AUSTRALIAN WINE AND BRANDY CORPORATION
17 JUNE 2003
US BIOTERRORISM ACT – RECORD KEEPING

Comments

Docket 02N-0277 (Recordkeeping)

1. Records should be retained for 2 years from the date they are created and not for two years prior to the date of shipment of the product. Wine may not be shipped until several years after it has been manufactured and to impose the timeframe from the date of shipment of the product would amount to an unwarranted burden.
2. As inner packaging is caught by the definition of "food" i.e. records are required to be kept regarding the source of the inner packaging that is in contact with wine, it is our view that there is no need for outer packaging (any packaging that does not come into direct contact with the product) to be included. In other words records should not be kept regarding packaging that does not come into direct contact with the product or in direct contact with the inner packaging.
3. It would be useful for a model form to be developed by the FDA as long as it is not mandatory i.e. to serve as an example only.
4. Transporters of food in foreign countries should not be caught by the record keeping requirement.
5. Only foreign facilities that are required to register under section 305 as foreign facilities should be required to keep records i.e. the owner, operator or agent in charge of a foreign facility.
6. Facilities conducting de minimis activities such as labelling a wine bottle should not be required to register as a foreign facility. The risk associated with such activity equates to the risk associated with outer packaging. It would be an unnecessary burden on foreign facilities that for example merely place labels on outer packaging/wine bottles to register with the FDA and to keep records.

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7. Foreign facilities should only be required to keep records from the immediate previous source and the immediate subsequent receiver (excluding transporters). So in the case of a winery, they would need to keep records relating to the source of their ingredients and the receiver of the goods (e.g. a packaging company) but not transporters. To require foreign facilities to keep records relating to immediate and subsequent transport would be an unnecessary burden.
8. Foreign facilities should not be required to keep records of intra-corporate transfers. It should be sufficient to satisfy the provisions of the Act that such bodies keep records relating to the immediate previous source and the immediate recipient of the product.
9. Foreign facilities should not be required to keep records relating to the quantity of ingredients used in manufacturing wine. A list of ingredients and the source should be sufficient to satisfy the objects of the Act. To require quantities would be an unnecessary burden on the wine industry.
10. The obligation to keep records for foreign facilities should only apply to the immediate and subsequent foreign facility. For example a bottling company should only be required to keep records regarding the source of the wine that is received. It should not be required to obtain a list of ingredients from the wine manufacturer. Similarly a wine manufacturer should only be required to identify the information regarding the source of the grapes etc. Using the example of grapes, it should not be required to obtain details from the grape grower (the farm) as to the ingredients used to grow the grapes.
11. If a wine is packaged by another foreign facility, the winemaker is not required to keep records. In this case, the wine packaging company should not be required to keep records as to the ingredients that make up the wine. It should be sufficient that the record reflects that the product "wine" was received from "X'" on "Y" day.

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12. What is an ingredient? Dos it extend to additives and processing aids e.g. tartaric acid, cassein?

13. If additives and processing aids are ingredients it would be an unreasonable burden to require a manufacturer to keep records as to the amount and source added to each batch of wine.

14. The requirement for records to be delivered to the FDA within 4-8 hours depending on the time of request seems unreasonably short especially for foreign facilities. It is proposed that the time for delivery be extended to at least 14 days from the time of request.

15. The paperwork requirements being imposed on foreign facilities as a result of the introduction of the Bioterrorism Act is significant. It is suggested that the processes and record keeping required under the Act and its Regulations be integrated into the current Customs process so that only one form/process needs to be completed.