Questions and Answers About Requirements for Additional Traceability Records for Certain Foods: Guidance for Industry

Draft Guidance

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For questions regarding this draft document contact the Human Foods Program at 240-402-1200.

U.S. Department of Health and Human Services
Food and Drug Administration
Human Foods Program

February 2026

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Questions and Answers About Requirements for Additional Traceability Records for Certain Foods: Guidance for Industry[1]

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I. Introduction

On November 21, 2022, the Food and Drug Administration (FDA, the Agency, or we) issued a final rule, Requirements for Additional Traceability Records for Certain Foods (87 FR 70910) (Food Traceability Rule), which established additional recordkeeping requirements for persons who manufacture, process, pack or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL). The final rule promulgated 21 CFR Part 1, Subpart S (21 CFR 1.1300-1.1465), which requires such entities to maintain records containing information on critical tracking events (CTEs) in the supply chain for these designated foods, such as initial packing, shipping, receiving, and transforming these foods. The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of these foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death. The regulation was issued in accordance with the FDA Food Safety Modernization Act (FSMA). This guidance answers questions to facilitate industry's understanding of the final rule.

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

[1] This draft guidance has been prepared by the U.S. Food and Drug Administration, Human Food Program's Office of Surveillance Strategy and Risk Prioritization and Office of Coordinated Outbreak Response, Evaluation, and Emergency Preparedness at the U.S. Food and Drug Administration.

Table 1 - Acronyms

Reference	Acronym
Community Supported Agriculture	CSA
Critical Tracking Event	CTE
First Land-based Receiver	FLBR
FDA Food Safety Modernization Act	FSMA
Food Traceability List	FTL
Hazard Analysis Critical Control Point	HACCP
Key Data Element	KDE
National Shellfish Sanitation Program	NSSP
Raw Agricultural Commodity	RAC
Retail Food Establishment	RFE
Traceability Lot Code	TLC

II. Background

FDA promulgated the Food Traceability Rule under section 204(d)(1) of FSMA, which directed the Agency to establish recordkeeping requirements, in addition to the requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350c) and FDA regulations in 21 CFR part 1, subpart J, for persons who manufacture, process, pack, or hold foods that FDA designates under section 204(d)(2) of FSMA as high-risk foods. FDA identifies such designated foods on the FTL. The new requirements established by the final rule will allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and deaths.

At the core of this rule is a requirement that persons subject to the rule who manufacture, process, pack, or hold foods on the FTL maintain records containing key data elements (KDEs) associated with specific CTEs. The rule also requires covered entities to maintain a traceability plan, which describes a firm's traceability procedures and how they identify the FTL foods that they handle. Covered entities must maintain records required by the rule for 2 years, provide records requested by FDA within 24 hours of a request (or within some reasonable time to which FDA has agreed), and provide records in an electronic sortable spreadsheet when necessary to help FDA prevent or mitigate a foodborne illness outbreak, assist in the implementation of a recall, or otherwise address a threat to the public health.

The final rule covers domestic firms as well as foreign firms producing food on the FTL for U.S. consumption, along the entire food supply chain. FDA has proposed extending the compliance date for all persons subject to the recordkeeping requirements to July 20, 2028.

This guidance includes questions and answers to assist industry with understanding the scope of the Food Traceability Rule and meeting the requirements that relate to the questions addressed in this guidance.

III. Questions and Answers

A. Farms

Question 1: Does the value of all of the products produced and sold by a farm count towards the $25,000 threshold for exemption from the rule? What about produce that is not on the FTL? What about non-produce items such as cheese?

Response 1: Section 1.1305(a)(1)(ii) states that the Food Traceability Rule does not apply to 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 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. This exemption relates to the value of all of the produce sold, regardless of whether the produce is on or off the FTL. However, it does not relate to the value of non-produce items.

The following examples illustrate the application of this exemption. For the purpose of providing clear and simple examples, we assume that a farm's sales are the same in every year, and we are not adjusting the $25,000 threshold for inflation.[2]

Scenario 1: Farm selling both produce on the FTL and produce not on the FTL

As a first example, a farm sells $20,000 of tomatoes (a produce item on the FTL) and $20,000 of summer squash (a produce item not on the FTL) annually. Since the total value of the produce ($40,000) is over the $25,000 threshold, the farm does not qualify for the exemption under § 1.1305(a)(1)(ii).

Scenario 2: Farm selling both produce on the FTL and non-produce food on the FTL

As a second example, a farm sells $20,000 of tomatoes (a produce item on the FTL) and $20,000 of soft cheese (a non-produce item on the FTL). The exemption in § 1.1305(a)(1)(ii) is only for "produce farms." In this situation, therefore, it is only the produce part of the farm's operations that is eligible for this exemption; but it is also only the produce sales that need to be considered in computing eligibility for the exemption. Because the produce sales are less than $25,000, the produce operation – which in this case is a tomato operation – is exempt from the requirements of the Food Traceability Rule. Because cheese is not produce, the cheese operation is not considered part of the produce operation, and therefore the cheese operation is not eligible for the exemption in § 1.1305(a)(1)(ii). (But note that other exemptions might apply. For example, if the farm operates a store that sells the cheese, that store could be exempt from the requirements of the rule under § 1.1305(i), which provides an exemption for certain small retail food establishments (RFEs).)

[2] To see inflation adjusted amounts, please see: FSMA Inflation Adjusted Cut Offs | FDA (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs).

Note that any farm that is not covered by the Produce Safety Rule as a function of 21 CFR 112.4(a) is also exempt from the Food Traceability Rule (with respect to the produce they grow) as set forth in § 1.1305(a)(1)(i). Under § 112.4(a), the Produce Safety Rule does not cover a farm or farm mixed-type facility with an average annual monetary value of produce (as "produce" is defined in § 112.3) sold during the previous 3-year period of $25,000 or less (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment. We recognize that there is a lot of overlap between the farms that the Food Traceability Rule exempts under § 1.1305(a)(1)(i), and the farms that the Food Traceability Rule exempts under § 1.1305(a)(1)(ii), which is the provision discussed earlier in this response. If a farm fits into either or both of these exemptions, it is exempt from the Food Traceability Rule. FDA provided the exemption in § 1.1305(a)(1)(i) so that farms that have already determined that they are not covered by the Produce Safety Rule as a function of 21 CFR 112.4(a) would not need to do any additional analysis to figure out their status under the Food Traceability Rule.

Question 2: In the context of a farm to school or farm to institution program, is the farm itself exempt?

Response 2: Section 1.1305(l) provides a partial exemption to "an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966, or any other entity conducting a farm to school or farm to institution program, with respect to a food that is produced on a farm (including food produced and packaged on the farm) and sold or donated to the school or institution." Per § 1.1305(l)(2), the school food authority or relevant food procurement entity must maintain a record for 180 days documenting the name and address of the farm that was the source of the food.

We consider the farm that is producing the food for such a program to be one of the entities "conducting" the farm to school or farm to institution program. Therefore, the participating farm would be exempt from the rule with respect to the food that is produced on the farm and sold or donated to the school or institution.

B. Fishing Vessels

Question 3: The partial exemption in § 1.1305(m) applies not only to the owner, operator, or agent in charge of a fishing vessel, but also to anyone who manufactures, processes, packs, or holds the food that was obtained from the fishing vessel, until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel. How does this work in practice? For example, if Kiet owns a fishing vessel that catches tuna and brings it to shore, after which Kiet arranges for the tuna to be transported to a processing facility that he operates, where the whole tuna is transformed into packaged tuna filets and then sold to a distribution center, what records, if any, need to be kept?

Response 3: In this situation, the partial exemption applies to both the fishing vessel and the processing facility, but not to the distribution center. Thus, neither Kiet nor anyone else associated with receiving the tuna on shore would be required to maintain the first land-based receiver (FLBR) records under § 1.1335. Furthermore, the processing facility Kiet operates would not be required to maintain any subpart S records relating to the tuna (such as receiving

records, transformation records, or shipping records), because at the time when the tuna is being held by the processing facility, Kiet – the owner of the fishing vessel – has not yet sold the tuna.

The distribution center in this example is not covered by the partial exemption in § 1.1305(m), because it receives the tuna filets after they are sold by Kiet. The distribution center would be required to maintain receiving records under § 1.1345(b), which sets forth the required records when an entity receives an FTL food from an entity that is exempt from the rule. Any subsequent events would be covered by the rule. For example, if the distribution center ships the tuna filets to a grocery store, the distribution center would maintain and send the required shipping records under § 1.1340 and the grocery store would maintain the required receiving records under § 1.1345(a).

Note that § 1.1305(m) is only a partial exemption. As described above, § 1.1305(m) provides an exemption from the subpart S requirement to maintain records relating to specific CTEs, such as first land-based receiving, receiving, transformation, and shipping. However, under § 1.1305(m)(2), if either Kiet's fishing vessel or Kiet's processing facility is required to register with FDA under section 415 of the FD&C Act, then that entity would be required to maintain "one-up, one-back" records in accordance with 21 CFR 1.337 and 1.345. Section 415 of the FD&C Act establishes FDA's Food Facility Registration program.[3]

Question 4: If the FLBR commingles fish (or other seafood) from multiple different fishing vessels that land at different times, do they need to maintain the FLBR KDEs from each vessel or can they utilize the exemption for commingled raw agricultural commodities (RACs)?

Response 4: In this situation, the FLBR may rely on the partial exemption for commingled RACs in § 1.1305(h), provided that the definition of commingling in § 1.1310 has been met. We recognize that commingling does not happen instantaneously and that commingling might involve seafood from vessels that landed at different times.

C. Raw Molluscan Shellfish

Question 5: When a raw molluscan shellfish product is exempt from the Food Traceability Rule, could it lose its exemption as it moves through the supply chain? If so, what records need to be kept?

Response 5: Section 1.1305(f) only provides an exemption for raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation Program (NSSP); subject to the requirements of part 123, subpart C, and § 1240.60; or covered by a final equivalence determination by FDA (available at: https://www.fda.gov/food/international-cooperation-food-safety/equivalence-and-food-safety#:~:text=The%20FDA's%20final%20equivalence%20determination,are%20equivalent%20to%20comparable%20U.S). Raw molluscan shellfish that are covered by one of these three programs are exempt from the rule because similarly rigorous traceability records are already required by these programs.

[3] For more on the requirement to maintain "one-up, one-back" records, see Response 29.

In some cases, such products remain exempt throughout their entire supply chain because they remain in their raw state and they remain covered by NSSP, or subject to the requirements of subpart C and § 1240.60, or covered by a final equivalence determination. However, there are some situations where the raw molluscan shellfish are transformed into a food that is no longer covered by the exemption. When this is the case, it is possible that the food will remain exempt because of a different exemption; but in some situations the food will no longer be exempt. The following examples illustrate three possible scenarios:

Scenario 1: Raw oysters served on the halfshell

Oysters on the halfshell that are received raw by restaurants remain subject to the § 1.1305(f) exemption throughout their entire supply chain. Most such oysters are subject to § 1.1305(f) because they are covered by NSSP and they are subject to the requirements of subpart C and § 1240.60. In other cases, the oysters are subject to § 1.1305(f) because they are imported from a country whose oysters are covered by a final equivalence determination.

Scenario 2: Canned clams

A manufacturer's receipt of raw clams is subject to the requirements of subpart C and § 1240.60, which means that the exemption in § 1.1305(f) would apply to that receiving event, and the manufacturer would therefore not need to keep any receiving records under the Food Traceability Rule. Once the manufacturer cooks and cans the clams, they are no longer raw, and the exemption in § 1.1305(f) therefore no longer applies. However, at this point the manufacturer can take advantage of the kill step exemption in § 1.1305(d)(3). In order to take advantage of that provision, the manufacturer would need to keep a record of the application of the kill step, as described in § 1.1305(d)(3)(ii). The manufacturer would then be exempt from keeping transformation and shipping records as a result of the kill step exemption; and as described above, the manufacturer would also be exempt from keeping receiving records because of the exemption relating to raw molluscan shellfish. Therefore, the only record that the manufacturer would need to keep in this scenario would be a record of the application of the kill step, which they are probably already required to maintain under another regulation. (See Response 28, 87 FR 70910 at 70926.)

Scenario 3: Raw breaded oysters

A manufacturer's receipt of raw oysters is subject to the requirements of subpart C and § 1240.60, which means that the exemption in § 1.1305(f) would apply to that receiving event, and the manufacturer would therefore not need to keep any receiving records under the Food Traceability Rule. But when the processor applies breading to the raw oysters, the exempt product (raw oysters) is transformed into a non-exempt product (raw breaded oysters, which are not subject to the requirements of subpart C and § 1240.60). As discussed in Question 21, transformation records under § 1.1350(a)(2) would therefore be required. Shipping records for the outgoing raw breaded oysters would also be required. This ensures traceability for this processed product through the remainder of the supply chain.

D. Retail Food Establishments and Restaurants

Question 6: How does the Food Traceability Rule apply to restaurants and RFEs that routinely purchase FTL foods from RFEs such as wholesale membership clubs, but who do so through the means utilized by consumers?

Response 6: Section 1.1305(k) provides RFEs and restaurants with a partial exemption for purchases made from other RFEs or restaurants that occur "on an ad hoc basis outside of the buyer's usual purchasing practice (*e.g.*, not pursuant to a contractual agreement to purchase food from the seller)." The preamble to the final rule explained:

"This partial exemption in § 1.1305(k) does not exempt RFEs and restaurants from the subpart S requirements when an RFE or restaurant purchases food from another RFE or restaurant as part of the buyer's usual purchasing practice, as opposed to on an ad hoc basis. For an ad hoc purchase of the sort that would be eligible for this partial exemption, the purchase is generally made through the means utilized by consumers (*e.g.*, through a check-out line), under circumstances where the selling RFE or restaurant might assume that the purchaser is a consumer. When a contractual relationship exists in which one RFE or restaurant serves as a regular commercial supplier for another RFE or restaurant, such purchases would be outside the scope of the partial exemption in § 1.1305(k)." (See Response 222, 87 FR 70910 at 70976.)

In order to qualify for this exemption, it is not necessary for such a purchase to be a one-off occurrence, or even a rare occurrence. We recognize that some RFEs or restaurants might often make purchases that fit the above description of an ad hoc purchase, in that they are made through the means utilized by consumers, as opposed to being made pursuant to a contractual relationship. Such purchases are eligible for the partial exemption in § 1.1305(k). As stated in Response 222 of the preamble to the final rule, it might not be feasible for a full set of KDEs to be kept and passed along under these circumstances. If the sale happens under circumstances where it may seem like the purchaser is a consumer (*e.g.,* through the check-out line), the exchange of KDEs would be hindered both by the need to serve the other people waiting in line, and by the fact that the individual making the sale (the cashier) is unlikely to be in possession of all of the KDEs. This is not simply a result of the cashier's job duties; it is also a result of the fact that the FTL food has already been taken out of inventory and placed on the shelf for purchase by consumers, which is likely to make it difficult to identify certain KDEs, such as the traceability lot code (TLC), for the specific item.

In situations like these where the partial exemption in § 1.1305(k) applies, the RFE (or restaurant) that made the sale is fully exempt, while the RFE or restaurant that made the purchase must only maintain a record documenting the name of the product purchased, the date of purchase, and the name and address of the place of purchase. In many cases, the required KDEs for the ad hoc purchase can be documented by a sales receipt. Additionally, the Food Traceability Rule allows a third party to establish and maintain the required records on behalf of a covered entity, though the covered entity remains responsible for ensuring that such records can be retrieved and provided onsite within 24 hours of request for official review (§ 1.1455(b)). An entity such as a wholesale membership club may be able to provide the required purchase information (i.e., the name of the product purchased, the date of purchase, and the name and

address of the place of purchase) for its members upon request, even when the purchase was not made pursuant to a contractual relationship. If this is the case, the RFE or restaurant that made the ad hoc purchase could consider the wholesale membership club to be the holder of the records that are required under the partial exemption, as long as the purchasing RFE or restaurant can provide the required records to FDA upon request within 24 hours.

Question 7: When a parent company operates multiple locations of an RFE or restaurant, if one location runs out of an FTL food and therefore sends an employee to another location that is operated by the same parent company, where they arrange to take the food from the shelf or from the kitchen and bring it to the location that has run out of the item, does the partial exemption in § 1.1305(k) apply?

Response 7: The definition of "shipping" includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm. It is therefore a shipping event when food moves from one location of a company to another location of the same company, including when it moves between retail or restaurant outlets that are part of the same "chain" of outlets. In some situations an intracompany shipment between retail or restaurant locations will be eligible for the partial exemption for ad hoc purchases in § 1.1305(k), while in other situations it will not be. The following scenarios demonstrate the distinction.

Scenario 1: Two locations with a general practice of sharing inventory

When two retail or restaurant locations that are part of the same company have a general practice of sharing inventory – for example, if one location essentially acts as a distributor for the other location – then the movement of FTL food from one location to the other would constitute regular (not ad hoc) shipments. The exemption in § 1.1305(k) would therefore not apply, and shipping KDEs would need to be maintained and sent for the movement of the FTL food from one retail or restaurant location to the other.

Scenario 2: Ad hoc movement of FTL food

When there is no general practice of sharing inventory between the two locations, the movement of an FTL food between two retail or restaurant locations that are part of the same company can constitute an ad hoc event for the purpose of the exemption in § 1.1305(k). The situation described in the question, in which one location runs out of an FTL food and therefore sends an employee to another location that is operated by the same parent company, where they arrange to take the food from the shelf or from the kitchen and bring it to the location that has run out of the item, could be an example of an ad hoc event. We would consider factors such as whether the transaction is outside of the receiving entity's usual practice, and whether the entity selling or providing the FTL food had already placed the food on the shelf for purchase by consumers (in the case of an RFE) or moved it to the area where it could be utilized by the kitchen (in the case of a restaurant), similar to the situations described in Response 222 of the preamble to the final rule (see 87 FR 70910 at 70976) and above in Response 6. Such actions indicate that the entity providing the food was intending to sell the food directly to consumers, which in turn suggests

that sending the food to another retail or restaurant location was unplanned and ad hoc. We recognize that, as discussed in Response 6, once a food item is on the shelf (or in the kitchen area) it can become difficult to identify certain KDEs, such as the TLC, for the specific item.

The employee from the receiving outlet does not necessarily need to go through the check-out line in order for the transaction to be considered ad hoc. While it is possible that a transaction between two outlets that are part of the same "chain" might be made through the means utilized by consumers, such a transaction could still be considered ad hoc even if it occurs in a different manner, e.g., through an impromptu discussion between employees of the two different outlets owned by the same parent company.

Question 8: If an RFE or restaurant arranges with a third party to purchase FTL foods on their behalf from another RFE or restaurant, what KDEs are required?

Response 8: Section 1.1305(k) provides RFEs and restaurants with a partial exemption for purchases that occur 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). This exemption is applicable regardless of whether the purchase is made by an employee of the purchasing entity, or by a third party that the purchasing entity engages to make an ad hoc purchase on their behalf from another RFE or restaurant. The purchasing RFE or restaurant would be required to maintain modified records as outlined in § 1.1305(k)(2) and as described in Question 6.

For situations where an RFE or restaurant purchases an FTL food from another RFE or restaurant pursuant to a contractual agreement, such purchases would be outside the scope of the partial exemption in § 1.1305(k). In that situation, both entities are required to maintain the appropriate shipping and receiving records outlined in the rule (see §§ 1.1340 and 1.1345) . This is true regardless of whether the purchase is made by an employee of the purchasing entity, or by a third party that the purchasing entity engages.

Question 9: How do the Food Traceability Rule requirements under § 1.1340 for shipping of FTL foods apply to purchases made by consumers from RFEs or restaurants using third-party platforms, such as third-party online ordering websites and delivery applications?

Response 9: As defined in § 1.1310, shipping is 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. The definition further states that shipping does not include the sale or shipment of a food directly to a consumer.

Therefore, if an RFE or restaurant sends a food directly to the consumer, this would not be considered a shipping event, and shipping KDEs would therefore not need to be maintained. This is true even if the sale was arranged using a third-party platform, for example, if the consumer purchased the food by going to a website that is operated by a third party (not by the RFE or restaurant).

In some situations, in addition to operating a website that allows consumers to purchase foods from various RFEs or restaurants, a third party might also arrange for transport of the food. As long as the food is being transported directly from the RFE or restaurant to the consumer – which is generally the case with these types of services – this would not be a shipping event.

However, if the food is not sent directly to the consumer from the RFE or restaurant and is instead sent to another business entity prior to being shipped to the consumer, then this would meet the definition of shipping and therefore require the maintenance of shipping KDEs.

Question 10: Is an FTL food purchased from a farmers' market stall subject to the same exemptions as an FTL food purchased from a store located on the farm?

Response 10: Yes, if the farmers' market stall is operated by the farm that produced the food, and the food is therefore sold by the owner, operator, or agent in charge of the farm that produced the food.

There are two exemptions that relate to sales of food by the farm that produced the food. Both of these exemptions apply not only to stores that are located on farms, but also to other RFEs operated by the farm, as follows:

1. Section 1.1305(b) relates to food produced on a farm that is sold or donated directly to a consumer by the owner, operator, or agent in charge of the farm. In this situation, the farm is exempt from the requirements of the rule. (And since consumers are never subject to the rule, the entire transaction is exempt.) We clarified in the preamble to the final rule that this exemption applies to all direct-to-consumer sales by farms, including applicable sales at farmers' markets, roadside stands, over the internet, and through community-supported agriculture (CSA) programs. (See 87 FR 70910 at 70959.)
2. Section 1.1305(j) applies to RFEs and restaurants with respect to food that is produced on a farm and both sold and shipped directly to the RFE or restaurant by the owner, operator, or agent in charge of that farm. In this situation, the RFE or restaurant receives a partial exemption, and only must maintain – for 180 days – a record documenting the name and address of the farm that was the source of the food. (Note that the farm does not receive an exemption (unless otherwise exempted) and must therefore maintain and send the usual shipping KDEs.) All sales that are made directly from the farm to the RFE or restaurant are eligible for this exemption, including sales from farmers' markets, roadside stands, over the internet, and through CSA programs. This approach is in keeping with our approach to § 1.1305(b).

However, in both of these exemptions the food has to be produced by the farm that is making the sale. In some situations a farmers' market stall (or another RFE that is operated by a farm) might sell food that was produced by another farm. In that situation, we would not consider the food to be sold by the farm that produced the food. (See Response 174, 87 FR 70910 at 70959.) Thus, neither the exemption in § 1.1305(b) nor the exemption in § 1.1305(j) would apply.

As an example, if Nai-Nai's Farm operates a farmers' market stall where they sell both food that they produced on their own farm and food that was produced at the neighboring Zayde's Farm,

then the exemptions in §§ 1.1305(b) and 1.1305(j) would only be available for the food that was produced on Nai-Nai's Farm.

Depending on the circumstances, other exemptions might apply to the food that was produced on Zayde's Farm. For example, if an employee of an RFE or restaurant goes to the farmers' market stall that is operated by Nai-Nai's Farm and makes an ad hoc purchase of an FTL food that was produced on Zayde's Farm, the partial exemption for ad hoc sales in § 1.1305(k) would apply.

It is also important to note that the farmers' market stall itself might qualify for an exemption as a small retailer under § 1.1305(i), in which case the entire stall would be exempt regardless of where the food was produced.

Question 11: How do I determine if a food is being sold by the owner, operator or agent in charge of a farm?

Response 11: As discussed in QA10, there are two exemptions that relate to sales by the owner, operator, or agent in charge of the farm that produced the food (see § 1.1305(b) and (j)). In determining whether an FTL food is being sold by the owner, operator, or agent in charge of the farm that produced that food, we look to whether or not the farm that produced the food is operating the RFE where the food is sold. As discussed in Response 10, this could be any retail location or platform that performs direct-to-consumer sales by the farm, such as a store located on the farm, a farmers' market stall, a roadside stand, an internet website, or a community-supported agriculture program. If the farm that produced the food is operating the RFE where the food is sold, then we consider the food to be sold by the owner, operator, or agent in charge of the farm that produced the food.

We recognize that the individual who performs the specific sales transaction might be a temporary employee or someone who otherwise does not have a leadership position within the farm. For example, a farmers' market stall might be staffed by an employee who does not have a leadership position, but who nonetheless has the authority to sell the food produced by the farm. As long as the stall is being operated by the farm that produced the food, then we consider the sale to have been made by the owner, operator, or agent in charge of that farm.

E. Commingling

Question 12: Do practices such as freezing, heading, or eviscerating of seafood constitute "processing" for the purpose of determining eligibility for the partial exemption for commingled RACs in § 1.1305(h)?

Response 12: The definition of "commingled raw agricultural commodity"[4] in § 1.1310 is limited to any commodity that is combined or mixed after harvesting but before processing. The partial exemption for commingled RACs in § 1.1305(h) is therefore only available if the commingling occurs before the product is processed. As stated in § 1.1310 (which derives from Section 204(d)(6)(D)(ii) of FSMA), for the purposes of the commingled RAC definition, the term "processing" means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization. Although freezing is listed as something that can alter the general state of a commodity, we do not think that all freezing events should be considered processing for the purpose of the commingled RAC definition and exemption. In the context of seafood, practices such as freezing are often important to maintain product safety and quality during transport on board a fishing vessel. When seafood is frozen (or headed and/or eviscerated, as discussed below) with the sole intent of preparing it for holding on board a harvest vessel, we do not think it is appropriate to consider this "processing" for the purpose of the commingled RAC definition and exemption.

Thus, for example, fish that is harvested by one fishing vessel, and frozen (or headed or eviscerated) while at sea to prepare it for holding on board that vessel, can still be eligible for the exemption if it is subsequently commingled with fish from another vessel after the vessels have landed. However, when activities such as heading, eviscerating, or freezing are done in other contexts, such as in a seafood processing facility or aquaculture farm, they would constitute "processing" for the purposes of this exemption.

This approach is consistent with FDA's seafood hazard analysis critical control point (HACCP) regulations. Under § 123.3(k)(1), with respect to fish or fishery products, processing includes heading, eviscerating, and freezing. However, under § 123.3(k)(2)(ii), the seafood HACCP regulations – which in general apply to entities that process fish or fishery products – do not apply to practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel. In the preamble to the final rule that promulgated the HACCP regulations, we explained our concern that, in the absence of such an exemption, harvest vessels that are presently heading or gutting fish would stop the practice to avoid being subject to the HACCP requirements. Because we did not want an inadvertent consequence of the HACCP regulations to be a reduction in product quality, and because we had tentatively concluded that safety hazards introduced by these operations are generally minimal, FDA decided that the HACCP regulations should not apply to practices such as heading, eviscerating, or freezing that are intended solely to prepare a fish for holding on board a harvest vessel (see 60 FR 65096, 65115 (Dec. 18, 1995)). Similar considerations apply here: We do not want an inadvertent

[4] *Commingled raw agricultural commodity*, as defined in § 1.1310, means any commodity that is combined or mixed after harvesting but before processing, except that the term "commingled raw agricultural commodity" does not include types of fruits and vegetables that are raw agricultural commodities to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in 21 CFR Part 112 apply. For the purpose of this definition, a commodity is "combined or mixed" only when the combination or mixing involves food from different farms under different company management; except that for food obtained from a fishing vessel, a commodity is "combined or mixed" only when the combination or mixing involves food from different landing vessels and occurs after the vessels have landed. Also, for the purpose of this definition, the term "processing" means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

consequence of the Food Traceability Rule to be a reduction in product quality, and we continue to believe that these activities are distinguishable from other types of processing.

Furthermore, in the context of the Food Traceability Rule, the exemption for commingled RACs is only available when the combining or mixing of the commodity involves food from different farms under different company management, or – for food obtained from a fishing vessel – when it involves food from different landing vessels and occurs after the vessels have landed. Freezing is routinely used on board a harvest vessel to preserve the quality of the seafood before it is landed. Quickly heading and eviscerating seafood products can also be important for product safety and quality, which is why these activities are also often performed almost immediately after harvesting, before the vessel has landed. Thus, if any type of freezing, heading, or eviscerating of a seafood product were considered to be a form of processing, the commingled RAC exemption would almost never be available to seafood products obtained from fishing vessels. Congress explicitly stated that most produce is ineligible for the commingled RAC exemption (see Section 204(d)(6)(D)(ii)(II) of FSMA), which leads us to conclude that Congress intended the exemption to be available to non-produce commodities such as seafood, under appropriate circumstances.

Question 13: Does the partial exemption for commingled RACs (§ 1.1305(h)) continue to apply if the food is no longer a RAC?

Response 13: No. This exemption is only applicable to RACs. Section 1.1310 states that "raw agricultural commodity" means "raw agricultural commodity" as defined in section 201(r) of the FD&C Act. That definition states, in relevant part, that the term "raw agricultural commodity" means any food in its raw or natural state. Products that do not meet the definition of RACs are not eligible for the exemption for commingled RACs.

We expect that there will be situations where a product is eligible for the exemption for commingled RACs, but as it moves through the supply chain it loses its eligibility because it ceases to be a RAC. For example, if shrimp are harvested from two different farms under different company management, and the shrimp from the two farms are combined or mixed after they are harvested but before they are processed (as that term is used in the definition of "commingled raw agricultural commodity"), the commingled whole raw shrimp would be eligible for the exemption for commingled RACs. However, if at a later time the commingled shrimp are peeled and deveined, they would no longer be a RAC. They would therefore no longer be eligible for the exemption for commingled RACs. See Question 21 for a discussion of what records are required in this situation.

Question 14: Does the partial exemption for commingled RACs in § 1.1305(h) apply when different species of fish (or other seafood) are commingled together?

Response 14: Under § 1.1310, commingled RAC means, in part, any "commodity" that is combined or mixed after harvesting but before processing. This definition assumes that the commingled product is treated as a single commodity, i.e., as a single article of commerce. For example, pollock from two different fishing vessels might be commingled before being shipped to a processing facility. In this situation, the commingled pollock is treated as a single

commodity (e.g., whole raw pollock). We anticipate that in the vast majority of situations commingling will only occur among the same species, because a commingled RAC moves through the supply chain as a single article of commerce.

If different species of fish are stored or shipped together, but not treated as a single commodity, then no commingling has occurred. For example, if an FLBR purchases pollock from one fishing vessel and salmon from another fishing vessel and sells them as part of a single shipment to a seafood processing facility where the pollock will be processed into packaged pollock filets and the salmon will be processed into packaged salmon fillets, no commingling has occurred. In this situation, the pollock and the salmon have not been combined or mixed as a single commodity; instead, they are kept separate and treated as distinct commodities. While they are sold as part of a single shipment, they are presumably listed as separate items within that shipment.

There might be a small number of circumstances where commingling of different species could occur. For example, an FLBR might buy a variety of small fish from different fishing vessels, combine the different species of fish from the different vessels, and ship them as a single commodity – for example "raw sardine/anchovy mix." The receiving facility could be a fish paste processor who is willing to purchase a mix of small fish as a single commodity to manufacture into fish paste. This type of commingling could be eligible for the commingled RAC exemption, assuming all of the elements of the exemption are met.

Question 15: If a commingled RAC that is partially exempt under § 1.1305(h) receives a kill step, how does the partial exemption for commingled RACs intersect with the exemptions related to products that receive a kill step? What records must be kept?

Response 15: When multiple exemptions apply to a given situation, an entity has the flexibility to utilize any of the applicable exemptions, as long as the entity complies with any obligations that might accompany the exemption (if it is only a partial exemption). A combination of exemptions can also be used, for example if the food is initially eligible for a given exemption but subsequently stops being eligible for that exemption.

In the situation presented here, if the relevant members of the supply chain are aware in advance that the food will receive a kill step, they can enter into written agreements under § 1.1305(d)(6) and thereby be exempt from the other requirements of the rule. The entity that applies the kill step would need to keep a record of their application of the kill step under § 1.1305(d)(3)(ii).

Assuming no such written agreements are in place, the incoming commingled RAC that arrives at the facility that is going to apply the kill step is potentially eligible for two different partial exemptions – § 1.1305(h), because it is a commingled RAC, and § 1.1305(d)(3), because it is a food that the processor subjects to a kill step. The key principle to apply is that the processor can choose to take either of the applicable exemptions (or some combination thereof), as long as they comply with any obligations that might accompany the exemption, and as long as they recognize that some exemptions are only available at certain points in time. Notably here, the commingled RAC exemption no longer applies once a food is processed, as discussed in Question 13. Taking all of this into account, either of the following two scenarios would be acceptable:

If the processor chooses to avail themself of the commingled RAC exemption, and if the processor is required to register under section 415 of the FD&C Act (which is very likely to be the case), then the processor's only obligation regarding the receipt of the incoming commingled RAC is to maintain records identifying the immediate previous source of the commingled RAC in accordance with § 1.337. This obligation stems from § 1.1305(h)(3). Once processing begins, the food is no longer a RAC (as discussed in Question 13), so the commingled RAC exemption no longer applies. At this point the processor can begin to avail themself of the kill step exemption, by keeping a record of the kill step as set forth in § 1.1305(d)(3)(ii). After the kill step has been applied, there are no further obligations relating to the food.

As a second option, the processor could choose only to avail themself of the kill step exemption in § 1.1305(d)(3). If they choose this option, they will be required to keep receiving records as described in § 1.1345. (Unless they have entered into a written agreement concerning their application of the kill step, as discussed above and in § 1.1305(d)(3)(i).) They would also need to keep a record of their application of the kill step, per § 1.1305(d)(3)(ii). After the kill step has been applied, there are no further obligations relating to the food.

Also note that a firm is never required to take an exemption just because it is available to them. A firm might decide that keeping full records for all of its FTL foods is easier than keeping track of exemptions. Thus, in this situation, a full set of receiving records under § 1.1345 is always an acceptable way to handle the receipt of the incoming commingled RAC. Similarly, a full set of transformation records under § 1.1350 can be maintained instead of a record of the kill step. And it is always permissible to maintain shipping records for the food that has received the kill step, even though there is no obligation to do so.

F. Initial Packing of a Food on the Food Traceability List

Question 16: Are there situations where a RAC on the FTL is sent to a different location without being "initially packed"? For example, if a harvester packs up an FTL food so that it can be transported to a packinghouse at a different location, is the harvester or the packinghouse the initial packer?

Response 16: Section 1.1310 defines "initial packing" to mean "packing a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time." "Packing" is defined in relevant part to mean "placing food into a container other than packaging the food." In the preamble to the final rule, we noted that, in general, packing means putting a product into a container that is distributed in commerce (e.g., packing clamshell containers into a cardboard box for shipment), and does not include placing a product into a temporary container to move it, such as from a field to a packinghouse (see 87 FR 70910 at 70990).

When a RAC is sent to a different location from the farm where it was harvested, the entity who sends the RAC to the new location is generally doing so by putting the product into some sort of container and distributing it into commerce. Thus, under the preamble's explanation, this entity would appear to be the initial packer. We continue to believe that this entity is presumed to be the initial packer. However, we recognize that many supply chains include a packinghouse, and that RACs are often not considered to be "packed" until they reach the packinghouse. This can

be the case even if the packinghouse is in a different location than the place where the food was harvested, and/or is under different ownership.

We encourage supply chain entities to communicate with each other to identify the initial packer. In situations where the first entity is sending the food to a packinghouse, and the first entity is aware that the packinghouse considers itself to be the initial packer, FDA will generally not substitute our own judgement for the judgement of the supply chain members in determining which entity should be considered the initial packer for the purposes of food traceability. If the packinghouse is considered the initial packer, it would need to keep the required initial packer KDEs in accordance with § 1.1330, and the harvester and (if applicable) cooler would need to provide the packinghouse with the harvesting and cooling information that is required to be provided to the initial packer under § 1.1325(a)(2) and (b)(2), either directly or through the supply chain.

We note that some types of RACs never get packed as securely as others. For example, watermelons generally do not get packed as securely as shell eggs. However, for the rule to function as intended, it is important that every RAC (except those obtained from a fishing vessel) have an initial packer who designates traceability lots and assigns TLCs. For a product such as watermelons, the same analysis applies as above. The first person who sends the watermelons to a different location from the farm where they were harvested should consider themselves to be the initial packer unless they are aware that the place where they are sending the watermelons is a place (such as a packinghouse) that considers itself to be the initial packer and will keep the required initial packing KDEs. This is the case even if the watermelons are being contained loosely in a manner that would not, for other types of produce, be considered "packed." If such loose packing is of the type that is used to transport watermelons throughout the supply chain, and if the next entity in the supply chain does not consider itself to be the initial packer, then the entity who first sends the watermelons to a different location from the farm where they were harvested should consider themself to be the initial packer.

Question 17: When initial packing happens in a field, how should the location description for the traceability lot code (TLC) source be recorded? Does it need to be the geographic coordinates for the specific field where the packing took place?

Response 17: Under § 1.1320, you must assign a TLC when you perform the initial packing of a RAC on the FTL (other than a food obtained from a fishing vessel). As defined in § 1.1310, the TLC source is the place where a food was assigned a TLC. Under § 1.1330(a)(14), the initial packer of the food must maintain records that contain the location description for where they initially packed the food (i.e., the TLC source). Location description is defined in § 1.1310 to mean key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country. Thus, the location description for the TLC source must capture this key contact information for the place where a food was assigned a TLC.

"The place where a food was assigned a TLC" does not need to be specific enough to identify the exact physical location (e.g., a specific field) where the TLC was assigned. The definition of

location description includes as one element the "physical location address (or geographic coordinates)." Either of these can be used when recording the location description for the TLC source. Thus, when a food is initially packed in the field of a farm, the street address of the farm can be used as the physical location address. If the farm does not have a street address, geographic coordinates can be used instead. However, these coordinates do not need to refer to the precise field where a given traceability lot was initially packed. The farm can select one set of geographic coordinates (for example, to reflect the main entrance of the farm) to use as part of its location description.

Note that specific information about the fields and other growing areas where FTL foods are grown and harvested is required in other parts of the Food Traceability Rule (see §§ 1.1315(a)(5)(i), 1.1325(a)(1)(v), and 1.1330(a)(5)). This information, in conjunction with other required information such as the street address of the TLC source (or geographic coordinates for the main entrance of the TLC source), will enable FDA to locate the potential source of a foodborne illness outbreak and help protect public health.

Question 18: I am an entity that receives unpacked produce from very small farms, e.g., backyard farmers, and then distributes it to other entities. I do not have information about the backyard farmers because my immediate supplier is a consolidator who buys the produce from the various backyard farmers, transports it all together (still unpacked) in his vehicle, and brings it to my facility and sells it to me. The consolidator does not have a business address because his operation only entails the use of his vehicle, and does not involve a brick and mortar location. What KDEs do I need to keep in this situation?

Response 18: Because the produce has not yet been packed, you do not need to keep receiving KDEs (see § 1.1345(c)). It is likely that under the Food Traceability Rule, you are the initial packer in this scenario because the food has not yet been packed, and you are presumably packing it sufficiently such that it can go to the next point in the supply chain. Even if you are only placing the food in temporary containers to be transported to a processor, you are most likely the initial packer as described in Question 17.

Section 1.1330(c) describes the KDEs that are required if you are initially packing a RAC (other than a food obtained from a fishing vessel) that you received from a person to whom the rule does not apply. In this situation, the consolidator is not subject to any of the requirements of the rule. He is handling food that has not been initially packed, so he does not need to maintain shipping or receiving KDEs; and he is not performing any other CTEs described in the rule. He is therefore a person to whom the rule does not apply. Yet he is the person from whom you received the food. He is not simply a transporter, because he is the person from whom you bought the food; you do not have a business relationship with the farmers. Therefore, you have received the food from a person to whom the rule does not apply, which means that if you are initially packing the food, you must keep the KDEs described in § 1.1330(c).

The KDEs in § 1.1330(c) do not include information about the location where the food was harvested, because we recognize that if you receive the food from a person to whom the rule does not apply, you may not know this information. The information required under § 1.1330(c) is all information that you should be able to obtain in this situation. Regarding the business

address of the consolidator, § 1.1330(c)(4) requires you to maintain a record of the location description for the person from whom you received the food. "Location description" is defined in § 1.1310 as key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country. Thus, in this situation, you would be required to maintain a record of the business name, phone number, and physical location address of the consolidator from whom you received the food. If the consolidator is self-employed and is not associated with a business name, then your records under § 1.1330(c)(4) could use his personal name (e.g., Juan Ramirez) as the "business name." Similarly, if the consolidator only handles food in his vehicle, and carries out his business operations from his home, then his home phone number (or cell phone number) could serve as the "phone number" for the purposes of the location description, and his home address could serve as the "physical location address" for the purposes of the location description.

Note that this response only applies in a situation where you do not have a business relationship with the farmers. If you had an arrangement with the farmers for them to sell or otherwise provide you with the produce, then each farmer would be "the person from whom you received the food" under § 1.1330(c)(4) for the food you received from that farmer. (This assumes that the farms would be exempt due to their size. If they were not exempt, and if you had business relationships under which they supplied you with produce, then you would be required to keep the information set forth in § 1.1330(a), which includes the location description for the farm where the food was harvested.) In this situation – if you had a business relationship with the farmers under which they supplied you with produce – the person who brought you the produce from the farm would be a transporter. He would therefore be exempt from the rule under §1.1305(n), and you would not be required to keep any KDEs relating to him.

While situations may arise (as in this scenario involving receipt of produce from a consolidator of unpacked produce from backyard farmers) where the Food Traceability Rule does not require the initial packer to maintain records relating to the farm where the food was harvested, it is important to note that you might be required to know certain information about that farm under other FDA regulations. For example, you might be required to know the identity of your foreign supplier (21 CFR 1.500) or supplier (21 CFR 117.3) for the purposes of conducting verification activities required under the regulations on Foreign Supplier Verification Programs for Food Importers (21 CFR Part 1, Subpart L) or Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR Part 117, Subpart G).

G. Transformation of a Food on the Food Traceability List

Question 19: If I break a pallet, do I need to maintain the transformation KDEs?

Response 19: Breaking a pallet – i.e., taking apart a pallet of food products so that individual boxes, containers, or cases can be sent to different places -- is not, in and of itself, a transformation event. The Food Traceability Rule defines transformation to mean 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. Breaking a pallet sometimes happens as part of a transformation event, in which case the transformation KDEs in § 1.1350 must be maintained. But if the breaking of the pallet is not part of a transformation event, then transformation KDEs do not need to be maintained.

As an example, a pallet of tomatoes might be broken so that the tomatoes can be sorted and repacked based on ripeness. Because repacking is a transformation event, the KDEs in § 1.1350 would need to be maintained in this situation. The repacker would become the TLC source, and in most situations a new TLC would be assigned. (As discussed in Response 436 in the preamble to the final rule, the repacker could decide to keep the same TLC if the tomatoes are repacked within the same traceability lot (repacking "like into like") (see 87 FR 70910 at 71035).)

In contrast, if a distribution center breaks a pallet to remove one case (or breaks a case to remove an item, such as a jar of peanut butter) – for example, because they only need one case to fulfill a customer's order – this does not constitute transformation. The contents of the pallet are not being repacked or otherwise transformed. In this situation, the transformation KDEs would not need to be maintained, the TLC would not change, and the distribution center would not become the TLC source.

Question 20: Is culling produce considered a transformation event under the Food Traceability Rule?

Response 20: Repacking of an FTL food is considered a transformation event under the Food Traceability Rule, based on the definition of transformation in § 1.1310. If culling produce (i.e., removing undesirable items of produce) occurs as a part of the repacking process, the KDEs for transformation would apply. In a situation where the culling process occurs outside of repacking an FTL food, this would not be considered a transformation event if the entity is not performing any other transformation activity. For example, if the quantity of a traceability lot of FTL food is changed because food is removed due to poor quality, but the original lot is not repacked or otherwise transformed, the quantity change would not be documented as a transformation event; it would be documented in the shipping and receiving KDEs. Specifically, the entity that performs the culling would keep a record of the quantity and unit of measure of the food in the lot they received under § 1.1345(a)(2), and they would keep a record of the quantity and unit of measure of the food in the lot they shipped under § 1.1340(a)(2). There may be a difference in quantity between these two records, reflecting the fact that some of the product was culled.

Question 21: How does the Food Traceability Rule apply to FTL foods that undergo continuous processing?

Response 21: When applying the Food Traceability Rule to continuous processing operations, you need to consider whether there are any FTL foods at the beginning of the processing event, and whether there are any FTL foods at the end of the processing event. You do not need to keep records for any FTL foods that are produced during an intermediate step in the processing event but that are then further processed into the final food.

This is illustrated by an example from Response 434 in the preamble to the final rule (87 FR 70910 at 71034), where we explained that if a food that is not on the FTL (e.g., nuts) is processed into an intermediate food that is on the FTL (e.g., nut butter) and is very soon thereafter fully processed at the same location into a finished food containing an FTL food that has not been subjected to a kill step (e.g., a confection with nut butter), we would consider this to be one processing event. The food produced through transformation would be the confection, which would be on the FTL because it contains nut butter. The incoming ingredients would include nuts, which are not on the FTL. Nut butter would not be considered an incoming ingredient because the manufacturing of the nut butter was incidental to the overall process of manufacturing the confection. Records under § 1.1350(a)(1) would therefore not be required (assuming none of the other incoming ingredients are on the FTL), and the only records of the transformation event would be those required under § 1.1350(a)(2). Response 434 also explains that if the nut butter is instead manufactured as a stand-alone product, and only later used as an ingredient in a confection, this would not be a continuous processing operation, and additional records would need to be maintained regarding the nut butter. The response discusses how to distinguish between continuous processing operations and operations that involve two separate manufacturing events.

The same approach – of considering the food at the start of the processing event and the food at the end of the processing event, but not keeping records for any intermediate foods that might briefly exist during the processing event – can be applied to other examples of continuous processing operations, as illustrated by the following:

Scenario 1: FTL food processed into an intermediate FLT food and then processed into a non-FLT food

If an FTL food (e.g., whole fresh papayas) is processed into an intermediate food that is on the FTL (e.g., fresh-cut papaya) and is very soon thereafter (as part of a continuous processing operation) fully processed at the same location into a finished food that is not on the FTL (e.g., frozen papaya chunks), we would consider this to be one processing event. You would need to maintain receiving KDEs for the FTL food (whole fresh papayas) you receive, but you would not need to maintain any additional KDEs. Transformation KDEs are not required because the definition of transformation in § 1.1310 states in part that transformation is an event whose output is a food on the FTL. Here you are conducting a single processing event that results in a food not on the FTL (frozen papaya chunks).

Scenario 2: Non-FTL food processed into an intermediate FLT food and then processed into a non-FLT food

If a food that is not on the FTL (e.g., whole strawberries) is processed into an intermediate food that is on the FTL (e.g., fresh-cut strawberries) and is very soon thereafter (as part of a continuous processing operation) fully processed at the same location into a finished food that is not on the FTL (e.g., frozen sliced strawberries), we would also consider this to be one processing event. However, you would not need to maintain any records under the rule because you are conducting a single processing event that begins with a food not on the FTL (whole strawberries) and results in a food not on the FTL (frozen sliced strawberries).

Scenario 3: Non-FTL food processed into an intermediate FLT food and then processed into an FLT food with a kill step

If a food that is not on the FTL (e.g., peanuts) is processed into an intermediate food that is on the FTL (e.g., peanut butter) and is very soon thereafter (as part of a continuous processing operation) fully processed at the same location into a finished food that is on the FTL but receives a kill step (e.g., peanut butter cookies), we would consider this to be a single processing event. You would not need to maintain any receiving records, because the food you received is not on the FTL. And you would be exempt from keeping transformation and shipping records under § 1.1305(d)(3), because although peanut butter cookies are on the FTL, you applied a kill step to the cookies (and therefore to the peanut butter). However, you would have to maintain a record of the kill step in order to receive the kill step exemption (see § 1.1305(d)(3)(ii)).

Continuous processing operations that involve processing a RAC before it is initially packed are also addressed in Response 434 in the preamble to the final rule (see 87 FR 70910 at 71034).

Question 22: What records must I keep if I transform an exempt food in a way that causes it to no longer be exempt?

Response 22: There are some situations where an incoming food is fully or partially exempt from the rule, but the food is then transformed in a way that causes it to no longer be exempt. For example, a commingled RAC might be processed in a way that causes it to no longer be a RAC, in which case it would no longer be exempt under § 1.1305(h). As described in Question 12, an example of this would be commingled shrimp that meet the requirements for the commingled RAC exemption in § 1.1305(h) until they are peeled and deveined, at which point they are no longer a RAC and are therefore no longer eligible for that exemption. As another example, as discussed in Question 5, raw oysters are generally exempt from the rule under § 1.1305(f); but breaded raw oysters are generally not exempt because the raw oysters have been transformed through the breading process into a food that is still on the FTL but not subject to the exemption. A firm might therefore receive exempt raw oysters and transform them into breaded raw oysters, which are not exempt.

In these situations, the firm is receiving an exempt food, performing a transformation event, and then shipping a non-exempt food. Because the incoming food is exempt, receiving records do not need to be kept, although certain other records might be required if the exemption is only a partial exemption (see, e.g., § 1.1305(h)(3)). Shipping records do need to be kept because the outgoing food is not exempt.

Regarding transformation, § 1.1350(a)(1) requires certain records to be kept regarding incoming FTL foods that are used in transformation, "if applicable." This provision is not applicable in situations where the incoming food is exempt. Therefore, the only transformation records that must be kept are those that are required under § 1.1350(a)(2), which relate to the food produced through transformation. These records are required because the food produced through transformation is not exempt.

Question 23: In our distribution center, we print out a sticker that we affix to each incoming case of food, to help with our internal tracking of the product. Is this considered relabeling the food? If so, do we need to keep transformation records when we put these stickers on FTL foods?

Response 23: In § 1.1310, transformation is defined in relevant part as "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 Food Traceability List." Relabeling is therefore a transformation event.

However, putting a sticker on a case of food to help with internal tracking does not constitute "relabeling." Similarly, adding a pallet license plate or other type of designation on a pallet does not constitute "relabeling." Neither of these activities is a transformation event.

Relabeling often happens in conjunction with other transformation activities, such as repacking. However, even when a food is relabeled without being repacked, it is still a transformation event. For example, as discussed in Response 308 of the preamble to the final rule, changing a brand name on a food's labeling would be a type of relabeling, and would therefore constitute transformation under the rule (see 87 FR 70910 at 70999).

H. Traceability Plan

Question 24: Are entities that manufacture, process, pack, or hold FTL foods required to have a traceability plan if they are exempt from some or all of the rule's requirements?

Response 24: Under § 1.1315(a), entities must establish and maintain a traceability plan if they are "subject to the requirements in this subpart." While we encourage all firms that manufacture, process, pack, or hold FTL foods to establish and maintain a traceability plan as a best practice, firms that are fully exempt from the rule are not "subject to the requirements in this subpart," and are therefore not required to establish and maintain a traceability plan. For example, certain small producers are fully exempt from the rule under § 1.1305(a). Such small producers are not required to have a traceability plan.

Firms that are partially exempt from the rule are still "subject to the requirements in this subpart," because they still have obligations under the rule. Partially exempt firms are therefore required to have a traceability plan. For example, if a farm's only FTL product is produce that is produced and packaged on the farm, with packaging that remains in place until the food reaches the consumer and that maintains the integrity of the product and prevents subsequent contamination or alteration of the product, then all of the farm's FTL food is eligible for the partial exemption in § 1.1305(c). This is only a partial exemption because there are still certain requirements: In addition to having packaging that remains in place as described above, it is also required that the labeling of the food that reaches the consumer include the name, complete address, and business phone number of the farm on which the food was produced and packaged. Because the farm is subject to these requirements, the farm must also have a traceability plan.

Note that some firms might handle a mix of fully exempt FTL foods and FTL foods that are not fully exempt. For example, under § 1.1305(b), the rule does not apply to farms with respect to food produced on the farm that is sold or donated directly to a consumer by the owner, operator, or agent in charge of the farm. If a farm sells some FTL food directly to consumers such that the food is eligible for this exemption but sells other FTL food through the supply chain such that it is not eligible for this exemption (or any other full exemption), then the farm would need to have a traceability plan. In this situation, the traceability plan could be limited to the farm's practices with respect to the FTL foods that are not fully exempt from the requirements of the rule.

I. Recordkeeping

Question 25: If another entity is maintaining required records on my behalf, can this third party also send the records to the next point in the supply chain on my behalf? If FDA requests the records, can this third party send the records to FDA on my behalf?

Response 25: Section 1.1455(b) allows another entity to establish and maintain records required by the rule on your behalf. If another entity is maintaining records on your behalf, they can also send those records to the next point in the supply chain on your behalf. However, as the covered entity you are ultimately responsible for ensuring the records are established, maintained, and sent (as appropriate) according to the requirements in the rule.

If another entity establishes and maintains required records on your behalf, § 1.1455(b) states that you are responsible for ensuring that such records can be retrieved and provided onsite within 24 hours of request for official review. In practice, when an FDA representative requests records, they often engage in a dialogue with the firm about how the records will be provided. If the records are being maintained by a third party, it may make sense for the third party to send the records directly to FDA, rather than providing them onsite at the location of the inspection, if applicable. However, if the FDA representative prefers an onsite review of the records, then the records would need to be retrieved and provided onsite within 24 hours of request for official review, as stated in § 1.1455(b). (Note that under § 1.1455(c)(2), electronic records are considered to be onsite if they are accessible from an onsite location.) If FDA requests that the records be sent in an electronic sortable spreadsheet, as is sometimes required under § 1.1455(c)(3)(ii), then it may make sense for the third party to send the electronic sortable spreadsheet directly to FDA. As mentioned above, the logistics of how to provide records (including an electronic sortable spreadsheet) can be discussed with the FDA representative.

Question 26: Am I responsible if my suppliers provide me with inaccurate or incomplete KDEs, which I rely on for the KDEs that I am required to maintain?

Response 26: We encourage supply chain partners to work together to ensure that all entities are ready to comply with the rule and to provide the necessary information to others within their supply chain. If you suspect that your supplier is not providing the accurate and complete data that you need to meet your Food Traceability Rule requirements, you should discuss this with your supplier.

Under the Food Traceability Rule, each covered entity is responsible for the KDEs that relate to the CTEs they perform. There are circumstances where your required KDEs will overlap with your supplier's required KDEs. For example, under § 1.1340(b), your supplier must provide you with the KDEs identified in § 1.1340(a)(1)-(7). You are required to maintain much of the same information as part of your receiving KDEs, as set forth in § 1.1345(a)(1)-(5) and (7).

Both you and your supplier have an independent responsibility to adhere to the rule's requirements for the CTEs you perform. Your supplier is responsible for maintaining accurate shipping KDEs under § 1.1340(a), and they are responsible for providing you with accurate information under § 1.1340(b). However, you have an independent responsibility to maintain accurate receiving KDEs under § 1.1345(a). If FDA makes a request for your receiving KDEs under § 1.1345(a), we will expect you to provide us with accurate information.

In some situations, FDA might request records from multiple covered entities in one FTL food's supply chain (e.g., from both you and your supplier). In other situations, we might only request records from one covered entity in the food's supply chain. When we find that a firm's data that is required under the Food Traceability Rule is inaccurate or incomplete, we consider the public health impact and any voluntary corrective action by the firm when determining regulatory follow-up. As a practical matter, we routinely allow firms an opportunity to make voluntary corrective actions, which could include working to correct data inaccuracy, including working with the source of inaccurate or incomplete data.

Response 427 in the preamble to the final rule (87 FR 70910 at 71031-32) explains why we did not create a "safe harbor" that would allow a receiving entity to assume that the rule's requirements do not apply when their supplier does not provide them with traceability information. Similarly, there is no "safe harbor" for a firm that receives incomplete or inaccurate records from their supplier. Receivers are responsible for maintaining the records required under § 1.1345. Relieving receivers of that responsibility when suppliers do not provide them with complete and accurate traceability information would encourage an approach that would seriously undermine the ability of the requirements to facilitate swift and effective traceability throughout the supply chain.

Question 27: When one company sells food on the FTL to another company, and they are both located at the same street address, is this a shipping and receiving event?

Response 27: Yes, this would be a shipping and receiving event. In the context of a transfer of food between two different companies, any arrangement to move the food from one location to another location – even in the rare situation where both locations are at the same street address – is a shipping and receiving event. Such events can be described as intercompany shipments.

An example of an intercompany shipment of food between two companies at the same street address could be a sushi bar that is owned by a sushi company, but that is physically located within a full-service grocery store that is owned by a different company. If the sushi bar buys FTL ingredients from the grocery store, the sushi bar would need to keep receiving records (and the grocery store would need to keep shipping records) unless an exemption applies. Note that in

this specific example, it is possible that the partial exemption in §1.1305(k), which relates to ad hoc purchases between RFEs and restaurants, might apply, as could other exemptions.

The requirements for the CTEs of shipping and receiving both include KDEs that relate to the location description from which the food was shipped and the location description where the food was received. In the rare situation of an intercompany shipment between two companies located at the same street address, many elements of the location description (as defined in § 1.1310) will be the same for both entities, including the physical location address. However, we anticipate that the location descriptions will be distinguishable by the business name and the phone number, which are both elements of the location description.

With respect to the movement of food within one street address, the definitions of shipping and receiving in the Food Traceability Rule treat the intracompany movement of food (i.e., within the same company) differently from intercompany shipments. Section 1.1310 defines shipping as "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," and goes on to state, "Shipping includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm." Similarly, receiving is defined as "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," and includes "receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm."

Thus, for the intracompany movement of food, shipping and receiving KDEs only need to be kept when the food is moved from one location at a particular street address of a firm to another location at a different street address of the same firm. Without this language, any movement of the food at all – for example, from one dock at a distribution center to another dock at the same distribution center, which might be a fairly large distance away – could be seen as a shipping and receiving event. To avoid this outcome, the definitions clarify that in the context of intracompany movement of food, the requirements for shipping and receiving are only triggered if the food moves from one street address to another street address.

Question 28: When an airline caterer provides food to an airline, is this a shipping event? Does it matter if the caterer is located at or near the airport complex? Do the records need to identify the location of the airplane receiving the food?

Response 28: As discussed in Response 216 of the preamble to the final rule (see 87 FR 70910 at 70975), most airline caterers prepare meals and other foods for sale to airlines, rather than directly to consumers. As such, the transport of food by an airline caterer to an airline would constitute a shipping event.

As described in Question 27, in the context of a shipment between two different companies, any arrangement to move the food from one location to another location – even in the rare situation where both locations are at the same street address – is a shipping and receiving event. Therefore, when an airline caterer provides food to an airline, this is a shipping and receiving event, even if the caterer is located at or near the airport complex. The caterer would therefore

need to maintain and send the required shipping records under § 1.1340, and the airline would need to maintain the required receiving records under § 1.1345.

As discussed in Question 27, if the airline caterer and the airline are located very close to each other, many elements of the location description (as defined in § 1.1310) might be the same for both entities, possibly including the physical location address. However, we anticipate that the location descriptions will be distinguishable by the business name and the phone number, which are both elements of the location description. The location description for the airline should include the physical location address of the airport where the transaction takes place, but more specific location information, such as the runway to which the food is sent, is not required. However, firms can always choose to maintain additional information that would improve their recordkeeping, even if such information is not required. For example, the flight number to which the food is sent might already be present in both firms' business records, and might be a useful data point to maintain; however, it is not required.

Question 29: How should a firm's records identify the TLC source in a situation where the TLC source is not staffed year-round (e.g., a farm that operates seasonally)?

Response 29: The final rule defines "traceability lot code source" to mean the place where a food was assigned a TLC. Once a TLC has been assigned, the location description for the TLC source is a KDE that has to be maintained at every subsequent point in the supply chain.

"Location description" is defined in § 1.1310 to mean key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country. By linking the TLC to the physical location where the food was handled, the location description for the TLC source plays a critical role in ensuring timely and accurate information for traceback investigations.

While the physical location address (or geographic coordinates) must correspond to where the food was handled, there may be situations where it is appropriate to include a phone number that does not connect to the physical location address. For example, if a farm that is the TLC source is closed for long stretches of time because they only operate seasonally, the location description for the TLC source could include the physical location address of the farm, but a phone number that connects to a different physical location (or that is not associated with any physical location, e.g., a cell phone number). While this phone number does not need to connect to the physical location of the farm, it must be a working phone number that connects to an individual who has familiarity with the farm's procedures for traceability, or who can quickly identify such an individual..

Other required KDEs include the location description for entities other than the TLC source. For example, shipping records are required under § 1.1340(a)(5) to include the location description for the location from which you shipped the food. Any time a location description is required, it is permissible to include a phone number that does not connect to the physical location address if you think a different phone number would promote more efficient and effective traceability. For example, if there are concerns that the physical location that handled the food might not be

staffed at the time of a records request from FDA, or that the person most knowledgeable about the firm's traceability practices will not be at the same physical location from which you shipped the food, it is permissible to include a phone number that does not connect to the physical location address. This phone number must be the working phone number of an appropriate individual, as described above. The location description must still include the physical location address (or geographic coordinates) for the location where the food was handled.

Question 30: I am a food manufacturer that is required to register under section 415 of the FD&C Act. There are several partial exemptions in the rule that state that if the affected entity is required to register with FDA under section 415 of the FD&C Act, such person must maintain records identifying the immediate previous source and the immediate subsequent recipient of the relevant food, in accordance with §§ 1.337 and 1.345. Section 1.337 requires records concerning both the nontransporter immediate previous source and the transporter immediate previous source. Similarly, § 1.345 contains requirements concerning both the nontransporter immediate subsequent recipient and the transporter immediate subsequent recipient. If one of these partial exemptions applies to me, do I need to keep records about transporters (i.e., about the transporter immediate previous source and the transporter immediate subsequent recipient)? Or do I only need to keep records about the nontransporter immediate previous source and the nontransporter immediate subsequent recipient?

Response 30: For the purposes of these partial exemptions, you do not need to keep records about transporters. You only need to keep records about the nontransporter immediate previous source and the nontransporter immediate subsequent recipient.

There are three provisions within the Food Traceability Rule where this issue arises: the partial exemption for commingled RACs (see § 1.1305(h)(3)); the partial exemption for fishing vessels (see § 1.1305(m)(2)); and the provision regarding modified requirements and exemptions (see § 1.1360(b)). All three provisions require, under certain circumstances, that an entity must maintain records identifying the "immediate previous source" of the food and the "immediate subsequent recipient" of the food "in accordance with §§ 1.337 and 1.345."

Sections 1.337 and 1.345 are part of 21 CFR Part 1, Subpart J, which implements section 414(b) of the FD&C Act. FSMA § 204(d) does not directly reference §§ 1.337 and 1.345; however, it directs FDA, in certain situations, to require certain persons "to maintain records that identify the immediate previous source of [a food to which a limitation or exemption applies under certain provisions] and the immediate subsequent recipient of such food." See FSMA § 204(d)(6)(F). FDA therefore adopted the three Food Traceability Rule provisions described above.

The Food Traceability Rule has an exemption for transporters of food (see § 1.1305(n)). As we explained in the preamble to the proposed rule, we find that in most of our investigations of potential foodborne illness outbreaks, it is not necessary to inspect records maintained by food transporters. This is because we generally are able to obtain the tracing information we need from other persons in the food's supply chain (see 85 FR 59984 at 59999). Similarly, the references to the "immediate previous source" of the food and the "immediate subsequent recipient" of the food in §§ 1.1305(h)(3), 1.1305(m)(2), and 1.1360(b) do not encompass the transporter immediate previous source and the transporter immediate subsequent recipient of the

food. These Food Traceability Rule provisions serve their purpose by requiring information regarding the entity that was the source of the food and the entity that subsequently received the food, not information about the transporters. This approach is in keeping with Congress's language in FSMA § 204(d)(6)(F).

What this means in practice is that entities who are subject to these Food Traceability Rule provisions are required to keep the records listed under § 1.337(a)(1)-(5), but not (6). Similarly, such entities are required to keep the records listed under § 1.345(a)(1)-(5), but not (6).

The above discussion relates only to the provisions in the Food Traceability Rule that require records identifying the "immediate previous source" and the "immediate subsequent recipient" of a food "in accordance with §§ 1.337 and 1.345." This discussion is not relevant to entities who are subject to Subpart J. If you are subject to Subpart J, you must comply with all of that subpart, including (as applicable) all of the provisions within §§ 1.337 and 1.345.

For reference, the records listed under § 1.337(a)(1)-(5) are as follows: (1) the name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign; (2) an adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce); (3) the date you received the food; (4) for persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists); and (5) the quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank).

Similarly, the records listed under § 1.345(a)(1)-(5), are as follows: (1) the name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign; (2) an adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce); (3) the date you released the food; (4) for persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists); and (5) the quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank).

J. Food Traceability List

Question 31: The FTL includes "Leafy greens (fresh-cut)," "Fruits (fresh-cut)," and "Vegetables other than leafy greens (fresh-cut)." How do I determine whether my product is "fresh-cut" for the purpose of identifying whether or not it is on the FTL? For example, are tailed parsnips considered fresh-cut vegetables? Are whole heads of lettuce that have had their outer leaves trimmed considered fresh-cut vegetables? Are quartered heads of cabbage considered fresh-cut vegetables?

Response 31: For the purpose of this guidance and for determining whether a product is on the FTL, "fresh-cut produce" means any fresh fruit or vegetable (or combination thereof) that has

been physically altered to no longer be in its whole state (e.g., by chopping, dicing, peeling, ricing, shredding, slicing, spiralizing, or tearing) without additional processing (such as blanching, freezing, cooking, canning, or packing in a juice, syrup, or dressing), with or without a wash or other treatment before being distributed in fresh form (e.g., to a consumer, an RFE, or a manufacturing/processing facility).[5]

Products such as tailed parsnips are still in their whole state. The removal of the root tail does not alter the parsnip to the point of it no longer being in its whole state. Similarly, trimming the outer leaves of a head of lettuce does not alter the head of lettuce to the point of it no longer being in its whole state. Such products are therefore not fresh-cut vegetables. On the other hand, a quartered head of fresh cabbage is no longer in its whole state, and is therefore a fresh-cut vegetable.

As discussed in the preamble to the final rule (87 FR 70910 at 70929), produce that is listed as rarely consumed raw in the Produce Safety Rule (see 21 CFR 112.2(a)(1)) is exempt from the Food Traceability Rule under § 1.1305(e) for the entirety of the supply chain, regardless of whether it is fresh-cut. For example, although all fresh-cut fruits and vegetables are on the FTL, a fresh-cut "rarely consumed raw" vegetable such as fresh diced butternut squash would be exempt under § 1.1305(e) because the fact that the butternut squash is fresh-cut does not change its status as "rarely consumed raw" for the purposes of § 1.1305(e).

[5] In 2018, FDA announced the availability for public comment of a draft guidance titled "Guide to Minimize Food Safety Hazards of Fresh-cut Produce" (83 FR 53197, October 22, 2018). When finalized, that guidance will reflect FDA's current thinking on that topic. The definition of "fresh-cut produce" included in that draft guidance for the purposes of that guidance is similar, but not identical, to the definition of fresh-cut produce included in this document. FDA's intent is that the definition of "fresh-cut produce" be the same in the final version of this guidance and in the final version of the guidance "Guide to Minimize Food Safety Hazards of Fresh-cut Produce." FDA's current thinking is that this definition will be as specified in this document.