

American Frozen Food Institute • 2000 Corporate Ridge, Suite 1000 • McLean, Virginia 22102

Telephone (703) 821-0770 • Fax (703) 821-1350 • E-Mail info@affi.com
http://www.affi.com • http://www.HealthyFood.org

December 22, 2003

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

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

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) welcomes the opportunity to provide comments with regard to the Food and Drug Administration's (FDA) interim final rule implementing the food facility registration provision of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (the Bioterrorism Act) (Docket No. 02N-0276). AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's more than 500 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 manufacturing, processing, transportation, distribution, and sale of products nationally and internationally.

The Bioterrorism Act calls on FDA to establish requirements to implement the food facility registration provision. AFFI appreciates the hard work and long hours FDA staff have devoted to preparing the interim final rule and ensuring that its key elements are known to and understood by the food industry. Nonetheless, AFFI believes additional guidance from FDA on several points is warranted and would help smooth the registration process for all concerned.

Confirmation of Registration

Some AFFI members have noted that their customers are demanding proof of registration. The only proof they can offer is their registration number(s), yet release of this number(s) raises security and confidentiality concerns. To alleviate these concerns, AFFI suggests that FDA provide registered facilities with a system-generated proof of registration that omits the registration number, thereby allowing the registrant to demonstrate compliance to others, while safeguarding against the possible unauthorized use of registration numbers.

2002N-0276

@190

2698 03 DEC 23 AM 11

Docket No. 02N-0276
American Frozen Food Institute
December 22, 2003

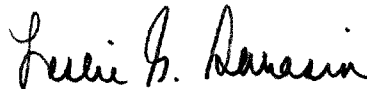
Further Written Clarification

As noted earlier, AFFI appreciates the many steps FDA has taken to inform industry and the public of the requirements of this interim final rule. Guidance given in the public outreach sessions attended by AFFI has answered many of the questions posed by AFFI members. To further enhance its education efforts, AFFI urges the agency to provide written transcripts of the public outreach sessions, and to post the questions raised at these sessions and the answers provided by the agency in Question & Answer format on FDA's website as soon as possible. Doing so will reduce misunderstanding about the scope and requirements of the interim final rule and limit the need for agency personnel to answer registrants' questions as the rule is implemented.

Conclusion

AFFI appreciates the opportunity to comment on the interim final rule for food facility registration under the Bioterrorism Act and looks forward to working cooperatively with the agency throughout the implementation process.

Sincerely,



Leslie G. Sarasin, CAE
President and
Chief Executive Officer