



U.S. FOOD & DRUG
ADMINISTRATION

IF YOUR FACILITY IS A VERY SMALL BUSINESS OR A SMALL (OR VERY SMALL) FARM MIXED-TYPE FACILITY, WHAT PC HUMAN FOOD EXEMPTIONS/MODIFIED REQUIREMENTS APPLY TO YOU?

Certain facilities that are very small businesses or small (or very small) farm mixed-type facilities may be exempt from or subject to modified requirements regarding the preventive controls requirements of the Preventive Controls (PC) for Human Food Rule, one of the FDA Food Safety Modernization Act (FSMA) foundational rules.

Does that include your facility or farm mixed-type facility? This fact sheet will help answer that question.

■ What are a “small business” and “very small business”?

A “small business” is a business, including any affiliates and subsidiaries, employing fewer than 500 full-time equivalent employees.

A very small business is a business (including any subsidiaries or affiliates) that averages less than \$1,000,000 (adjusted for inflation) in sales of human food plus the market value of human food that is manufactured, processed, packed, or held without sale (for example, held for a fee), per year during the previous three-year period. For current values adjusted for inflation, see “FSMA Inflation Adjusted Cutoffs” at: <https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>

■ Who is subject to the preventive controls requirements in the PC Human Food Rule?

Generally, domestic and foreign human food facilities that are required to register with FDA under the Federal Food, Drug, & Cosmetic Act are required to comply with the preventive controls requirements in the PC Human Food Rule, entitled Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. Note that applicability of the Current Good Manufacturing Practices (CGMP) requirements is determined separately and is not based on registration.

■ Who is not subject to the preventive controls requirements in the PC Human Food Rule?

Certain establishments are exempt from the PC Human Food Rule because they do not have to register with FDA. These include farms, restaurants (including cafeterias, fast food establishments, catering facilities, and hospital kitchens), retail food establishments (including grocery stores, convenience stores, and vending machine locations), nonprofit food establishments, and establishments that process only meat, poultry, and egg products that are inspected by the U.S. Department of Agriculture.

Even if you are required to register with FDA as a food facility, there may be other situations in which your facility is eligible for an exemption, subject to modified requirements, or subject to enforcement discretion, regardless of the size of the business. For more information, see [Guidance for Industry: What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Small Entity Compliance Guide and Enforcement Discretion Policy for certain FSMA Regulations](#).

■ **Can a facility be exempt from the preventive controls requirements of the PC Human Food Rule based on its size?**

Yes, a facility may qualify for an exemption from the preventive controls requirements of the PC Human Food Rule if it meets certain criteria related to the size of the business that would make the facility a “qualified facility,” e.g., it is a “very small business.” For requirements applicable to qualified facilities, see the question “What modified requirements apply to qualified facilities?” on page 3 of this fact sheet.

You may also qualify for an exemption from the PC requirements based on size if your facility is a farm mixed-type facility that is a small or very small business, and you conduct only certain low-risk activities on specified human food. A “farm mixed-type facility,” is an establishment that is a farm that would otherwise meet an exemption from registration except that it also conducts activities outside the farm definition that require the establishment to be registered. For more information about this exemption, see the section titled “Exemption for On-Farm Low-Risk Activities Conducted by Facilities That Are Small or Very Small Businesses” on page 4 of this fact sheet.

■ **What exemption from preventive controls requirements is applicable to some small and very small farm mixed-type facilities?**

If a facility is a farm mixed-type facility that is a small or very small business, and it conducts only certain low-risk activities on specified human food, it is entirely exempt from the preventive controls requirements. For more information about this exemption, see “Exemption for On-Farm Low-Risk Activities Conducted by Facilities That Are Small or Very Small Businesses” on page 4 of this fact sheet.

■ **Have compliance dates or enforcement policy changed since FDA published the PC Human Food Rule?**

Yes, for some facilities. In a [final rule](#) published in August 2016, FDA extended the compliance dates for the PC Human Food Rule for certain facilities to address concerns about the practicality of compliance with certain provisions, consider changes to the regulatory text, and better align compliance dates across the rules. Note that the extended compliance dates have passed for facilities that are neither small nor very small businesses. In January 2018, FDA published guidance indicating its intent to exercise enforcement discretion from all or part of the PC Human Food Rule in certain circumstances related to the “farm” definition (see [Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs](#)).

Qualified Facilities

■ What is a qualified facility?

A qualified facility is either (1) a “very small business” or (2) a business (including any subsidiaries or affiliates) whose average annual monetary value of the food sold during the previous three-year period was less than \$500,000 (adjusted for inflation) and whose average annual monetary value of food manufactured, processed, packed or held and sold directly to consumers, retailers, and restaurants within the same state or the same Indian reservation or within 275 miles of the facility was more than the monetary value of food sold by the facility to other purchasers. FDA anticipates that most “qualified facilities” will be ones that meet the definition of “very small business.”

■ What modified requirements apply to qualified facilities?

A qualified facility is required to submit **Form FDA 3942a**, attesting to its qualified facility status (meaning that the facility meets the financial requirements to be a qualified facility) and attesting that it is either:

1. Addressing identified hazards through preventive controls and monitoring the preventive controls; or
2. Complying with applicable non-federal food safety law (including state food safety laws), and notifying consumers of the name and complete business address of the facility where the food was manufactured or processed.

A qualified facility is also required to maintain the records they rely upon to support the attestations they make on Form FDA 3942a. In addition, qualified facilities are required to comply with the Current Good Manufacturing Practice requirements.

■ How do I send my Form FDA 3942a to FDA?

The form can be submitted in two ways:

- **Electronically** — Log into your FDA Industry Systems account at <http://www.fda.gov/furls> and follow the instructions. FDA encourages electronic submission.
- **Mail** — Send a completed paper Form FDA 3942a to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.
 - The form can be downloaded from: <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM620461.pdf>

Alternatively, you can request a copy of the form by writing to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740, or calling 1-800-216-7331 or 301-575-0156.

Additional information on how to submit Form FDA 3942a can be found in the guidance entitled “Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Instructions for Submitting your Attestation.”

■ **What compliance dates apply to my qualified facility? And when do I have to tell FDA that my facility is a qualified facility?**

Qualified facilities had to comply with the modified requirements for qualified facilities and with CGMP requirements by September 17, 2018. In addition, a qualified facility must retain records to support its status as a qualified facility starting January 1, 2016.

The attestation form ([Form FDA 3942a](#)) stating that your facility is a qualified facility must be submitted to FDA initially:

- By December 17, 2018, for a facility that begins manufacturing, processing, packing or holding food before September 17, 2018, or
- Before beginning operations, for a facility that begins manufacturing, processing, packing or holding food after September 17, 2018.

Beginning in 2020, your attestation must be submitted to FDA every two years between October 1 and December 31.

Your determination of whether your facility meets the definition of a qualified facility must be made no later than July 1 of each calendar year.

Exemption for On-Farm Low-Risk Activities Conducted by Facilities That Are Small or Very Small Businesses

■ **What exemption for on-farm low-risk activities might apply to a farm mixed-type facility that is a small or very small business?**

If a facility is a farm mixed-type facility that is a small or very small business, and the only activities that the non-farm part of the facility conducts are certain low-risk activities on specified human food, the facility is entirely exempt from the preventive controls requirements but is still subject to the CGMP requirements.

If the non-farm part of a farm mixed-type facility is engaged in activities other than the specified low-risk activities, but it meets the definition of a qualified facility, then the facility must follow the modified requirements applicable to qualified facilities, including submitting a Form FDA 3942a.

■ **What are some of those low-risk activities exempt from the preventive controls requirements in some circumstances?**

Certain low-risk activities on certain human foods are not subject to the requirements for hazard analysis or risk-based preventive controls, or to the modified requirements, if the activities are conducted on farms by farm-mixed type facilities that are small or very small businesses, and if these are the only activities they conduct that would be subject to hazard analysis and preventive controls or the modified requirements. The activities include packing and holding or manufacturing/processing certain human foods.

Some examples of the types of foods and activities that might receive an exemption are:

- Packing baked goods, candy, or preserves
- Storing pasteurized honey

- Packing trail mix and granola
- Boiling gums, latexes and resins
- Slicing bread
- Cutting lemons or limes
- Coating raisins with chocolate
- Grinding coffee beans
- Making potato chips

This is not an exhaustive list of foods and activities that may qualify for an exemption. See the [PC Human Food Small Entity Compliance Guide](#) for more details on the exemptions for on-farm low-risk activities conducted by small and very small businesses.

■ For More Information

- [Determination of Status as a Qualified Facility in the PC Human Food Rule and PC Animal Food Rule: Guidance for Industry](#)
- [Qualified Facility Attestation Using Form FDA 3942a \(for Human Food\) or Form FDA 3942b \(for Animal Food\): Instructions for Submitting Your Attestation](#)
- [Qualified Facility Attestation](#)
- [Form FDA 3942a: Qualified Facility Attestation for Human Food Facilities](#)
- [Guidance for Industry: What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food: Small Entity Compliance Guide](#)
- [FSMA Inflation Adjusted Cut Offs](#)
- [Draft Guidance for Industry: Determining the Number of Employees for Purposes of the “Small Business” definition in Parts 117 and 507](#)
- [Final Rule; Extension and Clarification of Compliance Dates for Certain Provisions](#)
- [Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry](#)