Contains Nonbinding Recommendations

Requirements for Additional Traceability Records for Certain Foods: What You Need to Know About the FDA Regulation: Guidance for Industry

Small Entity Compliance Guide

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U.S. Department of Health and Human Services
Food and Drug Administration
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Table of Contents

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This guidance represents the current thinking of the Food and Drug Administration (FDA, the Agency, or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

On January 4, 2011, President Obama signed the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) into law. As a component of FSMA's overhaul of U.S. food safety law to better ensure the safety and security of the nation's food supply, section 204(d) of FSMA requires that FDA establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods the Agency designates as high-risk to facilitate the rapid and effective traceability of such foods. These recordkeeping requirements are additional to the food traceability requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (added to the FD&C Act in title III, subtitle A, section 306, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188)) and the implementing regulations in subpart J of part 1 of title 21 of the Code of Federal Regulations (§§ 1.326 to 1.368) (the subpart J regulations). In section 204(d)(1) of FSMA, Congress directed FDA to adopt additional recordkeeping requirements to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death to humans or animals resulting from certain foods being adulterated under section 402 of the FD&C Act or misbranded with respect to allergen labeling under section 403(w) of the FD&C Act.

On November 21, 2022, FDA published the final rule entitled, "Requirements for Additional Traceability Records for Certain Foods" (Food Traceability Rule) (87 FR 70910). The regulation can be found at 21 CFR part 1, subpart S (§§ 1.1300-1.1465).

We have prepared this Small Entity Compliance Guide (SECG) in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document is intended to help small entities, including farms and small businesses, comply with the requirements of the Food Traceability Rule as established in 21 CFR part 1, subpart S. The regulations are binding and have the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Key Terms

The Food Traceability Rule uses a number of terms in specific ways. A full list of these terms appears in this guidance beginning on page 32. Table 1 lists some of the key terms used in this document.

Table 1 – Key Terms Used in the Food Traceability Rule

Term	**Definition**
Critical Tracking Event (CTE)	Event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity (RAC) other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.
Food Traceability List (FTL)	The list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d)(2) of the FSMA. The term FTL includes both the foods specifically listed and foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list.
Key Data Element (KDE)	Information associated with a CTE for which a record must be maintained and/or provided.
Kill step	Lethality processing that significantly minimizes pathogens in a food.
Location description	Key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country.
Traceability Lot	A batch or lot of food that has been initially packed (for raw agricultural commodities other than food obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.
Traceability Lot Code (TLC)	A descriptor, often alphanumeric, used to uniquely identify a

Term	Definition
	traceability lot within the records of the traceability lot code source.
Traceability Lot Code source	The place where a food was assigned a TLC.
Traceability Lot Code source reference	An alternative method for providing FDA with access to the location description for the traceability lot code source as required under this subpart. Examples of a traceability lot code source reference include, but are not limited to, the FDA Food Facility Registration Number for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source.

III. Questions and Answers

A. Who is Subject to the Food Traceability Rule? (§ 1.1300)

The requirements of the Food Traceability Rule apply to persons who manufacture, process, pack, or hold foods that appear on the Food Traceability List. FDA published the FTL on its website, https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list.

B. What is the Food Traceability List? (§ 1.1310)

The Food Traceability List (FTL) identifies the foods for which additional traceability records are required under the Food Traceability Rule. The additional recordkeeping requirements apply to the foods specifically listed on the FTL, and to foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list.

C. When Must I Comply with the Food Traceability Rule?

The compliance date for all persons subject to the Food Traceability Rule is Tuesday, January 20, 2026.

D. Who Is Exempt from the Food Traceability Rule? (§ 1.1305)

Certain persons and foods are fully exempt from the requirements of the Food Traceability Rule, while others may be eligible for partial exemptions. FDA has developed a software tool to help you determine whether an exemption may apply to you. You can access the tool at: https://collaboration.fda.gov/tefcv13/.

Table 2 – Full and Partial Exemptions from the Food Traceability Rule

Exemption	**Additional Details**	**Citation**
Farm (or farm activities of a farm mixed-type facility) with respect to the produce they grow, when the farm is not a covered farm under 21 CFR 112.4(a) (a provision in the produce safety regulation)	Farm or farm mixed-type facility with an average annual monetary value of produce sold during the previous 3-year period of $25,000 (on a rolling basis) or less, adjusted for inflation using 2011 as the baseline year for calculating the adjustment	§ 1.1305(a)(1)(i)
Produce farm averaging $25,000 or less in sales of produce and market value of produce, adjusted for inflation using 2020 as the baseline year	Calculation based on average annual sum of the monetary value of sales of produce and the market value of produce manufactured, processed, packed, or held without sale (e.g., held for a fee) during the previous 3-year period	§ 1.1305(a)(1)(ii)
Shell egg producers with <3,000 laying hens at a particular farm	Exemption applies to the shell eggs produced at that farm	§ 1.1305(a)(2)
Producers of raw agricultural commodities (RACs) other than produce or shell eggs averaging $25,000 or less in sales of RACs and market value of RACs, adjusted for inflation using 2020 as the baseline year	Calculation based on average annual sum of the monetary value of sales of RACs and the market value of RACs manufactured, processed, packed, or held without sale (e.g., held for a fee) during the previous 3-year period	§ 1.1305(a)(3)
Farm when food produced on that farm is sold or donated directly to a consumer by the owner, operator, or agent in charge of the farm		§ 1.1305(b)

Exemption	Additional Details	Citation
Food produced and packaged on a farm that meets certain packaging and labeling criteria	(1) The packaging of the food remains in place until the food reaches the consumer, and such packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and (2) The labeling of the food that reaches the consumer includes the name, complete address (street address, town, State, country, and zip or other postal code for a domestic farm and comparable information for a foreign farm), and business phone number of the farm on which the food was produced and packaged. FDA will waive the requirement to include a business phone number, as appropriate, to accommodate a religious belief of the individual in charge of the farm.	§ 1.1305(c)
Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance	Conditions set forth in 21 CFR 112.2(b), which is part of the produce safety regulation, must be met for the produce	§ 1.1305(d)(1)
Shell eggs when all eggs produced at the particular farm receive a treatment (as defined in 21 CFR 118.3) in accordance with 21 CFR 118.1(a)(2), which is part of the shell egg regulation		§ 1.1305(d)(2)
Food that you subject to a kill step, provided that you maintain certain information in records	You keep: (i) The information specified in § 1.1345 for your receipt of the food to which you apply the kill step (unless you have entered into a written agreement concerning your application of a kill step to the food in accordance with § 1.1305(d)(6); and (ii) A record of your application of the kill step;	§ 1.1305(d)(3)
Food that you change such that the food is no longer on the FTL, provided that you maintain records containing the information specified in § 1.1345 for your receipt of the food you change		§ 1.1305(d)(4)

Exemption	Additional Details	Citation
Food that you receive that has previously been subjected to a kill step or that has previously been changed such that the food is no longer on the FTL		§ 1.1305(d)(5)
Food that will be subjected to a kill step by an entity other than a retail food establishment, restaurant, or consumer; or that will be changed by an entity other than a retail food establishment, restaurant, or consumer, such that the food will no longer be on the FTL, provided that there are certain written agreements	(i) There is a written agreement between the shipper of the food and the receiver stating that the receiver will apply a kill step to the food or change the food such that it is no longer on the FTL; or (ii) There is a written agreement between the shipper of the food and the receiver stating that an entity in the supply chain subsequent to the receiver will apply a kill step to the food or change the food such that it is no longer on the FTL and that the receiver will only ship the food to another entity that agrees, in writing, it will: (A) Apply a kill step to the food or change the food such that it is no longer on the FTL; or (B) Enter into a similar written agreement with a subsequent receiver stating that a kill step will be applied to the food or that the food will be changed such that it is no longer on the FTL. (iii) Any such written agreement must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement; and (iv) Such written agreement must be maintained by both parties for as long as it is in effect and must be renewed at least once every 3 years.	§ 1.1305(d)(6)
Produce that is listed as rarely consumed raw in 21 CFR 112.2(a)(1), which is part of the produce safety regulation	Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.	§ 1.1305(e)

Exemption	Additional Details	Citation
Raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation Program, subject to the requirements of 21 CFR part 123, subpart C, and 21 CFR 1240.60, or covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish		§ 1.1305(f)
Persons who manufacture, process, pack, or hold food on the FTL during or after the time when the food is within the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.)		§ 1.1305(g)

Exemption	Additional Details	Citation
Commingled raw agricultural commodities, except that this exemption does not apply to fruits and vegetables covered by the Produce Safety Regulation (21 CFR part 112).	"Commingled" means the RAC is combined or mixed after harvesting but before processing. "Processing" means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization. A commodity is "combined or mixed" only when the combination or mixing involves food from different farms under different company management; except that for food obtained from a fishing vessel, a commodity is "combined or mixed" only when the combination or mixing involves food from different landing vessels and occurs after the vessels have landed. If a person who manufactures, processes, packs, or holds such commingled RAC is required to register with FDA under section 415 of the FD&C Act with respect to the manufacturing, processing, packing, or holding of the RAC, such person must maintain records identifying the immediate previous source of such RAC and the immediate subsequent recipient of such food in accordance with 21 CFR §§ 1.337 and 1.345. Such records must be maintained for 2 years.	§ 1.1305(h)(1)

Exemption	Additional Details	Citation
A raw agricultural commodity that will become a commingled RAC provided that certain conditions are met. This exemption does not apply to fruits and vegetables covered by the Produce Safety Regulation (21 CFR part 112).	The definition of "commingled" applies. In addition:(i) There is a written agreement between the shipper of the RAC and the receiver stating that the receiver will include the commodity as part of a commingled RAC; or (ii) There is a written agreement between the shipper of the RAC and the receiver stating that an entity in the supply chain subsequent to the receiver will include the commodity as part of a commingled RAC and that the receiver will only ship the RAC to another entity that agrees, in writing, it will either: (A) Include the RAC as part of a commingled RAC; or (B) Enter into a similar written agreement with a subsequent receiver stating that the RAC will become part of a commingled RAC; (iii) Any such written agreement must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement; and (iv) Such a written agreement must be maintained by both parties for as long as it is in effect and must be renewed at least once every 3 years. If a person who manufactures, processes, packs, or holds such commodity is required to register with FDA under section 415 of the FD&C Act with respect to the manufacturing, processing, packing, or holding of the applicable RAC, such person must maintain records identifying the immediate previous source of such RAC and the immediate subsequent recipient of such food in accordance with 21 CFR §§ 1.337 and 1.345. Such records must be maintained for 2 years.	§ 1.1305(h)(2)

Exemption	Additional Details	Citation
Retail food establishments and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment		§ 1.1305(i)
Retail food establishment or restaurant with respect to a food that is produced on a farm and both sold and shipped directly to the retail food establishment or restaurant by the owner, operator, or agent in charge of that farm	The retail food establishment or restaurant must maintain a record documenting the name and address of the farm that was the source of the food for 180 days.	§ 1.1305(j)
Both entities when a purchase is made by a retail food establishment or restaurant from another retail food establishment or restaurant, and the purchase occurs on an *ad hoc* basis outside of the buyer's usual purchasing practice (e.g., not pursuant to a contractual agreement to purchase food from the seller).	The retail food establishment or restaurant that makes the purchase must maintain a record (e.g., a sales receipt) documenting the name of the product purchased, the date of purchase, and the name and address of the place of purchase	§ 1.1305(k)
An institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966, or any other entity conducting a farm to school or farm to institution program, with respect to a food that is produced on a farm (including food produced and packaged on the farm) and sold or donated to the school or institution	The school food authority or relevant food procurement entity must maintain a record documenting the name and address of the farm that was the source of the food for 180 days	§ 1.1305(l)

Exemption	Additional Details	Citation
The owner, operator, or agent in charge of a fishing vessel; and also any persons who manufacture, process, pack, or hold the food that is obtained from the fishing vessel, until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel	If such person is required to register with FDA under section 415 of the FD&C Act with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with 21 CFR §§ 1.337 and 1.345. Such records must be maintained for 2 years.	§ 1.1305(m)
Transporter of food	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.	§ 1.1305(n)
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 includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).	§ 1.1305(o)
Persons who manufacture, process, pack, or hold food for personal consumption		§ 1.1305(p)
Persons who hold food on behalf of specific individual consumers provided certain conditions are met	Such persons: (1) Are not parties to the transaction involving the food they hold; and (2) Are not in the business of distributing food.	§ 1.1305(q)
Food for research or evaluation use provided certain conditions are met	Such food: (1) Is not intended for retail sale and is not sold or distributed to the public; and (2) Is accompanied by the statement "Food for research or evaluation use."	§ 1.1305(r)

Traceability Plan

E. What Traceability Plan Must I Have for Foods on the FTL that I Manufacture, Process, Pack, or Hold? (§ 1.1315)

If you are subject to the requirements of the Food Traceability Rule, you must establish and maintain a traceability plan containing the following information:

> (1) A description of the procedures you use to maintain the records you are required to keep under the Food Traceability Rule, including the format and location of these records;
> (2) A description of the procedures you use to identify foods on the FTL that you manufacture, process, pack, or hold;
> (3) A description of how you assign traceability lot codes to foods on the FTL in accordance with § 1.1320, if applicable;
> (4) A statement identifying a point of contact for questions regarding your traceability plan and records; and
> (5) If you grow or raise a food on the FTL (other than eggs), a farm map showing the areas in which you grow or raise such foods. The farm map must show the location and name of each field or other growing area where you grow a food on the FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area. For aquaculture farms, the farm map must show the location and name of each container (e.g., pond, pool, tank, cage) in which you raise seafood on the FTL, including geographic coordinates and any other information needed to identify the location of each container.

F. When Must I Update My Traceability Plan?

You must update your traceability plan as needed to ensure that it reflects your current practices and that you meet the requirements of the rule. You must keep your previous traceability plan for 2 years after you update it.

G. When Must I Assign Traceability Lot Codes to Foods on the FTL? (§§1.1320 and 1.1345(b)(1))

For foods on the FTL, you must assign a traceability lot code when you do any of the following:

- Initially pack a raw agricultural commodity other than a food obtained from a fishing vessel;
- Perform the first land-based receiving of a food obtained from a fishing vessel;
- Transform a food; or
- Receive a food from a person to whom the Food Traceability Rule does not apply, provided you are not a retail food establishment or restaurant.

You must **not** establish a new traceability lot code when you conduct other activities for a food on the FTL. For example, you must not establish a new traceability lot code when you ship a food on the FTL.

Records of Critical Tracking Events

H. What Records Must I Keep and Provide When I Harvest a Raw Agricultural Commodity (RAC) (Other Than a Food Obtained from a Fishing Vessel) on the FTL? (§ 1.1325(a))

If you harvest a RAC on the FTL, and the RAC is not obtained from a fishing vessel, you must keep records containing the following information:

(i) The location description for the immediate subsequent recipient (other than a transporter) of the food;

(ii) The commodity and, if applicable, variety of the food;

(iii) The quantity and unit of measure of the food (e.g., 75 bins, 200 pounds);

(iv) The location description for the farm where the food was harvested;

(v) For produce RACs, you must maintain a record that contains the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name.

(vi) For aquacultured food, you must maintain a record that contains the name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name.

(vii) The date of harvesting; and

(viii) The reference document type and reference document number.

You must provide the above information (except for the reference document type and number), along with your business name and phone number, to the initial packer of the RAC you harvest, either directly or through the supply chain. The information can be provided in electronic, paper, or other written form.

I. What Records Must I Keep and Provide When I Cool a Raw Agricultural Commodity (Other Than a Food Obtained from a Fishing Vessel) on the FTL Before It is Initially Packed? (§ 1.1325(b))

If you cool a RAC on the FTL before it is initially packed, and the RAC is not obtained from a fishing vessel, you must keep records containing the following information:

(i) The location description for the immediate subsequent recipient (other than a transporter) of the food;
(ii) The commodity and, if applicable, variety of the food;
(iii) The quantity and unit of measure of the food (e.g., 75 bins, 200 pounds);

(iv) The location description for where you cooled the food;
(v) The date of cooling;
(vi) The location description for the farm where the food was harvested; and
(vii) The reference document type and reference document number.

You must provide this information (except for the reference document type and number) to the initial packer of the RAC that you cool, either directly or through the supply chain. The information can be provided in electronic, paper, or other written form.

J. What Records Must I Keep When I Am Performing the Initial Packing of a Raw Agricultural Commodity (Other Than a Food Obtained from a Fishing Vessel) on the FTL? (§ 1.1330(a))

For each traceability lot of a RAC on the FTL you initially pack, when the RAC was not obtained from a fishing vessel, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The commodity and, if applicable, variety of the food received;
(2) The date you received the food;
(3) The quantity and unit of measure of the food received (e.g., 75 bins, 200 pounds);
(4) The location description for the farm where the food was harvested;
(5) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;
(6) For aquacultured food, the name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name;
(7) The business name and phone number for the harvester of the food;
(8) The date of harvesting;
(9) The location description for where the food was cooled (if applicable);
(10) The date of cooling (if applicable);
(11) The traceability lot code you assigned;
(12) The product description of the packed food;
(13) The quantity and unit of measure of the packed food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
(14) The location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
(15) The date of initial packing; and
(16) The reference document type and reference document number.

K. What Additional Information Must I Keep When I Am Performing the Initial Packing of Sprouts (Except Soil- or Substrate-Grown Sprouts Harvested Without Their Roots)? (§ 1.1330(b))

For each traceability lot of sprouts (except soil- or substrate-grown sprouts harvested without their roots) you initially pack, in addition to the information required under § 1.1330(a) (see Section II.J XX), you must also maintain records containing the following information and linking this

information to the traceability lot:

(1) The location description for the grower of seeds for sprouting and the date of seed harvesting, if either is available;
(2) The location description for the seed conditioner or processor, the associated seed lot code, and the date of conditioning or processing;
(3) The location description for the seed packinghouse (including any repackers), the date of packing (and of repacking, if applicable), and any associated seed lot code assigned by the seed packinghouse;
(4) The location description for the seed supplier, any seed lot code assigned by the seed supplier (including the master lot and sub-lot codes), and any new seed lot code assigned by the sprouter;
(5) A description of the seeds, including the seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment;
(6) The date of receipt of the seeds by the sprouter; and
(7) The reference document type and reference document number.

L. What Records Must I Keep When I Am Performing the Initial Packing of a Raw Agricultural Commodity (Other than a Food Obtained from a Fishing Vessel) on the FTL That I Received From a Person Who Is Not Subject to the Food Traceability Rule? (§ 1.1330(c))

For each traceability lot of a RAC (other than a food obtained from a fishing vessel) on the FTL you initially pack that you receive from a person who is not subject to the Food Traceability Rule, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The commodity and, if applicable, variety of the food received;
(2) The date you received the food;
(3) The quantity and unit of measure of the food received (e.g., 75 bins, 200 pounds);
(4) The location description for the person from whom you received the food;
(5) The traceability lot code you assigned;
(6) The product description of the packed food;
(7) The quantity and unit of measure of the packed food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
(8) The location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
(9) The date of initial packing; and
(10) The reference document type and reference document number.

M. What Records Must I Keep When I Am the First Land-Based Receiver of a Food on the FTL that was Obtained From a Fishing Vessel? (§ 1.1335)

For each traceability lot of a food obtained from a fishing vessel for which you are the first land-based receiver, you must maintain records containing the following information and linking this information to the traceability lot:

(a) The traceability lot code you assigned;

(b) The species and/or acceptable market name for unpackaged food, or the product description for packaged food;
(c) The quantity and unit of measure of the food (e.g., 300 kg);
(d) The harvest date range and locations (as identified under the National Marine Fisheries Service Ocean Geographic Code, the United Nations Food and Agriculture Organization Major Fishing Area list, or any other widely recognized geographical location standard) for the trip during which the food was caught;
(e) The location description for the first land-based receiver (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
(f) The date the food was landed; and
(g) The reference document type and reference document number.

N. What Records Must I Keep and Provide When I Ship a Food on the FTL? (§ 1.1340)

For each traceability lot of a food on the FTL you ship, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The traceability lot code for the food;
(2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
(3) The product description for the food;
(4) The location description for the immediate subsequent recipient (other than a transporter) of the food;
(5) The location description for the location from which you shipped the food;
(6) The date you shipped the food;
(7) The location description for the traceability lot code source, or the traceability lot code source reference; and
(8) The reference document type and reference document number.

You must provide this information, except for the reference document type and reference document number, to the immediate subsequent recipient that is not a transporter of each traceability lot that you ship. The information can be provided in electronic, paper, or other written form.

You do not have to keep and provide records of the above information for any shipment of a RAC not obtained from a fishing vessel that occurs before the RAC is initially packed.

O. What Records Must I Keep When I Receive a Food on the FTL? (§ 1.1345(a), (c))

For each traceability lot of a food on the FTL you receive, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The traceability lot code for the food;
(2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
(3) The product description for the food;
(4) The location description for the immediate previous source (other than a transporter) for the food;
(5) The location description for where the food was received;

(6) The date you received the food;
(7) The location description for the traceability lot code source, or the traceability lot code source reference; and
(8) The reference document type and reference document number.

You do not need to keep records of this information for receipt of any RACs not obtained from a fishing vessel that you receive before the food is initially packed, or for receipt of a food obtained from a fishing vessel if you are the first land-based receiver of that food.

P. What Records Must I Keep When I Receive a Food on the FTL from a Person Who Is Not Subject to the Food Traceability Rule? (§ 1.1345(b))

For each traceability lot of a food on the FTL you receive from a person to whom the Food Traceability Rule does not apply, you must maintain records containing the following information and linking this information to the traceability lot:

(1) The traceability lot code for the food, which you must assign if one has not already been assigned (except that this requirement does not apply if you are a retail food establishment or restaurant);
(2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
(3) The product description for the food;
(4) The location description for the immediate previous source (other than a transporter) for the food;
(5) The location description for where the food was received (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
(6) The date you received the food; and
(7) The reference document type and reference document number.

Q. What Records Must I Keep When I Transform a Food on the FTL? (§ 1.1350)

For each new traceability lot of food you produce through transformation, you must maintain records containing the following information and linking this information to the new traceability lot:

For the food on the FTL that you use in transformation (if applicable), the following information:

(i) The traceability lot code for the food;
(ii) The product description for the food to which the traceability lot code applies; and
(iii) For each traceability lot used, the quantity and unit of measure of the food used from that lot.

For the food you produced through transformation, the following information:

(i) The new traceability lot code for the food;
(ii) The location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
(iii) The date transformation was completed;
(iv) The product description for the food;

(v) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds); and
(vi) The reference document type and reference document number for the transformation event.

For each traceability lot produced through transformation of a RAC (other than a food obtained from a fishing vessel) on the FTL that was not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c) (see Sections II.J and II.L), and, if the RAC is sprouts, the information specified in § 1.1330(b) (see Section II.K).

Retail food establishments and restaurants do not have to maintain records of this information for foods they do not ship (e.g., foods they sell or send directly to consumers).

Procedures for Modified Requirements and Exemptions

R. Under What Circumstances Will FDA Modify the Requirements of the Food Traceability Rule That Apply to a Food or Type of Entity or Exempt a Food or Type of Entity from the Requirements of the Food Traceability Rule? (§ 1.1360(a))

FDA will modify the requirements of the Food Traceability Rule applicable to a food or type of entity, or exempt a food or type of entity from the requirements of this rule, when we determine that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health.

S. What Records Must I Maintain if I Am Subject to FDA's Food Facility Registration Requirements but I Qualify for Modified Requirements or an Exemption from the Food Traceability Rule Requirements? (§ 1.1360(b))

If modified requirements or an exemption of the type described in § 1.1360(a) (see Question R) apply to you and you are required to register with FDA under section 415 of the FD&C Act (in accordance with the Food Facility Registration regulation) with respect to the manufacturing, processing, packing, or holding of the applicable food, you must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with 21 CFR §§ 1.337 and 1.345 for 2 years.

T. When Will FDA Consider Whether to Adopt Modified Requirements or Grant an Exemption from the Requirements of the Food Traceability Rule? (§ 1.1365)

FDA will consider modifying the requirements of the Food Traceability Rule applicable to a food or type of entity, or exempting a food or type of entity, on our own initiative or in response to a citizen petition submitted under 21 CFR 10.30 by any interested party. More information on how to submit a citizen petition can be found at https://www.fda.gov/regulatory-information/dockets-management/instructions-submitting-citizen-petitions-cps-electronically.

U. What Must Be Included in a Petition Requesting Modified Requirements or an Exemption from the Requirements? (§ 1.1370)

In addition to meeting the requirements on the content and format of a citizen petition in 21 CFR 10.30, a petition requesting modified requirements or an exemption from the requirements of the Food Traceability Rule must:

(a) Specify the food or type of entity to which the modified requirements or exemption would apply;
(b) If the petition requests modified requirements, specify the proposed modifications to the requirements of the Food Traceability Rule; and
(c) Present information demonstrating why application of the requirements requested to be modified or from which exemption is requested is not necessary to protect the public health.

V. What Information Submitted in a Petition Requesting Modified Requirements or an Exemption, or Information in Comments on Such a Petition, is Publicly Available? (§ 1.1375)

FDA will presume that information submitted in a petition requesting modified requirements or an exemption from the requirements of the Food Traceability Rule, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under 21 CFR part 20, Public Information, and will be made public as part of the docket associated with the petition.

W. What Process Applies to a Petition Requesting Modified Requirements or an Exemption? (§ 1.1380)

In general, the procedures set forth in 21 CFR 10.30, Citizen Petition, govern FDA's response to a petition requesting modified requirements or an exemption from the Food Traceability Rule. FDA will publish a notice in the *Federal Register* requesting information and views on a submitted petition, including information and views from persons who could be affected by the modified requirements or exemption if the petition were granted. An interested person may submit comments on such a petition in accordance with 21 CFR 10.30(d).

FDA will respond to the petitioner in writing, as follows:

(1) If we grant the petition either in whole or in part, we will publish a notice in the *Federal Register* setting forth any modified requirements or exemptions and the reasons for them.
(2) If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial.

FDA will make readily accessible to the public, and periodically update, a list of petitions requesting modified requirements or exemptions, including the status of each petition (for example, pending, granted, or denied).

X. What Process Will FDA Follow When Adopting Modified Requirements or Granting an Exemption on Our Own Initiative? (§ 1.1385)

If FDA, on our own initiative, determines that adopting modified requirements or granting an exemption from the requirements of the Food Traceability Rule for a food or type of entity is appropriate, we will publish a notice in the *Federal Register* setting forth the proposed modified requirements or exemption and the reasons for the proposal. The notice will establish a public docket so that interested persons may submit written comments on the proposal. After considering any comments timely submitted, we will publish a notice in the *Federal Register* stating whether we are adopting modified requirements or granting an exemption, and the reasons for our decision.

Y. When Will Modified Requirements That We Adopt or an Exemption That We Grant Become Effective? (§ 1.1390)

Any modified requirements that FDA adopts or exemption that we grant will become effective on the date that notice of the modified requirements or exemption is published in the *Federal Register*, unless otherwise stated in the notice.

Z. Under What Circumstances May FDA Revise or Revoke Modified Requirements or an Exemption? (§ 1.1395)

FDA may revise or revoke modified requirements or an exemption if we determine that such revision or revocation is necessary to protect the public health.

AA. What Procedures Apply if FDA Tentatively Determines that Modified Requirements or an Exemption Should Be Revised or Revoked? (§ 1.1400)

If FDA tentatively determines that we should revise or revoke modified requirements or an exemption, we will provide the following notifications:

(1) We will notify the person that originally requested the modified requirements or exemption (if we adopted modified requirements or granted an exemption in response to a petition) in writing at the address identified in the petition; and
(2) We will publish a notice in the *Federal Register* of our tentative determination that the modified requirements or exemption should be revised or revoked and the reasons for our tentative decision. The notice will establish a public docket so that interested persons may submit written comments on our tentative determination.

After considering any comments timely submitted, we will publish a notice in the *Federal Register* of our decision whether to revise or revoke the modified requirements or exemption and the reasons for the decision. If we do revise or revoke the modified requirements or exemption, the effective date of the decision will be 1 year after the date of publication of the notice, unless otherwise stated in the notice.

Waivers

BB. Under What Circumstances Will FDA Waive One or More of the Requirements of the Food Traceability Rule for an Individual Entity or a Type of Entity? (§ 1.1405)

FDA will waive one or more of the requirements of the Food Traceability Rule when we determine that:

(a) Application of the requirements would result in an economic hardship for an individual entity or a type of entity, due to the unique circumstances of the individual entity or type of entity;
(b) The waiver will not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act; and
(c) The waiver will not otherwise be contrary to the public interest.

CC. When Will FDA Consider Whether to Waive a Requirement of the Food Traceability Rule? (§ 1.1410)

FDA will consider whether to waive a requirement of the Food Traceability Rule on our own initiative or in response to the following:

(a) A written request for a waiver for an individual entity; or
(b) A citizen petition requesting a waiver for a type of entity submitted under 21 CFR 10.30 by any person subject to the requirements of the Food Traceability Rule.

DD. How May I Request a Waiver for an Individual Entity? (§ 1.1415)

You may request a waiver of one or more requirements of the Food Traceability Rule for an individual entity by submitting a written request to FDA as described at www.fda.gov. The request for a waiver must include the following:

(a) The name, address, and point of contact of the individual entity to which the waiver would apply;
(b) The requirements of the Food Traceability Rule to which the waiver would apply;
(c) Information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the entity, including information about the unique circumstances faced by the entity that result in unusual economic hardship from the application of these requirements;
(d) Information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act; and
(e) Information demonstrating why the waiver would not otherwise be contrary to the public interest.

EE. What Process Applies to a Request for a Waiver for an Individual Entity? (§ 1.1420)

After considering the information submitted in a request for a waiver for an individual entity, we will respond in writing to the person that submitted the waiver request stating whether we are granting the waiver (in whole or in part) and the reasons for the decision.

Any waiver for an individual entity that FDA grants will become effective on the date we issue our response to the waiver request, unless otherwise stated in the response.

FF. What Must Be Included in a Petition Requesting a Waiver for a Type of Entity? (§ 1.1425)

In addition to meeting the requirements on the content and format of a citizen petition in 21 CFR 10.30, a petition requesting a waiver for a type of entity must:

(a) Specify the type of entity to which the waiver would apply and the requirements of the Food Traceability Rule to which the waiver would apply;
(b) Present information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the type of entity, including information about the unique circumstances faced by the type of entity that result in unusual economic hardship from the application of these requirements;
(c) Present information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act; and
(d) Present information demonstrating why the waiver would not otherwise be contrary to the public interest.

GG. What Information Submitted in a Petition Requesting a Waiver for a Type of Entity, or Information in Comments on Such a Petition, Is Publicly Available? (§ 1.1430)

FDA will presume that information submitted in a petition requesting a waiver for a type of entity, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under 21 CFR part 20, Public Information, and will be made public as part of the docket associated with the petition.

HH. What Process Applies to a Petition Requesting a Waiver for a Type of Entity? (§ 1.1435)

In general, the procedures set forth in 21 CFR 10.30 govern FDA's response to a petition requesting a waiver. An interested person may submit comments on such a petition in accordance with 21 CFR 10.30(d). FDA will publish a notice in the *Federal Register* requesting information and views on a submitted petition requesting a waiver for a type of entity, including information

and views from persons who could be affected by the waiver if we granted the petition. We will respond to the petitioner in writing, as follows:

(1) If we grant the petition either in whole or in part, we will publish a notice in the *Federal Register* setting forth any requirements we have waived and the reasons for the waiver.
(2) If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial.

We will make readily accessible to the public, and periodically update, a list of petitions requesting waivers for types of entities, including the status of each petition (for example, pending, granted, or denied).

II. What Process Will FDA Follow When Waiving a Requirement of the Food Traceability Rule on Our Own Initiative? (§ 1.1440)

If FDA, on our own initiative, determines that a waiver of one or more requirements for an individual entity or type of entity is appropriate, we will publish a notice in the *Federal Register* setting forth the proposed waiver and the reasons for such waiver. The notice will establish a public docket so that interested persons may submit written comments on the proposal. After considering any comments timely submitted, we will publish a notice in the *Federal Register* stating whether we are granting the waiver (in whole or in part) and the reasons for our decision.

Any waiver for a type of entity that FDA grants will become effective on the date that notice of the waiver is published in the *Federal Register*, unless otherwise stated in the notice.

JJ. Under What Circumstances May FDA Modify or Revoke a Waiver? (§ 1.1445)

FDA may modify or revoke a waiver if we determine that:

(a) Compliance with the waived requirements would no longer impose a unique economic hardship on the individual entity or type of entity to which the waiver applies;
(b) The waiver could significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act; or
(c) The waiver is otherwise contrary to the public interest.

KK. What Procedures Apply If FDA Tentatively Determines that a Waiver Should be Modified or Revoked? (§ 1.1450)

If FDA tentatively determines that we should modify or revoke a waiver for an **individual entity**, we will notify the person that had received the waiver in writing of our tentative determination that the waiver should be modified or revoked. The notice will provide the waiver recipient 60 days in which to submit information stating why the waiver should not be modified or revoked.

Upon consideration of any information submitted by the waiver recipient, we will respond in writing stating our decision whether to modify or revoke the waiver and the reasons for the decision. If we modify or revoke the waiver, the effective date of the decision will be 1 year after the date of our response to the waiver recipient, unless otherwise stated in the response.

If FDA tentatively determines that we should modify or revoke a waiver for a **type of entity**, we will provide the following notifications:

> (i) We will notify the person that originally requested the waiver (if we granted the waiver in response to a petition) in writing at the address identified in the petition.
>
> (ii) We will publish a notice in the Federal Register of our tentative determination that the waiver should be modified or revoked and the reasons for our tentative decision. The notice will establish a public docket so that interested persons may submit written comments on our tentative determination.

After considering any comments timely submitted, we will publish a notice in the Federal Register of our decision whether to modify or revoke the waiver and the reasons for the decision. If we do modify or revoke the waiver, the effective date of the decision will be 1 year after the date of publication of the notice, unless otherwise stated in the notice.

Records Maintenance and Availability

LL. How Must I Maintain Records Required by the Food Traceability Rule? (§ 1.1455(a))

You must keep records as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records). Electronic records may include valid, working electronic links to the information required to be maintained under the Food Traceability Rule. All records must be legible and stored to prevent deterioration or loss.

MM. Can Another Entity Establish and Maintain Records for Me? (§ 1.1455(b))

Yes, you may have another entity establish and maintain records required under the Food Traceability Rule on your behalf, but you are responsible for ensuring that such records can be retrieved and provided onsite within 24 hours of request for official review.

NN. When Must I Make Required Records Available to FDA? (§ 1.1455(c)(1))

You must make all records required under the Food Traceability Rule available to an authorized FDA representative, upon request, within 24 hours (or within some reasonable time to which FDA has agreed) after the request, along with any information needed to understand these records, such as internal or external coding systems, glossaries, abbreviations, and a description of how the records you provide correspond to the information required.

OO. May I Store Records Offsite? (§ 1.1455(c)(2))

Yes, offsite storage of records is permitted if such records can be retrieved and provided onsite

within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

PP. What Additional Requirements Apply If There Is a Threat to the Public Health? (§ 1.1455(c)(3))

When necessary to help FDA prevent or mitigate a foodborne illness outbreak, or to assist in the implementation of a recall, or to otherwise address a threat to the public health, including but not limited to situations where FDA has a reasonable belief that an article of food (and any other article of food that FDA reasonably believes is likely to be affected in a similar manner) presents a threat of serious adverse health consequences or death to humans or animals as a result of the food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act, you must make available, within 24 hours (or within some reasonable time to which FDA has agreed) of a request made in-person or remotely (e.g., by phone) by an authorized FDA representative, the information you are required to maintain under the Food Traceability Rule, for the foods and date ranges or traceability lot codes specified in the request. If FDA's request for this information is made by phone, we will also provide the request to you in writing upon your request; however, you must provide the requested information within 24 hours (or within some reasonable time to which FDA has agreed) of the phone request.

Except as specified in § 1.1455(c)(3)(iii) and (iv), when the information requested by FDA under the above circumstances is information you are required to maintain under §§ 1.1325 through 1.1350 of the Food Traceability Rule (concerning records of critical tracking events), you must provide such information in an **electronic sortable spreadsheet**, along with any other information needed to understand the information in the spreadsheet.

QQ. When There Is a Threat to The Public Health, Who Does Not Have to Provide the Requested Information in an Electronic Sortable Spreadsheet? (§ 1.1455(c)(3)(iii))

You may provide the information requested by FDA under 21 CFR 1.1455(c)(3) in a form other than an electronic sortable spreadsheet if you are:

(A) A farm whose average annual sum of the monetary value of their sales of raw agricultural commodities and the market value of raw agricultural commodities they manufacture, process, pack, or hold without sale (e.g., held for a fee) during the previous 3-year period is no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment;

(B) A retail food establishment or restaurant with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment; or

(C) A person (other than a farm, retail food establishment, or restaurant) whose average annual sum of the monetary value of their sales of food and the market value of food they manufacture, process, pack, or hold without sale (e.g., held for a fee) during the previous 3-year period is no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

RR. What If I Am Unable to Provide the Requested Information in an Electronic Sortable Spreadsheet Because of Religious Beliefs? (§ 1.1455(c)(3)(iv))

FDA will withdraw a request for an electronic sortable spreadsheet under § 1.1455(c)(3)(ii), as appropriate, to accommodate a religious belief of a person asked to provide such a spreadsheet.

SS. Must I Maintain All Records in English? (§ 1.1455(c)(4))

Records do not have to be maintained in English. However, upon FDA request, you must provide within a reasonable time an English translation of records required under the Food Traceability Rule.

TT. How Long Must I Keep the Required Records? (§ 1.1455(d))

Except as specified otherwise in the Food Traceability Rule, you must maintain records containing the required information for 2 years from the date you created or obtained the records.

UU. If I Keep Electronic Records, Must I Comply with the Requirements of 21 CFR Part 11? (§ 1.1455(e))

Records that are established or maintained to satisfy the requirements of the Food Traceability Rule and that meet the definition of electronic records in 21 CFR 11.3(b)(6) are exempt from the requirements of 21 CFR part 11 ("Electronic Records; Electronic Signatures"). However, records that satisfy the requirements of the Food Traceability Rule but that are also required under other applicable statutory provisions or regulations remain subject to part 11, if not otherwise exempt.

VV. If I Already Keep Records of Some of the Information Required Under the Food Traceability Rule, Must I Duplicate These Existing Records to Comply with the Rule? (§ 1.1455(f))

No, you do not need to duplicate existing records you have (e.g., records that you keep in the ordinary course of business or that you maintain to comply with other Federal, State, Tribal, territorial, or local regulations) if they contain the information required by the Food Traceability Rule. You may supplement any such existing records as necessary to include all of the information required by the rule.

WW. Must I Keep All the Required Information in a Single Set of Records? (§ 1.1455(g))

No, you do not have to keep all of the information required by the Food Traceability Rule in a single set of records. However, your traceability plan must indicate the format and location of the records you are required to keep under the rule, in accordance with § 1.1315(a)(1).

Consequences of Failure to Comply

XX. What Consequences Could Result from Failing to Comply with the Requirements of the Food Traceability Rule? (§ 1.1460)

The violation of any recordkeeping requirement under section 204 of the FSMA, including the violation of any requirement of the Food Traceability Rule, is prohibited under section 301(e) of the FD&C Act, except when such violation is committed by a farm.

An article of food is subject to refusal of admission under section 801(a)(4) of the FD&C Act if it appears that the recordkeeping requirements under section 204 of the FSMA (other than the requirements under subsection (f) of that section), including the requirements of the Food Traceability Rule, have not been complied with regarding such article.

Updating the FTL

YY. When and How Will FDA Update the FTL? (§ 1.1465)

FDA intends to update the FTL approximately every five years, subject to available resources. First, we would update the Risk-Ranking Model for Food Tracing with new data and information. As part of this process, we intend to provide stakeholders with a mechanism to submit relevant data for the Agency's consideration. Based on the data and the updated Model, we could develop a proposed revised FTL. We would then publish a notice in the *Federal Register* stating the proposed changes and the reasons for the changes. The notice would also request information and views on the proposed changes. After considering any information and views submitted on the proposed changes to the FTL, we would publish a second notice in the *Federal Register* stating whether we are making any changes to the FTL and the reasons for the decision. If FDA revises the list, we will also publish the revised list on our website.

Any deletions from the FTL would become effective immediately. Any additions to the FTL would become effective two years after the date of the *Federal Register* notice announcing the revised list, unless we state otherwise in the notice. This period of time would provide entities handling any new additions to the FTL sufficient time to come into compliance.

IV. Definitions

The definitions of terms in section 201 of the FD&C Act apply to such terms when used in the Food Traceability Rule. In addition, the following definitions apply to words and phrases as they are used in the rule:

Commingled raw agricultural commodity means any commodity that is combined or mixed after harvesting but before processing, except that the term "commingled raw agricultural commodity" does not include types of fruits and vegetables that are raw agricultural commodities to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in 21 CFR part 112 apply. For the purpose of this definition, a commodity is "combined or mixed" only when the combination or mixing involves food from different farms under different company management; except that for food obtained from a fishing vessel, a commodity is "combined or mixed" only when the combination or mixing involves food from different landing vessels and occurs after the vessels have landed. Also, for the purpose of this definition, the term "processing" means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

Cooling means active temperature reduction of a raw agricultural commodity using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process.

Critical tracking event means an event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.

Farm means farm as defined in 21 CFR 1.328. For producers of shell eggs, "farm" means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program, as set forth in 21 CFR 118.3.

First land-based receiver means the person taking possession of a food for the first time on land directly from a fishing vessel.

Fishing vessel means 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, as set forth in the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(18)).

Food Traceability List means the list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d)(2) of the FSMA. The term "Food Traceability List" includes both the foods specifically listed and foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by

drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes 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 raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Initial packing means packing a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time.

Key data element means information associated with a critical tracking event for which a record must be maintained and/or provided in accordance with the Food Traceability Rule.

Kill step means lethality processing that significantly minimizes pathogens in a food.

Location description means key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country.

Manufacturing/processing means 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: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities 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 means 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. An example of such a 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 means 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 includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Packing means placing food into a container other than packaging the food and also includes 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 does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act.

Person includes an individual, partnership, corporation, and association.

Point of contact means an individual having familiarity with an entity's procedures for traceability, including their name and/or job title, and their phone number.

Produce means produce as defined in 21 CFR 112.3.

Product description means a description of a food product and includes the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style. For seafood, the product name may include the species and/or acceptable market name.

Raw agricultural commodity means "raw agricultural commodity" as defined in section 201(r) of the FD&C Act.

Receiving means an event in a food's supply chain in which a food is received by someone other than a consumer after being transported (e.g., by truck or ship) from another location. Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

Reference document means a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food. A reference document may be established by you or obtained from another person. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.

Reference document number means the identification number assigned to a specific reference document.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are

restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term "retail food establishment" includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, 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" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. A "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) 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.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) 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.

(3) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

Shipping means an event in a food's supply chain in which a food is arranged for transport (e.g., by truck or ship) from one location to another location. Shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food. Shipping includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

Traceability lot means a batch or lot of food that has been initially packed (for raw agricultural commodities other than food obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.

Traceability lot code means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.

Traceability lot code source means the place where a food was assigned a traceability lot code.

Traceability lot code source reference means an alternative method for providing FDA with access to the location description for the traceability lot code source as required under the Food Traceability Rule. Examples of a traceability lot code source reference include, but are not limited to, the FDA Food Facility Registration Number for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source.

Transformation means an event in a food's supply chain that involves manufacturing/processing a food or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the FTL. Transformation does not include the initial packing of a food or activities preceding that event (e.g., harvesting, cooling).

Transporter means 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.

You means a person subject to the Food Traceability Rule under 21 CFR 1.1300.

V. Resources

Exemption tool: https://collaboration.fda.gov/tefcv13/

FDA's Food Traceability Final Rule website: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods

Federal Register Notice: Requirements for Additional Traceability Records for Certain Foods: https://www.federalregister.gov/documents/2022/11/21/2022-24417/requirements-for-additional-traceability-records-for-certain-foods

Food Traceability List: https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list

Food Traceability Rule Citations: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-1/subpart-S

Food Traceability Rule: Critical Tracking Events and Key Data Elements - Clickable PDF: https://www.fda.gov/media/163132/download

Frequently Asked Questions on FSMA's Food Traceability Rule: https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule

FSMA Inflation Adjusted Cut Offs: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs