



# Food Safety Modernization Act Produce Safety Rule

## An Introduction to the Dropped Covered Produce Requirements

A common question asked by fruit and vegetable growers is whether they are prohibited from selling produce that happens to drop to the ground before harvest under the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR). The PSR is a U.S. Food and Drug Administration (FDA) regulation that establishes minimum food safety standards for farms that grow, harvest, pack, or hold fruits and vegetables in an effort to reduce foodborne illness. While compliance dates for this regulation began in 2018, the Vermont Agency of Agriculture, Food & Markets Produce Program has been working with farms since 2015 to help the industry prepare for compliance. This factsheet was developed to help answer growers' questions relating to dropped covered produce.

### What is dropped covered produce?

Dropped covered produce is produce that is covered by the Produce Safety Rule (i.e., subject to the regulation) and has dropped to the ground before harvest. The Produce Safety Rule states that “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 almonds)” (21 CFR part 112.114).



### Can dropped produce be sold or distributed for fresh eating?

No. The Produce Safety Rule prohibits covered farms from distributing dropped covered produce.

### Are certain farms exempt from this requirement?

Yes. Farms excluded or exempt from the Produce Safety Rule are not subject to this requirement. However, all farms should follow produce safety best practices and avoid selling dropped covered produce for fresh eating.

### Why is dropped covered produce potentially unsafe for fresh eating?

Covered produce that unintentionally drops to the ground before harvest may be contaminated with pathogens in the farm environment, such as pathogenic *E. coli* or *Salmonella*, and become unsafe for fresh eating. Simply cleaning off the dropped produce or visually inspecting it for damage may not be enough to assess whether it is safe to eat. This is because the damage from produce dropping to the ground can introduce pathogens into the produce as well as make it more susceptible to introduction during washing or packing (FDA, 2018). Once pathogens are introduced inside damaged produce it becomes practically impossible to safely eliminate pathogens.



## Are certain types of produce exempt from this requirement?

Yes. This requirement applies to covered produce on covered farms. Produce that is not covered by the Produce Safety Rule is not subject to this requirement. Examples include:

- Produce on the FDA's Rarely Consumed Raw (RCR) list, such as potatoes and winter squash, are not covered produce and not subject to this requirement.
- Produce intended solely for personal or on farm consumption is not covered produce and not subject to this requirement.
- Produce that is not a Raw Agricultural Commodity (RAC), such as produce processed on the farm for value added products, is not covered produce and not subject to this requirement.
- Fresh produce sold for further commercial processing that adequately reduces the presence of microorganisms of public health significance, such as produce sold for further processing into wine or beer, is eligible for the commercial processing exemption.
- Produce sold not for human consumption is not covered produce and not subject to this requirement. Examples include produce sold for animal consumption and produce sold as seed or for propagation.

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 almonds).



## Are there certain requirements if produce is sold for commercial processing?

Yes. Farms that sell fresh produce for commercial processing are eligible for an exemption but must meet the commercial processing requirements in 21 CFR §112.2(b). These requirements include:

- The produce must receive commercial processing that adequately reduces the presence of microorganisms of public health significance;
- The farm must disclose in documents accompanying the produce that the produce “is not processed to adequately reduce the presence of microorganisms of public health significance”;
- Farms must take measures to separate excluded produce from covered produce throughout harvesting, packing, and holding activities, and, food contact surfaces that contact excluded produce and covered produce must be adequately cleaned between uses (such as food contact surfaces on packing lines and harvest containers). [See note below.](#)

Produce eligible for the commercial processing exemption is not required to meet the dropped covered produce requirement because it is exempt. However, it's important to keep in mind that other food safety regulations, buyer requirements, or customer preferences may limit the sale of dropped produce for commercial processing. The Vermont Department of Health's Food and Lodging program can provide further information for manufactured food producers.

**Note:** The PSR requires that written assurances accompany produce eligible for the commercial processing exemption. However, the FDA issued enforcement discretion for this requirement, stating that, “the agency intends to exercise enforcement discretion for the written assurance requirements, while it considers rule making that takes into consideration the complexity of supply chain relationships and the resources required to meet the current requirements of these provisions” (FDA, Enforcement Discretion for Certain FSMA Provisions).





## What information must be shared with farm visitors such as Pick-Your-Own customers?

The PSR requires covered farms to notify visitors of the farm’s food safety policies, including policies relating to not harvesting dropped covered produce. Farms may notify customers in a variety of ways, such as with signage located near picking areas and handwashing and bathroom facilities, with verbal instructions, or in other ways to ensure visitors are following food safety practices and not harvesting dropped covered produce. Figure 1 is an example of a sign that a farm may choose to use to communicate this message to Pick-Your-Own customers.



Figure 1

## Example Farm Scenarios

Below are several scenarios that demonstrate how farms covered under the PSR may choose to comply with dropped covered produce requirements.

### A Diversified Farm Growing Greenhouse and Field Tomatoes

One of the farm’s main crops is greenhouse and field-grown tomatoes. Greenhouse tomatoes are trellised and field tomatoes are kept staked throughout the growing period. The farm trains harvest workers to not harvest tomatoes that drop to the ground before harvest, including tomatoes that have dropped to the ground but remain attached to the plant. Tomatoes that happen to fall to the ground during harvest are also not harvested.



### A Berry Farm Selling Fruit to Wineries

A berry farm sells fresh berries to wineries for use in fruit wines. The farm follows the commercial processing exemption requirements including a written disclosure that accompanies the produce. The farm chooses to follow food safety best practices and avoids harvesting dropped berries, even though the farm is not technically required to meet the dropped covered produce requirement for exempt produce.



### A Pick-Your-Own Apple Orchard

An orchard primarily sells fresh apples for human consumption. The farm allows customers to harvest dropped apples only if the apples are not for human consumption and the customers follow the farm’s food safety practices when picking drops. Customers who harvest dropped apples report using them for feeding wildlife.





## Additional Resources

Learn more about the FSMA Produce Safety Rule, dropped covered produce, and related food safety terms, programs, and regulations.

### FSMA Final Rule on Produce Safety

Website: [go.usa.gov/xpGKp](https://www.fda.gov/xpGKp) (URL is case sensitive)

FSMA Produce Safety Rule requirements, compliance dates and frequently asked questions.

### FDA Dropped Covered Produce Factsheet

Website: [go.usa.gov/xpGKd](https://www.fda.gov/xpGKd) (URL is case sensitive)

The Food and Drug Administration factsheet on dropped covered produce.

### FDA Rarely Consumed Raw Factsheet

Website: [go.usa.gov/xpGKF](https://www.fda.gov/xpGKF) (URL is case sensitive)

Rarely Consumed Raw (RCR) produce is not subject to the FSMA Produce Safety Rule. This factsheet provides information as to why RCR produce is exempt from the Produce Safety Rule and what commodities are considered RCR.

### Vermont Department of Health Food & Lodging Program

Website: [www.healthvermont.gov/environment/food-lodging](https://www.healthvermont.gov/environment/food-lodging)

The Food and Lodging Program works to protect Vermonters' health and prevent disease by promoting sanitation and ensuring food safety and also serves as an educational resource for the public and the food service industry.

## References

**FDA, 2018.** "Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-standards-growing-harvesting-packing-and-holding-produce-human-consumption>.

**FDA.** "Enforcement Discretion for Certain FSMA Provisions." [www.fda.gov/media/110052/download](https://www.fda.gov/media/110052/download)

The Vermont Produce Program is available to answer questions about the FSMA Produce Safety Rule, produce farm inspections, and program services.

Contact [AGR.FSMA@vermont.gov](mailto:AGR.FSMA@vermont.gov) or (802) 828-2433.

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