July 8, 2003

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 02N-0277 -- Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 Fed. Reg. 25188 (May 9, 2003))

Dear Sir or Madam:

The undersigned are a coalition of trade associations representing all tiers of the beverage alcohol industry. Members of our associations are involved in the production, importation, distribution/wholesaling, and retailing of beverage alcohol products that are sold throughout the United States. On behalf of our respective members, we welcome the opportunity to submit this comment in response to the Food and Drug Administration's (FDA) notice of proposed rulemaking implementing the recordkeeping provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

As an industry, we fully support the goals and objectives of the Bioterrorism Act to guard against a threatened or actual terrorist attack on the U.S. food supply. Our members are dedicated to ensuring a safe and secure food supply not only for the purposes of the Bioterrorism Act, but also for the continued goodwill and good name associated with each of our members' respective brands of product. In that regard, if a bioterrorism threat were to occur, we can assure you that our industry and the rest of the food community would be "first in line" to take all measures to address and resolve any such threat, with the well being of the American consumer always in the forefront.

We share and endorse the points raised in the comments filed by other members of the food community, such as the comments filed by the National Food Processors Association (NFPA) and the National Association of Manufacturers (NAM). To that end, our comments are directed to five main points:

(1) the recordkeeping rule should focus upon identifying the immediate previous source and subsequent recipient of food products and should rely upon existing commercial records to ensure an effective and streamlined tracing system;

(2) general emergency contact information should be required, rather than contact information for a specific "responsible individual," thereby recognizing the changing dynamics of the workplace;

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(3) the response time to provide records must be reasonable and FDA's focus should be upon the information from those records and not the records themselves or where they may be maintained;

(4) an FDA request for records should provide clear procedural safeguards to ensure that FDA's authority is exercised in a consistent manner and appropriate measures should be put in place to protect trade secrets and other confidential information that may be reflected in those records; and

(5) the application of FDA's rule should be prospective recognizing that ingredients used to produce a finished product may have been purchased and housed prior to the implementation of FDA's recordkeeping rule and should have an effective date across-the-board of 18 months after issuance to ensure that all entities, transporters and nontransporters, affected by this rule have the ability to effect a successful compliance framework.

Recordkeeping Information Requirments

As detailed in both the NFPA and NAM comments, the U.S. food industry has developed highly successful and effective systems to deliver safe food to consumers and has a proven track record of removing unsafe food from distribution promptly. These systems focus upon identifying the immediate previous source and subsequent recipient of a food product and utilize existing company records. These systems successfully have been used to meet the priority objective of taking immediate action to protect the public health from a threat of potentially compromised food.

These tracking systems should be incorporated into FDA's final rule to ensure that the jointly-shared priority objective of protecting the U.S. food supply is not somehow sacrificed or compromised by imposing upon all affected entities information requirements that are unlikely to enhance the existing, effective systems. In that regard, FDA recognizes that commingling of ingredients when producing a final product is a common industry practice and thus would not require the identification of the specific source of an ingredient used to produce the finished product. FDA's current proposal states that the specific source of each ingredient should be identified if "reasonably available." Since this term could be subject to a variety of interpretations, we urge FDA to make it infinitely clear in its final rule that no such requirement is applicable to circumstances where ingredients are commingled for whatever purpose in producing a food product.

As FDA well knows, the ability of the food industry to respond quickly and effectively to a risk to the U.S. food supply has been a longstanding record of success, without such detailed information. Similarly, lot information is not necessarily captured down to the retail level and the absence of tracking food lot by lot throughout the entire food distribution chain has not compromised the safety of American consumers. Simply put, we submit that the existing systems already enable companies to trace sources of incoming food and the distribution of outgoing food ("one step up" and "one step down" commercial records) effectively and efficiently, and thus meet the objectives of the Bioterrorism Act.

Emergency Contact Information

We urge that FDA utilize the contact information that will be provided through its registration process, rather than impose an additional requirement through its recordkeeping rule. Further, this contact information should be for an "emergency contact," rather than a specific individual. Requiring information about a "responsible individual" does not serve the purposes of the Bioterrorism Act for a variety of reasons, including potential delays in reaching a specific individual, possible confusion created when a specific individual is the only contact in emergency circumstances and inevitable personnel changes.

Response Time to Provide Records

We submit that the proposed timeframes to make records available to FDA may be problematic due to a variety of circumstances, including at what time of the day the request was made and the scope of the request. The most important matter is to provide FDA with the information it seeks, rather than the records themselves. Consequently, we support the recommendations of NFPA and NAM for a more practicable record access time requirement, such as a 24-hour timeframe to provide the physical records.

Similarly, since FDA should be most interested in the information necessary to track and locate a potential threat, we urge that affected companies should have the flexibility concerning where to maintain and/or provide access to the required documents. In that regard, a corporate parent may retain records at headquarters for all of its facilities and, as long as the requisite documents are maintained, it should not matter where they are located.

Records Request and Confidential Information

As discussed fully in the NFPA and NAM comments, we submit that any records request should require prior approval from an "authorized FDA representative" and that the request should be in writing with a summary of the threat basis so that affected entities can conduct their own parallel investigations and take appropriate action. Procedural safeguards also should be put in place to guard against any disclosure to unauthorized personnel of confidential information that may be obtained as a result of FDA's access to a company's records.

Prospective Application and Compliance Deadlines

Many food companies already have purchased the raw materials to produce their products sometime before the proposed implementation of FDA's recordkeeping rule. In that regard, FDA's final rule should make clear that its application is prospective and that the information requirements of the rule are triggered by the covered activity that occurred on and after the effective date of the rule. For any activity that preceded the effective date, an entry of "n/a" or otherwise could be utilized as appropriate.

We also urge that FDA establish a compliance date for its recordkeeping rule of 18 months after its issuance. A sliding scale of compliance dates depending upon the size of the entity is not reflective of the movement of food products through the distribution chain. An 18 month across-the-board deadline for covered activities will better achieve the objectives of the Bioterrorism Act.

Conclusion

Thank you for the opportunity to present our views concerning FDA's actions to implement the recordkeeping provision of the Bioterrorism Act. We commend FDA for its diligent efforts in preparing proposals to implement the Bioterrorism Act in such short order. Subject to the few comments referenced above, we submit that FDA's recordkeeping proposal appears to be in sync with the commercial marketplace -- a marketplace that historically has supported and pursued tracking systems to ensure a safe and secure food supply.

As always, we stand ready to work with you at any time to assist in the development of implementing regulations that will result in the efficient and effective implementation of this Act. If we can be of any further assistance, please do not hesitate to contact us.

Sincerely,

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Harry G. Wiles
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