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

ATTN: Docket No. 02N-0277

To Whom It May Concern:

The International Warehouse Logistics Association (IWLA) welcomes this opportunity to submit comments with regard to the regulation proposed by the U.S. Food and Drug Administration (FDA) entitled "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

IWLA is an international association of companies, which provide public and contract warehousing and related logistics services (public warehouses). A significant number of IWLA members in the United State and Canada provide food grade warehousing and related third-party logistics services to manufacturers, wholesalers, distributors and retailers of food products.

### Third-Party Logistics Providers

A public warehouse is typically referred to as a third-party logistics provider or 3PL. In food distribution, the customer of the 3PL warehouse might be the producer, the manufacturer, the repackager, the food broker, the wholesaler, retailer or a fourth-party logistics provider (4PL). A 4PL is an entity that integrates all of the companies involved along the supply chain. In the case of a public warehouse, the 4PL would arrange for the services of the public warehouse on behalf of the 4PL's customer. A 4PL may not actually operate a facility or own transport vehicles.

### Proposal Does Not Accomplish the Statutory Intent

The Bioterrorism Act provides, in part, that the Secretary may by regulation establish requirements regarding the establishment and maintenance of records. The records that must be kept are those that allow the Secretary to identify the immediate previous sources (IPS) and the immediate subsequent recipients (ISR) of food. The proposal provides for two sets of IPSs and ISRs – one for nontransporter and one for transporters.

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The proposal assumes that all food products meet the food distribution paradigm where food products move in a “straight line” from producer/manufacturer to wholesaler to retailer. This paradigm assumes that:

1. a product moves from company A to company B;
2. the transaction between A and B is transparent; and
3. company A or B arranges for transportation in a transparent transaction with the transporter.

Unfortunately, not every food product moves in this way through the distribution system. The proposal is not applicable to distribution systems that utilize 3PLs and 4PLs, such as food brokers and transportation brokers. As a result, it will not be possible for FDA to have the ability to trace back and trace forward quickly in the event of a terrorist event or other food-related emergency.

### **Illustrative Scenarios**

The following scenarios will help to describe the problem. The scenarios are intended to be illustrative, not comprehensive.

Scenario 1: The customer of the public warehouse is the manufacturer of cans of peas. The warehouse serves as a 3PL distribution center for the manufacturer.

- a. Cans of peas are transported directly from the manufacturing plant to the public warehouse.

Result: The public warehouse will be able to identify the IPS.

- b. The manufacturer of the peas arranges for Yellow Truck to deliver the product to the warehouse and a truck owned and operated by Yellow Truck delivers the product.

Result: the public warehouse will be able to identify the immediate previous transporter (IPT).

- c. Due to lack of available trucks, Yellow Truck brokers the load to Blue Truck. The manufacturer typically will not be advised that the load has been brokered to Blue. The bill of lading will reference Yellow although the truck is owned by Blue.

Result: Who is the IPT? Yellow or Blue? The proposal requires a contact person and phone number. Should this be the contact person for Yellow or Blue? Remember that in this scenario the manufacturer and the warehouse thinks the trucking company being used is Yellow, but the truck driver is actually working for Blue. The bill of lading will say Yellow, but the truck signage will say Blue.

Scenario 2: The warehouse customer is a retailer. Cans of peas are purchased by a retailer, to be relabeled and sold under the retailer's store brand. The retailer contracts with the public warehouse to provide 3PL storage and relabeling.

- a. The retailer contracts with a food broker to acquire cans of peas from various manufacturers. Several truckloads of cans of peas arrive from various manufacturers to a freight terminal where the peas are consolidated and shipped to the public warehouse.

Result: The only entity known to the public warehouse as the IPS is the freight terminal. The retailer may not know the source of the cans of peas. The only entity with knowledge of the source of the cans of peas is the food broker, who has no responsibility under the proposal.

- b. The retailer purchases the cans of peas directly from the manufacturer(s), but relies on the services of a freight broker to arrange the transportation. (Note: the typical freight broker normally does not own equipment, but rather subcontracts to other carriers.)

Result: Although the warehouse can identify the IPS, it will be difficult for the warehouse to identify the IPT? Is the IPT the owner of the truck that delivered the product? The owner of the trucking company (such as Yellow) who in turn brokered the load to Blue or the freight forwarder, who currently is not subject to the regulations?

Scenario 3: The warehouse customer is a food broker who purchases cans of peas, relabels, and sells to local retailers. (Note: it is often the case that, in reality, the food broker will not want to divulge the source of the peas, out of a fear that the warehouse will choose to compete with the broker.)

- a. The food broker advises the warehouse to expect a truckload of cans of peas next Tuesday. The truck arrives with a bill of lading that states that the IPS would ABC Freight Terminal.

Result: The only option for the warehouse is to record ABC Freight Terminal as the IPS, as there is no requirement that the food broker disclose the actual IPS.

- b. The food broker uses the services of a freight broker to transport the cans of peas in the above situation. (The food broker has contracted with the freight broker who in turn has brokered the load to Yellow who has brokered the load to Blue.)

Result: Who does the warehouse record as the IPT? Will the FDA be able to trace the source of the peas in an emergency?

Scenario 4: A large national retailer purchases cans of peas from a source in Mexico.

- a. The warehouse receives the truck from Mexico, where it is unloaded and reloaded into trucks for distribution. This type of operation is referred to in the industry as “cross docking.” In a cross-docking situation, the product may be kept on the premises for a few hours up to a few days.

Result: In this instance, is the warehouse or company providing the cross-docking service a transporter or a nontransporter? Is cross-docking a transport function under the regulation?

Although these scenarios address activity upstream from the warehouse, the same scenarios are applicable downstream. It is useful, however, to discuss a scenario for food that is transported from the warehouse. The proposal assumes that a warehouse will always know to whom the food product is destined. In many instances, however, when the product leaves the warehouse, the warehouse no longer has any knowledge of the product’s destination. The bill of lading may indicate the consignee, but may not indicate the intermediate transportation stops or the actual destination. Since the warehouse is not the owner of the product and if the truck is not owned by the warehouse, a product may be rerouted without there being any reason to notify the warehouse. The chain of custody between manufacturer and customer is effectively broke.

### **Recommendation**

The only way to ensure that FDA will be able to trace back and trace forward quickly in the event of a terrorist event or other food-related emergency is to require each entity that has physical possession of a food product to maintain a record of the IPS and ISR, regardless of whether the entity is a transporter or a stationary facility.

In the preamble, FDA dismisses the notion that the statute could be read to provide that at every step of the movement of the food, the immediate previous source is the person who had the food before they delivered it to the next person. That next person would be the immediate subsequent recipient.

“Under that reading, if company A processes the food and sends it to company B via several modes of transportation, the chain of custody would be as follows: (1) Company A; (2) Red Truck Co.; (3) train; (4) Blue Truck Co.; and (5) company B. In this scenario, the immediate subsequent recipient for company A is Red Truck Co. The immediate previous source for Red Truck Co. is company A and the immediate subsequent recipient is the train. The immediate previous source for the train is Red Truck Co. and the immediate subsequent recipient is

Blue Truck Co. The immediate previous source for Blue Truck Co. is the train and the immediate subsequent recipient is company B.” []

FDA dismisses this interpretation – “This type of tracing would not allow the agency to efficiently and effectively trace back from company B to company A or get to company A quickly to trace forward other food sent out by company A.”

In fact, this interpretation is the only interpretation that will ensure that FDA has the ability to trace forward or back. Otherwise, because of the use of freight and food brokers and other similar entities, company B may not know the identity of company A, creating significant gaps in the information needed by FDA.

### **Required Information Elements**

The information that is required to identify the nontransporter and transporter immediate previous source and the nontransporter and transporter immediate subsequent recipient are comparable. While the information asked for in the proposal appears to be reasonable, in reality much of the required information will be difficult or costly or impossible to obtain. The mistake made in the proposal, at least with respect to a public warehouse, is the assumption that this information will be readily and consistently available, when this is not the case. We offer the following recommendations.

1. The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source and, whether domestic or foreign.

Comment: The immediate previous transporter should be required to provide this information to the recipient. The transporter is the entity with the first-hand knowledge of the identity of the IPS. Further, in the case of an outbound shipment it should be the requirement of the transporter or party responsible for arranging the transportation to provide the warehouse or shipper with the required information.

2. An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce).

Comment: There are instances where product received in bulk packaging, such as carton or shrink-wrapped pallet. In these instances, the public warehouse has to rely on the description provided by the customer of what is contained within the outside packaging. Unless authorized by the customer, e.g., the owner of the product, the warehouse is not legally permitted to open and inspect the bulk package.

A recommended modification would be: “An adequate description of the type of food believed to have been received and contained within the outer packaging...”

3. The date the food was received.

Comment: Agree.

4. The lot or code number or other identifier of the food (to the extent this information exists).

Comment: With respect to a public warehouse, the lot or code number should be required to the extent that it is also required by the warehouse customer.

5. The quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle).

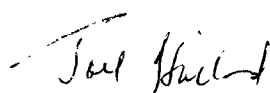
Comment: With respect to a public warehouse, the rule should require that the information relating to quantity and how the food is packaged be maintained in the same manner as required by the warehouse customer.

6. The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the transporters who transported the food to you or transported the food from you.

Comment: The rule should require that this information be supplied by the transporter and include the name of the company or person who is legally responsible for operation of the transport vehicle.

On behalf of the members of the International Warehouse Logistics Association, thank you for your consideration of these comments.

Sincerely,

  
JOEL HOILAND  
President and CEO