

Ensuring Food Safety: Wineries



Wineries in the United States must adhere to many regulations when selling wine, including those regarding food safety. The goal of this document is to provide guidance to winery businesses about the Food Safety Modernization Act (FSMA) and other regulations that affect wine production facilities. All wineries must comply with certain subparts of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule regulation (21 CFR Part 117), including:

- Subpart A, 21 CFR 117.4: Education and Training
- Subpart B: CGMPs
- Subpart F: Requirements Applying to Records That Must Be Established and Maintained

Under the Preventive Controls for Human Food Rule (21 CFR Part 117), alcoholic beverage facilities that have 1) Registered with the FDA (and re-register every two years) under Section 415 of the Federal Food, Drug, and Cosmetic Act AND 2) Have obtained a permit from the Secretary of the Treasury through the Alcohol and Tobacco Tax and Trade Bureau (TTB) are exempt from:

- Subpart C: Hazard Analysis, and Risk-based Preventive Controls for Human Food
- Subpart G: Supply Chain Program

What the FSMA Preventive Controls for Human Food Rule says:

117.5(i)(1) 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) Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) 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) Under section 415 of the Federal Food, Drug, and Cosmetic Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages. (2) Subparts C and G of this part do not apply with respect to food that is not an alcoholic beverage at a facility described in paragraph (i)(1) of this section, 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.

Operations that include a vineyard (grape growing) and winery (wine production) are considered a mixed-type facility. In this case, additional FSMA regulations such as the FSMA Produce Safety Rule may be required. Details of these requirements can be found in the North Central Region FSMA Center documents “Ensuring Food Safety in the Vineyard: Table Grapes” and “Ensuring Food Safety in the Vineyard: Wine Grapes”. Depending on business type, a winery may be considered a retail food establishment. In this case, registration with the FDA is not required. Rather, the winery must comply with state or local regulatory agency requirements for retail food establishments.

Current Good Manufacturing Practices (cGMPs)

Current Good Manufacturing Practices (21 CFR Part 117, Subpart B) has nine sections:

1. Personnel (§117.10): requirements for training of employees to maintain adequate personal cleanliness, and following hygienic practices in the workplace;
2. Plant and grounds (§117.20): requirements on how food plants and surrounding grounds must be maintained;
3. Sanitary operations (§117.35): requirements on adequate plant maintenance, cleaning and sanitizer substances and toxic materials, pest control, sanitation of food contact and non-food contact surfaces, and storage and handling of cleaned portable equipment and utensils;
4. Sanitary facilities and controls (§117.37): requirements for water supply, plumbing, sewage disposal, toilet facilities, hand-washing facilities, and rubbish and offal disposal;
5. Equipment and utensils (§117.40): requirements pertaining to equipment and utensils; food contact surfaces; holding, conveying, and manufacturing units; cold storage; instruments and controls; and compressed air or other gases;
6. Processes and controls (§117.80): requirements to ensure that manufacturing, processing, packing, and holding food are conducted in accordance with adequate sanitation principles, including ensuring that raw materials, ingredients, and finished products are protected from contamination and allergen cross-contact;
7. Warehousing and distribution (§117.93, §1.908): requirements on storage and transportation of food;
8. Holding and distribution of human food by-products for use as animal food (§117.95): requirements appertaining to the holding, labeling, and distribution of human food by-products that are used for animal food; and
9. Defect action levels (§117.110): Requirement for utilizing quality control operations that reduce natural or unavoidable defects to the lowest level possible, and references to the established levels above which may cause a product to be considered adulterated.

Best practices to consider with cGMPs

A sanitation program is of vital importance to wineries of all sizes. Poorly implemented sanitation has the potential to affect product quality, stability, revenue generation, and reputation. Processing facilities and their premises need to be free of debris, vegetation, and standing water that can become breeding places for pests (i.e. birds, rats, insects, etc.). Equipment and tools must be designed and used in a manner that is safe for food production and must be easy to clean and sanitize. A clear system (schedules and record-keeping) minimizes confusion, increases efficiency, and helps ensure that cleaning and sanitation steps are done properly and on a regular basis. Pets are not allowed in the areas where wine is produced. Guard or guide dogs may be allowed in some areas if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Training is required for all employees to ensure they are practicing hygienic and food safety practices (more in the next section).

Examples of what Current Good Manufacturing Practices (cGMPs) say

117.10(b) All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food.

117.20(a) Grounds: The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. (b) Plant construction and design: The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding).

Employee Health, Hygiene, and Training (Subpart A)

Workers must receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene. All employees must maintain good personal hygiene. Employee training must be appropriate to the food (wine grapes, ingredients, and/or wine), the facility, and the employees' assigned duties (from vineyards (if applicable) through production, bottling, warehousing, and distribution). Workers must know when they should not come to work (sickness) and the appropriate clothing and shoes to wear.

What the FSMA Preventive Controls for Human Food Rule says

§117.4(b)(2) Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must receive training in the principles 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. §117.4(d): Records that document training required by paragraph (b)(2) of this section must be established and maintained.

Record Keeping (Subpart F)

The Preventive Controls for Human Food Rule mandates that wineries comply with the relevant record-keeping requirements (21 CFR 117.305). A winery should have all the necessary documents up-to-date and readily available.

What the FSMA Preventive Controls for Human Food Rule says

117.305 General requirements applying to records. Records must: (a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records; (b) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities; (c) Be accurate, indelible, and legible; (d) Be created concurrently with performance of the activity documented; (e) Be as detailed as necessary to provide history of work performed; and (f) Include: (1) Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility); (2) The date and, when appropriate, the time of the activity documented; (3) The signature or initials of the person performing the activity; and (4) Where appropriate, the identity of the product and the lot code, if any. (g) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

- There is a checklist available on the [NCRFSMA website](http://www.ncrfsma.org) (www.ncrfsma.org) titled "[Audit Checklist for Manufacturers of Human Food](https://www.ncrfsma.org/files/page/files/humanfoodsafety_for_processors_update_12_19_17.pdf)" that provides details on requirements for cGMPs (https://www.ncrfsma.org/files/page/files/humanfoodsafety_for_processors_update_12_19_17.pdf)
- Find more [information about FSMA](http://www.fda.gov/food/guidanceregulation/fsma) on the FDA's website. (www.fda.gov/food/guidanceregulation/fsma)
- Learn about the [Bioterrorism Act and Registration for Food Facilities](http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm2006831.htm). (www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm2006831.htm)

My Winery Checklist – Best Practices for Preventive Controls for Human Food Rule

- ✓ *We train employees and supervisors on proper hygiene. Visitors and volunteers are also aware of our hygiene protocols.*
- ✓ *We train everyone in proper handwashing techniques, including posting how-to hand wash signs in restrooms.*
- ✓ *We instruct employees on appropriate measures to minimize the spread of illness (i.e. sickness policy).*
- ✓ *We ensure workers are free of cuts, open wounds, and infections.*
- ✓ *We maintain training records for two years.*
- ✓ *We schedule regular walk-through inspections to ensure the facility and processes are conducted under conditions that prevent biological, chemical, and physical contamination to the wine.*
- ✓ *Floors, walls, ceilings, equipment, and tools are easy to clean and kept in good repair.*
- ✓ *We keep fermentation tanks and processing equipment as sanitary as possible and away from contamination from birds, rodents, and/or pets.*
- ✓ *We have a pest management program.*
- ✓ *Clean water and adequate water pressure is available for cleaning and sanitizing.*
- ✓ *Drainage and sewer are kept in proper working condition.*
- ✓ *We clearly label and properly store (sealed containers) all chemicals, additives, etc.*
- ✓ *We write standard operating procedures (SOPs) for all our winemaking processes as a best practice. For any process that involves cleaning and sanitation steps, we include them (with specific instructions).*
- ✓ *We document these training and sanitation practices.*
- ✓ *We keep written record of all wine grapes used in processing, and we maintain documentation from growers affirming the processing of the grapes into wine.*
- ✓ *We maintain up-to-date chemical and material/additive inventories.*

These institutions are equal opportunity providers. For the full non-discrimination statement or accommodation inquiries, go to www.extension.iastate.edu/diversity/ext.

**IOWA STATE
UNIVERSITY**
Extension and Outreach



North Central Region
Center for FSMA Training, Extension
and Technical Assistance



**THE OHIO STATE
UNIVERSITY**

COLLEGE OF FOOD, AGRICULTURAL,
AND ENVIRONMENTAL SCIENCES

Prepared by: Melanie Ivey PhD, The Ohio State University; Angela Shaw PhD, Iowa State University, Smaranda Andrews PhD, Iowa State University; Shannon Coleman PhD, Iowa State University; Jennie Savits MS, Midwest Grape and Wine Industry Institute/Iowa State University; Jacques Overdiep III, Iowa State University.

Funding provided by the Food and Drug Administration, the Iowa Department of Agriculture and Land Stewardship and the Midwest Grape and Wine Industry Institute.

This material was developed by the North Central Regional Center under a grant from the Food and Drug Administration. FDA has provided technical assistance in developing this material; however, this information has not been formally approved by FDA. It does not represent any agency determination or policy.

