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-0278; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) is pleased to provide comments with regard to the Food and Drug Administration's (FDA) interim final rule implementing the prior notice of imported food provision under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (the Bioterrorism Act) (Docket No. 02N-O278). 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 prior notification of imported food. AFFI recognizes the daunting task faced by the agency in developing regulations that balance the desire to inspect imported food with the need to avoid disruptions to trade and the nation's food supply. AFFI appreciates the agency's efforts in that regard. In several areas of the interim final rule, however, AFFI believes the food industry would benefit from additional guidance and clarification from the agency. Those areas are discussed in more detail below.

Sample Products

Thousands of food samples arrive in the United States every month from abroad. These samples are used for quality control, ingredient sampling, product testing, and other purposes. Given FDA's task to monitor and track all imported foods and register all food facilities, a

2002N-0278 C263

simple prior notice approach is appropriate for those types of products sent to the United States for analysis, but not manufacturing.

There are numerous ways to simplify the process, yet maintain the integrity of the system. For example, U.S. companies who can certify that samples sent to an analytical facility will not find their way into manufacturing or commerce could be allowed to file a blanket PN for all samples imported to that facility. Furthermore, FDA could explicitly waive the requirement for the registration number when the shipment consists of samples of ingredients or finished goods manufactured by a facility that does not make products for consumption in the U.S (and therefore has no registration number) or of products made by a competitor (who is unlikely to be willing to supply the shipper with its registration number.)

The Agency could add a field to the PN system that indicates that an imported product is a "sample." This field could include a subcategory entitled "Competitive Sample" that, if checked, would override the usual requirement for a registration number, in effect, indicating that a product is a competitive sample and, therefore a registration number cannot be provided. This would have the same impact as indicating that food is imported directly from a farm (farms, for the most part, are not required to have a registration number.)

Another possible solution might be treating competitive samples in the same manner as food sent as gifts from family living outside the United States, as described in the answer to Question 32 in the *Prior Notice of Imported Food Questions and Answers* published by FDA on December 15, 2003. In that answer, FDA advises the sender who does not have a manufacturer/producer registration number for a food gift to use the name and address of the firm that appears on the label and explains that a registration number need not be provided for such gifts. AFFI proposes that competitive samples be treated in the same way.

Assignment of Prior Notice Numbers

AFFI requests clarification on the length of time a company filing prior notice should expect to wait for the PN system and the Automated Broker Interface of the Automated Commercial Systems (ABI/ACS) to generate a prior notice number, as well as the steps a company should take if the expected waiting time has elapsed without receipt of a number. AFFI believes additional information from the agency on this point would help make the prior notice system run more smoothly for industry and the agency.

Prior Notice Requirements for Farms

Many foreign farms export the crops they grow – crops that satisfy the agency's definition of food in its natural state – directly to the U.S. Because the interim final rule on registration excludes an exemption for farms, most of these foreign farms may not be required to register. AFFI understands that the PN system should recognize these operators as "farms" and not require a registration number. AFFI requests guidance regarding the steps these farms should follow to ensure their crops move through the prior notice system without agency objection, given that the farms will not have a registration number to provide as part of the prior notice.

Single Prior Notice Number

AFFI reiterates its position that only one prior notice number should be assigned per shipment. It is still unclear how multiple prior notice numbers per shipment enhance inspections at ports of entry. While AFFI appreciates the agency's efforts to ease the burden of this requirement with the use of repeater screens in the PN system, companies will still be required to expend valuable staff time on this requirement. AFFI proposes that FDA require only one submission per load, with that submission including the relevant information about the contents of the load.

Cargo Release

AFFI believes a system should advise retailers when their products have cleared all FDA entry processes. Such a system would benefit producers, retailers and ultimately consumers and, if provided through the Free And Secure Trade (FAST) system, would help ensure that unsafe products are not moved into saleable inventories.

Clarification of Trip Numbers

AFFI requests a clarification of the definition of trip numbers for truck shipments. AFFI believes that load tender numbers or manifest numbers should be used as trip numbers.

Currently, loads are tendered to carriers with these numbers, and the carrier uses the numbers for billing reference. If there is a problem, the current system makes it easy for carriers to locate questionable loads and their shippers.

Refusal of Prior Notice

AFFI seeks a clarification concerning the process for resubmission should a prior notice be refused for reasons other than failure to satisfy prior notice requirements. Once the failure is rectified, should companies use the PN system or the ABI/ACS to resubmit the load for clearance? A detailed explanation of the resubmission process would help maximize use of agency resources.

Conclusion

AFFI appreciates the opportunity to comment on the agency's interim final rule on the Bioterrorism Act's prior notice provisions. AFFI looks forward to continuing to work with FDA to protect public health without unduly burdening importers or interfering with the smooth functioning of the commercial food supply. Please do not hesitate to contact us if you have any questions.

Sincerely,

Leslie G. Sarasin, CAE
President and
Chief Executive Officer