Comments of
International Air Transport Association

Regulations implementing H.R. 3448, Public Health Security and Bioterrorism Response Act of 2002

Docket Number: 02N 0277

July 8, 2003

Submitted by:

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02N-0277

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VIA FACSIMILE

July 8, 2003

Food and Drug Administration
Docket Management Branch (HFA-305)
5630 Fishers Lane
Room 1601
Rockville, Maryland 20852

Re: Establishment and maintenance of records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Docket No. 02N-0277

The International Air Transport Association (IATA) by means of this letter is providing its comments in respect of the Notice of Proposed Rule Making (NPRM) referenced above. The NPRM sets out proposed 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). The NPRM further solicits stakeholder comment in respect of same.

IATA is the industry association for the world's air carriers operating scheduled international air transport services. It consists of approximately 280 members, including all major U.S. carriers offering scheduled international air transport services, both passenger and cargo. It is important to note the particular advantages such as speed, reliability and scheduled services that the airline industry offers to international and U.S. shippers that are all part of a global and highly competitive marketplace. In general, consumers and the shipping public that this industry serves, have come to rely on just-in-time inventory and expect time-definite service.

IATA has previously provided comments to the FDA relating to the development of Regulations under H.R. 3448, emphasizing that airline knowledge of manufacturer or grower information is limited due to the nature of the air waybill data collection and recording.

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International Air Transport Association

As the FDA is aware, air carriers have some of the most stringent security measures of any mode of transport, and air carriers have worked closely in the past with the USDA, TSA and United States Customs service with respect to documenting the importation of goods, including foodstuffs, into the United States. Co-operation between government agencies with overlapping mandates will allow for governmental security needs to be met, while reducing the regulatory burden upon transportation industry participants.

IATA is of the view that certain information elements required under proposed section 1.352 of the Regulations are of particular concern in that these elements are not known to the carrier and are not part of the information captured in air waybills or cargo manifests. IATA notes, however, that this information is submitted, or could be submitted, by other parties to the United States Customs Service, such as by the importer or the importer's customs broker. Moreover, U.S. Customs is currently developing a new set of mandatory information that could satisfy FDA tracing activities.

IATA notes that information known to carriers that provide air cargo transport is limited to knowledge of the data set out in the cargo manifest and the air waybill. Air carriers are not in a position of being able to collect data regarding food products (e.g. brand or container size) as set out in proposed section 1.352(a) in a manner that would ensure accuracy or be verifiable, particularly in that many perishable commodities are tendered for carriage at the last minute. The shipper or importer remains the best source to provide such information to the FDA or any other government agency delegated to receive such information on behalf of the FDA.

Proposed section 1.361 would require that records must be made available within 4 hours of a request if the request is made between 8 a.m. and 6 p.m., Monday through Friday, or within 8 hours of a request if made at any other time. The Description of the Proposed Regulations indicates that this refers to local standard time. IATA understands this to refer to local time at the location of the facility to which a request for information is directed. IATA notes that compliance with these proposed availability requirements becomes difficult when the facilities being polled may be overseas. IATA thus draws the attention of the FDA to this issue of practical application of the response criteria set out in proposed section 1.361. IATA further notes the submissions of other parties filing comments in this regard.

IATA appreciates this opportunity to provide comments to the FDA. Should any further information be required of IATA in respect of this submission, please do not hesitate to contact the undersigned.

Sincerely,

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