



CHEESE IMPORTERS ASSOCIATION OF AMERICA

CIAA MEMBER BULLETIN: FDA Proposes Additional Traceability Requirements for Certain Foods, Including Soft Cheeses

Earlier this week, the U.S. Food and Drug Administration (FDA) issued a [proposed rule](#) that would add traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods FDA has designated for inclusion on the Food Traceability List (FTL). These proposed recordkeeping requirements are mandated by Section 204(d) of the Food Safety Modernization Act for certain “high-risk foods” identified by FDA and would be in addition to what is already required by existing FDA regulations (i.e. one step forward, one step backwards). When finalized, the proposal would standardize the data elements and information food companies must establish and maintain, and the information they would need to send to the next entity in the supply chain to facilitate rapid and accurate traceability needed to prevent or mitigate foodborne illness outbreaks.

At a high level, the proposal will require entities that manufacture, process, pack or hold foods on the FTL to establish and maintain records containing Key Data Elements (KDEs) associated with different Critical Tracking Events (CTEs). FDA identified the following foods for including on the FTL based upon a [risk ranking model for food tracing](#):

Foods	Description
Cheeses, other than hard cheeses	Includes all soft ripened or semi-soft cheeses, and fresh soft cheeses that are made with pasteurized or unpasteurized milk
Shell eggs	Shell egg means the egg of the domesticated chicken
Nut butter	Includes all types of tree nut and peanut butters; does not include soy or seed butters
Cucumbers	Includes all varieties of cucumbers
Herbs (fresh)	Includes all types of herbs, such as parsley, cilantro, basil
Leafy greens, including fresh-cut leafy greens	Includes all types of leafy greens, such as lettuce, (e.g., iceberg, leaf and Romaine lettuces), kale, chicory, watercress, chard, arugula, spinach, pak choi, sorrel, collards, and endive
Melons	Includes all types of melons, such as cantaloupe, honeydew, and watermelon
Peppers	Includes all varieties of peppers
Sprouts	Includes all varieties of sprouts
Tomatoes	Includes all varieties of tomatoes
Tropical tree fruits	Includes all types of tropical tree fruit, such as mango, papaya, mamey, guava, lychee, jackfruit, and starfruit

Fruits and Vegetables (fresh-cut)	Includes all types of fresh-cut fruits and vegetables
Finfish, including smoked finfish	Includes all finfish species, such as cod, haddock, Alaska pollack, tuna, mahi mahi, mackerel, grouper, barracuda, and salmon; except does not include siluriformes fish, such as catfish [1]
Crustaceans	Includes all crustacean species, such as shrimp, crab, lobster, and crayfish
Mollusks, bivalves	Includes all species of bivalve mollusks, such as oysters, clams, and mussels; does not include scallop adductor muscle.
Ready-to-eat deli salads	Includes all types of ready-to-eat deli salads, such as egg salad, potato salad, pasta salad, and seafood salad; does not include meat salads

The proposed rule identifies growing, receiving, transforming, creating, and shipping as critical tracking events for which an entity must develop records that contain key data elements. The data element that must be generated depends upon the tracking event that occurs:

- Growing: The proposed rule would require the grower of the food to establish and maintain records containing and linking the traceability lot code of the food that include the growing area coordinates. The proposed rule contains additional KDEs for sprout growers.
- Receiving: The proposed rule would require the receiver to establish and maintain records containing and linking the traceability lot code for the food to the following information:
 - Location identifier and location description for the immediate previous source (other than a transporter) of the food;
 - Entry number assigned to the food (if imported);
 - Location identifier and location description of where the food was received, and the date and time the food was received;
 - The quantity and unit of measure of the food (e.g., 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds);
 - Traceability product identifier and traceability product description for the food
 - Location identifier, location description, and point of contact for the traceability lot code generator;
 - Reference record type(s) and reference record number(s) (e.g., “Invoice 750A,” “BOL 042520 XYX”) for the records relating to receipt of the food;
 - The name of the transporter who transported the food to the receiver; and
 - If the entity is the first receiver (the first person (other than a farm) who purchases and takes physical possession of a listed food) except for seafood from a fishing vessel, must maintain the following additional records:
 - Traceability lot code (if not previously established, the first receiver would be required to establish the traceability lot code and maintain records linking the traceability lot code to the other KDEs);
 - Location identifier and location description of the originator of the food
 - Business name/phone number/ point of contact of harvester of the food and the date(s) and time(s) of harvesting;
 - Location identifier and location description of the place the food was cooled, and the date and time of cooling (if applicable); and
 - Location identifier and location description of the place where the food was packed, and the date and time of packing.
- Creating: A person who creates a food (making or producing of a food through manufacturing or processing using only ingredient(s) that are not on the that are not on the FTL) on the FTL would

be required to establish and maintain records containing and linking the traceability lot code of the food created to the following information:

- Location identifier and location description of where the food was created, and the date creation was complete;
 - The traceability product identifier and traceability product description for the food;
 - The quantity and unit of measure of the food; and
 - Reference record type(s) and reference record number(s) for records relating to creation.
- **Transforming:** The transformer of the food would be required to establish and maintain records containing and linking the new traceability lot code of the food produced through transformation (changing a food on 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), but does not include the initial packing of a single-ingredient food or creating a food) to include the following information:
 - Traceability product identifier and traceability product description for the foods used in transformation;
 - The quantity of each traceability lot of the food used in transformation;
 - Location identifier and location description for where the food was transformed and the date the transformation was completed;
 - The new traceability product identifier and traceability product description for the food produced through transformation;
 - The quantity and unit of measure of the food produced through transformation (e.g., 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds); and
 - Reference record type(s) and number(s) for records relating to transformation.
 - **Shipping:** The proposed rule would require persons who ship a food on the FTL to establish and maintain records containing and linking the traceability lot code(s) for the food to the following information, as well as send these records to the subsequent recipient:
 - Entry number(s) assigned to the food (if imported);
 - The quantity and unit of measure of the food;
 - Traceability product identifier and traceability product description for the food;
 - Location identifier, location description, and point of contact for the traceability lot code generator;
 - Location identifier and description of the immediate subsequent recipient of the food (other than a transporter);
 - Location identifier and location description for the location from which the food was shipped, and the date and time the food was shipped;
 - Reference record type(s) and reference record number(s) for documents relating to shipment;
 - Transporter's name who transported the food from the shipper;
 - If the shipper is a farm, the following information must also be sent to the immediate subsequent recipient:
 - A statement that the shipper is a farm;
 - Location identifier and location description of the originator of the food (if not the shipper);
 - The business name, point of contact, and phone number of the harvester of the food (if not the shipper), and the date(s) and time(s) of harvesting;

- Location identifier and location description of the place where the food was cooled (if not by the shipper), and the date and time of cooling; and
- Location identifier and location description of the place where the food was packed (if not by the shipper), and the date and time of packing.

The proposed rule also requires who manufacture, process, pack or hold foods on the FTL to establish and maintain traceability program records. These records must contain:

- A description of relevant reference records;
- A List of foods on the FTL that are shipped;
- A description of how traceability lot codes are assigned; and
- Other information needed to understand the data contained in the require records (such as internal or external coding systems or classification schemes, glossaries, and abbreviations).

Finally, the proposed rule also includes a number of exemptions from the additional traceability requirements such as:

- Certain farms and other originators that produce relatively small quantities of food;
- Farms that sell directly to consumers (such as at farmers' markets, roadside stands, over the internet, and through community supported agriculture program);
- Certain food produced and packaged on a farm;
- Produce and shelled eggs that undergo certain processing;
- Produce that is rarely consumed as raw;
- Certain commingled raw agricultural commodities (RACs) that are subject to the Produce Safety Rule;
- Certain retail food establishments;
- Foods that are produced on a farm and sold directly to the school or institution;
- Activities of certain fishing vessels.
- Food transporters;
- Non-profit food establishments;
- Persons who manufacture, process, pack or hold food for personal consumption;
- Persons who hold food on behalf of specific individual consumers, provided that they are not parties to the transaction and are not in the business of distributing food; and
- Foods subsequently subject to processing that significantly minimizes pathogens, such as cooking or pasteurization so long as records of the application of this processing step are maintained.

The FDA is accepting public comment on the proposed rule until January 21, 2020 via [regulations.gov](https://www.regulations.gov) (Docket No. FDA-2014-N-0053).

The CIAA is closely evaluating the impact of this proposed rule on its members. Please share any feedback you believe should be considered in any comments CIAA would submit to FDA on this proposal to the Husch Blackwell LLP team at CIAAGeneralCounsel@huschblackwell.com.

