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May 14, 2004

**By Fax and Mail**

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

**RE: Docket No. 2002N-0278 – Comments on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

Dear Sir or Madam:

I am writing on behalf of the Retail Industry Leaders Association (RILA) to express our views on the reopening of the comment period on the Interim Final Rule published in the *Federal Register* on April 14, 2004 (69 F.R. 19763) entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Comment Period."

By way of background, the Retail Industry Leaders Association, formerly the International Mass Retail Association, is an alliance of the world's most successful and innovative retailer and supplier companies – the leaders of the retail industry. RILA members represent more than \$1 trillion in sales annually and operate more than 100,000 stores, manufacturing facilities and distribution centers nationwide. Its member retailers and suppliers have facilities in all 50 states, as well as internationally, and employ millions of workers domestically and worldwide. Through RILA, leaders in the critical disciplines of the retail industry work together to improve their businesses and the industry as a whole.

RILA represents many product importers who recognize that they have responsibilities in the wake of the events of September 11, 2001, to provide timely and accurate information to the government for the purpose of assessing risks posed principally by containerized cargo. RILA's members have been on the front lines of securing their global supply chains and have worked very close with the U.S. government, especially U.S. Customs & Border Protection (CBP) on programs including the Customs-Trade Partnership Against Terrorism (C-TPAT) and Operation Safe Commerce (OSC).

RILA filed comments in April 2003 on the initial Notice of Proposed Rulemaking (NPRM) on the Prior Notice requirements of the Bioterrorism Act. In those comments, RILA called for closer cooperation between the Food & Drug Administration (FDA) and CBP. While we were pleased to see the two agencies work together on developing the Interim Final Rule, we still believe that changes can be made to the Prior Notice system that will help to alleviate the duplication that importers face when complying with the Advance Electronic Cargo Manifest requirements under the Trade Act of 2002.

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The following are responses to the questions from the April 14 *Federal Register* Notice.

### C-TPAT/FAST Questions

1. ***Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST? If so, how should this be accomplished?***

The simple answer to this question is yes. RILA fully believes that benefits under C-TPAT and FAST should not be limited solely to CBP. Those companies who have been deemed to be C-TPAT certified or validated should enjoy expedited processing from other agencies as well. We fully recognize the limitations on current government operating systems to talk to each other, but the agencies need to find a way to be able to communicate to each other which companies are C-TPAT or FAST qualified. As the agencies continue to improve their cooperation, CBP should share its list of certified and validated C-TPAT companies with the FDA to be able to use when conducting their risk assessment under the Prior Notice requirements of the Bioterrorism Act. In addition, FDA should make sure that its operatives in the field fully understand the C-TPAT program and the benefits that come along with membership.

2. ***If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the advance electronic information rule, would a shorter timeframe be needed for members of FAST?***

RILA fully believes that the timeframes for submitting Prior Notice under the Bioterrorism Act should be consistent with the timeframes for submitting Advance Electronic Cargo Manifest information under the Trade Act of 2002. RILA suggested this in its April 2003 comments. The timeframes should be the same for *all modes* of transportation, not just for shipments via truck. However, with regards to shipments from FAST members, we believe the time frames should be reduced, as they are under CBP's requirements.

3. ***Should the security and verification processes in C-TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?***

In order to avoid duplication of efforts, we believe that CBP and FDA should continue to work together to achieve the common goal of security the supply chain. Many of those companies who import products that are regulated by the FDA are already participating in C-TPAT. FDA and Customs should work together, along with the trade community, to identify potential areas where the C-TPAT security and verification processes can or should be modified. In order to do this, each party needs to understand what the other parties needs or requirements are. In addition, the agencies need to understand from the trade community as to whether or not the needs and requirements are feasible.

### Flexible Alternative Questions

1. ***If timeframes are reduced in FDA's prior notice final rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?***

If the FDA decides to reduce the timeframes in the Prior Notice final rule, which we strongly support, we would encourage FDA to allow for the transmission of the information sooner than the 5 day period currently in effect. Many times these companies have the

information well in advance of the required timeframes. These companies would like to transmit the information as soon as possible. Again, as these companies transmit the required information under the Advance Electronic Cargo Manifest requirements of the Trade Act of 2002, they should be allowed to submit the required information under the Prior Notice requirements of the Bioterrorism Act. In a perfect world, the companies would only have to submit information once that would satisfy both regulations.

- 2. In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?***

It is highly unlikely that FDA has the manpower or expertise to inspect all of the companies in the supply chain from the manufacturer forward, especially foreign manufacturers. In RILA's view, this is a duplication of efforts already underway by CBP under C-TPAT. If anything, FDA should leverage off of the C-TPAT program. Creating a second voluntary program could only lead to confusion within the trade community, especially if there are different requirements. C-TPAT participants are already required to ensure the security of all of their supply chain partners. This includes the foreign manufacturers and other facilities who might "touch" the product. Under C-TPAT, supply chain partners must have procedures in place for facility security, procedural security, transportation security, personnel security and conveyance security. All of these requirements seek to prevent the infiltration of a facility and a container. We believe these requirements are sufficient to address any concerns that FDA might have with potential infiltration.

Regarding other flexible alternatives FDA needs to improve several aspects of the current submissions process. First, FDA should allow for multiple container submissions on one prior notice. Second, correct the HTS numbers that are still not flagged as requiring prior notice, so these submissions can be handled via the Automated Broker Interface/Automated Commercial System (ABI/ACS) interface. After addressing current problems, the FDA might want to look at simplifying the process for those importers who repeatedly import the same product. One idea would be for the FDA to create a relational database to give unique ID numbers to an importer's specific items. This would speed submission, reduce time to enter the data, and increase compliance with the regulation. Most food importers will bring in the same product, in the same package, from the same country, over and over. If we are "numbering" the facilities that the food passes through, why not "number" the products as well? It's understandable to type in a food product's packaging/case pack/HTS/Description and related manufacturer/supply chain information once. But it is also time consuming to have to repeat the same information because we have a multiple container shipments of the same products, and it also increases the potential for mistakes.

- 3. In considering flexible alternatives for submission of prior notice, should FDA consider additional means of ensuring that all companies subject to the registration of food facilities interim final rule ((68 FR 58894, October 10, 2003) (21 CFR part 1, subpart H)), have an updated registration on file with FDA that has been verified?***

RILA does not believe that a flexible alternative for Prior Notice submission should rely on whether or not a food facility is registered. How does the FDA propose to "verify" an updated

registration? Will the FDA be visiting all of the registered food facilities to “verify” the registration? This will be especially difficult for foreign food facilities. One thing that the FDA could do to increase compliance with both the Prior Notice and Facility Registration would be to improve the current FDA website to be able to handle more users as well as make the site available in multiple languages.

- 4. Are there conditions of participation that FDA should consider, e.g., inspections of companies in the supply chain from the manufacturer to those who may hold the product, reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?***

As was discussed earlier, RILA does not believe that the FDA has the available resources to conduct such inspections. The FDA, along with other agencies, should leverage off of the successful C-TPAT program that already addresses the concerns of security along the supply chain. RILA does not believe the FDA should create a new “inspection” program, but should give expedited benefits to C-TPAT members.

- 5. Should the food product category be considered as a criteria or element of expedited prior notice processing or other flexible alternatives? If so, should certain foods be excluded from expedited prior notice processing? If so, what should be the basis for determining which foods should be excluded?***

RILA does not believe that product categories should determine whether or not a shipment receives expedited processing. There are numerous elements that should be considered when doing a risk assessment including food product category, country of origin, etc., but we do not believe product categories should be excluded from expedited prior notice processing.

- 6. If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?***

RILA fully believes that the timeframes under the Bioterrorism Act Prior Notice requirements and those under the Trade Act of 2002 Advance Electronic Cargo Manifest requirements should be exactly the same. Hence, the timeframes should be phased in at the same time. This will make it easier on the trade community as well as the agencies.

- 7. Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?***

Yes. The FDA should offer as much help to the importing community as possible to ensure full compliance with the requirements under the Bioterrorism Act. This should not be limited to Prior Notice, but will be especially important once the final regulations on Record Keeping are issued.

## **Conclusion**

RILA fully understands and supports the need for increased supply chain security, especially protecting our food supplies. We are encouraged by the increased cooperation that we have seen between the FDA and CBP to achieve this goal. However, we believe that there is still room for improvement. The agencies should continue to work together along with the trade community to ensure that the goals are met without overburdening the trade community and disrupting global commerce.

We look forward to working with the agency on this matter. If you have additional questions about RILA or its position on this matter, please contact Jonathan Gold, Vice President, International Trade Policy at (703) 841-2300.

Sincerely,

A handwritten signature in black ink that reads "Sandra L. Kennedy". The signature is written in a cursive style with a large initial 'S' and a distinct 'K'.

Sandra L. Kennedy  
President