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

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December 19, 2003

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

Re: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness Act of 2002; Interim Final Rule; Docket No. 02N-0278.

Comments of the Grocery Manufacturers of America, Inc.

Dear Sir or Madam:

The Grocery Manufacturers of America, Inc. ("GMA") is pleased to have this opportunity to provide comments on the interim final rule of the Food and Drug Administration ("FDA") to implement section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"), which provides for prior notice of imported food.

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.

General Comments

GMA and its member companies share with the FDA the goal of enhancing the security of the food supply. Each of GMA's member companies has a deep and abiding commitment to food safety and food security. Our evaluation of FDA's interim final rules to implement the Bioterrorism Act has been heavily influenced by the commitment we share with FDA to provide a safe and secure food supply to the American people.

In general, GMA believes that the interim final regulation is a major improvement over the proposed regulation on prior notice. The major concerns that GMA expressed, particularly over the workability of the proposal, were addressed in the interim final regulation. Moreover, the recently disclosed compliance policy appears to ensure that companies will have an ample period to adjust to the prior notice requirement without risk of enforcement action for prior notices that are not fully compliant with the provisions of the interim final regulation. GMA is especially pleased that FDA appears to have entered a "new era" of cooperation with the food industry.

However, there are elements of the prior notice regulations that present impracticable situations that are not contemplated by the statute and that are unnecessary requirements added by FDA. Specifically, the requirement for the food facility registration number as a part of the mandatory information of the prior notice and the submission of an individual prior notice for each article of food as it applies to imported food samples in a single shipment do not consider the general practices of the food industry.

To determine that a prior notice is deficient due to the lack of a registration number, places overly burdensome and unreasonable requirements on the food industry. There are numerous legitimate reasons that food companies may seek to import food products from manufacturers whose registration number is unknown or the facility is not required to register with FDA. Also, the review process established in Interim Rule § 1.285(j) would easily be overwhelmed by potentially hundreds of requests the Agency may receive daily to resolve refusals of admission that are based solely on the absence of a registration number.

In addition, the submission of an individual prior notice for every imported food sample in a single shipment is particularly cumbersome. A single shipment may include as many as 50 individual food samples that may each require a separate prior notice. To complete, process and review these 50 prior notices are an inefficient use of the companies' and FDA's resources.

Therefore, to ensure that the purpose of the Bioterrorism Act is achieved and to reduce the burden on industry and the Agency, an alternative means of addressing these

procedural oversights for the importation of food products should be implemented. An option available to FDA is to modify the existing prior notice form to address the frequent instances where the registration number may not be available. This will allow the Agency to deal directly with these routine occurrences and focus its resources on food imports that may present a risk of serous health hazards, as intended by the Act. Also, the review process would be reserved for intermittent issues, which was the purpose of Interim Rule § 1.285(j). Finally, a variant of the existing prior notice (prior notice for food samples, for example) may be developed to accommodate shipments that include numerous and varying samples so that only one prior notice may be submitted per single shipment.

Specific Comments

1. *Content of the Prior Notice - Registration Number*

The Act requires that a prior notice include information that identifies the manufacturer of the food. Neither the text of the legislation nor the legislative history indicates that the identity must be in the form of the registration number. Indeed, such a constraint would be counter to the expressed intent of Congress to limit the impact on trade because the consequences of such an interpretation would inherently restrict imports. It assumes that all food offered for import into the United States would be intended for consumption in the United States and thereby manufactured by a registered company.

In fact, many companies may submit prior notice for import food products that do not contain the food facility registration number for purposes of Quality Assurance/Quality Control ("QA/QC") and other analysis. For example, it is not uncommon for samples of competitors' products that are discovered in locations other than the United States to be imported for evaluation. The prior notice for such a product would be deemed inadequate and the shipment refused admission because it is very unlikely that the importing company would be able to obtain the competitor's food facility registration number. However, there is a possibility that the food facility may already be registered with FDA. Alternatively, if the food manufacturer does not produce food for consumption in the United States, registration would be unnecessary. In both instances, the company and food product are in compliance with the relevant provision of the Federal Food, Drug and Cosmetic Act ("FD&C Act"). However, the requirement established by FDA for a food facility registration number is the sole barrier to entry into the United States.

Additionally, food companies have centralized QA/QC functions to ensure that product manufactured by various facilities located in geographically dispersed areas meet a single global standard. To conduct the proper analysis, samples are collected and evaluated in laboratories that may be located in the United States. However, this very

simple function is seriously impeded. The facility where the food is manufactured is unlikely to be registered with the FDA because the food is not intended for consumption in the United Stated, but is manufactured for a specific geographical region and imported for QA/QC purposes only. Clearly, refusal of admission of a harmless food sample due to the lack of the registration number was not a result that the Congress envisioned with the enactment of the Bioterrorism Act.

Of course, these situations must be multiplied by thousands to adequately represent the number of food companies in the United States that may import samples of food products. In practice, each food company may average approximately 1000 or more different imported food samples annually. The number of requests to review the prior notice for these food samples would easily overwhelm the review process established in Interim Rule § 1.285(j).

These examples do not account for the many other events where food samples may be imported, such as for trade shows and conventions. Although, it appears to be minor, the United States hosts hundreds of trade shows and conventions annually. These situations may increase the number of incomplete prior notices and potential violations due to the lack of a food facility registration number, which may also request review by FDA.

Needless to say, the prior notice requirement and the review process fails to address the many and routine occurrences where the registration number is unknown, the food facility is not required to register and other similar situations that may arise from the customary practices of the food industry such as the evaluation of food samples.

2. Multiple Food Samples in a Single Shipment

The interim final rule requires that prior notice be submitted for each article of food. Food is defined consistent with the FD&C Act with the exception of food contact substances and pesticides. In practice, to implement this requirement as it may apply to a single shipment of multiple food samples, each individual food sample offered for import would require its own prior notice submission. On average, a shipment of samples may contain one or up to 50 different food samples and may result in a ridiculous number of prior notice submissions.

The resources exerted to complete, process and review numerous prior notices for a single shipment is better directed to other areas of food security. As discussed in a later section, it would be appropriate for FDA to develop a prior notice form that allows all food samples in a single shipment to be consolidated onto a single prior notice, which may assist the Agency in more thorough review of imports.

3. *Proposed Modification to Prior Notice*

a. Registration Numbers

GMA understands the importance of FDA's mission under the Bioterrorism Act and appreciates the tremendous undertaking by the Agency to secure the nation's food supply. However, trade and legitimate business pursuits are the backbone of a vibrant and health economy and should be restricted only to the extent necessary. These goals are not mutually exclusive and modification of the prior notice requirement will accommodate both important goals.

The information required in a prior notice should be amended so that the absence of a food facility registration number does not render the notice inadequate. Space in the prior notice form may be created to allow the notifier to insert a reason for the lack of a registration number. Such explanation may be as simple as "food facility registration number unknown" or "shipment contains food samples only."

FDA may incorporate additional measures and restrictions that would establish the criteria for unusual shipments. Presumably, the computer system would be able to sort through the prior notices and identify shipments that require inspection. For example, if a shipment that claims the lack of a registration number due to food samples, but the quantity is vastly disproportionate to a normal sample shipment, FDA may well decide to inspect the shipment. These procedures ensure that both food shipments are not permitted into the country without adequate safeguards and reduce the burden on the food industry to comply with nearly impossible requirement for the food facility registration number.

Moreover, the number of potential requests for reviews under Interim Rule § 1.285(j) that FDA may receive would be voluminous. If, on average, a food company imports approximately 200 food samples annually and companies requested only 10% of that number for review by the Agency, the deluge of requests would easily overwhelm the capabilities of the FDA to review requests in the 5 day time period provided in the regulations. By directly addressing the problematic aspects of the prior notice requirement, FDA is mitigating the possible negative ramifications on other areas of the programs.

b. One Prior Notice for Food Samples in a Single Shipment

To decrease the burden on the food industry, FDA should develop a variant of the existing prior notice form to allow notifiers to submit a single prior notice for multiple food samples in a single shipment. As previously stated, shipments of food sample may contain a large number of different articles of food, which would require the submission

of an individual prior notice for each article. Consolidating prior notices for food samples in a single shipment will streamline FDA review process and minimize the paperwork required to be completed by the notifier, while maintaining compliance with the Bioterrorism Act. FDA may chose to limit the use of the consolidated prior notice for food samples in a single shipment to notifications submitted through FDA's prior notice system and not through the Customs and Border Protection Automated Broker Interface of the Automated Commercial System ("ABI/ACS")

Conclusion

Due to the restrictions of the prior notice requirement, the food industry is confronted with major obstacles that prevent companies from continuing their ordinary business practices and impede the importation of compliant food products from entering the United States. Therefore, GMA respectfully requests the Agency to revise the prior notice requirement in accordance with the suggestions in these comments.

Sincerely,

Susan M. Stout
Vice President, Federal Affairs