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Discussion Paper: Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement

Background

The U.S. Food and Drug Administration (FDA or we) published in the *Federal Register* of November 21, 2022, a final rule titled "Requirements for Additional Traceability Records for Certain Foods" (87 FR 70910) (Food Traceability Rule) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). The Food Traceability Rule establishes 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 rule mandates lot-level tracking for foods on the FTL, requiring entities that perform specific activities to assign unique codes, known as Traceability Lot Codes (TLCs), to each lot of the food. The entity that assigns the TLC is known as the TLC source. Once a food has been assigned a TLC, the records required at each subsequent point in the supply chain must include that TLC, as well as including information about the TLC source. The TLC can only be changed if the food is transformed. The goal of lot-level tracking is to enable rapid tracing of contaminated foods, allowing FDA to find the source of that food faster, narrowing the scope of recalls, and removing affected products from the supply chain quickly.

The Food Traceability Rule establishes first of its kind national standards for supply chain traceability from farm to restaurant/retail. Entities who handle FTL foods must maintain specific key data elements (KDEs), such as the TLC, for each traceability lot of the food that they handle. The required KDEs depend on what critical tracking events (CTEs) – such as initial packing, transformation, receiving, and shipping – are being performed by the entity. The rule also requires covered entities to share specific KDEs with their supply chain partners. Entities along a supply chain must therefore coordinate to share relevant data elements with subsequent entities in the chain, in a compatible and timely manner.

Since issuing the Food Traceability Rule in 2022, FDA has conducted extensive stakeholder outreach and education on the rule, in addition to providing technical assistance, tools, and other resources to assist industry with implementation. As the regulated industry worked to comply with the rule's requirements, entities from across the supply chain voiced concerns with the initial 3-year implementation timeframe, stating that they needed more time to come into compliance. Even those few entities who were well positioned to meet the final rule's

requirements by the original compliance date of January 20, 2026, expressed concern about the timeline, in part because of their reliance on receiving accurate data from their supply chain partners who are not similarly situated.

As a result, FDA has proposed extending the compliance date for all persons subject to the recordkeeping requirements to July 20, 2028. In Section 780 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (the Continuing Appropriations Act), Congress directed FDA not to enforce the Food Traceability Rule prior to that same date of July 20, 2028. FDA intends to comply with this Congressional directive.

Purpose and Scope of this Document

Section 780 of the Continuing Appropriations Act also directed FDA to engage quarterly with regulated entities to identify and implement, as appropriate, additional flexibilities for satisfying the Food Traceability Rule's lot-level tracking requirement. Congress further stated that within 180 days of the Continuing Appropriations Act's enactment, FDA should provide industry stakeholders with recommendations for these additional flexibilities.

In keeping with this Congressional directive, FDA has planned and begun implementing a series of quarterly engagements with industry. The first such engagement was a March 6, 2026, listening session hosted by the Partnership for Food Traceability (PFT), where FDA heard from members of industry about their progress implementing lot-level tracking, challenges facing regulated entities, and potential solutions. The second engagement will be an FDA public meeting, titled "Challenges and Solutions for Lot-Level Traceability," to be held on June 15, 2026. A second FDA public meeting is scheduled for November 6, 2026, with another focused discussion with industry hosted by PFT to take place in September 2026. These quarterly engagements are in addition to our regular engagements with industry through meetings and webinars, and ongoing technical assistance to industry though the Technical Assistance Network (TAN).

We want these engagements with regulated entities and other interested parties to be as productive as possible, so that they can inform our development of any additional flexibilities we ultimately offer for satisfying the Food Traceability Rule's lot-level tracking requirement. At this point in time, with most of the quarterly engagements still ahead of us, we have not made a decision about the scope of flexibilities that would best address the challenges being faced by regulated entities while still protecting public health and maintaining the benefits of the Food Traceability Rule. However, we recognize Congress's desire for FDA to be transparent with stakeholders about this process, and specifically about where things stand approximately 180

days after enactment of the Continuing Appropriations Act. One goal of this discussion paper is to provide this transparency.

We also hope and anticipate that this discussion paper will promote deeper and more productive future engagements with stakeholders, including at the June 15 public meeting. We encourage those making remarks at the June 15 public meeting to consider the questions in this discussion paper as you develop your remarks for that meeting.

We also want to provide all stakeholders with an opportunity to actively engage with FDA on this topic. We therefore invite and encourage all interested parties to submit feedback on this discussion paper to https://www.regulations.gov, Docket No. FDA-2014-N-0053. Feedback does not need to cover every question that is asked in this document; you are encouraged to focus on whichever aspects of this discussion paper are of the most interest to you. To ensure that we can fully consider your feedback as we continue our quarterly engagements and work to expeditiously identify flexibilities to implement, please submit your feedback no later than July 15, 2026.

Please note that this discussion paper does not reflect an exhaustive list of options that FDA would be willing to consider with respect to potential flexibilities for satisfying the Food Traceability Rule's lot-level tracking requirement. This document is meant to capture the areas where we currently have the most questions, or where we think further dialogue would be especially helpful. Please also note that the order in which the topics are listed is not meant to represent a prioritization or a preference for any topic.

Discussion Topics

Reasonable range of traceability lot codes for distributors shipping to retailers

We have heard from many in regulated industry about the challenges with lot-level tracking as an FTL food moves through a distribution center and is shipped to a retail location. Because FTL foods are sometimes received in mixed-lot pallets, and because further mixing of lots can occur as products move in and out of designated product holding areas (pick slots), some distribution centers have stated that they would have to scan every case to accurately track the movement of TLCs through their facilities. There is a concern that this would be logistically challenging and perhaps cost-prohibitive. Some members of regulated industry have therefore proposed that distribution centers that ship to retailers be allowed to maintain and share records that reflect a range of all possible TLCs that could reasonably be associated with a shipping event. Some have suggested that the distribution center's traceability plan would describe how a reasonable range was determined based on inventory management practices. We have several questions for stakeholders on this potential flexibility:

1. How does industry define a "reasonable" range of TLCs? Would it be feasible to have a specified limit (e.g., a single TLC can be replaced by a range of 2 or 3 TLCs, but no more than 3) and, if so, what factors would be considered in establishing the limit? How would such a limit work in practice, given that many shipments contain more than one TLC? If a hard limit is not workable, how else can a "reasonable" range be defined?
2. What guardrails would need to be in place to ensure that this flexibility would not erode the public health benefits of the rule?
3. At most, how many different TLCs are likely to be on one pallet?
4. At most, how many different TLCs are likely to be in a pick slot at any given time?
5. How likely is it that an incoming pallet will contain multiple TLCs from the same TLC source? How likely is it that an incoming pallet will contain multiple TLCs from different TLC sources?
6. For an outgoing shipment, do you envision that the reasonable range of TLCs would be a range from the same TLC source, or do you envision that it might encompass a range from multiple TLC sources? Would it be feasible to limit the range of TLCs to being from the same TLC source?
7. What are the fundamental best practices that distribution centers should incorporate to be confident that the range of TLCs provides accurate information and is not overly broad? If these best practices are in place, how often would you need to record a reasonable range of TLCs (as opposed to being confident about which TLCs were in a given shipment)?
8. Would the distribution center be required to provide a range of TLCs for a given quantity of product (e.g., no more than 10 cases for a given range of TLCs), or would the range apply to all the product (of a specific product description) that is in the entire shipment?
9. How would you communicate a range of TLCs to a retailer? For example, can advance shipping notices (ASNs) transmit a range of TLCs currently?
10. Would any changes or investments to your system to provide a reasonable range of TLCs also be helpful for coming into full compliance with the rule? Would any changes or investments to your system to provide a reasonable range of TLCs set you back on your path to coming into full compliance with the rule?

Inferred traceability lot codes, with flexibility, for distributors shipping to retailers

Many in regulated industry have stated that distribution centers often infer or calculate which TLCs are being shipped to a retailer, rather than confirming at the time of shipment (e.g., by scanning) which TLCs are being shipped. This inference can be made in a variety of ways, such as through a warehouse management system that takes into account when incoming TLCs were received, how they were placed in pick slots, and the order in which employees are trained to

pick (e.g., first-expired, first-out). We have heard that this approach is fairly accurate, but that regulated industry is concerned that if they relied on this approach to comply with the rule, they would invariably have some errors in their data. Some in regulated industry have expressed optimism that over time, with better systems, technology, and training, this approach could become very accurate (comparable to scanning). We are interested in exploring whether it might be possible to support the development of systems that could eventually be highly accurate at inferring lot codes, while simultaneously providing flexibility as firms work toward that goal.

As an example of this approach, if a distribution center inferred that certain TLCs were part of a shipment to a retailer (e.g., 10 boxes of TLC 5, 10 boxes of TLC 6, 10 boxes of TLC 7), they could maintain and send forward these inferred TLCs, and accompany the inferred TLCs with a statement of other TLCs that might also have been included in the shipment (e.g., TLC 4, TLC 8). The distribution center's traceability plan would explain their method for inferring which TLCs were shipped and for identifying other TLCs that might have been in the shipment. This approach could be seen as a variation of the "reasonable range of lot codes" approach, but it would more closely reflect the aspiration of full compliance with the rule, because the inferred TLCs would be presented in a manner that – if accurate – would be in full compliance with the rule.

We have several questions for stakeholders on this potential flexibility:

1. Would the above example (in which a distribution center could state a number of other TLCs that might have been in a shipment, in addition to the TLCs that they infer are in the shipment) be a viable way to provide flexibility to distribution centers that currently infer which TLCs are in a shipment? Are there other ways to provide flexibility for such distribution centers that could ensure similar or better accuracy? Are there some distribution centers for which this flexibility would not be helpful?
2. We anticipate that there may need to be a limit on how many additional TLCs could be stated. What factors should be considered in establishing that limit?
3. How could this flexibility serve as a steppingstone to compliance with the rule as written? It seems like this could happen in one of two ways: 1) by encouraging distribution centers to hone their ability to infer TLCs to the point where they can do so with a high degree of accuracy, or 2) by providing a temporary way to trace TLCs while more precise methods (e.g., RFID) are being developed and adopted. Do either or both of these seem likely?
4. How would you communicate this TLC information to a retailer? For example, can ASNs transmit other TLCs that might have also been included in a shipment (in addition to

transmitting the TLCs that the shipper believes to have been included in the shipment, i.e., the inferred TLCs)?

Eaches

We have heard that there are challenges with maintaining KDEs for FTL food items that are no longer part of a case, known as "eaches". For example, a distribution center may have broken the case to send a few items (less than a case) to one or more customers. Because individual items are unlikely to have a TLC written on them (whereas the TLC might have been written on the label of the case), it is more difficult to maintain a full set of KDEs for the individual items when they are shipped (as well as when they are received). Our current understanding is that this circumstance would only apply to a low volume of food being shipped to any one customer. We have the following questions to help inform our thinking about possible flexibilities for eaches:

1. Is there an industry or generally understood definition of eaches?
2. Are there circumstances where a case may be broken up to create eaches throughout the supply chain, or does this only occur immediately prior to shipment to retail?
3. How common are eaches in different sectors, for example, convenience stores, grocery stores, and restaurants?
4. What additional labeling information could appear on the outside of the container in which the eaches are shipped to ensure adequate traceability as the product moves through the supply chain from distribution to retail? Are there obstacles to providing information in this way?
5. From a distribution center perspective, approximately what percentage of outgoing inventory is shipped as eaches?
6. Are eaches created only when small quantities of a food are needed, or are there other scenarios in which they are created?
7. What are the traceability challenges for eaches? We have heard there are challenges to tracking the TLC and TLC source for eaches; however, is information on other KDEs such as the product description, quantity, and supplier available (via purchase order, for example)?
8. Would either of the two previously described flexibilities ("reasonable range of TLCs" or "inferred TLCs, with flexibility") help address the difficulties associated with eaches? If so, how? If not, why not?

Returns and Reclamations

Regulated industry has identified challenges with maintaining KDEs as required by the rule for individual items that are sent back to the supplier as a return or reclamation. We have the following questions to help inform our thinking regarding possible flexibilities for returns and reclamations:

1. Are returns and reclamations of individual items considered under the industry definition of "eaches"?
2. Are there standard industry definitions for "returns" and "reclamations"?
3. What are the biggest challenges with maintaining KDEs in these circumstances? Which KDEs are most challenging to maintain?
4. Are there flexibilities you would propose that would help address the challenges associated with returns and reclamations?

Food Waste Recovery

The Continuing Appropriations Act directed FDA, among other things, to provide assistance to industry regarding how to handle food waste recovery. Under the Food Traceability Rule, the definition of "shipping" in 21 CFR 1.1310 states that shipping does not include the donation of surplus food. Therefore, retailers or other entities who donate food do not need to maintain any KDEs relating to the donation.

We are seeking clarity from stakeholders on what, if any, challenges exist around food waste recovery that are not covered by the existing exemption for donated food.

Intracompany shipments

We have heard from regulated industry that there are inefficiencies with the requirement to maintain KDEs for intracompany shipments when no transformation is occurring. We have the following questions about these challenges:

1. Do you understand the rule to require duplicate records in the context of intracompany shipments? Note that 21 CFR 1.1455(f) states that you do not need to duplicate existing records you have if they contain the information required by the rule, and that you can supplement any such existing records as necessary to include all of the required information. Also note that under 21 CFR 1.1455(g), you do not need to keep all of the required information in a single set of records. In light of these provisions, are there nonetheless circumstances under which duplicate records would need to be kept for intracompany shipments? If so, please describe those circumstances.

2. Are you tracking TLCs now in your system, and do you think it provides accurate information about how TLCs move between different locations within your company (i.e., for intracompany shipments)? If so, please describe how your system tracks this movement of TLCs.
3. What specific challenges exist that are unique to intracompany shipments? Are there ways in which compliance with the rule is more difficult for intracompany shipments than it is for intercompany shipments? Are there particular types of intracompany shipments that are most challenging?
4. What flexibility would be helpful to address concerns about intracompany shipments? Under your proposed flexibility, would you be able to keep track of which TLCs your company originally received (i.e., from another company)? Would you be able to keep track of which TLCs your company ultimately shipped to another company? Would you be able to track the movement of a specific TLC through different locations within your company (i.e., where the TLC moved in the course of intracompany shipments)? Would TLC and TLC source information be available to FDA at retail (i.e., at the retail food establishment (RFE) or restaurant where the food ultimately goes), regardless of whether or not the retail location is part of your company?

Shipments for retailers transforming food and sending to other retailers

In some restaurants and RFEs, retail kitchens will manufacture FTL foods (e.g., sushi) for sale in their retail location but also send some of the food to other retail locations in the vicinity. For the food that is sold on-site at that location, they would not have to maintain transformation records because they are selling the food directly to consumers, as stated in 21 CFR 1.1350(c). But transformation (and shipping) records would be required for the food that is sent to a nearby RFE or restaurant. We have heard from regulated industry that it is impractical to maintain transformation KDEs for food that is manufactured in retail kitchens, even when some of that food is being sent off-site. We have the following questions regarding flexibilities for this scenario:

1. Are there flexibilities that could alleviate the concerns associated with this scenario? Would those flexibilities raise other concerns, either logistically or in relation to public health protection? Should any flexibilities in this space be limited in some way, e.g., to situations where the majority of the transformed food is sold on-site?
2. Are there other implementation concerns that exist for these entities?
3. What are best practices that could help entities in this situation fully comply with the rule?

Data Standardization

We have heard from regulated industry that it would be helpful to have a data standard for KDE capture designated for food traceability. FSMA does not allow FDA to prescribe specific technologies for the maintenance of records under the Food Traceability Rule. We would appreciate additional information from stakeholders on the following questions:

1. Is there a specific data standard that you think industry should coalesce around?