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# Understanding FSMA's Preventive Controls Rule: A GUIDE FOR GRAIN BUSINESSES

Do you grow, harvest, store, or process food-grade grain or grain products? This resource may help you determine if you need to comply with the Food Safety Modernization Act's Preventive Controls for Human Food Rule.

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In the past several decades, regional grainsheds—areas of localized production, processing, and use of staple crops—have expanded significantly. The growth of these systems is exciting, and also raises important questions. Specifically, how does food-grade grain production, processing, and marketing fit into federal food safety regulatory frameworks? As local grains move from fields to consumers' plates, bowls, and glasses, it is critical to understand the potential role and application of the federal Food Safety Modernization Act's Preventive Controls for Human Food Rule (FSMA PCR).

FSMA was enacted in 2011 after a series of highly publicized food safety incidents and recalls. The FSMA rules embody a proactive and risk-based approach to food safety regulation. The PCR, one of FSMA's main components, requires food production and processing businesses to evaluate potential food safety hazards, take action to prevent

or reduce those hazards, and create monitoring systems to ensure the actions taken are effective.

Determining whether the PCR applies to grain producers, processors, or food businesses can be complicated. For the smaller-scale diversified farms and mills that comprise the growing regional grain sector, one primary challenge is navigating the PCR's definitions and determining how they apply to the range of activities needed to move local grains from field to market.

This resource will help food-grade grain farms and food businesses understand if and how the PCR impacts their operation. Whether or not a business needs to comply with the PCR depends on its activities and size. The following pages include a flowchart, key terms, and a set of factsheets. The flowchart helps identify the likely PCR compliance category for a given farm or food business. The key terms define important regulatory language needed to understand PCR compliance. The factsheets are divided into common scenarios for businesses in the regional grain value chain: (1) farms that grow and store grains; (2) facilities that conduct value-added processing; and (3) retail food establishments or restaurants. For those who own multiple businesses (for example, a farm and separate processing facility), multiple factsheets may apply.



## How to Use This Resource

To use this resource, begin by working through the questions in the flowchart on [page 3](#). The key terms on [pages 4-7](#) are pulled from the regulatory language; it may be helpful to refer to them as you work through the materials. After completing the flowchart, follow the link to a relevant factsheet for further reading.

*The information included in this guide is intended for educational purposes only and does not constitute legal advice. Each operation and situation is unique and state laws may vary. Farmers and other food and agricultural businesses should consult with an attorney licensed in their state for legal assistance. The guidance in this resource focuses on how the PCR may apply to food-grade grain growing and processing activities; however, other food safety rules may apply to other crops or meat your farm or food business may raise or process for sale.*

## Applying FSMA to Regional Grain Value Chains

The first step to understanding whether the PCR applies to your business is determining whether your operation falls within the PCR's regulatory definition of a "farm" or a "facility." A food facility manufactures, processes, packs, or holds food for human consumption, regardless of whether the food enters interstate commerce (moves beyond a given state's borders). Such facilities must register with the Food and Drug Administration (FDA), and are subject

to some or all of the PCR's food safety requirements. Farms are generally exempt from the requirement to register with FDA, and therefore from compliance with the PCR, as long as they satisfy the PCR's specific definition of what constitutes a farm.

**If a farm conducts activities beyond those that are part of the regulatory farm definition, it would be considered a "farm mixed-type facility." A farm mixed-type facility must register with FDA and some**

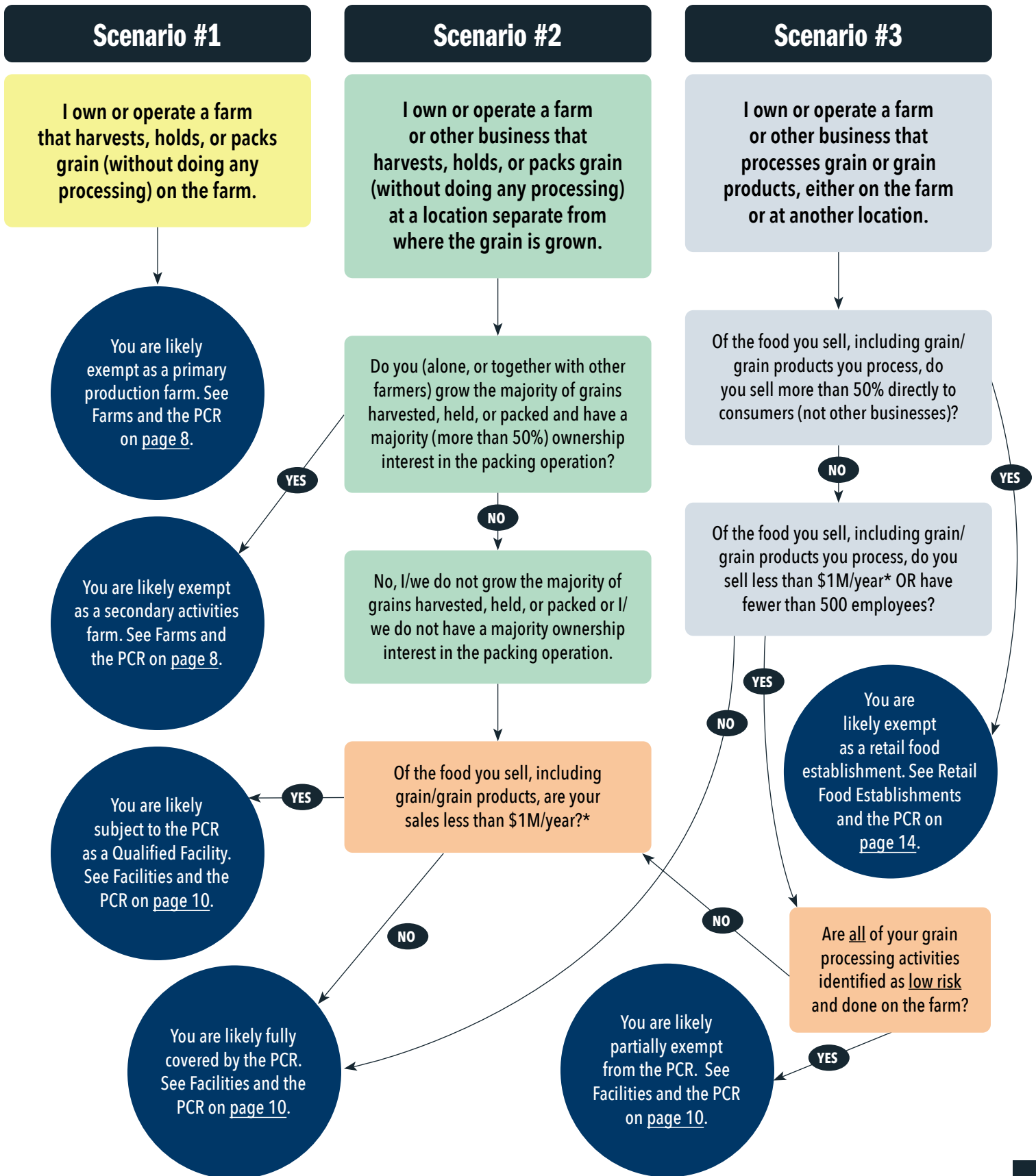
**portion of the PCR's requirements would likely apply to the facility.**

How grain production and processing activities are categorized, the location where these activities take place, and a business' size and marketing practices are also factors that will affect whether the PCR applies to a food-grade grain farm or grain processor.

Find more information about regulatory terminology on [pages 4 and 5](#) and in the [Farm](#) and [Facilities](#) factsheets.

# FSMA AND REGIONAL GRAIN VALUE CHAINS

The flowchart below is a decision tree, describing relevant activities and factors and drawing on the key terms explained on pages 4 through 7. You may need to refer to these key terms as you move through the flowchart. To begin, select the scenario that best describes your operation(s). Working through each scenario will direct you to additional guidance and information.



# KEY TERMS

The following key terms are based on the definitions contained in FDA's food safety regulations. Some edits have been made for clarity or to connect the definition more directly to grain growing and processing activities. To access the full regulatory definitions, see FDA's regulations at [21 C.F.R. 1.227](#) and [21 C.F.R. 117.3](#).

## Entity Definitions



### Facility

Any establishment or structure that manufactures, processes, packs, or holds food for consumption in the U.S. This includes mobile facilities. An individual's private residence is not a facility, nor are transport vehicles.



### Farm

An operation that grows, harvests, packs, or hold crops; raises animals; or some combination of these activities. The regulatory definition of a farm allows for limited on-farm processing activities. An operation may also satisfy the regulatory definition of a farm if some harvesting, packing, or holding activities take place at an off-farm location, as long as certain requirements are met.



### Farm Mixed-Type Facility

An establishment that is a farm and conducts processing activities beyond the scope of the regulatory farm definition. Farm-mixed type facilities must register with the FDA. Most food processing activities are considered outside of the farm definition.



### Retail Food Establishment

An establishment with the primary function to sell food directly to consumers (not other businesses), meaning 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. "Retail food establishment" includes some farm-operated direct-to-consumer sales models, such as farm stands, farmers markets, Community Supported Agriculture (CSA) programs, and online farmers market and online grocery delivery platforms.



### Restaurant

A facility that prepares and sells food directly to consumers for immediate consumption, i.e., to people who will eat the food. Consumers do not include other businesses.

## Activity Definitions



### Harvesting

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 includes separating the edible portion of a crop from the crop plant and removing or trimming parts of the plant such as the foliage, husks, and stems.
- Gathering, hulling, shelling, sifting, and threshing are all examples of harvesting.
- Examples of harvesting also include drying/dehydrating grains in the growing area and cleaning seeds that are the harvested crop including removal of leaves, stems, and husks, such as for flax seeds.
- When conducted on a farm, dehulling is a harvest activity.



### Holding

Storing food. The term holding also includes activities performed incidental to storage of a food, meaning activities necessary to safely and effectively store and distribute food. Holding also includes activities performed as a practical necessity for distribution of a particular food, such as blending lots of the same type of grain.

- Grain cleaning such as pre-cleaning with a rotary screener and screening grain (e.g., using scalpels and shakers to remove rocks and other extraneous material) are examples of holding.
- Additional examples of holding include aeration for safe or effective storage (e.g., to manipulate grain temperatures); loading food into a vehicle or placing food in a building or its associated fixtures or equipment as a practical necessity for distribution of the food (e.g., placing grain in a bin); and turning for safe or effective storage (e.g., turning grain to monitor grain condition and quality, or turning grain to manage grain temperature and moisture).



### Packing

Placing food into a container during post-harvest activities. Packing also includes repacking and activities such as sorting, culling, grading, weighing, or conveying that ensure safe or effective packing. "Packing" is distinct from "packaging," which is a processing activity, and means placing food into a container that directly contacts the food and that the consumer receives.



### Processing

Used interchangeably with manufacturing; making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients.

- Extracting (including by pressing, by distilling, and by solvent extraction), grinding, labeling, milling, mixing, and packaging are all examples of processing.

## Other Relevant Terms



### Food Grains

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 (including cereal grains, pseudocereals, 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, cottonseed, flax seed, rapeseed (canola), soybean, and sunflower seed. Pulse crops such as cowpeas, chickpeas, and dry beans are also understood to be food grains if they are primarily grown and processed for use as meal, flour, baked goods, cereals, and oils, rather than for direct consumption.



### Raw Agricultural Commodity

A Raw Agricultural Commodity (RAC) is any food in its raw or natural state, including all fruits and vegetables that are washed or otherwise treated in their unpeeled natural form prior to marketing. Food grains are a type of raw agricultural commodity when they are unprocessed.



### Inflation-Adjusted Cutoffs\*

Sales thresholds that trigger compliance obligations in several FSMA rules, including the PCR. These thresholds are based on sales averaged over the last three years and adjusted for inflation. The baseline year for these adjustments is 2011. Currently, the adjusted annual average sales value cut off for a "very small business" is \$1,122,988. See FDA's website (<https://tinyurl.com/FSMAinflation>) for the most recently updated cutoff. Sales values subject to this three-year average and inflation adjustment are indicated in the flowchart with an asterisk (\*).



### Current Good Manufacturing Practices

Baseline sanitary and process requirements that predate FSMA and are designed to minimize food safety risks during food production. The cGMP regulation (21 C.F.R. § 117 Subpart B), which FSMA updated and expanded upon, encompasses standards for personnel, plant and grounds, sanitary operations, facilities, controls, equipment and utensils, processes, warehousing and distribution, and defect action levels. There are also requirements for holding and distributing human food byproducts for use as animal food.



### Hazard Analysis and Risk-Based Preventive Controls

A series of standards established in the PCR to evaluate possible food safety hazards and take action to mitigate or prevent those hazards for all food manufactured, processed, packed, or held at a facility. Facilities must also monitor efficacy of any preventive actions taken. The HARPC regulation (21 C.F.R. § 117 Subpart C) also includes requirements for a food safety plan, recall plan, and qualifications for personnel who oversee HARPC implementation at a facility.



### Supply-Chain Program

The PCR supply-chain program standards (21 C.F.R. § 117 Subpart G), which require a receiving facility to establish and implement a written risk-based plan to address any raw materials or other ingredients for which the receiving facility has identified a hazard that is not controlled during the manufacturing process. The supply-chain program standards do not apply to facilities that only store food.



### Low-Risk Activity/ Food Combinations

Certain packing, holding, and processing activities involving specific foods identified as low risk by FDA from a food safety perspective. Farms that conduct low-risk packing, holding, or processing activities may be eligible for an exemption from some PCR provisions. Several activity/food combinations identified as low risk related to grains and grain products are listed below. For the full list of low-risk activity/food combinations, see FDA's regulations at [21 C.F.R. § 117.5\(g\)-\(h\)](#).

- **Extracting** (including by pressing, by distilling, and by solvent extraction) oil from grains
- Grinding, cracking, crushing, or **milling** grains
- **Sifting** milled grain products (e.g., flour, bran, corn meal) or tree nut products (e.g., chestnut flour)
- **Flaking** oats
- **Making** trail mix and granola from other grain products; popcorn from grains; baked goods from milled grain products (e.g., breads and cookies); processed seeds for direct consumption; dried pasta from grains; sugars and syrups from grains (e.g., rice, sorghum syrup); or vinegar from other grain products (e.g., malt vinegar)
- **Mixing** milled grain products (e.g., flour, bran, and cornmeal), including to make different kinds of flour (e.g., all-purpose flour), and mixing milled grain products and other products to create baking mixes (e.g., corn muffin mix)
- **Packing** or repacking, **sorting**, storing, or **packaging** trail mix and granola; other grain products (e.g., popcorn); processed seeds for direct consumption; baked goods (e.g., bread and cookies); oils (e.g., flax oil, sunflower oil); sugars and syrups from grains (e.g., rice, sorghum syrup); vinegar from other grain products (e.g., malt vinegar); or other processed food that does not require time/temperature control for safety
- **Labeling** milled grain products that do not contain food allergens (e.g., corn meal) or that are single-ingredient foods (e.g., wheat flour, wheat bran); other grain products that do not contain food allergens (e.g., popcorn); processed seeds for direct consumption; trail mix and granola; baked goods that do not contain food allergens; sugars and syrups from grains (e.g., rice, sorghum syrup); vinegar from other grain products (e.g., malt vinegar); and any other processed food that does not require time/temperature control for safety and that does not contain food allergens.
  - "Food allergens" references the major food allergens identified by law at [21 U.S.C. 321\(qq\)](#), which includes wheat and soybeans and will include sesame beginning in 2023.

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# FARMS AND THE PREVENTIVE CONTROLS RULE

Using [the flowchart](#), you have determined that your operation is likely a farm. If your operation meets the regulatory definition of a farm (as either a primary production or secondary activities farm), then you are exempt from registration with FDA and therefore exempt from the Preventive Controls for Human Food Rule (PCR).



## Making Sure Your Operation Meets the Regulatory Definition of a Farm

To determine whether your operation meets the regulatory definition of a farm, you will need to consider the range of activities you conduct and the location where those activities occur. In addition to growing and harvesting, the farm definition includes packing and holding as farm activities, given that many farms must engage in packing and holding to successfully get their crops from field to market. The PCR defines “harvesting,” “packing,” “holding,” and “manufacturing/processing,” and each of these categories encompasses many specific activities necessary to prepare and store raw agricultural commodities (RACs) such as grains for use as food.

In general, the activities you perform to grow, harvest, pack, and hold grain on your farm will fall within the farm definition. As long as you do not do any further processing beyond

what is needed to store and distribute grain, you likely meet the regulatory definition of a farm.

How grain production activities fit within the definitions of harvesting, holding, and packing in large part determines whether a farm needs to comply with the PCR. For example, some types of grain cleaning as well as dehulling are harvest activities when conducted on a farm. Activities associated with proper storage of grains or that are necessary to distribute grain for use as food are holding activities. The Key Terms section on [page 5](#) includes definitions for words including harvesting, holding, packing, and processing and provides additional examples. A farm that only conducts activities within the definitions of harvesting, holding, and packing likely meets the regulatory definition of a farm, and the PCR would not apply.



## THE “FARM” DEFINITION GENERALLY DOES NOT INCLUDE PROCESSING, WITH LIMITED EXCEPTIONS.

Activities that transform grain into a processed food are not included within the definitions of harvesting, holding, and packing. However, some limited processing activities, such as packaging and labeling grains when these activities do not involve additional processing, are included within the “farm” definition; for example, bagging and labeling small quantities of whole grains after cleaning in preparation for sale directly to consumers.

If this is the only processing activity a farm conducts, the PCR would not apply. If you are

conducting additional processing, whether of grains or of other food products, then you may be a farm mixed-type facility. See Facilities and the Preventive Controls Rule on [page 10](#) for more information.



## AN ENTITY DOES NOT HAVE TO GROW AND HARVEST CROPS TO BE CONSIDERED A FARM.

The farm definition accounts for the fact that harvesting, packing, and holding grains may occur at a location other than where grain was grown, such as at a shared cleaning or storage operation. This type of facility is known as a secondary activities farm. To be a secondary activities farm, the majority of the grain that is cleaned, dehulled, or stored must come from a farm or multiple farms that have a majority ownership interest in the operation.

For example, if a group of grain producers form a cooperative to clean and store grain, then the storage facility would be considered a secondary activities farm, assuming over half of the grain stored at the facility comes from the farmer-members that fully own the cooperative. In this case, the packing operation would not have to register with FDA or comply with the PCR.

This definition may change in coming years, as FDA has received feedback that the definition is difficult to understand and apply to many off-farm packing and holding operations. While FDA considers making future changes to the definition, it is not enforcing the PCR requirements against facilities that would qualify as secondary activities farms except that they do not meet the majority ownership requirement described above. Under FDA’s [enforcement discretion policy](#), such facilities would still need to register with FDA, but would not be held to PCR requirements.

An entity that packs or holds grain and is not associated with the farms that grow or provide that grain would be regulated as a facility and subject to the PCR. See Facilities and the Preventive Controls Rule on [page 10](#) for further discussion of how the PCR applies to these entities.



**The “farm” definition encompasses two types of farms.**

### **Primary production farm:**

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 aquaculture), or any combination of these activities. The term “farm” includes operations that, in addition to these activities, also pack or hold raw agricultural commodities.

### **Secondary activities farm:**

An operation, not located on a primary production farm, devoted to harvesting, packing, or holding raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, or raises the majority of the raw agricultural commodities harvested, packed, or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.

For the full farm definition, see [21 C.F.R. § 1.227](#).

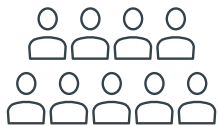


**Other FSMA rules may apply depending on the specifics of your operation.**

The information here focuses on food-grade grain production and processing and how the PCR may apply to farms and food businesses that grow and process these crops. If you grow fruits and vegetables to sell, the Produce Safety Rule may also apply. The Preventive Controls for Animal Food Rule, Sanitary Transportation for Human and Animal Food Rule, and proposed Food Traceability Rule may also be relevant to your operation. You can find out more information about these other FSMA rules through your [regional FSMA training center](#), state department of agriculture, local cooperative extension office, or other local agriculture associations and technical support providers.

# FACILITIES AND THE PREVENTIVE CONTROLS RULE

Using [the flowchart](#), you have determined that you are likely a facility or a farm mixed-type facility. This type of entity is subject to the Preventive Controls for Human Food Rule (PCR); however, not all facilities that pack, hold, or process food for human consumption are subject to all PCR provisions. The sections below identify different types of entities to which some exemptions from the PCR may apply. For each type of entity, there is also information about steps to comply with any relevant PCR provisions. Additional compliance information and resources are provided toward the end of the document.



## Small business

Fewer than 500 full-time equivalent employees.



## Very small business

Under \$1,000,000 in average annual food sales (based on a three-year average, and adjusted for inflation. See the Key Terms on [page 6](#) for information about inflation-adjusted cutoffs).

## FARM MIXED-TYPE FACILITIES THAT ONLY CONDUCT LOW-RISK PROCESSING

A farm mixed-type facility is an operation that does more than the limited processing activities specified in the farm definition. If you are a farm mixed-type facility that meets the definition of either a small or a very small business, then you may qualify for certain exemptions under the PCR. Most PCR requirements do not apply to farm mixed-type facilities that are small or very small businesses and conduct only low-risk on-farm processing. Farms that do low-risk, on-farm processing but also engage in processing that is not identified as low risk in the regulation are not eligible for this exemption. Likewise, facilities that conduct low-risk processing but are not co-located on a farm are not eligible for this exemption.

The Key Terms on [page 7](#) includes discussion of low-risk activity/food combinations and examples of processing related to grains that FDA regulations identify as low risk. Some common low-risk grain processing activities include milling grain, baking bread from milled grain products, flaking oats, making popcorn, and making granola or trail mix from grain products such as oat flakes.



## ALL FACILITIES

Certain facilities that only conduct specified low-risk processing activities on-farm, as well as facilities that only store unprocessed grains intended for further distribution and processing, are exempt from portions of the PCR. For example, neither a farm mixed-type facility that is a small or very small business and conducts only low-risk processing on-farm nor a standalone grain storage facility that is operated separately from a grain farm would have to comply with HARPC and supply-chain program requirements, as discussed in the Key Terms on [page 6](#).

To comply with the PCR, all facilities, including farm mixed-type facilities doing only low-risk processing on-farm and storage facilities only holding grains for further processing, must:

- Register as a food facility [with FDA](#).
- Follow employee training requirements as specified in [Subpart A](#).
- Implement cGMPs as specified in [Subpart B](#).
- Follow recordkeeping requirements as specified in [Subpart F](#).

## QUALIFIED FACILITIES

Farm mixed-type facilities that conduct processing beyond what is identified in the low-risk activity/food combinations may be qualified facilities. A facility that meets the regulatory definition of a very small business (see sidebar on [page 10](#)) is a qualified facility. Qualified facilities are not subject to HARPC and supply-chain program requirements; however, they must file certain documentation (called an “attestation”) every two years with FDA, explained on [page 12](#).

To comply with the PCR, qualified facilities must:

- Register [with FDA](#).
- Submit biennial attestation to FDA, explained on [page 12](#).
- Follow employee training requirements, as specified in [PCR Subpart A](#).
- Implement cGMPs, as specified in [PCR Subpart B](#).
- Follow recordkeeping requirements, as specified in [PCR Subpart F](#).

## FULLY COVERED FACILITIES

Facilities that are not eligible for any exemptions mentioned in the sections above must fully comply with the Preventive Controls for Human Food Rule.

To comply with the PCR, fully covered facilities must:

- Register [with FDA](#).
- Follow employee training requirements, as specified in [PCR Subpart A](#).
- Implement all provisions of the PCR, including HARPC as specified in [PCR Subpart C](#) and supply-chain program obligations as specified in [Subpart G](#).
- Follow recordkeeping requirements as specified in [PCR Subpart F](#).

## FACILITIES THAT PACK, HOLD, OR PROCESS ALCOHOLIC BEVERAGES

For FSMA PCR purposes, operations such as breweries and distilleries that manufacture, process, pack, or hold alcoholic beverages must register with FDA as facilities. However, such operations are exempt from the HARPC and supply-chain program provisions of the PCR. Other federal and state laws likely apply.

To comply with the PCR, entities engaged in alcohol production, storage, and distribution must:

- Register [with FDA](#).
- Follow employee training requirements as specified in [PCR Subpart A](#).
- Implement cGMPs as specified in [Subpart B](#).
- Follow recordkeeping requirements as specified in [Subpart F](#).

## ADDITIONAL COMPLIANCE RESOURCES

### Facility Registration

Facilities may register with FDA online. See FDA's website on facility registration for additional information. See also US Food and Drug Administration, [Registration of Food Facilities: What You Need to Know About the FDA Regulation: Guidance for Industry, Small Entity Compliance Guide](#) (May 2018) and [US Food and Drug Administration, Guidance for Industry: Questions and Answers Regarding Food Facility Registration](#) (Seventh Edition) (August 2018).

### Qualified Facility Attestations

Entities considered qualified facilities are subject to modified requirements, including submitting documentation to FDA every two years that attests to, or certifies, two factors:

- First, the facility must attest to its status as a qualified facility. The facility does not need to submit sales records to FDA as part of this attestation, but must maintain such records documenting eligibility as a qualified facility (for example, records that demonstrate sales below the inflation-adjusted cutoff).
- Second, the owner or operator of the facility must attest to either identifying any possible hazards associated with the food being produced, implementing preventive controls to address the hazards, and monitoring the efficacy of those controls, or attest that the facility is in compliance with any relevant nonfederal food safety laws. As with sales, the facility does not have to submit a food safety plan or other records related to this attestation, but it is advisable to maintain any such relevant records at the facility.

Attestations must be [submitted to FDA](#) every two years via Form FDA 3942a and the facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year. This requirement could be met by maintaining a spreadsheet that includes total sales for each of the past years and a running three-year average, compared against the inflation-adjusted cutoff on [FDA's website](#) for that year.



### Requirements for Employee Training

All entities covered by the PCR—whether eligible for a low-risk activity/food combination exemption, a qualified facility, or fully covered—must ensure employees have appropriate training. Every individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) must have the education, training, or experience (or combination of these) necessary to perform their assigned duties. Employee training must address principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to assigned duties. Supervisory personnel are responsible for ensuring all individuals working in a facility receive the required training for their assigned duties, and must have the education, training, or experience (or combination) necessary to supervise the production of clean and safe food.

Facilities that must follow HARPC requirements must also have a written food safety plan. At least one “preventive controls qualified individual” (PCQI) must prepare, or oversee preparation of, the food safety plan. The [Food Safety Preventive Controls Alliance \(FSPCA\)](#) facilitates PCQI training based on an FDA-approved curriculum, and is currently the only course with a standardized curriculum recognized by FDA.

All facilities must establish and maintain records that document compliance with employee training requirements and cGMPs. However, farms and establishments that are exempt from HARPC and from implementation of a supply-chain program do not require full PCQI training. Instead, local consultants and organizations may offer cGMP training more appropriate to the activities and scale of these operations.



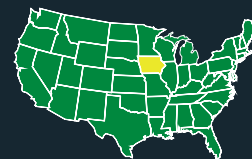
## Regional Information Hubs

### WHERE TO FIND ADDITIONAL COMPLIANCE ASSISTANCE

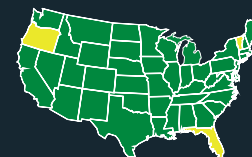
For further guidance about the PCR or other FSMA rules, grain farmers and processors may wish to consult with the contacts and resources available via the four regional FSMA training centers.

Farmers and processors may also want to reach out to their local extension agents, the food safety division in their state's department of agriculture, or other local agriculture associations or technical service providers.

We also encourage farmers and processors to visit FDA's website (<https://tinyurl.com/FDApqr>) for additional information about the PCR.



For the Midwest, the North Central Region Center for FSMA Training, Extension, and Technical Assistance based at Iowa State University serves as a key hub for information and connection with educators who can advise producers regarding their specific farm and processing operations.



The other regional FSMA centers, based at the University of Vermont, University of Florida, and Oregon State University, are also critical resources for farmers and processors in other regions of the country seeking direction about PCR and other FSMA rule requirements.



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# RETAIL FOOD ESTABLISHMENTS, RESTAURANTS, AND THE PREVENTIVE CONTROLS RULE

Using [the flowchart](#), you have determined that you are likely a retail food establishment or restaurant. Like farms, retail food establishments and restaurants are exempt from registering with FDA as food facilities and therefore exempt from complying with the Preventive Controls for Human Food Rule (PCR). If your grain farm or grain processing business meets the regulatory definition of a retail food establishment or restaurant, you are not covered by the PCR. However, other state or local food safety laws may apply.





## RETAIL FOOD ESTABLISHMENTS AND RESTAURANTS

**Retail food establishment** is a broad category of businesses that process, pack, or hold food, and sell food directly to consumers as their primary function. Consumers are people who eat the food themselves or provide it to people within their own household. If an establishment's annual sales of food products directly to consumers exceed its annual sales to all other buyers, then its primary function is retail sales.

Certain types of farm-operated enterprises that sell food directly to consumers are explicitly included in the regulatory definition of retail food establishments. These enterprises include farm stands, farmers markets, Community Supported Agriculture (CSA) programs, and other direct-to-consumer sales platforms operated by the farmer, including online. Grain farms that conduct some grain processing and employ primarily a direct-to-consumer sales model may be considered retail food establishments that are exempt from registering with the FDA and complying with the PCR.

For example, an operation that mills grain on-farm and sells flour directly to consumers through a CSA-style grain share would likely

be a retail food establishment, as would an operation that bakes bread or makes popcorn from its grain and sells those products at a farm stand. Standalone processing facilities, such as mills, with a majority of annual sales direct-to-consumer may also be retail food establishments and fully exempt from the PCR. For example, if a majority of a mill's sales are directly to consumers through an online retail platform operated by the mill, it is a retail food establishment.

Enterprises that are categorized as retail food establishments under the FSMA PCR may be categorized differently within their state or local jurisdiction. Mills or farms conducting value-added processing should determine which state or local food safety laws may be applicable to their operations. For example, licensing or permitting may be required at the state or local level. Many states have cottage food laws that allow food processing in noncommercial private residence kitchens or on farms. Cottage food laws often pertain to specific food products and may have a cap on the amount of annual sales permitted.

Like a retail food establishment, a **restaurant** is an entity that

prepares and sells ready-to-eat food directly to consumers. Entities such as cafeterias, lunchrooms, and hospital, nursing home, and day care kitchens are restaurants. Cafes, food stands, bars, and catering facilities are also restaurants. Bakeries that mill grain on premises to prepare and sell products made with freshly milled grain are likely exempt from registering with FDA and therefore from complying with the PCR as either a restaurant or a retail food establishment. Restaurants must also follow other applicable state and local food safety laws and obtain any required licensing or permitting.



**DISCLAIMER:** This document provides general legal information for educational purposes only. It is not meant to substitute, and should not be relied upon, for legal advice. Each operation and situation is unique, state laws vary, and the information contained here is specific to the time of publication. Accordingly, for legal advice, please consult an attorney licensed in your state. If you would like to view the legal research and citations that inform this resource, please contact [CAFS@vermontlaw.edu](mailto:CAFS@vermontlaw.edu). We also encourage readers to visit FDA's PCR website for more information: <https://tinyurl.com/FDApcr>.

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**TO LEARN MORE:**

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