FDA Agents Increase Number of Surprise Inspections at Wineries

Understanding the agency's role in regulating wineries as food manufacturers

Barbara Snider

Barbara Snider works with the partners at Hinman & Carmichael as senior counsel in all aspects of beverage law, most recently focusing on TTB and FDA compliance matters. She has broad experience as a regulatory, business and litigation attorney. She practiced at Cooper, White & Cooper LLP in San Francisco and as in-house associate general counsel for what is now Frontier Communications, a NYSE communications company, with responsibility for all legal affairs for six Western states. Snider and her husband developed their first vineyard in Knights Valley, Calistoga and later, a high altitude mountain vineyard in the Red Hills Lake County. She handled all legal, regulatory, compliance and marketing matters for the vineyards and wine brand.

THE FEDERAL FOOD & Drug Administration (FDA) has recently caught the attention of alcoholic beverage manufacturers with surprise inspections at their facilities. As winery personnel should know by now, all alcoholic beverages, including wine, are considered food products that are subject to oversight by both the **Alcohol and Tobacco Tax and Trade Bureau** (TTB) and the FDA.

While FDA regulations affect all alcoholic beverage manufacturers, the purpose of this article is to briefly summarize pertinent FDA regulations as specifically applied to wineries and provide practical suggestions for dealing with the inevitable FDA inspection.

Laws Expanding FDA Regulation Over Alcoholic Beverage Manufacturers

The 2002 Bioterrorism Act (BTA)[1] began a new phase of FDA oversight of the wine production process, requiring wineries to register with the FDA by 2003.[2] Under the BTA, the ability to track all food sources, both backward and forward, is key. Wineries must now keep track of all food sources (yeast, fining, eggs, etc.) as follows: (1) record the date the food source is received, the lot number and source; (2) record which specific food ingredients were used in each wine product by date, lot number (or other similar identification) and quantity; and (3) record each destination to which each finished wine product is shipped.

The 2011 Food Safety Modernization Act (FSMA)[3] made sweeping changes to food safety laws, thus expanding the scope of FDA oversight and changing the FDA focus from responding to food contamination to preventing food contamination. It also broadened the responsibilities of wineries, mandating new employee training programs and record keeping. FSMA directed the FDA to inspect *all* food manufacturers (including "low risk" manufacturers, such as alcoholic beverage producers) within seven years of the passage of the act.[4] In the past, the FDA seldom inspected wineries because they were considered "low risk" since fermentation and the chemical processes basically kill all pathogens. As a result, inspections under FSMA are new for wineries, and they need to be prepared.

New registration and record keeping requirements for wineries under FSMA impose important changes. Wineries must now renew their FDA registration every two years—between October 1 and December 31 of each even-numbered year. Effective January 4, 2020, all registrations must be made electronically.[5]

FSMA and the FDA's newer Good Manufacturing Practices (GMP) regulations require wineries to comply with two new and important provisions: Subpart B, directing wineries to provide and document a training program for employees in sanitation and food hygiene and safety, and Subpart F, requiring new record keeping. The good news is that all alcoholic beverage manufacturers are still exempt from the more onerous requirements in Subpart C (Hazard Analysis and Risk-based Preventative Controls—HARPC) and Subpart G (Supply-Chain Program), both of which require written and thoroughly documented hazardous risk analyses and preventative risk plans.[6]

FDA Inspections

Some wineries have yet to receive the FDA's "knock on the door" (with no prior notice required). While others have already been inspected, you should know the law requires an inspection at least every five years. The best way to prepare is to do frequent internal inspections to assure compliance with all the regulations. It is particularly important to keep all records and/or reports up-to-date. Experience suggests the best prepared wineries follow these steps:

1. Designate one or two persons who will be available on-site for an unexpected inspection.
2. Assure all necessary documents/reports are up-to-date and readily available. This includes the Bioterrorism reports, Sanitation Standard Operating Procedures (SSOPs), sanitation logs and even copies of approved Certificate of Label Approvals (COLAs).
3. Make sure all employees have been trained in sanitation processes, personal hygiene and food safety processes, and that training for each employee is well documented.

4. Develop a written flow chart of the winery processes demonstrating sanitation at each stage of winemaking, as well as written SSOPs for these processes.

5. Assure that if you receive grapes, crush and/or ferment outdoors, the areas are kept as sanitary as possible (the FDA has specifically raised concerns regarding birds, dogs and cats in the area that could contaminate the grapes/juice). Temporary overhead shade covers installed during harvest are preferred for these areas.

6. Make sure *everything* in the winery is clearly labeled, even down to sanitizer spray bottles and the like.

7. Assure the bottling rooms/areas are separated from the other processing areas and are clean and sanitized. (The FDA considers the bottling area the most vulnerable area for possible contamination.)

8. Make sure you keep all toxic cleaning compounds, sanitizing agents and pesticide chemicals labeled and stored in a separate area away from any food ingredients (yeast, etc.), food-contact surfaces, and food-packaging materials. And assure the only toxic materials used and stored in the winery are limited to those required for: (a) maintaining clean and sanitary conditions, (b) use in laboratory testing procedures, (c) plant and equipment maintenance and operation, or (d) for use in the plant's operations.

Effective measures must be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials. No pets should be allowed in the food processing areas. Guard or guide dogs may be allowed in some areas of the winery only if the presence of the dog is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials.[7]

9. Make sure there is sufficient water, hot water and water pressure for sanitizing, and that all drainage and sewage facilities are in working order with no backflows.

10. Assure adequate toilet and hand-washing facilities (with warm water) are available for employees, with proper signage requiring all employees to wash their hands.

Remember the Bioterrorism Report Requirement?

FDA inspectors will also want to review your Bioterrorism Reports. You need to keep records of all food sources/ingredients received and used in the winery (yeast, fining, eggs, etc.). The record should include: (1) Name of the firm providing the food source, (2) Name of responsible individual, (3) Address, (4) Telephone number, (5) Fax number and e-mail address, if available, (6) Type of food, including brand name and specific variety, (7) Date received, (8) Lot number or other identifier if available, (9) Quantity and type and size of packaging (e.g., 750 ml bottles), (10) Name of carrier that delivered the item, (11) Carrier's address and telephone number, and (12) if available, carrier's fax number and e-mail address.

The BTA also requires that your reports: (1) keep track of each ingredient and quantity used in each wine that is produced and bottled, (2) include the source of the packaging used and (3) list each entity to whom each finished product is shipped. These reports are helpful should you need to track backwards to specifically identify a source of any contamination. These BTA records enable a winery to track a specific ingredient used in each wine or a particular pallet of bottles/packaging that may have a problem and can greatly reduce the amount of product that might have to be recalled in the event of a problem.

The FDA has not prescribed specific penalties for failing to register, keeping accurate records or providing required notices. But any failure is considered a prohibited act, and violators are subject to civil or criminal court action. Further, any foods imported from non-registered foreign facilities or without proper prior notice could be detained at the port of entry.

Sanitation

The primary focus of FDA inspections is sanitation. The FDA does not require a "sterile" environment but it does require a "sanitized" environment.

Per the FDA: "Sanitize means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer."[8]

We have been asked if there are any specific FDA GMPs for wineries. The answer is "not really." The FDA issues general GMP sanitation standards applicable to all food facilities but none specifically for wineries, and many of the general GMP standards are not particularly adaptable to wineries. Rather than simply list the FDA GMPs or every sanitation process and material possible (as many articles do), we decided to just visit a few representative wineries and their winemakers to see what is actually being done in the everyday operations of wine cellars. Wineries we visited are located in Napa, Santa Barbara and Sonoma counties. For a good cross-section, we wanted to have at least one winery producing high quality wine that fit into each of the traditional case production categories: (1) under 50,000, (2) 50,000 to 99,999, (3) 100,000 to 499,999 and (4) over 500,000 cases.[9] While admittedly not an extensive study, what we found most interesting is that every winery we visited, whether small, medium, or large, followed remarkably similar cleaning/sanitation practices.

SANITATION STANDARD OPERATING PROCEDURES (SSOPS)

Each winery developed its own written SSOPs best suited for the individual winery situation, with individual SSOPs for each stage of production to maintain consistency in cleaning/sanitizing. Importantly, they also kept logs documenting the date, time and procedure each time equipment was cleaned/sanitized.

THE CLEANING/SANITIZING PROCESSES

The winemakers universally agreed that "cleaning" is the most important part of the cleaning/sanitizing process.[10] There were some differences in the specific cleaning detergents used, but all of our winemakers regularly use peracetic acid, citric acid and hot water for some or all stages of the cleaning/sanitizing processes. Physical scrubbing was universally included as an important part of the cleaning/sanitizing process. Winery use of hot water varied from 185° F to 225° F for 20 to 30 minutes. Other mainstays in the cellar are 70 percent food-grade alcohol and sulfur dioxide, which are universally used by all (some winemakers admitted they simply use plain old vodka to keep their thieves sanitized).

Regarding ozone, half of the wineries use it for some sanitation (primarily barrels) while the other half don't like it, citing the risk of possible spotty coverage and the need to generate ozone and monitor its use closely because of the risks. Using ozone really seemed to depend on the individual winery size and the specific winery environment.

All wineries we talked with thoroughly cleaned/sanitized all equipment related to harvest and crush (bins, presses, tanks, barrels, etc.) at the beginning of harvest. During harvest, our wineries also clean all equipment as well as floors a minimum of once a day. Harvest bins were cleaned well after emptying to remove any visible debris from grapes, both inside and out, before next use. This applies equally as well to mechanical harvesters. Experience indicates that sugars that are not rinsed off could cause lactic problems on all the crop harvested the next day.[11] All mechanical harvesting (and mobile bottling) services should be able to show their cleaning/sanitizing records to the winery prior to providing the service.

All of the wineries were in agreement that monitoring and checking every sanitation process regularly are essential to assure complete sanitation and to avoid any build-up of biofilm or microorganisms in equipment, barrels and the cellar in general. Most regularly swab to assure complete sanitization.

Could Your Winery be Exempt from Registering with the FDA?

The most common exemption is for "Retail Food Establishments."[12] To qualify, the winery's primary function must be to sell wine directly to consumers (DTC). A winery will qualify for the Retail Food Exemption if the annual monetary value of sales of all wine products directly to consumers exceeds the annual monetary value of sales of wine products to all other buyers (i.e., at least 51 percent DTC revenues). The term "consumers" does not include businesses. The FDA will calculate all DTC sales revenues, including those from internet, mail order and tasting room sales, and DTC does not have to be a face-to-face sale.

The FDA also did away with any size restrictions for the exemption explaining: "Even if some establishments that use mail, catalog and internet orders in determining their primary function are larger establishments and can reach consumers on a national level, we do not believe that is inconsistent with section 102(c) of FSMA, which does not specify that FDA's amendment to the retail food establishment definition only pertains to establishments of a specific size." [13]

Conclusion

Compliance is a complex issue with many moving parts. Better to be prepared than to be found wanting during an inspection and perhaps fined and faced with the likelihood of follow-up inspections. Checklists, records and logs of all actions taken will always be helpful in providing a safe harbor. Maintain contacts with your industry trade associations and ask questions ahead of time. Know the rules before you get that "knock on the cellar door." **WBM**

DISCLAIMER: The viewpoints expressed in this article are provided for educational and informational use only and are not to be construed as legal advice or a guarantee, warranty or prediction regarding the outcome of your legal matter. If you need legal advice, please consult with legal counsel.

References

1 The Public Health Security & Bioterrorism Preparedness & Response Act, Public Law 107-188, June 12, 2002.

2 Only wineries that qualify as a "Retail Food Establishment" or as a "Qualified Facility" are exempt from the FDA registration and record-keeping requirements.

3 Food Safety Modernization Act, Public Law 111-353, January 4, 2011.

4 It does not appear the FDA will get to all wineries by the end of 2017, but rest assured they will continue the inspections into 2018 and beyond.

5 Federal Register, Vol.81, No.135, July 14, 2016/Rules and Regulations, p.45912.

6 Federal Register, Vol.78, No.11, January 16, 2013/Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventative Controls for Human Food, 3646 at pp. 3707-3709; 21 C.F.R. 117.5 –Exemptions.

7 21 C.F.R. 117.35.

8 21 C.F.R. 110.3(o).

9 Our thanks to the following wineries for opening their doors to us: Napa: Frank Family Vineyards, Calistoga; Saddleback Cellars, Oakville; Sequoia Grove Winery, Rutherford. Santa Barbara: Fess Parker Winery & Vineyard (both the Los Olivos and Santa Maria facilities). Sonoma: Rack & Riddle, Healdsburg; St. Francis Winery & Vineyards, Santa Rosa and Simi Winery, Healdsburg.

10 Some experts have opined that 80% of the cleaning/sanitizing process should be spent on "cleaning" vs. "sanitizing". See, e.g., "Microbial Monitoring & Winery Sanitation Practices for Quality Control", Ted Rieger, *Wine Business Monthly*, October, 2015, quoting Dr. Randy Worobo, Cornell University.

11 See, e.g., "Industry Roundtable: Cellar Sanitation," Bill Pregler, *Wine Business Monthly*, November 2011.

12 There is also a very narrow exception for "Qualified Facilities" with sales only to entities located within 275 miles from the winery in the same state and no more than $500,000 in sales during the prior three-year period.

13 Federal Register, Vol. 81, No. 135, July 14, 2016/Rules and Regulations, p. 45912 at 45916-45924.