AT A GLANCE: KEY POINTS IN THE PRODUCE SAFETY RULE DRAFT GUIDANCE

CHAPTER 6: GROWING, HARVESTING, PACKING AND HOLDING ACTIVITIES (SUBPART K)

What is the goal of this chapter?

To help farmers comply with the growing, harvesting, packing and holding activities requirements in the Produce Safety Rule. This chapter covers a variety of food safety issues likely to be encountered in day-to-day farm operations. Your personnel should understand farm practices and procedures and the applicable requirements of the Produce Safety Rule.

> *References to "you" in this document (as well as in the Produce Safety Rule and draft guidance) mean the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of the rule.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.*

If you grow both covered produce and produce that is not subject to the Produce Safety Rule, what must you do and what are some recommendations?

You may grow, harvest, pack and hold crops that are covered by the Produce Safety Rule, and others that are not (referred to in the rule as "excluded produce.") Activities involving both kinds of produce could overlap (in the same place, at about the same time, using the same equipment and tools, and/or involve the same personnel). There are requirements in the rule to minimize the potential for contamination of covered produce in these situations, and the draft guidance provides recommendations on how to meet them.

So, what do you do? One option is to meet the rule's requirements for all your produce, whether it is covered or not. That way you'll just have one set of operating procedures.

If you don't follow the rule's requirements for produce not covered by the rule, you must keep the covered and excluded produce separate. You should identify the location where covered and excluded produce are grown, harvested, packed and held and evaluate your practices to ensure separation. You could, for example, plant covered produce in a different location from where you plant excluded produce. For packing or holding, if you handle all your produce at the same time, you could separate covered from excluded produce using barriers, or you could designate specific areas with enough space for separate activities. Another option is to harvest, pack or hold covered produce before doing the same for excluded produce.

For more information and examples, see the "Separation of Covered and Excluded Produce" section in Chapter 6 of the draft guidance.

You must also adequately clean and sanitize, as necessary, all shared food contact surfaces before uses with covered produce.

You should also identify equipment and tools used for both excluded and covered produce. You could assign separate equipment and tools for each kind of produce, or you could establish procedures for cleaning and, as necessary, sanitizing equipment and tools between uses.

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

You are not, however, required to keep covered and excluded produce separate when you place them into the same container for distribution. This might be the case if you are selling gift baskets or putting together community supported agriculture (CSA) boxes.

What measures are required to identify, and not harvest, produce that is likely to be contaminated and what are some recommended practices?

Immediately before and during harvest activities you are required to take all measures reasonably necessary to identify, and not harvest, produce that is reasonably likely to be contaminated.

But when we say "reasonably necessary measure," what do we mean? At a minimum, a visual assessment of the growing area and all produce to be harvested must be performed to identify any potential hazards. Signs that produce is reasonably likely to be contaminated include the presence of animal feces, fur, hair or feathers, and signs of damage by animals, such as bite marks or uprooted plants. You'll also want to consider other sources of contamination, such as flooding.

The visual assessment should cover the entire harvest area, including areas that will be mechanically harvested, and the soil above produce grown underground.

Harvest personnel must be trained to recognize produce that cannot be safety harvested. You should also specify when your workers need to alert a supervisor or responsible party that a hazard has been identified so that the appropriate steps can be taken. Your procedures should include such steps as identifying the area that will not be harvested by cordoning it off, placing colored flags, or otherwise identifying the affected area.

More information and examples are available in the draft guidance, specifically in:

- ***Chapter 6, in the section entitled "Identifying and Not Harvesting Contaminated Covered Produce,"***
- ***Chapter 1, in the section entitled "Covered Farms," and***
- ***Chapter 2, in the sections entitled "Additional Training for Persons Who Conduct Harvest Activities" and "Training Records."***

Are there requirements for handling harvested produce and how should I go about handling my harvested produce in a safe way?

Yes, you must handle harvested produce in a manner that protects against contamination with known or reasonably foreseeable hazards. Practices to consider include avoiding contact between cut surfaces of produce and the soil. For example, harvested lettuce heads that have been cut from the root should be placed on a clean surface while awaiting trimming rather than being placed directly on the soil.

You should also try to reduce bruises, punctures or other injuries to the harvested produce to avoid creating pathways for contaminants. Other practices to consider include ensuring that harvest containers are free of rough edges, avoiding rough handling, and avoiding overfilling containers.

How must produce that has been dropped to the ground before harvest be handled?

You must not distribute dropped produce. This 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 produce that is intentionally dropped to the ground during harvesting (such as almonds).

Most produce can be damaged by the force of the impact when dropped to the ground and that damage could allow for the introduction or proliferation of foodborne pathogens. It's important to keep in mind that damage to dropped produce may not become visible for days to weeks.

Are there requirements for packaging my produce, and what are some options to meet these requirements?

Yes, you must package 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). Most produce continues to "breathe" after being packaged, which means that if the produce is packaged in a way that doesn't allow for new oxygen to come in, and carbon dioxide to be filtered out, you will find increased carbon dioxide in the package. This can create favorable conditions for *Clostridium botulinum* to produce deadly toxins. You can prevent this by using open, perforated, and otherwise oxygen-permeable packaging.

Also, when conditions are likely to favor *C. botulinum* growth and toxin formation, farmers may consider using antimicrobial compounds or treatments, or keep the temperature of the produce below 38°F.

What do I need to think about when collecting, transporting or distributing harvested produce?

Most farms will use containers of some sort to collect, transport and distribute harvested produce. These containers are considered food-packing materials. Generally speaking, food-packing materials include food packaging, containers or materials that come in direct contact with food.

When using a food-packing material, it must be adequate for its intended use. To help you comply with this requirement, you should:

- Identify the types of food-packing materials that you use and determine whether each material is reusable or designed for single use;
- Determine whether the container or material is unlikely to support the growth or transfer of bacteria, taking into consideration other factors such as handling, maintenance, and storage practices; and
- Determine whether reusable materials can be adequately cleaned.

You should periodically evaluate your practices to determine whether your food-packing materials are adequate, as your practices or use of these materials could change over time. There are several factors to consider, including: the type of material and its durability, the construction, your handling practices, and your produce. You and your personnel should look out for materials with cracks, pits, jagged edges, rough areas, score marks or other damage that can provide a pathway for bacteria to grow, or be transferred to produce.

Food-packing materials are subject to both subparts K and L of the Produce Safety Rule. (These subparts are covered in chapters 6 and 7 of the draft guidance, the latter focusing on equipment (including food-packing materials), tools, buildings and sanitation.

Here is an example to illustrate how a farm might evaluate the strengths and vulnerabilities of its food-packing material and related practices:

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

- The wax-impregnated, corrugated fiberboard 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 as a single-use food-packing material, and continues to periodically evaluate the use and handling of the boxes.

For more information and examples, see the "Food-Packing Material" section in Chapter 6 of the draft guidance.

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.