



# ENZYME TECHNICAL ASSOCIATION

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April 3, 2003

## Via Electronic and Federal Express

Attn: Stuart Shapiro, FDA Desk Officer  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
New Executive Office Building  
725 17<sup>th</sup> St., NW  
Room 10235  
Washington, DC 20503

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

**Re: FDA Docket No. 02N-0276, Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness & Response Act of 2002**

Dear Mr. Shapiro:

The Enzyme Technical Association ("ETA") respectfully submits these comments with regard to the Food and Drug Administration's ("FDA") proposed rule entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness & Response Act of 2002" ("proposed rule"), and published in the Federal Register on February 3, 2002. (See 68 Fed. Reg. 5378). ETA is a trade association of companies that represent manufacturers and distributors of enzyme preparations in the United States, Canada, and Mexico. ETA has been in existence since 1970 and has taken an active role in assisting in the development of regulations and policies that affect the enzyme industry. Its membership represents a majority of the North American enzyme industry.

Under The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act") (Pub. L. 107-188), Congress mandated that FDA promulgate regulations requiring the registration of all facilities "engaged in manufacturing, processing, packing, or holding food for consumption in the United States."<sup>1</sup> ETA commends FDA on its efforts to protect the United States food supply, and largely supports the provisions contained in the proposed rule. However, ETA must respectfully disagree with FDA's definition of "food", specifically as it applies to food processing aids, and food contact substances, and their

<sup>1</sup> See section 305 of the Bioterrorism Act.

02N-0276

C 73

Mr. Stuart Shapiro

April 3, 2003

Page 2

components. ETA believes that this proposed definition expands the registration requirement well beyond Congress' intent and will dramatically and needlessly increase the burden on the food industry. ETA also believes that the proposed requirement to collect facility emergency information which includes a home phone number is both impractical and unnecessary to FDA's proper performance of its functions under the Bioterrorism Act. Finally, ETA asks for clarification on the proposed definition of "facility".

**I. The Proposed Definition of "Food" Expands the Registration Requirement Beyond Congressional Intent and Is Unnecessary to the Proper Performance of FDA's Functions**

The Bioterrorism Act requires registration of all facilities "engaged in manufacturing, processing, packing, or holding food for consumption in the United States." See Section 305 of the Bioterrorism Act (*emphasis added*). This statutory language would appear to limit the application of the registration requirement to facilities working with "edible" food only. However, in defining the word "food" for the purpose of identifying facilities that would be subject to registration, FDA's proposed rule fails to consider the Bioterrorism Act's qualifying language "for consumption." As a result, the FDA proposed rule appears to require facilities that merely manufacture food contact items, such as packaging material, food processing equipment, substances applied to the food processing equipment, and components of such items to register with the FDA. ETA must respectfully disagree with the scope of the proposed regulation as it believes that the proposal currently exceeds Congressional intent.

In support of its proposed definition for "food", FDA relies on the definitions of "food" provided in Section 201(f) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 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. In addition to edible food items, FDA states that the statutory definition of "food" includes food and feed additives, and substances that migrate into food from food packaging and other articles that contact food. See 68 Fed. Reg. at 5382. FDA's basis for expanding the definition of "food" to food additives and food contact items is based on its traditional authority over "food additives" which, as set forth in Section 201(s) of the FFDCA, are defined in part as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for such use) . . ."

However, it is clear that Congress did not intend for the food facility registration requirement to have the breadth suggested by FDA. As stated at the outset, Congress intended to limit the registration requirement to facilities working with "food for consumption." According to the Webster's II New College Dictionary, the definition of "consume" means "to eat, or drink up; ingest." See Webster's II New College Dictionary at 242. Therefore, the statutory qualification of "food for consumption" limits application of the registration process to companies working with food and food components that can be eaten, or are edible in bulk form. For example, sugar

is a food ingredient that is both a common food component or ingredient, and that is also edible in bulk form (e.g., table sugar).

Based on this analysis, the food facility registration requirement could not have been understood by Congress to apply to food contact items such as packaging and food processing equipment, let alone the components or applications to such items. ETA also questions whether Congress would expect application of the requirement to certain direct food additives such as processing aids, particularly where those processing aids are removed from the food or converted into constituents normally included in food, or added to food for their technical or functional effect on the processing only.<sup>2</sup> None of these substances are considered edible in bulk form, and thus, they would not fit within the scope of "food for consumption." In fact, the insignificance of these processing aids on the final finished food product intended for consumption is such that FDA does not require that they be listed on the finished food product labeling. *See* 21 C.F.R. § 101.100.

Moreover, including these nonedible substances within the scope of the proposed regulation imposes a significant burden on the industry with minimal, if any, increased security for the U.S. food supply. ETA notes that the five intentional and accidental incidences of food contamination identified by FDA to estimate the benefits of the proposed regulation do not involve contamination by food processing aids or food contact items, nor is ETA aware of such incidences. Therefore, ETA recommends that FDA modify the definition of "food" so that it is consistent with the concept of "food for consumption," and thus, excludes food contact substances, other indirect additives, and processing aids.

## **II. The Proposal to Collect Personal Contact Information Is Unnecessary to the Proper Performance of FDA's Function and Lacks Utility**

Pursuant to the Paperwork Reduction Act of 1995, FDA invited comment on whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information would have practical utility. ETA has reviewed the information that FDA proposes to collect and is particularly concerned about the plan to collect personal information (i.e., emergency contact's home phone number). Not only does this requirement raise issues of individual privacy, ETA believes that a phone number will provide little practical utility in assisting FDA in performing its function.

In support of the need to collect home phone information, FDA states that it must be able to get in touch with an individual at each potentially affected facility who can respond immediately to a

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<sup>2</sup> We recognize that Congress identified 21 C.F.R. § 170.3 as a source for information on "general food categories" and that processing aids are listed in that regulation. However, the statutory language appears to be advisory in nature, and could not be used to mean that Congress intended to include processing aids that are not in a finished food product within the definition of "food for consumption."

Mr. Stuart Shapiro  
April 3, 2003  
Page 4

threat at any hour. *See* 68 Fed. Reg. at 5385. While ETA agrees with the need for a facility contact number that is reachable at any hour, it believes that the provision of a "home phone" will not accomplish this purpose. A "home phone" is dubious, at best, as an emergency contact source. The individual who has provided the "home phone" information frequently will not be at home, may be on vacation, or may not have accessibility to a phone if on travel. Other members in the individual's household who answer the emergency call may not be able to reach the individual or direct the caller to another point of contact.

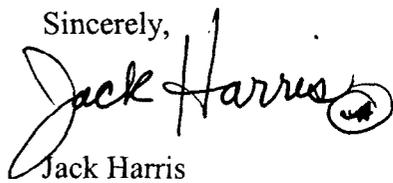
Instead, ETA believes that an immediate response system would be better satisfied by the provision of an emergency 24 hour contact number that is directly connected with the facility. The emergency contact system could be in the form of a beeper that is passed around to individual facility personnel who are identified as "on call" and are authorized to take appropriate actions to respond to an emergency, or it could be as sophisticated as a 24-hour facility operator system in which the personnel manning the emergency call have the information necessary to contact the appropriate personnel who can immediately respond to the emergency. While FDA should leave the details of the 24-hour contact number system to the individual facilities, such a system would clearly address FDA's need to have access to immediate facility communication in the event of a threat to the U.S. food supply.

### **III. Definition of Facility Should Be Clarified**

In proposing a definition for "facility", FDA suggests that a single facility may be more than one structure under one management at one general physical location, and further explains that if more than one structure is involved, the structures must be "contiguous" to qualify as a single facility for purposes of registration. *See* 68 Fed. Reg. at 5381. ETA understands that the proposed definition of "facility" would appear to require two facility registrations where two structures under single management are across town from each other. However, it is less clear about the registration requirements for two structures under single management that have different addresses, but are physically next to each other, or across the street from each other, or around the block from each other. Based on ETA's understanding of the concept of "establishment" under the drug and device registration requirements, ETA would expect that these latter examples would require the registration of one facility. Nevertheless, it requests that FDA clarify its expectations in the final rule.

ETA appreciates the opportunity to comment on the food facility registration proposed rule, and is hopeful that FDA will seriously consider adopting the modifications discussed above.

Sincerely,

A handwritten signature in black ink that reads "Jack Harris". The signature is written in a cursive style with a large, sweeping initial "J".

Jack Harris  
Chair