



The FDA’s Food Traceability Rule Moves Industry Beyond “One-Up, One-Down” Traceability for Certain Foods

Finalized in November 2022, the new rule will enhance the speed and accuracy of tracebacks to prevent lengthy, broad-scope recalls by advancing industry’s adoption of IFT-recommended, events-based traceability best practices.

In 2010, Congress mandated that the FDA move from just reacting to foodborne illness outbreaks to actively preventing them through the Food Safety Modernization Act (FSMA). Enhancing the speed and accuracy of traceability is a key component in achieving this mandate, specified in the recently finalized rule FSMA Section 204. The faster and more accurately the FDA can identify the source of a foodborne illness outbreak, the more quickly a contaminated product can be removed from commerce, and the fewer Americans will suffer the morbidity and mortality associated with exposure to foodborne pathogens.

Through its traceability pilots with industry, IFT identified nine important traceability principles and practices necessary to optimize speed and accuracy of tracebacks and recalls. IFT recommended the FDA advance these traceability best practices through FSMA 204 in IFT’s seminal traceability report published in 2012. The FDA incorporated several of these best principles and practices as foundational elements of the draft rule, and, through revisions, incorporated even more as foundational elements of the final rule. Congress’ limitations to the FDA’s statutory authority around restricting requirements to “high-risk foods” prevented the FDA from implementing the entirety of IFT’s 2012 recommendations.

Novel concepts from IFT’s 2012 traceability report that are foundational in the new rule:

- Enhanced requirements for traceability beyond one-up, one-down requirement for listed foods
- An events-based framework that anchors data capture and sharing requirements to physical flows of product through supply chains summarized in critical tracking event (CTE)/key data element (KDE) matrices to enable efficient sharing in summary form between trading partners
- A requirement to develop and maintain a Traceability Plan for those who hold, handle, or process listed foods

- Clear requirements around which data elements the FDA needs from industry about which foods

IFT's traceability experts have analyzed the rule's articulation of each of these aspects. Below we share brief summaries. We will delve into additional educational content on each of these core concepts over the coming weeks and months.

The Critical Tracking Event (CTEs)/Key Data Element (KDE) Framework for Event-Based Traceability

The final rule adheres even more closely to the best practices for event-based traceability than the draft rule did, anchoring definitions for CTEs to where the event occurred rather than who (either an individual or the entity) owned, oversaw, or operated the facility where the CTE occurred. This provides important clarity. The FDA now expects entities who hold, handle, or process listed foods across multiple locations, such as self-distributed retailers, to capture required data elements at both their distribution centers and their retail locations, even though the product has not been sold and is still under the control of the same entity. Based on IFT's recent experience with the [Leafy Greens Traceability Pilots](#), this represents a change in practice for retailers who will need to adopt new processes to comply with this requirement, specifically around capturing the traceability lot code KDE.

This change and requirement are well justified by both findings in IFT's original 2012 pilots and more recent 2021 pilots as one that will improve both speed and accuracy of tracebacks, ultimately better limiting the scope and duration of recalls and foodborne pathogens' impacts, in line with Congress' original directive to the FDA. However, this change will introduce greater complexity into distributors' and retailers' shipping, receiving, and inventory practices.

Traceability Plan Requirement Supports Successful Implementation Consistent with Original IFT Recommendations and Available Resources

Another change from the draft to final rule is the FDA's new requirement that impacted entities—those who handle, pack, hold, or transport listed foods—create and maintain a traceability plan. This is crucial to the rule's successful implementation and will likely extend its benefits beyond listed foods. A traceability plan is a foundational best practice IFT recommends for all industry actors that will minimize the costly impacts of potential recalls. Traceability plans should be living documents that are created and maintained through regular updates to provide important training and guidance that support staff in adhering to processes necessary to achieve fast, accurate, and now, rule-compliant traceability levels. Traceability plans will vary depending on the foods an entity handles as well as the entity's role in the supply chain, but all will include components such as procedures for establishing, sharing, and maintaining required data elements; a process for assigning or capturing traceability lot codes; identification of points of contact; and a map requirement for certain farms. IFT's [Traceability Course](#) and [Traceability Workbook](#) walk users through how to develop a traceability plan. IFT experts are updating both the course materials and the workbook to ensure compliance with the final rule and encourage impacted entities to use these resources to achieve successful, enhanced, rule-compliant traceability implementation.

Traceability Lot Code – The Most Key KDE

Perhaps the biggest change in industry practices stipulated by the rule is related to the FDA's requirements around when traceability lot codes may be assigned (and when they may *not*) and instead need to be captured and maintained. The FDA emphasized and reiterated its rationale for traceability lot code requirements as being critical to their ability to achieve the speed and accuracy required of them in Congress' original mandate. The traceability lot code, specifically

its maintenance across multiple trading partners, will allow the FDA to “skip steps” in their traceback processes to ascertain the source of contaminated foods and minimize the scope and duration of recalls more quickly.

While IFT concurs that maintenance of a consistent code across the supply chain can support achievement of this objective, we also recognize several challenges to industry actors in implementation. The rule does not specify the format for this data element, nor does it provide sufficient guidance to firms on how to ensure that the traceability lot code they assign is universally unique. The rule also recognizes that firms have many reasons for assigning lot codes, beyond the scope of this rule, and thus does not preclude firms from assigning their own internal lot codes, if they so desire. This could result in products having both a traceability lot code and other lot codes, which could be confusing and potentially undermine the FDA’s accuracy goal as there are no universal formatting requirements for the traceability lot codes that would ensure they could always be recognized and differentiated from other lot codes as product is moved through inventory and/or between supply chain partners. This challenge or complexity introduced by both issues will be most acute for downstream actors like distributors and retailers who, by virtue of their position in the supply chain, will be most likely to encounter challenges related to multiple suppliers using identical traceability lot codes and/or receiving product bearing multiple lot codes, where it is unclear which code is the traceability lot code.

IFT’s experts are developing resources to support industry in their implementation of this important, but challenging, aspect of the rule. To start, IFT recommends following standard methodologies and structures to develop and assign unique identifiers. Principally, global uniqueness is assured with a central registry or through the algorithmic construction of the identifier. GS1 methods for globally unique identification of objects, entities, and locations are a valuable means of achieving global uniqueness in traceability lot codes, especially for large, complex food companies and retailers, due to hardware and software support, identifier persistence, and associated supply chain visibility standards, such as EPCIS and GS1 Digital Link. Alternatively, IFT’s work in developing the [GDST standard](#) for seafood revealed the benefits of alternative, low-cost, or open-access options for usage in upstream CTEs both in registry-based approaches, such as utilizing URLs for company identification, and algorithmic approaches such as Universally Unique Identifiers (UUIDs). The ability to leverage standards by the Internet Engineering Task Force in addition to GS1-enabled upstream supply chain actors and their vendors further unique identification options, who may be more familiar with the usage of web-based Uniform Resource Identifiers to identify objects and locations in a globally unique manner. These alternative approaches are generally accessible to all supply chain partners and have seen usage in many scenarios, regardless of scale, profitability, or supply chain role because they can enable sufficient flexibility to support increasingly common dynamic product portfolios and business models (e.g., meal kits and other businesses with frequent portfolio changes). IFT encourages impacted entities concerned about implementation of this aspect of the rule to leverage one of these standardized approaches to achieve compliance most efficiently and effectively.

Where the Rule Ends

Not food system-wide – just listed foods. While the traceability framework defined by the rule could be used to establish end-to-end traceability throughout the food system, the scope of the rule is limited to listed foods and, in some cases, further restricted by exemptions. Listed foods were identified through a peer-reviewed, risk-ranking process that applies only to foods with a significant recent history of severe foodborne illness outbreaks, including certain cheeses, produce items, nut butters, shell eggs, and seafood as detailed on the FDA’s [Food Traceability List](#) (FTL). This risk-ranking model further identifies the “form” of the food in question—fresh

tomatoes make the list, for example, while frozen tomatoes are excluded due to their lack of historic foodborne illness outbreaks.

Record-keeping requirements are highly variable. Because the list includes both raw agricultural commodities and transformed foods, such as cheeses and nut butters created from unlisted foods, and foods that are destined to be processed such that they are no longer on the FTL, the scope of where the rule stipulates its enhanced traceability requirements must start and may end differs from food to food on the list. Some listed foods often retailed in their raw form, such as tropical fruits, cucumbers, fresh herbs, or peppers, may require enhanced traceability that is more consistent with an “end-to-end” packer-to-retailer or food-service type of traceability. However, record-keeping requirements end after receiving events for foods that result in a “change in form” (e.g. from fresh tomatoes to frozen tomatoes) that differs from the form specified by the FTL. Although record-keeping requirements may not be required, IFT recommends maintaining records through the transformation events for foods resulting in a “change in form.” For listed foods like certain nut butters and cheeses that are manufactured from unlisted ingredients, traceability requirements do not begin until the transformation event. Further, the rule provides several conditions that end enhanced traceability requirements before the retail or food service “end” of the supply chain for listed foods. Application of a kill step, either by an entity or by their downstream trading partner, is one of the biggest exemptions that can truncate requirements for enhanced traceability or obviate them completely for manufacturers and even their upstream suppliers if agreements are put in place around kill-step application. Finally, harvesting listed foods directly into their retail-facing packaging labeled with the name, address, and contact information of the farm that the food was produced on, also obviates requirements for downstream actors to capture and maintain such information.

The suite of full and partial exemptions reflects the complexity of the food system. While some exemptions, like those associated with a kill step, are grounded in risk management, others, like entity-size based exemptions demonstrate a desire to reduce undue burden for supply chain actors. Industry actors can evaluate their exemption status through a workflow on the [FDA website](#). IFT will be publishing additional resources on the full and partial exemptions included in the new rule and their applicability to various points in the supply chain.

To support better understanding and implementation of the rule, experts from IFT’s Global Food Traceability Center will be posting food-specific guidance materials, including clear, concise CTE/KDE matrices, on our website in the coming weeks. Stay tuned!