with, other activities, such as cleaning, sanitizing or maintenance. Are your personnel aware of when and how these inspections should be performed and what findings to report?
- **Evaluate your use of transport equipment.** You should identify transport equipment, such as pallets, forklifts, tractors and trucks, to assess whether they are being used in a manner that minimizes the potential for contamination of produce or food contact surfaces. Transport equipment must be adequately clean before and while transporting your produce.
- **Evaluate the accuracy, maintenance and number of instruments and controls used to measure, regulate, or record conditions to control or prevent the growth of potentially hazardous microorganisms.** These include test strips, meters and various kinds of thermometers that could be used for such purposes as testing temperatures in composting piles or the antimicrobial concentration in a sanitizing solution. There should be periodic accuracy checks and a calibration schedule for the relevant instruments and controls used on the farm.

Can I use materials like wood or foam?

The draft guidance recommends 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. If you choose to use equipment and tools made of these materials, the equipment and tools must be of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained.

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. Porous materials, such as fabric, cardboard, foam, and carpet, can trap moisture, making it difficult to remove organic material and bacteria. Both porous and non-porous materials can facilitate contamination if they are damaged or their surfaces are not intact.

A farm's conditions and practices should also be considered. This chapter of the draft guidance gives examples, including ones involving the use of wood and foam, of how a farm could evaluate their equipment and tools, conditions and practices based on the requirements. In some of the examples, a farm's evaluation leads to operational changes, while in others no changes are made.

For more information and examples, see the "Equipment and Tools" section in Chapter 7 of the draft guidance, specifically the subsection on examples.

BUILDINGS

Buildings subject to the Produce Safety Rule include any fully- or partially-enclosed buildings (such as structures that have a roof but no walls) used for covered activities, in other words activities that involve growing, harvesting, packing and holding produce. This would include storage sheds, buildings, or other structures used to store produce or food.

contact surfaces, such as harvest containers, plastic bags, cardboard boxes and other food-packing materials as well as certain equipment. Buildings subject to the rule can be permanent or temporary structures.

What are some of the requirements and recommendations for buildings subject to the Produce Safety Rule?

Buildings are required to be of suitable size, construction, and design to allow for maintenance and sanitary operations that would reduce the potential for contamination of produce or food contact surfaces. You are also required to have adequate drainage in all areas of your buildings where normal operations release or discharge water or other liquid waste on the ground or floor of the building. You should identify all the buildings used for covered activities. You should consider the activities that occur and their frequency, placement of equipment, and number of people within a building at any given time. Other factors to be considered include ventilation and facilitation of pest control.

How should I evaluate my buildings for “suitable size”?

The building should offer enough room for covered activities to be conducted without allowing for cross-contamination between produce or food contact surfaces and building materials, non-food contact surfaces, or clothing. You should also consider whether the placement of equipment and other materials in the building allow for enough space for proper maintenance and sanitation.

How should I evaluate my buildings for “suitable construction”?

Buildings should be constructed in a way that facilitates maintenance of sanitary conditions. For instance, this means that windows, doors, and roofs of fully-enclosed buildings should be constructed in a way that prevents leaks, and the entry of dirt, dust, debris, and pests. Building materials and construction should be durable enough to withstand use. For example, floors should be able to withstand foot and equipment traffic without becoming damaged or permitting the entry of pests. Buildings should also allow access for examination and maintenance of equipment and the building itself. You should periodically evaluate and visually assess your building materials and construction.

How should I evaluate my buildings for “suitable design”?

The design of the building should consider the separation of operations to reduce the potential for contamination. For example, a careful layout and installation of equipment within buildings could include installing physical barriers to separate activities, or dedicating areas to specific activities with sufficient space or barriers between them.

For more information and examples related to these three questions about evaluating your buildings, see the “Buildings” section in Chapter 7 of the draft guidance, specifically the subsection on size, construction and design.

What does “adequate drainage” mean?

Farms should take steps to ensure that the drainage system, including the drain grate, accommodates the release of liquid used in operations. To be clear, we are not necessarily referring to small pools of water that form temporarily in buildings used for growing

activities; in these types of buildings, such as greenhouses, from time to time, watering practices could result in temporary pools on the floor of the growing areas, and this occurrence is not likely to contribute to the contamination of produce.

Farms should, however, take measures to facilitate proper drainage to ensure that pooled water is not left standing for long periods of time. Farms should take note that floor drains are known to serve as harborage sites for *Listeria monocytogenes*.

What other measures should I be taking to prevent contamination?

You should evaluate your buildings, including making a visual assessment, for the potential for contamination, including floors, walls, ceilings, fixtures, drains, ducts, or pipes. You should particularly be looking out for leaks, ducts or pipes that drip liquid or generate moisture, surfaces of buildings that are not adequately cleaned, and damage throughout the building. Appropriate action should be taken when necessary, such as repairing or replacing building components, like broken piping systems that leak onto produce or food contact surfaces. You should clean and sanitize building components, including drains, as necessary and in a way that prevents contamination and minimizes the risk that water used in the cleaning process will splash onto produce or food contact surfaces.

What are the requirements and recommendations for keeping pests out of my buildings?

You are required to take measures to protect produce, food contact surfaces, and food-packing materials from becoming contaminated by pests. You should look for potential points of entry and potential routes of pest movement. Pest attractant or harborage areas (such as those with debris for nesting, food scraps and pooled water) should be minimized in and around buildings. The frequency of monitoring for pests should be based on several factors, including: potential for pest activity, observations of pests, and environmental conditions. There are several pest control strategies that could be appropriate. These include covering or repairing holes in your buildings, minimizing debris (that could be used for nesting) and food scraps, installing screens, and taking prompt action to eliminate them as they appear.

What are some of the requirements and recommendations for domesticated animals?

To prevent contamination of produce, food-contact surfaces, and food-packing materials by domesticated animals, including dogs and cats, you must either exclude animals from fully-enclosed buildings where produce, food contact surfaces, and food-packing materials are exposed, or keep them away from the produce and covered activities in such buildings. You should take a look at the presence and actions of domesticated animals on your farm to help you determine how to prevent them from being sources of contamination. You could, for example, keep screens on windows and install doors or gates that dogs, cats and other animals cannot jump over.

More information about the recommendations related to animals on the farm can be found in this chapter, including preventing contamination from animal excreta and litter by domesticated animals.

Additionally, more information related to animals can be found in Chapter 3 (Health and Hygiene), Chapter 5 (Domesticated and Wild Animals), and Chapter 6 (Growing, Harvesting, Packing and Holding Activities) of this draft guidance.

■ SANITATION

What are some of the requirements and recommendations for toilet facilities?

Toilet facilities must be available and easily accessible to all personnel working on your farm and visitors. Toilet facilities should be within walking distance of where employees are working and should be able to accommodate the number of employees that may need to use the facilities. The design and maintenance of toilet facilities should be evaluated to ensure that they have proper drainage and that they do not leak sewage or liquid waste. You should also evaluate where toilets are located. For instance, if you have one toilet facility that is used by personnel working in various parts of a building, you might want to design the building in such a way that minimizes walking through areas used for packing, holding or growing produce to reach the toilet. Portable toilet facilities could be located downhill from growing areas and away from water sources to reduce the potential for runoff in case of an accidental spill or leak.

You should also have procedures, including schedules, in place for monitoring, servicing and cleaning your toilet facilities. Factors to consider: Who did you assign to perform these activities? Are these facilities monitored frequently enough that they are well supplied with things like toilet paper? Are the toilet facilities cleaned often enough to be sanitary? Do the toilet facilities allow for sanitary disposal of waste and toilet paper? Do service personnel and vehicles have sufficient space to access the facilities?

What are some of the requirements and recommendations for hand-washing facilities?

You are required to provide hand-washing facilities for both personnel and visitors to your farm. These facilities must be readily accessible during harvest, packing and holding activities and during growing activities in a fully enclosed building. You should consider personnel and visitor activities to help determine number and location of handwashing facilities. They must be supplied with soap, running water, drying devices and the appropriate disposal of both solid (towels) and liquid waste. You should set up procedures and schedules for monitoring, servicing, cleaning and sanitizing your handwashing facilities. You should also evaluate your solid and liquid waste disposal systems to ensure they do not contribute to contamination of agricultural water sources or distribution systems, produce, food contact surfaces, or areas used for covered activities.

What are some of the requirements and topics covered in the recommendations for controlling or disposing of sewage?

Sanitary disposal of human waste reduces the likelihood that it will contaminate produce, food contact surfaces, areas used for a covered activity, or agricultural water sources or distribution systems. You must dispose of sewage into an adequate system, maintain the system to prevent contamination, and manage and dispose of leaks or spills in a manner that prevents contamination. You should evaluate your sewage system, which could include a municipal sewage system, an individual septic system, or a self-contained unit (which might be portable), and any associated plumbing. You should periodically inspect these systems, including for proper seals, degradation or damage over time, and evaluate whether they can sufficiently handle increased use, if appropriate. If you know or suspect that a sewage system has failed, you should stop using water systems that drain or transmit waste to the sewage system and determine the cause of the leak in order to make repairs. In the event of a leak or spill, you should contact your local public health or waste management authorities for assistance in complying with their regulations for sewage disposal.

Management of a spill or leak of human waste could include:

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

What must I do if there is a natural disaster, like a flood, hurricane or earthquake, that could affect my sewage system, and what are some recommendations?

After such events, you must take appropriate steps to ensure your sewage system continues to operate in a manner that does not contaminate produce, food contact surfaces, covered activity areas, or agricultural water sources or distribution systems. You should inspect the system and correct any damage, or consider whether growing, harvesting, packing and holding activities should be put on hold until sewage or septic systems can be repaired.

What are some of the requirements and recommendations to control and dispose of trash, litter, and waste on my farm?

Trash, litter, and waste in areas used for covered activities are required to be conveyed, stored, and disposed of to protect against contamination and minimize the potential for pests. Some things you should evaluate in your system for controlling and disposing of waste material are:

- What waste collection, like trash cans, and waste holding containers, like dumpsters, are you using, and where are they located? Are they away from produce or food contact areas, and available in places where waste is generated?
- Do the containers accommodate the volume of waste generated and prevent leaks?
- How frequently do you transfer waste from trash cans to dumpsters or other waste storage containers?
- Could there be runoff from trash collection and storage areas that could contaminate produce or food contact surfaces?

You should establish periodic cleaning, sanitizing and maintenance schedules for your waste collection and storage containers and equipment, such as forklifts, used to transport these items.

What are some of the requirements and recommendations that apply to plumbing?

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

- 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.
- Properly transport sewage and liquid disposable waste.
- Prevent backflow from, or cross-contamination between, piping systems that discharge waste water or sewage and those that carry water used for covered activities, sanitary operations, or hand-washing facilities.

Ultimately, you must maintain these systems to avoid them becoming a source of contamination. There are several recommended practices discussed in the draft guidance, including that you should equip all water supply piping with backflow prevention devices. You should also periodically inspect your plumbing systems to look for the absence of back-flow devices, potential cross-connections or dead ends, damage, blockages, or other problems that could contribute to contamination. You should also look out for inadequate water pressure and volume, which could impact your ability to conduct sanitary operations, such as properly cleaning food contact surfaces, or providing water to multiple hand-washing stations.

■ RECORDS

What type of records are required for cleaning, and sanitizing equipment and tools?

You are required to establish and keep documentation of the date and method of cleaning and sanitizing of equipment used during covered harvesting, packing and holding activities. The record should include the concentration of cleaning and sanitizing solutions. You could, for example, develop records, such as a log, for groups of equipment that are cleaned and sanitized in the same way with the same solutions.

Chapter 8 (Records) of this draft guidance provides further clarification on records recommendations.

For further explanation of the underlined words, see the [Key Terms Glossary](#).

The [draft guidance](#) contains more details and examples of FDA's recommendations and current thinking. It is recommended that you review the draft guidance for complete information.