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MEMORANDUM

November 21, 2022

BY ELECTRONIC MAIL

FROM: Olsson Frank Weeda Terman Matz PC

RE: Requirements for Additional Traceability Records for Certain Foods; Final Rule

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The Food and Drug Administration ("FDA" or "the agency") published in the FEDERAL REGISTER the Final Rule on "Requirements for Additional Traceability Records for Certain Foods," 87 Fed. Reg. 70,910 (Nov. 21, 2022) ("Final Rule" or "Traceability Rule"). The Final Rule was promulgated pursuant to the Federal Food Safety Modernization Act ("FSMA") and establishes additional recordkeeping requirements for persons who manufacture, process, pack, or hold certain foods the agency has designated for inclusion on the Food Traceability List ("FTL") under a new Subpart S to 21 C.F.R. Part 1.[1] Foods not on the FTL and foods that do not contain foods on the FTL as an ingredient are not subject to the additional records requirements of Subpart S. Other exemptions may be available, and the Final Rule does not apply to foods under the exclusive jurisdiction of United States Department of Agriculture ("USDA").

The detailed FTL list is provided in the Appendix to this memorandum and includes the following:

- certain soft cheeses,

[1] For ease of reading, citations to the provisions of the new Subpart S will be to the section number only, without the full citation to Title 21 of the Code of Federal Regulations.

- shell eggs,
- fresh leafy greens,
- fresh herbs, peppers, sprouts, cucumbers, tomatoes
- fresh tropical tree fruits, melons,
- fresh cut fruits and vegetables (all types except those listed in 21 C.F.R. § 112.2(a)(1)).[2]
- nut butters,
- ready-to-eat deli salads,
- fresh and frozen finfish (histamine-producing species, species potential contaminated with or associated ciguatoxin – examples listed in Appendix I),
- smoked finfish,
- fresh and frozen crustaceans, and
- fresh and frozen molluscan shellfish and bivalves.

Based on comments received on the Proposed Rule (Sept. 8, 2020), FDA has provided certain additional flexibilities, which we described herein. Most notably, FDA has extended the date on which affected participants in the distribution chain must come into compliance from two (2) years (under the Proposed Rule) to three (3) years after the effective date. *The effective date* for the final Traceability Rule will be sixty (60) days after publication; *therefore, the compliance date will be January 21, 2026.*

Although this is a final rule, FDA intends to provide outreach and training, guidance, and other materials to assist with compliance. OFW Law will monitor and provide any relevant updates from FDA on the Final Rule. Additionally, we would be happy to assist in obtaining clarification from FDA on any aspects of the Final Rule through guidance.

Table of Contents

[2] This would exclude produce that is rarely consumed raw, specifically the produce on the following exhaustive list: 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.

A. Background

On October 15, 2018, the Center for Food Safety and the Center for Environmental Health sued FDA over FDA's failure to meet the statutory deadlines to publish the designation of "high-risk foods" and issue the recordkeeping proposal under FSMA section 204. In June 2019, a Consent Decree was reached, and FDA agreed to a series of deadlines:

- FTL: Sept. 8, 2020 – Deadline for FDA to designate the list of "high risk" foods as required by the FSMA Section 204(d)(2)(A).
- Proposed Rule: Sept. 8, 2020 – Deadline for FDA to publish a proposed rule, including record-keeping requirements for high-risk foods, also as required by FSMA Section 204(d)(2)(A). OFW Law's memorandum on the Proposed Rule can be found here. FDA received over 1,100 comments on the Proposed Rule from a wide variety of stakeholders.
- Final Rule: Nov. 7, 2022 – Deadline for FDA to submit a Final Rule to the Office of the Federal Register, including record-keeping requirements for high-risk foods, also as required by FSMA Section 204(d)(2)(A). Publication of the Final Rule must occur by Nov. 22, 2022.

With the publication of the Final Rule on November 21, 2022, FDA has met its obligations under the Consent Decree.

B. Executive Summary

The Final Rule establishes additional traceability recordkeeping requirements for entities persons who manufacture, process, pack, or hold foods on the FTL (collectively "FTL food entity(ies)") and requires FTL food entities provide to their supply chain partners Key Data Elements ("**KDE**s")[3] for certain Critical Tracking Events ("**CTE**s")[4] in the handling of the food, consistent with the developing industry consensus approach to food tracing.

[3] **KDE**s, as defined in the Final Rule, "means information associated with a critical tracking event [CTEs] for which a record must be maintained and/or provided in accordance with this subpart." § 1.1310.

[4] **CTE**s, as defined in the Final Rule "means an 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." § 1.1310.

Generally, the Final Rule:

- requires FTL food entities to establish and maintain a Traceability Plan[5];
- provides the records and information that FTL food entities must keep, and for how long they must keep them, and send forward. This varies depending on the type of supply chain activities the FTL food entity performs with respect to FTL food;
- mandates that FTL food entities assign, record, and share traceability lot codes for FTL foods and link the lot codes to other information identifying the foods throughout the supply chain;
- requires, where necessary, FTL food entities to provide an electronic sortable spreadsheet containing information FDA requests on CTEs involving particular FTL foods for the date ranges or traceability lot codes specified in the agency's request;
- provides avenues for FTL food entities requesting a waiver of one or more of the requirements and lays-out exemptions; and
- extends the compliance date for all persons subject to the rule to three (3) years after the effective date, *i.e.*, January 21, 2026.

C. FDA Enforcement Authority and Consequences of Non-Compliance

Failure to comply with the Traceability Final Rule, once fully in effect, would be deemed a "prohibited act." Section 204(j)(1) of FSMA amends section 301(e) of the Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 331(e)) to make it a prohibited act to violate any recordkeeping requirement under section 204 of FSMA, except when such violation is committed by a farm. Penalties for prohibited acts include all of the FDA's enforcement authority, including injunction, criminal prosecution, product seizure, administrative detention, and facility registration suspension or revocation. There is presently no authority for FDA to levy fines for violation of the food provisions of the FD&C Act outside of a criminal prosecution.

FDA further asserts that failure to comply with the Final Rule could form the basis for refusal of admission of imported food. This could include placement of a non-compliant FTL food entity on the list of facilities, regions, or countries subject to Detention without Physical Examination ("DWPE"), also known as being on "Import Alert."

D. Forthcoming FDA Guidance on Traceability

FDA generally intends to provide outreach and training, as well as guidance and other materials, to help all sectors of the food industry come into compliance with the Final Rule. FDA has already announced a Traceability Workshop which will be held on December 7, 2022, which OFW will monitor and provide relevant updates. In addition, FDA mentions in the Final Rule that it:

- will explore ways to provide additional guidance for importers as needed regarding the identification of foods on the FTL,

[5] This was referred to in the Proposed Rule as the "traceability program records."

- will issue a small entity compliance guide ("SECG") that explains the requirements of subpart S in plain language, with the goal of assisting small FTL food entities, including farms and small businesses, in complying with these new requirements,
- will provide guidance and technical assistance to help entities comply, including potentially providing an electronic template for entering information into a sortable spreadsheet format,
- might consider addressing how firms might use existing systems and standards to meet subpart S requirements in future guidance for industry, and
- developing best practices guidance on various consumer notification practices for different business models to facilitate product recalls.

In addition, FDA's Technical Assistance Network ("TAN") is a resource for FTL food entities with questions. Questions to TAN are answered by information specialists who provide a central source of information to support industry understanding and implementation of FSMA standards. The TAN staff have compiled answers to frequently asked questions on the proposed rule and will continue to respond to questions on the final rule.

OFW will monitor for guidance and other pronouncements from FDA on traceability, including the frequently asked questions posted to TAN, and provide relevant updates.

E. The Final Rule

I. The FTL and Updating the FTL (§ 1.1465)

The FTL is included as a reference to the Final Rule. The FTL "means the list of foods for which additional traceability records are required to be maintained, as designated in accordance with … [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."

FDA will update the FTL periodically in accordance with section 204(d)(2) of the FSMA, which prescribes the conditions under which foods may be added to or removed from the FTL. When considering an update, the FDA will publish a notice in the FEDERAL REGISTER stating the proposed changes to the list and the reasons for these changes and requesting information and views on the proposed changes. After considering any comments on the proposed changes, the FDA will publish a notice in the FEDERAL REGISTER stating any changes and the reason for the decision. If the agency revises the list, the FDA will also publish the revised list on its website.

When the FDA updates the FTL, any deletions from the list will become effective immediately. Any additions to the list will become effective two (2) years after the date of publication.

II. Traceability Plan (§§ 1.1315 to 1.1400)

FTL food entities must establish and maintain a Traceability Plan containing:

1. A description of the procedures you use to maintain the records you are required to keep under this subpart, 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 (*see* below), if applicable;
4. A statement identifying a point of contact for questions regarding your traceability plan and records; and
5. Additionally, if you grow or raise food(s) on the FTL (other than eggs), you must include a farm map showing the areas in which you grow or raise such foods.
    i. The farm map must show the location and name of each field (or other growing area) in which you grow food(s) on the FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area.
    ii. For aquaculture farms, the farm map must show the location and name of each container (*e.g.*, pond, pool, tank, or cage) in which you raise seafood on the FTL, including geographic coordinates and any other information needed to identify the location of each container.

You must also update your Traceability Plan as needed to ensure that the information provided reflects your current practices and to ensure that you are complying with the requirements of this subpart. You must retain your previous traceability plan for two (2) years after you update the Traceability Plan.

III. Traceability Lot Codes (§ 1.1320)

A Traceability Lot Code must be assigned by an FTL food entity when they:

- initially pack raw agricultural commodities ("RAC") other than a food obtained from a fishing vessel;
- perform the first land-based receiving of a food obtained from a fishing vessel; or
- transform a food by manufacturing/processing a food or by changing the food or its packaging or labeling.

These Traceability Lot Codes are used to identify food(s) as they move through the supply chain and maintain other records relating to their activities.

Except as otherwise specified, you must ***not*** establish a new Traceability Lot Code when you conduct other activities (*e.g.*, shipping) for food(s) on the FTL.

Some important definitions follow:

- **Traceability Lot:** means a batch or lot of food that has been *initially packed* (for RACs 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 food(s) was assigned a traceability lot code. This replaced, from the Proposed Rule, "traceability lot code generator." The change came after public comments to ensure emphasis is placed on *where* the code was assigned, rather than the specific individual or entity who assigned the 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 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.

For assigning traceability lot codes, FDA declined in the Public Comments to specify a particular method or system by which an FTL food entity must assign traceability lot codes because the agency determined that "it is appropriate for [the covered entity] to have the flexibility to choose the approach that best suits their needs. Several food industry-supported traceability initiatives offer best practices and standards for uniquely identifying a food using a combination of a globally unique product identifier, firm-assigned internal lot code, and standard date code. This information, taken together, could be used as a traceability lot code, provided it meets the definition of 'Traceability Lot Code.'"

FDA decided to provide flexibility regarding how an FTL food entity chooses to assign such codes. However, the Traceability Plan must include a description of *how* they assign them.

Shippers and receivers of FTL foods must provide the Traceability Lot Code and other information identifying the food to the recipients of the food, including information relating to the Traceability Lot Code Source (*i.e.*, the FTL food entity that assigned the Traceability Lot Code to the food). To avoid disclosing confidential information about their suppliers, instead of directly identifying the traceability lot code source of an FTL food, the shipper may instead choose to provide a traceability lot code source "reference," such as an FDA Food Facility Registration number or a web address (which could be configured to require authentication for access), that provides an alternative means for FDA to identify and contact the traceability lot code source for the food.

IV. Critical Tracking Events Framework

CTEs are events in the supply chain of an FTL food where FDA has deemed it necessary for records (specifically, KDEs, which vary based on which regulated party is maintaining the records (*see* below)) to be kept. In the Final Rule, these CTEs involve the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity (RAC) other than food

obtained from a fishing vessel, first land-based receiving of food obtained from a fishing vessel, shipping, receiving, or transformation of the food.

The FDA deleted entirely the proposed CTE for growing an FTL food, which included requirements to assign traceability lot codes, document growing area coordinates for each traceability lot, and document specific KDEs for sprouts. Rather, the Final Rule requires persons who grow or raise an FTL food (other than eggs) to maintain, as part of their traceability plan, a farm map showing the area, including geographic coordinates, in which they grow or raise the FTL food.

V. Exemptions (§ 1.1305)

The Final Rule provides the following full and partial exemptions for FTL food entities.

- **Exemptions for certain small producers.** This includes certain:
  - *Small Produce Farms* – farms or the farm activities of farm mixed-type facilities with respect to the produce they grow, when the farm is not a "covered" farm in accordance with section 112.4(a) of the Produce Safety Rule and/or produce farms when the average annual sum of the monetary value of their sales of produce and the market value of produce they manufacture, process, pack, or hold without sale (*e.g.*, held for a fee) during the previous three (3) year period is no more than $25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.
  - *Shell egg producers* – with fewer than three thousand (3,000) laying hens at a particular farm, with respect to the shell eggs they produce at that farm.
  - *Other small producers of RAC* – producers of RAC other than produce or shell eggs (*e.g.*, aquaculture operations) when the average annual sum of the monetary value of their sales of RAC and the market value of the RAC they manufacture, process, pack, or hold without sale (*e.g.*, held for a fee) during the previous 3-year period is no more than $25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.
- **Exemption for farms when food is sold or donated directly to consumers.** This includes food produced on the farm (including food that is also packaged on the farm) that is sold or donated directly to a consumer by the FTL food entity in charge of the farm.
- **Inapplicability to certain food produced and packaged on a farm.** This includes food produced and packaged on a farm, provided that:
  - 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
  - the labeling of the food that reaches the consumer includes the name, complete address 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 the religious belief of the individual in charge of the farm.

- **Exemptions and partial exemptions for foods that receive certain types of processing.** This includes foods that receive certain types of processing:
    - Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance;
    - Shell eggs when all eggs produced at the particular farm receive a treatment that achieves at least a 5-log destruction of *Salmonella enteritidis* for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act.
    - Food that you subject to a kill step, provided that you maintain records containing specific information;
    - Food that you change such that the food is no longer on the FTL provided that you maintain records;
    - 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;
    - Food that will be subjected to a kill step by an FTL food 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 the additional requirements laid out in the Final Rule are met.
- **Exemption for produce that is rarely consumed raw.** Includes produce listed as rarely consumed raw in section 112.2(a)(1) of the Produce Safety Rule.
- **Exemption for raw bivalve molluscan shellfish**. Includes raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation Program.
- **Exemption for persons who manufacture, process, pack, or hold certain foods subject to regulation by the USDA.** Includes 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.).
- **Partial exemption for commingled RAC:** This includes commingled RAC (which, as defined in section 1.1310, do *not* include types of fruits and vegetables to which the standards for the growing, harvesting, packing, and holding of produce for human consumption under the Produce Safety Rule), assuming all requirements for agreements regarding processing by a subsequent recipient are met as specified in the Final Rule.
    - However, if a person who manufactures, processes, packs, or holds such commodity is required to register with the FDA under section 415 of the FDCA 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. Such records must be maintained for two (2) years.
- **Exemption for small retail food establishments and small restaurants.** This includes retail food establishments and restaurants with an average annual monetary value of food sold or provided during the previous three (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.

- **Partial exemption for retail food establishments and restaurants purchasing directly from a farm.** This includes retail food establishments or restaurants regarding food that is produced on a farm (including food produced and packaged on the 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.
    - However, when a retail food establishment or restaurant purchases food directly from a 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. The retail food establishment or restaurant must maintain such a record for one hundred and eighty (180) days.
- **Partial exemption for retail food establishments and restaurants making certain purchases from another retail food establishment or restaurant.** This includes either entity 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).
    - However, when a retail food establishment or restaurant purchases a food on the FTL from another retail food establishment or restaurant, 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.
- **Partial exemption for farm to school and farm to institution programs.** This includes institutions 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.
    - However, when a school or institution conducting a farm-to-school or farm-to-institution program obtains food from a farm, 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. The school food authority or relevant food procurement entity must maintain such a record for one hundred and eighty (180) days.
- **Partial exemption for owners, operators, or agents in charge of fishing vessels:** This includes owner, operator, or agent in charge of the fishing vessel, and persons who manufacture, process, pack, or hold the food until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel.
    - However, with respect to any person who receives this partial exemption, if such person is required to register with FDA under section 415 of the FDCA (the FSMA facility registration requirement) 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. Such records must be maintained for two (2) years. This partial exemption is intended to cover situations where the food is still

owned by the owner, operator, or agent in charge of the fishing vessel, but it is being handled by a different entity.

- **Exemption for transporters.** This includes those who transport food.
- **Exemption for nonprofit food establishments.** This includes nonprofit food establishments.
- **Exemption for persons who manufacture, process, pack, or hold food for personal consumption.** This includes persons who manufacture, process, pack, or hold food for personal consumption.
- **Exemption for certain persons who hold food on behalf of individual consumers.** This includes persons who hold food on behalf of specific individual consumers, provided that these persons:
  - are not parties to the transaction involving the food they hold; and
  - are not in the business of distributing food.
- **Exemption for food for research or evaluation.** This includes food for research or evaluation use, provided that such food:
  - is not intended for retail sale and is not sold or distributed to the public; and
  - is accompanied by the statement "Food for research or evaluation use."

In addition to the exemptions, the Final Rule codifies what was in the Proposed Rule and establishes procedures under which persons may request modified requirements (§§ 1.1360 to 1.1400) or an exemption from the new traceability recordkeeping requirements for a specific food or a type of entity on the grounds that application of the requirements to that food or type of entity is not necessary to protect the public health.

VI. Traceability Program Records

The following is a brief overview of the comments the FDA received for record requirements. We then provide an overview of the Final Rule record requirements. Additional detail is provided in the footnotes. ***Please contact OFW Law if you have specific questions regarding your recordkeeping obligations.***

VII. Records of Harvesting and Cooling (§ 1.1325)

After receiving many comments on the Proposed Rule asserting the burden imposed on farms, FDA made several changes to the requirements as they relate to the information about the growing, harvesting, cooling, and packing of FTL foods.

- For each RAC (not obtained from a fishing vessel) on the FTL that an entity harvests or that an entity cools before it is initially packed, the entity must *maintain* records containing the following information:
  - The location description for the immediate subsequent recipient (other than a transporter) of the food;
  - The commodity and, if applicable, variety of the food;
  - The quantity and unit of measure of the food (*e.g.*, 75 bins, 200 pounds);

- The location description for the farm where the food was harvested;
- The location description for the farm where the food was harvested;
  - *For harvested 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;
  - *For harvested 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; and
- (vi) The date of harvesting or cooling; and
- (vii) The reference document type and reference document number.

- For each RAC (not obtained from a fishing vessel) on the FTL that an entity harvests or cools before it is initially packed, the entity must *provide* (in electronic, paper, or other written form) the business name, phone number, and the information above to the initial packer of the RAC the entity harvests from or cools (directly or indirectly).

FDA is also considering issuing a "Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities" to help entities subject to the Final Rule requirements understand how the agency will classify certain activities of farms and facilities. No schedule for the issuance of such a Guidance has been provided.

VIII. Records of Initial Packing (§ 1.1330)

Instead of the proposed designation of "first receiving" of food as a CTE, the Final Rule FDA establishes requirements for the initial packing of a RAC other than a food obtained from a fishing vessel and for the performance of the first land-based receiving of food obtained from a fishing vessel.

The initial packer must *maintain* records containing the following information and linking this information to the traceability lot:

- The commodity and, if applicable, variety of the food received;
- The date the initial packer received the food;
- The quantity and unit of measure of the food received (*e.g.*, 75 bins, 200 pounds);
- The location description for the farm where the food was harvested;
  - *For harvested 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;
  - *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;
- The business name and phone number for the harvester of the food.;
- The date of harvesting;
- The location description for where the food was cooled (if applicable);
- The date of cooling (if applicable);
- The traceability lot code the initial packer assigned;
- The product description of the packed food;
- The quantity and unit of measure of the packed food (*e.g.*, 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
- The location description for where the food was initially packed (*i.e.*, the traceability lot code source), and (if applicable) the traceability lot code source reference;
- The date of initial packing; and
- The reference document type and reference document number.

The Final Rule also specifies the what records the initial packer of sprouts must *maintain* (except soil- or substrate-grown sprouts harvested without their roots):
- The location description for the grower of seeds for sprouting and the date of seed harvesting, if either is available;
- The location description for the seed conditioner or processor, the associated seed lot code, and the date of conditioning or processing;
- 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;
- 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;
- A description of the seeds, including the seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment;
- The date of receipt of the seeds by the sprouter; and
- The reference document type and reference document number.

IX. Records of First Land-Based Receiving of Food Obtained from a Fishing Vessel (§ 1.1335)

The first land-based receiver of food obtained from a fishing vessel must *maintain* records of the following:
- The traceability lot code they assigned;
- The species and/or acceptable market name for unpackaged food, or the product description for packaged food;
- The quantity and unit of measure of the food (*e.g.*, 300 kg);
- The harvest date range and location (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;
- 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;
- The date the food was landed; and
- The reference document type and reference document number.

X. Records of Shipping (§ 1.1340)

In response to comments, FDA deleted some of the Proposed Rule requirement of the proposed shipping KDEs and FDA made the following, relevant, changes: Deleted requirements related to the entry number assigned to imported food; deleted requirements concerning product identifiers and location identifiers; deleted the requirement to record the time of shipment; and replaced the term "traceability lot code generator" with "traceability lot code source," and we are allowing entities to provide to their customers a traceability lot code source reference instead of the location description for the traceability lot code source.

The Final Rule prescribes the following as KDEs that a *shipper* must *maintain and send to the recipient* of the food. These requirements do *not* apply to any shipment of food that occurs *before* the food is initially packed (if the food is a RAC not obtained from a fishing vessel). This information includes:
- The traceability lot code for the food;
- The quantity and unit of measure of the food (*e.g.*, 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
- The product description for the food;
- The location description for the immediate subsequent recipient (other than a transporter) of the food;
- The location description for the location from which the food was shipped;
- The date the food was shipped;
- The location description for the traceability lot code source or the traceability lot code source reference; and
- The reference document type and reference document number (§ 1.1340(a)(8)).

XI. Records of Receiving (§ 1.1345)

The Final Rule contains requirements for circumstances in which FTL food entity receives an FTL food from a person to whom the Final Rule does not apply. The Final Rule states for each traceability lot of an FTL food that an FTL food entity receives from a person to whom this Final Rule does not apply (*e.g.*, a person who is exempt from the Final Rule such as a very small farm), the FTL food entity must maintain records with pertinent information and linking this information to the traceability lot. This information includes:

- The traceability lot code for the food, which the FTL food entity must assign if one has not already been assigned (except that this requirement does not apply to RFEs and restaurants);
- The quantity and unit of measure of the food (*e.g.*, 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
- The product description for the food;
- The location description for the immediate previous source (other than a transporter) for the food;
- 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;
- The date the food was received; and
- The reference document type and reference document number.

The receiving records requirements for *maintaining* records do not apply to the receipt of a food that occurs before the food is initially packed (if the food is a RAC not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

XII. Records of Transformation (§ 1.1350)

The Final Rule establishes recordkeeping requirements for both those who "transform" food to become an FTL food. Records only need to be kept regarding incoming ingredients if those incoming foods are on the FTL. For foods that are "created" to become foods on the FTL, the required records will only relate to the finished product, not the incoming ingredients, unless those ingredients themselves are FTL. In addition, transformation KDEs do not apply when a RAC (other than food obtained from a fishing vessel) is transformed before it is initially packed; instead, only the initial packing KDEs will apply. The required records of transformation must include the following information and link this information to the new traceability lot:

- For the food on the FTL used in transformation (if applicable):
  - The traceability lot code for the food;
  - The product description for the food to which the traceability lot code applies; and
  - For each traceability lot used, the quantity and unit of measure of the food used from that lot.
- For the food produced through transformation, the following information:
  - The new traceability lot code for the food;
  - 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;
  - The date transformation was completed;
  - The product description for the food;
  - The quantity and unit of measure of the food (*e.g.*, 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds); and
  - The reference document type and reference document number for the transformation event.

For each traceability lot produced through the transformation of a RAC (other than food obtained from a fishing vessel) on the FTL that was not initially packed prior to your transformation of the food, records must be *maintained* containing the information specified in section 1.1330(a) or (c), and, if the RAC is sprouted, the information specified in section 1.1330(b). *See* Records of Initial Packing (§ 1.1330), *supra*.

The Final Rule excludes from the transformation requirements for RFEs and restaurants with respect to foods they do not ship.

XIII. Records Maintenance by Third Parties

The Final Rule allows FTL food entities to have another entity establish and maintain required records on their behalf, although the person subject to the Final Rule remains responsible for ensuring the records can be provided onsite to FDA within twenty-four (24) hours of the FDA's request for official review. Electronic records are considered onsite if they are accessible from an onsite location.

Certain smaller entities – the same small farm, RFE, and restaurant entities that are otherwise exempt from the Final Rule's recordkeeping provisions – are exempt from the requirement to provide this information in an electronic sortable spreadsheet, though they must still provide the information in other electronic or paper form.

In exigent circumstances (*e.g.*, investigation of an ongoing foodborne disease outbreak), FDA asserts the authority to request information remotely (*e.g.*, by phone) instead of onsite at the FTL food entity's place of business.

XIV. Compliance Dates

The compliance date for all persons subject to the Final Rule will be three (3) years after publication in the FEDERAL REGISTER, *i.e.*, January 21, 2026. We note that FDA declined to include later compliance dates based on the size of the FTL food entity or the supply chain segment.

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We hope this memorandum is useful. We would be pleased to assist with any questions and/or support with the implementation of the Final Rule.

Appendix (I): The Food Traceability List

Food Traceability List	Description
Cheeses, other than hard cheeses, specifically:	
• Cheese (made from pasteurized milk), fresh soft or soft un-ripened	Includes soft un-ripened/fresh soft cheeses. Examples include, but are not limited to, cottage, chevre, cream cheese, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
• Cheese (made from pasteurized milk), soft ripened or semi-soft	Includes soft ripened/semi-soft cheeses. Examples include, but are not limited to, brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
• Cheese (made from unpasteurized milk), other than hard cheese[1]	Includes all cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
Shell eggs	Shell egg means the egg of the domesticated chicken.
Nut butters	Includes all types of tree nut and peanut butters. Examples include, but are not limited to, almond, cashew, chestnut, coconut, hazelnut, peanut, pistachio, and walnut butters. Does not include soy or seed butters.
Cucumbers (fresh)	Includes all varieties of fresh cucumbers.
Herbs (fresh)	Includes all types of fresh herbs. Examples include, but are not limited to, parsley, cilantro, and basil. Herbs listed in 21 C.F.R. § 112.2(a)(1), such as dill, are exempt from the requirements of the rule under 21 C.F.R. § 1.1305(e).

Food Traceability List	Description
Leafy greens (fresh)	Includes all types of fresh leafy greens. Examples include, but are not limited to, arugula, baby leaf, butter lettuce, chard, chicory, endive, escarole, green leaf, iceberg lettuce, kale, red leaf, pak choi/bok choi, Romaine, sorrel, spinach, and watercress. Does not include whole head cabbages such as green cabbage, red cabbage, or savoy cabbage. Does not include banana leaf, grape leaf, and leaves that are grown on trees. Leafy greens listed in section 112.2(a)(1), such as collards, are exempt from the requirements of the rule under section 1.1305(e).
Leafy greens (fresh cut)	Includes all types of fresh-cut leafy greens, including single and mixed greens.
Melons (fresh)	Includes all types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, muskmelon, and watermelon.
Peppers (fresh)	Includes all varieties of fresh peppers.
Sprouts (fresh)	Includes all varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts. Examples include, but are not limited to, alfalfa sprouts, allium sprouts, bean sprouts, broccoli sprouts, clover sprouts, radish sprouts, alfalfa & radish sprouts, and other fresh sprouted grains, nuts, and seeds.
Tomatoes (fresh)	Includes all varieties of fresh tomatoes.
Tropical tree fruits (fresh)	Includes all types of fresh tropical tree fruit. Examples include, but are not limited to, mango, papaya, mamey, guava, lychee, jackfruit, and starfruit. Does not include non-tree fruits such as bananas, pineapple, dates, soursop, jujube, passionfruit, Loquat, pomegranate, sapodilla, and figs. Does not include tree nuts such as coconut. Does not include pit fruits such as avocado. Does not include citrus, such as orange, clementine, tangerine, mandarins, lemon, lime, citron, grapefruit, kumquat, and pomelo.
Fruits (fresh cut)	Includes all types of fresh-cut fruits. Fruits listed in section 112.2(a)(1) are exempt from the requirements of the rule under section 1.1305(e).

Food Traceability List	Description
Vegetables other than leafy greens (fresh cut)	Includes all types of fresh-cut vegetables other than leafy greens. Vegetables listed in section 112.2(a)(1) are exempt from the requirements of the rule under section 1.1305(e).
Finfish (fresh and frozen), specifically:	
• Finfish, histamine-producing species	Includes all histamine-producing species of finfish. Examples include, but are not limited to, tuna, mahi mahi, mackerel, amberjack, jack, swordfish, and yellowtail.
• Finfish, species potentially contaminated with ciguatoxin	Includes all finfish species potentially contaminated with ciguatoxin. Examples include, but are not limited to, grouper, barracuda, and snapper.
• Finfish, species not associated with histamine or ciguatoxin	Includes all species of finfish not associated with histamine or ciguatoxin. Examples include, but are not limited to, cod, haddock, Alaska pollock, salmon, tilapia, and trout.[2] Siluriformes fish, such as catfish, are not included.[3]
Smoked finfish (refrigerated and frozen)	Includes all types of smoked finfish, including cold smoked finfish and hot smoked finfish.[4]
Crustaceans (fresh and frozen)	Includes all crustacean species. Examples include but are not limited to shrimp, crab, lobster, and crayfish.
Molluscan shellfish, bivalves (fresh and frozen)[5]	Includes all species of bivalve mollusks. Examples include, but are not limited to, oysters, clams, and mussels. Does not include scallop adductor muscle. Raw bivalve molluscan shellfish that are (1) covered by the requirements of the National Shellfish Sanitation Program; (2) subject to the requirements of 21 C.F.R. part 123, subpart C, and 21 C.F.R. 1240.60; or (3) covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish are exempt from the requirements of the rule under section 1.1305(f).
Ready-to-eat deli salads (refrigerated)	Includes all types of refrigerated ready-to-eat deli salads. Examples include, but are not limited to, egg salad, potato salad, pasta salad, and seafood salad. Does not include meat salads.

[1] "Hard cheese" includes hard cheeses as defined in 21 C.F.R. § 133.150, Colby cheese as defined in 21 C.F.R. § 133.118 and caciocavallo siciliano as defined in 21 C.F.R. § 133.111. Examples of hard cheese include, but are not limited to, cheddar, romano, and parmesan.
[2] For a more comprehensive list, *see* here.
[3] Data for catfish were excluded from the Risk-Ranking Model because Siluriformes fish (such as catfish) are primarily regulated by USDA.
[4] "Smoked finfish" refers to a finfish product that meets the definition of a smoked or smoke-flavored fishery product in 21 C.F.R. § 123.3(s).
[5] Under 21 C.F.R. § 123.3(h), *molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.