

AT A GLANCE: KEY POINTS IN THE PRODUCE SAFETY RULE DRAFT GUIDANCE

GLOSSARY OF KEY TERMS

There are **definitions in the Produce Safety Rule** that cover terms used throughout the rule. It may be helpful to you to familiarize yourself with them. Some are summarized here.

The draft guidance contains more details and examples of FDA's recommendations and current thinking. It is recommended that you review the draft guidance for complete information.

Adequately: As much as is necessary to accomplish the intended purpose in keeping with good public health practices. For example, *adequately reduces the presence of pathogens* means that the practice or process sufficiently reduces the potential health risk from harmful bacteria.

Applicable health condition: A condition or illness that presents a risk to public health because it is potentially serious and can be passed on from one person to another.

Biological soil amendment: Vegetative- or animal-based materials added to soil to help plant growth or improve the capacity of the soil to retain water.

Biological soil amendments of animal origin: Materials that come from animals, such as manure or non-fecal animal byproducts, including leftover scraps from the kitchen (table waste).

- Includes **agricultural teas**, water extracted from biological materials (such as manure or non-fecal animal byproducts, table waste, etc.).

Covered produce: Fruits or vegetables that are subject to the requirements of the Produce Safety Rule. Includes the harvestable or harvested part of the crop, which means in some cases that parts of the plant that are not edible are still covered by the rule. For example, a nut with its shell/hull is considered covered produce because the entire unit is harvested even if the shell is not typically edible.

Endangered Species Act: A 1973 law that provides for the conservation of plants and animals that are threatened or endangered and the ecosystems on which they depend for survival.

Farm: There are three types of farms covered by the Produce Safety Rule.

- **Primary Production Farms:** An operation under one management in one general physical location (but not necessarily sharing a common border or touching) devoted to the growing or harvesting of crops, the raising of animals (including seafood), or any combination of these activities.

Also includes operations that:

- pack or hold raw agricultural commodities;



- pack or hold processed food that is consumed on that farm (or another farm by the same management).
- manufacture or process food provided that all food is consumed on that farm or another under the same management.
- manufacture/process food that is not consumed on that farm or another farm under the same management but consists only of:
 - drying/dehydrating to create a distinct commodity (such as producing raisins from grapes)
 - treating to manipulate the ripening of raw agricultural commodities
 - packaging and labeling produce when these activities do not involve additional manufacturing/processing
- **Secondary Production Farm:** An operation, not located on a primary production farm, devoted to harvesting, packing, and/or holding of raw agricultural commodities grown, harvested and/or raised on the primary production farm. This is covered by the farm definition if the primary production farm owns, or jointly owns a majority interest.

In January 2017, FDA issued an enforcement discretion for the requirements in the Preventive Controls for Human and Animal Food Rules for certain activities that are similar to those that occur on farms but are not included in the farm definition. Future rulemaking may expand the farm definition to cover those activities and make them subject to the produce rule and not the preventive controls requirements. This future action would not affect activities currently covered by the Produce Safety Rule.

- **Farm mixed-type facilities:** An establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the Federal Food, Drug and Cosmetic Act and also be subject to the preventive controls rules.

Food contact surfaces: Surfaces that come in contact with food. They are also surfaces from which there is drainage or other transfer of materials that contacts food or other surfaces that contact food during the normal course of operations. Also includes equipment and tools used during harvest, packing and holding that comes in contact with food.

Foodborne pathogens: Microorganisms, including bacteria, that are transferred through food and can cause illnesses or deaths.

Food-packing materials: Containers or materials that directly contact food. This may include containers used to collect harvested produce (e.g., harvest bins, buckets, and totes) in growing areas and containers used to transport produce to packing or holding areas.

Harvesting: Activities that are traditionally performed on farms to remove fruits and vegetables from the place they were grown and prepare them for use as food. Harvesting is limited to on-farm activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating such produce without additional manufacturing/processing. Examples of harvesting include cutting (or otherwise separating) the edible portion of the produce from the plant and removing or trimming

part of it (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing produce grown on a farm.

Harvestable or Harvested Part: Not every part of the plant that is harvested can be eaten. Produce can include components of the “harvestable or harvested part” of the plant that would not be edible. For example, we consider the entire unit (nut or kernel, hull, and shell) the “harvestable or harvested part” of the crop. 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.

Pests: Essentially, any animals, birds or insects that could contaminate your produce, including rodents, bugs and birds.

Produce Safety Alliance: One of the public-private Alliances funded primarily by the FDA. PSA, a cooperation with Cornell University, FDA and the U.S. Department of Agriculture, developed a standardized training and education program to increase produce safety knowledge and prepare the produce industry and associated groups for FSMA implementation. PSA is training produce growers to help them understand and implement the regulatory requirements of the Produce Safety Rule.

Qualified End-user: The consumer of the food. Or a restaurant or retail food establishment 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 from that farm.

Note: The term ‘consumer’ does not include a business.

Qualified exemption: You are eligible for this exemption and required to meet modified requirements of the Produce Safety Rule if you meet these criteria:

- the average annual monetary value of the food your farm sold directly to qualified end-users (see definition above) must be greater than that sold to all other buyers during the same period; and
- the average annual monetary value of all food your farm sold during the preceding three-year period must be less than \$500,000, as adjusted for inflation.

Rarely consumed raw (RCR): Produce that the FDA has determined are almost always eaten only after being cooked. The following is a complete list of produce that has been designated RCR and therefore not subject to 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.

See [Rarely Consumed Raw Fact Sheet](#)

Raw Agricultural Commodity (RAC): 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 as defined in the Federal Food, drug and Cosmetic Act.

Restaurant: A facility that prepares and sells food directly to consumers for immediate consumption. “Restaurant” does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers. Restaurants include:

- Entities that serve food, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens; and
- Pet shelters, kennels, and veterinary facilities in which food is provided to animals

Retail food establishment: An establishment that sells food products directly to consumers as its primary function. It can include facilities that manufacture, process, pack, or hold food if the establishment’s primary function is to sell that food directly to consumers (not businesses). A “retail food establishment” includes grocery stores, convenience stores, vending machine locations and certain farm-operated businesses selling food directly to consumers as their primary function.

Sale of food directly to consumers from an establishment located on a farm, or by a farm-operated business, includes sales:

- At a roadside stand or farmers’ market
- Through a community supported agriculture (CSA) program.
- Through other sales platforms, including door-to-door sales; mail, catalog and Internet orders, including online farmers’ markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

* For the purposes of this definition, “**farm-operated business**” means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

You: References made to “you” in the Produce Safety Rule (as well as in the draft guidance and overviews) 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.

For more information, visit the [definitions section](#) in the final Produce Safety Rule.