

FSMA Frequently Asked Questions: ***What are the Special Rules for Qualified Exempt Farms?***

1. My farm meets the criteria for a Qualified Exempt Farm. Does FSMA still apply to me?

Qualified Exempt Farms (QEFs) do not have to comply with FSMA's regulations that govern growing, harvesting, holding and packing produce. However, there are special requirements for QEFs related to ***record-keeping, notice to customers, and losing QEF status.***

2. What record-keeping requirements apply to Qualified Exempt Farms?

To be Qualified Exempt, your farm's three-year average of annual total food sales must be less than \$500,000 (*see note on inflation adjustment below*), and the majority of the value of those sales must be directly to consumers and 'qualified end-users'. (Qualified end users are restaurants and other retail food establishments, such as direct-to-store sales to grocery stores, located in your same state or within a 275 mile radius of your farm.) To claim this exemption, you must have records to prove:

- a. Your total food sales for each year;
- b. The amount of your food sales made directly to consumers; and
- c. The locations of your non-direct-to-consumer customers.

DEADLINE: You must ***begin keeping these records for 2016*** in order to prove your QEF status starting in 2019. If your farm is less than three years old, FDA will accept records for whatever period of time you've been in business.

In addition, ***every year you must review your records to verify your QEF status***, and keep a written record of that review. You must ***start documenting this review in Jan. 2019 if your total annual produce sales are between \$250,000 and \$500,000, and if your annual total produce sales are less than \$250,000 you have until Jan. 2020.*** These records do not have to be submitted to FDA, but they must be retained and made available upon request.

INFLATION ADJUSTMENT: The \$500,000 total food sales threshold for qualified exemption will be adjusted for inflation, with 2011 as the base year. So in reviewing your annual sales records, you will actually be comparing your sales to an inflation-adjusted benchmark. FDA will publish the adjusted number every year on its website; ***the actual average annual total food sales threshold most likely will be higher than \$500,000.***

3. What are the customer notice requirements for Qualified Exempt Farms?

You must provide the name of your farm and your farm business address at the point-of-sale, such as on a sign at a farmers market stand; on an invoice; on an electronic receipt for online sales; or on any label that you affix to a product package. If your annual ***produce sales are between \$250,000 and \$500,000, you must start providing this notice in Jan. 2019;*** if your annual ***produce sales are less than \$250,000 you have until Jan. 2020.***

PRODUCT LABELS: If you sell any foods that are required by law to have a product label, such as value-added processed foods, that label must also include your farm's name and business address. QEFs have until ***Jan. 1, 2020*** to implement this labeling requirement.

4. What else can FDA enforce against me as a Qualified Exempt Farm?

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 farm, or if they think withdrawing your qualified 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 FSMA's Produce Rule standards, you are still at risk for criminal penalties under the Food, Drug and Cosmetic Act if you distribute food contaminated with pathogens. You are also still liable in civil court for making someone sick with contaminated food. Whether you are qualified exempt or not, knowing the food safety risks on your farm and having a plan for controlling those risks is good business, and good farming and good neighborly.

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, and
- c. Consider the actions you take to address the food safety concerns FDA identifies.

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 set timelines for responding to FDA's notice of its intent to withdraw, and you have the ability to challenge the withdrawal or 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 it 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.

5. What happens if my exemption gets withdrawn?

If FDA or the state farm food safety agency withdraws your qualified exemption, you must come into compliance with the full requirements of the Produce Rule within 120 days. For an overview of the Produce Rule Requirements, see the FSMA FAQ Sheet '***What are the Basic Requirements of the Produce Rule?***'

If you later believe you have grounds for restoring your qualified exemption, you must make a written reinstatement request, including data and information to show that you have resolved any problems, and that denying your QEF status is no longer necessary to protect public health or prevent a foodborne illness outbreak.