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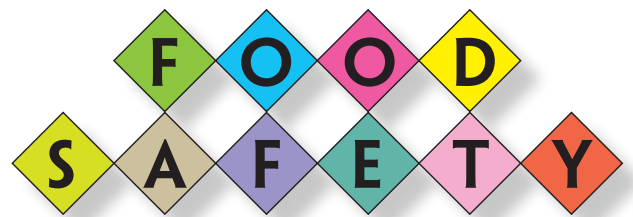
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WINERY SAFETY



FOOD SAFETY MODERNIZATION ACT

Inspections, compliance strategies and opportunities for comment



BY Rebecca Anderson Smith,
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Wineries have been subject to oversight by the Food and Drug Administration (FDA) for years, but because these operations pose a relatively low risk of food-safety hazards, the heavily burdened agency's focus has rarely drifted to wineries and vineyards. This paradigm has begun to shift, due in part to the enactment of the federal Food Safety Modernization Act (FSMA) in January 2011.

The FDA is now seeking comment from members of the public regarding the reach, breadth and science relating to the potential impact of the FSMA on wineries. Several key proposed rules are out for public comment until November 2013, and more regulations (with additional opportunities to comment) are expected in the next two years. The resulting developments in food-safety regulation will have important implications for the wine sector.

The FSMA requires the FDA to inspect every registered food facility in the United States, including wineries, by 2018. Alongside this inspection directive, the FSMA directs the FDA to implement certain key preventative measures

to ensure food safety in the U.S., including developing a food-tracing program and setting certain minimum food-safety protocols for high-risk foods. The FSMA gives the agency considerable authority to develop and implement new regulations in pursuit of those food-safety goals.

The FSMA directs the FDA to inspect every registered facility in the United States, including wineries, by 2018.

As it attempts to meet the ambitious food-safety goals of the FSMA, the FDA is seeking science-based feedback and guidance from the wine sector regarding the way that this sector functions, and what food-safety concerns (if any) are actually at issue during the winemaking process.

FDA oversight of wineries pre-FSMA

The Federal Food, Drug, and Cosmetic Act defines "food" broadly, to include nearly anything (including wine) meant for human or animal consumption, and this broad definition brings wine under the FDA regulatory authority. Until recent years, any oversight that the FDA did exercise for wineries was cursory,

and winery oversight was left largely to other agencies. During the past 10 years, however, that pattern has begun to shift.

After the passage of the federal Bioterrorism Act in 2002, any facility engaged in manufacturing, processing, packing or holding food for consumption in the U.S. was required to register with the FDA. Wineries, custom-crush operations and even mobile bottling operations all fell within the scope of this federal requirement and have been required to register with the FDA since 2003.

The Bioterrorism Act also gave the FDA authority to impose record-keeping requirements on registered facilities and to enter and inspect those facilities under its federal food-safety authority, though winery inspections have long been the exception rather than the rule.

Even without the FDA oversight, wineries have long been subject to a complicated regulatory structure, with multiple agencies exercising oversight over aspects of the wine operation. For example, the same wineries that submit FDA registration under the federal Bioterrorism Act are also required to register or obtain permits from the TTB. State and local regulations, including both state law and county health ordinances, can raise additional complications (though these issues are out of the scope of the current article).

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Requirements for Winery Facilities	
Requirement	Applies to
Facility registration through the FDA	Any facility that manufactures, processes, packs or holds food for human or animal consumption in the United States (including wineries, truck-mounted bottling operations, custom-crush and storage facilities), but not most retail facilities or farms.
Record keeping	All registered facilities.
Subject to FDA inspection	All registered facilities.
Must comply with current Good Manufacturing Practices	All registered facilities.
Subject to proposed Preventative Controls Rule*	Most food processors and wineries that sell a) unpackaged, non-alcohol food including juice or grapes not destined for winemaking, or pomace destined for human consumption; or b) packaged non-alcohol food that composes more than 5% of the total facility sales.
Subject to proposed Produce Safety Rule*	Farms or vineyards that grow, harvest, pack or hold raw fruits and vegetables (for example, table grapes or restaurant gardens), subject to limited exceptions.
Subject to FDA recall authority	All food facilities, transporters and warehouses.
Subject to FDA administrative detention authority	All food facilities, transporters and warehouses.

* Not yet a final regulation

Because the FSMA directs the FDA both to increase its inspection frequency and to conduct its operations in cooperation with state and local food-safety authorities, wineries are receiving new attention, both from the FDA and from state and local compliance officers. In fact, the FDA is explicitly authorized to rely on inspections of other federal, state and local agencies to meet its increased inspection mandate, so these regulatory requirements may continue to be considered side by side in the future.

FSMA today: An update to the status quo

The FSMA is the first major update to U.S. food safety law in 70 years, and it was designed to shift the focus of the law from a reactive system to a comprehensive, prevention-based, food-safety program, from planting to shelf, across the U.S. Designed as a “farm to fork” approach, the FSMA touches every piece of the food and beverage production chain and implements variable (and often complex) standards based on the particular risks associated with certain food-production activities.

Due in part to steady efforts from the wine sector and other stakeholders to educate Congress about the low food-safety risk associated with winemaking, the FSMA’s application to wineries was limited from the outset. Under Section 116 of the Act, a facility that produces an alcoholic beverage and must register

with or be permitted by the Alcohol and Tobacco Tax and Trade Bureau (TTB) is excused from all but a few of the FSMA requirements. Still, the FSMA granted the FDA the following key authorities over winemaking operations:

The FDA has publicly acknowledged that it sees wine production as a relatively low-risk activity, but it has also unambiguously stated that it will apply FSMA to wineries.

- **Registration requirements:** The FSMA adapted the Federal Bioterrorism Act’s registration requirements and requires wineries to register biennially with the FDA. If the FDA determines that the food “manufactured, processed, packed, received or held” by a registered facility poses a serious health risk, the FSMA allows suspension of that facility’s registration and bar the facility from selling its products until the risk is resolved. (FSMA Section 102).

- **Mandatory recalls and administrative detention:** The FDA may order a mandatory recall of a product if it determines that there is a reasonable probability that the product is adulterated or misbranded—and that the exposure to that product poses a health risk to humans

or animals. It also has the authority to hold (or “administratively detain”) a food product, if it has reason to believe it is adulterated or misbranded, to prevent it from entering the market. It is not clear how this labeling oversight will be impacted by TTB’s current oversight of wineries. The FSMA directs the FDA to develop regulations that set out exactly how and when it will exercise this authority (FSMA Sections 206 and 207).

- **Import controls:** The FSMA gives the FDA authority to establish a certification program for importers seeking to expedite the FDA’s review of their facilities and products. It also gives the FDA limited authority to set out regulations governing the treatment of imported products (FSMA Sections 302 and 304).

- **Inspection authority:** The FDA has authority, under the federal Bioterrorism Act, to inspect registered facilities including wineries and even mobile bottling lines. The FSMA directs the FDA to inspect every registered facility in the U.S. by 2018. Subsequent inspections will be based on risk assessments and facility compliance history.

Even when the FSMA was adopted, however, it was clear that the limitations in Section 116 were directed at alcoholic beverage production, and not at ancillary activities at those facilities. Section 116 (c) includes a special directive: “This section shall not be construed to exempt any food, other than alcoholic beverages... from the requirements of (FSMA).”

For non-alcoholic foods, additional requirements apply. The onerousness of these requirements is often tied to the particular level of food-safety risk that a product poses. For example: Foods designated as a “high-risk food,” are subject to more intense risk-management procedures and testing, while foods subject to a kill-step during processing (including pasteurization, distilling, fermenting or brewing) enjoy more limited oversight.

The FDA cites two reasons for this special treatment of alcoholic beverages. First, alcoholic beverage producers are already subject to considerable oversight by the TTB, which made additional oversight by the FDA redundant in many regards. Second, both the FDA and Congress have acknowledged that compared to other consumables, wine poses a relatively low food-safety risk and therefore may “warrant lower priority from a public health perspective than other foods.”

Pomace, hard press and other surprising “foods”

Section 116, however, does not take every activity at a winery out of the

scope of the FSMA. Wineries or breweries that a) distribute an unpackaged, non-alcohol food item; or b) sell pre-packaged food in an amount greater than 5% of the total facility sales must comply with the entire Act with regard to those foods, even if they meet the requirements set in Section 116. For the purposes of the regulations, any food item that can be exposed to direct human touch during its stay at the winery is considered "unpackaged," even if it is packaged (or repackaged) at the winery.

This twist can pose some surprising pitfalls for unsuspecting wineries. A winery that assembles gift baskets containing bottles of its own wine and prepackaged boxes of crackers purchased from a supplier is receiving and distributing food other than alcoholic beverages (crackers) in a prepackaged form, and so would trigger FSMA requirements if these sales exceeded the 5% threshold.

Conversely, a winery that presses and bottles estate olive oils would need to consider not only the core Section 116 requirements but also the broader food-safety protocols of the rest of the FSMA. Honey, tasting room plates and other food items that are ancillary to the winery's primary winemaking function could also trigger additional food-safety regulatory oversight.

When considering whether a winery also sells food, wineries need to remember that the FDA's definition of "food" is quite broad. "Food" products may even include products that are created during the course of wine production (juice, hard press or pomace sold to a third party, for example).

As for the by-products of wine production, the FDA tentatively concluded that they become subject to the FSMA when they are physically separable from the alcoholic beverage they are used to produce. So, while grapes in the press are subject only to the core Section 116 requirements, pomace destined for animal feed triggers broader FSMA regulation.

The FDA is now seeking comment from members of the public regarding the reach, breadth and science relating to the potential impact of FSMA on wineries.

In proposed regulations, the FDA suggested that it will consider only the **non-alcohol** food-production activities at such a facility subject to the broader FSMA requirements, and apply Section 116's core requirements to the remaining alcoholic beverage production occurring at the site.

While these reassurances go a long way toward protecting wineries, this "physically separable" analysis has serious implications for the wine sector: Where, for example, does the sale of partially fermented juice fall in this regulatory scheme? Hard press? Juice sales to another wine producer? The regulations are silent (or at the very least unclear) about these "middle-ground" sales of

products that are not quite alcoholic beverages, though they are destined for that end use.

In evaluating whether the Section 116 designations are triggered, wineries must keep in mind that the record-keeping requirements of the FSMA and the federal Bioterrorism Act require all facilities to identify where a food product came from and where it went. Wineries in the practice of selling juices and grapes to other facilities should be able to identify whether those products will be used in an alcoholic beverage, or whether they will be consumed as a non-alcoholic "food," subject to the broader FSMA requirements.

FSMA tomorrow: Why the current proposed rules matter for wineries

The FSMA sets forth the general contours of broad new food-safety requirements, but leaves the FDA to fill in many details in the form of binding regulations. In January 2013, the agency began that process by issuing two important draft regulations (the Preventative Controls Rule and the Produce Safety Rule) for public review and comment.

The Preventative Controls Rule was issued under Section 418 of the FSMA, and it requires food processors to analyze food-safety risks at their facilities and put a plan into place to minimize those risks, taking steps to assure food safety that are above and beyond their existing current Good Manufacturing Practices (cGMPs).

The proposed new rule will not apply to activities within the Section 116 designation, but it will impact any activity in a winery that involves either the sale or

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manufacturing of any foods that are “physically separable” from the alcoholic beverages produced by a winery. These foods include grapes sold for raw consumption (or to a buyer who will not be making wine with them), pomace sold as a component of a human food product, olive oil, crackers, cheese, honey, juices sold for non-alcoholic beverages and gift food baskets (provided that they exceed the 5% threshold).

In particular, wineries should be aware that food sold as part of a pairing in a tasting room falls outside the scope of Section 116. Sale of these foods are regulated by the FDA under the FSMA.

Although the FDA has not set a clear rule for it yet, the consensus is that tasting rooms off-site from a winery (for example, in a town square) will generally be treated as restaurants. Restaurants are subject to most, but not all, of the FSMA and have special requirements that are beyond the scope of this text.

The FDA has also not taken a position regarding whether the sale of partially fermented juice, or unfermented juice sold for winemaking at a different facility, will be subject to the proposed rule (although by law, the exception in Section 116 should be read to apply only to beverages both above 0.5% alcohol by volume and

intended for human consumption).

Finally, the current Preventative Controls Rule governs only food products for human consumption: A new Preventative Controls Rule for animal foods (including pomace sold for animal feed) is expected to be circulated in 2014. Facilities that sell pomace as animal feed will be governed by that separate rule, and that activity will still be considered a food sale outside the scope of Section 116.

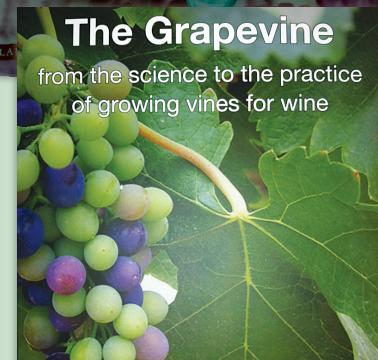
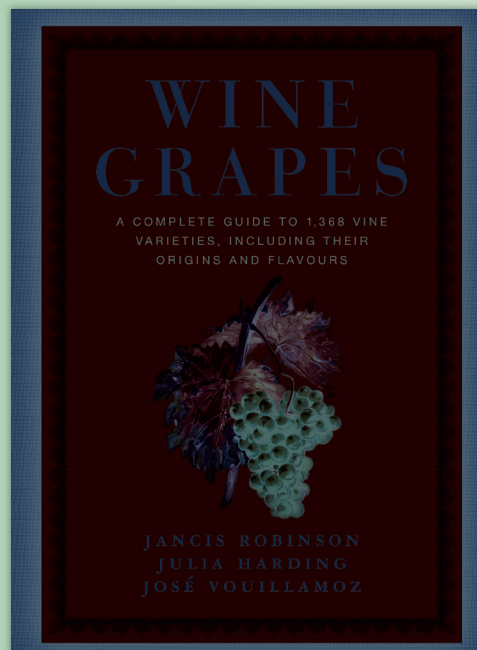
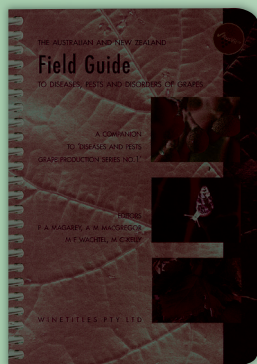
Still, even wineries whose activities are firmly outside the scope of the Preventative Controls Rule should keep a wary eye on FDA deliberations. When the proposed rule was published for comment, the FDA went to great lengths to discuss, in broad terms, its interpretation of Section 116 and the role of that special section in implementing the FSMA as a whole.

This analysis is important for every winery: Because Section 116 sets the initial bar for whether a facility or activity is bound by the larger FSMA regulatory regime, any decision that the FDA makes about Section 116 will have impacts far beyond the Preventative Controls Rule. The agency is expected to issue regulations elaborating on the Section 116 designation when it issues the final Preventative Controls Rule.

Moreover, Section 116 facilities are still required to comply with the Act’s core requirements, and they may still be subject to future rulemaking authority by the FDA as it continues to work to understand and apply the Act. Not all rules are issued simultaneously, so, while the Produce Safety Rule and the Preventative Controls Rule are currently out for public comment, other rules are expected to be circulated by the FDA soon.

Wineries are receiving new attention, both from the FDA and from state and local compliance officers.

Rules for foreign supplier verification and accreditation of third-party auditors (a key piece of the compliance process) were circulated in late July 2013, for comment by late November 2013. Rules about cGMP and preventive controls for food for animals (which will impact facilities currently selling pomace as animal feed), traceability protocols and import certifications are expected in the near future.



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Final thoughts

While the core requirements for the wine sector are not entirely new, the FSMA increased inspection directive means that more wineries will be interacting with the FDA than in previous years. Wineries are currently subject to FDA inspection and should be prepared to demonstrate to an inspector that they are in compliance with the core requirements of Section 116.

Facility registrations should be up to date, basic Good Manufacturing Practices should be in place, and winery personnel should be able to speak knowledgeably about the facility's compliance with relevant county health requirements.

For many wineries, this may mean revisiting their compliance efforts with an eye toward avoiding food safety pitfalls. For example, the FDA has gone so far as to pronounce that a truck-mounted bottling operation that travels from winery to winery is a food facility subject to federal registration requirements, because bottling wine is an activity included in the definition of "manufacturing/processing," even under the pre-FSMA regulations. Careful attention to these regulatory details will serve wineries well.

The question of what the FSMA will mean to the wine sector in two years or 20 is still an open one. The FSMA does grant the FDA broad authority, but the way that authority will be exercised depends heavily on the rules that are currently being developed and commented on.

Onerous FDA oversight is not a forgone conclusion: The agency has sought (and will continue to seek) comments from members of the public regarding the reach, breadth and science behind each of its proposed rules. The FDA has publicly acknowledged that it sees wine production as a relatively low-risk activity, but it has also unambiguously stated that it will apply the FSMA to wineries.

The current comment period is a unique opportunity for the wine sector: The FDA is actively soliciting feedback from the public regarding interpretation and application of Section 116 (the gateway to FSMA winery applications) in the context of the Preventative Controls Rule.

In July 2013, the FDA announced its intention to extend the deadline for comments on the Preventative Controls Rule and Produce Safety Rule an additional 60 days, from Sept. 16, 2013, to mid-November 2013. Comments on the recent Foreign Supplier Verification and Third-Party Auditor Accreditation rules will be accepted until late November.

Further information about comment submission can be found at fda.gov/Food/GuidanceRegulation/FSMA/ucm261689.htm. [PWV](#)

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Read more about winery responsibilities and record-keeping for FDA inspections in "What Wineries Need to Know About the Food-Safety Modernization Act," a story from Wine Business Monthly, at winesandvines.com/pdf/Howe_FSM.pdf

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