

The Food Safety Modernization Act and the Wine Industry: An Overview

A Legal Resource Provided by Davis Wright Tremaine LLP

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FSMA Overview

The Food Safety Modernization Act (“**FSMA**”) and the regulations established thereunder (set forth by the U.S. Food and Drug Administration (“**FDA**”)) put into place a number of new food safety requirements that apply to wine-grape growing and the production of wine. Many of FSMA’s rules specifically exempt alcohol companies from their requirements. An overview of FSMA’s applicable provisions follows:

1. **Facility Registration:** As required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, wineries (and breweries and distilleries) must register biennially with the FDA as a food facility, regardless of whether or not the wine is shipped in interstate commerce. Alcohol beverages are considered “food;” therefore, with few exceptions, wine production facilities generally must register with the FDA. Operations that only grow and harvest wine grapes (i.e., farms / vineyards) are not required to register with the FDA, but certain manufacturing or processing activities may trigger the registration requirement for these operations.
2. **Produce Safety Rule:** Although winegrowers are not subject to the provisions of the Produce Safety Rule when the grapes grown will be turned into wine, such winegrowers may be subject to certain record-keeping requirements for grapes that will be turned into wine.
3. **Preventive Controls for Human Food Rule:** The Preventive Controls for Human Food Rule (“**PCHFR**”) establishes food safety requirements for food manufacturing facilities. The food safety requirements include updated current good manufacturing practices, hazard analysis and risk-based preventive controls, and supply-chain programs. The PCHFR exempts wineries from the requirements of the hazard analysis and risk-based preventive controls provisions, as well as from the supply-chain program provisions provided two requirements are met: (1) the winery is required to obtain a permit from, register with, or obtain approval of a notice or application from the TTB as a condition of doing business in the United States; and (2) the winery is registered with the FDA as a facility because it manufactures alcohol beverages. Wineries are still required to comply with the updated current good manufacturing practices (“**cGMPs**”), as well as record-keeping requirements.

The updated cGMPs address the following topics: personnel (e.g., handwashing and access to toilets); plant and grounds (e.g., pest prevention and waste removal); sanitary operations (e.g., sanitation of food contact surfaces and types of cleaning chemicals used); sanitary facilities and controls (e.g., water supply and plumbing); equipment and utensils (e.g., adequately cleanable equipment and proper temperature controls for cooling equipment); processes and controls (e.g., preventing allergen cross-contamination and proper handling of raw materials); and warehousing and distribution (e.g., preventing allergen cross-contamination and other contamination of the food), among a couple other topics. FDA published guidance for small entities on compliance with the PCHFR, including its cGMP requirements; find the guidance on the cGMPs [here](#), starting on page 27.

In terms of record-keeping, a winery should be able to access copies of documentation proving its exempt status as a winery (e.g., documentation from TTB and FDA facility registration) within 24-hours of a request from the FDA. Written standard operating procedures for compliance with the cGMPs are not required, but if a winery writes down those procedures, the winery should retain those documents for at least two years

after the date they were prepared. In the unlikely event that any information contained in these documents is confidential business information, the winery should note that on each page of such document, as documents used to show compliance with the requirements of the PCHFR are subject to public records requests. For more specific information on the PCHFR, see [21 C.F.R. pt. 117](#).

4. **Sanitary Transportation Rule:** Depending on how the grapes and/or bulk wine are transported, such transportation operations may trigger a requirement to comply with the Sanitary Transportation Rule. At its most basic, this rule seeks to ensure that vehicles and other transportation equipment is clean and sanitary. For more specific information on the Sanitary Transportation Rule, see [21 C.F.R. §§ 1.900 et seq](#); FDA guidance for small entities on this rule can be found [here](#).



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