# FDA Bioterrorism

Doug Campbell
eSkye Software

*Doug Campbell is VP of Winery Systems at eSkye Software and has been involved in developing software solutions to the wine industry since 1989. From the dark days of DOS, he created a software program called PC Blend that is still in operation today. That long-lived product led to the development of the Blend Suite of software that eSkye offers today which tracks not only tracks wine production, but also vineyard operations, case good inventory, sales, marketing and distribution. Considering himself lucky to have had a software company that was successful even through the dot com burst in 2000-2001, he decided to sell his previous company, Blend Winery Software, to eSkye Software in February 2004 and is now working towards expanding eSkye's software offerings to a global market.*

# FDA Bioterrorism

*New regulations for the wine industry*

*Doug Campbell, VP Winery Systems*
*eSkye Software*

## Bioterrorism Reporting

*What is it?*

- The FDA has the responsibility of protecting the food supply of the US
- To protect that food supply, they have passed new regulations to require detail trace-through of all elements of food production and transportation
- Because wine (along with distilled spirits and bottled water) has been declared a food product, we must comply

## Bioterrorism Reporting

*What is it (in FDA-speak)?*

- You must have the ability to trace all ingredients used in your production from all IPS (Immediate Previous Source) and the transportation of those ingredients
- You must have the ability to trace all products produced and their ISR (Immediate Subsequent Recipient) and the transportation of those foods

## Bioterrorism Reporting

*What does it mean?*

- A new level of compliance tracking must be added to the already existing tracking that you are already doing for the TTB
- As a food producer, you must provide a complete list of all ingredients involved in wine production
- You must be able to respond to the FDA within 24 hours with a full product trace if they find a contaminated product or ingredient
- You must be able to trace 2 years from the date of the release of your product all the way back to the origin of the product

## Bioterrorism Reporting

*Who must comply?*

- Any producer who has more than 11 FTE's (full time equivalent employees)
- Any producer who has less than 11 FTE's who also sells more than 50% of their product direct to consumers (in other words, the FDA considers them a farm)

## Bioterrorism Reporting

*When do you have to comply by?*

- Largest wineries (> 500 FTE's) must be in compliance by December 9, 2005
- Medium size wineries (> 11 FTE's) must be in compliance by June 9, 2006
- Small wineries (< 11 FTE's) must be in compliance by December 9, 2006

## Bioterrorism Reporting

*What does it cover?*

- Sale and transportation of juice, bulk wine and finished goods
- Purchase and transportation of grapes, juice and bulk wine
- Transportation and detail tracking (by lot number IF there is a lot number on the item) of anything added during wine production and any part of the packaging that touches the final product

## Bioterrorism Reporting

*What does it cover?*

- Transportation and detail tracking of anything you use that technically impacts your product in production (i.e. Barrels)
- Transportation and detail tracking of samples drawn and received

## Bioterrorism Reporting

*What does it exclude?*

- Additions in the vineyard
- Packaging materials that ***don't*** touch the final product
- Financial and Pricing data
- Recipes for food production (which means that they don't care how much of an ingredient you use, 1 gram or 1 kg – there is no threshold for reporting)

## Bioterrorism Reporting

*What are the details?*

- Additions (Yeast, enzymes, acids, sugar)
- Filtration and fining agents
- Bottles and corks (or screwtop closures)
- Barrels
- Gasses
- Bulk wine
- Samples

## Bioterrorism Reporting

*Requirements for Production*

- Detailed transporter, supplier and bonded winery information to include contact names, phone numbers and addresses
- Collect transporter information when receiving Weigh Tags, shipping Juice/Wine, receiving Juice/Wine, and receiving Additions, Glass, Corks and Barrels
- Using lot tracking when doing additions to wine and using glass and corks

## Bioterrorism Reporting

*Requirements for Finished Goods*

- Track all finished goods by lot number of the wine, the bottle and the cork.
- Determining how to individually identify multiple bottling dates or separate blends that are bottled differently
- Tracking transporter and recipient information for each shipment

## Bioterrorism Reporting

*Wine Industry Specific Problems*

- Blending
- Barrel Topping
- Multiple bottling dates for one product
- Changing cork lot or glass lot within one bottling run
- Borrowing materials to make up a short-fall
- Custom Crush
- The art of winemaking

## Bioterrorism Reporting

*Dates to Remember*

- Largest wineries (> 500 FTE's) must be in compliance by December 9, 2005
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## Bioterrorism Reporting

*Recommendations to the Industry*

- Order larger quantities of additives less often and request suppliers to ship same lot number when possible
- Track receipt of all dry goods by lot number
- When making additions, record the lot number of the specific ingredient (if there are lot numbers)
- If there are not lot numbers on an ingredient, make sure that the staff identifies the specific ingredient

## Bioterrorism Reporting

*Recommendations to the Industry*

- Track receipt and issues of glass and corks by lot number
- Make copies of every Bill of Lading and keep in the Production office
- Do periodic physical inventories of all additives and packaging materials
- Centralize data storage of production records for quick retrieval

## Bioterrorism Reporting

*Potential ideas for the future*

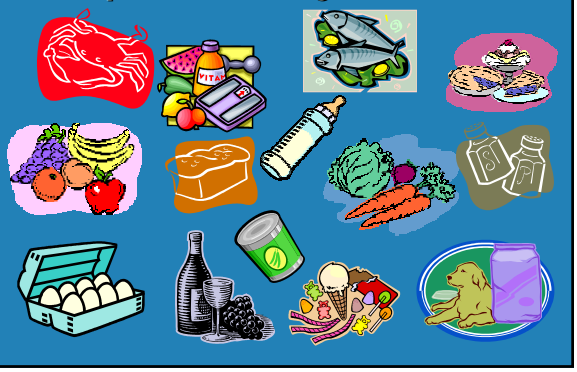
- Use barcoding to identify all additives, glass and corks to reduce data entry time and help prevent errors
- Mark cases with wine lot number, cork lot number and glass lot number
- Laser code bottles with lot identifiers
- Utilize RFID technology to uniquely identify each case

U.S. Department of Health and Human Services
FDA Food and Drug Administration

**Overview of Bioterrorism Act Establishment and Maintenance of Records Final Rule**

**Selected slides from a seminar given by the FDA in Seattle in January 2005**

## Examples of FDA-Regulated Food



## Definitions (cont.)

- **Recipe**: means the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product
- Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe

## Record Retention Periods

| Food having significant risk of spoilage, loss of value, or loss of palatability within . . . | Non-transporter Records | Transporter Records |
|---|---|---|
| 60 days | 6 months | 6 months |
| > 60 days but within 6 months | 1 year | 1 year |
| > 6 months | 2 years | 1 year |
| **All animal feed, including pet food** | **1 year** | **1 year** |

## Consequences: New Prohibited Acts

It is a prohibited act to:

- Fail to establish or maintain records
- Refuse access to or verification or copying of any such required record
- Fail to make records available to FDA as required by section 414 or 704(a) of the act and this regulation

## What are the record availability requirements?

- When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals (SAHCODHA)…
- …Any records and other information accessible to FDA under section 414 or 704(a) of the act must be made readily available for inspection and photocopying or other means of reproduction as soon as possible, not to exceed 24 hours from the time of receipt of the official request.

## Economic Impact of Final Rule

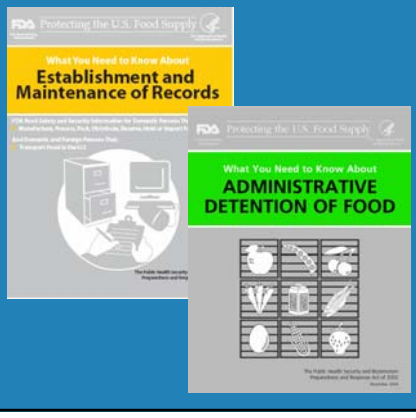
- Approximately 707,672 total facilities covered
  - 597,172 domestic facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food in the U.S.
  - 110,500 foreign facilities that transport food in the U.S.

## Economic Impact of Final Rule

**Estimated per facility recordkeeping costs:**

- Learning costs: $120.00
- Records redesign: $411.00
- Additional records maintenance: $219.00

Guides available on the FDA website




## Bioterrorism Reporting

*Contact Information*

- FDA Web Site
  **http://www.fda.gov/oc/bioterrorism/bioact.html**
  *see section 306 – Records Maintenance*
- eSkye Software Web Site
  **http://www.eskyesoftware.com**
- My e-mail
  **dcampbell@eskyesoftware.com**