

FDA FACT SHEET

Produce Safety Rule (21 CFR 112)

“RARELY CONSUMED RAW” PRODUCE

What is “Rarely Consumed Raw” Produce?

- “Rarely consumed raw” produce are fruits and vegetables that are almost always cooked before being consumed. Our use of produce that is “rarely consumed raw,” therefore, is intended to mean those produce commodities that are almost always eaten only after being cooked (i.e., heat treated in some form). Cooking is a kill-step that can adequately reduce the presence of microorganisms that are of public health significance.

Why is “Rarely Consumed Raw” Produce Exempt from the Produce Safety Rule?

- Cooking produce before it is consumed, whether commercially or by the consumer, can reduce the risk of serious adverse health consequences or death, which could occur if these commodities are consumed raw. Therefore, FDA concludes it is not reasonably necessary to subject produce that is “rarely consumed raw” to the requirements under the Produce Safety Rule.

While exempt from the Produce Safety Rule, produce that is “rarely consumed raw” is and will continue to be covered under the adulteration provisions and other applicable provisions of the Federal Food, Drug and Cosmetic (FD&C) Act, and any other applicable implementing regulations.

What Produce is Considered “Rarely Consumed Raw” by the Produce Safety Rule?

Produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

If produce is not included in the exhaustive list above, then it is considered “covered produce” by the Produce Safety Rule, unless an exemption applies¹.

How did FDA develop the “Rarely Consumed Raw” List?

The “rarely consumed raw” produce list was developed using survey data from the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA).

- NHANES/WWEIA is a national food survey conducted as a partnership between the U.S. Department of Health and Human Services (DHHS) and the U.S. Department of Agriculture (USDA).
- NHANES/WWEIA examines a nationally-representative sample of about 5,000 persons each year located across the country. The sample is selected to represent the U.S. population of all ages.

¹ See 21 CFR §112.2 for discussion on exemptions

- The dietary interview component of the NHANES/WWEIA survey incorporates two days' worth of 24-hour dietary intake data. This is the data that FDA analyzed when writing the Produce Safety Rule.
- In order for produce to be considered “rarely consumed raw”, consumption data had to be available from NHANES/WWEIA, and the consumption data had to show that:
 - o Produce is consumed uncooked by less than 0.1% of the United States population;
 - o Produce is consumed uncooked on less than 0.1% of eating occasions; and
 - o Produce consumption (in any form – raw, processed, or other) was reported by at least 1% of weighted number of survey respondents.
- Certain limitations apply to the analysis of the NHANES data. For instance, consumption data were not available for some produce commodities. If consumption data were not available for a produce commodity, then FDA could not reliably determine if the commodity is “rarely consumed raw”.

Relevant Terms and Concepts from the Produce Safety Rule:

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs.

- A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower.
- A vegetable is 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) grown for an edible part such that vegetable means the harvestable or harvested part of any 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 (such as basil or cilantro).

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 and 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).

- 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).

For more information:

- *Food That Is Covered and That Is Not Covered (§§ 112.1 and 112.2, and Definition of “Produce” in § 112.3(c)).* 80 FR 74384 – 74391. <https://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf>
- ProduceSafetyNetwork@fda.hhs.gov
- *What We Eat in America.* <https://www.ars.usda.gov/northeast-area/beltsville-md/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweianhanes-overview/>

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