

# FDA Lot Tracking

What it Means to Small Wine Producers

## FDA Lot Tracking and What it Means to Small Wine Producers

To protect the national food supply, Congress passed the Bioterrorism Act of 2002. By virtue of increased reporting requirements to the FDA, the provisions of the act increase the ability to track food products so possible sources of contamination or tampering can be identified. The law applies to food producers and wineries of all sizes.

Large wineries had to meet the new requirements by the end of 2005. Medium-sized wineries, defined as those with more than 11 full-time employees, were expected to be compliant by June 9, 2006. Small wineries, those with fewer than 11 full-time employees, had until December 9, 2006. (There remains an exemption for wineries with less than 11 full-time employees who sell at least 50 percent of their products by value directly to consumers out of their own facilities.)

If you don't understand the new requirements, we've summarized them below in plain language. *Please recognize that this isn't legal advice and shouldn't be considered the last word on this topic. Our goal is to help make this somewhat complex topic more accessible. If you have any questions, you should carefully review the original FDA source materials or seek professional advice.*

The FDA's definition of food is simple; "articles used for food or drink, for man or animals... and articles used for components of any such article." For wine producers, components mean anything that comes in contact with the finished product such as the bottle, cork etc. and, of course, additives. Since wine goes through so much processing, anything that actually adds chemical components to the wine is deemed an ingredient. The act makes a distinction between ingredients and processing.

### **Here are the new record-keeping requirements:**

- You must track all ingredients such as yeast, malo-lactic bacteria, diammonium phosphate, tartaric acid, sulfur dioxide, tannin additions, enzymes, oak chips, fining agents (bentonite, protein), oak barrels, wooden fermentors.
- You must keep a record of the source of an ingredient, which would be the company that supplied it, and the transporter that delivered it.
- You must be able to link each wine with the grapes that made it, the vineyard from which the grapes originated, and the truck that delivered the grapes.
- You do not have to track packaging materials such as labels and boxes, or items that are part of processing such as crushing/de-stemming equipment, pumps, hoses, inert tank storage, presses, and inert gases (nitrogen, argon).

If you are audited by the FDA, you will be expected to show the records that contain this information "as soon as possible but in no event more than 24 hours." If an additive purchased by a winery is found to be contaminated, the FDA can remove any wine that includes the contaminant.

**Here is a simple example of how these rules could apply to your operation:**

You order a shipment of yeast that will be used in several batches of wine. You must track the lot number of that yeast, and record every batch of wine in which it is used—all the way to the bottle. Your records must accurately preserve this information, and they must also include which customers purchased wine containing that yeast (unless sold to an individual at retail).

If that lot of yeast is contaminated and you are unable to identify which batches and bottles contain it, then all of your wine could be subject to recall. Repeat this process for every ingredient in every one of your products.

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