

April 4, 2003

**By Hand Delivery**

Mr. Stuart Shapiro  
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Office of Information and Regulatory Affairs  
Office of Management and Budget  
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Room 10235  
Washington, DC 20503

**By Electronic Mail**

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

**RE: Docket No. 02N-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 International Mass Retail Association (IMRA) to express our views on the Notice of Proposed Rulemaking (NPRM) published in the *Federal Register* on February 3, 2003 (68 F.R. 5428) entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Bioterrorism Act).

By way of background, IMRA is the world's leading alliance of retailers and their product and service suppliers committed to bringing price-competitive value to the world's consumers. IMRA members represent over \$1 trillion in sales annually and operate over 100,000 stores, manufacturing facilities, and distribution centers nationwide. Our member retailers and suppliers have facilities in all 50 states, as well as internationally, and employ millions of Americans. As a full-service trade association, IMRA provides industry research and education, government advocacy, and a unique forum for its members to establish relationships, solve problems, and work together for the benefit of the consumer and the mass retail industry.

**Summary**

IMRA 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. While we fully support efforts to obtain accurate and timely information, we have serious concerns about the approach taken in this proposed rule on several points:

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1. The NPRM duplicates programs and efforts of the Bureau of Customs and Border Protection (Customs);
2. The NPRM unduly burdens importers;
3. The NPRM needlessly creates a new and unsecured reporting system;
4. The NPRM will seriously impact trade with Canada and Mexico;
5. The NPRM provides inconsistent definitions of traditional international trade and Customs terms; and
6. The NPRM does not provide sufficient time for importers to adjust.

### **The NPRM duplicates Programs and Efforts of the Bureau of Customs and Border Enforcement**

In December 2002, Customs promulgated new regulations to collect advanced cargo information on inbound ocean shipments 24 hours prior to the lading of the cargo at foreign ports. At the same time, Customs is working through rulemaking procedures required by the Trade Act of 2002 for the collection of advanced electronic cargo information for both imports and exports being carried by all modes of transportation. These rules must be put in place by October of this year.

These new advance cargo rules and proposals have proved exceptionally complex to develop, impose and administer. The government and the trade community continue to work out the details of these regulations, which, when they are fully promulgated, will have a major impact on business practices in the international trade and transportation industries and will require the development of new private sector and public sector information systems to handle the loads.

While IMRA recognizes that the FDA has its own statutory requirements, we urge the agency to recognize that the imports covered by its proposed rules *are also covered* by the proposed rules that Customs has already developed and is in the process of developing.

Indeed, the Bioterrorism Act directs the FDA to work closely with Customs to develop a process for collecting the advanced information. IMRA strongly believes that many of FDA's information needs can be handled in a coordinated fashion with the Department of Homeland Security and the Bureau of Customs Enforcement and Border Security. The best security can be achieved if the government ensures that importers deal with one set of regulations that do not require duplicate information to be filed with more than one agency.

### **The NPRM unduly burdens importers**

As noted above, the trade community has spent months working on the implementation of the 24-hour rule as well as preparing for the upcoming rules for all modes of transportation. The activities include educating foreign vendors and suppliers, upgrading information technology systems and continuing a dialog with Customs to better understand targeting needs and to coordinate a response to the real threats. The FDA regulations come in the middle of this process and impose new burdens on these companies that mirror what Customs has already done.

Equally important, the NPRM requirements go far beyond what was anticipated in the Bioterrorism Act, which lists only seven data elements, as witnessed by the five-page example of the prior notice submission.

Much of this information will have to be gathered from many different sources, and are not readily available to importers. For example, transportation information such as the anticipated date and time of arrival are not usually in the purview of the importer, but of the carrier. In the many months of work and debate on collection of pre-arrival information as part of Customs rulemaking, this bifurcation of cargo and transportation information has become a truly knotty problem. IMRA firmly believes that a coordinated public-private system must be developed to collect cargo information from importers and transportation information from carriers. Any attempt to collect all this information from a single source will ultimately fail to meet the country's security objectives.

In addition, the NRPM fails to take into account that transportation information can and does frequently change. As a result, the current rule could seriously impede the free movement of cargo. The NPRM must provide opportunities for the shipper/importer to make amendments as circumstances change.

#### **The NPRM needlessly creates a new and unsecured reporting system**

The "Background" section of the NPRM notes that the FDA already receives much of the information they are seeking from Customs through the FDA's Operational and Administrative System for Import Support (OASIS). IMRA sees no reason why the FDA should develop a brand new Internet-based reporting system for importers/shippers/agents to use.

More important, IMRA sees many problems with the security and the business confidentiality of such a system. First, FDA proposes to collect data over the Internet with no explanation how this information will be adequately secured. Second, it is not clear how FDA plans to protect "business confidential" information such as factory names or shipper names. Congress is sensitive to this issue. As part of the Trade Act of 2002 they directed Customs to develop advanced electronic cargo information systems that were both secure and protected business confidentiality and competition. FDA would do well to follow the same requirements.

#### **The NPRM will seriously impact trade with Canada and Mexico**

Stakeholders meeting with the agency have underscored that "one size fits all" does not work in the environment where perishable foods are involved. Indeed, a broad theme has been the need to maintain flexibility when setting the minimum time required for prior notice that takes account of different modes of transportation, the nature of perishable food and the needs of U.S. businesses operating close to the U.S. border.

Despite this, the NPRM appears to ignore "just-in-time" inventory practices that are particularly important in North American trade on the products covered by the rule.

In the Trade Act of 2002, Congress clearly recognized that there must be different rules for different modes of transportation. Time frames that work for ocean cargo do not work for truck or rail cargo. FDA needs to recognize this. Many IMRA members use vendors/suppliers in Canada and Mexico who are located close to the border. This is critical for the purposes of "just-in-time" inventory. In these instances, it is not uncommon for a container to be stuffed, sealed and delivered in the U.S. on the same day, usually within a couple of hours, if perishables

are involved. Much of the information that the NPRM requires won't be available by noon the previous day.

In addition, the proposed increase in hold times for food imports will have serious effects on port and border congestion. Congestion is a major problem at U.S. ports and border entries. For this reason, other U.S. agencies such as Customs have chosen to create programs such as Free and Secure Trade (FAST) on the Northern Border which incorporates participation in the Customs-Trade Partnership Against Terrorism (C-TPAT), as a means of securing the supply chain without unduly burdening trade or adding to congestion along the border, which could be a security issue itself. The NPRM, on the other hand, will delay containers, forcing them to sit at facilities where they could well become targets. A container in motion is less likely to be a target than one that sits.

### **The NPRM provides inconsistent definitions of traditional international trade and Customs terms**

The FDA sets out to create new definitions for internationally recognized Customs and trade terms. The NPRM itself notes that several of these definitions conflict with Customs definitions. IMRA strongly believes that there needs to be consistency in the use of internationally recognized trade terms. The FDA should not create new definitions that will only confuse the trade community and result in the collection of inaccurate information.

In proposed section 1.227(c)(9), "*Port of Entry*" is defined as "the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States." The NPRM itself notes that this definition is inconsistent with the definition used by Customs. Use of the FDA definition will lead to confusion and likely result in the incorrect completion of the prior notice. The term should be changed to "Port of First Arrival," and the definition of "Port of Entry" should be modified to make it compatible with the term as it appears in 19 C.F.R. §101.1, and as it is traditionally understood by the import sector.

In proposed section 1.277(c)(2), FDA adds a new definition for the "*origin*" of imported goods as the "country from which the article of food was shipped defined as loaded aboard the conveyance that brings it into the United States." This definition does not take into account the use of "feeder" vessels to move cargo from the country of origin (where the products are from) to another location for transfer to a larger vessel destined for the U.S. The importer/shipper does not necessarily know when and where this may occur. Moreover, ocean vessels frequently discharge containers destined for the U.S. in Canada, where they are transferred to a motor carrier for transport to the U.S.

The proposed definition requires that the submitter reflect the "origin" of the goods as the place it was put on the conveyance to the U.S. We do not understand how the FDA will use this information to determine if the product has been tampered with. Certainly, the rule will confuse importers and require them to (needlessly) attempt to obtain the cargo routing from the master carriers. We believe that the requirement should be changed to reflect the country where the product originated and or was last stored.

### **The NPRM does not provide sufficient time for importers to adjust**

Compliance with the NPRM will take significant time and investment on the part of the trade community. Because FDA is asking importers to provide information that they regularly

do not have, the rule imposes significant changes in business practice that go well beyond the process of filling in an Internet-based form. For instance, importers and their carriers will have to develop internal and external information systems and interoperability of those systems in a manner that is different from the current systems being developed to comply with Customs regulations. Importers will also have to train internal personnel as well as company vendors and suppliers.

For this reason, we urge FDA to follow the same approach that Customs has taken with the 24-hour rule. We would urge transition periods during which the agency helps the trade with compliance and then stage enforcement actions. If the FDA experience is anything like the Customs experience, the agency is likely to find that it has an imperfect knowledge of how the real transportation chain works and that collecting information is quite a bit more difficult than it may seem. Indeed, even the Customs service has admitted that it rushed into the 24-hour rule and has had to back off on enforcement. IMRA firmly believes that the agency will not be ready to fully enforce a rule of this magnitude come October of this year.

### **Conclusion**

IMRA fully understands and supports the need for increased supply chain security, especially protecting our food supplies. However, we believe that any new rules or regulations carefully balance the need for security versus the needs for the free flow of commerce. Unfortunately, IMRA does not believe the NPRM achieves this delicate balancing act.

We strongly encourage FDA to partner with Customs to develop a system that will meet both agencies' needs instead of competing to develop two separate and different reporting requirements. We are well aware that the two agencies operate under different statutes, but we believe that cooperation will result in a better system at less cost to the trade community and ultimately to the taxpayer. Clearly the developing of the Automated Commercial Environment (ACE), which includes modules for FDA enforcement, would be a huge help in this instance. Unfortunately ACE is still many years away. But that does not mean that cooperative efforts should be eschewed. For this reason, IMRA requests that the FDA withdraw the NPRM in lieu of cooperative efforts with Customs as part of its development of regulations under the Trade Act of 2002.

If you have additional questions about IMRA or its position on this matter, please contact Jonathan Gold, Director, International Trade Policy at (703) 841-2300.

Sincerely,

A handwritten signature in cursive script that reads "Sandra L. Kennedy".

Sandra L. Kennedy  
President