

Proposed § 1.328 defines “transporter’s immediate subsequent recipient” as the person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter. A transporter’s immediate subsequent recipient includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity.

Proposed § 1.328 defines “you” as a person or facility subject to this subpart under § 1.326. FDA is proposing to use “you” throughout the proposed rule for easier readability.

4. Do other statutory provisions and regulations apply? (Proposed § 1.329)

Proposed § 1.329 would require that in addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods. Regulations in this subpart are in addition to existing recordkeeping regulations, such as the regulations for low acid canned foods, juice, infant formula, color additives, bottled water, animal feed, and medicated animal feed. (See 21 CFR 113.100(d); 21 CFR 120.12; 21 CFR 106.100(g); 21 CFR 80.39; 21 CFR 129.35; § 589.2000; and 21 CFR 225.102 & 225.110, respectively).

5. Can existing records satisfy the requirements of this subpart? (Proposed § 1.330)

Proposed § 1.330 states that the regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a person subject to the regulations keeps records of all of the information as required by this subpart in compliance with other Federal, State, or local regulations, or for any other reason, e.g., as a result of its own business practices, then those records may be used to meet these requirements. Such records may include, but are not limited to, purchase orders, bills of lading, invoices and shipping documents. Some current FDA regulations require records, including those for low acid canned foods, juice, infant formula, color additives, bottled water, animal feed, and medicated animal feed. (See 21 CFR 113.100(d); 21 CFR 120.12; 21 CFR 106.100(g); 21 CFR 80.39; 21 CFR 129.35; 21 CFR 589.2000; and 21 CFR 225.102 & 225.110, respectively). However, none of the existing FDA regulations are sufficient alone to meet the requirements we are proposing in these regulations. A person who has been complying with these regulations only would have to add

records addressing the new elements. The burden is on the person subject to these regulations to ensure it keeps all applicable records. Our intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these proposed regulations. We are proposing the specific information a covered person must keep, but we will not specify the form or type of system in which those records must be maintained.

*B. Establishment and Maintenance of Records to Identify the Nontransporter and Transporter Immediate Previous Source of All Food*

What information is required in the records established and maintained to identify the nontransporter and transporter immediate previous source? (Proposed § 1.337)

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 previous sources of food. Based on FDA’s interpretation of this statutory authority and what is “needed” to “identify” the immediate previous source, proposed § 1.337(a) would require that you establish and maintain records for all food as follows:

- Proposed § 1.337(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 nontransporter immediate previous source, whether domestic or foreign;
- Proposed § 1.337(a)(2) would require 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);
- Proposed § 1.337(a)(3) would require the date you received the food;
- Proposed § 1.337(a)(4) would require the lot or code number or other identifier of the food (to the extent this information exists);
- Proposed § 1.337(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 § 1.337(a)(6) 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 transporters who transported the food to you.

Proposed § 1.337(a) would require that you include information reasonably available to you to identify the specific source of each ingredient that was used

to make every lot of finished product, so that incoming ingredients can be linked to the outgoing finished products. If FDA cannot immediately narrow the trace back to a specific source, tracing becomes much more difficult, there is an increased risk to consumers, and some food sources are unfairly implicated. FDA believes this is a necessary and beneficial requirement for consumers, and will help conserve FDA’s limited resources, by focusing our investigation only on those entities who handled the at-risk food. FDA’s investigation of the unaffected sources is time consuming and may have a negative business impact on the incorrectly implicated sources. These sources should not be penalized by exposure to unwarranted scrutiny and perhaps unwarranted adverse publicity because of inadequate recordkeeping by others in the distribution chain. In addition, in a recall situation, a business could limit the economic impact by being able to limit its recall to only a specific group of products instead of having to conduct a broader recall. What is reasonably available may vary from case to case.

FDA recognizes that the food industry often relies on multiple sources of ingredients to make food products, and that it is common practice to commingle ingredients from different sources prior to incorporating them into a finished product. For example, some food processors commonly store raw materials like corn syrup and flour in tanks and silos. In some instances, these tanks and silos are not dedicated by suppliers, but are topped off as supplies run low, resulting in routine commingling of raw ingredients from a number of suppliers. Moreover, it is FDA’s understanding that flour or grain silo crowns do not uniformly dissipate, resulting in uneven distribution of ingredients. FDA acknowledges that changing this longstanding system to require dedicated supplier storage to facilitate source specific recordkeeping would involve significant financial costs.

It is not FDA’s intent to require the reconfiguration of each manufacturing plant. These proposed regulations, however, would require you to capture the information that is reasonably available to you to connect finished products with the immediate previous source of each of the food products used to make that finished product. FDA understands that in some multiple sourcing contexts this information only may allow for a reduction in the number of potential sources for a specific food product, but may not necessarily