

**Comments on Federal Register Notice Reopening of Comment Period:
Prior Notice of Imported Food Under the Public Health Security and
Bioterrorism Preparedness Act of 2002**

The U.S. Business Alliance for Customs Modernization (BACM) welcomes the opportunity to comment on the prior notice interim final rule (IFR) originally published in the Federal Register of October 10, 2003 (68 FR 58974). The comments herein were invited by the Food and Drug Administration (FDA) under the Federal Register notice of April 14, 2004 (69 FR 19763) reopening the comment period. BACM is a coalition of U.S. companies that import and export extensively, filing over 2 million entries valued at more than \$130 billion per year. BACM is dedicated to modernization of U.S. Customs laws, regulations and policies and is committed to the facilitation of trade to the greatest extent possible consistent with customs compliance. Please see the end of these comments for a full list of BACM member companies.

BACM acknowledges the value of the recent steps taken by the Food and Drug Administration in its educational outreach efforts to the trade industry on the prior notice requirements of the Bioterrorism Act. We support and highly encourage continued greater communication between the trade community and FDA and firmly believe it to be essential to the development of workable, efficient and cost effective regulations that protect the borders of the United States while still allowing the uninterrupted flow of legitimate trade. BACM also appreciates the opportunity to provide additional feedback on all aspects of the prior notice rule process now that the trade has actual experience with the systems, timeframes and outlined data elements of that rule.

Implementation Process

BACM strongly recommends that FDA extend its discretionary enforcement period beyond the currently published August 12, 2004 date. In order to continue its important role in maintaining a positive U.S. economic outlook the trade community must retain its ability to provide for efficient and effective supply chains while fully supporting the important security mandates outlined under the Bioterrorism Act. A critical tool in achieving this goal is the phased-in enforcement plan, as outlined in the FDA's compliance guide, which allows for the necessary time and training to occur for both importers and government officials under a new and relatively untested system. Of particular importance was the intent to gather data to identify specific errors occurring with individual companies and to provide additional feedback and training to those companies that may be experiencing problems with accuracy and or timeliness of filing. BACM had understood that feedback would be provided in the form of a written communication from FDA to the importer and/or its broker in order to allow the importer time to fix any systems or process issues that may exist in regards to their current submission processes. Potential submission issues could result from one or more multiple sources (manufacturer, carrier, broker and/or importer of record) depending on the error recorded. It is critical that specific errors are promptly relayed back to importers in order for the phased-in process to translate into an "uninterrupted flow of food imports" in August 2004.

BACM understands that this portion of the first two (2) phases of enforcement has not yet been provided. The inability to provide company specific information appears to be the result of incomplete FDA/CBP systems upgrades. Until such time that these upgrades can be provided and companies can be educated regarding their individual compliance status, BACM strongly urges that the full enforcement deadline of August 12, 2004 be extended. Firms and individuals would be required to demonstrate a good faith effort at compliance while the transitional policy remained in place. BACM would support the idea that failure to submit prior notice should be fully enforced as of August 12, but believes that incomplete or inaccurate submissions should continue to be enforced by means other than a complete rejection of the loads at the border. BACM understands that full enforcement must occur and that the deadlines cannot be extended indefinitely. However, we firmly believe that an extension must occur at this time in order for these implementation issues to be considered and resolved.

C-TPAT/FAST

BACM agrees with the proposal that food products subject to the FDA's prior notice requirements be eligible for the full benefits allowed with both the CTPAT and FAST programs. While fully supporting the border security concept, many food importers have been disillusioned with the CBP border security programs to the extent that their company's participation in those programs has not allowed them the same access to the expedited processing and other program benefits due to regulation of those products by the FDA. If all of their shipments will be scrutinized upon arrival anyway because of FDA requirements, there is a high probability that companies will conclude there is little to no incentive for spending resources on participating in these CBP programs. Allowing for integrated targeting processes, including a reduction in the risk targeting factors for food shipments as well as other product categories, would translate into expedited processing, reduced exams and other benefits for food import shipments under the program.

BACM does not support modification of the security and verification processes in CTPAT to accomplish this critical objective. Food safety and product integrity is already an integral part of the industry's own internal policies. They have always been concerned and accountable for the safety and security of their products without regard to the more recent border security programs. Internal programs and food related safety processes could easily be incorporated under the guidelines established for the program by CBP.

Flexible Alternatives

BACM supports the idea of flexible alternatives for implementation of the prior notice regulation requirements.

Research and Development Samples

Feedback regarding the food industry's standard practice of importing multiple R&D samples from multiple origins and manufacturers for research and testing purposes has already been provided to the FDA. Current submission requirements under the prior notice regulations pose significant problems in maintaining this critical component of food industry practice and flexible alternatives must be considered in order to resolve this important issue.

We believe the purposes of the Act can be fulfilled where the importer does not have access to the registration number. Prior notice submissions require other identifying information that could potentially be used as a substitute for the actual registration number, such as the identity of the manufacturer and country of origin, the address of the manufacturing facility, the Manufacturer's Identification (MID) number. In most instances the FDA data base should be sufficient to apprise FDA whether one or more facilities are registered for the products in question and inspection of goods can always be accomplished at the port of entry if deemed necessary. Food importers who provide information sufficient to identify food source, manufacturer, country of export, shipper, and the other information required by statute should be allowed to import food samples without the manufacturers registration number. Some alternatives to consider would be:

- ?? Modify the submission to provide for a mechanism that would flag the sample shipments and therefore allow entry without the manufacturer's registration number. Specific requirements for exempting a shipment from the registration number could be provided as a guidance document to the trade.
- ?? Replacing the manufacturer's registration number with other identifying information for that manufacturer such as name, address, MID, etc. Based on this information it would be possible for the FDA to query their internal system and "match up" the manufacturer with its FDA registration number.
- ?? Allowing for either the manufacturer's registration number or the shipper's registration number on the submission.

BACM is prepared to work with the FDA to find a long-term solution to this significant commercial issue.

We appreciate the opportunity for providing additional feedback and comments regarding the prior notice process to date and respectfully request that you consider implementing the trade suggestions as appropriate to the regulation.

Sincerely,

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BP America Inc.
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General Electric Company
General Motors Corporation
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Lowe's Companies, Inc.
Microsoft Corporation
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Sears, Roebuck and Co.
Sony Electronics Inc.
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Ford Motor Company
General Mills, Inc.
Hewlett Packard Company
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Mattel, Inc.
Nike Inc.
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