

FSMA Checklist for Facilities Manufacturing Alcoholic Beverages



1. Is the facility

- a. A **Qualified Facility**, a business with average annual sales of less than \$500,000 AND at least 51 percent of the annual monetary value of food sales direct to consumers, or local retailers or restaurants (within the same state or within 275 miles), OR
- b. A **Very Small Business**, averaging less than \$1 million, adjusted for inflation, annually, during the three-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).
- YES**
What is required?
 - Notify FDA about status; AND
 - Notify FDA it complies with applicable non-Federal food safety regulations and notify consumers of the name and complete business address of the facility where the food was manufactured or processed.
 - Maintain records to support the attestations of qualified facility.
 - Must be original records, legible, and be kept for two years.
- NO**
What is required?
Must comply with:
 - Subpart A (education and training).
 - Subpart B (Current Good Manufacturing Practices, Sanitary Facilities and Controls)
 - Subpart F (Recordkeeping).

Partial Exemptions

1. Who is exempt from the requirements for Subpart C and Subpart G?

- Subparts C and G of this part don't apply to alcoholic beverages at a facility that meets the following two conditions:
 - a. The facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; AND
 - b. The facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

- Subparts C and G of this part don't t apply to food that's not an alcoholic beverage at this facility, provided it's:
- a. Is in prepackaged form that prevents any direct human contact with such food; AND
 - b. Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

2. A winery also can be defined as a qualified facility if they are in compliance with one of the following definitions.

- a. "Qualified Facility" OR
- b. Very small business

3. What is still required if a winery is a qualified facility?

- a. Notify FDA about its status; AND
- b. Notify FDA that it complies with applicable non-Federal food safety regulations and notify consumers of the name and complete business address of the facility where the food was manufactured or processed.
- c. Maintain records to support the attestations of qualified facility.
 - Must be original records, legible, and be kept for two years.

The notification is in the form of an attestation, and must be submitted every two years, during the same time frame as the facility is required to update its facility registration. By January 2020, this attestation must be submitted online, unless FDA gives waiver to submit by mail. Electronic submissions can be filed at www.fda.gov/furls.

4. If the winery is not considered a qualified facility, what's required?

- a. Subpart A Compliance
 - Each individual engaged in manufacturing, processing, packing, or holding food (including temporary or seasonal personnel) or in the supervision thereof must:
 - Have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individuals assigned duties AND
 - Receive training in the principals of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility, and the individual's assigned duties.
 - Additional qualifications for supervisory personnel.
 - Records that document this training.
- b. Subpart B.
- c. Subpart F.

The winery also must keep track of each ingredient used in each wine that's produced, bottled, and shipped by the winery.

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