

Quiz: What are YOUR Requirements for FSMA?

Directions: Read each choice for the question. Decide which choice best fits your business. Follow the instructions located to the right of your choice until you identify the type of business you are according to FSMA. Look on page 2 to see your requirements.

Question 1

- a. Manufacture human food **not** sold directly to Go to Question 2
consumers
- b. Only Store Unexposed Packaged Foods..... See “Warehouse” (pg. 2)
- c. Manufacture human food and/or **only** sell See “Retail Establishment” (pg. 2)
directly to consumers

Question 2

- a. More product is sold to qualified end users¹..... See “Qualified Facility” (pg. 2)
than to other purchasers **and** the average
annual monetary value² is less than
\$500,000
- b. My company does not meet the above criteria..... Go to Question 3

Question 3

- a. More than 500 employees..... Go to Question 4
- b. Less than 500 employees..... Go to Question 5

Question 4

- a. Must comply with PMO³..... See “Business subject to PMO” (pg 2)
- b. Do not comply with PMO..... See “Other Businesses” (pg. 2)

Question 5

- a. Total annual monetary value² is less than See “Qualified Facility” (pg. 2)
\$1 million
- b. Total annual monetary value² is more than Go to Question 6
\$1 million

Question 6

- a. Must comply with PMO..... See “Business subject to PMO” (pg 2)
- b. Do not comply with PMO..... See “Small Business” (pg. 2)

¹ Definition- **Qualified End User:** the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the qualified facility that sold the food or not more than 275 miles from such facility and is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

² If you are having a hard time determining your **annual monetary value** of food, see attached link. It better explains the definition of a qualified facility.

<http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM499509.pdf>

³ PMO- Pasteurized Milk Ordinance

Business Subject to PMO

Compliance Date: September 17, 2018

- If not also a qualified facility, you are required to follow all of FSMA
- PCQI Required
- GMPs, hazard analysis, preventive controls, recall plan
- Preventive controls include allergen, sanitation, process, and supply chain control.
- Record keeping, verification, and validation are all very important.

Other Businesses

Compliance Date: September 17, 2016

- PCQI Required
- GMPs, hazard analysis, preventive controls, recall plan
- Preventive controls include allergen, sanitation, process, and supply chain control.
- Record keeping, verification, and validation are all very important.

Warehouse

Compliance Date: September 17, 2016

Information found in Subpart D

- GMPs Apply
- Establish and implement temperature controls.
- Monitor/verify temperature controls and perform/document any corrective actions.
- Maintain records of temperature controls, corrective actions, and verification

Qualified Facility

(Very Small Business)

Compliance Date: September 17, 2018

Information found in Subpart A 117.5 and Subpart D

- Must submit attestations (exemption) to FDA to be considered a qualified facility.
(<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm496264.htm>)
- Exempt from hazard analysis, preventive control, recall plan
- Must prepare GMPs according to the law.
- Must monitor, record, verify, and validate that GMPs are sufficient

Small Business

Compliance Date: September 17, 2017

- PCQI Required
- GMPs, hazard analysis, preventive controls, recall plan
- Preventive controls include allergen, sanitation, process, and supply chain control.
- Record keeping, verification, and validation are all very important.

Retail Establishment

- Exempt from FSMA—if you do not have to register with the FDA currently