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 consumers .......................... Go to Question 2
b. Only Store Unexposed Packaged Foods ............................................. See “Warehouse” (pg. 2)
c. Manufacture human food and/or only sell directly to consumers ........ See “Retail Establishment” (pg. 2)

Question 2
a. More product is sold to qualified end users than to other purchasers and the average annual monetary value is less than $500,000 .......................... Go to Question 3
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 PMO ............................................................. See “Business subject to PMO” (pg 2)
b. Do not comply with PMO ............................................................ See “Other Businesses” (pg 2)

Question 5
a. Total annual monetary value is less than $1 million ........................ See “Qualified Facility” (pg. 2)
b. Total annual monetary value is more than $1 million .................... Go to Question 6

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)

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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.


3 PMO- Pasteurized Milk Ordinance

This document has been created by Kathryn Worley, Clemson University Dept. of Food, Nutrition, and Packaging Science. 2016.

*Disclaimer: This document is solely a guide and is subject to change based on the particular situation or any changes in the law.
**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.

**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](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

**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.

**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.

**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

**Retail Establishment**

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

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