

Select Definitions from Preventive Controls for Human Food Rule

1. **Harvesting** applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food.
 - a. Harvesting is limited to activities performed on raw agricultural commodities, or processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing on a farm.
 - b. Harvesting does not include activities that transform a raw agricultural commodity into a processed food* as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.
 - c. Examples of harvesting include
 - i. cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g. foliage, husks, roots or stems).
 - ii. cooling
 - iii. field coring,
 - iv. filtering,
 - v. gathering,
 - vi. hulling,
 - vii. removing stems and husks from,
 - viii. shelling,
 - ix. sifting,
 - x. threshing,
 - xi. trimming of outer leaves of; and
 - xii. washing raw agricultural commodities grown on a farm

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

3. **Manufacturing/processing** means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops of ingredients.

- a. Examples of manufacturing/processing activities include:
 - i. baking,
 - ii. boiling,
 - iii. bottling,
 - iv. canning,
 - v. cooking,
 - vi. cooling,
 - vii. cutting,
 - viii. distilling,
 - ix. drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins),
 - x. evaporating,
 - xi. eviscerating,
 - xii. extracting juice,
 - xiii. formulating,
 - xiv. freezing,
 - xv. grinding,
 - xvi. homogenizing,
 - xvii. irradiating,
 - xviii. labeling,
 - xix. milling,
 - xx. mixing,
 - xxi. packaging (included modified atmosphere packaging),
 - xxii. pasteurizing,
 - xxiii. peeling,
 - xxiv. rendering,
 - xxv. treating to manipulate ripening,
 - xxvi. trimming,
 - xxvii. washing, or
 - xxviii. waxing.

b. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing or holding.

- 4. **Packing** means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g. activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity**, as defined in section 201(c) of the Federal Food, Drug, and Cosmetic Act, into a processed food* as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.
- 5. **Packaging** (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

6. ***Processed Food** means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydrating or milling.
7. **Qualified End User**, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in 1.227 of this chapter) that:
 - a. Is located;
 - i. In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or
 - ii. Not more than 275 miles from such facility; and
 - b. Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.
8. ****Raw Agricultural Commodity** 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.
9. **Retail Food Establishment** means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations.

Please note: The definition of "retail food establishment/store" may vary between regulations. The definition above is taken directly from the Food Safety Modernization Act Preventive Controls for Human Food. State regulations may have a different definition of "retail food establishment/store".

**Found in the Federal Food, Drug and Cosmetic Act

* Found in 21 USCS § 321