



THE ASSOCIATION FOR

**DRESSINGS**  
& SAUCES

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July 7, 2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
E-mail: [www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments)

RE: Establishment and Maintenance of Records Under the Public  
Health Security and Bioterrorism Preparedness and Response Act  
**Docket No. 02N - 0277**

The Association for Dressings and Sauces is the international trade association representing manufacturers of salad dressings, mayonnaise and condiment sauces and the suppliers to the industry. ADS submits the following comments on the Food and Drug Administration's (FDA) proposed regulation: Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"), which was published in the May 9, 2003, *Federal Register* (68 *Federal Register* 25187).

According to the proposed regulation, "the Bioterrorism Act directs the Secretary to take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary under the new regulations." The FDA has outlined the information that it would not have access to, including quantitative information used in a formula. However, the FDA would have access to other confidential information that, if made public, could have a negative impact on the company. ADS comments that the FDA must take steps to ensure that information either viewed or copied remains confidential.

In proposed section 1.328, the FDA includes "substances that migrate into food from food packaging and other articles that contact food" as one example of what constitutes "food." In addition, the FDA indicates, "outer food packaging is not considered a substance that migrates into food." ADS supports the exemption of outer food packaging from the proposed regulation. Similarly, the risk to human and animal health from contamination of inner food packaging and food contact items is relatively small as compared to the risks of consumable food items. We would, therefore, urge the FDA to consider a less rigorous documentation program for inner food packaging and/or food contact items than for consumable food products.

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ADS agrees with FDA's efforts in proposed section 1.337(a) not to require the segregation of an ingredient in those instances where the ingredient is received from multiple sources and commingled prior to being incorporated into finished product (e.g., allowing one silo to contain flour from multiple suppliers). The financial costs to dedicate a tank/silo to each supplier for each ingredient would clearly create an undue burden on the industry.

Proposed section 1.337(a)(5) requires that records be kept on the quantity of the food and how it is packaged. All products are not packaged in neat containers. For some products (e.g., liquids), the raw material may be received in bulk such as tanker loads, therefore, recording the type of packaging would not be applicable. ADS recommends requiring that records be kept on the quantity or how the product is received (e.g., 5,000 gallons or 5 – 1,000 gallon totes) depending on the product.

FDA should treat processing aids and incidental additives as it proposes to treat ingredients that are commingled. In this way, a company would need to be able to identify the source(s) of the processing aids and incidental additives in use in a facility when specific food products were produced, but would not be required to know the specific source of the processing aid or incidental additive used to produce a specific lot of food.

In proposed section 1.352(a)(6), the FDA seeks comment on whether the "individual responsible" for the transported food item should be the operator of the conveyance or whether it can be someone within the transportation corporation who has overall responsibility for the vehicle and the food being transported. ADS recommends that the "individual responsible" should be someone within the transportation corporation who has overall responsibility for the vehicle and the food being transported. We believe the transportation company should maintain records that link the operator to a shipment, but knowing who has overall responsibility for the shipment and the food being transported would be crucial if a food security violation occurred.

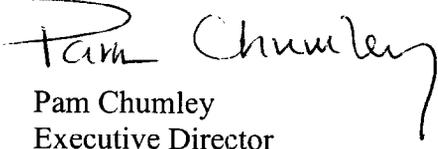
Proposed section 1.360 indicates that the FDA proposes to exempt electronic records from the requirement to comply with 21 CFR Part 11 "Electronic Records; Electronic Signatures." ADS agrees with this recommendation and believes that this exemption would help to minimize the cost to implement this regulation, as companies that use electronic records would not have to reconfigure their systems to comply with part 11.

Under the Bioterrorism Act, access to records requires that FDA possess a "reasonable belief." FDA should provide a statement that specifically demonstrates the basis of the "reasonable belief," additional information regarding the basis for the request, and the scope of records to be examined. The district director for the FDA district in which the records are located should approve this statement. Together, the written statement and indication of district director review and approval will provide assurance that records access authority is being implemented in an appropriate manner that is consistent with the Act.

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We appreciate your consideration of these comments.

Sincerely,

  
Pam Chumley  
Executive Director