

Food Safety Modernization Act:
For Facilities manufacturing Alcoholic beverages regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the U.S. Treasury Department.

1. These facilities are exempt from Subpart C (Hazard Analysis and Risk-Based Preventive Controls) and Subpart G (Supply-Chain Program)

2. Is the facility

A. A business with average annual sales of <\$500,000 AND at least 51% of the annual monetary value of food sales direct to consumers, or local retailers or restaurants (within the same state or within 275 miles). (**Qualified Facility**)

OR

B. A business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-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). (**Very Small Business**)

Yes

No

3. What is required?

1. Notify FDA about status; AND
2. 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.
3. Maintain records to support the attestations of qualified facility
 - a. Must be original records, legible, and be kept for 2 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, must be submitted online, unless FDA gives waiver to submit by mail.

An otherwise Qualified Facility that does NOT notify FDA is subject to the requirements for Hazard Analysis and Preventive Controls.

4. What is required?

Must Comply with

1. Subpart A (Education and Training)
2. Subpart B (Current Good Manufacturing Practices, Sanitary Facilities and Controls)
3. Subpart F (Record-Keeping)

See the back of this form for more details.

FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food

Subpart	Title
A	General Provisions, Including Education and Training
B	Current Good Manufacturing Practice.
C	Hazard Analysis and Risk-Based Preventive Controls.
D	Modified Requirements.
E	Withdrawal of a Qualified Facility.
F	Requirements Applying to Records That Must Be Established and Maintained.
G	Supply Chain Program

Partial Exemptions:

1. Who is exempt from the requirements for Subpart C (Hazard Analysis and Risk-Based Preventive Controls) and Subpart G (Supply-Chain Program)?

Subparts C and G of this part do not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

- (i) 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
- (ii) The facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(B) Subparts C and G of this part do not apply with respect to food that is not an alcoholic beverage at this facility, provided such food:

- (i) Is in prepackaged form that prevents any direct human contact with such food; AND
- (ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

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

- A. "Qualified Facility" as defined by FSMA: Business with average annual sales of <\$500,000 AND at least 51% of the annual monetary value of food sales direct to consumers, or local retailers or restaurants (within the same state or within 275 miles) that are purchasing the food for sale directly to consumers as such restaurant or retail facility.

OR

- B. Very small business, a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-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)

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

A qualified facility is required to:

1. Notify FDA about its status; AND
2. 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.
3. Maintain records to support the attestations of qualified facility
 - a. Must be original records, legible, and be kept for 2 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 submission www.fda.gov/furls

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

Wineries must specifically comply with

1. Subpart A (Education and Training)

- 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

2. Subpart B (Current Good Manufacturing Practices, Sanitary Facilities and Controls)

3. Subpart F (Record-Keeping)

- The winery must also keep track of each ingredient used in each wine that is produced, bottled, and shipped by the winery.
 - The FDA has not prescribed specific penalties, but simply reminds food facility operators and importers that non-compliance with registration, prior notice, or recordkeeping requirements (once they are mandatory) are prohibited acts, and violators are subject to civil or criminal court action.

The FDA is developing several guidance documents on subjects that include:

- Hazard analysis and preventive controls,
- Environmental monitoring,
- Food allergen controls,
- Validation of process controls,

- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rules.

<https://www.regulations.gov/document?D=FDA-2011-N-0920-1979>

https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm#Compliance_Dates

<http://www.beveragelaw.com/booze-rules/2017/5/22/why-the-fda-is-inspecting-wineries>

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM551983.pdf>