IFDA MANUAL

FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

IFDA
international foodservice distributors association

Acknowledgements:

IFDA Food Safety Leadership Committee

We extend our deepest gratitude to the IFDA Food Safety Leadership Committee, whose members met regularly to discuss issues related to the implementation of FDA's Final Rule on Food Traceability. Their expertise, dedication, and contributions led to the development of this manual. Committee members include:

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I. Introduction and Summary

The US Food and Drug Administration (FDA) published its Final Rule on Requirements for Additional Traceability Records for Certain Foods (Traceability Rule) on November 21, 2022. The Traceability Rule, codified at 21 C.F.R. Part 1, Subpart S, fulfills FDA's statutory obligation under section 204 of the Food Safety Modernization Act of 2011 (FSMA) to establish additional recordkeeping requirements for entities that manufacture, process, pack, or hold foods that FDA designates as being "high risk" foods.

The Traceability Rule requires entities to maintain records containing specific "key data elements" (KDEs) when they engage in "critical tracking events" (CTEs) regarding foods listed on FDA's Food Traceability List (FTL) or foods that contain FTL foods as ingredients. Entities engaging in certain activities at specified points in the supply chain will be required to assign a unique "traceability lot code" (TLC) to each FTL food. All subsequent entities in the supply chain will then need to link all KDE records to the food using the food's TLC. Entities will also need to maintain "traceability plans" outlining how they will comply with the Traceability Rule, provide FDA access to traceability records within 24 hours of a request, and adhere to various additional recordkeeping requirements. Failure to maintain records required under the rule is a prohibited act under section 301(e) of the Federal Food, Drug, and Cosmetic Act (FDCA) and could subject entities to regulatory enforcement action.

This manual is designed to assist IFDA members in understanding the basic requirements of the Traceability Rule most likely to be applicable to foodservice distributors and to explain how IFDA members can develop and implement food traceability systems to facilitate compliance with the rule. This manual does not, however, make specific recommendations, and it is not intended to substitute for the judgment of individual IFDA members. As a manual intended for IFDA, a trade association representing foodservice distributors, this manual covers activities that are typical of foodservice distributors, such as the receipt, storage, packing/repacking, and distribution of foods. IFDA members who engage in other activities that this manual does not address in detail (*e.g.*, manufacturing or processing) should consider those activities as well in developing their food traceability systems.

The Appendix to this manual provides a number of resources IFDA members may wish to consult in developing their compliance programs. Moving forward, FDA plans to publish additional communications, trainings, and educational materials to facilitate compliance with the Traceability Rule. IFDA members should keep apprised of these developments.

II. General Overview of the Traceability Rule

A. Who is covered by the rule?

The Traceability Rule applies to all entities that manufacture, process, pack, or hold foods that appear on FDA's FTL, including both domestic entities and foreign entities who import FTL foods into the United States.[1] This will likely encompass the operations of nearly all foodservice distributors. While the rule establishes a limited set of exemptions for certain types of entities, these exemptions are unlikely to apply to foodservice distributors.[2]

B. Which foods are on FDA's FTL?

Foodservice distributors will only be required to maintain records under the Traceability Rule for FTL foods and foods that contain FTL foods as ingredients, subject to some exemptions. The following foods are currently listed on the FDA's FTL:

Cheeses, Other than Hard Cheeses	Shell Eggs	Nut Butters	Cucumbers (fresh)	Herbs (fresh)
Leafy Greens (fresh)	Melons (fresh)	Peppers (fresh)	Sprouts (fresh)	Tomatoes (fresh)
Tropical Tree Fruits (fresh)	Fruits (fresh-cut)	Vegetables (fresh-cut)	Finfish (fresh and frozen)	Smoked Finfish (refrigerated and frozen)
	Crustaceans (fresh and frozen)	Molluscan Shellfish, Bivalves (fresh and frozen) (unless exempt per § 1.1305(f))	Ready-To-Eat Deli Salads (refrigerated)	

Appendix section IV.D and FDA's FTL website provide additional detail on the specific foods that are covered by each of these categories. While the regulation only requires entities to maintain records for FTL foods, it is possible that foodservice distributors, their suppliers, and/or their customers may opt to require records for a broader universe of foods. As discussed below, foodservice distributors will need to consider this possibility when designing their traceability systems.

1. 21 C.F.R. § 1.1300; *see also* 87 Fed. Reg. 70910, 70941 (Nov. 21, 2022) ("The requirements of the final rule apply to all persons who manufacture, process, pack, or hold foods on the FTL (unless an exemption applies), regardless of whether the person is in the United States or a foreign country.") [hereafter "Final Rule Preamble"].
2. These include exemptions for small retail food establishments and restaurants, nonprofit food establishments, and entities that operate farm-to-school and farm-to-institution programs. 21 C.F.R. § 1.1305. Similarly, while the rule allows entities to request economic hardship waivers, we anticipate that most foodservice distributors will not qualify for such waivers, and we therefore do not discuss these provisions in this manual. *Id.* § 1.1405–1.1450.

FDA intends to review the FTL at least every five years to assess the need for updates.[3] If, in doing so, FDA tentatively concludes that it is appropriate to add or remove items from the FTL, it will propose changes in the Federal Register, allow for public comment, and publish its final decision in the Federal Register.[4] Additions to the FTL will become effective two years from the date of the final Federal Register notice, whereas deletions will become effective immediately.[5] Foodservice distributors should therefore monitor for changes to the FTL on a periodic basis.

C. What is the rule's compliance date, and what are the potential penalties for failing to comply with the rule?

The compliance date for the final rule is **January 20, 2026**. On this date, all entities in the supply chain will be expected to comply with the rule. FDA has stated that it will not conduct routine inspections under the rule until 2027; however, it reserves the right to conduct for-cause inspections under the rule in the interim.[6] FDA has further stated that it will not require entities to maintain records required under the Traceability Rule for FTL foods that are "already in distribution" before the compliance date.[7] Consistent with how it has implemented prior FSMA rules, the agency intends to focus on education, rather than enforcement, during the early implementation stages of the rule.[8]

Failure to maintain records required by the rule is a "prohibited act" under section 301(e) of the FDCA.[9] This means that FDA could, in principle, subject entities who violate the rule to various forms of enforcement action, including injunctions or criminal penalties. In practice, however, and consistent with past agency practice, FDA will, in most cases, likely encourage voluntary compliance before taking such actions (*e.g.*, through issuance of inspectional findings and/or warning letters). FDA also has the authority to refuse the admission of imported foods for which records have not been maintained under the rule.[10]

3. Final Rule Preamble at 71050–51. FDA may review the FTL more frequently "if substantial new data or information critical to public health emerges." *Id*. at 71051.
4. 21 C.F.R. § 1.1465.
5. 21 C.F.R. § 1.1465.
6. FDA, Frequently Asked Questions: FSMA Food Traceability Rule, Question TE.1 (updated Sept. 28, 2023).
7. Final Rule Preamble at 71068.
8. Final Rule Preamble at 71049.
9. 21 C.F.R. § 1.1460(a).
10. 21 C.F.R. § 1.1460(b).

III. Developing a Food Traceability System

In this section, we provide step-by-step recommendations for how foodservice distributors can develop food traceability systems to facilitate compliance with the Traceability Rule.

A. Establish a cross-functional leadership team.

Foodservice distributors should, as a threshold matter, identify who will be responsible for developing and implementing their traceability systems. Unlike some other FSMA rules, the Traceability Rule does not impose specific requirements regarding the qualifications of the individuals responsible for developing traceability policies and procedures. Foodservice distributors therefore have general flexibility in determining who will carry out these tasks.

Given the broad operational implications of the rule, as well as the significant resources—including capital expenditures—that may be required to come into compliance, **foodservice distributors will likely benefit from involving senior leadership in these efforts from the outset** (*e.g.*, through regularly scheduled status reports, or by having a senior leadership liaison join the cross-functional team). They would also be well served to assemble cross-functional teams to carry out this responsibility. These teams should include, for example, representatives from a company's operations, food safety, regulatory affairs, legal, supplier/vendor relations, sales/customer relations, supply chain/procurement, and IT divisions. The exact composition of these teams will vary by company and may evolve over time as foodservice distributors develop a better understanding of the rule's scope and the resources required to carry out these responsibilities.

B. Determine the extent to which the Traceability Rule applies to your products and operations.

The Traceability Rule broadly applies to any entity that engages in CTEs regarding FTL foods, subject to various exemptions and modified requirements. Thus, to determine the extent to which the rule applies to their operations, foodservice distributors will need to consider (1) which of the foods they receive are covered by the rule; (2) whether any such foods qualify for an exemption; (3) which CTEs their facilities conduct; and (4) whether they receive foods from any exempt entities. If foods are not covered by the rule, or if they qualify for an exemption, foodservice distributors will generally still be required to maintain "one-up, one-back" traceability records for those foods under FDA's existing Subpart J requirements.[11]

1. **Determine which of the foods you receive are FTL foods.**
   As a preliminary step, foodservice distributors should determine which of the foods they receive are FTL

11. 21 C.F.R. Part 1, Subpart J.

foods. FTL foods include both foods listed on the FTL and multi-ingredient foods that contain an FTL food as an ingredient, if the FTL ingredient is in the same form listed on the FTL (*i.e.*, fresh, fresh-cut, frozen, or refrigerated). For example, both fresh tomatoes and sandwiches containing fresh tomatoes would be FTL foods, since the FTL lists tomatoes in "fresh" form. Frozen pizzas topped with tomatoes would not be FTL foods, since the FTL does not list tomatoes in "frozen" form. The table below provides additional examples of foods that would and would not be covered by the rule:

FTL Food	Multi-Ingredient Foods Covered By Rule	Multi-Ingredient Foods Not Covered by Rule
Spinach (fresh)	Fresh salad mix including spinach	Frozen spinach quiche
Papaya (fresh-cut)	Fruit salad containing fresh-cut papaya.	Trail mix with dried papayas
Peanut butter	Peanut butter cracker sandwich (peanut butter not baked)	Peanut butter cookies (baked)
Mozzarella (fresh soft)	Fresh caprese sandwich	Frozen pizza with mozzarella topping

Foodservice distributors will need to develop robust internal scoping procedures to identify which foods they receive are FTL foods. The Traceability Rule does not provide for specific methods through which entities must assess which of the products they handle are FTL foods. Foodservice distributors therefore have flexibility in developing their scoping procedures and, given the volume and range of potential FTL foods they receive, may benefit from considering multiple strategies for accomplishing this task. Some potential strategies available to foodservice distributors include:

- Establishing new supplier data-sharing policies and procedures that obligate suppliers to identify which foods in a shipment are covered by the rule (*e.g.*, through supplier surveys, new item questionnaires, or the creation of a new field in product specification sheets).
- Adopting specific master data standards and/or labeling requirements (*e.g.*, GS1 identifiers and GS1-128 barcodes,[12] the Produce Traceability Initiative (PTI),[13] and the Global Dialogue on Seafood Traceability (GDST)[14]) designed to capture the data elements required under the rule, and requiring suppliers to comply with those standards.
- Assuming that all foods in certain product categories (*e.g.*, produce) are FTL foods and requiring suppliers to pass forward KDE records for those foods.

2. Determine whether FTL foods qualify for an exemption.

Once foodservice distributors determine that a food is an FTL food, they will need to assess whether the food is subject to an exemption. Again, the Traceability Rule does not provide for specific methods through which entities must assess which of the products they handle are exempt from the rule and, given the volume of foods they receive, foodservice distributors may face particular challenges in assessing which foods they receive qualify for exemptions. In many cases, foodservice distributors may not have access to the information necessary to determine whether an exemption applies unless their suppliers provide that information. As such, foodservice distributors should consider adopting various strategies for obtaining this information from their suppliers, such as vendor surveys, requiring the use of certain data/labeling standards, requesting written assurances regarding a food's exempt status, and/or contractual agreements, as discussed above.

12. https://www.gs1us.org/.
13. https://producetraceability.org/.
14. https://traceability-dialogue.org/.

The exemptions below are most likely to apply to the foods that foodservice distributors receive:[15]

- Exemption for foods that receive certain types of processing (§ 1.1305(d)).
- Exemption for produce that is rarely consumed raw (§ 1.1305(e)).
- Exemption for food subject to exclusive USDA jurisdiction (§ 1.1305(g)).
- Exemption for raw bivalve molluscan shellfish (§ 1.1305(f)).
- Exemption for commingled raw agricultural commodities (§ 1.1305(h)).
- Exemption for certain foods produced and packaged on farms (§ 1.1305(c)).

For a detailed description of these exemptions, see Appendix section IV.G.

3. Determine which CTEs your facilities conduct.

As an additional preliminary step, foodservice distributors will need to determine which CTEs their facilities conduct. The three CTEs most likely to apply to foodservice distributors' operations are "receiving," "shipping," and "transformation," which the rule defines as follows:[16]

- **Receiving:** 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 . . . [including] 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.
- **Shipping:** 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 . . . [not including] the sale or shipment of a food directly to a consumer or the donation of surplus food . . . [but including] 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.
- **Transformation:** 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]. Manufacturing/processing activities include, but are not limited to, baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity, evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging, pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing.

Based on these definitions, all foodservice distribution facilities will likely engage in "receiving" and "shipping" CTEs and will therefore need to maintain receiving and shipping KDEs for nearly all FTL foods they receive and ship, with the exception of any foods shipped directly to consumers or donated surplus foods. These requirements will apply even when foodservice distributors conduct intracompany shipments between different physical locations.

In most cases, however, foodservice distributors will need to closely assess their operations to determine whether certain activities also trigger the "transformation" CTE requirement. While some activities—such as manufacturing/processing, commingling, repacking, and relabeling—squarely qualify as transformation, others may not. For example, FDA stated in the preamble to the final rule that the "breaking of a master case" during foodservice distribution would constitute transformation if "as part of the breaking of the master case, the product is repacked or repackaged," but would not constitute transformation if the distributor "is simply breaking a master case (*e.g.*, a pallet containing 20 individual

15. Additional exemptions exist for foods intended for personal consumption, 21 C.F.R. § 1.1305(p), and foods intended for research or evaluation use, id. § 1.1305(r), neither of which likely apply to the foods received by foodservice distributors. The rule also establishes various exemptions for certain types of entities (*e.g.*, small retail food establishments and restaurants, nonprofit food reestablishments, and entities that operate farm-to-school and farm-to-institution programs), none of which likely apply to foodservice distributors.

16. 21 C.F.R. § 1.1310. The rule also establishes CTEs for harvesting raw agricultural commodities (RACs), cooling RACs before initial packing, initial packing of RACs, and first land-based receiving of foods obtained from a fishing vessel, but we understand that, in most instances, foodservice distributors are unlikely to engage in these CTEs.

cases) into separate shipments (*e.g.*, 4 shipments of 5 cases each)."[17] Foodservice distributors may therefore need to assess whether activities constitute transformation on a situational basis and may, at times, need to engage with FDA on this question.

To the extent foodservice distributors engage in cross-docking activities, they will also need to carefully assess whether those activities constitute "receiving" and "shipping" under the rule. FDA has taken the position that cross-docking activities generally will not trigger the rule's recordkeeping requirements if, in the course of such activities, foods:

1. Are only briefly placed on the loading dock at the cross-docking facility;
2. Are held under procedures that maintain essential transportation conditions (*e.g.*, temperature controls); and
3. Are not entered into the inventory of the cross-docking facility.[18]

In practice, there will likely be many instances where specific cross-docking activities do not neatly satisfy these conditions. Thus, to determine whether a given cross-docking activity triggers the rule's requirements, foodservice distributors will need to assess the activity against the above-listed factors. Foodservice distributors should consider these factors when assessing whether other similar activities, such as drop-shipping, trigger the receiving and shipping KDE recordkeeping requirements. Even if foodservice distributors conclude that such activities do not trigger the rule's recordkeeping requirements, suppliers may request, as a business matter, that foodservice distributors assist with passing forward records to their customers. Foodservice distributors should therefore be prepared to manage such requests.

4. **Determine whether you receive FTL foods from exempt suppliers.**
To the extent foodservice distributors receive FTL foods from upstream entities that are exempt from the rule (*e.g.*, certain small producers such as local farms)—and who therefore have not assigned TLCs to the foods and will not pass forward shipping KDE records—foodservice distributors will need to deploy alternative strategies for assigning TLCs and obtaining the information needed to develop receiving KDE records, as discussed below in section III.E. In some cases, this may require mandating that exempt suppliers provide additional records about the foods they ship. As such, foodservice distributors may benefit from assessing which, if any, of their suppliers are exempt from the rule's recordkeeping requirements (*e.g.*, because they qualify for the rule's exemption for certain small producers[19]). This could, for example, be built into existing supplier onboarding/verification procedures.

C. Conduct a gap analysis.

While not required by the rule, foodservice distributors may benefit from conducting a gap analysis to assess the extent to which the traceability records they currently maintain may facilitate compliance with the Traceability Rule. Such records could include, for example, records foodservice distributors maintain under FDA's "one-up, one-back" Subpart J requirements and/or other records they currently receive from their suppliers, such as advanced shipping notices (ASNs), purchase orders (POs), pallet placards, bills of lading (BOLs), and selection/pick stickers. While, as discussed below, foodservice distributors will likely not be able to rely solely on existing records to fulfill the rule's requirements, the rule does permit entities to rely on existing records, without duplication, to the extent such records contain information required by the rule.[20] Foodservice distributors should therefore assess the degree to which they can efficiently leverage existing records when developing traceability systems under the rule.

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17. Final Rule Preamble at 70998.
18. Final Rule Preamble at 70983.
19. 21 C.F.R. § 1.1305(a).
20. 21 C.F.R. § 1.1455(f).

As part of this gap analysis, foodservice distributors should assess potential gaps across their operations, including with regard to personnel, processes, hardware, and technology, and will need to consider, among other factors, the extent to which additional investments in technologies, personnel, and other resources will be necessary to address compliance gaps. While the rule does not require the use of electronic records or the adoption of specific data standards, foodservice distributors could also consider whether the adoption of new data standards (*e.g.*, the GS1 traceability standards[21]) and/or supplier data-sharing policies and agreements will be of value in facilitating compliance with the rule, and should assess, from an early stage, the appropriate mechanisms for implementing such solutions (*e.g.*, through new or revised contractual arrangements with suppliers).

D. Develop traceability plans.

Foodservice distributors will be required to maintain written "traceability plans" that document the systems they have implemented to comply with the rule.[22] These traceability plans must contain the following elements:

1. A description of the procedures the foodservice distributor uses to maintain records required under the rule (*e.g.*, receiving, transformation, and shipping KDE records), including the format and location of these records;

2. A description of the procedures the foodservice distributor uses to identify foods on the FTL that it manufactures, processes, packs, or holds;

3. A description of how the foodservice distributor assigns TLCs to foods on the FTL, if applicable; and

4. A statement identifying a point of contact for questions regarding the foodservice distributor's traceability plan and records. This person should be familiar with the traceability rule and the entity's traceability program, but need not satisfy any specific qualification requirements (*e.g.*, they need not be a Preventive Controls Qualified Individual).[23]

FDA has not prescribed a specific method or format for traceability plans, so foodservice distributors will have flexibility in determining how to fulfill this requirement. Foodservice distributors can maintain a single traceability plan for all FTL foods they handle, rather than separate plans for each FTL food.[24] Foodservice distributors will need to update their traceability plans "as needed" to reflect their current practices, but FDA has not established a set frequency for updating traceability plans.[25] Upon updating their traceability plans, foodservice distributors will need to retain records of their prior plans for at least two years.[26] Foodservice distributors should note that the "traceability plans" required under this rule are distinct from the "recall plans" they currently maintain, although they may be able to leverage the traceability records required under this rule to facilitate product recalls.

E. Obtain and maintain receiving KDEs.

When receiving from non-exempt suppliers, foodservice distributors will be required to maintain the following receiving KDE records for each FTL food they receive:[27]

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21. *See* GS1—Traceability, https://www.gs1.org/standards/traceability.
22. 21 C.F.R. § 1.1315(a).
23. Final Rule Preamble at 71002.
24. Final Rule Preamble at 71000.
25. 21 C.F.R. § 1.1315(b).
26. 21 C.F.R. § 1.1315(b).
27. 21 C.F.R. § 1.1345(a). As noted above, receiving KDEs are required even for FTL foods received through intracompany shipments, which encompass any instances in which foods are transferred between locations with different street addresses, even if the two locations are owned or operated by the same company. *Id.*

1. **The traceability lot code (TLC) for the food.** The supplier or another upstream entity will have already assigned a TLC to the food, and foodservice distributors will be required to link records to these pre-assigned TLCs. FDA has not specified a specific format for TLCs, but the agency has noted that entities may be able to use existing unique identifiers, such as lot codes, batch codes, and other production codes, as TLCs.[28] Because TLC formats will likely vary significantly by supplier, and because some pallets or loads may contain multiple TLCs, foodservice distributors will likely need to work with their individual suppliers to identify a food's TLC (or, in the alternative, request that all suppliers provide TLCs in a pre-determined, standardized format). FDA has also not specified how KDE records must be "linked" to TLCs, but has stated that examples of linking methods could include listing KDEs for a CTE together in a single row of an electronic sortable spreadsheet, printing KDEs for a single CTE on the same commercial document (*e.g.*, a BOL), or using a common identifier on multiple records (*e.g.*, a TLC or the reference document number).[29]

2. **The quantity and unit of measure of the food.** Examples include "6 cases," "25 reusable plastic containers," "100 tanks," "200 pounds."

3. **A product description for the food.** The product description should include the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style and, for seafood, may include the species and/or acceptable market name. FDA has clarified that if firms use GS1 Global Trade Item Numbers (GTINs), they can include GTINs as part of their product descriptions.[30]

4. **A location description for the immediate previous source for the food (other than a transporter), for where the food was received, and for the TLC source (*i.e.* where the food was assigned a TLC).** Each location description should include a business name, phone number, physical location address (or geographic coordinates), and city, state, and zip code (and/or comparable information for foreign locations). In lieu of TLC source records, you can maintain records of the **TLC source reference**, which FDA defines as an "alternative method for providing FDA with access to the location description for the TLC source" such as an FDA food facility registration number or a web address linking to the TLC source description that can only be accessed through a government email address.[31] TLC source references would likely also include other unique identifiers such as DUNS numbers or GS1 Global Location Numbers. Though not required, TLC source references can be provided through QR codes or the GS1 Digital Link standard.[32]

5. **The date you received the food.** If a receiving process spans multiple days, this KDE should reflect the date on which the receiving process began.[33]

6. **The reference document type and number.** A reference document is a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the KDEs for a CTE, such as a BOL, PO, ASN, work order, invoice, database record, batch log, production log, field tag, catch certificate, or receipt.[34] Reference documents can be created by foodservice distributors or by their suppliers. The reference document number is an identification number assigned to each specific reference document.[35]

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28. Final Rule Preamble at 70996.
29. Final Rule Preamble at 71001.
30. Final Rule Preamble at 70997 (this can be done by adding GTINs to the required product description information or by using GTINs as shorthand for some or all required information, assuming the latter is accompanied by an explanatory glossary or key).
31. 21 C.F.R. § 1.1310.
32. FDA, Frequently Asked Questions: FSMA Food Traceability Rule, Question TTLC.2 (current of Jan. 25, 2023).
33. Final Rule Preamble at 71030.
34. 21 C.F.R. § 1.1310.
35. 21 C.F.R. § 1.1310.

When receiving from exempt suppliers, foodservice distributors will first need to assign TLCs to the foods, and then link the following receiving KDE records to the food's TLC:[36]

1. The **quantity and unit of measure** of the food.

2. A **product description** for the food.

3. A **location description** for the **immediate previous source** for the food (other than a transporter) and for **where the food was received**. When receiving FTL foods from upstream entities that are exempt from the rule, you will not be required to maintain records of the location description for the TLC source or the TLC source reference.[37]

4. The **date** you received the food. If a receiving process spans multiple days, this KDE should reflect the date on which the receiving process began.[38]

5. The **reference document type and number**.

The Traceability Rule does not identify specific methods through which entities must receive and maintain receiving KDE records but, as noted in section III.G below, these receiving KDEs mirror the shipping KDEs that most suppliers will be *required to pass forward* to foodservice distributors. Thus, in theory, foodservice distributors should receive most of the information they need to maintain receiving KDEs from their suppliers, with the exception of the date of receipt and reference document KDEs, which foodservice distributors will need to generate on their own. This will be largely contingent upon whether suppliers themselves comply with the rule and pass forward the required records and on the integrity of the methods through which suppliers provide this information (*e.g.*, ASNs, pallet placards).[39]

Accordingly, foodservice distributors may wish to adopt various strategies designed to facilitate the receipt of accurate and complete KDE records from their suppliers, such as requiring suppliers to provide KDE records in a format that complies with specific data/labeling standards (*e.g.*, GS1, PTI, GDST, and/or ASNs), entering into contractual arrangements with suppliers to require that they provide all necessary shipping information, and/or dedicating internal resources to assess the quality and accuracy of supplier records. These strategies should account for the fact that foodservice distributors will need to both store their receiving KDE records and pass forward the information contained in these records for use in developing KDE records for subsequent CTE events (i.e., transformation and shipping). To the extent foodservice distributors adopt labeling requirements, it will likely be advisable to require that suppliers place data carriers (such as barcodes, QR codes, RFID tags, etc.) on two adjacent sides of all packages.

In some instances, suppliers may pass forward KDE records for foods that are not subject to the rule, *e.g.*, if a supplier decides that, to facilitate compliance with the rule, it will maintain and pass forward KDE records for all foods they ship. Foodservice distributors may therefore benefit from ensuring that their traceability systems are adequately designed to manage such data.

Finally, foodservice distributors should note that the rule applies to both foreign and domestic facilities that manufacture, process, pack, or hold FTL foods.[40] This means that even foodservice distributors' foreign suppli-

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36. 21 C.F.R. § 1.1345(b). Again, foodservice distributors will have flexibility in determining how they will assign TLCs.

37. 21 C.F.R. § 1.1345(b).

38. Final Rule Preamble at 71030.

39. FDA has taken the position that, even when a supplier fails to pass forward required records, receivers cannot automatically assume that the supplier and/or food is exempt from the Traceability Rule, nor is FDA willing to allow for a "safe harbor" for receivers whose suppliers fail to pass forward required records. Instead, FDA expects receivers who are given incomplete or illegible records to "ask the source to provide, in legible/readable form, the complete information required [by the rule]" and to "use the years leading up to the compliance date for the rule to work with their suppliers to ensure that all entities are ready to comply with the rule and to provide the necessary information to others within their supply chain, as required under the rule." Final Rule Preamble at 71031.

40. Final Rule Preamble at 70941.

ers will be required to keep, maintain, and pass forward KDE records for FTL foods. In some cases, foodservice distributors may need to make foreign suppliers aware of these requirements and take necessary measures to ensure that these suppliers provide all necessary KDE records with their FTL products.

F. Obtain and maintain transformation KDEs.

As noted above, foodservice distributors will need to closely assess their operations to determine whether certain activities trigger the transformation CTE requirement. When foodservice distributors engage in transformation activities, they will be required to maintain the following KDE records:

1. The **TLC**, **product description**, and **quantity and unit of measure** of any FTL food used as an input in producing the transformed FTL food (*e.g.*, where you repack or relabel a lot of produce, you will need to maintain these KDEs for the initial lot and link them to the new TLC for the transformed food).

2. The **new TLC** for the transformed food. Foodservice distributors will need to assign TLCs to the foods themselves and, as noted above, will have flexibility in determining how they complete this task. FDA has clarified that repacked products can retain the TLC from the original traceability lot if all food is repacked from the same original lot.[41]

3. The **location description** for where they transformed the food (*i.e.*, the **TLC source**), and (if applicable) the **TLC source reference**.

4. The **date** transformation was completed.

5. The **product description** for the transformed food.

6. The **quantity and unit of measure** of the transformed food

7. The **reference document type** and **reference document number** for the transformation event.

FDA does not prescribe specific methods by which entities must create and maintain these records, so foodservice distributors will have the flexibility to consider various strategies for doing so (*e.g.*, adoption of specific data/labeling standards).

G. Obtain, maintain, and pass forward shipping KDEs.

Foodservice distributors will need to maintain the following shipping KDE records for all FTL foods that are shipped and, with the exception of item (6), will need to pass these records forward to the receiving customer:[42]

1. The **TLC** for the food. If the foodservice distributor has transformed the food, this will be the TLC assigned by the foodservice distributor. Otherwise, this will be the same TLC reflected in the receiving KDEs for the food.

2. The **quantity and unit of measure** of the food.

3. A **product description** for the food.

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41. Final Rule Preamble at 71035. FDA provides the example of a single lot of tomatoes that is repacked "so that it is still a single lot, but the individual tomatoes have been sorted into packages within that lot based on their size." *Id.*

42. 21 C.F.R. § 1.1340.

4. A **location description** for the **immediate subsequent recipient** for the food (other than a transporter), for **where the food was shipped**, and for the **TLC source** (or, alternatively, the **TLC source reference**).

5. The **date** the food is shipped.

6. The **reference document type and number**. This is the only receiving KDE that shippers must maintain but not pass forward to the recipient of the food.

As noted elsewhere, FDA does not prescribe specific methods by which entities must create and maintain these records, so foodservice distributors will have the flexibility to consider various strategies for doing so (*e.g.*, adoption of specific data/labeling standards). Because most shipping KDEs will mirror the receiving or transformation KDEs already on file for each FTL food, foodservice distributors may be able to leverage data systems to efficiently pass that information forward to the shipping process.[43] Foodservice distributors should consider working with their customers to align on expectations around data sharing mechanisms and procedures and should work internally to identify efficient measures for storing receiving and transformation KDE records in a manner that facilitates the development of shipping KDE records.

FDA has taken the position that shippers are required to pass forward shipping KDE records even when the receiving entity is exempt from the Traceability Rule.[44] Thus, while foodservice distributors may sometimes ship foods to customers who are exempt from the rule, (*e.g.*, when shipping foods to farm-to-school programs or donating surplus foods to nonprofit food establishments[45]), they will still be required to pass forward shipping KDE records to those customers.

H. Comply with additional recordkeeping requirements.

Foodservice distributors can maintain records required under the rule in paper, electronic, or true copy form.[46] All required records, along with any information required to understand the records (*e.g.*, coding systems), must be made available to FDA within 24 hours upon request, unless FDA agrees to an alternative timeframe, and foodservice distributors must retain required records for at least 2 years from the date the records are created or obtained, unless otherwise specified in the rule.[47] FDA is developing an electronic "Product Tracing System" (PTS) that it will use to store, process, and analyze traceability data submitted under the rule. Industry will have the option to upload traceability records directly to the PTS via an electronic portal, but will not be required to do so.[48]

The rule allows covered entities to contract with other entities to maintain records on their behalf, as long as the covered entity can retrieve and provide the records onsite within 24 hours of an FDA request.[49] This, in turn, could result in situations where foodservice distributors' customers request that foodservice distributors maintain records on the customers' behalf. When developing their traceability programs, foodservice distributors should consider whether they will be willing to fulfill such requests and, if so, they should consider how they will design their traceability programs to allow for this. For example, foodservice distributors will likely want to ensure that, when entering into such arrangements, they are responsible only for maintaining records regarding the foods they distribute to the customers (and not those the customer sources from other distributors). Foodservice distributors should also align with their customers on specific procedures by which

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43. When designing their traceability programs, foodservice distributors may benefit from identifying aspects of their operations that may be vulnerable to disruptions in standard data flows (*e.g.*, returns, lost cases, and misdelivered products) and developing mitigation strategies to account for those potential vulnerabilities.
44. Final Rule Preamble at 70980.
45. 21 C.F.R. §§ 1.1305(l), 1.1305(o).
46. 21 C.F.R. § 1.1455(a). Electronic records can include valid, working electronic links to required information. *Id*.
47. 21 C.F.R. §§ 1.1455(c), 1.1455(d).
48. FDA, Frequently Asked Questions: FSMA Food Traceability Rule, Question TPTS.1 (updated Sept. 28, 2023).
49. 21 C.F.R. § 1.1455(b).

customers can request access to their records. These procedures should account for the fact that, in many cases, customers will need to provide records to FDA within 24 hours of a request which, in turn, will leave foodservice distributors with less than 24 hours to produce the customer's records.

The rule also requires that entities provide FDA with an electronic sortable spreadsheet containing relevant KDE records when necessary to (1) help FDA prevent or mitigate a foodborne illness outbreak, (2) assist in implementation of a recall, or (3) otherwise address a threat to the public health (e.g., where FDA believes a food poses a threat of serious adverse health consequences or death to humans or animals as a result of being adulterated or misbranded).[50] These requests must be limited to specific foods and date ranges or TLCs,[51] and FDA has stated that it intends to "tailor the[se] information request[s] as much as possible so that firms can focus their efforts on the most relevant information."[52] As with other record requests under the rule, entities are required to provide these spreadsheets within 24 hours of FDA's request, unless FDA agrees to an alternative timeframe.[53]

Finally, while not required by the rule, foodservice distributors may consider implementing additional measures to ensure ongoing compliance with the rule. These could include, for example, periodic mock traceability exercises and employee trainings.

50. 21 C.F.R. § 1.1455(c)(3).

51. 21 C.F.R. § 1.1455(c)(3).

52. Final Rule Preamble at 71047.

53. If requests are made by phone, FDA will follow-up with a written request, but entities must provide the electronic sortable spreadsheet within 24 hours of receiving the phone request. 21 C.F.R. § 1.1455(c)(3).

IV. Appendix

A. Food Traceability Rule — Foodservice Distributor Supplier Expectations

The US Food and Drug Administration's (FDA's) Final Rule on Requirements for Additional Traceability Records for Certain Foods will take effect on **January 20, 2026**. The rule requires entities to maintain records containing specific "key data elements" (KDEs) when they engage in "critical tracking events" (CTEs) regarding foods listed on FDA's Food Traceability List (FTL) or foods that contain FTL foods as ingredients (collectively, FTL foods). Entities engaging in certain activities at specified points in the supply chain will be required to assign a unique "traceability lot code" (TLC) to each FTL food, and subsequent entities in the supply chain will need to link KDE records to the food using the food's TLC.

As a supplier, you will be required to pass forward the following "shipping" KDEs to your foodservice distributor customers for each FTL food you supply:

- The product's TLC.
- The quantity and unit of measure.
- The product description.
- The location description for the immediate subsequent recipient, for where the food was shipped, and for the TLC source or TLC source reference.
- The date of shipment.

To fulfill these requirements, and to ensure that foodservice distributors can fulfill their own regulatory obligations, we expect you to comply with the following:

1. **You must determine whether your operations are exempt from the Traceability Rule, and you must notify your foodservice distributor customers of this determination before the January 20, 2026, compliance date, and then as necessary on an ongoing basis (*e.g.*, with each shipment or as part of your master data).** If you conclude that your operations are exempt, then you must notify your foodservice distributor customers of that conclusion and identify the basis for that conclusion in writing. We will presume that any suppliers who do not provide such notifications are subject to the rule. If you are subject to the rule, you must develop a written traceability plan and take other necessary measures to ensure compliance with the rule. You should take these steps well in advance of the January 20, 2026 compliance date.

2. **You must identify which foods you send to your foodservice distributor customers are FTL foods.** You should provide this information to your foodservice distributor customers before the January 20, 2026, compliance date, and then as necessary on an ongoing basis, preferably as part of the product's master data. If you determine that any of the FTL foods you supply are exempt from the rule, you must inform your foodservice distributor customers of that conclusion and identify the applicable exemption in writing.

3. **You must pass forward shipping KDE records for each FTL food you supply.** In doing so, you must comply with the following expectations:

   a. Provide the shipping KDEs in electronic format via advanced ship notice (ASN), electronic product

code information services (EPCIS) standard, or other electronic data exchange (EDI) transactions *before* the delivery date.

b. In addition to (a), provide any hard copy paper records along with the bill of lading (BOL) at the time of delivery.

c. Ensure that all shipping KDE records are complete and accurate.

d. Clearly identify the TLC for each FTL food and use a standardized TLC format across shipments.

e. Clearly identify each individual KDE and use a standardized format for KDEs across shipments.

4. **To the extent possible, you should also comply with the following best practices:**

   a. Use a FSMA 204 attribute to identify which foods in a shipment are FTL foods and convey this information as part of your master data during item setup (*e.g.*, using a Global Data Synchronization Network (GDSN) or Product Lifecycle Management (PLM) FSMA 204 attribute).

   b. Place data carriers that encode to the TLC and the TLC source or TLC source reference (*e.g.*, barcodes, QR codes, RFID tags, etc.) on two adjacent sides of all packages, unless otherwise agreed upon.

   c. Include pallet tags that reference all TLCs in a pallet (*e.g.*, GS1 Serial Shipping Container Code (SSCC)) and identify all mixed pallets (*i.e.* pallets with multiple TLC lots).

We recommend consulting with legal counsel if you have additional questions about your obligations under the rule.

B. Food Traceability Rule — Foodservice Distributor Customer Expectations

The US Food and Drug Administration's (FDA's) Final Rule on Requirements for Additional Traceability Records for Certain Foods will take effect on **January 20, 2026**. The rule requires entities to maintain records containing specific "key data elements" (KDEs) when they engage in "critical tracking events" (CTEs) regarding foods listed on FDA's Food Traceability List (FTL) or foods that contain FTL foods as ingredients (collectively, FTL foods). Entities engaging in certain activities at specified points in the supply chain will be required to assign a unique "traceability lot code" (TLC) to each FTL food, and subsequent entities in the supply chain will need to link KDE records to the food using the food's TLC.

If you receive FTL foods from your suppliers, you will be subject to the rule's recordkeeping requirements unless otherwise exempt. We therefore recommend that you review the rule, assess the extent to which it applies to your operations, and take all necessary steps to ensure compliance (*e.g.*, by developing a written traceability plan). Regardless of whether you are exempt from the rule, your foodservice distributor suppliers will be required to send you the following "shipping" KDEs in order to fulfill their own compliance obligations:

- The product's TLC.
- The quantity and unit of measure.
- The product description.
- The location description for the immediate subsequent recipient, for where the food was shipped, and for the TLC source or TLC source reference.
- The date of shipment.

The following recommendations will allow you to effectively collaborate with your foodservice distributor suppliers and facilitate compliance with your regulatory obligations:

1. Be prepared to receive the above-listed shipping KDEs in the format specified by your foodservice distributor, which may include a distributor website, electronic data exchange, or invoices.

2. Notify your foodservice distributor suppliers as soon as possible (and well in advance of the January 20, 2026, compliance date) if you need to discuss any additional data delivery requirements regarding the receipt of FTL foods and/or the transmission of traceability records. Please note that it will be up to the foodservice distributor's discretion whether to accommodate requests for additional data delivery requirements that go beyond the scope of the regulations.

3. Notify your foodservice distributor suppliers as soon as possible (and well in advance of the January 20, 2026, compliance date) if you would like to negotiate an arrangement under which your foodservice distributors maintain certain records required under the rule on your behalf. Please note that it will be up to the foodservice distributor's discretion whether to accommodate requests for such arrangements.

If you are unable to comply with these best practices, or to the extent you identify other relevant compliance issues, you should contact your foodservice distributor suppliers as soon as possible. We recommend consulting with legal counsel if you have additional questions about your obligations under the rule.

C. Supply Chain Examples

GENERAL PRODUCE SUPPLY CHAIN:

Transformation Step by Foodservice Distributor

Initial Packer

Initial Packing
- Assign TLC #1
- Maintain "initial packing" KDEs

Shipping KDEs
- TLC #1
- Quantity and unit of measure
- Product description
- Location description for the immediate subsequent recipient
- Location description for where food was shipped
- Location description for TLC source OR TLC source reference
- Date of shipment
- Reference document type and number*

*not passed forward

Produce Processor

Receiving KDEs
- TLC #1
- Quantity and unit of measure
- Product description
- Location description for immediate previous source
- Location description for where food was received
- Location description for TLC source OR TLC source reference
- Date of receipt
- Reference document type and number

Transformation KDEs
- Assign TLC #2
- TLC, product description, and quantity and unit of measure for FTL foods used as inputs
- Location description of TLC source or TLC source reference
- Date of transformation
- Product description
- Quantity and unit of measure
- Reference document type and number

Shipping KDEs

GENERAL PRODUCE SUPPLY CHAIN:

Transformation Step by Foodservice Distributor

Produce Processor

Receiving KDEs

Transformation KDEs

Shipping KDEs
- TLC #2
- Quantity and unit of measure
- Product description
- Location description for the immediate subsequent recipient
- Location description for where food was shipped
- Location description for TLC source OR TLC source reference
- Date of shipment
- Reference document type and number*

*not passed forward

Foodservice Distributor

Receiving KDEs
- TLC #2
- Quantity and unit of measure
- Product description
- Location description for immediate previous source
- Location description for where food was received
- Location description for TLC source OR TLC source reference
- Date of receipt
- Reference document type and number

Transformation KDEs
- Assign TLC #3
- TLC, product description, and quantity and unit of measure for FTL foods used as inputs
- Location description of TLC source or TLC source reference
- Date of transformation
- Product description
- Quantity and unit of measure
- Reference document type and number

Shipping KDEs

GENERAL PRODUCE SUPPLY CHAIN:

Transformation Step by Foodservice Distributor

Foodservice Distributor

Receiving KDEs

Transformation KDEs

Shipping KDEs
- TLC #3
- Quantity and unit of measure
- Product description
- Location description for the immediate subsequent recipient
- Location description for where food was shipped
- Location description for TLC source OR TLC source reference
- Date of shipment
- Reference document type and number*

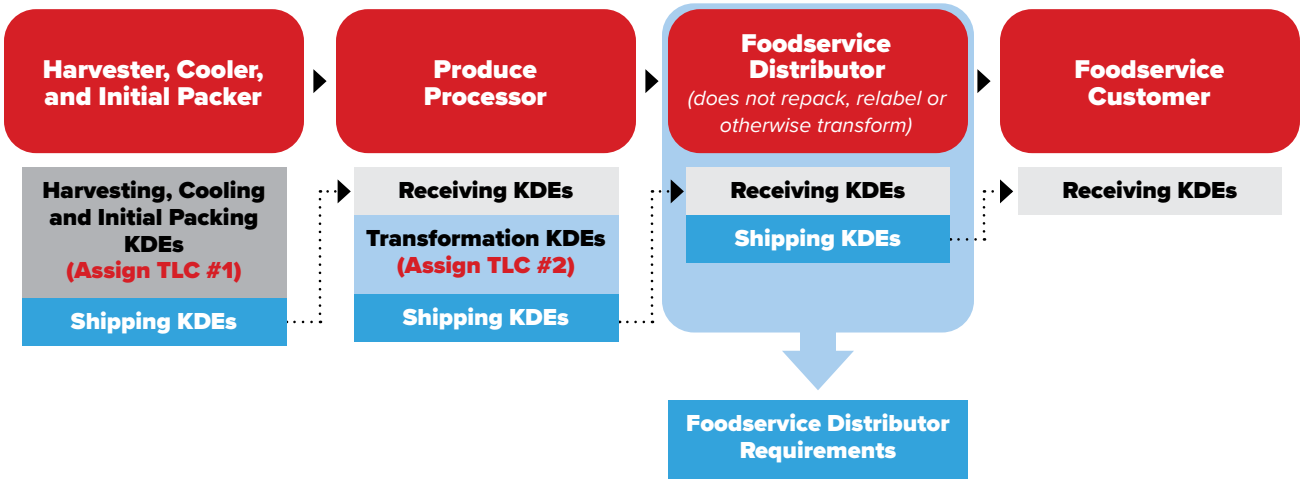
Foodservice Customer

Receiving KDEs
- TLC #3
- Quantity and unit of measure
- Product description
- Location description for immediate previous source
- Location description for where food was received
- Location description for TLC source OR TLC source reference
- Date of receipt
- Reference document type and number

*not passed forward

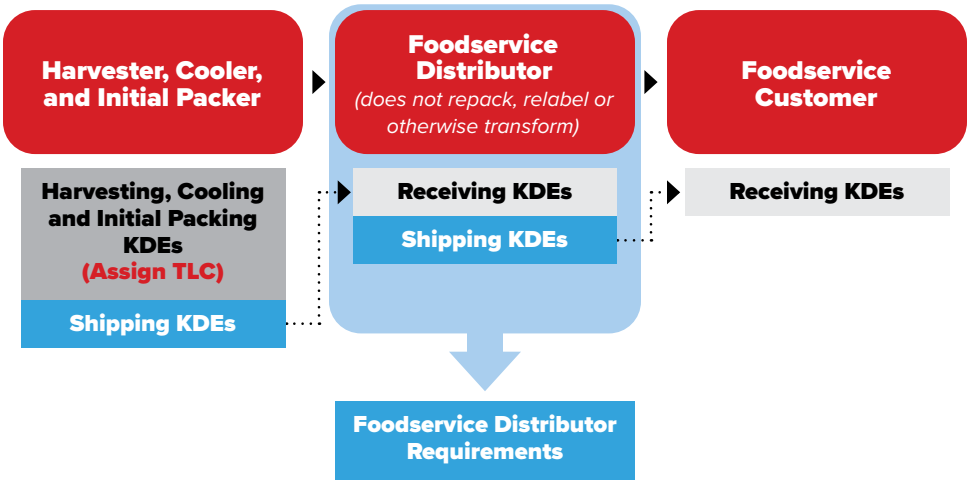
GENERAL PRODUCE SUPPLY CHAIN:

No Transformation Step by Foodservice Distributor



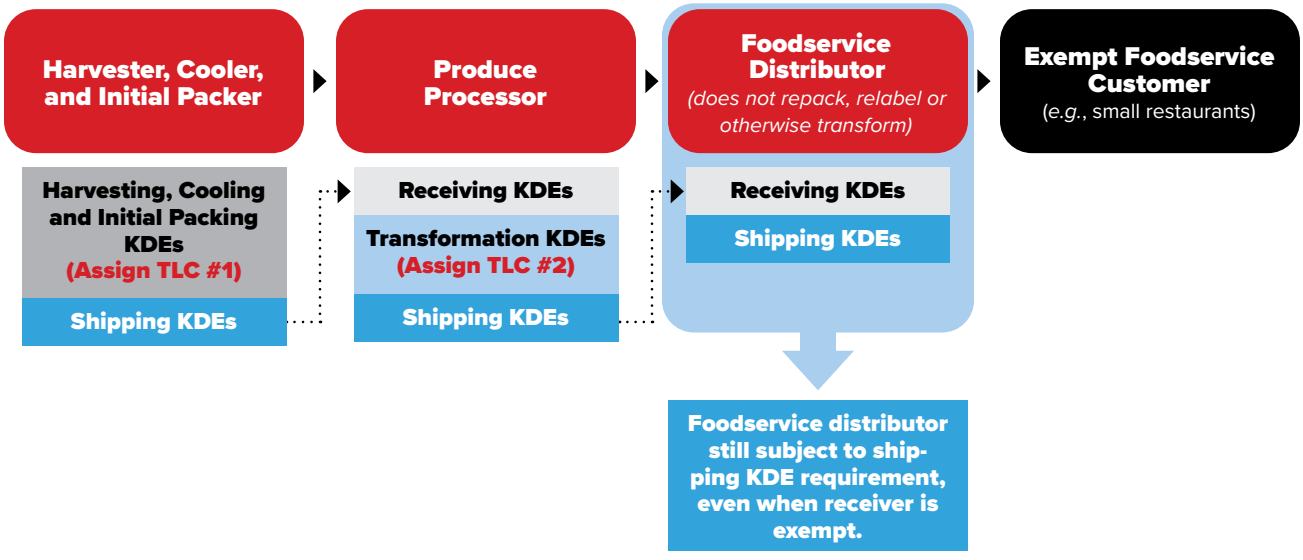
GENERAL PRODUCE SUPPLY CHAIN:

No Produce Processor



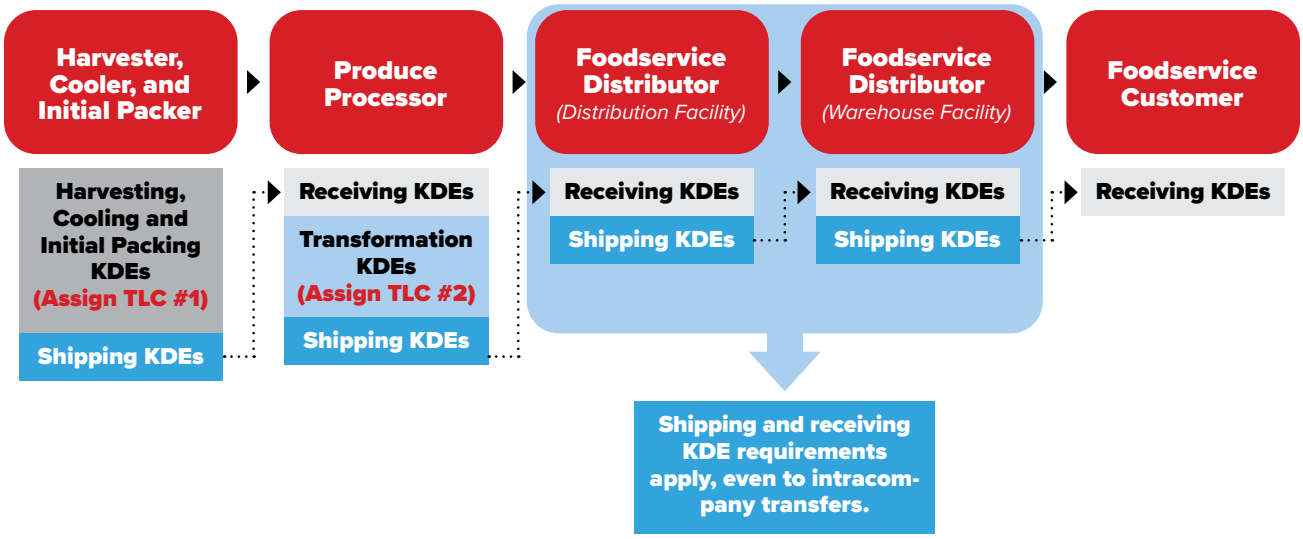
GENERAL PRODUCE SUPPLY CHAIN:

Shipping to an Exempt Customer



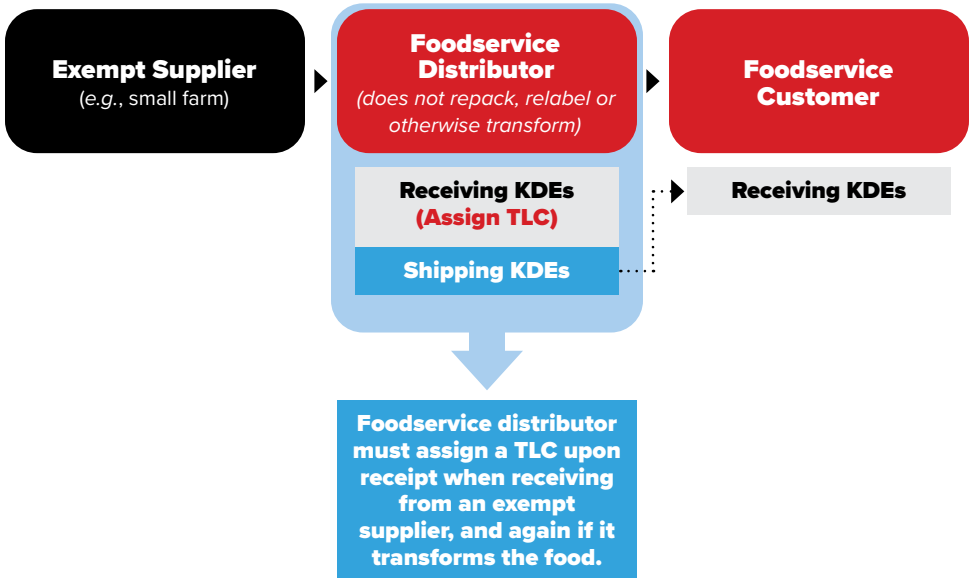
GENERAL PRODUCE SUPPLY CHAIN:

Intra-Company Shipment



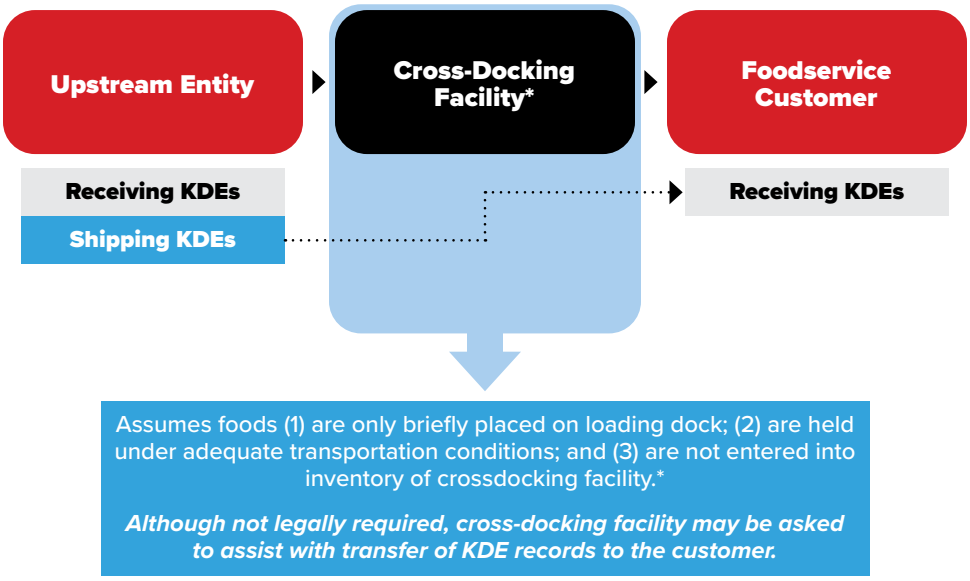
GENERAL PRODUCE SUPPLY CHAIN:

Receipt of FTL Foods from Exempt Supplier



GENERAL SUPPLY CHAIN EXAMPLE:

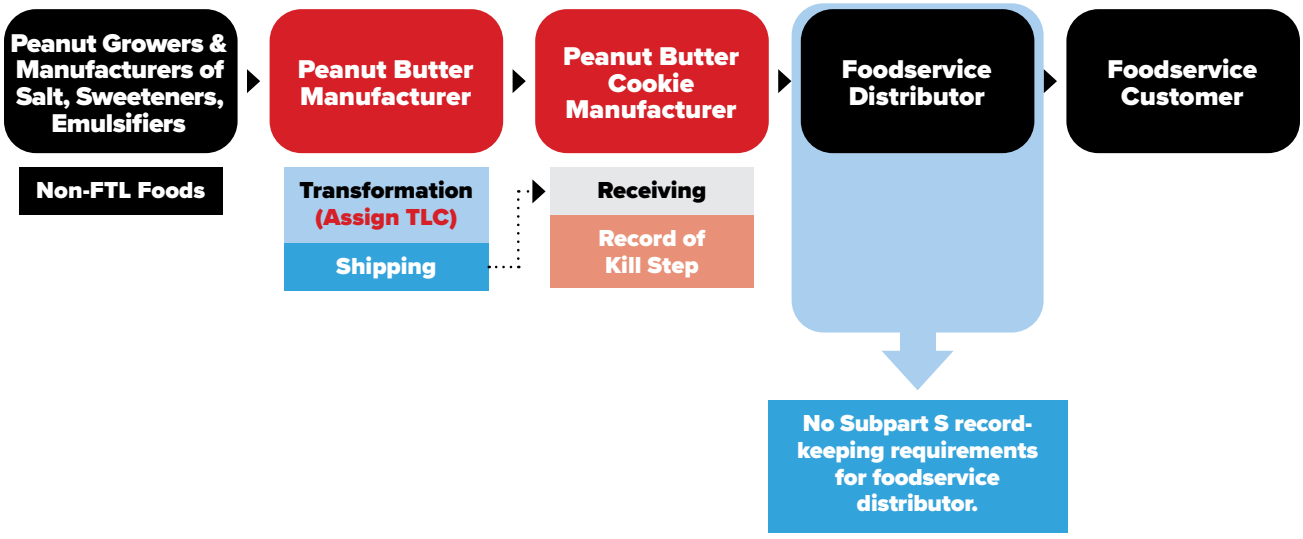
Cross-Docking



*Should be assessed on a case-by-case basis

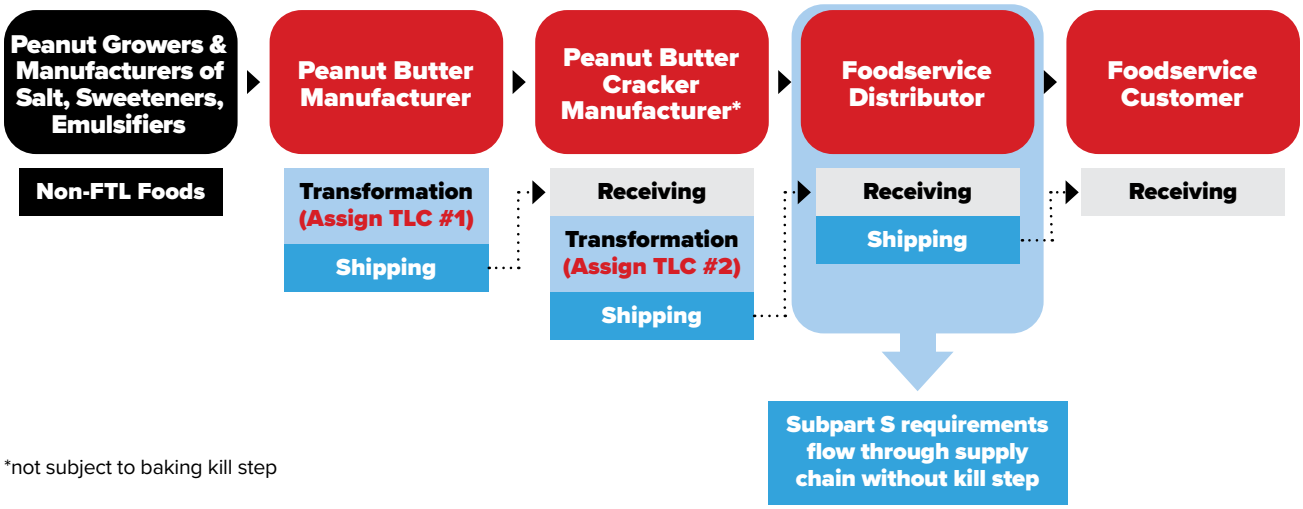
PEANUT BUTTER COOKIE:

Kill Step



PEANUT BUTTER-FILLED CRACKER:

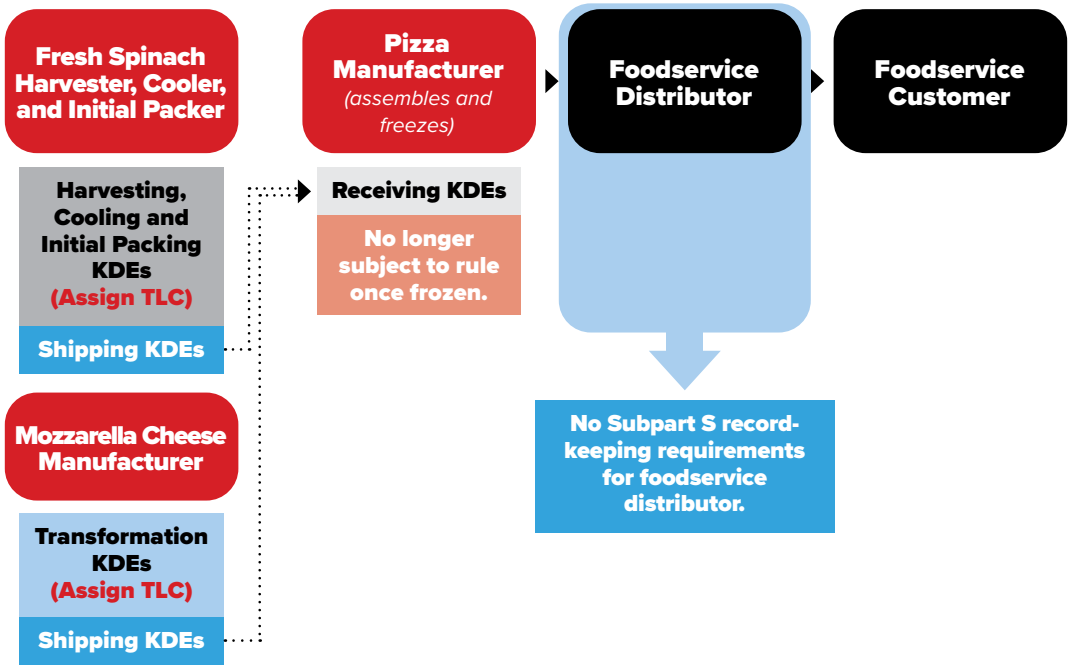
No Kill Step



*not subject to baking kill step

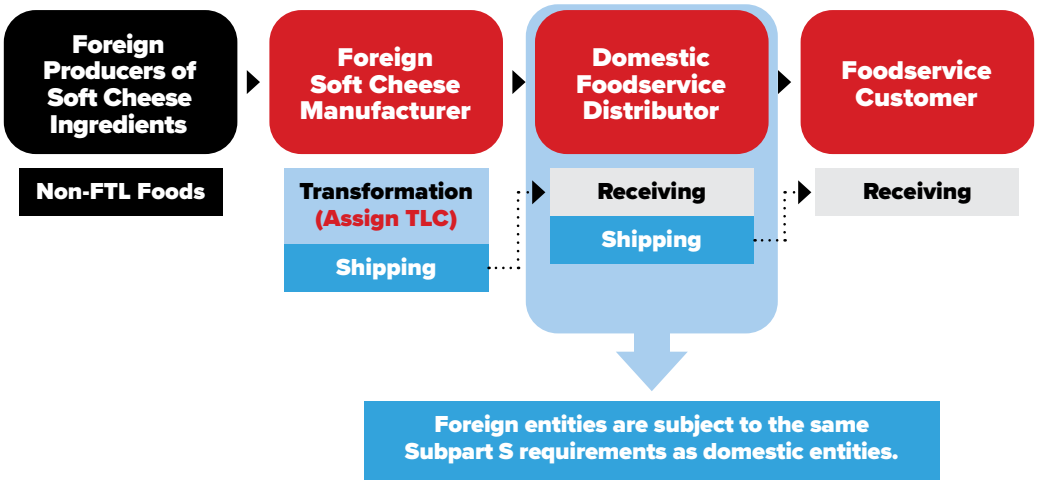
FROZEN PIZZA WITH SPINACH AND MOZZARELLA TOPPING:

FTL Food Changed to Non-FTL Form

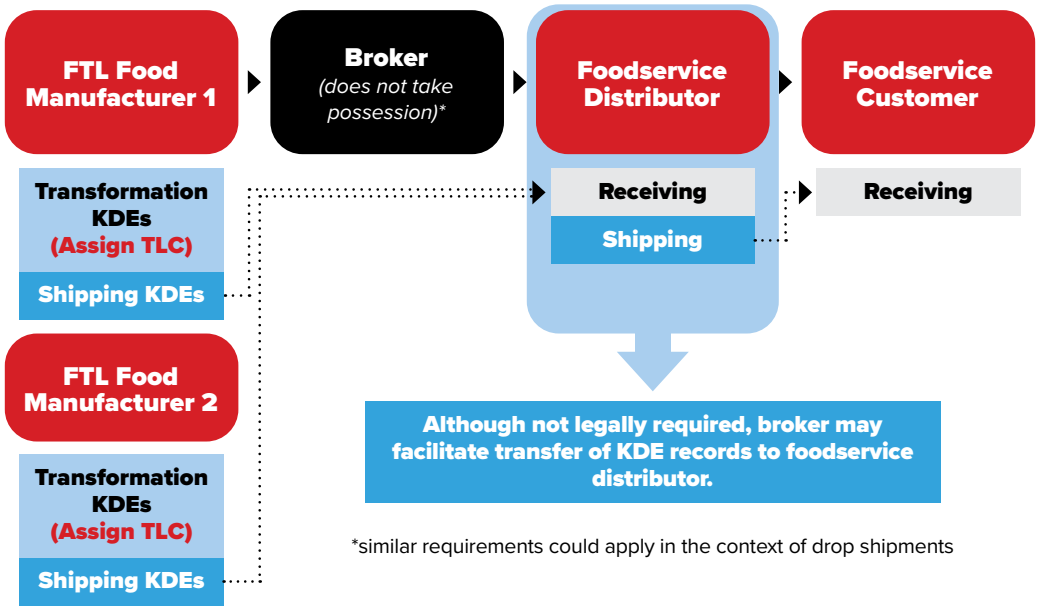


SOFT CHEESE:

Imported Food



Sourcing FTL Foods from a Broker



*similar requirements could apply in the context of drop shipments

D. FTL Product Descriptions

The table below summarizes the descriptions FDA has provided, to date, of the FTL food categories:

FTL Food	FTL Description[54]	Additional FDA Guidance
Cheeses, other than hard cheeses, specifically: • Cheese (made from pasteurized milk), fresh soft or soft unripened • Cheese (made from pasteurized milk), soft ripened or semi-soft • Cheese (made from unpasteurized milk), other than hard cheese	*Cheese (made from pasteurized milk), fresh soft or soft unripened* includes soft unripened/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*, includes all cheeses made from unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.	"Hard cheese" includes hard cheeses as defined in 21 CFR 133.150, Colby cheese as defined in 21 CFR 133.118 and cacioca-vallo siciliano as defined in 21 CFR 133.111. Examples of hard cheese include, but are not limited to, cheddar, romano, and parmesan.[55] Does not include "cheese sauce (shelf-stable)"[56] or cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.[57] While this category includes various cheeses made from pasteurized milk, such cheeses are eligible for a partial exemption under 21 CFR § 1.1305(d)(3) if they are subsequently pasteurized (or subject to another kill step). This includes pasteurized process and pasteurized prepared cheese and cheese products (*e.g.*, pasteurized process cheese, pasteurized process cheese food, pasteurized cheese spread, pasteurized blended cheese, pasteurized prepared cheese product), as well as processed mozzarella cheese.[58]
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 butter or seed butters.	Includes nut butters produced using either raw or roasted nuts. Does not include nut meals and powders, nut flours, and nut flavoring extracts. If peanut butter is used to make peanut butter chips without the application of a kill step, the peanut butter chips are included.[59]

54. *See* FDA, Food Traceability List.
55. *See* FDA, Food Traceability List, n. 1.
56. Final Rule Preamble at 70964.
57. Final Rule Preamble at 70933.
58. Final Rule Preamble at 70932.
59. Final Rule Preamble at 70931.

FTL Food	FTL Description[54]	Additional FDA Guidance
Cucumbers (fresh[60])	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 CFR 112.2(a)(1), which currently includes dill (seeds and weed) and peppermint, are exempt from the requirements of the rule under 21 CFR 1.1305(e).	Includes any part of the herb that is fresh and sold for human consumption. Does not include dried spices, seasonings, and flavorings.[61]
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 21 CFR 112.2(a)(1), which currently includes collards, are exempt from the requirements of the rule under 21 CFR 1.1305(e).	Fresh leafy greens listed as rarely consumed raw in § 112.2(a)(1), such as collards, are exempt from the requirements of subpart S under § 1.1305(e) of the final rule.[62]
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.	Category also includes winter melon and bitter melon.[63]
Peppers (fresh)	Includes all varieties of fresh peppers.	Does not include dried peppers.[64]
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.	Includes mung bean sprouts.[65]

60. FDA defines "fresh" to mean that "the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation, except [that]. . . . [t]he following do not preclude the food from use of the term fresh: (i) The addition of approved waxes or coatings; (ii) The post-harvest use of approved pesticides; (iii) The application of a mild chlorine wash or mild acid wash on produce; or (iv) The treatment of raw foods with ionizing radiation not to exceed the maximum dose of 1 kiloGray." 21 CFR 101.95. FDA further states that "[a] food meeting the ['fresh'] definition . . . that is refrigerated is not precluded from use of 'fresh' as provided by this section." *Id.*
61. Final Rule Preamble at 70930.
62. Final Rule Preamble at 70929.
63. Final Rule Preamble at 70928.
64. Final Rule Preamble at 70930.
65. Final Rule Preamble at 70930.

FTL Food	FTL Description[54]	Additional FDA Guidance
Tomatoes (fresh)	Includes all varieties of fresh tomatoes.	Does not include dried tomatoes.[66]
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, pineapples, 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.	Derivatives of some fruits that are not considered tropical tree fruits may be on the FTL in other commodity categories, *e.g.*, coconut butter in the "nut butter" category.[67] Fresh guava is covered under the ' 'Tropical Tree Fruits (fresh)'' commodity. If fresh guava is used as an ingredient in guava paste, the guava paste would also be included on the FTL. However, if the guava paste is subjected to a kill step, the exemption language in 21 CFR 1.1305(d) would apply.[68]
Fruits (fresh-cut)	Includes all types of fresh-cut fruits. Fruits listed in 21 CFR 112.2(a)(1), which currently includes sour cherries, cranberries, dates, and figs, are exempt from the requirements of the rule under 21 CFR 1.1305(e).	Does not include frozen fruits, frozen vegetables, dried fruits, dried vegetables, or fruit beverages.[69] Does not include produce items on FDA's rarely consumed raw list.[70]
Vegetables other than leafy greens (fresh-cut)	Includes all types of fresh-cut vegetables other than leafy greens. Vegetables listed in 21 CFR 112.2(a)(1) are exempt from the requirements of the rule under 21 CFR 1.1305(e). 21 CFR 112.2(a)(1) includes the following: asparagus; beets, garden (roots and tops); beets, sugar; corn, sweet; eggplants; ginger; horseradish; okra; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.	Does not include vegetables that are sold as ''frozen'' or ''fresh-frozen.''[71]

66. Final Rule Preamble at 70930.
67. Final Rule Preamble at 70928–29.
68. Final Rule Preamble at 70929.
69. Final Rule Preamble 70226.
70. FDA has defined "produce that is rarely consumed raw" to consist of 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. *See* 21 CFR 112.2(a)(1).
71. Final Rule Preamble at 70929.

FTL Food	FTL Description[54]	Additional FDA Guidance
Finfish (fresh and frozen), specifically: • *Finfish, histamine-producing species.* • Finfish, species potentially contaminated with ciguatoxin. • Finfish, species not associated with histamine or ciguatoxin	*Finfish, histamine-producing species* includes all histamine-producing species of finfish. Examples include, but are not limited to, tuna, 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.[72] Siluriformes, such as catfish, are not included.	Does not include canned seafood (*e.g.*, canned tuna).[73]
Smoked finfish (refrigerated and frozen)	Includes all types of smoked finfish, including cold smoked finfish and hot smoked finfish.[74]	"Smoked finfish" refers to a finfish product that meets the definition of a smoked or smoke-flavored fishery product in 21 CFR 123.3(s), which is defined as "the finished food prepared by: (1) Treating fish with salt (sodium chloride), and (2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke."[75]
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)	Includes all species of bivalve mollusks.[76] Examples include, but are not limited to, oysters, clams, 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 CFR part 123, subpart C, and 21 CFR 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 21 CFR 1.1305(f).	

72. For a more comprehensive list, see Chapter 3 of the Fish and Fishery Product Hazards and Controls Guidance.
73. Final Rule Preamble at 70934.
74. See, FDA, Food Traceability List, n. 1.
75. See, FDA, Food Traceability List, n. 1.
76. Bivalve mollusks are typically characterized as having 2 shells, connected by a flexible ligament, which encase and shield the soft vulnerable parts of the creature.

FTL Food	FTL Description[54]	Additional FDA Guidance
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.	Includes antipasti salad, but if antipasti salad contains meat and is subject to USDA jurisdiction, it would be exempt under 21 CFR 1.1305(g).[77]

E. KDE Checklists

The following checklists outline the KDE records foodservice distributors will need to maintain for FTL foods that they receive, transform, and/or ship:

Receiving (Non-Exempt Supplier)	Receiving (Exempt Supplier)
• TLC (assigned by supplier) • Quantity and unit of measure • Product description • Location description for immediate previous source • Location description for where food was received • Location description for TLC source OR TLC source reference • Date of receipt • Reference document type and number	• TLC (assigned by foodservice distributor) • Quantity and unit of measure • Product description • Location description for immediate previous source • Location description for where food was received • Date of receipt • Reference document type and number
Transformation	**Shipping**
• TLC, product description, and quantity and unit of measure for FTL foods used as inputs • TLC of transformed food • Location description of TLC source or TLC source reference • Date of transformation • Product description • Quantity and unit of measure • Reference document type and number	• TLC • Quantity and unit of measure • Product description • Location description for the immediate subsequent recipient • Location description for where the food was shipped • Location description for the TLC source OR TLC source reference • Date of shipment • Reference document type and number

77. Final Rule Preamble at 70930.

F. Compilation of FDA Resources

FDA has published various educational and training materials on its Food Traceability Rule website, including:

- A small entity compliance guide summarizing the rule's requirements.
- An interactive tool for determining whether an entity is exempt from the rule.
- A slide deck listing the KDEs associated with each CTE.
- Presentations explaining how the rule would apply to the produce, seafood, cheese, and various additional supply chains.
- An FAQs page that addresses various components of the rule.
- Recordings of a stakeholder call and public webinar that the agency has held to discuss the rule.

G. Summary of Exemptions Likely to Apply to Foodservice Distributors' Operations

The exemptions below are most likely to apply to the foods that foodservice distributors receive:

- Exemption for foods that receive certain types of processing.[78]
  - **Foods subjected to or destined for a kill step[79] and foods changed to or destined for use in non-FTL form.**
    - If foodservice distributors receive **FTL foods that have already been subject to a kill step or that have already been changed to non-FTL form**, then they are not required to maintain Subpart S records for those foods.[80] For example, peanut butter cookies that were already baked by an upstream entity are exempt because they have received a kill step; a trail mix that contains dried papaya would be exempt because the papaya no longer is in fresh form; a frozen pizza with diced onion and pepper would be exempt because the peppers and onions no longer are in their fresh form.
    - If foodservice distributors receive **FTL foods and then apply a kill step or change them to non-FTL form themselves**, then they will not need to maintain subsequent Subpart S records for the food (*i.e.*, transformation or shipping KDEs).[81] They will, however, still need to maintain receiving KDEs for the foods (unless they have entered written agreements with their suppliers regarding application of the kill step or changing the food to non-FTL form, as noted below) and records of the application of the kill step.
    - If foodservice distributors receive **FTL foods that are destined for a kill step or a change to non-FTL form at some point before reaching a retail food establishment, restaurant, or consumer**, then they will not be required to maintain Subpart S records for the food *if* they enter into written agreements with their suppliers stating that the foodservice distributor or a subsequent entity will apply a kill step or change the food to non-FTL form.[82] If a subsequent

78. 21 C.F.R. § 1.1305(d).
79. The rule defines a "kill step" as "lethality processing that significantly minimizes pathogens in a food." 21 C.F.R. § 1.1310. Kills steps must be applied under controlled conditions, and do not include typical cooking/preparation conducted by restaurants, retailers, or consumers. Final Rule Preamble at 70966.
80. 21 C.F.R. § 1.1305(d)(5).
81. 21 C.F.R. § 1.1305(d)(3), (4).
82. 21 C.F.R. § 1.1305(d)(6).

entity in the supply chain will perform the kill step or change, then foodservice distributors must enter similar agreements with their customers. These written agreements must contain (1) an effective date, (2) the printed names and signatures of the persons entering into the agreement, and (3) the substance of the agreement. The parties must maintain these agreements for as long as they are in effect, and must renew the agreements at least once every three years. Foodservice distributors can amend existing supplier and customer agreements to include these agreement terms, if desired, or develop new agreements. In doing so, they will have the flexibility to make these agreements on a per-lot, per-shipment, or other basis (*e.g.*, to cover all shipments from a given supplier).[83]

- **Produce that is exempt from FDA's Produce Safety Rule because it receives commercial processing that adequately reduces the presence of microorganisms of public health significance.[84]** This exemption applies to all produce that is exempt from FDA's Produce Safety Rule under 21 C.F.R § 112.2(b).

- **Shell eggs sourced from farms at which all eggs receive a treatment in compliance with FDA's Egg Safety Rule.[85]** To qualify for this exemption, all shell eggs at a farm must be subject to a treatment that achieves at least a 5-log destruction of *Salmonella* Enteritidis for shell eggs or processing in accordance with the Egg Products Inspection Act,[86] and must be held and transported in compliance with the Egg Safety Rule's refrigeration requirements.[87]

- **Exemption for produce that is rarely consumed raw.[88]** Foodservice distributors are not required to maintain Subpart S records for produce commodities that are listed as "rarely consumed raw" under FDA's Produce Safety Rule. These commodities include: asparagus; black beans; great northern beans; kidney beans; lima beans; navy beans; pinto beans; garden (roots or tops) beets; sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts.[89]

- **Exemption for food subject to exclusive USDA jurisdiction.[90]** Meat, poultry, and egg products will become exempt from the Traceability Rule upon arrival at a USDA-regulated facility, and will remain exempt at all subsequent stages in the supply chain. Foodservice distributors will therefore not be required to maintain Subpart S records for meat, poultry, and egg products that have left USDA-regulated facilities, but will have to maintain Subpart S records to the extent they handle such foods prior to arrival at a USDA-regulated facility.

- **Exemption for raw bivalve molluscan shellfish.[91]** Foodservice distributors are not required to maintain Subpart S records for raw bivalve molluscan shellfish that fall within one of the following categories:

    1. Raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation Program (NSSP) (including shellfish subject to NSSP requirements because a state has adopted the NSSP Model Ordinance into state law);

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83. Final Rule Preamble at 70966.
84. 21 C.F.R. § 1.1305(d)(1).
85. 21 C.F.R. § 1.1305(d)(2).
86. 21 C.F.R. § 118.3.
87. 21 C.F.R. § 118.1(a)(2).
88. 21 C.F.R. § 1.1305(e).
89. 21 C.F.R. § 112.2(a)(1).
90. 21 C.F.R. § 1.1305(g).
91. 21 C.F.R. § 1.1305(f).

2. Raw bivalve molluscan shellfish that are subject to FDA's Seafood HACCP recordkeeping requirements for "molluscan shellfish" products;[92] or

3. Raw bivalve molluscan shellfish that are covered by a final equivalence determination by FDA (*i.e.*, where FDA has found that a foreign country has implemented a system of food safety control measures for raw bivalve molluscan shellfish that provides at least the same level of sanitary protection as comparable food safety measures in the US).

- **Exemption for commingled raw agricultural commodities (RACs).[93]** Foodservice distributors will not be required to maintain Subpart S records for commingled RACs, which the rule defines to include RACs from *different farms or fishing vessels* that are combined before processing, excluding any fruits and vegetables that are subject to FDA's Produce Safety Rule.[94]

  This would include, for example herbs that are sourced from a number of small farms in a region, and then combined before processing. This exemption also applies to RACs that are destined to be commingled by a subsequent entity in the supply chain, as long as the shipper and receiver enter into a written agreement stating that the receiver will commingle the RACs, or that the receiver will only ship the RACs to subsequent entities who agree, in writing, to commingle the RACs. Foodservice distributors will still need to maintain Subpart J records for RACs that are exempt under this provision.

- **Exemption for certain foods produced and packaged on farms.[95]** Foodservice distributors will not be required to maintain Subpart S records for FTL foods produced or packaged on a farm, if such foods meet the following conditions:

  1. The food's packaging remains in place until the food reaches the consumer;

  2. The packaging maintains the integrity of the product and prevents subsequent contamination or adulteration; and

  3. The consumer-facing labeling contains the name, complete address, and business phone number[96] of the farm on which the food was produced and packaged.

  Foods that might qualify for this exemption include those packaged by a farm in individual non-vented cellophane wrapping or in sealed plastic.[97] Foods packaged in clamshells with holes, cardboard boxes, vented crates, plastic bags with holes, and netted bags do not qualify for this exemption, since, in FDA's view, such packaging does not adequately maintain the integrity of foods.[98]

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92. 21 C.F.R. Part 123, Subpart C; *id*. § 1240.60

93. 21 C.F.R. § 1.1305(h).

94. 21 C.F.R. § 1.1310. The rule specifically clarifies that "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" and that "'processing' means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization." *Id*.

95. 21 C.F.R. § 1.1305(c).

96. FDA may waive the requirement to include a business phone number, as appropriate, to accommodate the religious belief of the person in charge of the farm. *Id*.

97. Proposed Rule Preamble at 59996.

98. Final Rule Preamble at 70960.

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