



**FLAVOR AND EXTRACT MANUFACTURERS
ASSOCIATION OF THE UNITED STATES**

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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 Flavor and Extract Manufacturers Association of the United States (FEMA), 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). FEMA is the national association of flavor manufacturers and represents the vast majority of flavor companies in the United States. FEMA members create flavors for use in a wide variety of food and beverage products.

Recipe

The proposed definition of recipe is internally inconsistent, and therefore we request clarification on the precise meaning of this important term. 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. The Bioterrorism Act and accompanying legislative history make it clear that the records authority does not apply to all aspects of recipes. A complete list of ingredients used in a flavor formula is considered a closely held trade secret and it should be considered part of the meaning of recipe.

Multi-Use Materials

We are concerned about the impact of this proposed regulation on materials that could be used to manufacture foods, but that could also be safe and legal to use in the manufacture of non-food products. The Bioterrorism Act amends the Federal Food, Drug & Cosmetic Act which defines food as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article," (21 U.S.C. § 321 (f)). Under The Bioterrorism Act, the recordkeeping authority applies to food. We request that in the final rule FDA make it clear that these proposed requirements only apply to food and food ingredients.

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We are concerned that ambiguous regulations could result in compliance officials requesting access to records for products that *could be* used as food, even when the material is intended for use in a non-food product. It was the intention of Congress that these provisions apply to food and therefore they should not apply to non-food products.

A short list of examples of materials and classes of materials that may be used in both food or non-food products includes: essential oils, such as lemon, peppermint or lavender oil, antioxidants, soy-based products, gelatins, and propylene glycol, a carrier of flavors and fragrances. There are many more examples of products that are approved for use in both foods and non-food consumer products.

Request for Additional Compliance Time

FDA proposes 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.

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. 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.

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 Clarifications

We request that FDA provide a definition of “responsible individual” as used in the regulation. We suggest that the responsible individual be defined as the contact person normally responsible for initiating the purchase or sale of an article of food.

We request clarification regarding which company official or officials FDA would contact when requesting records access under these regulations.

Finally, we believe it is important to clarify that multiple records can be used to provide an adequate description of an article of food. Many times confidentiality requirements result in records being maintained in different locations. We request clarification that records may be stored in separate locations as long as the combined records adequately describe the article of food as well as the previous and subsequent sources of the article.

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,

A handwritten signature in black ink, appearing to read "Glenn Roberts". The signature is written in a cursive style with a large initial "G".

Glenn Roberts
Executive Director