



**Driving Trucking's Success**

April 4, 2003

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

RE: Notice of Proposed Rulemaking  
February 3, 2003  
Registration of Food Facilities and Prior Notice of Imported Foods  
Under the Public Health Security and Bioterrorism Preparedness  
And Response Act of 2002

(electronic – <http://www.fda.gov/dockets/ecomments>)

American Trucking Associations, Inc. (ATA), with offices at 2200 Mill Road, Alexandria, Virginia 22314-4677, is the trade association that represents the American trucking industry<sup>1</sup>. As the national representative of the trucking industry, ATA is vitally interested in matters affecting the nation's motor carriers, including the implementation of security requirements affecting the transportation of food. For this reason, ATA and its affiliated conference, the Agricultural Transporters Conference (ATC) are submitting these comments on the prior notification and facilities registration provisions of the Bioterrorism Act.

This letter is in response to the Department of Health and Human Services' Food and Drug Administration's Notice of Proposed Rulemaking (NPRM) for Registration of Food Facilities and Prior Notice of Imported Foods Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act") published in the *Federal Register* on February 3, 2003. Beginning December 12, 2003, the Bioterrorism Act requires that FDA collect prior notice of imported food shipments, no less than 8 hours and not more than 5 days prior to importation.

### **Background**

The trucking industry is a critical link in the economic interdependency among the United States, Canada and Mexico, moving approximately 74 percent of the value of freight between

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<sup>1</sup> Through our affiliated trucking associations, and their over 30,000 motor carrier members, affiliated conferences, and other organizations, ATA represents every type and class of motor carrier.

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the United States and Canada, and about 83 percent of the value of U.S.-Mexico freight<sup>2</sup>. The increasing trade volumes that have been generated among the three North American Free Trade Agreement (NAFTA) partners have not only been good for the economic well being of our countries, but also have allowed businesses throughout North America to diversify, expand, improve their asset utilization, and access new markets for their products. According to U.S. Customs, during 2001 6.8 million trucks entered the U.S. from Canada, while 4.4 million entered from Mexico, resulting in more than 13 million truck crossings a year on the northern border, and more than 8 million crossings on the U.S. southern border. NAFTA has generated a large increase in the amount of trade in the food, beverage and agriculture sectors throughout North America: U.S.-Canada trade in these areas has increased from \$16 billion in 1997 to \$20.4 billion in 2001, while U.S.-Mexico trade for the same period increased from \$8.1 billion to \$11.6 billion.<sup>3</sup>

ATA has a number of serious concerns regarding this FDA NPRM, which are discussed throughout this response. Briefly, some of our major concerns include:

- FDA should not propose to create a new separate import data system, and instead should work with systems already in place, and actively participate in the development of new systems such as the Automated Commercial Environment;
- FDA must realize that there are various types of motor carrier operations in existence, and recognize that a one-size-fits-all approach does not work;
- The NPRM does not address how motor carriers can ascertain that pre-file information has been sent by importers to FDA for clearance prior to the truck arrival at port of entry;
- The NPRM's definition of "holder of food" should not be interpreted to subject various segments of a motor carrier's operations to registration requirements; and
- Nowhere in the NPRM is consideration given to cross-border and supply-chain security programs established by other agencies improving targeting and cargo security.

## **I. Prior Notification**

The NPRM specifies that pre-notification must be submitted by "purchaser or importer of an article of food (or their agent) who resides or maintains a place of business in the U.S." by noon the calendar day prior for FDA-regulated freight crossing the border. In addition, the NPRM states that amendments to the pre-arrival notifications may be made up to 2 hours prior to arrival at the port of entry. The FDA requires that entry-level information be forwarded by importers or their agents – which could include the shipper and/or the customs broker. Under current practices, carriers never receive the detailed information as to individual manufacturer, point of origin, size of container, and product specificity demanded by the FDA proposed rules. Therefore, this information will never be in the hands of a motor carrier prior to picking up the

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<sup>2</sup> Bureau of Transportation Statistics, U.S. Department of Transportation

<sup>3</sup> Trade and Economy: Data Analysis, International Trade Administration, U.S. Department of Commerce, <http://www.ita.doc.gov/td/industry/otea/usfth/top80cty/top80cty.html>

load or crossing the border unless profound and costly alterations occur in industry practices, information systems, and customer relations. It is not feasible, practical, or cost effective that a motor carrier would be able to provide this significantly detailed information to the FDA.

### **Need for Separate Data System**

ATA questions the need for a separate FDA data collection system from the currently-used OASIS system. Considering that FDA is a participant in the development of Customs Automated Commercial Environment (ACE) and its International Trade Data System (ITDS) ATA does not believe that FDA should establish a separate system at this time. If a “new” web-based OASIS system is created by FDA, this would imply that the trade community would have to absorb the costs for any programming to communicate with the system. Furthermore, considering the future implementation of ACE/ITDS, ATA questions if this new FDA system would then be absorbed into the ACE/ITDS. This is an important point for members of the trade community, who will soon be asked to spend millions of dollars to build into the new ACE/ITDS system, which will become the permanent system that will be used for imports and exports.

Members of the trade community, primarily customs brokers, argue that FDA’s system should continue to receive information via the Automated Commercial System. Presently, brokers send cargo information via the Automated Broker Interface (ABI) system to the ACS which then forwards it to OASIS. This issue was brought up in February 2003 at two separate meetings where members of the community and FDA representatives were present. At one of these meetings, the Trade Support Network (TSN) meeting, U.S. Customs Commissioner Robert Bonner, indicated that the ACE/ITDS system will be the single government entity where all trade data and information should be filed for all agencies involved in cross-border or international freight data collection. This one-stop ACE/ITDS system will promote operational efficiencies, both within the government and within trade. If the FDA creates a separate system, this means that the trade community must key the same information into several different systems, increasing the risk of clerical errors and the risk that freight will be stopped at the borders. Of course, this approach would also increase costs with no apparent benefit to either FDA or the trade community.

ATA urges the FDA to work closely with the new Bureau of Customs and Border Protection (BCBP) of the Department of Homeland Security (DHS) to find a way to incorporate the agency’s data requirements into ACE/ITDS. This could be accomplished by either expanding or modifying the scope of the data collection capabilities of the system to include importers or their agents.

### **One Size Does Not Fit All**

Many of the movements of goods by truck over the border and through the United States are not done on a rigidly scheduled basis. Rather, these movements are done on demand, often on an expedited basis. For air, ocean, and rail, this scenario does not apply, because they tend to adhere to more rigid schedules. In addition, the way goods are shipped – whether they are foodstuffs or widgets or clothing – varies according to which transport mode is used. In order to accommodate the operational differences among the transportation modes, and the different types of operations within each mode, ATA suggests that the FDA avoid implementing a “one

size fits all” rule. Rather, we suggest, as is currently being done by Customs for the Trade Act of 2002 requirements, that the agency look at the operational capabilities and realities of the different modes to formulate mode-specific rules for pre-notification. We also suggest that the agency work closely with BCBP to ensure that the rules for importation and exportation of food do not conflict with Customs requirements.

### **Advanced Targeting Time**

The FDA NPRM proposes that freight data be presented to the agency by noon the day prior to regulated freight crossing the border. This results in the agency having almost 18 hours to screen the data, which seems excessive to perform adequate risk analysis and targeting. These pre-notification FDA requirements should be in some way harmonized with the pre-notification requirements for trucks being currently discussed between the trade community and BCBP. If FDA’s intent is to request pre-notification of cargo information to undertake appropriate risk analysis of such cargo, ATA recommends that FDA work closely with BCBP to allow for FDA’s system to interface with Customs’ Automated Targeting System. Again, ATA will not support a separate cargo targeting system by FDA.

### **Arrival/Timing Issues**

FDA’s proposed requirement to receive information the day prior to arrival at the border on the exact port of arrival and the time of arrival is very problematic operationally. First, these informational requirements conflict with BCBP’s ACE/ITDS requirements, which are more flexible, allowing carriers to change ports and arrival times in response to operating requirements. Second, the requirement for accuracy of timing within one hour prior and three hours after the expected arrival time is unfair to importers, shippers, and motor carriers that all must contend with unexpected events that change plans.

For example, a less-than-truckload (LTL) carrier will consolidate and redistribute various shipments within a hub and spoke system, as required by the various shippers and importers who are the motor carrier’s customers. During these operations, individually manifested loads are loaded up to the last minute before departure, sent to a location across the border, which is the next transshipment cross docking operation, where the load is redistributed onto other vehicles for routing until the shipment reaches the consignee.

The constraints imposed by the FDA proposed rules significantly curtail the efficiency of these just-in-time operations and presents logistical challenges currently not impeding the U.S. freight distribution system.

Changing the port of arrival should not be a cause for alarm and should not trigger a full inspection and the associated delays. Rather, motor carriers should be able to exercise their options in choosing a more expeditious route to cross the border, based on weather conditions and/or traffic conditions, among other reasons. Arrival time at any given port of entry may be influenced by the same conditions and is, therefore, subject to fluctuations. For these reasons, crafters of the ACE/ITDS system have shied away from asking carriers (or others) to provide this type of information.

### **Certification of Pre-Notification for Transportation Providers**

From the motor carrier's perspective, a major concern regarding the proposed rule is that trucking companies picking up FDA-regulated freight in Canada or Mexico bound for the U.S. have no means of validating that the importer, shipper, or customs broker has indeed filed the appropriate pre-notification notice. FDA has suggested that motor carriers require proof of pre-filing. ATA questions what form of proof the FDA (or other border regulatory agencies) would consider acceptable to release the motor carrier from responsibility in the case that the pre-notification was not appropriately filed. It is not clear if the FDA is planning on issuing an official document to the importer, shipper, or customs broker that the motor carrier could request from these entities to ensure that the cargo information has been pre-filed with FDA. For trucking companies, the possibility that their trucks might be turned back or held for clearance at a port of entry simply because of an importers' failure to pre-file, or for the importer or the FDA to correct the problem, is an unacceptable situation. The motor carrier's potential loss of productivity due to equipment being denied entry, or being held, could have a serious negative impact on the bottom line of cross-border trucking operations. In addition, such downtime could have a serious negative impact on truck drivers' compensation because of the loss in miles driven. The agency should explain how a motor carrier could be assured that the information has been transmitted in a timely manner. In mixed load situations, many importers would be penalized by the action of one party over which neither they nor the carrier have control.

## **II. Registration of Facilities**

### **Definition of Holder of Food**

The very broad definition for "holders of food" leaves truck terminals, gas stations, private homes, hotels and motels, truck stops, and even trucks themselves vulnerable to being defined as "holders of food" and thereby subject to burdensome reporting requirements. Truck drivers are required by law to stop and rest after a certain number of hours on duty, which can result in the driver being forced to stop in various types of locations as mentioned above. Trucks loaded with FDA-regulated foodstuff (bottled or canned goods, for example) imported from plants in Mexico or Canada into the interior of the U.S. will likely be required to make a stop in order to comply with the Federal Motor Carrier Safety Administration's (FMCSA) safety regulations. ATA believes that the locations at which the truck stops for its required rest period should not fall under the definition of "holders of food." Also, on occasion a carrier may park a loaded trailer at a terminal for further dispatch, which normally occurs within 24 hours, during which time the food remains in the trailer. It is also not unusual for a LTL shipment of food to require a delivery appointment necessitating that it be held at the destination terminal until the day of the appointment. This could be several days, especially if a weekend is involved. Again, ATA believes that such an occurrence should not be within the definition of "holding," which would require the carrier to register with FDA.

FDA should narrow the definition of "holder of food" in keeping with the intent of the law and the realities of trucking industry's business practices.

### **Expedited Transportation and Less-Than-Truckload Issues**

For expedited food shippers and/or importers, the requirement to pre-file freight information the day prior to importation would virtually eliminate the entire expedited transportation industry. Expedited freight carriers consider FDA's suggestion that importers simply go ahead and file information on a possible shipment one day in advance "just in case," would clog the system with useless entries, create extra work for everyone, and pose additional demands on thinly-stretched agency targeting resources. Such a proposal is very inefficient, both from a regulatory and a business perspective.

For LTL carriers, who consolidate the shipments of various customers into a single trailer, FDA's rule poses an additional challenge. For example, FDA should consider that an LTL carrier may have dozens of shipments in a single trailer with only one shipment being regulated by FDA. In such a scenario, ATA does not believe that the entire trailer should be held up. FDA could request to have the one regulated shipment off-loaded, keeping in mind that the shipment might be located at the front of the trailer. This is a critical operational issue for LTL motor carriers, whose productivity is based on keeping freight in motion and whose other customers expect their shipments to be delivered in a timely manner. This is an especially big concern for small package carriers, which may have thousands of overnight or expedited shipments on one trailer.

#### **FDA and Food Supply Chain Import Security**

In 2002, the former U.S. Customs Service, now BCBP, developed and established its Customs-Trade Partnership Against Terrorism (C-TPAT), a voluntary program designed to ensure security for the entire supply chain, including manufacturers, importers, transportation providers, brokers, and other entities that might be involved in international trade. The main thrust of C-TPAT is to ensure that the various links in the supply chain are "known entities." By separating the low risk producers, importers, carriers, and brokers, agencies can better utilize limited resources to target entities that represent a higher risk than the known entities.

To incorporate the motor carrier industry into the C-TPAT program, Customs established the Free and Secure Trade (FAST) program to facilitate the movement of C-TPAT cargo being transported by trucks. Utilizing bar-codes and eventually EDI transmissions for pre-notification of the arrival of cargo at the border under FAST, Customs is able to deal with known entities at all links in the supply chain and to receive cargo information prior to arrival at the port of entry for targeting purposes. We urge FDA to work with BCBP to become an agency partner in C-TPAT, in order to take advantage of this already existing security program that could assist FDA to better secure the importation of foodstuffs into the U.S. and prevent a duplication of government agency efforts at the borders.

### **III. Conclusion**

ATA and the trucking industry share FDA's and our entire nation's concern for securing our national and economic security. In addition to reactive measures our industry has taken to comply and work with various proposals by Congress and regulatory agencies, the trucking industry has also initiated a number of proactive measures regarding the security of our operations after, and even well before, the terrorist attacks of September 11.

For many years, motor carriers have faced the challenge posed by organized groups involved in cargo theft. In the trucking industry, cargo theft alone represents between \$12-15 billion dollars in losses every year. To help coordinate efforts among the various segments of our industry to fight cargo theft, ATA established a council over a decade ago comprised of security directors of trucking companies. After September 11, ATA expanded our industry's efforts to ensure that a commercial vehicle not be used to transport a weapon of mass destruction or that it be used as a weapon itself. This effort resulted in the creation of an American trucking industry Anti-Terrorism Action Plan (ATAP). ATAP has allowed trucking industry representatives to present a solid front to stem the possibility of a terrorist attack on our transportation industry and infrastructure. ATA has closely coordinated many of ATAP's principal initiatives with state and federal government agencies to help monitor our transportation modes and our nation's highways.

In addition to coordinating with various segments of the transportation industry, ATA has also had to interact with a large number of government agencies that have been developing separate security initiatives that could have an impact on trucking operations. One of the reasons ATA supported the creation of a Department of Homeland Security was to assist in coordinating and consolidating under a single department and chain of command these various government agencies. Clearly, there are agencies outside of DHS that will continue to have an important role to play in ensuring our nation's security. However, ATA believes that it is essential that all agencies planning on developing security initiatives impacting international trade coordinate closely with agencies within DHS, such as BCBP and the Transportation Security Administration (TSA) in order to avoid duplicity of efforts by both government agencies and the trade community. With this primary concern in mind, ATA, therefore, requests that FDA work closely with the present systems that are being operated by BCBP and that it also actively participate in the development of projects, such as ACE/ITDS, that will eventually result in an improved international trade operating environment for both industry and government, in lieu of pursuing the duplicative and burdensome requirements of this NPRM.

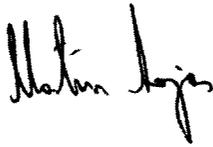
In summary, ATA urges that the following issues be taken into consideration by FDA when drafting the final rule:

- It is critical that FDA work with the BCBP in ensuring that the data elements that the FDA needs are being captured within the ACS and that they are included within the ACE/ITDS system instead of developing a separate system;
- FDA must understand that there are various types of operations within the trucking industry, and each type of operation or segment must be taken into consideration when developing the final rule;
- FDA must also clarify how the agency expects motor carriers to know that the cargo information has been pre-filed by the importer prior to the truck arriving at the border. An official document or system would need to be developed so that motor carriers can set up their runs accordingly;
- One of the issues of most concern within the NPRM is the potential for the definition of "holder of food" to be construed too broadly impacting the ability of drivers and motor carriers to comply with hours of service regulations by the FMCSA; and,

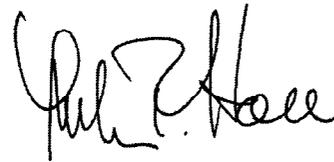
- Lastly, FDA should review programs such as C-TPAT and FAST to understand how these programs ensure that the security of the entire supply chain not be at risk. Such programs provide a way of improving resource utilization by targeting those entities that pose a high risk compared to low risk known-entities.

ATA appreciates the opportunity to comment on this NPRM, and we look forward to working with FDA and all other government agencies in ensuring our national and economic security. Should you have any questions related to these comments, please call Martin Rojas at (703) 838-7950.

Sincerely,



Martin Rojas  
Director  
Office of Customs, Immigration & Cross  
Border Operations



Fletcher Hall  
Executive Director  
Agricultural Transporters Conference