



GROCERY MANUFACTURERS OF AMERICA

MAKERS OF THE WORLD'S FAVORITE BRANDS OF
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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

Re: Docket No. 02N-0278

Enclosed please find the Grocery Manufacturers of America's preliminary comments and suggestions to the Food and Drug Administration concerning implementation of Section 307 (prior notice of food imports) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Sincerely yours,

James H. Skiles
Vice President, General Counsel

02N-0278

EC23

Before the
U.S. Food and Drug Administration

Implementation of
Public Health Security and Bioterrorism Preparedness and Response Act
of 2002
(PL 107-188)

Docket No. 02N-0278
(Prior Notice)

**COMMENTS OF THE GROCERY MANUFACTURERS OF
AMERICA, INC.**

August 30, 2002

Introduction

The Grocery Manufacturers of America, Inc. ("GMA") appreciates the opportunity to provide preliminary comments and suggestions to the Food and Drug Administration concerning implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act" or the "Act") (PL 107-188). GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than \$460 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

FDA is to be commended for the orderly, open, and efficient manner in which it has approached the implementation of the Bioterrorism Act. As FDA well knows, the time period provided by the Congress for the adoption of regulations required to implement various provisions of the Act is only 18 months. The regulations that FDA is required to adopt—on establishment registration, recordkeeping, and prior notice of food imports—have the potential to disrupt seriously the flow of food in commerce. It is, therefore, critically important that FDA's process for the development of proposed regulations, consideration of comments, and adoption of final regulations continue to provide for maximum public input and that FDA remain fully committed to the issuance of final regulations within the time period provided in the Bioterrorism Act. GMA intends to cooperate fully with FDA to achieve timely and appropriate implementation of the Act.

These comments address section 307 of the Bioterrorism Act which requires that prior notice be provide to FDA of imported foods. GMA has also filed comments on sections 305 (establishment registration), 306 (recordkeeping), and 303 (administrative detention).

General Comments on Prior Notice

Section 307 of the Bioterrorism Act amends section 801 of the Federal Food, Drug, and Cosmetic Act ("FDC Act") to require prior notice of imported food shipments. The notice is required to describe the article of food, the manufacturer and shipper, the grower (if known within the time period in which the notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of entry. A shipment of food offered for entry into the United States without a prior notice is to be refused admission (at least until a notice is filed).

The prior notice requirement has great potential to interfere with the movement of food products into the United States. If not implemented carefully and with particular attention paid to the practicalities of the importation of food from hundreds of countries, by land, air, and water, there is the very real possibility that ports of entry will resemble massive food bazaars in an underdeveloped country as food piles up in confusion over whether and when notice was provided.

It is imperative, therefore, that FDA work closely with the U.S. Customs Service (as the Act requires) to embrace existing systems of notice to Customs (the Automated Broker Interface and Automated Commercial System) and FDA (the Operational and Administrative System for Import Support) as a way to facilitate the orderly and efficient provision of prior notice to FDA. Given the existing notice requirements to Customs and FDA and the high degree of overlap between the information now provided to Customs/FDA and the information required under the Act to be set forth in a prior notice, it is incumbent on FDA and the Customs Service to find a way to utilize the existing notice systems to satisfy the new prior notice requirement. There is simply no need to create a new mechanism for the receipt of prior notice by FDA that would operate in parallel to the existing Customs/FDA systems. Yet another system would create an information nightmare for the food industry and importer communities and for FDA, without advancing the purposes of the Bioterrorism Act.

Ideally, the electronic mechanism that FDA uses to receive the prior notice -- building as we suggest on the existing electronic Customs/FDA notice systems -- should include a "notice received" feature. In many situations, companies and importers will have ample time to provide the prior notice to FDA and to provide a subsequent notice if the initial notice was not properly received by FDA. However, if FDA does not acknowledge receipt of the notice, the notifier will not learn of the problem until the food arrives at a port of entry and is refused admission. The efficient operation of ports of entry will be enabled if FDA's system of prior notice minimizes the instances in which prior notice could have been effectuated but, because of some system failure, the notice was not received into the system.

It is especially important that FDA's system for prior notice accommodate the receipt and acknowledgement of notice on a 24/7 basis. Although we do not believe that it is necessary for FDA to staff each port of entry on a 24/7 basis, it is essential that the importation of food not be restricted to those times in which FDA has personnel available physically at each port. In the case of truck traffic, for example, notice may well be provided and trucks may well arrive at all hours of the night and day. FDA must, therefore, have the capability for prior notice to be submitted and its receipt acknowledged so that, absent an FDA decision to sample a shipment, the shipment may proceed to be imported with the notice requirement satisfied.

Specific Comments

1. "Article of Food"

The Act requires that a prior notice be submitted "in the case of an article of food that is being imported or offered for import into the United States" (section 307). Although the Bioterrorism Act does not define "article of food," it is plainly clear that the Congress intended for prior notice to be provided for those items that meet the definition of "food" in section 321(f) of the FDC Act, 21 U.S.C. § 321(f).

2. Content of the Notice

With a single exception—the identity of the grower of the article of food—all of the information that the Act requires to be contained in a prior notice is already captured in the existing Customs (ABI/ACS) and FDA (OASIS) systems. The regulations to implement the prior notice system need not, therefore, depart from the existing notice systems, except with respect to the timing of the notice (see below).

The regulations should provide for the identity of the grower to be provided only: (1) if known at the time of the notice; and (2) in the case of raw or minimally processed commodities. FDA should add a field to its OASIS system to receive the "identity of the grower," but the failure to fill in the field should not render the notice ineffective. Rather, a "blank" grower field should be interpreted to mean that the person submitting the notice did not know the identity.

The regulations should not purport to place on persons who import articles of food into the United States any affirmative obligation to determine the grower of the article. There is no basis in the Act to conclude that the Congress intended for there to be such an affirmative obligation.

2a. "Country of Origin"

The Act requires that the "country of origin" of the article of food be included in the prior notice. The regulations for prior notice should state clearly that the "country of origin" for FDA purposes is identical to the "country of origin" under Customs law and regulations. Moreover, for multiple component articles, the "country of origin" should be the article itself and not each individual component.

3. Timing of Prior Notice

The appropriate timing of prior notice is, perhaps, the most difficult issue to resolve. Under the Bioterrorism Act, FDA is to set the period for notice at the "minimum" amount of time needed to receive and review the notice and to make a determination whether to inspect and/or sample the food being offered for import. The Act further provides that FDA may not require the notice to be provided more than five days before the anticipated importation. The five-day period corresponds, of course, to current Customs Service practice; entries may be filed with Customs up to five days before the anticipated time of importation.

We suggest that insofar as possible, the time periods for prior notice correspond to current Customs practice. We also suggest that the minimum time for prior notice depend on the form of transportation used for the shipment.

For air transportation, notice would be required on a "wheels up" basis. Depending on the departure location, this will give FDA anywhere from 1 to 8 or more hours notice. Flights from contiguous countries and the Caribbean will generate shorter notice, while flights from Europe and Asia longer.

For ocean transportation, we suggest that the notice period be fixed at a four-hour minimum. We believe that this period will accommodate the realities of the importation of tariff-quota and non-quota merchandise by ocean transportation, Customs procedures and requirements, and the needs of FDA to have ample notice to make informed decisions about the utilization of its inspectional resources.

The appropriate and reasonable period of notice for truck transportation is difficult to determine. Under current Customs practice, entry documents are provided at the border with no advance notice provided through the Customs ABI/ACS systems or through OASIS. FDA must recognize that it will be extremely difficult to provide prior notice for much truck transportation from Canada and Mexico into the United States. Many of the trucks that depart from Canada and Mexico to the United States do so from locations that are a mere hour or two from the border. It is certainly not feasible for notice to be provided any earlier than the time of departure to the border. Moreover, the time of arrival at the border is influenced by factors outside of the control of the shipper—weather, traffic, and delays at the border.

First, we suggest that FDA allow for advance notice to be provided for regularly scheduled truck shipments. Thus, for example, a company that sends one or more trucks to the United States on a daily or weekly basis should be allowed to provide a schedule to FDA that satisfies the prior notice requirement. Second, FDA should accept a notice of between one and two hours for truck shipments and recognize and provide for the fact that many of those notices will need to be amended at the border to more

accurately reflect the content of the shipment, which may not be fully known (especially for produce and seafood) until the truck is fully loaded and on its way. A notice should not be deemed to be ineffectual if the description of the article of food is general ("seafood; tuna and/or salmon and or swordfish) rather than specific.

In sum, a workable prior notice system will necessarily involve a flexible "timing" requirement.

Conclusions

Great care must be exercised by FDA in fashioning its prior notice regulations. Equal attention must be paid to developing a system for prior notice that is integrated with the existing Customs and FDA notice systems. Otherwise, there is a real risk that FDA will be overburdened with redundant and unhelpful notices and will be less, rather than better, able to focus on "high risk" importations. Moreover, if the prior notice system that FDA imposes is not practically achievable, there will be disruptions in the supply of food to consumers and serious trade ramifications with our trading partners.