

Terrorism Threat Forces Wineries to Submit to FDA Jurisdiction



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THE SAD events of September 11, 2001 permanently changed America in various ways—many of which have af-

fectured the hospitality industry as a whole and, in particular, the wine industry. The latest fallout of 9/11 to hit wineries is the Bioterrorism Preparedness Act of 2002.

This recent law gives FDA broad powers to protect the American food supply whenever adulteration of an article or ingredient of food is suspected. In carrying out its mandate, FDA is requiring all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the US to register with the FDA and to provide advance notice of food importation. Eventually—after regulations are finalized—these same companies will also be required to maintain detailed records that will allow FDA to trace the movement of food from one facility to another in the event of health endangering contamination.

Some of the requirements are already in effect. The December 12 deadline for food facility registration will have passed by the time you read this article, but wineries can't afford to forget about it. Facility registrations must be updated or re-submitted under certain circumstances described below. For wineries that import, strict advance notice re-

quirements also became mandatory on December 12. The record keeping requirements are not in effect yet but threaten to be a big impact item for the wine industry in the future; some of the information needed by FDA is not covered by records currently required by TTB and so it is not maintained in any organized fashion by most wineries.

Food Facility Registration

By now, hopefully, most wineries have been through the initial registration process. However, only a small percentage of food facilities had registered by the beginning of December. Many vintners may not have realized that the requirement applied to them. For those who may not have registered yet, and others who wish to understand the process for purposes of ongoing maintenance of their winery registration, a brief summary is provided here.

The registration requirement covers all facilities that process grapes into wine, bottle, label or store alcoholic beverages—including wineries, bonded wine cellars, tax paid wine bottling houses and crush facilities. A separate registration must be made for each facility. Facilities must register even if they do not sell in interstate commerce.

Registration is free and does not need to be renewed annually. However, registration must be updated whenever mandatory information changes. Registration must be cancelled when a food facility goes out of business, changes hands or moves (see the section on ongoing responsibility below).

How to Register

Registration may be done by mail, fax or on-line. On-line registration is *strongly* encouraged because it greatly reduces the FDA's intake workload and provides instant

acknowledgement to the registrant. Registrations submitted by fax, mail or CD will be handled in the order received, and confirmation of registration may take weeks or months.

For access to the on-line registration system, click the login link on the Food Facilities Registration Home Page (<http://www.cfsan.fda.gov/~furls/ovffreg.html>) or on the FDA Industry Systems Home Page (<https://www.access.fda.gov/>).

Gather the information you will need before you start. FDA estimates that it could take 45 minutes to input the information and 15 minutes for the authorizing individual to check and confirm the information. If you must leave your computer to search for information, be aware that the system will automatically log you off after 30 minutes of inactivity. If you log off with a partially completed registration, you will need to start from the beginning when you log in again. None of the information you have already entered for the unfinished registration will be saved.

Firms that do not have easy access to the Internet may download from the FDA web site PDF copies of forms for printing or electronic fill-out, or request printed forms by calling 1-800-216-7331 or 301-575-0156. To submit forms by mail, the address is: U.S. Food and Drug Administration, HFS-681, 5600 Fishers Lane, Rockville, MD 20857. To submit by fax, the number is (301) 210-0247.

Regarding Foreign Facilities

Registration on behalf of a foreign food supplier must be done by a US agent located in the United States who has been designated as the facility's agent for FDA registration purposes. This person also serves as the foreign

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facility's emergency contact for FDA purposes, unless a different emergency contact is specified.

Foreign facilities are exempt from registration if the foods they process are further processed by another foreign facility before export to the US. However, if the subsequent handler of the product only applies a label or performs other minimal activities, then both facilities must register.

Ongoing Responsibility

All registered facilities must update the registration within 60 days of a change to any required information. This includes:

- Name, address, phone number of facility;
- Name, address, phone number of parent entity (company that owns the facility, required only if the company name is different from the facility name);
- Contact information for person submitting the registration;
- Emergency contact information;
- Up to four trade names used by the facility.

NOTE: *The form has space for only*

four trade names. FDA's system cannot accept more than four trade names, so only four need to be reported. Hint: If your winery uses more than four bottling trade names, choose four that are not likely to change, in order to minimize the need to update the registration later.

Many types of changes require only an update to an existing registration. Updating a registration on-line is easy because you can simply edit the existing information when you access the registration electronically.

Keep in mind that facilities must *cancel* their existing registration and *re-register* when they change physical location. Facilities must also cancel their registration within 60 days when they cease operations, or sell the facility to a new owner.

On-line Registration Account Management

Before using the on-line registration system, you must first create an account. Thereafter, the facility registrations you create with that account can be accessed via links that appear whenever you sign on to your account. It is

also possible to access a facility's registration from an account other than the one where it was created, or from a "sub-account"; in these cases you must first create a link to the facility's registration by entering the registration number and personal identification number assigned to the facility.

Each account is linked to a specific individual's name and contact information, not to the company as a whole or to particular facilities. One account may be used for multiple facilities. Most companies will need only one account, but large companies may elect to create additional accounts or optional sub-accounts to allow multiple individuals access to facility registrations.

Prior Notice Requirements for Imported Products

Beginning December 12, 2003, importers must provide advance notice to FDA of food shipments entering the US. The only notable exceptions are (a) food accompanying an individual for his or her personal use, or (b) food made at the sender's home and sent as a personal gift to a US citizen for non-business reasons. Everything else, including commercial samples, quality control samples, and food that will be later exported after leaving the port of arrival, is covered by the prior notice requirement, although for certain categories less information is required.

Prior notice requirements apply to *each* "article of food," not simply to each "shipment." Each different brand, type, or packaging/size is considered a separate "article of food." Therefore, one shipment might contain *several* food products and require *several* prior notices!

Prior notice must be given electronically, through Customs' Automated Broker Interface or through FDA's Prior Notice System Interface. If on-line systems are down, prior notice may be submitted by e-mail or fax. The appropriate e-mail address(es) and fax number(s) will be posted on the FDA web site (www.fda.gov). The mechanism for electronic submission of advance notice was expected to go on line in December, but at the time this article was written just days before the deadline, it was not yet operational.

Notice must be given no longer than five days in advance and no fewer than:

- Two hours in advance of arrival if shipped or carried by an individual traveling by motor vehicle,
- Four hours in advance of arrival if



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shipped or carried by an individual traveling by rail or air,

- Eight hours in advance of arrival if shipped or carried by an individual traveling by boat,

- In advance of mailing if mailed through the Postal Service (does not include express carriers).

Food carried or mailed must be accompanied by confirmation of FDA receipt of prior notice.

FDA claims that most of the information required by its prior notice requirement is usually provided to Customs by brokers and importers. To the extent that is true, the requirement may be less burdensome than it appears. However, for industry members who are alarmed by the requirement, it is not too late to try to change the provisions of the final regulation.

The prior notice provisions are currently contained in an interim final rule that is still subject to change. The initial comment period ended December 24, 2003, but FDA plans to reopen the comment period for an additional 30 days in March 2004.

Record Keeping Requirement

Only a proposed rule concerning record keeping requirements has been published to date, and as we said earlier, compliance is not yet mandatory. Everything said here about the details of the record keeping requirements is based on the proposed rule, and is subject to change.

Once the final regulation is in force, wineries will be required to keep for two years records that will allow FDA to identify the immediate previous sources and immediate subsequent recipients of wine and all other food items they use and/or produce. Fortunately, the proposed rule exempts wineries making retail sales from the requirement to record information on the immediate subsequent recipients when wine is sold direct to consumers.

Records must be kept onsite or at a reasonably accessible location. When FDA believes that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records or other information to which FDA has access must be available for inspection and reproduction within four hours if the request is made between 8:00 AM and 6:00 PM, Monday through Friday, or within eight hours if the request is made at any other time.

Which Records Must Be Kept

Records must include information that is reasonably available to identify the specific source, whether foreign or domestic, of all foods received, including each ingredient that was used to make every lot of finished product.

Similar to the winery records required by TTB, the records required by the Bioterrorism Act may be kept in any format, paper or electronic, as long as they contain all the required information listed below. If a winery has existing records that contain all the required information, they do not need to be duplicated to comply with FDA's new requirements.

NOTE: *FDA defines "food" to include not only the edible portion of the food, but also the packaging that comes in direct contact with the food. For wineries, that would include barrels, bottles and corks.*

For immediate previous sources:

- Name of the firm
- Name of responsible individual
- Address
- Telephone number
- Fax number and e-mail address, if available
- Type of food, including brand name and specific variety
- Date received
- Lot number or other identifier if available
- Quantity and type and size of packaging (e.g., 750 ml bottles)
- Name of carrier that brought the item to you
- Carrier's address
- Carrier's telephone number
- If available, carrier's fax number and e-mail address

For immediate subsequent recipients:

- Name of the firm
- Name of responsible individual
- Address
- Telephone number
- Fax number and e-mail address, if available
- Type of food, including brand name and specific variety
- Date released
- Lot number or other identifier if available
- Quantity and type and size of packaging (e.g., 750 ml bottles)
- Name of carrier that took the item from you
- Carrier's address
- If available, carrier's fax number and e-mail address

Compliance Dates

Only after publication of the final rule will compliance with the new record keeping requirements become mandatory. Then, compliance will be required within six months for large companies (at least 500 employees), within 12 months for firms with more than 10 and fewer than 500 employees, and within 18 months for firms with 10 or fewer employees.

Penalty for Non-compliance

FDA has not prescribed specific penalties, but simply reminds food facility operators and importers that non-compliance with registration, prior notice or record keeping requirements (once they are mandatory) are prohibited acts, and violators are subject to civil or criminal court action. Foods imported from non-registered facilities or without proper prior notice are subject to being detained at the port of entry. However, FDA has also said that, during the initial months following the December 12 deadline, their enforcement policy will emphasize industry outreach and education rather than disciplinary actions.

How to Get Help

There is a wealth of information available from FDA on line; we studied a good bit of it to bring this summary to you! If you have questions beyond the scope of this article, you will probably find the answers on FDA's web site. A good place to start is this overview page: <http://www.fda.gov/oc/bioterrorism/bioact.html>. An index of help pages relating to facility registration and account management can be accessed at this link: <http://www.cfsan.fda.gov/~furls/helpol.html>.

If you can't find the answer you need on line, or don't have ready access to the Internet, you may phone the FDA help line any business day from 7 AM to 11 PM EST, at 1-800-216-7331 or 301-575-0156. You may also fax questions to FDA at 1-301-210-0247, or e-mail questions to furls@fda.gov.

What Kind of Big Brother Will FDA Be?

What can we expect under these new regulations? In the near term, we are probably in for weeks of frantic scrambling and perhaps months of international reaction as a result of the heavy burden the new regulations will place

on foreign companies and their importers. In the longer term, hundreds of thousands of domestic and foreign companies will face permanently increased daily workloads to accommodate the new advance notice and record keeping requirements.

Fortunately, this situation is different from other new regulations we've reported in the past. In this case, the alcoholic beverage industry is not facing new requirements alone; in fact, our industry represents only a tiny fraction of the affected entities. Hopefully, public pressure and political sensitivity to widespread business burdens will help to shape these requirements into optimally manageable forms while they are still malleable.

It is also notable that the tone of FDA's on-line information and help desk staff has been consistently supportive. And clearly, FDA has made a tremendous investment in planning, training and public education, with impressive results—especially given tight timelines FDA had to work under for implementation. But when enforcement priorities shift into a more punitive gear later next year, that tone may change. So it remains to be seen what kind of new Big Brother the wine industry now has. 