



GROCERY MANUFACTURERS OF AMERICA

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

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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; Reopening of Comment Period;
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 further comments on implementation of the prior notice requirement for imported food under section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("The Bioterrorism Act"). GMA member companies have substantial experience with the prior notice system since implementation of the interim final rule issued by the Food and Drug Administration ("FDA") on October 10, 2003, (68 Fed. Reg. 58974), which began in December, 2003.

GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than \$500 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.

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A. *General Comments*

When it issued the interim final rule, FDA wisely provided for a phased approach to compliance with the prior notice requirement. Indeed, the decision to issue an interim final rule with further opportunity for comment, reflected a recognition on FDA's part that the establishment of a workable prior notice system that meets the dual goals of enhancing FDA's ability to ensure the safety of the food supply without unnecessarily impeding the flow of food across our nation's border, could best be accomplished over a period of time with multiple opportunities for input from the affected industries and an ongoing assessment of the workings of the prior notice system.

The prior notice system has now been operational for seven months. It might seem to the casual observer that this is a sufficient period of time for the food industry to adjust to the new requirement and for FDA and the industry to assess comprehensively whether it works well or not. We suggest that there is as yet no basis to conclude that the prior notice system will work as intended and that FDA should revise and extend the current "educational" approach to enforcement. FDA should not begin to fully enforce the prior notice requirement later this year, as is its current plan.

FDA has recently published an initial statistical analysis of the operation of the prior notice system based on data collected during the first two months of its operation. ("Compliance Summary Information: Prior Notice, April 2, 2004") These data do not demonstrate that full enforcement of the prior notice requirement later this year could reasonably be expected to occur without major disruption to the supply of food into the United States. For example, FDA's data show that apparent compliance with the prior notice requirement for shipments by truck is low. Further, FDA has not required yet that facility registration numbers be included in prior notices. As we discuss later in these comments, GMA believes that the requirement to include registration numbers is ill advised and the requirement will be a major source of incomplete prior notices and thus a major cause of food supply disruption.

We conclude from the data that FDA has made public that it is too early to determine whether the prior notice system will function as intended. Notably, during the "educational" phase of FDA's enforcement, FDA has not provided importers (or brokers) with company or shipment specific information about the prior notice that was provided. Companies have no basis, therefore, to determine whether their efforts to design and implement compliant prior notice

system have been successful. Many GMA member companies have received no information about the prior notices that they have submitted (or that have been submitted on their behalf). The only information that FDA has provided to importers about prior notices that appear to be non-compliant is general information about the prior notice requirement. This is inadequate "education." Before FDA begins full enforcement of the prior notice requirement, it should develop and implement a notice-specific informational system that provides detailed feedback to submitters where a prior notice is deemed by FDA to be non-compliant. Without such a feedback system, companies will have insufficient knowledge to determine whether their systems are prior notice compliant without incurring the expense and delay that will accompany the rejection of prior notices. Many companies have invested millions of dollars to comply with the prior notice requirement. Full enforcement without a period of meaningful education will deprive these companies of the opportunity to "tinker" with their systems to ensure compliance.

*B. Registration Numbers Are Not a Mandated
Part of Prior Notice*

FDA's decision to include facility registration numbers as a mandatory part of prior notice is not required under the Bioterrorism Act and is ill advised. The requirement will unavoidably impede the importation of products, increase burdens on the industry and FDA, and create an incentive for companies to relocate certain facilities outside the United States in order to avoid prior notice problems. Not a one of these results is required under the Bioterrorism Act and FDA should promptly modify the interim final regulation.

It is abundantly clear that the Bioterrorism Act does not require that registration numbers be included in prior notice. The Congress as part of the Bioterrorism Act enacted both the registration requirement and the prior notice requirement. In section 307, Congress enumerated certain information that is required, *by law*, to be included in a prior notice. That enumeration does not include facility registration numbers. The failure of the Congress to include registration numbers in the enumerated statutory elements of prior notice is powerful evidence that Congress did not intend for FDA to so require it.

Moreover, because the registration and prior notice requirements are not coextensive (registration is required only for certain facilities that produce food for consumption in the United States while prior notice applies to a considerably broader universe of foods that enter the country, even if not for consumption here), requiring registration numbers on prior notices necessarily results in some

percentage of prior notices being ineffective. A person importing a food from a facility that is not required to be registered cannot be charged with providing a registration number for a facility that itself is not required to be registered.

The ill-advised requirement for registration numbers creates particular problems in several instances. For example, companies routinely acquire samples of competitors' products being sold outside the United States and ship them to the United States for examination and analysis. Acquiring the registration numbers of competitors' facilities is obviously not viable. Thus, in virtually every instance in which a competitive sample is shipped to the United States, the prior notice will, by definition, be inadequate. This makes no sense.

A second example involves product or ingredient samples acquired outside the United States and shipped to the United States for evaluation. Oftentimes, foreign companies who are not currently producing product for consumption in the United States produce these products or ingredient samples. These companies are thus exempt from registration. Few, if any of them would be willing to register solely for the purpose of facilitating an evaluation of their product or ingredient by a company located in the United States. Yet, without a registration number, it will not be possible for these products or ingredients to be efficiently imported into the United States.

There are other circumstances in which a product is properly offered for import into the United States (properly meaning here that the product was produced in a registered facility) and yet the importer does not have access to the registration number of the facility. FDA has not provided an efficient mechanism for the fulfillment of the prior notice requirement in any of these situations.

The problems created by the inclusion of registration numbers are an element of prior notice that can be easily addressed. First, the prior notice interim final regulation should be revised to provide that the facility registration number should be included in a prior notice when available. Second, FDA should provide for an option for the submitter to indicate that the registration number is not available and then to further indicate (perhaps from a drop down list of reasons) the explanation for the absence of the registration number (Standard explanations might include "competitive samples" or "product imported for evaluation only from a facility not required to be registered.") When a prior notice is submitted without a registration number, FDA would need to determine whether, under the circumstances of the particular prior notice, the facility identified on the prior notice is registered. It can do this, of course, by reference to its registration database. In many instances, FDA will be able to determine

that there is no requirement that the facility be registered and thus, there can be no impediment to the acceptance of the prior notice. Further, we suggest that FDA could properly use its enforcement discretion to permit, for example, the importation of small quantities of competitive samples, where the prior notice did not contain the registration number of the facility that produced the product. (These prior notices will be readily identifiable: Beverage company A filing a prior notice to import small quantities of beverage company B's products.)

Finally, if FDA were to follow the suggestions described above, it could well also decide to subject prior notices, which do not contain facility registration numbers to heightened scrutiny. It would not be difficult, for example, to program FDA's computers to "flag" prior notices where the submitter has selected the "no registration number" option.

There are substantial numbers of competitive samples and similar food samples that are imported every year. Without relief from the requirement for registration numbers in prior notices, companies will have no choice but to reconsider the use of U.S.-based facilities to conduct the examination and analysis of these samples. Companies will appropriately avoid the risk that shipments will be delayed or refused admission due to the absence of registration numbers.

FDA is obligated to interpret the registration and prior notice provisions of the Bioterrorism Act in a manner that avoids conflict. Given that the scope of the two requirements is different, FDA must adjust its view on including registration numbers in prior notices to produce a harmonious interaction between the two provisions. Failure to make that adjustment is likely to create numerous disruptive consequences for the flow of food across the U.S. border, without adding to the security of the food supply. That is not a result that the Congress intended.

C. *Customs and FDA Time Periods For Notice Should be Conformed; FDA Should Expedite the Prior Notice Process for CT-PAT and FAST Participants*

When FDA first proposed prior notice regulations, the proposal contained unrealistically lengthy periods for prior notice to be submitted. In response to overwhelming negative comments on the proposal, FDA drastically scaled back the time periods for prior notice. FDA attributed its willingness to scale back the time periods to enhanced cooperation with Customs and Border Protection ("CBP"). More recently, FDA has asked whether further expedition of the prior

notice process is feasible and whether flexible alternatives should be provided for C-TPAT and FAST participants. GMA urges FDA to conform the period for prior notice to the time periods under the CBP Advance Electronic Presentation of Cargo Information final rule (68 Fed. Reg. 68140, December 5, 2003). Further, FDA should accord food companies who participate in the CT-PAT and/or FAST program expedition with regard to prior notice **and** expedition with regard to clearance under section 801(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 381(a).

FDA has posed numerous questions in the notice, which reopened the comment period on the interim final rule. We will address those questions below. Initially, however, we urge FDA to explore ways to harmonize and make more efficient the dual processes to which imported foods are now subject. Specifically, FDA should seek to develop mechanisms in its field offices that will facilitate clearance of products under section 801(a) of the FDC Act. Currently, companies are encountering the following situation: products are allowed entry into the United States because the prior notice was deemed adequate, but there is then a lengthy period (weeks) before the product is cleared for use. Often, product is required to be held pending FDA clearance for use, even though no samples or other examination of the product occurs post initial entry.

The security of the food supply is not enhanced when companies are required to keep food products in temporary storage for considerable periods of time, awaiting FDA clearance. For product arriving by truck, for example, the temporary storage may be the truck itself. Having a truck loaded with food sit adjacent to a facility to which the product is to be delivered for an indefinite period potentially exposes the truck and its contents to the attention of persons who might wish to tamper with the food. Moreover, unreasonable long delays in releasing product interrupt supply chains and can result in degradation of the product.

We suggest, therefore, that FDA reevaluate its internal processes to determine how best to coordinate the entry process (prior notice) and the clearance process that permits food to be used. Neither the food industry nor consumers are benefited by expeditious prior notice clearance and dilatory release.

D. *Specific FDA Questions*

With regard to FDA's C-TPAT and FAST questions, we offer the following comments:

1. Food products should be eligible for the full-expedited processing and information transmission benefits allowed with C-TPAT and FAST. FDA should expedite the clearance of foods for use when companies, which participate in the C-TPAT/FAST programs, import those foods. CBP and FDA should modify their respective systems for the receipt of advance notice and prior notice to "flag" importations under C-TPAT and FAST. These notices should receive priority attention for entry and clearance purposes.
2. If FDA were to reduce the period to submit a prior notice for shipments arriving by land/truck to one hour (consistent with the CBP period), a shorter time period would not be needed for members of FAST. Rather, FDA should develop procedures to ensure that products imported through the FAST program get expeditious review and release.
3. FDA should not modify the security and verification processes in C-TPAT for food and animal feed shipments. Existing C-TPAT requirements are entirely suitable for application to food and animal feed.

With regard to FDA's flexible alternative questions, we offer the following comments:

1. As we have noted in several places in these comments, merely reducing the timeframes for submission of prior notice, would not sufficiently expedite the clearance of product for participants in FAST. In addition to addressing the prior notice time periods, FDA needs to develop mechanisms to expedite the release of product for sale and use. Little is gained if shipments are permitted to move promptly across the borders of the United States, only to encounter delays arising from the release process under section 801(a).
2. No comment.
3. FDA should not further encumber the prior notice system with requirements that are intended to ensure that facilities are registered.

4. FDA should not impose additional conditions of participation for FAST members. The requirements for FAST participation imposed by CPB provide adequate assurance that expedited clearance is appropriate. FDA should focus its attention on ensuring that it provides prompt examination and clearance for shipments by FAST members. As noted above, many GMA members are encountering increasing delays in decisions on whether FDA intends to sample products that have been admitted into the United States. Accelerated clearance at the border would be a benefit to commerce, but the benefit would be largely negated if FDA does not improve on the time periods for examination and release.

5. We do not believe that food product category in and of itself should cause a food to be excluded from expedited prior notice processing. Furthermore, while the food product category can usefully guide FDA in determining whether to examine and sample a product, we do not believe that the food product category should be a criterion in determining for inclusion in expedited prior notice processing.

6. Consistency in the time frames for prior notice and CBP advance electronic information submissions is highly desirable. As CBP phases in the advance electronic information rule, FDA should conform prior notice time periods to the time periods under the CBP. Differing time periods for the two notices are a potential source of inadvertent error. Additionally, it is far more efficient for companies to acquire the data needed to file the notices and to file them in the same time periods.

7. FDA must engage in substantially more and varied educational programs before the full enforcement of the prior notice requirement begins. In addition to training programs for submitters and transmitters, FDA should develop mechanisms to provide notice-specific feedback to submitters and transmitters when errors are detected in notices. Without this notice specific feedback, it will be very difficult for companies to improve their prior notice processing and compliance systems while avoiding the disruption of shipments that are delayed or refused admission because of correctable prior notice problems.

E. *Conclusion*

GMA appreciates the opportunity to provide further input to FDA on the prior notice system. We believe that it is essential that FDA extend the educational phase of enforcement and provide notice-specific input to companies during an extended educational phase. Without an extension of the educational

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phase of enforcement, we believe that there is a substantial likelihood that the flow of food into the United States will be impeded.

Sincerely,

A handwritten signature in black ink that reads "Susan M. Stout". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Susan M. Stout
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