What Wineries Need to Know About the Food Safety Modernization Act

This act aims to ensure that the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

Pat Howe

Patricia Howe has more than 30 years of winemaking production experience as winemaking technical director at Domaine Chandon and Mumm Napa, and some time at the late Allied Domecq/Beam Wine Estates. She has a BS in fermentation science and an MS in food science (sensory science emphasis), both from UC Davis, and also worked there as teaching laboratory manager. Her past business experience includes time as owner/president of ASCENT Laboratories, LLC, an applied sensory and analytical wine laboratory in Napa, and most recently at ETS Laboratories. She is currently the owner/winemaker of Patricia Howe Wines, adjunct instructor for VESTA and review process manager for the American Vineyard Association.

UNDER THE NEW FOOD Safety Modernization Act (FSMA), it is expected that **Food and Drug Administration** (FDA) inspectors, or their delegates from a state or local agency, will be visiting every winery at least once in the next seven years, and then regularly thereafter. Inspections of wineries have already taken place in about 114 wineries across the United States over the past four years with a voluntary remediation rate of about 14 percent, according to the FDA website.

The FSMA, the most sweeping reform of food safety laws in more than 70 years, was signed into law by president **Barack Obama** on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. This act gives the FDA new and enhanced mandates and authorities to protect consumers and promote public health.

According to the FDA website, "FSMA calls for enhanced partnerships and integration with our federal, state, local, tribal and territorial partners. The Partnership for Food Protection (PFP), of which the FDA is a member, has been working to develop an integrated food safety system with strengthened inspection, laboratory and response capacity. The Federal-State Integration team has been and will continue working closely with state, local, tribal and territorial partners to develop and implement the Integrated Food Safety System (IFSS)."

Although wine is not usually considered a major food safety risk due to the low pH and presence of alcohol—resulting in no documented cases of human pathogenic microbes in wines—there have been international incidents related to non-microbe food safety which the American industry must consider. The Italian wine methanol scandal of 1986, which resulted in 26 deaths and dozens of hospitalizations traced to adulteration at 30 wineries, along with the 1985 Austrian diethylene glycol adulteration scandal, are two of the most commonly cited examples of non-microbial issues with international consequences. Non-chemical contaminants, such as broken glass, also made the news in the 2010 recall of wines in the U.K. due to issues with a faulty corker. Adulteration and contamination from harmful chemicals and other substances are more likely than microbial food-borne illness to be issues with wine.

How Will the Food Safety Modernization Act Affect Wineries?

Wendell Lee, general counsel at the **Wine Institute** in San Francisco, said that wineries have no need to be alarmed about FSMA inspections. "FDA inspections have been rare in California; and while the Food Safety Modernization Act imposes great obligations on the FDA, wineries and other TTB-permitted premises have been exempted from the FSMA's more burdensome provisions," Lee said.

"Wine Institute, along with other industry trade associations, were successful in convincing Congress that the TTB's already burdensome primary regulatory control over wineries and the extremely low safety risk that wine and other alcohol products pose to the general public justify exempting TTB-permitted facilities from having to comply with many of the FSMA mandates," said Lee. The exemption, for example, will not compel wineries to implement preventive control requirements as otherwise required by FSMA.

One of the potentially burdensome requirements of the FSMA is preventative control. To approach food safety from a preventative standpoint, the FSMA requires the development of Hazard Analysis & Critical Control Points (HACCP) programs, a management system in which food safety is addressed through the analysis and control of biological, chemical and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. These programs identify steps in the production process that might introduce risk then apply control and monitoring steps at these points to reduce safety and contamination issues.

Although HACCP is most frequently applied to control microbial (pathogenic) problems, it certainly works for non-pathogenic spoilage organisms and chemical or physical contaminants as well and, as such, can be an excellent program for improving quality in wines. Several large wineries have incorporated HACCP plans as a voluntary measure to improve safety while both documenting and justifying quality programs at their facilities. Quality programs in the context of HACCP will have specific goals and outcomes

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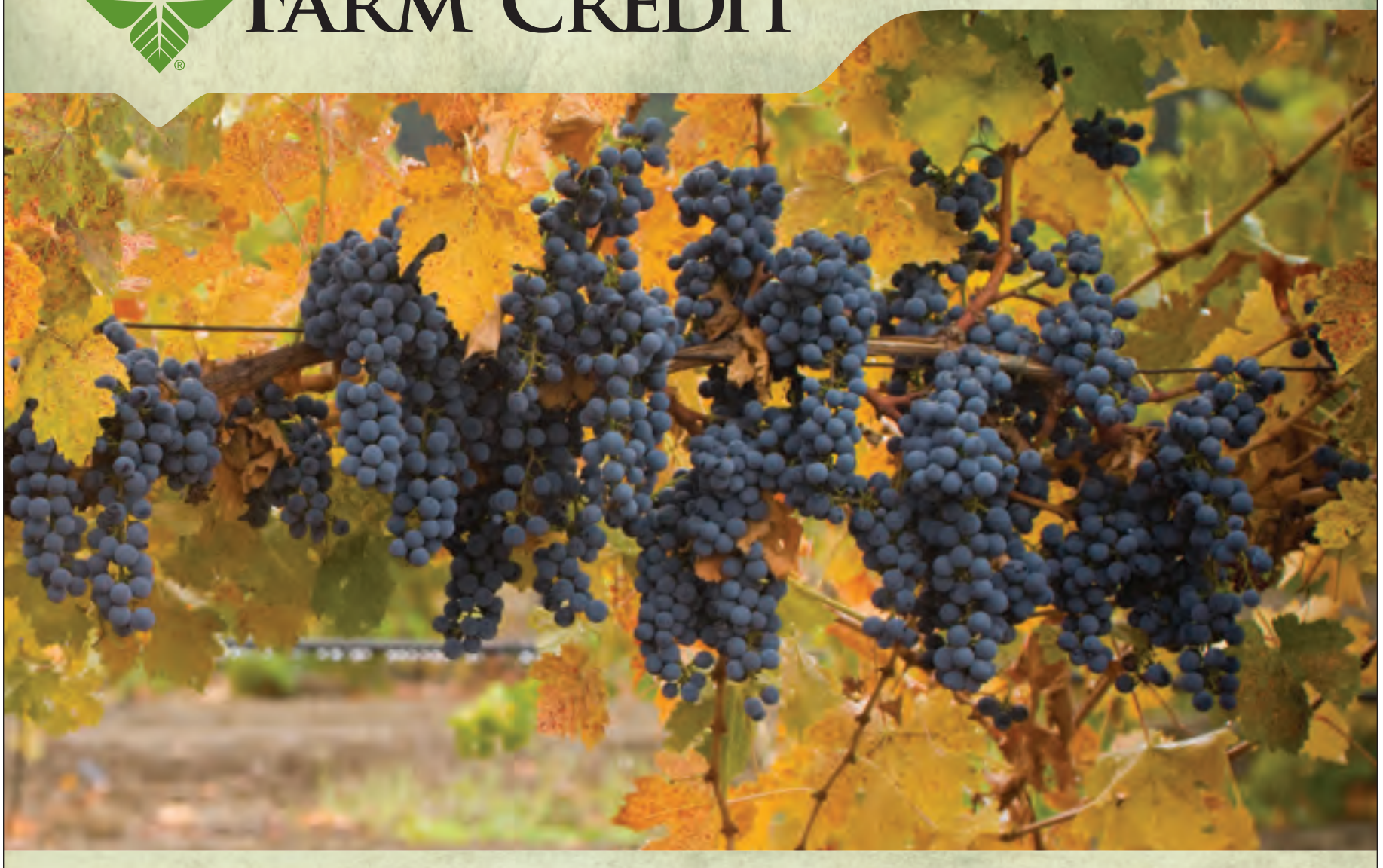

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which relate to the intensity and degree of potential risk and can focus a facility to concentrate on getting the most out of its programs, whether it be for safety or for quality.

"While the FDA has always had inspection authority over wineries, many of the Food Safety and Modernization Act's more onerous provisions do not apply to facilities that produce, receive and distribute alcoholic beverages," Lee said.

The current FDA inspection program for food plants is based on both industry and company safety and performance as evaluated by the FDA inspections and any documented health issues. The FDA is prioritizing the inspections by using a newly developed, risk-based model for domestic inspections. It takes industry-specific risks into account and will be revised and reviewed on an annual basis.

Last year's industry-wide inherent risk factors were Outbreaks, Class 1 Recalls and Adverse Events. The alcoholic beverage industry had none of these three types of risks, and it will be in its best interest to keep this good product safety record. Because pathogens are unlikely to be an issue, the precautions taken by the industry should focus on preventing chemical and physical contamination and adulteration. The firm-specific compliance factors were based on the five-year compliance history of the specific firm. Wineries are unlikely to be inspected with this type of regularity, and this should continue if the industry maintains an excellent food (wine) safety record.

Bioterrorism Act of 2002: Time for a Review?

Wineries are considered food plants by the FDA, which should be no surprise. Every winery should be registered with the FDA for compliance with the Bioterrorism Act, which required domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the U.S. to register with the FDA by Dec. 12, 2003.

If you are already registered, you will need to re-register under provisions of the FSMA, which requires re-registration of all food facilities by December 2012 and also requires updated registration every two years thereafter. Although the FDA originally hoped to begin re-registration under the FSMA as of Oct. 1, 2012, email notifications and website updates announced that registration became available as of Oct. 22 2012. Registrants can submit registration renewals to the FDA using the online food facility registration module or paper Form FDA 3537. Updates can be found at the FDA's website: *www.access.fda.gov*.

If your winery is not already registered with the FDA, note that under the Bioterrorism Act, owners, operators or agents in charge of domestic or foreign facilities that manufacture/process, pack or hold food for consumption in the U.S. are required to register the facility with the FDA. Domestic facilities are required to register, whether or not food from the facility enters interstate commerce. Foreign facilities that manufacture/process, pack or hold food are also required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility before the food is exported to the United States. However, if the subsequent foreign facility performs only a minimal activity, such as putting on a label, both facilities are required to register.

In addition to registering, the Bioterrorism Act requires record keeping on the sources of food received and the destination of food shipped. These records can be electronic or hard copy and do not have to duplicate any existing systems if they already contain the required information.

What Records Must be Established and Maintained by Non-Transporters of Food?

For non-transporters (i.e., persons who own food or who hold, manufacture, process, pack, import, receive or distribute food for purposes other than transportation), the records have to:

1. Identify the immediate non-transporter's previous sources, whether foreign or domestic, of all foods received, including:
   - The name of the firm, address, telephone number, fax number and email address, if available.
   - Type of food, including brand name and specific variety (e.g., Brand X cheddar cheese, not just cheese; romaine lettuce, not just lettuce).
   - Date received.
   - Quantity and type of packaging (e.g., 12-ounce bottles).
   - The immediate transporter's previous sources, including the name, address, telephone number—and, if available, fax number and email address. Persons who manufacture, process, or pack food also must include the lot or code number or other identifier if the information exists.
2. Identify the immediate non-transporter's subsequent recipients of all foods released, including:
   - The name of the firm, address, telephone number, fax number and e-mail address, if available.
   - Type of food, including brand name and specific variety.
   - Date released.
   - Quantity and type of packaging.
   - The immediate transporter's subsequent recipients, including the name, address, telephone number—and, if available, fax number and email address. Persons who manufacture, process or pack food also must include the lot or code number or other identifier if the information exists.
   - Information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

Persons who distribute food directly to consumers (the term "consumers" does not include businesses) are excluded from the requirement to establish and maintain records to identify the immediate subsequent recipients (they are subject to the requirements to identify the immediate previous sources).

Persons who operate retail food establishments that distribute food to persons who are not consumers must establish and maintain records to identify the immediate subsequent recipients only to the extent the information is reasonably available.

What Records Must be Established and Maintained by Transporters of Food?

The term "transporters" includes persons who have possession, custody or control of an article of food in the U.S. for the sole purpose of transporting the food, whether by road, rail, water or air. The term "transporters" also includes foreign persons that transport food in the U.S., regardless of whether the foreign persons have possession, custody or control of food for the sole purpose of transporting it.

For transporters, records have to include the names of the transporter's immediate previous source and the transporter's immediate subsequent recipient, origin and destination points, date the shipment was received and the date released, number of packages, description of freight, route of movement during the time the food was transported and transfer point(s) through which the shipment moved.

Winery-specific FAQ Regarding the Bioterrorism Act from the FDA Website

1.10 Q: [Added November 2005] Is a winery subject to this regulation?

A: Yes. Section 1.326 states that persons who manufacture, process, pack, transport, distribute, receive, hold or import food are covered by this regulation. The winery is considered a manufacturer and must establish and maintain records of the food (including ingredients) that it receives as well as the food (wine) that it releases, in accordance with sections 1.337 and 1.345. If the winery also grows and harvests grapes that it uses to manufacture the wine, then it would be engaged in a mixed activity. In this instance, the growing facility may qualify for the farm exemption; the manufacturing activity would remain subject to the non-transporter record requirements.

1.11 Q: [Added November 2005] Some wineries are co-located with gift shops where wine can be sampled and purchased. Are these gift shops/tasting areas exempt from the rule?

A: No. A gift shop co-located with a winery is an example of a mixed facility that engages in both manufacturing and retail activities and therefore does not qualify for the restaurant exemption provided by section 1.327(b). However, if the gift shop and winery are under the same ownership, they are vertically integrated, as discussed in the response to Comment 13 in the Final Rule preamble and elsewhere in the document. Records do not have to be established and maintained for transfers of wine from the winery to the gift shop. Records must be established and maintained for food received from other sources in accordance with section 1.337. The gift shop does not have to establish and maintain records of food it releases directly to consumers, in accordance with the retail exemption provided by section 1.327(d).

Preparing for an FDA Inspection

FDA inspections of wineries may include Bioterrorism and FSMA issues, but it is possible that the inspector may have never been in a winery before. Winery owners and managers should keep in mind some of the following points:

1. The FDA has inspection authority over wineries. And yes, they have always had this authority.
2. The FDA will be inspecting wineries as part of the mandate of the FSMA.
3. Wineries are considered food plants by the FDA. As such, they must register with the FDA under the Bioterrorism Act of 2002 and re-register biennially under the FSMA.
4. Wineries are also expected, as registered food facilities, to meet the requirements of the Bioterrorism Act of 2002 with respect to maintaining records of the sources and destination of foods (wines) and food (wine) additives.
5. Wine, due to its low pH (below 4.5) qualifies as "acid food."
6. Food plants are held to current Good Manufacturing Practices (GMPs). It is likely that FDA inspectors may be looking for winery compliance with current Good Manufacturing Practices. Many winery owners and managers have no familiarity with GMPs; GMPs are in many cases left deliberately vague to allow interpretation of best practices. The actual GMPs are only about 10 printed pages, and most wineries would benefit from application of these practices as they apply in a winery ("acid food") setting.
7. Wineries are excluded from the FSMA requirement for preventative measures, such as HACCP programs, but might want to become familiar with these principles. Developing a wine safety program can optimize processes and controls and improve general wine quality, in addition to preventing non-pathogenic chemical or physical adulteration.
8. Bioterrorism requirements include record keeping, showing the sources of foods (wines) and food (wine) additives and non-consumer recipients of foods (wines).

The European wine safety issues from past decades include methanol and refrigerant adulteration, but physical contamination of something as simple as broken glass could potentially result in injury and the resulting increase in inspections and could easily occur in any facility using glass containers. In any case, many would prefer the FDA inspections to focus on increasingly common pathogenic issues involving Listeria, Salmonella, E. coli and

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the like, so the industry should do its best to cooperate with inspectors, be prepared for inspections and understand the compliance expectations so that the inspectors can get on their way to do their jobs in higher-risk industries.

As Wendell Lee of the Wine Institute summarized, "Wineries aren't completely exempt from FSMA, but their obligations have been greatly and significantly reduced. Wineries will still need to register as a food facility (which they should have done under the previous U.S. Bioterrorism Act) and still be subject to mandatory recall authority of the FDA (which it already had under previous laws), for example, but wineries are exempt from the FSMA's provisions that require food facilities to develop and implement preventive control requirements, among other things. And while the FDA may be inspecting wineries in the future as the agency meets its own obligations under FSMA, winery proprietors should realize that the exemption spares them from all of FSMA's most burdensome provisions." **WBM**

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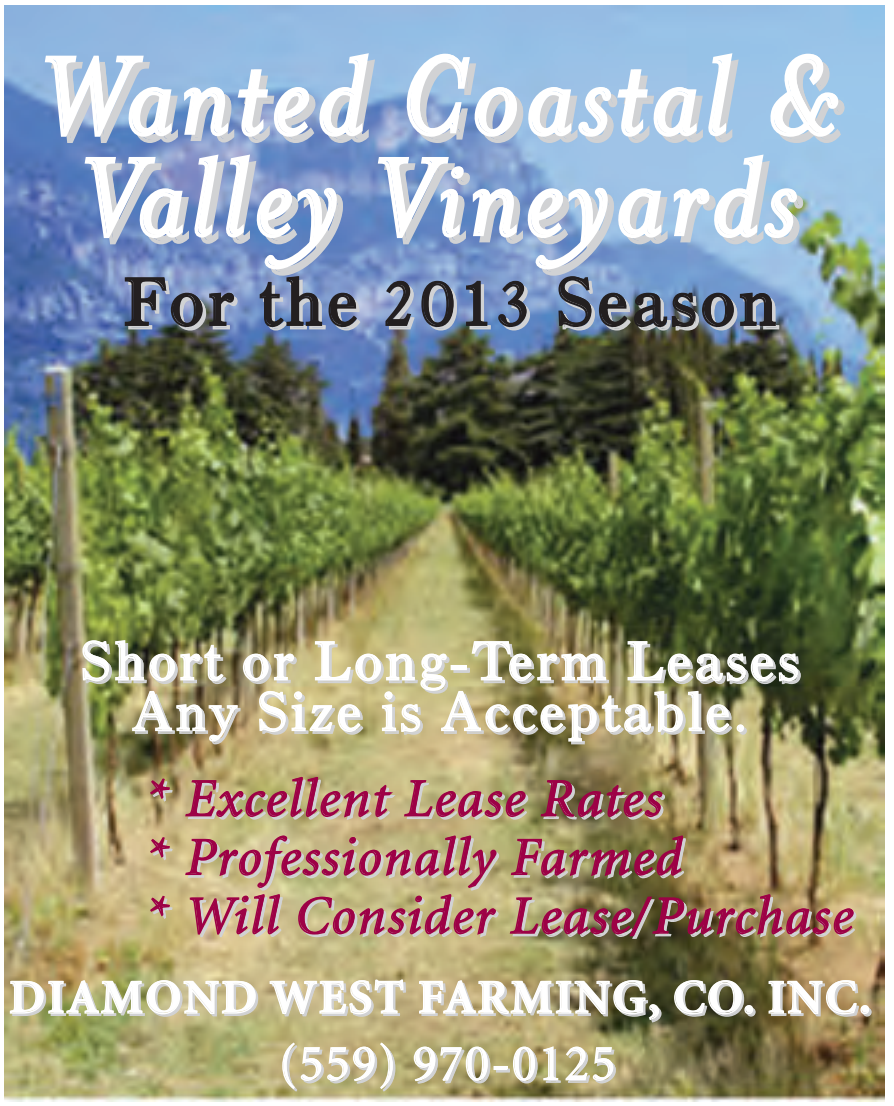

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