

identify one specific source of the food product.

For example, a company that bakes cookies may source flour from five different companies rather than depend on a single company as its supplier. The flour from the five companies may be stored in one common silo prior to being used in the manufacture of the cookies. In this scenario, the manufacturer could identify, depending on the date the flour was received from each company and placed in the silo and when the silo was emptied, the various companies that were the sources of the flour. Under this situation, the information is not reasonably available to determine a single source of the flour used in a particular lot of cookies. In this case, the information reasonably available to you would be the identity of all of the potential sources of the flour for each finished lot of cookies.

Conversely, if the manufacturer did have dedicated silos for each supplier of flour, then the information would be reasonably available to the manufacturer to specify the specific source of the flour for each finished product.

Proposed § 1.337(a)(4) would require maintenance of the lot or code number or other identifier of the food (to the extent this information exists) to allow FDA the capability to limit its investigation to the implicated food. For instance, if a company repeatedly and consistently orders a particular food from a supplier, and the threat is associated with a single shipment or some shipments but not others, it is important to have the capability to isolate the shipment or shipments in question from others. This would be more cost effective and less burdensome to FDA. In addition, if the threat affects the transporter, identifying information such as lot numbers or other identifiers would facilitate the location and isolation of the conveyance that may have become contaminated by the implicated food. This cannot readily be done without information that specifically identifies the food.

Proposed § 1.337(a)(5) would require you to record the quantity of the food and how it is packaged to assist FDA in identifying the implicated food and also allow FDA to determine the scope of the threat. With this information contained in the records, FDA would be able to determine the quantity of the potentially adulterated food that is in the stream of commerce, i.e., whether it is one crate or 1,000 crates of tomatoes. In addition, as part of a tracing investigation, FDA would be able to identify at each location whether all of the potentially adulterated food has been accounted for or whether any part of a shipment had

been diverted. Both the immediate previous source and immediate subsequent recipient would be required to keep records of the quantity of food received or released to allow FDA to determine that the quantity of food sent was the quantity received. This would ensure that FDA is best able to protect public health by being able to identify and locate adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

Proposed § 1.337(a)(6) would require you to keep in your records information to identify the transporter who transported the food to you. This requirement to identify the transporter is in addition to proposed § 1.337(a)(1), which requires you to keep in your records information that identifies the nontransporter immediate previous source.

#### *C. Establishment and Maintenance of Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipient of All Food*

What information is required in the records established and maintained to identify the nontransporter and transporter immediate subsequent recipient? (Proposed § 1.345)

The Bioterrorism Act authorizes FDA to require by regulation the establishment and maintenance of records “needed” by the Secretary for inspection to allow the Secretary to “identify” the immediate subsequent recipient of food. Based on FDA’s interpretation of this statutory authority and what is “needed” to “identify” the immediate subsequent recipient, proposed § 1.345(a) would require that you establish and maintain records for all food you release that identifies information that is substantially similar to that discussed in the requirements to identify the nontransporter immediate previous source.

#### *D. Requirements to Establish and Maintain Records to Trace the Transportation of All Food*

1. Who is required to establish and maintain records for tracing the transportation of all food? (Proposed § 1.351)

The Bioterrorism Act expressly states persons who transport food are subject to these regulations. Proposed § 1.351 would require you, if you are a domestic person, to establish and maintain records for tracing those immediately before (transporter’s immediate previous source) and immediately after you (transporter’s immediate subsequent

recipient) in the transportation process if you transport food.

2. What information is required in the transportation records? (Proposed § 1.352)

Proposed § 1.352(a) would require that you establish and maintain the following records for each food you transport:

- Proposed § 1.352(a)(1) would require the 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 possession, custody, or control of the food immediately before you, and the date you received it from that person;

- Proposed § 1.352(a)(2) would require the 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 possession, custody, or control of the food immediately after you, and the date you delivered it to that person;

- Proposed § 1.352(a)(3) would require 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);

- Proposed § 1.352(a)(4) would require the lot or code number or other identifier of the food (to the extent this information exists);

- Proposed § 1.352(a)(5) would require the quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle); and

- Proposed § 1.352(a)(6) would require the 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.

The proposed requirements are intended to provide the necessary information to allow FDA to trace the transportation of all food. In proposed § 1.352(a)(1) and (a)(2), the required information would consist of whoever had the food before you and after you. This person could be either a nontransporter or another transporter. In a multiple transporter situation, you may be receiving the food from another transporter and/or delivering it to another transporter. The proposed requirements in § 1.352(a)(1) and (a)(2) are intended to capture this information regardless of whether you receive food from a nontransporter or another transporter, or deliver it to a nontransporter or another transporter. You would only be responsible for maintaining a record of the required information with respect to the person