



1073 '03 JUL -7 P2:37

2025 M Street, NW • Suite 800
Washington, DC 20036
Tel 202-367-1127 • Fax 202-367-2127
E-mail info@astaspice.org
Web www.astaspice.org

July 7, 2003

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

ATTN: Docket No. 02N-0277 (Establishment and Maintenance of Records)

On behalf of the American Spice Trade Association (ASTA), I am pleased to submit comments on the proposed regulation: "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," (The Bioterrorism Act) 68 Fed. Reg. 25188 (May 9, 2003). ASTA was founded in 1907 and represents the interests of approximately 300 members including companies that grow, dehydrate, and process spices in the United States for domestic consumption and for export. ASTA's members include U.S.-based agents, brokers, and importers, companies based outside of the U.S. that grow spices and ship them to the U.S., and other companies associated with the U.S. spice industry. ASTA's members manufacture and market the vast majority of spices sold in the U.S. at retail, and to food processors. ASTA is active in research and education on spices, government relations, and trade relations.

Clarification of Covered Records

We are requesting clarification of precisely what records must be maintained under this proposal. Proposed § 1.345 would require an adequate description of the type of food released, as well as the date the food was released. We are concerned that the use of the term "released" is ambiguous in the commercial environment.

Following import, spices are frequently transferred to a facility for primary treatment and then they may be transferred to another facility for milling or other processing. In between such stops there are transporters involved. Physical possession of spices or other food products does not always correspond to the party that holds title to them. We request that the final rule clarify what is meant by the term "released" and the relationship of this term to holding legal title, or ownership of the food.

Outer Packaging

In the proposed rule, FDA requests comments on whether the recordkeeping requirements should apply to outer packaging. We believe that outer packaging should not be covered by these recordkeeping requirements. We agree that the risk to human and animal health from contamination of outer packaging is relatively small compared to the risk from contamination of the immediate packaging that comes in direct contact with food. In the final rule, we request that FDA clearly define the covered packaging as being limited to food contact packaging.

02N-0277

CAH

Tracking by Lot Numbers

In the proposed regulation, the information required includes the lot or code number or other identifier. As it relates to records of packaging, this requirement would be extremely burdensome and would not enhance FDA's ability to trace contaminated food. In the final regulation, we request that the only packaging records required be those that would identify the type and manufacturer of the packaging.

Recipes

The proposed definition of recipe is ambiguous. The proposal states that recipe "means the quantitative formula used in the manufacture of the food product, but not the identity of the individual ingredients of the food." We request clarification of this definition.

We are also concerned that provisions of the proposed rule are inconsistent with the protection of recipes required in the Bioterrorism Act. The Bioterrorism Act and accompanying legislative history make it clear that the records authority does not apply to recipes. A complete list of ingredients used in a seasoning blend is considered a closely held trade secret. We urge FDA to define recipe as both the quantitative and qualitative ingredients in a proprietary formula and to further clarify that such information is not covered by the proposed recordkeeping requirements, or by the records access authority.

Records Availability Requirements

The proposed regulation would require that covered records be made available to FDA within 4 hours of a request if the request is made between 8 a.m. and 6 p.m., Monday through Friday, or within 8 hours of a request if made at any other time. It is unreasonable to expect the production of food manufacturing records in such a short amount of time. Requiring that covered records be made available within 24 hours of a qualified request would be reasonable and adequate to assist FDA addressing a case of possible contamination.

Request for Additional Compliance Time

FDA is proposing that firms be in full compliance with these regulations within 6 months of publication of final regulations. Given the scope and complexity of the proposed requirements, we request that large firms as defined in the proposal be given 18 months to comply following publication of the final rule. Smaller firms should be given an additional 6 to 12 months depending on their number of employees.

We appreciate the opportunity to comment on this proposed regulation. We are of course available to discuss any of these issues at your convenience.

Sincerely,



Elizabeth Erman
Executive Director