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August 30, 2002

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

Re: Docket No. 02N-0276 (Registration)

To Whom It May Concern:

The American Frozen Food Institute (AFFI) is pleased to provide initial comments with regard to FDA's upcoming rulemaking to implement the food facility registration provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. No. 107-188) (the Act or statute). AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 550 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationally and internationally.

The Act requires that "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary." Congress directed FDA to promulgate regulations to implement this requirement.

1. Who Should Register

AFFI believes the language of the Act is clear with regard to the types of facilities for which a registration must be submitted. The text of the Act,

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together with the language of the Conference report, should be adequate to resolve any questions that may arise in that regard.

AFFI believes it would be prudent, however, for the agency to offer some clarification in rulemaking as to who may submit the required registration. The Act places the obligation for registration on the owner, operator, or agent in charge of a facility. Most entities involved in the manufacture, processing, packing, and holding of food, however, own or operate multiple "facilities," as Congress has defined that term.

Accordingly, AFFI urges FDA to make clear in its implementing regulation that a company, operating from its headquarters location, may submit a single registration encompassing all of the facilities it owns, operates, or for which it is acting as an agent. This approach is not only fully consistent with the language of the Act but will help streamline the administrative burden associated with the new regulation.

2. What Information Should Be Required

There are several other issues raised by the Act's registration provision that warrant careful attention by FDA. First, AFFI urges the agency to specify clearly in its regulation what information must be provided as part of a registration. Consistent with the statute, that information should consist only of the name and address of each facility covered by the registration and any trade names (e.g., registered names, subsidiaries, and/or d/b/a's) under which the owner, operator, or agent in charge of the facility does business.

Any suggestion that the Act's reference to "trade names" includes the brand names under which a registrant markets its products should be soundly rejected by the agency. The plain language of the Act makes clear that the term "trade names" refers to the registering entity, not its products (i.e., "and all trade names under which the registrant conducts business").

Interpreting the registration provision of the Act otherwise (i.e., to require identification of company's brand names) would involve the submission of large, and constantly changing, bodies of data. It also would do nothing to advance the public policy goal the registration requirement is intended to serve, namely to

help FDA identify and locate quickly those entities that are connected with a food product that poses a threat of serious adverse health consequences or death.

The same analysis applies with regard to general food category information under Section 170.3 of the regulations. The statute makes reference to these food categories, suggesting that such information could be collected from registrants. AFFI strongly urges the agency not to require the submission of Section 170.3 information.

Facilities manufacture, process, pack, and hold thousands of different types of products. The nature of those products, moreover, changes constantly over time. Assigning Section 170.3 categories to this vast array of products, and updating that information with FDA, would impose an enormous burden both on the agency and on the food industry. And, despite the industry's work, because of the dynamic nature of the food supply, the information provided likely would never be completely current.

It is also unclear how access to this information would enhance protection against terrorist threats to our food supply. FDA established the food categories in Section 170.3 for a distinct and wholly different purpose – to facilitate safety assessments of food additives and the promulgation of food additive and GRAS affirmation regulations. Section 170.3 categories bear no necessary relationship, therefore, to the types of finished food products available in the commercial food supply. Their usefulness in identifying, recalling, or otherwise isolating potentially dangerous products, therefore, is highly questionable.

3. Facilitating the Registration Process

AFFI strongly endorses Congress' suggestion in the Act that FDA provide for and encourage electronic filing of facility registrations. Internet-based registration opportunities will speed the registration process for both registrants and FDA and, once initial programming is undertaken, help minimize ongoing administrative costs.

AFFI also believes it would be helpful for FDA and food industry trade associations, including the Institute, to work together to inform industry members about the obligation to register and the avenues for doing so. For example, FDA

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might permit AFFI and others to make the relevant registration forms available on their websites. Members could then download and submit them to FDA. With assistance from the agency, associations could also prepare and post materials discussing the registration requirement and the information that must be submitted. A question and answer document could also be developed to answer questions that are likely to arise frequently.

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AFFI appreciates the opportunity to provide input on the regulation that will implement the registration requirement of the Act. AFFI looks forward to working with the agency to develop this and other required rulemakings in a manner that will maximize public health protection without unduly burdening food manufacturers, processors, and handlers or interfering with the smooth functioning of the commercial food supply.

Sincerely,



Leslie G. Sarasin, CAE

President and Chief Executive Officer