

FSMA FAQs: What Are the Special Rules for Qualified Exempt Facilities?

1. My food facility meets the criteria for a Qualified Exempt Facility. Does FSMA still apply to me?

Qualified Exempt Facilities (QEFs) do not have to comply with the FSMA PC Rules' Hazard Analysis and Risk-Based Preventive Controls (HARPC) or Supply Chain Program (SCP) requirements. However, there are special requirements for QEFs related to **attestation**, **notice to consumers**, and **losing QEF status**.

And while your QEF is not required to comply with the full HARPC provisions, you are subject to FSMA's Good Manufacturing Practices rules (GMPs). To learn more about the GMP requirements, see the FSMA FAQ '[What Are FSMA's GMP Rules?](#)'

2. What are the attestation requirements?

You must submit two written declarations ('attestations') to FDA to establish your QEF status.

- a. An attestation that your average annual food sales for 2016-18 were less than \$1,101,103¹. You do not have to submit the sales records to support the attestation, but you must retain sufficient financial records to prove your claim if requested.
- b. An attestation that you have either:
 - i. identified potential hazards associated with the food being produced, implemented preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that they are effective; **OR**
 - ii. are in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

You do not have to submit records to support this attestation to FDA. But you do need to maintain records that support the attestation, and you must make those records available in the event of an inspection. [FDA provides an available online document explaining the attestation process and forms.](#)

If your business is new and not yet registered with FDA, you must submit these attestations prior to starting operations. If you are already a registered facility and want to notify FDA of your QEF status, then you must submit your attestation form by July 31 of the applicable calendar year. Beginning in 2020, you must renew your QEF attestations between October 1 and December 31 of each even-numbered year, in conjunction with your biennial facility registration renewal. For more information about how to register your facility, see the FSMA FAQ '[Is My Food Business Required to Register with FDA?](#)'

3. What are the consumer notice requirements?

If you make the state law compliance attestation discussed in 2.b.ii above, then you must also disclose to consumers the name and complete business address of the facility where your food was manufactured or processed. This can be done on a product label, a sign at point of sale, any documents arriving along with the food in the normal course of business (i.e. an invoice), or in electronic form for internet sales.

4. Can I lose my QEF status?

FDA and state regulators working with FDA can revoke your qualified exemption if an active investigation of a foodborne illness outbreak is directly linked to your business, or if they think withdrawing your qualified

¹ This threshold amount is good for 2019. The dollar thresholds for the qualified exemptions are to be adjusted annually for inflation, and FDA publishes the adjusted numbers every April.

exemption is necessary to prevent or control an outbreak. However, there is a process regulators must follow before withdrawing your exemption, and a chance for you to contest losing QEF status or have it reinstated after being withdrawn.

NOTE: Even if you have a qualified exemption from parts of the PC Rules, you are still at risk for criminal penalties under the Food, Drug and Cosmetic Act if you distribute food contaminated with pathogens. You could also be liable in civil court for the injuries people suffer from eating your contaminated food.

KNOW YOUR RIGHTS: Before FDA can issue an order to withdraw your qualified exemption, it must:

- a. Provide you with written notice of the reasons it would use to justify withdrawal of the exemption;
- b. Provide you an opportunity to respond within 15 days; and
- c. Consider the actions you take to address the food safety concerns FDA identifies as reasons for withdrawing the exemption.

Withdrawing a qualified exemption should be a last resort: FDA can also consider other actions that would address any problem, such as a warning letter, product recall, or product seizure. The FSMA regulations also provide you the ability to challenge the withdrawal or apply to have your exemption reinstated.

IMPORTANT PROTECTION: If FDA takes away your exemption due to an active foodborne illness investigation directly linked to your farm, and then determines that the outbreak wasn't linked to your farm after all, the agency must automatically reinstate the exemption.

NOTE: If you receive a notice of FDA's intent to withdraw your qualified exemption, you should seek assistance from legal professionals immediately. The PC Rules include detailed procedures and requirements regarding the process for issuing an exemption withdrawal order, including who must issue the order, what the order must contain, how to appeal it, how to request an informal hearing, when an exemption withdrawal can be revoked, and the process for reinstating the exemption of a qualified facility that was withdrawn.

IF YOUR STATUS IS WITHDRAWN: QEFs that have their exemption withdrawn must come into compliance with the full PC Rule, including Hazard Analysis and Risk-Based Preventive Controls (HARPC) and Supply Chain Program (SCP) requirements. If you don't appeal the withdrawal, you must achieve compliance within 120 days from receiving FDA's notice of its intent to withdraw; If you appeal and lose, you have 120 days from the date your appeal is rejected. To learn more about these parts of the PC Rules, see the FSMA FAQ '[What Are the Basic Requirements of HARPC and SCP?](#)'

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