BEFORE THE

FOOD AND DRUG ADMINSTRATION

ROCKVILLE, MD

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ESTABLISHMENT AND MAINTENANCE OF RECORDS

UNDER THE PUBLIC HEALTH SECURITY

AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT

DOCKET NO. 02N-0277

JULY 8, 2003

COMMENTS OF THE CARGO AIRLINE ASSOCIATION

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I. INTRODUCTION

The Cargo Airline Association (hereinafter "CAA") is the nationwide trade organization representing the interests of the all-cargo air carrier industry. A current membership list is attached hereto. On May 9, 2003, the Food and Drug Administration (hereinafter "FDA") published a Notice of Proposed Rulemaking (NPRM) proposing regulations that would require the establishment and maintenance of records by certain persons who manufacture, process, pack, transport, distribute, receive, hold or import food into the United States. 68 *Fed. Reg.* 25188 (May 9, 2003). Comments are due to be filed on or before July 8, 2003. CAA is very concerned with the potential impact these regulations have on the air cargo industry, our shipping customers and the economy as a whole. Therefore, CAA respectfully submits the following Comments.

II. THE ALL-CARGO AIR CARRIER INDUSTRY

The aviation industry and specifically the air cargo segment is an integral part of the U.S. economy. Domestic and international companies have come to rely on the air transportation system to maintain competitiveness in the global marketplace. The all-cargo component of air cargo transportation is a major part of this system. As a result, any potential impact on the way in which any cargo, including food, is transported by air must be examined with the unique needs of the all-cargo industry and its shipping customers in mind.

It is important to note that all-cargo transportation is provided by various types of operations, including aircraft specializing in heavy air freight and the integrated express carriers responsible for providing time-definite, door-to-door transportation of all types of cargo. Regardless of the type of air cargo service provided, speed, reliability and consistency are key elements of the air cargo business, especially in the food marketplace where time is of the essence handling and delivering food. Indeed, many industry members offer money-back guarantees if delivery commitments are not met. Therefore, any delay or burdensome or inconsistent requirements have a significant and direct impact on the air cargo carriers and the shipping public that the industry serves. With the advent of just-in-time inventory, shippers rely on the time-definite service offered by air cargo carriers. A major user of the just-in-time concept is the food community, including fresh fish, perishable food items and pet food.

Since the events of September 11, 2001, all segments of the air transportation industry have taken many additional safeguards to ensure the security of air cargo transportation. Many of the enhancements made within the all-cargo community have been proactively aimed at

protecting the viability of the cargo within our system. Currently, the industry is working with the Transportation Security Administration (TSA) to recommend an even more comprehensive set of new regulations for the transportation of cargo. Moreover, the industry has been working very closely with the Bureau of Customs and Border Protection (Customs) in Customs' proposed advanced mandatory submission of certain information. We urge FDA to coordinate with these agencies in order to secure our borders without compromising the flow of commerce.

III. STATUTORY AUTHORITY

The proposed rule has been issued to implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Bioterrorism Act, P.L. 107-88, 116 Stat. 662 (June 12, 2002) (hereinafter "Act"). The Act contains several provisions to enhance the safety and security of the U.S. food supply. Throughout the many provisions of the Act, Congress specifically **directs** the FDA to issue regulations whereas, in other sections, it simply leaves the enactment of any regulations to the agency's own discretion. Under Section 306 (a), the Secretary of Health and Human Services **may** by regulation establish requirements regarding the establishment and maintenance of records. Therefore, a literal reading of this particular statutory language would conclude that the FDA is not required to issue the regulations at issue herein, but rather has discretion not to issue regulations or to determine other more appropriate means to further the purposes of the Act. In addition, FDA has the flexibility to issue regulations to persons "who manufacture, process, pack, transport, distribute, receive, hold, **or** import food." Act, Section 306 (a). The statutory language, by the use of the term "or" implies that FDA does not necessarily have to apply any regulations to **all** those persons engaged in the listed activities above. CAA submits that different regulations or no regulations could be

issued to the various entities based on the activities provided. This particular section also provides that FDA consult and coordinate with other Federal departments and agencies before issuing any regulations. Section 306 (a). It is therefore logical to assume that Congress intended for FDA to coordinate with other agencies to determine if such records already exist within other Federal departments in order to address credible threats of serious adverse health consequences or death to humans or animals. Upon such coordination, FDA should only issue additional recordkeeping regulations, if absolutely necessary. CAA respectfully submits that the information currently provided to FDA, Customs and other Federal agencies is sufficient for the FDA to further the purposes of the Act.

FDA, however, takes a different reading of the Act. FDA is relying on Section 306 (d) of the Act that directs the agency to promulgate proposed and final regulations no later than December 12, 2003. 116 Stat. 670, §306 (d). FDA recognizes that the use of term "may" in one section and "shall" in another section creates ambiguity and specifically invites comments on such ambiguity. 68 *Fed. Reg.* 25189. CAA submits that Section 306 (d) and its deadline of December 12, 2003, would apply only **if** FDA elects to issue regulations and FDA's clear discretionary authority to issue recordkeeping regulations in the first place remains unchanged by Section 306 (d).

III. THE PROPOSED RULE

With regard to transporters, the proposed rule would require the following information: (a) name of the firm and responsible individual, address, phone number, and if available, the fax number and e-mail address of the person who had the food immediately before you, and the date

you received it from that person; (b) the name of the firm and the responsible individual, address, phone number, and, if available, the fax number and e-mail address of the person who had the food immediately after you, and the date you delivered it to that person; (c) an adequate description of the type of food, including brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce); (d) the lot or code number or other identifier of the food (to the extent this information exists); (e) the quantity and how the food is packaged (e.g., 6 ct bunches, 25 lb carton, 12 oz bottle); (f) identification of each and every mode of transportation (e.g., company truck, private carrier, rail air, etc.) and the individual responsible, from the time you first received the food until the time you delivered it. Proposed Section 1.352. The above information must be retained for a period of two years after the date the records were created and one year if the food is perishable. Proposed Section 1.360.

FDA states its intent in developing these regulations is "to provide the proper balance between ensuring that FDA has information it needs to complete a tracing investigation and ensuring adequate and reasonable flexibility for industry to comply." 68 *Fed. Reg.* 25189. CAA respectfully submits that the proper balance has not been struck with these proposed regulations in that some of the data elements requested are unnecessary and too burdensome on an industry already highly regulated by several agencies requiring the same or similar information. For example, the air cargo industry currently establishes and maintains industry air waybills, bills of lading and commercial invoices which are required by Customs to be maintained for a period of five years. Moreover, as mentioned above, Customs will be proposing a new set of advanced mandatory information including other data elements that could satisfy FDA in its effort to establish a complete tracing of activities. CAA therefore supports the FDA and Customs

working together with the industry avoid any unnecessary burdens by implementing this rule which requires additional or more detailed data than what is already maintained.

a. Redundant Information Required for Nontransporters and Transporters

CAA particularly is concerned with the redundancy of requiring nontransporters to keep the same records on the immediate previous source and the immediate subsequent recipient regardless of whether they are transporters or nontransporters. Under this approach, it is conceivable that a shipper tendering food to a transporter would be required to keep records on the transporter and in turn, the transporter would have to keep the very same records on the shipper. As a practical matter, the transporter generally does not have the information required at the level of detail proposed because most air carriers rely on the information provided from those persons tendering the cargo. This process is further complicated when an air carrier operates a charter flight for a freight consolidator and detailed data regarding food is not provided by the consolidator. Therefore, CAA respectfully urges FDA to modify its approach and require that the records be established and maintained by the shipper or immediate previous source, not the transporter. It is unclear what security function is served by replication of the same data by at least two different entities. In fact, it could take FDA longer to compare the records of both nontransporters and transporters when a valid threat to the food supply is identified. At a minimum, to avoid the above scenario, FDA should amend the proposed rule and require that the transporter keep only manifest information, limited to the data elements required by the Bureau of Customs and Border Protection. This would include information regarding the shipper and consignee and would allow for adequate tracing of the shipments.

b. The Responsible Individual should be Name(s) provided by the Shipper and Individual Determined by the Transporter

CAA is also concerned with the FDA requesting that records be kept identifying each and every mode of transportation and the individual responsible, from the time the carrier first received the food until the time the food is delivered. Proposed Section 1.352. At the time a shipment is tendered to a transporter or carrier, the shipper provides a name of shipper (i.e., immediate previous source) and consignee (i.e., immediate subsequent recipient). Those names are already maintained and can clearly be regarded as "responsible individual(s)". Once the shipment is within the custody and control of the carrier, security measures are already in place to protect and maintain the integrity of the cargo. Air transportation can include the pickup and delivery of cargo and does not necessarily involve just one mode of transportation, but rather is a complex system of intermodal transportation. While many times cargo must be tendered to another company for the ultimate delivery of any particular item, many of our members are integrated carriers, i.e., they employ the very trucks and employees that deliver the cargo. Therefore, once the cargo is within the carrier's custody, it stays within their custody until the point of delivery. It is unclear why the FDA would require the name of individual responsible from the point of pickup to the point of delivery. CAA respectfully submits that the transporter should be given the flexibility to determine the "responsible individual" within their company, i.e., a responsible corporate official, which should be sufficient to provide FDA with adequate tracing. That person could then be responsible for the coordination of obtaining the necessary documents for tracing. Regardless of whether air carriers are integrated or not, once the food is within their control, no records on the various specifically named individuals involved in all parts of the transportation should have to be established or maintained. As previously stated, air

cargo carriers have enhanced the security within their systems thereby ensuring the integrity of the cargo under its control. CAA urges the FDA to amend its Section 1.352 to state that the names provided by a shipper to identify the immediate previous source and immediate subsequent recipient, as well as a corporate representative determined by the transporter is sufficient to satisfy the recordkeeping requirements.

c. Applicability of Who is Subject to the Rule is Too Limited

With regard to the transportation of food, the proposed regulation requires a "domestic person", defined as "any person located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico", to establish and maintain records. Proposed Section 1.328, 1.351. Consequently, the requirements would not apply to transporters located outside the United States, such as trucking companies located in Canada and Mexico. If the intent of the Act is to protect our nations food supply, the regulatory provisions must apply to all entities involved in the transportation of food into and within the United States.

It is important to note that Customs' current requirements would apply to the case of a trucking company transporting imported food into the United States and manifesting data would be maintained. As CAA has previously suggested, FDA could easily coordinate with Customs to get the data from them in the event a threat to the nation's food supply is discovered rather than develop its own distinct recordkeeping regulations.

d. Record Availability Requirements Should be More Flexible

The proposed record retrieval section provides that information must be made available within 4 hours of a request if the request is made between 8:00 a.m. and 6:00 p.m., Monday through Friday, or within 8 hours of a request if made at any other time. Proposed Section 1.361. Additional flexibility should be built into this section to provide some protections when the information is not readily available. For example, carriers generally have ready access to records of shipments that occurred within a recent time period, however, over time, retrieval of any archived records could be more problematic. Therefore, CAA suggests that additional language be incorporated into Section 1.361 to allow the transporter, in consultation with the FDA, to produce the information "as soon as practicable", if it determines that compliance within 4 or 8 hours is not feasible. Also, different time zones may apply depending on where the records are located and where the information is requested. The rule is unclear, as currently written, which time zones would apply. CAA requests clarification from the FDA on the appropriate time zone to use in calculating which record retrieval period applies.

e. Form and Manner of Information and Records should Remain Flexible

Finally, in the rule as proposed, FDA does not specify the form or type of system in which the requested data elements must be kept. In fact, FDA notes that the information could be maintained in several different forms and can be maintained electronically, but should be made available to FDA if a valid threat to the food supply is identified. 68 *Fed. Reg.* 25189, 25198.

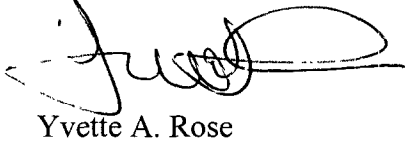
CAA fully supports this approach. As a practical matter, some of the information is already kept and reported for Customs purposes in various forms and formats. CAA supports the

language of Proposed Sections 1.330 and 1.360 which state that the regulations do not require the duplication of existing records if those records contain all of the information required and that the maintenance of electronic records is acceptable.

IV. CONCLUSION

For the reasons stated above regarding the uniqueness of the all-cargo air carrier industry and especially the express portion of our membership, CAA is very concerned with the rule as proposed and cannot support the data elements proposed without more coordination with the Bureau of Customs and Border Protection and the TSA. CAA is happy to work with FDA via a working group[1] to address our concerns outlined above. The unique nature of the all-cargo air carrier industry and all the members of that segment of the industry must be considered and the proposals balanced against the potentially drastic impacts on the flow of commerce.

Respectfully submitted,



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[1] To be truly effective, any such working group should include all segments of the industry and the organizations that represent them.

CARGO AIRLINE ASSOCIATION
MEMBERSHIP LIST

ALL-CARGO AIRLINES

* Airborne Express	Seattle, WA
* Atlas Air, Inc.	Purchase, NY
* Emery Worldwide	Redwood City, CA
* Evergreen International Airlines, Inc.	McMinnville, OR
* Federal Express	Memphis, TN
* United Parcel Service	Louisville, KY
Air Transport International	Little Rock AR
Capital Cargo International	Orlando, FL
DHL Airways, Inc.	Miami, FL
First Air	Gloucester, Canada
Gemini Air Cargo	Dulles, VA
Kitty Hawk	Dallas, TX
Northern Air Cargo	Anchorage, AK
USA Jet Airlines, Inc.	Belleville, MI

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Columbia Metropolitan Airport	Columbia, SC
Dayton International Airport	Dayton, OH
FIDC/Fairbanks International Airport	Fairbanks, AK
Louisville International Airport	Louisville, KY
Memphis-Shelby County Airport Authority	Memphis, TN
Metropolitan Washington Airport Authority	Washington, DC
New Orleans International Airport	New Orleans, LA
Oakland International Airport	Oakland, CA
Reno/Tahoe International Airport	Reno, NV
Rickenbacker International Airport	Columbus, OH

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Harrow & Co.	New Canaan, CT
Integrated Airline Services, Inc.	Denver, CO
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