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) was signed into law on January 4, 2011. Its purpose is 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 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.

Federal law considers wineries to be food manufacturing plants. 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.

FSMA is divided into seven subparts:

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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 below.

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

Because alcohol is toxic to most biological pathogens, wine production is considered to be “low risk”, which is why wineries are exempted from the requirements of subparts C and G. However, wine production can still be at risk from chemical and physical hazards, such as residue from cleaning products, fining agents, and SO₂ and other preservatives and additives.

FSMA requires mandatory training for all winery employees, including seasonal or temporary workers, in the principles of food hygiene, food safety and personal hygiene. Records documenting this training must be maintained by the winery for a minimum of two years.

FDA has updated the Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food (21 CFR Part 117) mandated by Subpart B. These measures require 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 are needed to prevent chemical residue from fertilizers and pesticides used in the vineyard from contaminating the wine production facility. Potential measures to prevent contamination include storing vineyard chemicals and equipment away from the wine production facilities, requiring employees and visitors to remove contaminated clothing and footwear before entering the wine production area, and sanitary and hygienic practices noted in the preceding paragraph.

FDA or a delegated state agency conducts inspections of wineries for compliance with FSMA requirements. FDA is not required to provide advance notification of an inspection.

To prepare for a FSMA inspection, a winery should designate inspection responsibility to one or two winery employees who can be on-site without advance notice. 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. All winery records should be up to date and readily available for use by the inspectors, including required Bioterrorism reports on ingredients received and used in wine making, approved COLAs, and the training records described in the previous paragraph. All supplies and materials used in the winery should be clearly labeled.

Standard operating procedures (SOPs) and/or flow charts detailing the winery’s production processes will help to facilitate the FSMA inspection. The SOPs should describe procedures used to prevent contamination and minimize hazards during production, especially during outdoor grape sorting and crushing operations, cleaning procedures, and bottling.

**Is my winery eligible for modified requirements?**

Modified FSMA requirements may apply to a winery that is considered to be a “qualified facility” or a very small business.
A qualified facility 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 the winery’s location.

A very small business is defined as a business, including any subsidiaries and affiliates, with average annual sales of less than $1,000,000 (adjusted for inflation) during the preceding three years, including the market value of wine manufactured, processed, packed or held without sale.

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 the wine processing facility. The winery’s attestation can be based on licenses, inspection reports, certificates, permits, credentials or certification by an agency such as a state agriculture department. A qualified facility or very small business must maintain supporting records of these attestations for a period of 2 years.

A winery that began production before September 17, 2018 needed to submit its notice for consideration as a qualified facility to FDA by December 17, 2018. A winery that started production after September 17, 2018 must submit the qualified facility notification to FDA before starting operation. A winery is required to update its facility registration and submit its 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.

Winery 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 rules by September 18, 2017.

Winerys considered to be qualified facilities or very small businesses were required to comply with these rules 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.

**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.

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