

FDA FACT SHEET

Produce Safety Rule (21 CFR 112)

DROPPED COVERED PRODUCE

What is dropped covered produce?

Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce 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 as part of harvesting (such as walnuts).

Produce that grows off the ground, such as apples, and that drops to the ground before it is harvested, is considered dropped covered produce, unless it is otherwise excluded (*e.g.*, if dropping is an intentional part of the harvesting process). For example, when an apple drops to the ground before it is harvested, it is dropped covered produce, whether or not the covered farm has already begun harvesting apples from that orchard such that the farm might consider the apple to have unintentionally fallen “during” its harvesting of the orchard. The apple in this example dropped before the apple was harvested.

Additionally, produce that grows off the ground, such as staked tomatoes, and that drops to the ground before it is harvested, is considered dropped covered produce, even if the produce is still attached to the plant when it contacts the ground.

Can I distribute dropped covered produce into the fresh market?

No. The Produce Safety Rule prohibits the distribution of covered produce that drops to the ground before harvest. However, the following produce is not subject to the requirements in the Produce Safety Rule, and therefore not subject to the dropped covered produce prohibition:

- Produce that is on the rarely consumed raw list (see 21 CFR § 112.2(a)(1));
- Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; or
- Produce that is not a Raw Agricultural Commodity (RAC).

If produce drops to the ground, can it be used for food for human consumption that receives commercial processing?

Yes, if a covered farm complies with the commercial processing exemption requirements in 21 CFR § 112.2(b), produce that would otherwise be covered by the rule is eligible for exemption from other provisions in the Produce Safety Rule, including the prohibition against distributing dropped covered produce.

Produce is eligible for the commercial processing exemption if the following conditions in 21 CFR § 112.2(b) are met, including:

- The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., processing in accordance with the requirements of the juice HACCP regulations in 21 CFR part 120; refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products); and
- The covered farm discloses in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.”
- The Produce Safety Rule also requires that the covered farm obtain and keep certain required documentation (written assurance) from the farm’s customer that provides assurances that subsequent processing that adequately reduces the presence of microorganisms of public health significance will be performed. However, FDA issued a guidance document in January 2018 indicating our intent to exercise enforcement discretion with regard to the written assurances requirements in several of the FSMA rules, including the Produce Safety Rule, while we undertake a rulemaking that takes into consideration the complex supply chain relationships and resource requirements.

When produce will receive commercial processing, does it need to be separated from other covered produce?

Yes. If you grow, harvest, pack, or hold produce that is not covered in this part (i.e., excluded produce in accordance with 21 CFR § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed, or held in accordance with the Produce Safety Rule, you must take measures during these covered activities, as applicable, to:

- (a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and
- (b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.

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- *FSMA Final Rule on Produce Safety.*
<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>
- *Produce Safety Network:*
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