

Key Terms Glossary

The proposed rule, "[Requirements for Additional Traceability Records for Certain Foods](#)," includes proposed definitions for several key terms used in the regulation. It may be helpful for you to familiarize yourself with those proposed definitions, which are summarized here.

This glossary does not always use the exact language of the proposed definitions, which can be found in proposed § 1.1310. This glossary also includes additional explanations of some of the definitions, which is excerpted or summarized from the preamble portion of the proposed rule (section V.C). We recommend that you review the proposed rule for complete information.

Category: A code or term used to classify a food product in accordance with a recognized industry or regulatory classification scheme, or a classification scheme a person develops for their own use. Examples of industry or regulatory classification schemes include the GS1 Global Product Classification standard, the United Nations Standard Products and Services Code, the Food and Agriculture Organization of the United Nations 3-Alpha Seafood Species Code, and the European Union Common Procurement Vocabulary.

Cooling: Active temperature reduction of a food using hydrocooling, icing, forced air cooling, vacuum cooling, or a similar process, either before or after packing.

Creating: Making or producing a food on the Food Traceability List (FTL) using only ingredient(s) that are not on the FTL. Creating does not include originating or transforming a food. Proposed recordkeeping requirements related to the creation of a listed food are discussed in sections V.D and V.E.4 of the proposed rule.

Critical Tracking Event (CTE): An event in the supply chain of a food involving the growing, receiving (including receipt by a first receiver), transforming, creating, or shipping of the food. Each CTE has specific recordkeeping requirements, discussed further in the proposal.

Farm: The proposed rule would define "farm" as it is [defined in the subpart J](#) traceability regulation and other FDA food safety regulations. The definition further states that, for producers of shell eggs, "farm means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program (matching the definition of a farm in the shell egg production regulations.)"

First Receiver: The first person (other than a farm) who purchases and takes physical possession of a food on the FTL that has been grown, raised, caught, or (in the case of a non-produce commodity) harvested. A first receiver of a food might be a manufacturer/processor, distributor, or other non-farm entity who receives a food that has been originated.

An entity that receives a listed food after it has been created (e.g., the first purchaser of a nut butter product) would not be a first receiver under the proposed rule. The proposed rule specifies specific Key Data Elements (KDEs) that first receivers would be required to establish and maintain in section V.E.2.

Fishing Vessel: Any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing, or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing.

Food Traceability List: The list of foods for which additional traceability records would be required, if the proposed rule is finalized. The term "Food Traceability List" includes both to the foods specifically listed and foods that contain listed foods as ingredients.

Growing Area Coordinates: The geographical coordinates (under the global positioning system (GPS) or latitude/longitude) for the entry point of the physical location where the food was grown and harvested.

Harvesting: Activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities (RACs) from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on RACs, or on processed foods created by drying/dehydrating a RAC without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a RAC into a processed food. Examples of harvesting include cutting (or otherwise separating) the edible portion of the RAC from the crop plant and removing or trimming part of the RAC (e.g., foliage, husks, roots, or stems).

Examples of harvesting also include collecting eggs, taking of fish and other seafood in aquaculture operations,

milking, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing RACs grown on a farm.

We propose not to include “cooling” as an example of harvesting activities in this proposed rule, even though it is included in the subpart J definition of “harvesting,” because for traceability purposes we wish to distinguish cooling from harvesting.

Holding: The storage of food, including activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating RACs when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)).

Holding would also include activities performed as a practical necessity for the distribution of that food (such as blending of the same RAC and breaking down pallets) but would not include activities that transform a RAC into a processed food. The proposed definition specifies that holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

As discussed in the proposed rule, we believe that persons who do not physically possess food are not engaged in holding of food within the meaning of the proposed rule. The proposed rule discusses in greater detail circumstances where an importer may import a food on the FTL, but never take physical possession of it, or when retail food establishments maintain records at a centralized location rather than the physical location where a food is being held. We recommend reviewing the proposed rule in detail for additional information regarding the application of the proposed rule under these circumstances.

Key Data Element: Information associated with a CTE for which a record would have to be established and maintained. Proposed requirements for records containing KDEs associated with CTEs are discussed further in section V.E. of the proposed rule.

Kill Step: Processing that significantly minimizes pathogens in a food. Examples of kill steps include cooking, pasteurization, heat treatment, high-pressure processing, and irradiation, as long as those processes are conducted in a manner that significantly minimizes pathogens in the food. We discuss proposed requirements for foods on the Food Traceability List that are subjected to a kill step in section V.F. of the proposed rule.

Location Description: A complete physical address and other key contact information, specifically the business name, physical location name, primary phone number, physical location street address (or geographical coordinates), city, state, and zip code for domestic facilities and comparable information for foreign facilities, including country; except that for fishing vessels, “location description” would mean the name of the fishing vessel that caught the seafood, the country in which the fishing vessel’s license (if any) was issued, and a point of contact for the fishing vessel.

Location Identifier: A unique identification code that an entity assigns to the physical location name identified in the corresponding location description; except that for fishing vessels, “location identifier” would mean the vessel identification number or license number (both if available) for the fishing vessel.

Lot: The food produced during a period of time at a single physical location and identified by a specific code. A lot may also be referred to as a “batch” or “production run.” While each firm determines the size or quantity of a lot, we recommend that lots consist of product produced under uniform conditions, be as small as possible, and generally not exceed 24 hours of production. Limiting the size of a lot allows for more precise traceability of a product and helps narrow the scope of potentially recalled product.

Manufacturing/processing: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include the following: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-Type Facility: An establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. The proposed definition further states that an example of a mixed-type facility is a farm mixed-type facility, which is an establishment that is a farm but also conducts activities outside the farm definition that require the establishment to be registered.

Nonprofit Food Establishment: A charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term would include central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment would be required to meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code.

Originating: An event in a food's supply chain involving the growing, raising, or catching of a food (typically on a farm, a ranch, or at sea), or the harvesting of a non-produce commodity.

Originator: A person who grows, raises, or catches a food, or harvests a non-produce commodity.

Packing: Placing food into a container other than packaging the food. "Packing" would also include re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but would not include activities that transform a RAC into a processed food.

Person: The term "person" includes an individual, partnership, corporation, and association. This matches the definition of "person" in section 201(e) of the FD&C Act.

Physical Location Name: The word(s) used to identify the specific physical site of a business entity where a particular CTE occurs. Examples could be "Packing Shed 2," "Store #7228," or "Warehouse A." The physical location name might be the same as an entity's business name if the entity has only one physical location.

Point of Contact: An individual having familiarity with an entity's procedures for traceability, including their name, telephone number, and, if available, their email address and fax number.

Produce: The proposal would adopt the definition of "produce" in § 112.3 in the produce safety regulations, which defines "produce" to mean any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs.

Receiving: An event in a food's supply chain in which a food is received by a customer (other than a consumer) at a defined location after being transported (e.g., by truck or ship) from another defined location. Receiving is a CTE for which KDEs are required to be kept. Further discussion regarding the proposed KDEs for receiving can be found in section V.E.3 of the proposed rule.

Reference Record: A record used to identify an event in the supply chain of a food, such as a shipping, receiving, growing, creating, or transformation event. The proposed definition states that types of reference records include, but are not limited to, bills of lading (BOL), purchase orders, advance shipping notices (ASNs), work orders, invoices, batch logs, production logs, and receipts. We discuss the use of reference records in product tracing beginning in section V.D.1.

Reference Record Number: The identification number assigned to a reference record, such as a purchase order number, bill of lading number, or work order number.

Retail Food Establishment: An establishment that sells food products directly to consumers as its primary function. The definition in the proposed rule further specifies the following:

- the term "retail food establishment" includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell such food directly to consumers;
- a retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers;
- the term "consumers" in the definition does not include businesses; and
- retail food establishments include, but are not limited to, grocery stores, convenience stores, and vending machine locations.

The definition of "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function, including:

- at a roadside stand or farmer's market;
- through a community supported agriculture (CSA) program. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

- at other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

The definition further states that the sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers in the same circumstances just specified with respect to sale of food directly to consumers from an establishment located on a farm.

Although not specified in this definition of “retail food establishment,” the proposed rule explains that we regard restaurants, online food retailers, and meal kit delivery companies as other examples of such establishments.

Shipping: An event in a food's supply chain in which a food is arranged for transport (e.g., by truck or ship) from a defined location to another defined location at a different farm, a first receiver, or a subsequent receiver. This would mean that, for example, shipping would not include arranging for transport of a food between different locations of a single farm. The definition in the proposed rule further specifies that shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food.

We discuss the traceability records we propose to require for shipment of foods on the FTL in section V.E.5 of the proposed rule.

Traceability Lot: A lot of food that has been originated, transformed, or created.

Traceability Lot Code: A descriptor, often alphanumeric, used to identify a traceability lot. As with location descriptions and location identifiers, traceability lot codes are typically stored in business systems and printed in human readable and machine-readable format on food product packaging. We discuss the generation and use of traceability lot codes in product tracing in section V.D.1.

Traceability Lot Code Generator: The person who assigns a traceability lot code to a product.

Traceability Product Description: A description of a food product typically used commercially for purchasing, stocking, or selling, and includes the category code or term, category name, and trade description.

The proposed definition of “traceability product description” further states that for single-ingredient products, the trade description includes the brand name, commodity, variety, packaging size, and packaging style; for multiple-ingredient food products, the trade description includes the brand name, product name, packaging size, and packaging style.

The same term might be used for different components of the traceability product description of a food. For example, “cucumber” may be used as both the category and the commodity.

Traceability Product Identifier: A unique identification code (such as an alphanumeric code) that an entity assigns to designate a specific type of food product. As with traceability lot codes and traceability product descriptions, traceability product identifiers are typically stored in business systems and printed in human and machine-readable format on food product packaging. We discuss the use of traceability product identifiers in section V.E.3.

Transformation: An event in a food's supply chain that involves changing a food on the FTL, its package, and/or its label (regarding the traceability lot code or traceability product identifier), such as by combining ingredients or processing a food (e.g., by cutting, cooking, commingling, repacking, or repackaging). This would not include initial packing of a single-ingredient food or creating a food. The definition of “transformation” in the proposed rule might differ from the way the term is defined in other traceability systems and approaches; however, as discussed in the proposed rule, we believe this definition is appropriate for use with traceability records for foods on the FTL. We discuss the traceability records we propose to require for transformation events in section V.E.4 of the proposed rule.

Transporter: A person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air. We propose to exempt transporters from this rule, if finalized.

Vessel Identification Number: The number assigned to a fishing vessel by the International Maritime Organization, or by any entity or organization, for the purpose of uniquely identifying the vessel. We request comment on whether the proposed definition provides appropriate flexibility regarding the manner in which fishing vessels are uniquely identified.