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Driving Trucking's Success

July 8, 2003

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

RE: Notice of Proposed Rulemaking
May 9, 2003
Recordkeeping Requirements and Administrative Detention
Under the Public Health Security and Bioterrorism Preparedness
And Response Act of 2002
Dockets #02N-0275 and 02N-0277

(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 U.S. trucking industry¹. 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)², are submitting these comments in response to the Department of Health and Human Services' Food and Drug Administration's (FDA) Notice of Proposed Rulemaking (NPRM) for recordkeeping requirements and administrative detention rules under the Bioterrorism Act published in the *Federal Register* on May 9, 2003.

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 the

¹ 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.

² The Agricultural Transporters Conference of the ATA is the only national organization representing the interests of commercial transporters of agricultural commodities and foodstuffs.

2002 N-0275

EMC 61

United States and Canada, and about 83 percent of the value of U.S.-Mexico freight³. 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.⁴

Commercial agricultural transportation accounts for the movement of a significant percentage of all food either imported into the United States or transported domestically. This is especially true of perishable foods -- especially produce -- where more than 90 percent of shipments are by truck. Food grains, liquid bulk shipments of milk, wine, flour, and other foods are transported by tank carriers. Commercial operations for transporting perishable foods are vastly different, with significantly diverse time requirements, from operations for transporting processed foods.

The proposed FDA regulations for recordkeeping and maintenance, found in section 1.352 of the proposed rules, do not reflect the realities of the agricultural commodity transport component of the trucking industry. For many commercial agricultural carriers, the establishment and maintenance of records containing all information required in the proposed rule, for each food they transport, is not practical and may be nearly impossible in the case of some foods. This is especially true for produce and liquid bulk food transport.

The same section (1.352) requires a detailed description of the food being transported. Again, we must point out that there are differences between bulk and packaged food transportation. For example, a bulk trucking company will pick up a load of bulk liquids, such as orange juice, milk, or corn syrup, or dry bulk products such as flour or cornstarch. The carrier will know that it is to pick up 5,000 gallons of orange juice. A generic description of the product and the number of gallons or pounds loaded is the only information to which the bulk carrier is given access. The detailed descriptive information requirements in the proposed rule, which includes listing brand names, specific variety, and packaging types for packaged food products, should not apply to bulk loads because the carrier has no access to such information, and some requirements of this section are not applicable.

Therefore, we strongly urge the FDA to gain a more thorough understanding of the operations of the varying segments of the food transport system through site visits and discussions with these

³U.S. Department of Transportation, Bureau of Transportation Statistics, Transborder Surface Freight Data.

⁴ 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>.

sectors in order to appropriately revise the required recordkeeping and maintenance data elements proposed in the agency's rule.

In addition, ATA and the ATC have a number of concerns about FDA's proposals, including the continuing lack of a clear definition for "holders" of food; compliance time frames for small businesses; the agency's inaccurate economic impact assessment estimates; documents that will meet the recordkeeping requirements; exemptions from the recordkeeping requirements; the time line required for retrieval of documents; the description of merchandise; lack of agency detention facilities; and the carrier's right to appeal detention. A discussion of these issues follows.

GENERAL ISSUES

Definition of Holder of Food

The lack of a definition for "holders of food" continues to leave a carrier's terminal operating facility, gas stations, truck stops, and even trucks themselves vulnerable to being defined as "holders of food" and thereby subject to burdensome reporting requirements. FDA needs to clarify and narrow the definition of "holder of food" to exclude trucks, truck terminals, and facilities in keeping with the intent of the law and the realities of trucking industry's business practices. In addition, the definition of "holder of food" should specifically detail who FDA considers "holders of food" and under what circumstances food is being held in transport.

One Size Does Not Fit All

Trucking operations differ from sector to sector within the industry. A less-than-truckload carrier does not operate exactly the way a truckload carrier would. Nor does either of them operate the same as an express carrier. Even within the agricultural carrier sector of the industry, carriers of perishable foods and non-perishable foods have vast differences in their operations.

Within the motor carrier industry as a whole, truckload carriers, less-than-truckload carriers, small package carriers, tank truck and bulk carriers, and others that would be involved in the transport of either fresh produce or canned, bottled or other foodstuff, all have unique operations. For instance, while truckload carriers will generally haul one shipment per trailer, less-than-truckload carriers may have forty or more shipments on one trailer, which are sorted and delivered by means of a hub-and-spoke sorting system. Tank carriers may also commingle freight from more than one customer. Small package carriers haul freight bound for homes and businesses, and, like LTL's, generally have many shipments on one truck or trailer – some of which may be subject to FDA's jurisdiction – that are sorted and re-sorted in a hub-and-spoke system until they reach a final delivery truck.

In order to accommodate the operational differences among the sectors of the trucking industry, ATA and ATC suggest that the FDA avoid implementing a "one size fits all" rule for transportation providers. 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 and sectors of each transport mode to formulate mode-specific rules. For example, we suggest that the agency work closely with Customs to ensure that any rules for importation and exportation of food do not conflict with Customs requirements.

FDA and Food Supply Chain Import Security

In 2002, the former U.S. Customs Service, now the Bureau of Customs and Border Protection (CBP), 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. C-TPAT's function 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.

ATA and the ATC suggest that the FDA work with Customs in order to take advantage of the cross-border supply chain security program already in place, to avoid burdensome duplication of effort.

Economic Impact Estimates

The numbers FDA uses in its economic impact analysis for the trucking industry are significantly underestimated. The U.S. Department of Transportation (U.S. DOT) has close to 600,000 "operating authorities" on file, which includes domestic carriers and Canada and Mexico-domiciled carriers. It is impossible to know how many of these entities are actually currently doing business. We do know, however, that there are at least 3.16 million licensed commercial truck drivers.⁵ These numbers, while they cannot pinpoint exactly how many trucking companies are currently operating in the U.S., give us a good idea that the number is a great deal higher than the FDA estimate of 15,000 trucking companies and packers affected.

For an indication of the number of trucking companies operating just at the southern border, turn to a report done for the U.S. DOT by the International Association of Chiefs of Police, released in September 2000.⁶ This study determined the number of trucking companies operating at the southern border to be 80,000. Of that number, 63,000 were determined to be Mexico-based companies. These numbers were extracted by examining U.S. Customs (now the CBP) records at the southern border. If, according to Customs and FDA estimates,⁷ 20 to 30 percent of freight crossing the border is FDA-regulated, this means at a minimum, the number of Mexican trucking companies crossing the southern border alone with FDA-regulated goods would be 12,000 or

⁵ Bureau of Labor Statistics, Department of Labor, Household Data Annual Averages, Table 39, for 2001, published 2002.

⁶ Estimates of Commercial Motor Vehicles Using the Southwest Border Crossings, by Economic Data Resources and International Association of Chiefs of Police for U.S. Department of Transportation, September 20, 2000.

⁷ FDA satellite download discussion May 7, 2003.

more. This number does not begin to include motor carriers hauling FDA-regulated goods at the northern border and domestically. We suggest that the economic impact on U.S. motor carriers is far greater than FDA has projected.

Recordkeeping Requirements

Information Requirements and the Bill of Lading

FDA representatives recently indicated that, contrary to initial discussions in August of 2002, the agency will not “endorse” the bill of lading as the document that fulfills the recordkeeping requirements of the Act. We urge FDA to reconsider its position. If the agency deems the information on the bill of lading insufficient to meet its needs, this will force carriers (and others) to create a new recordkeeping system, thus incurring large additional costs and potential duplication.

Bills of lading for motor carriers are legal documents, and contain sufficient information for the agency to be able to fulfill its Bioterrorism Act responsibilities. The information to be included on the bill of lading is proscribed by the U.S. DOT at 49 CFR Part 373.101, which states:

“Every motor common carrier shall issue a receipt or bill of lading for property tendered for transportation in interstate or foreign commerce containing the following information:

- (a) Names of consignor and consignee
- (b) Origin and destination points
- (c) Number of packages
- (d) Description of freight
- (e) Weight, volume, or measurement of freight (if applicable to the rating of the freight)

And 49 CFR Part 379.3 dictates that a motor carrier’s bills of lading must be kept for one year. We believe that one year, as in the FMCSA regulations, is sufficient time for motor carriers to retain the bills of lading for both non-perishable and perishable goods. Motor carriers do not segregate their bills of lading by product, so the 2-year time limit requested by FDA for retention of bills for non-perishable goods exceeds requirements set forth by the FMCSA and would place an onerous burden on motor carriers to sort these documents – which number into the hundreds of thousands for some carriers -- yearly. A requirement that motor carriers keep several sets of records in order to satisfy FDA requirements is burdensome, and likely to produce roadblocks when the agency needs records quickly.

ATA and the ATC request that for the sake of accuracy and regulatory consistency, the FDA Final Rule recognize that compliance with FMCSA’s bill of lading regulations constitutes compliance with the motor carrier’s obligations under §1.352. The information required by FMCSA’s regulations for purposes of ensuring orderly transport of goods in commerce are more than adequate to enable FDA to trace food shipments without the need to impose further burdensome information requirements on motor carriers. This is especially true because the motor carrier will not be the sole source of information upon which FDA will rely when tracing goods.

ATA and the ATC concur with the Truckload Carriers Association (TCA) and the Distribution and LTL Carriers Association in requesting that FDA expressly provide in its Final Rule that compliance with FMCSA's requirements under 49 CFR Parts 373.101 and 373.103 constitute compliance with §1.352.

In addition, the FDA's proposed record retention requirements for motor carriers need to be consistent with FMCSA's retention requirements for bills of lading. ATA and the ATC concur with the TCA and the Distribution and LTL Carriers Association that record retention requirements under §1.360 should be revised and made the same for both perishable and non-perishable goods, and the FDA should adopt FMCSA's one-year retention requirement for bills of lading.

FDA has not addressed the question of records retention when a motor carrier goes out of business, which is addressed in 49 CFR Part 379.9. We suggest the agency coordinate its requirements with FMCSA's requirements in this area as well.

In addition, while food items have different characteristics than Hazardous Materials (Hazmat), maintaining their security in transportation and collecting information concerning them could be very similar. Therefore, we recommend that FDA review the shipping paper requirements for Hazmat when finalizing its Bioterrorism Act regulations. The federal requirement for retention of Hazmat bills of lading is 375 days⁸. This period of time would be more realistic and appropriate.

As set forth in the proposed regulations, it is unclear whether a carrier's freight brokers would be required to maintain records. While these brokers do not ever have actual physical possession of freight, they act as the middleman for carriers and shippers and have knowledge of where the freight came from and where it went.

There is concern in the motor carrier industry about FDA's requirements creating duplication of effort amongst the various entities required to keep records. The agency should work with food processor associations, aimed at perhaps sharing information electronically with the agency to avoid duplication of efforts. Because motor carriers must store information about the hand-off of freight from/to them and processors need to store the same information, it would be beneficial to share as much information as possible and minimize duplicate data entry.

"Responsible Parties"

Both §§1.352(a)(1) and (a)(2) refer to "responsible individuals." For determining a "responsible party" for purposes of the FDA regulations, we need to know how specific these rules will be for tracking every person handling a shipment across a dock. At a trucking company's cross-dock facility, will the "responsible party" be the manager of the facility or anyone who touches a shipment? And when a carrier gathers information from a shipper for a pickup, is the name of the actual person handling the shipment sufficient, or does FDA want the name of a management contact that requested the pick-up?

⁸ 49 CFR Part 172.201.

When carriers pick up and deliver goods, in most instances, the person handling a pick up or delivery at a customer's warehouse location is a warehouse worker with little responsibility for the shipment. These warehouse workers are charged with either filling an order or taking an order off of a truck. They bear little overall responsibility for the freight itself. In this scenario, would a signature on a bill of lading meet the "responsible party" requirement? If not, motor carriers could have difficulty complying with this portion of the proposed regulations.

Less-than-truckload motor carriers, which carry freight long distances by utilizing a hub-and-spoke system to sort freight bound for different destinations, will be especially hard hit by the "responsible party" requirement. From a less-than-truckload standpoint, §1.352(a)(6) will be very difficult to enforce. If one responsible individual will not suffice, the carrier and the FDA will potentially be required to maintain information on a large number of employees. For example, a shipment that is picked up will fall under the responsibility of:

- the pick-up driver
- the outbound dock workers
- the linehaul driver
- several dock workers at the intermediate/breakbulk terminal
- the delivery driver.

The above list does not take into account all of the supervisors who will come in contact with the shipment. And this list assumes that only two LTL carrier terminals will be involved in the move. It is foreseeable that LTL motor carriers will be forced to place a surcharge on food shipments to cover the additional cost associated with handling FDA-regulated shipments, as is currently being done with Hazmat shipments..

In proposed §1.352(a)(6), we also note that when freight is in transit the driver is the responsible party, but while a shipment transfers at an LTL carrier's service center, that service center's manager would be the responsible party. Speaking in general terms, in a warehouse environment, numerous dock workers and other employees have access to the shipment and all people handling or having access to the shipment are not documented. We have questions about the database of record retrieval contacts that the agency will maintain. How will this database be kept up to date? How frequently will updates be done? How many company contacts will FDA require to be in the database? How large will the database be? Is this information to be kept confidential and exempted from FOIA requests?

In short, we request that the agency outline the process that would be utilized to request information or records. Will the agency need business phone numbers for contacts ("responsible parties") or does the agency intend to collect home and work contact information? How will this contact be made? For very large motor carriers that may have more than 300 operating locations and more than 20,000 employees, with hundreds of thousands of shipments in their systems at any given time, an automated tracking system will more than likely be utilized. However, access to information in such a system would, of course, be restricted and a very limited number of people would be able to respond to requests for information. FDA's Final Rule should outline

the information recovery process and that process must be one that will work for carriers of all types and for the FDA, if the desired tracking results are to be realized.

Exemptions to Recordkeeping Requirements

We take strong exception to the exemption from recordkeeping requirements provided for foreign carriers, and suggest that FDA should include Canada and Mexico-domiciled transportation providers in this requirement. Many Canadian and Mexican-owned motor carriers routinely operate in the United States. When the southern border is opened to Mexican carriers to travel into the U.S., this number will increase.

If FDA deems it is able to perform its Bioterrorism Act mission of tracking shipments without information from Mexican and Canadian motor carriers, we question why U.S.- based motor carriers must comply with this requirement. If Customs figures for Mexico-domiciled carriers, referenced in the "Economic Impact Estimates" section, above, – i.e., 63,000 out of 80,000 carriers operating across the southern border are Mexico-domiciled -- are correct, the majority of cross-border FDA-regulated shipments at the southern border may be exempted.

We suggest that a) either Canadian and Mexican carriers be included in this requirement, or b) that all motor carriers – U.S., Canadian and Mexican – be exempted from this requirement.

In addition, has the FDA considered the sometimes convoluted and complicated ownership-partnership relationships that abound in the trucking industry? For instance, if a trucking company owns a Canadian subsidiary, how does that impact the Canadian subsidiary's reporting requirements? If a Canadian trucking company is in partnership with a U.S. company, depending on the percentage of U.S. ownership, how does that impact the reporting requirements on the Canadian side? If a Mexican motor carrier has a contractual or interline relationship with a U.S. company, what is the reporting responsibility of that Mexican carrier?

We also suggest that the agency reconsider its exemption for private carriers.

Compliance for Small Businesses

Small businesses – which include most motor carriers in the United States -- are not required to comply with FDA's regulations on the same time schedule as larger entities. For small businesses (fewer than 500 but more than 10 full-time employees), the FDA proposes a 12-month compliance period, and for very small businesses (10 or fewer employees) an 18-month compliance period. But for larger businesses, the agency proposes a time frame of 6 months from the date the final rule is published. However, FDA has made an exception to these time frames if a contractual relationship exists between a smaller and larger company. In that case, the smaller company, which is on either the 12 or 18 month compliance timetable, would have to comply with the 6-month time frame for the larger business. We suggest that FDA reconsider this exception, and allow small businesses to comply on the 12 and 18 month schedule.

Timeline for Retrieval of Records

ATA and ATC are also concerned about the time line for retrieval of records and whether that time line will meet the agency's needs in all circumstances. Will the agency always need 4 hours during working hours and 8 hours on weekends in order to track any and all types of food

emergencies? Are there differing levels of food emergencies that may require lesser or greater timelines? If so, these should be clearly communicated.

In addition, the time requirement as outlined in the proposed rule may be onerous for some motor carriers that do not operate their terminal facilities 24 hours a day, 7 days a week. In some cases, terminals are closed on weekends, and companies may utilize this down time for extensive IT maintenance, which in turn would interfere with timely retrieval of records, if needed.

Descriptions of Merchandise

In general, motor carriers or other transportation providers want to be concerned only with transportation information. Descriptions of merchandise -- such as food -- appear on a shipper's bill of lading, but lot numbers and brand names of merchandise are not required, and they are not usually part of the product descriptions given to transporters. Lot numbers fall under the purview of the shipper and the importer, but not the motor carrier. For any shipment information, motor carriers are at the mercy of shippers, who create the bills of lading. In §1.352(a)(3), the carrier's responsibility for the description of the food should be limited to the description provided by the shipper. With thousands of food types, the transporter should not be required to be a food type expert. For cross-border carriers, more detailed descriptions of cargo may encroach in the forbidden area of "doing Customs business," which is the exclusive territory of a customs brokers. FDA should shine its enforcement light in this area on shippers and allow motor carriers to be held accountable for information on the bill of lading only.

More specifically, §1.352 must provide, as the HazMat Regulation (HMR) does, a declaration, certified by the shipper, that the freight being offered for transportation is in fact a foodstuff and is properly described. Having made that declaration the shipper must then be required to provide the information in §1.352(a)(1) on the original bill of lading at the time of pick-up. LTL and truckload carriers cannot afford the time required for its drivers to collect the information line by line during a pick-up event. The lost productivity associated with the line by line collection of information would have a dramatic adverse effect on the very thin profit margins of carriers. Likewise, the information collected from the shipper under §1.352(a)(2) should also be required in a pre-printed format readily available and verifiable by the carrier's driver upon delivery. Addressing the information to be captured under §1.352(a)(3), motor carriers would find it very difficult to verify the adequate description of the type of a food and, therefore, the certification statement by the shipper is very important to the process. However, even with a certification statement, the process could be improved through the use of an identification system like the HMR's requirement for a UN/NA number for any HazMat shipment. Mirroring the HMR, drivers could check the certified bill of lading with identifying number on the freight tendered to ensure a match prior to leaving the food shipper's dock.

A recurring question in the transportation security scenario is how motor carriers are to deal with shrink-wrapped pallets. Some goods are routinely palletized for shipping ease or at the request of the customer, and a truck driver does not have the ability to unwrap and rewrap these pallets in order to do a piece count or a lot number check. Motor carriers should be exempted from this requirement to check or record lot numbers. In addition, for motor carriers bringing FDA-regulated goods into the U.S. from Canada and Mexico, the CBP's Automated Commercial

Environment Multi-Modal Manifest system, an electronic manifest that will be used by all modes, including motor carriers, does not require lot numbers.

The information required in §1.352(a)(4) must also be clearly displayed on the bill of lading and a requirement of the shipper. When this information is not available a written statement to that effect, by the shipper, must be required.

The requirement of §1.352(a)(5) is very similar to the requirements of the HMR and should, by rule, be a requirement of the shipper to be on the bill of lading and of the carrier to verify the information prior to accepting the shipment into transportation. Again, wording in a certifying statement declaring the accuracy of this information would be appropriate.

ATA and the ATC acknowledge FDA's need to capture the information in §1.352 and have it readily available to retrieve. However, the requirements of §1.352(a)(6) create a burden not recognized by the FDA. For instance, LTL carriers consolidate numerous shipments onto one trailer and move them across substantial distances through a relay system of defined routes and terminals. As an example: a driver in a city serviced by the LTL carrier may pick up an LTL food shipment. It could then be exposed to a number of non-carrier employees as the driver makes other pick-ups at various docks during the day. When the driver returns to the terminal, the food shipment may be unloaded onto that terminal's dock by the driver that picked it up or may be unloaded by another employee of the carrier. It may sit on the dock for a period of time, accessible to all employees of the carrier working on that dock, or it may be immediately loaded onto another trailer, for transportation over-the-road, by the employee that unloaded it from the pick-up trailer, or by another employee of the carrier. While waiting for the over-the-road trailer with the food shipment to be filled, that food shipment is again available to all of the carrier's employees working on that dock. The shipment could then move to a consolidation center of the LTL carrier and be transferred by a new set of employees to yet another trailer to travel to either another consolidation center or to the final delivery terminal. Once it arrives at the delivery terminal, the food shipment will be transferred to the trailer to go to the consignee. This transfer may be made by the driver that will deliver the food shipment or by another employee of the carrier. As you can see, if the shipment is handled at each dock by more than one employee -- which is very common in the LTL industry -- the requirements of this section, to list each individual responsible, create compliance difficulties. Therefore, we request that FDA consider requiring only the name of one individual with knowledge of the carriers operation to be listed.

The requirement in §1.352(a)(3), that a motor carrier must provide a "brand name" description raises cargo security concerns. Having more detailed descriptions on paperwork, such as a bill of lading or manifest, will increase the risk of theft and make it easier for bioterrorists to target certain shipments.

Administrative Detention

Detention Facilities

Because FDA has no detention facilities at the border (nor at any location within the United States), there is an outstanding question of where the agency will hold detained food shipments. Agency personnel indicated that at the border Customs-bonded warehouses "might" be used, but

the details of how this would be done still remain unknown. Another idea, brought up at FDA's May 7, 2003, satellite download meeting, was that the agency would hold detained shipments in a bonded carrier's warehouse after the bonded carrier picked up the goods. This circumstance again brings up the question of whether that carrier is a "holder of food."

Carrier's Right to Appeal

When food shipments are detained by the FDA, the burden to move the appeals process forward rests on the owner of the food, and the agency has attempted to delineate this pathway. However, forgotten in this detention process is the motor carrier, whose equipment and/or driver(s) may also be detained or rerouted. If a motor carrier's equipment is detained along with an FDA-regulated shipment, neither the law nor proposed regulations appear to provide a way for carriers to appeal detention of this equipment. Motor carriers face a serious loss of productivity and a negative financial impact when equipment has been detained. In addition, such down time could have a serious negative impact on truck drivers' compensation because of the loss in miles driven. The agency needs to develop a process for motor carriers to have a voice in this process so equipment can be retrieved.

In addition, if the goods – along with the motor carrier's equipment – are wrongly detained, FDA has indicated that either the importer or carrier or shipper still must pay the storage fees and cannot recover these fees from the government. These are two areas that FDA needs to look at carefully and determine equitable solutions.

Conclusion

ATA and ATC, as well as the entire trucking industry share FDA's and our nation's concern for securing our food supply. In addition to reactive measures the trucking 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 trucking operations after, and even well before, the terrorist attacks of September 11.

In addition to coordinating with various segments of the transportation industry, ATA has been interacting with government agencies developing separate security initiatives that will have an impact on trucking operations. ATA believes that it is essential that all agencies developing security initiatives that will impact international trade coordinate closely with agencies within DHS, such as BCBP and the Transportation Security Administration (TSA). In addition, FDA needs to coordinate its efforts with any federal agency involved in the regulation of the trucking industry, such as the U.S. DOT.

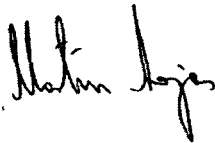
In summary, ATA urges that the following issues be taken into consideration by FDA when drafting the final rule:

- FDA must understand that there are various and diverse types of operations within the trucking industry, and, further, the agency must consult with and study each type of operation or segment to take its operations into consideration when developing a final rule;

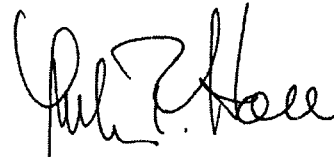
- The agency needs to more definitively define “holder of food” so motor carriers and drivers are not included;
- FDA should review programs such as C-TPAT and FAST to understand how these programs ensure that the security of the entire supply chain not be at risk.
- The agency needs to coordinate its efforts with other federal agencies involved in the regulation of motor carriers and motor carrier security;
- Small businesses should be allowed, without exception, to comply with the recordkeeping requirements on a longer time frame;
- The agency’s economic impact analysis must be re-examined and corrected;
- FDA should accept the bill of lading to fulfill the recordkeeping requirement for transporters and reconsider the inclusion of lot numbers and brand name descriptions in motor carrier required records;
- The agency should reconsider exemptions for Canadian carriers, Mexican carriers, and private carriers;
- FDA needs to re-examine and reevaluate the time line provisions for retrieval of records to make them more flexible; and
- The agency must develop a more predictable and equitable process for administrative detention of food.

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) 838-795 or Fletcher R. Hall at 703-838-7999.

Sincerely,



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



Fletcher Hall
Executive Director
Agricultural Transporters Conference

RULES

(To be Printed on White Paper)

UNIFORM STRAIGHT BILL OF LADING

ORIGINAL—NOT NEGOTIABLE

Carrier's Pro No. _____
 Shipper's Bill of Lading No. _____
 Consignee's Reference/PO No. _____
 Carrier's Code (SCAC) _____

Name of Carrier _____

RECEIVED, subject to individually determined rates or contracts that have been agreed upon in writing between the carrier and shipper, if applicable, otherwise to the rates, classifications and rules that have been established by the carrier and are available to the shipper, on request;

From _____ Date _____
 Street _____ City _____ County _____ State _____ Zip _____

the property described below, in apparent good order, except as noted (contents and condition of contents of packages unknown) marked, consigned, and destined as shown below, which said carrier agrees to carry to destination, if on its route, or otherwise to deliver to another carrier on the route to destination. Every service to be performed hereunder shall be subject to all the conditions not prohibited by law, whether printed or written, herein contained, including the conditions on the back hereof, which are hereby agreed to by the shipper and accepted for himself and his assigns.

Consigned to _____
On Collect on Delivery Shipments, the letters "COD" must appear before consignee's name

Destination Street _____
 City _____ County _____ State _____ Zip _____

Delivering Carrier _____ Trailer No. _____

Additional Shipment Information _____

Collect on Delivery \$ _____ and remit to: _____	C.O.D. charge Shipper <input type="checkbox"/>
Street _____ City _____ State _____	to be paid by Consignee <input type="checkbox"/>

Handling Units No. Type	Packages No. Type	HM	Kind of Package, Description of Articles, Special Marks and Exceptions (Subject to correction)	Weight (Subject to Correction)	Class or Rate Ref. (For Info. Only)	Cube (Optional)

Mark "X" to designate Hazardous Materials as defined in Department of Transportation Regulations

NOTE (1) Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property as follows

The agreed or declared value of the property is specifically stated by the shipper to be not exceeding _____ per _____

NOTE (2) Liability Limitation for loss or damage on this shipment may be applicable. See 49 U.S.C. § 14706(c)(1)(A) and (B).

NOTE (3) Commodities requiring special or additional care or attention in handling or stowing must be so marked and packaged as to ensure safe transportation with ordinary care. See Sec. 2(e) of NMFC Item 360.

Freight charges are PREPAID unless marked collect
 CHECK BOX IF COLLECT

FOR FREIGHT COLLECT SHIPMENTS:
 If this shipment is to be delivered to the consignee, without recourse on the consignor, the consignor shall sign the following statement:
 The carrier may decline to make delivery of this shipment without payment of freight and all other lawful charges.

 (Signature of Consignor)

Notify if problem enroute or at delivery _____ Name _____ Fax No. _____ Tel. No. _____ (for informational purposes only)

Send freight bill to: _____ Company Name _____ Street _____ City _____ State _____ Zip _____

Shipper _____ Carrier _____
 Per _____ Per _____ Date _____

Shipper Certification	Carrier Certification
This is to certify that the above named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation Per _____ Date _____	Carrier acknowledges receipt of packages and required placards. Carrier certifies emergency response information was made available and/or carrier has the Department of Transportation emergency response guidebook or equivalent document in the vehicle. Per _____ Date _____ Package Nos. _____

RULES

UNIFORM BILL OF LADING TERMS AND CONDITIONS

Sec. 1. (a) The carrier or the party in possession of any of the property described in this bill of lading shall be liable as at common law for any loss thereof or damage thereto, except as hereinafter provided.

(b) No carrier shall be liable for any loss or damage to a shipment or for any delay caused by an Act of God, the public enemy, the authority of law, or the act or default of shipper. Except in the case of negligence of the carrier or party in possession, the carrier or party in possession shall not be liable for loss, damage or delay which results: when the property is stopped and held in transit upon request of the shipper, owner or party entitled to make such request; or from faulty or impassible highway, or by lack of capacity of a highway bridge or ferry; or from a defect or vice in the property; or from riots or strikes. The burden to prove freedom from negligence is on the carrier or the party in possession.

Sec. 2. Unless arranged or agreed upon, in writing, prior to shipment, carrier is not bound to transport a shipment by a particular schedule or in time for a particular market, but is responsible to transport with reasonable dispatch. In case of physical necessity, carrier may forward a shipment via another carrier.

Sec. 3. (a) As a condition precedent to recovery, claims must be filed in writing with: any participating carrier having sufficient information to identify the shipment.

(b) Claims for loss or damage must be filed within nine months after the delivery of the property (or, in the case of export traffic, within nine months after delivery at the port of export), except that claims for failure to make delivery must be filed within nine months after a reasonable time for delivery has elapsed.

(c) Suits for loss, damage, injury or delay shall be instituted against any carrier no later than two years and one day from the day when written notice is given by the carrier to the claimant that the carrier has disallowed the claim or any part or parts of the claim specified in the notice. Where claims are not filed or suits are not instituted thereon in accordance with the foregoing provisions, no carrier shall be liable, and such claims will not be paid.

(d) Any carrier or party liable for loss of or damage to any of said property shall have the full benefit of any insurance that may have been effected, upon or on account of said property, so far as this shall not void the policies or contracts of insurance, PROVIDED, that the carrier receiving the benefit of such insurance will reimburse the claimant for the premium paid on the insurance policy or contract.

Sec. 4. (a) If the consignee refuses the shipment tendered for delivery by carrier or if carrier is unable to deliver the shipment, because of fault or mistake of the consignor or consignee, the carrier's liability shall then become that of a warehouseman. Carrier shall promptly attempt to provide notice, by telephonic or electronic communication as provided on the face of the bill of lading, if so indicated, to the shipper or the party, if any, designated to receive notice on this bill of lading. Storage charges, based on carrier's tariff, shall start no sooner than the next business day following the attempted notification. Storage may be, at the carrier's option, in any location that provides reasonable protection against loss or damage. The carrier may place the shipment in public storage at the owner's expense and without liability to the carrier.

(b) If the carrier does not receive disposition instructions within 48 hours of the time of carrier's attempted first notification, carrier will attempt to issue a second and final confirmed notification. Such notice shall advise that if carrier does not receive disposition instructions within 10 days of that notification, carrier may offer the shipment for sale at a public auction and the carrier has the right to offer the shipment for sale. The amount of sale will be applied to the carrier's invoice for transportation, storage and other lawful charges. The owner will be responsible for the balance of charges not covered by the sale of the goods. If there is a balance remaining after all charges and expenses are paid, such balance will be paid to the owner of the property sold hereunder, upon claim and proof of ownership.

(c) Where carrier has attempted to follow the procedure set forth in subsections 4(a) and (b) above and the procedure provided in this section is not possible, nothing in this section shall be construed to abridge the right of the carrier at its option to sell the property under such circumstances and in such manner as may be authorized by law. When perishable goods cannot be delivered and disposition is not given within a reasonable time, the carrier may dispose of property to the best advantage.

(d) Where a carrier is directed by consignee or consignor to unload or deliver property at a particular location where consignor, consignee, or the agent of either, is not regularly located, the risk after unloading or delivery shall not be that of the carrier.

Sec. 5. (a) In all cases not prohibited by law, where a lower value than the actual value of the said property has been stated in writing by the shipper or has been agreed upon in writing as the released value of the property as determined by the classification or tariffs upon which the rate is based, such lower value plus freight charges if paid shall be the maximum recoverable amount for loss or damage, whether or not such loss or damage occurs from negligence.

(b) No carrier hereunder will carry or be liable in any way for any documents, coin money, or for any articles of extraordinary value not specifically rated in the published classification or tariffs unless a special agreement to do so and a stipulated value of the articles are endorsed on this bill of lading.

Sec. 6. Every party, whether principal or agent, who ships explosives or dangerous goods, without previous full written disclosure to the carrier of their nature, shall be liable for and indemnify the carrier against all loss or damage caused by such goods. Such goods may be warehoused at owner's risk and expense or destroyed without compensation.

Sec. 7. (a) The consignor or consignee shall be liable for the freight and other lawful charges accruing on the shipment, as billed or corrected, except that collect shipments may move without recourse to the consignor when the consignor so stipulates by signature or endorsement in the space provided on the face of the bill of lading. Nevertheless, the consignor shall remain liable for transportation charges where there has been an erroneous determination of the freight charges assessed, based upon incomplete or incorrect information provided by the consignor.

(b) Notwithstanding the provisions of subsection (a) above, the consignee's liability for payment of additional charges that may be found to be due after delivery shall be as specified by 49 U.S.C. § 13706, except that the consignee need not provide the specified written notice to the delivering carrier if the consignee is a for-hire carrier.

(c) Nothing in this bill of lading shall limit the right of the carrier to require the prepayment or guarantee of the charges at the time of shipment or prior to delivery. If the description of articles or other information on this bill of lading is found to be incorrect or incomplete, the freight charges must be paid based upon the articles actually shipped.

Sec. 8. If this bill of lading is issued on the order of the shipper, or his agent, in exchange or in substitution for another bill of lading, the shipper's signature on the prior bill of lading or in connection with the prior bill of lading as to the statement of value or otherwise, or as to the election of common law or bill of lading liability shall be considered a part of this bill of lading as fully as if the same were written on or made in connection with this bill of lading.

Sec. 9. If all or any part of said property is carried by water over any part of said route, such water carriage shall be performed subject to the terms and provisions and limitations of liability specified by the "Carriage of Goods By Sea Act" and any other pertinent laws applicable to water carriers.

Cathy Durfey

From: System Administrator [postmaster@isa.fda.gov]
Sent: Tuesday, July 08, 2003 1:54 PM
To: Cathy Durfey
Subject: Delivered: ATA/ATC Comments re FDA Dockets Numbers 02N-0275 and 02N 0277.

Importance: High



ATA/ATC
Comments re FDA Dock
message

<<ATA/ATC Comments re FDA Dockets Numbers 02N-0275 and 02N 0277>> Your

To: fdadockets@oc.fda.gov
Cc: Fletcher Hall; Dave Osiecki; Martin Rojas; Margaret Irwin;
Richard Holcomb
Subject: ATA/ATC Comments re FDA Dockets Numbers 02N-0275 and 02N 0277
Sent: Tue, 8 Jul 2003 13:53:36 -0400

was delivered to the following recipient(s):

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