THE FOOD SAFETY MODERNIZATION ACT AND THE WINE INDUSTRY: AN OVERVIEW

A legal resource for the Oregon Winegrowers Association

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Davis Wright Tremaine LLP is a full service law firm providing services to the wine industry in the areas of mergers and acquisitions and other business transactions, land use and real estate, alcohol regulatory and licensing, intellectual property, employment, and litigation.

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 the new 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, all wine production facilities 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.

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, winegrowers are subject to certain record-keeping requirements for grapes that will be turned into wine. These requirements, including compliance dates, are discussed in a separate article (*see* The Food Safety Modernization Act Produce Safety Rule Compliance Guide).

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, as well as record-keeping requirements.

   The updated current good manufacturing practices 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 current good manufacturing practices requirements; find the guidance on the current good manufacturing practices 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 current good manufacturing practices 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.

The deadlines for complying with the updated current good manufacturing practices depend on the size of the business. For **very small businesses**, those averaging less than $1 million per year in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, the compliance date is **September 17, 2018**. For **small businesses**, those with fewer than 500 full-time equivalent employees, the compliance date was **September 18, 2017**. For **all other businesses**, the compliance date was **September 19, 2016**. For more specific information on the PCHFR, see 21 C.F.R. pt. 117.