

Proposed § 1.328 defines the “nontransporter immediate previous source” as a nontransporter who last had an article of food before transferring it to another nontransporter.

Nontransporter immediate previous source includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity. Government entities include school systems, public hospitals, prisons, commissaries, etc.

Proposed § 1.328 defines “nontransporter immediate subsequent recipient” as a nontransporter who acquires an article of food from another nontransporter. Nontransporter immediate subsequent recipient also includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity.

Proposed §§ 1.337(a)(1) and 1.345(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 and nontransporter immediate subsequent recipient, respectively, whether domestic or foreign. We propose these requirements to mean the address and information of the specific location of where the statutorily covered activity occurred, and not that of a corporate headquarters at another location than where the activities took place. For example, a food product may be processed at a manufacturing plant, shipped to a packing facility, and then transported to a retail store all owned by the same corporation. The proposed requirements would apply to each individual location that received or released the food, even if each facility is owned by the same corporation. This would mean that firms would need to establish and maintain records accessible at each specific plant, packing facility, and retail store. FDA’s intention is that these requirements identify the physical location of the food at each step of the way as it travels through the chain of distribution, from the farm or sea to the consumer. FDA requests information on whether this requirement to keep records on intra-corporate transfers will impose new burdens upon firms or whether firms keep these records currently.

Proposed § 1.328 defines “perishable food” as food that is not heat-treated, not frozen, and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions.

The “perishable food” definition has been modeled after the current

Regulatory Procedures Manual definition of “perishable commodity” for purposes of this proposal. Examples include, but are not limited to, fluid milk (but not ultrapasteurized), live fish, lobster, crab, other crustaceans, shellfish, fresh fruits and vegetables. The agency is seeking comment on whether we have best defined “perishable food” for purposes of these regulations.

In addition, FDA is defining “perishable foods” for the purposes of establishing a shorter record retention time for those foods as opposed to nonperishable foods. FDA seeks comments on the proposed definition of perishable foods and whether the agency should use that definition as the basis for establishing record retention times.

Proposed § 1.328 defines “pet food” as food for nonfood-producing animals. Nonfood-producing animals include household pets, such as dogs and cats, and also include other nonfood-producing animals such as horses and circus and zoo animals.

Section 306 of the Bioterrorism Act does not extend to recipes. Proposed § 1.328 defines “recipe” as the quantitative formula used in the manufacturing of the food product, but not the identity of the individual ingredients of the food. If finalized as proposed, FDA would have access to the records containing the ingredients used in a food product, but would not have access to the quantities of the ingredients used to make a product. The act currently requires manufacturers to disclose to the public the ingredients they use on the labels of their food products. It is critical to a tracing investigation that the ingredients and the sources of the ingredients are identified.

Proposed § 1.328 defines “restaurant” as a facility that prepares and sells food directly to consumers for immediate consumption. As with farms, persons who engage in more than one type of activity may meet the definition of restaurant as to some of those activities while not meeting the definition of restaurant as to other activities. Those persons would be required to keep records as to those activities covered by this subsection that do not meet the definition of restaurant.

Some examples of restaurants as defined in the proposed regulations include: Cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens.

Due to possible ambiguity in the term “catering facilities,” FDA states in the proposed restaurant definition that facilities that provide food to interstate conveyances, such as airplanes, passenger trains, and cruise ships, rather than directly to consumers, are not restaurants. Facilities that provide food to interstate conveyances are not considered restaurants because they do not serve food directly to consumers for immediate consumption. For example, a facility that provides sandwiches to a passenger train for eventual sale to passengers would not be considered a restaurant. However, the snack bar on the train that sells the sandwiches to consumers would be considered a restaurant. FDA has historically inspected these facilities that provide food to interstate conveyances and considers them processors, rather than restaurants.

Because the proposed regulations also apply to persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for animal consumption in the United States, by analogy, the term “restaurant” also includes pet shelters, kennels, and veterinary facilities in which food is provided to animals.

Proposed § 1.328 defines “retail facility” as a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries. The limited exclusion from establishing and maintaining records of the immediate subsequent recipient applies only to food sold directly to consumers. A facility that sells food to wholesalers and/or other retailers, in addition to consumers, would have to keep records of the immediate subsequent recipients because wholesalers and retailers are not considered consumers for purposes of these proposed regulations.

Proposed § 1.328 defines “transporter” as a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food. A person who owns food or who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation is not a transporter.

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