

Does the U.S. Preventive Controls Rule apply to my operation?

If you export produce to the United States and do not meet the Food Safety Modernization Act (FSMA) definition of a “Farm”, you may be subject to the FSMA *Final Rule for Preventive Controls for Human Food*, also known as the Preventive Controls (PC) Rule.

If your operation is classified as a “Farm”, then you may be subject to the Produce Safety Rule rather than the Preventive Controls Rule.

In both cases, you could qualify for **modified requirements under the Foreign Verification Supplier Program (FSVP)**. See the CanadaGAP backgrounder on the FSVP for more information.

The FSMA defines two types of Farms:

- Primary Production Farm
- Secondary Activities Farm

In general terms, a Primary Production Farm is an operation that is under a single management, in one general location (but not necessarily contiguous) **and** is primarily devoted to the growing and/or harvesting of crops. Activities such as storage and packing can also be included in the scope of activities for a Primary Production Farm. To be considered a Primary Production Farm, the **production of crops** must be a part of the operation. If your operation is classified as a Primary Production Farm, and you pack and store a given commodity, you can pack and store the same commodity from other farms, without affecting your status as a Primary Production Farm.

Again, in general terms, a Secondary Activities Farm is an operation that is not located on a Primary Production Farm and is primarily devoted to activities such as packing and storage, provided a majority of the produce being packed and or stored has been produced on the Primary Production Farm that owns or jointly owns a majority interest in the Secondary Activities Farm.

To determine if your operation falls within the FSMA Farm definition, you will also need to be familiar with a variety of FSMA definitions as found in the PC Rule. When the FSMA uses words such as “Harvesting, Packing, Holding or Manufacturing/Processing”, they have specific meanings within the context of the regulations. The meanings of these and other words can be significantly different from the common understanding and/or the definitions in the CanadaGAP Glossary for the same words. Some key definitions from the PC Rule are included at the end of this document.

To help you determine whether the activities that you perform are within the “Farm” definition, a guidance document is available, titled “Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Guidance for Industry”. Although forty pages in length, the document provides numerous examples that can be useful in better understanding definitions and in determining whether the PC Rule applies to your operation.

Most operations that are packing, repacking and wholesaling fresh produce for the U.S. market will fall under the PC Rule, unless the business is directly connected (through ownership) to a Farm. In the latter

case, the activities of packing and storing could fit under the Produce Safety Rule. For Canadian suppliers, the modified FSVP requirements could apply.

Fresh produce brokers are not subject to either the Produce Safety Rule or the Preventive Controls Rule. However, they can play a role in helping others in the supply chain (i.e., the supplier and/or the receiving company) to maintain compliance as regards supplier verification and traceability records.

After assessing your operation, you may find that some of the activities performed fall within the “Farm” definition, and others do not. In the FSMA terminology, this is classified as a “Mixed-type Facility”. Any activity which falls outside of the “Farm” definition is subject to the PC Rule.

Although the FSMA recognizes some exemptions, this summary does not discuss exemptions to the PC Rule. An example of an exemption is if your operation meets the “Qualified Facility” definition. Consult the PC Rule to review the exemptions. It is also important for Canadian exporters to review information about the FSMA Final Rule on *Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals*, as **modified requirements** apply to many Canadian operations.

Accessing the Documents:

To access the full version of the Preventive Controls Rule with associated definitions, follow the instructions below:

- Go to <https://www.regulations.gov/document?D=FDA-2011-N-0920-1979>
- Scroll down the text to near the end and look for the section beginning with the title Regulatory Text.
- Alternatively, you can download a PDF version by clicking on the PDF icon near the top right of the page. Page numbers are located on the top right of each page. The regulatory text begins on page 56145, and is titled PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

To access the document titled *Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Guidance for Industry*:

- Go to <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517567.htm>
- Scroll down the page to the download link in the blue text box.

How does the Preventive Controls Rule differ from the Produce Safety Rule?

If Subject to the Preventive Controls Rule	If Subject to the Produce Safety Rule
The operation must register with the US Food and Drug Administration (FDA).	The operation is not required to register.
<p>The operation is required to perform an analysis called a “Hazard Analysis and Risk-Based Preventive Controls” (HARPC) of their operation in order to develop a food safety plan which significantly minimizes or prevents all food safety hazards that are likely to occur.</p> <p>This approach is similar to the development of a Hazard Analysis Critical Control Points (HACCP) Plan. A significant difference is that a preventive control may be required at points other than at a Critical Control Point (CCP). The HARPC and Food Safety Plan is to be based upon Current Good Manufacturing Practice (cGMP) as defined by the FSMA and explained in the Preventive Controls Rule.</p>	<p>The operation is required to implement food safety practices as stipulated by the Produce Safety Rule and is not required to prepare a food safety plan or HARPC.</p>
HARPC must be prepared and overseen by a Preventive Controls Qualified Individual.	No requirement for oversight by a PC Qualified Individual, although under the Produce Safety Rule, employees and trainers must also have relevant education, training, and experience as required to perform the person’s assigned duties in a manner that ensures compliance with the provisions of the Rule.
All Preventive Controls must be monitored/ tested to verify implementation and effectiveness. It is expected that the Preventive Controls Qualified Individual verifies on a weekly basis that monitoring activities have been completed at the frequency identified in the HARPC.	<p>Monitoring and/or testing only as stated by the Produce Safety Rule.</p> <p>No requirement for oversight by a PC Qualified Individual.</p>
All records are required to be approved and signed off by a PC Qualified Individual.	No requirement for oversight by a PC Qualified Individual.
You are required to establish and implement a risk-based Supply Chain Program for raw materials and ingredients. Operations have the responsibility to verify that suppliers have implemented food safety procedures to control identified risks. This may require that the supplier’s operation is audited by a qualified auditor. You may be required to review the results of the supplier’s audit and/or food safety records to verify that identified risks are being adequately controlled.	<p>Compliance of suppliers subject to the Produce Safety Rule must be confirmed.</p> <p>No requirement for a documented Supply Chain Program or to review a supplier’s audit results or food safety records.</p>

Key Definitions

As taken from the U.S. Food and Drug Administration,
FSMA Final Rule on Preventive Controls for Human Food

Farm means:

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

- (i) Pack or hold raw agricultural commodities;
- (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and
- (iii) Manufacture/process food, provided that:
 - (A) All food used in such activities is consumed on that farm or another farm under the same management; or
 - (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
 - (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/ dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
 - (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and
 - (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or **(2) Secondary activities farm.** A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

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. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. 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. Examples of harvesting include 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). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

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)). 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. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/ dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/ processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that

require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 117.180(c)(2). Examples of potential qualified auditors include:

- (1) A government employee, including a foreign government employee; and
- (2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

- (1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
- (2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.