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

Via overnight mail and e-mail: <http://www.fda.gov/dockets/ecomments>

RE: Docket No. 02N-0278
Comments on Prior Notice of Imported Food Under the Public Health Security
and Bioterrorism Preparedness and Response Act of 2002

Dear Sirs/Madams;

FedEx Trade Networks Transport & Brokerage, Inc. strongly supports the efforts of the Food and Drug Administration (FDA) to protect the food supply. We respectfully offer the following comments on the Notice of Proposed Rule Making (NPRM) published in the Federal Register of February 3, 2003, Docket No. 02N-0278.

Reporting System

Under section 801 (m)(1) of the Act, prior notice is required for all food "*being imported or offered for import into the United States.*" The FDA is proposing that the prior notice, amendments, and updates be submitted electronically to the FDA utilizing the FDA's Prior Notice System. The web-based FDA Prior Notice System is under development with an anticipated operational date of no later than December 12, 2003 (NPRM, page 5459).

Use of a web-based system will not accommodate the high volume of transactions experienced by many of the largest brokers and importers.

Over 99% of all transactions to import goods into the United States, including food, flow through U.S. Customs Automated Broker Interface (ABI) system. If brokers are required

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to use Customs ABI **and** the FDA's web-based Prior Notice System, processing transactions becomes inefficient and redundant.

In order to illustrate, brokers have to prepare a complete entry on the ABI system and wait for Customs' approval. Once approval is received, the person preparing the entry must log out of the ABI system and log onto the Internet and the FDA web site. Once there, the person would manually transfer all the entry data received back from Customs into the FDA system. In addition to being time-consuming, this process introduces the potential for clerical errors.

Further, in the NPRM discussion section on proposed regulation § 1.287, page 5434, FDA states, "*we currently receive the majority of information we base admissibility decisions on electronically from U.S. Customs. Thus, we already have the electronic capability to process and screen the information.*" If the Operational and Administrative System for Import Support (OASIS) is capable of providing the electronic information for "admissibility" determinations then the information also should meet the pre-arrival requirements.

We request that FDA work with Customs to modify the ABI systems to take the additional data elements necessary to satisfy the requirements of the Act. Currently, OASIS, with its Customs ABI connectivity, provides most of the necessary information. With minor modifications, essentially in timing of data availability, ABI can provide the information required by the FDA prior to arrival of shipments of food.

Please note that the trade community has lobbied Congress long and hard to provide adequate funding for future Customs automation systems. Included in the funding appropriation is the International Trade Data System (ITDS). ITDS was conceived to avoid the development of multiple government agency system interfaces by providing a single governmental application. FDA has been an active member of the ITDS steering committee and we request that ITDS be utilized, when it becomes available, to provide the required data.

Time Frame For Reporting

The Act does not specify a time period for advance reporting: "*provided by a specific period of time in advance of the time of importation...which shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days.*"

The FDA is proposing submission of the prior notice by noon on the day prior to arrival. This does not take into consideration the variations in the mode of transportation.

We believe that the FDA, like Customs before it, should meet with the air express carrier, air cargo, trucking, rail, and ocean industry representatives to work through the many complex issues surrounding the need for and time frames for providing advanced accurate information.

We request that the FDA work with each mode of transportation to understand how cargo in that mode moves and what can be done, in conjunction with the carriers and brokers, to ensure high compliance with the substantive requirements of the law.

Definitions

Country from which the article of food was shipped: For multi-modal shipments, we believe that the country from which the article of food was shipped should be the country from which the goods were “exported” to the United States and should be the same as in the U.S. Customs regulations defining *country of export*.

For example, if a shipment is exported to the U.S. from Brussels, Belgium and moved to Paris, France for loading on an aircraft traveling to the U.S., we believe the country to be listed should be Belgium. The trade is familiar with this definition and that is how the information will be reported on the Customs’ entry. There is no reason to require two definitions for the same data element.

Food: It is important that the FDA have a clear definition of what is “food” to avoid delays of already fragile products. Listing items in terms of the Harmonized Tariff Schedule would be the clearest means of avoiding disputes.

Originating country: We believe that the definition of this item be the same as the “country of origin” definition under the U.S. Customs regulations. The trade is familiar with the Customs definition and having one common definition would serve to improve the accuracy of the data. Adding a whole different scheme would place a great burden on trade.

Port of entry: To the trade community, this term has come to mean the port where the Customs entry is made. Again, we suggest standardizing definitions with U.S. Customs and calling this the “port of arrival.” In the discussion on definitions, proposed § 1.277, 2.f, FDA states, “the port of entry must be defined as the port of arrival.”

Port of destination: There should be an additional definition for the port where the goods are destined for Customs entry in the U.S. Air carriers and express air carriers frequently move goods through one port to a final destination. Some locations, such as Hawaii and Alaska, can be used merely as intermediate stops; necessary for fueling and other carrier needs. Other intermediate stops are used as trans-loading locations for efficient and economical movement of cargo.

Failure to Submit Adequate Prior Notice

We believe that, if there is a failure to submit adequate prior notice, the goods should be allowed to move to the port of destination. Failure to allow this could cause severe economic hardship to carriers and delay other critical time-sensitive merchandise on aircraft, trucks or ocean vessels. Stopping at an intermediate destination just to remove one shipment would serve no benefit to either FDA or the carrier. In fact, the net effect of

such a requirement may very well be the refusal of many carriers to accept shipments of imported food articles, with subsequent negative effect on the U.S. economy and individual consumers

Often intermediate transit locations do not have the FDA infrastructure that is available at the port of destination. For Airlines, they are also subjected to careful DOT security requirements and, as a result, there should be little risk of transiting goods moving into commerce without FDA release. Their facilities should qualify as “secure facilities” under the regulations and allowing goods to move to them provide the strict controls discussed in the proposed regulations.

Who Can Submit Prior Notice

Use of Customs Brokers: We agree that a licensed customs broker should handle the filing of the data with FDA required for entry of imported food. As filing this data is merely part of the overall requirement for entry of goods, the FDA might discuss with Customs as to whether this constitutes “customs business” and should only be allowed if submitted by a party that has the “right to make entry” under 19 USC 1484 (importer, broker or broker appointed by the nominal consignee).

In-bond Shipments: We believe that, while carriers should be allowed to submit the prior notices, that this should not be exclusive. Exporters, consignees, and their brokers should also be allowed to submit them for in-bond shipments.

Further, as proposed, the number of data elements to be reported by the carrier in the prior notice, including the classification of the food product, is the equivalent of filing the Customs entry summary. As such, this activity could be construed as a violation of the Customs regulations by the carrier for transacting Customs business without a license.

FDA Should Provide a *De Minimis* Exemption

In the NPRM the FDA was careful to provide an exemption under Sec. 1.276 for food carried by an individual. We believe that commercial realities require that there also needs to be an exemption granted for low valued shipments arriving by commercial transport. These low valued shipments are not in real commercial quantities and present little risk to the public. We would suggest that shipments valued under \$200 be considered *de minimis* and be offered the same exemption as items carried by an individual. This would be consistent with U.S. Customs exemptions under 19 USC 1321.

Amendments to Prior Notice

We believe that FDA should be more understanding of the normal occurrences in the movement of international cargo and provide less restrictive systems for amending prior notices.

Of particular concern is when amendments are required to be made as a result of normal air carriage issues; such as shortages and overages, delayed flights and diverted flights. For example, it is not unusual for an entire aircraft to be diverted after the aircraft has departed. This can be as a result of weather issues or by order of the DOT. The parties designated to file the prior notice would not know about this change. In these circumstances, either the carrier's manifest should be accepted or there should be an exemption made to the requirement that these goods be refused admission.

Other modes of transportation have similar issues and accommodations need to be made for truck, rail and ocean shipments as well.

Other Issues for Consideration

Port of Destination – The final regulations should provide for the normal situation goods arriving at one port, but destined for another port for entry purposes. We discussed this above in requesting that a port of destination be included in the definitions. These goods move under Customs bond.

Transiting Goods – The final regulations should provide for goods that are simply transiting the United States. The reported data elements on the prior notice should be within the ability of the carrier to provide from the carrier's manifest information.

Importers Who are not U.S. Companies – It is very common along the U.S.-Canada border that the actual importer, for Customs purposes, is the shipper or another foreign company. The regulations should take this into consideration.

Conclusion

FedEx Trade Networks Transport & Brokerage, Inc., appreciates the opportunity to comment on FDA's Proposed Notice of Rule Making. We look forward to working with FDA to implement a prior notification process that maximizes the protection of the public food supply.

Respectfully Submitted,

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