

snack foods; candy; and canned foods. "Substances that migrate into food from food packaging" include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food.

The provisions of this proposed rule apply to records of both nontransporters and transporters. Section 414(b) of the act provides that FDA may require recordkeeping with regard to records that are needed for inspection to allow the agency to identify the immediate previous sources and the immediate subsequent recipients of food. The proposed rule establishes two sets of immediate previous sources and immediate subsequent recipients, one for nontransporters and one for transporters. For nontransporters, the proposed rule defines immediate previous source as the nontransporter from which the company received the food. The immediate subsequent recipient for nontransporters is the nontransporter to which the company sent the food. The definition of nontransporter immediate previous source and immediate subsequent recipient describes them as persons who own food or who hold, process, pack, import, receive, or distribute food for purposes other than transportation. Nontransporters are also expected to keep records of the transporters that they receive food from and send food with. Nontransporters will thus be required to keep records on both transporters and nontransporters for both previous sources and subsequent recipients.

With respect to transporters (persons who have possession, custody, or control of food for the sole purpose of transporting it), the proposed rule provides for the company to establish and maintain records about its own transportation activities and the person from whom it received the food and the person to whom the food is delivered. The person from whom the food is received by the transporter is the immediate previous source. This could be a nontransporter as described previously or another transporter. The person to whom the food is delivered by the transporter is the immediate subsequent recipient. This person could be another transporter or a nontransporter. These records allow FDA to follow the chain of custody of the food through each transportation step, which may include a variety of forms of transportation (e.g., plane, train, and truck).

Because it is critically important 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, FDA has defined for nontransporters the immediate previous source and immediate subsequent recipient as the previous nontransporter or next nontransporter. This will allow FDA in most cases to efficiently and effectively determine where the food was contaminated and to locate where the contaminated food was sent. However, the contamination could occur during the transportation process as well. The records of transporters will ensure that FDA has the potential in all cases to determine the source of contamination and trace the food back and forward through the transportation chain. FDA recognizes that requiring nontransporters to keep records on both previous and subsequent transporters and nontransporters is potentially burdensome. FDA is mandating this in order to facilitate the efficient investigation of food related emergencies (records on nontransporters) and to increase the likelihood of a successful traceback by ensuring all those who handle the food are examined (records on transporters).

We also recognize that there could be other interpretations of the statute. 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. If it is discovered at company B that the food is contaminated, since company B only has records to identify Blue Truck Co. as its immediate previous source, FDA would have to trace back from company B to Blue Truck Co. and from there to the train, then to Red Truck Co., until FDA finally arrives at company A, the source of the contamination. 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.

We are requesting comments on whether the approach with two sets of immediate previous sources and immediate subsequent recipients in this proposed rule is a reasonable interpretation of the statute. We also request comments on whether all transporters, including small independent transporters, have the capability to maintain records for the 1 and 2 year record retention periods. FDA also requests comment on the extent to which the recordkeeping burden on nontransporters (previous and subsequent transporters and nontransporters) creates new burdens for firms. We are also interested in suggestions for alternative recordkeeping arrangements that would allow for the complete and efficient investigation of food-related emergencies. In addition, we request comments on whether an approach different from the proposed rule that would require or create incentives for nontransporters to obtain and keep records on all the transporters that transport food between the nontransporters, by obtaining the records from the transporters, would be a reasonable interpretation of the statute.

Proposed § 1.328 defines "manufacturing/processing" as making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Some examples of manufacturing/processing include, but are not limited to, cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. FDA is defining "manufacturing" and "processing" together because the meanings of the terms overlap. For example, combining two materials into a finished product, such as macaroni and cheese, could be considered "manufacturing," "processing," or both. Since both manufacturers and processors are subject to these regulations, FDA does not believe it is necessary to distinguish between manufacturing and processing in the proposed rule.

Proposed § 1.328 defines "nontransporter" as a person who owns food or who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation.