

## Food Safety Modernization Act Winery Requirements

**FSMA established new requirements for wine producers, including documentation, record-keeping and mandatory training**

The Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, was enacted to protect public health by improving safety and security of the nation's food supply, and by changing the focus of the national food safety regulations from response to prevention of food contamination. The law is broken into several different rules that apply to different sectors of the food system, including farms, food processors and food transporters. Under FSMA, wineries are considered to be food processors.

FSMA includes five major elements:

- Preventative controls to reduce the likelihood of contamination;
- Inspection and compliance;
- Safety measures for imported food products;
- Mandatory recall authority; and
- Collaboration among federal, state, local, tribal and foreign food safety agencies.

### What is the FSMA Preventative Control Rule for Human Food?

FSMA's Current Good Manufacturing Practices (GMP) and Hazardous Analysis and Risk-based Preventative Control Rule for Human Food applies to food produced for human consumption, including wine. This rule is divided into seven subparts:

Subpart A	General Provisions, including Education and Training
Subpart B	Current Good Manufacturing Practices
Subpart C	Hazard Analysis and Risk-based Preventative Controls
Subpart D	Modified Requirements
Subpart E	Withdrawal of a Qualified Facility
Subpart F	Requirements Applying to Records that must be Established and Maintained
Subpart G	Supply Chain Program

Wine producers licensed by the Alcohol and Tobacco Tax and Trade Bureau (TTB) are exempted from Subparts C and G. However, most wineries must comply with Subparts A, B, D, E and F (subparts D and E are mostly procedural), unless they are eligible for modified FSMA requirements (as described in the following section).

FSMA Subparts C and G do not apply to food at wineries if the food is prepackaged, preventing any direct human contact with the food, and if the food does not constitute more than five percent of the overall sales of the winery.

The Food and Drug Administration (FDA) defines a food hazard as "any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury".

- Biological hazards include microbiological pathogens.
- Chemical hazards include pesticide or cleaning substance residue, natural toxins, unapproved food or color additives, and natural toxins.
- Physical hazards include stone, glass and metal fragments.

Most wineries are exempt from the requirements of subparts C and G because alcohol is toxic to most biological pathogens. Although wine production is considered to be "low risk", wine can still be contaminated by chemical hazards, such as residue from cleaning products, fining agents, and SO<sub>2</sub> and other preservatives and additives, and physical hazards, such as broken glass in bottles. Although wineries are not required to create a hazard analysis and risk-based

preventative control plan under subpart C, they are still liable for any injury caused by their product. Hence, it would be wise to develop a plan to address these risks. The plan could include clearly labeling all chemicals and other substances used in wine making, procedures for using cleaning agents for sanitation, measuring SO<sub>2</sub> additions, and ensuring that all bottles are turned upside down and blown out with inert gas before use.

## Is my winery eligible for modified requirements?

A winery that is considered to be a “qualified facility” or a very small business may be eligible for modified FSMA requirements.

A winery must have average annual sales of less than \$500,000, including sales by subsidiaries and affiliates, and must make at least half of its sales to consumers or local retailers/restaurants within 275 miles of its location to be eligible for modified FSMA requirements as a “qualified facility”.

To be considered “a very small business”, a winery must have average annual sales of less than \$1,000,000 (adjusted for inflation) during the preceding three years, including all sales by subsidiaries and affiliates, and including the market value of wine manufactured, processed, packed or held without sale.

A winery that is considered to be a qualified facility or very small business is required to notify FDA about its status and to formally attest that it addresses identified hazards in the wine production process through preventative controls that are monitored for effectiveness or comply with state, local, county, tribal or other applicable non-Federal food safety requirements. The winery must also notify consumers of the name and complete business address of its processing facility. The winery’s attestation can be based on licenses, inspection reports, certificates, permits, credentials or certification by an agency such as the Washington State Department of Agriculture. A winery must maintain records to support these attestations for a minimum of 2 years.

A winery that started production before September 17, 2018 needs to submit its notice to FDA for consideration as a qualified facility by **December 17, 2018**. A winery that starts production after September 17, 2018 must submit the qualified facility notification to FDA before it starts operation.

Wineries are required to update their facility registration and submit their notification regarding qualified facility/very small business status to FDA every two years. Beginning in January 2020, these notifications must be submitted to FDA on-line using form FDA 3942a.

## What are FSMA’s education and training requirements?

Winery managers must ensure that all winery staff are qualified to perform their assigned duties.

Subpart A requires mandatory education, training, and experience (or a combination thereof) for **all** winery employees, including seasonal or temporary workers, needed to manufacture, process, pack or hold clean and safe food, as appropriate for the individual’s assigned duties. In addition, each employee must receive training in the principles of food hygiene, food safety and personal hygiene.

The responsibility for ensuring compliance with Subpart A must be assigned to supervisors who have the education, training or experience necessary for supervising wine production and bottling.

Records documenting all training must be maintained by the winery for a minimum of two years.

## What are Current Good Manufacturing Practices?

Subpart B, the Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food (21 CFR Part 117), requires that a winery take reasonable measures and precautions for:

- Disease control:
  - By excluding any person with illness, open lesions including boils, sores, or infected wounds, from contact with grapes, wine, production equipment or bottling equipment.
- Cleanliness
  - By requiring all workers in direct contact with grapes/wine, equipment and bottling equipment to conform to hygienic practices including personal cleanliness, hand washing, confining food, gum, beverages and tobacco use from the production area, and taking precautions to protect against contamination.
  - Maintenance of grounds and plant, including pest management, operating systems for wastewater disposal/treatment, removing litter and waste, properly storing equipment, providing adequate lighting and ventilation.
- Sanitary operations:
  - Maintaining the production and storage facilities in a clean and sanitary condition, frequently cleaning production and bottling equipment, ensuring that cleaning compounds and sanitizing agents are safe for food production, and that the winery is equipped with adequate sanitary facilities including water supply, plumbing, floor drainage, sewage disposal, toilet and hand-washing facilities.
- Equipment and utensils:
  - Maintaining, cleaning and constructed so that it can be kept in a clean and sanitary condition.
- Processes and controls:
  - Consistent with sanitation principles, and for sanitary storage of wine additives.

If your winery is located at a vineyard, precautions should be taken to prevent vineyard fertilizers and pesticides from contaminating the wine production facility. Some potential measures to prevent contamination from vineyard chemicals include storing vineyard chemicals and equipment away from the wine production facilities, and requiring employees and visitors to remove contaminated clothing and footwear before entering the wine production area.

### What are FSMA's record keeping requirements?

FDA requires that wineries retain all training records and attestations (including those described in the preceding section) for a minimum of two years. A winery must also retain records for a minimum of two years that document the source of winegrapes, chemicals and other compounds used for wine production, and document the shipping destination of wine that is sold. Records on supplies and materials should include lot numbers and origin or destination for all materials that enter or leave the wine production facility, including yeast, DAP and other nutrients, and fining agents.

### What happens during a Food Safety inspection?

As noted previously, the FDA considers wineries to be food manufacturers subject to FSMA requirements. Food manufacturers licensed by the State of Washington to produce, market, sell and distribute food products are required to follow the safe food production, management and handling practices specified in the Washington Food, Drug & Cosmetic Act and the Washington Food Processing Act. The Washington State Department of Agriculture (WSDA) enforces the food safety requirements for all Washington wineries. WSDA is not required to provide the winery with advance notification for the inspection.

During a food safety inspection, a WSDA food safety officer will verify that the winery is operating in substantial compliance with Washington food safety laws and regulations using WSDA's Food Establishment Inspection Debit Criteria. If a winery scores at least 90 points on the inspection

with no Critical violations, it will be considered to be operating in substantial compliance with state requirements.

If a winery scores less than 90 points on the inspection, or is found to have a Critical violation, the WSDA will issue a Notice of Correction to the winery. The winery is required to correct all violations. A follow-up inspection will be conducted within 30 days to ensure that all violations were corrected.

### **When does the FSMA Preventative Control Rule become effective?**

Wineries that are considered to be small businesses (with fewer than 500 full-time employees, including any subsidiaries and affiliates) were required to comply with the FSMA Preventative Control Rule by September 18, 2017.

Wineries considered to be either qualified facilities or very small businesses were required to comply with the rule by September 17, 2018.

The compliance date for all other wineries (those that are not considered qualified, small or very small businesses) was September 19, 2016.

Additional information on FSMA requirements can be found at [www.fda.gov](http://www.fda.gov).

### **Does my winery have any other food safety compliance requirements?**

As food manufacturing plants, all wineries must be registered with the Food and Drug Administration (FDA) under the Bioterrorism Act, keep records of every source of grapes received and destination of wine shipped, and re-register every two years.

### **What is Winegrowers doing for you?**

Winegrowers works to stay current on regulation changes and inform the membership of the steps required to stay in compliance.

November 7, 2018