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August 30, 2002

Docket No. 02N-0278
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Implementation of Section 307 (Prior Notice) of Bioterrorism Act (Docket No. 02N-0278)

Dear Sir or Madam,

The Food Marketing Institute[1] (FMI) is pleased to respond to the Food and Drug Administration's (FDA's) request for comments on the Agency's implementation of Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), Pub. L. 107-188. Although FMI supports necessary and appropriate measures to combat bioterrorism, we are concerned that the minimum prior notice period required under the Bioterrorism Act for imported foods may be disruptive to commerce. Accordingly, as explained more fully below, we recommend that FDA establish different minimum notification periods for different modes of importation, e.g., truck, air. The Agency should not require any more notice than is necessary to perform essential anti-bioterrorism functions.

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[1] FMI conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all food retail store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 60 countries.

A. Legal Background

Section 307 of the Bioterrorism Act amends Section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new paragraph (m), which requires the following information to be submitted to FDA on imported food before the food will be admitted into the United States:

- the article;
- the manufacturer and shipper of the article;
- the grower, if known within the specified period of time that notice is required to be provided;
- the country from which the article originates;
- the country from which the article is shipped; and
- the anticipated port of entry for the article.

The purpose of the notice is to allow FDA to inspect imported articles at the point of entry into the United States.

Section 801(m)(2)(A) requires FDA to promulgate regulations setting forth the minimum amount of time prior to the importation of the product that such notice must be given. The minimum amount of time must be sufficient for the Agency to receive, review, and appropriately respond to such notice, but may not exceed 5 days. In determining the length of the prior notice period, the Agency is authorized to consider, among others, the following factors: the effect on commerce; the locations of the various ports of entry into the United States; the various modes of transportation; and the types of food imported into the United States. If FDA has not promulgated final implementing regulations within 18 months of the Bioterrorism Act's enactment (i.e., December 12, 2003), the prior notice requirement becomes effective and notice must be given between 8 hours and 5 days prior to importation.

If notice has not been provided, the food will not be permitted to enter the United States. The food will be held at the port of entry or a secure facility until the required notice is provided.

B. Implementation of Section 307: Retail Issues

1. Time of Prior Notice

One of the key issues that FDA must address in the rulemaking to implement Section 307 is the length of time in which notice must be provided to the Agency that a food will be imported. As discussed more fully above, the statute provides that notice must be made within 5 days of arrival; the default minimum notification period is 8 hours, although FDA may by regulation select a shorter period.

Food retailers source imported products in a variety of ways, depending on the size and resources of the retailer, as well as its general business philosophy. Most agree, however, that the trend will be toward increased global sourcing.

At this point, the factor with the greatest impact on the minimum notification period appears to be the mode of transportation and the proximity of the product to the border. Specifically, we understand that, under the current system, produce from Canada or Mexico may be ordered, packed, transported across the border, and delivered to a U.S. retailer all within the 8 hour minimum notification period. Accordingly, requiring at least 8 hours prior notice before food could be imported would disrupt the cross-border flow of fresh produce.

We recommend that FDA establish separate minimum notification time periods for different modes of transportation. For example, for product transported by air, FDA might require notice at least 4 hours prior to arrival or during the period commencing when the airplane departs and ending at the date of importation. Similarly, given the very brief period during which truck or rail transportation may occur, we recommend that FDA permit notice no later than the time at which customs entry documents are filed pursuant to 19 C.F.R., Part 142. Changes to the port of entry that are necessitated during transport by transportation conditions or commercial necessity should be accomplished by notifying the port of entry of a change to the import notification.

2. Person Filing Notice

Section 307 is silent with regard to the party who must submit the required import notice to FDA. Accordingly, we recommend that FDA's regulations provide flexibility in this area. In particular, even though the importer of record may ultimately be responsible for the imported food products and their compliance with all U.S. legal requirements, brokers may in fact prepare and file the required notification. As long as FDA receives the necessary information and has *in rem* jurisdiction over the foods themselves, industry should be allowed to determine the party who will file the necessary prior notice.

3. FDA Acknowledgement of Notice

We encourage FDA to promulgate regulations that will require the Agency to acknowledge receipt of the notice that must be provided under Section 307. To the extent that notice is provided electronically, FDA's acknowledgement should likewise be provided electronically and response should be immediate.

4. FDA Availability

Given the significant increase in responsibility that the prior notification provision places on FDA for the safe and efficient import of foods, we recommend that the Agency extend hours of operation at points of entry to 24-hour coverage.

5. Conditions for Holding Product

As required by Section 307, product for which a prior notice has not been provided in advance will be held at the port of entry for the article until the necessary notice is submitted to FDA. FDA's regulations should provide that product will be held under conditions that will maintain product integrity to the extent feasible. Products held for lack of notification should be held separately from products subject to FDA's administrative detention authority.

6. Grower's Identity

Section 307 requires the notification to identify the grower "if known within the specified period of time that notice is required to be provided." In many cases, the identity of the grower is not known to the importer of record at any time. Therefore, importers should be able to declare the identity of the grower to be "unknown" on the notification without deterring entry of the product into the United States.

* * *

We hope that you will consider the foregoing recommendations as you develop regulations to implement Section 801(m) of the FD&C Act. If we may provide any additional information in this regard, or if we may be of assistance in any other way, please do not hesitate to contact Deborah White (202/220-0614) or myself.

Sincerely,

Tim Hammonds

Tim Hammonds
President and CEO

cc: Mr. L. Robert Lake, Esq.
Ms. Leslye M. Fraser, Esq.
Ms. Mary Ayling