



# Comment on Proposed Food Traceability Rule

RE: Docket Number Docket No. FDA-2014-N-0053 and/or Regulatory Information Number (RIN) 0910-AI44

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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

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Re: Docket Number Docket No. FDA-2014-N-0053 (Requirements for Additional Traceability Records for Certain Foods) and/or Regulatory Information Number (RIN) 0910-AI44

## The Institute of Food Technologists (IFT) and the Global Food Traceability Center (GFTC)

IFT is a non-profit, scientific organization. It consists of thousands of members, who along with dedicated IFT staff, are committed to creating and upholding a scientifically sound society focused on overcoming barriers to feed our future safely. IFT's Global Food Traceability Center (GFTC) provides the global food system stakeholders resources, standards, and vision to help improve food safety, diminish risk, avert devastating health consequences and economic loss through enhanced food supply chain traceability. Together, the Institute and its Center work to realize their vision of a world where science and innovation contribute to a safe, nutritious, and sustainable food supply for everyone.

IFT has completed several task orders for the FDA (Food and Drug Administration) and served a core advisory role in the development of the Food Safety Modernization Act (FSMA), convening and conducting pilots, and developing a comprehensive report of recommendations<sup>1</sup>. In 2013, IFT formed the GFTC to support the next anticipated FSMA implementation phase. The GFTC continues to advance the science and practice of traceability, publishing category-specific guidance for achieving end-to-end traceability in 2014<sup>2</sup> and co-leading the Global Dialogue in Seafood Traceability (GDST), a pre-competitive convening to advance a unified framework for seafood traceability. GDST convened hundreds of global stakeholders (NGOs, tech vendors, fishers, processors, retailers, and others) across global supply chains, identified accessible methodologies to meet the needs of upstream actors, developed actionable Critical Tracking Event (CTE)- Key Data Element (KDE) matrices for wild caught and farmed seafood, engaged a dozen supply chains in pilots, and published a comprehensive global standard for seafood traceability in 2020<sup>3</sup>. This work informs GFTC's knowledge base on advances in identifier technology, stakeholder needs at the beginning of supply chains, and the challenges in globally

<sup>1</sup> McEntire and Bhatt. 2012. Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report. Available from: [https://www.ift.org/-/media/gftc/pdfs/ift\\_fda\\_producttracingpilotsfinalreport.pdf?la=en&hash=0C3519FD083651860AF89835E1A517AC413C6AF0](https://www.ift.org/-/media/gftc/pdfs/ift_fda_producttracingpilotsfinalreport.pdf?la=en&hash=0C3519FD083651860AF89835E1A517AC413C6AF0).

<sup>2</sup> Zhang and Bhatt. 2014. A Guidance Document on Best Practices in Food Traceability. *Comprehensive Reviews in Food Science and Food Safety*. Available from: <https://onlinelibrary.wiley.com/doi/full/10.1111/1541-4337.12103>.

<sup>3</sup> GDST Standard 1.0 and Materials. Available from: <https://traceability-dialogue.org/gdst-1-0-materials/>



integrated food supply systems. GFTC has continued to support the dozens of GDST signatories in their commitment and beta launch of the standard in their supply chains, as well as engaged in ongoing work with upstream stakeholders to quantify accessibility of the standard and remaining challenges in traceability participation for first-mile actors.

As a trusted developer of targeted and pragmatic educational content for both government and industry professionals, IFT looks forward to partnering with stakeholders impacted by the FTL to realize the vision of accurate, rapid end-to-end traceability. Much of IFT-GFTC's work with GDST stakeholders has been tool development to enable or ease implementation. Part of this effort is testing tools' efficacy to ease the burden of traceability, particularly for less digitized and smaller-scale supply chain actors. Experienced in a variety of modalities from publications for self-paced learning and inquiry to interactive instruction delivered via live or virtual platforms; IFT is well-poised to support advancement of traceability and food safety knowledge and culture.

## Summary

IFT commends the FDA on publishing the proposed rule and the steps the rule takes to enhance record keeping and traceability for foods that have caused food borne illness outbreaks and recalls. Outbreaks and recall costs to public health, producers, mid-supply chain actors, and others are substantial wide ranging, well documented, and clearly justify the regulatory action proposed in the rule to drive broader adoption of better practices and processes. The best practices to identify the source and scope of contamination and hazard most rapidly were developed and documented<sup>1,4</sup> through an extensive process of stakeholder engagement and piloting led by IFT between 2008 and 2012. Detailed in IFT's report of product tracing pilots released over 8 years ago<sup>1</sup>, best practices for food tracing have been well-defined for nearly a decade. While there has been some voluntary uptake of these practices in the intervening years, outbreaks of food borne illnesses continue to occur with a frequency that is undermining consumer confidence in important foods for health and nutrition, including several types of produce, nut butters, and seafood. Safety of these foods is doubly important from a public health perspective. First, for preventing outbreaks of acute illness and all the related costs to people and businesses. Second, for preventing underconsumption of these important foods driven by concerns on safety, which has been tied to development of chronic diseases. Therefore, we are fully supportive of FDA's stated objectives for this rule to reduce the time and scope of recalls through requirement of a first receiver to end of supply chain lot-level traceability record within 24-hours (Proposed § 1.1455(b)(1)).

IFT notes the proposed rule does not incorporate all of our original traceability recommendations or deviates from current traceability science and industry best practices<sup>5</sup>. IFT recognizes that these deviations are, for the most part, driven by limitations in the FDA's regulatory authority regarding traceability. The most notable of these deviations occur at the ends of the supply chain, where the critical tracking events and key data elements most relevant to public health exist. This treatment and related creation of a new role ("first receiver") and non-standard critical tracking event (CTE, "creation")

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<sup>4</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/1750-3841.12298>

<sup>5</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/1750-3841.12278>



introduces new challenges for impacted businesses, both those who are early adopters of traceability in their supply chains, and those new to traceability. These new, non-standard roles create confusion and will result in businesses that adopt traceability more broadly than required by the food traceability list (FTL) to have one CTE-KDE matrix for food traceability list (FTL) foods and another, simpler one for non-FTL foods. This regulatorily-driven complexity also creates confusion or at least complication around supply chain role. Under the standard conceptualization of supply chain traceability each actor has a responsibility to capture, maintain, and transmit key data elements (KDEs; Figure 1). The genesis of supply chain data rests with the producer/farmer/harvester, regardless of their treatment by the rule and the rule’s emphasis on the first receiver as the party responsible for recording and retaining records that are ultimately generated by their upstream supply chain partners (Figure 1). Thus, this rule will require downstream actors to obtain information from upstream actors exempted from record generation and transmission responsibilities under the rule. This shift in responsibility for record capture and retention downstream also creates the possibility that downstream actors may have multiple traceability roles – first receiver and transformer, etc. These complexities may generate confusion among impacted stakeholders and will require close attention throughout implementation to ensure all actors understand and successfully execute their role(s).

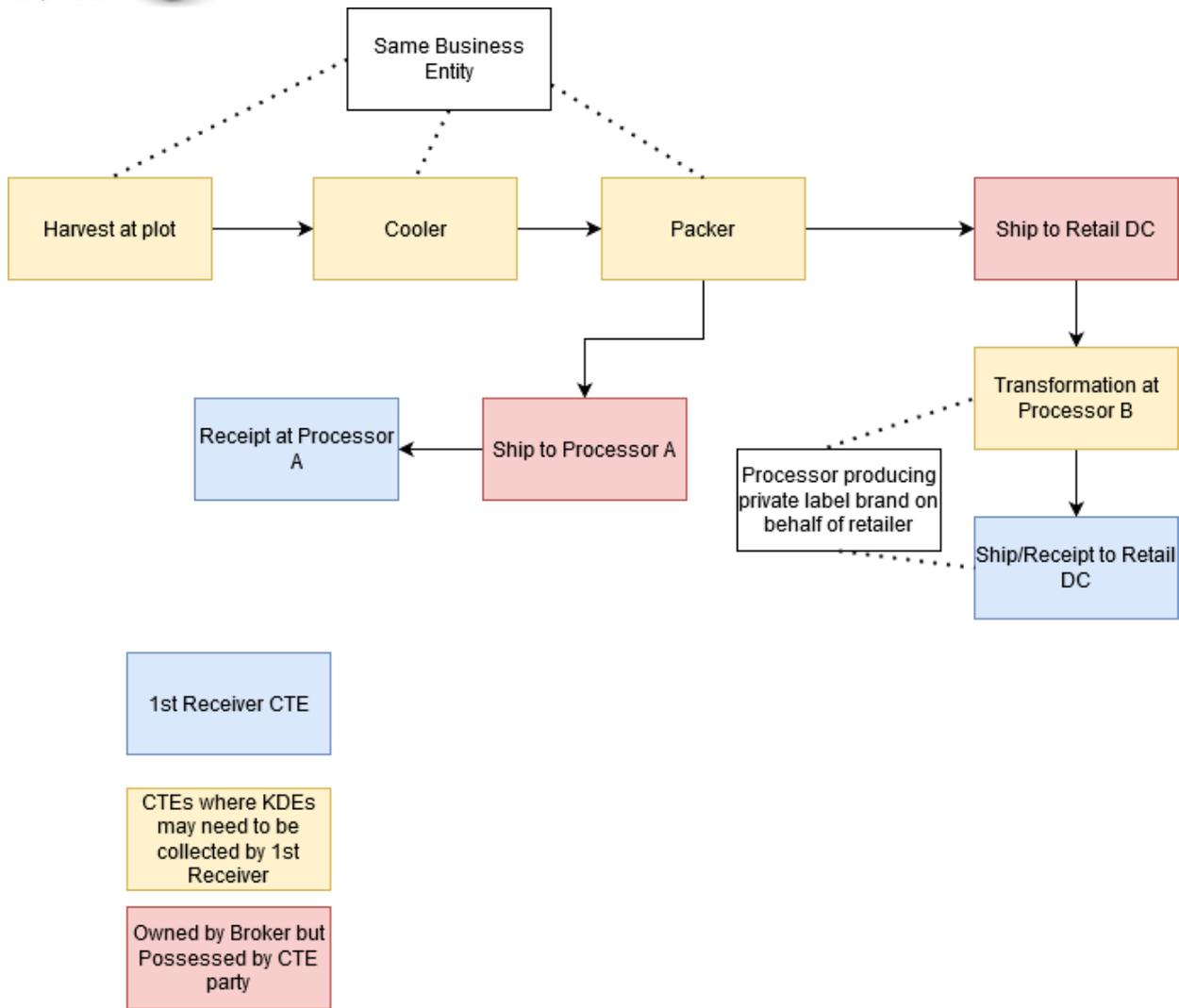


Figure 1. Illustration of a produce supply chain and undue complexity introduced by the first receiver concept. A shift to focusing on critical activities rather than ownership and/or business entities would make the proposed rule more consistent with traceability best practices.

IFT, with its Global Food Traceability Center, has a long history of active engagement in food safety and traceability in partnership with the FDA, non-profits and the private sector including undertaking task orders, conducting primary research, leading pre-competitive industry platforms, creating implementation tools, and delivering educational programming. IFT looks forward to participating in this exciting new journey and stands ready to partner with the FDA and private enterprise in implementing the Food Traceability Rule.

**Key Takeaways:**

1. **Globally unique identification** is key to effective end-to-end traceability systems, allowing effective linking of records across multiple supply chain nodes. FDA has alluded to the importance of unique identification but may be insufficiently clear in ensuring global uniqueness. For instance, FDA describes location identifiers in § 1.1310 as “a unique identification code that an entity assigns to the physical location name identified in the corresponding location description.” IFT has found that methodology



and structure of unique identifiers present opportunities for easing industry implementation and embedding pertinent information. 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 continue to be valuable, 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. IFT’s work in developing the GDST standard for seafood revealed 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 globally uniquely. 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 found that especially among upstream supply chain actors, no/low-cost identifiers were essential to enabling interoperability with downstream systems. **IFT advocates that FDA describe methods for ensuring global uniqueness in identifiers as to support flexible, accessible traceability systems that meet the needs of impacted industries and objectives of the proposed rule.**

2. Successful implementation requires **further definition of CTE-KDE matrices to support necessary new levels of data sharing among supply chain partners**. This remaining need for category-specific (e.g., field-grown leafy greens, seafood) global standardization is critical to meet industry needs for interoperability in supply chains of listed foods and meet the requirements of the proposed rule.<sup>6</sup> IFT advocates for **category-specific convenings and technical working processes** to develop and implement these category-specific global data standards to support interoperability.

3. Introducing the **traceability lot code concept is necessary and appropriate. But IFT recommends modifying the definition name to something like “traceability code.” This will denote the code’s special recordkeeping significance and reduce confusion with “lot code,” a term with varied current business usage**<sup>7</sup>. Lot code allocation is essential for food traceability due to existing food supply chain practices. While there is a need for other logistical unit specific identifiers allocated for general business purposes, defining traceability codes specific to origination, creation, and transformation CTEs will improve public health response by enhancing recordkeeping and tracking of them. However, some of the approaches to FDA’s definitions could introduce confusion with existing industry parlance and vernacular. Specifically, the FDA has put forward a definition for lot and traceability lot, but the former’s definition is not essential for the purposes of the proposed rule. Businesses may use a variety of logistical unit specific identifiers with different definitions and contexts (e.g., pick code, license plate number, etc.), but may now be defined as “lot” depending on interpretation. **IFT advocates for only**

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<sup>6</sup> Note: FSMA section 204 pertains to enhanced recordkeeping for “high risk” foods. FDA has chosen to modify this language to foods pertaining to the Food Traceability List, or “listed foods”. We will use the latter language to describe foods pertaining to the proposed rule.

<sup>7</sup> Note: “Traceability Lot Code” will continue to be used throughout the document to reflect the current language in the proposed rule.



introducing the traceability lot code definition, changing the concept to a simple but unambiguous term (i.e., “traceability code”), and removing the definition of “lot” to reduce potential confusion with other business practices.

4. **Creating a CTE-KDE matrix for regulatory driven traceability that diverges from existing business traceability matrices could lead to fragmented approaches to food traceability.** Food Traceability is used for multiple use cases, not just regulatory compliance. The proposed rule creates a KDE-CTE framework that differs from the framework already used by many businesses who have already embraced end-to-end traceability. In particular, the introduction of regulatorily driven CTEs that differ from the business designated CTE for the same event results in 2 matrices/traceability systems for a single supply chain. This presents hurdles to businesses to maintain two systems and is not ideal. Furthermore, FDA’s “first receiver” definition tries to unify expectations for recordkeeping regardless of food category. However, this is not practicable and implementable for upstream actors as it can make event-based tracking inconsistent. The interplay between producers, brokers, product marketing organizations, and processors, vary significantly when comparing fresh produce to seafood products, for instance. Best practices for data collection are consistently organized around critical tracking events at each stage of the supply chain from harvest/origination through consumption. **IFT advocates for consistency with an events-based approach, particularly for upstream events and avoiding this “first receiver” solution in the final rule.**

5. The proposed rule directs impacted entities to **“Establish and Maintain” records, a concept which requires additional clarification prior to implementation.** While other rules promulgated in Title 21 of the Code of Federal Register (CFR) use this phrase, its usage is more conventional and straightforward for records which change on a periodic basis rather than a near continuous basis as the records required in this rule. Supporting documentation, including the Frequently Asked Questions, have clarified this, but addressing it directly within the rule would solidify expectations for dynamic recordkeeping requirements. **IFT advocates updating this directive to define “establish and maintain” in this rule’s context and explicitly address and acknowledge the evolving realities of digital record keeping.**



## Technical Elements – Review and Recommendations

The Proposed Rule includes some but not all IFT’s 2012 recommendations.

From 2008 to 2014, IFT, in collaboration with stakeholders in the US food system (including but not limited to FDA, state government, industry, consumer groups, and academia), conducted extensive work in support of the development and implementation of the Food Safety Modernization Act (FSMA). In Section 204(a) of FSMA, the US Congress asked FDA to perform traceability pilots to assess the technical landscape in the US food industry. FDA chose IFT to spearhead, coordinate, execute, and write up the conclusions and recommendations from the pilot activities. The set of recommendations described how regulation could best meet the objectives of improving both the accuracy and speed with which food businesses and their supply chain partners could execute recalls and remove hazardous foods from commerce to protect society from adverse human and economic outcomes associated with contaminated foods. While technology, food science, and business practices have evolved in the intervening years, IFT believes the original recommendations still ring true today. Therefore, IFT has reviewed the current proposed rule for its alignment with McEntire and Bhatt’s (2012) recommendations<sup>8</sup>. IFT realizes FDA faced statutory restrictions on its authority to require traceability (e.g., only high-risk foods), which limited its ability to implement some recommendations from the 2012 pilot report in the proposed rule.

Original recommendation (McEntire and Bhatt, 2012 <sup>3</sup> )	REASON FOR REC.	INCLUDED (Y/N)	COMMENTARY
<i>Establish uniform record keeping requirements</i>	<i>Accuracy and Speed</i>	<i>N</i>	<i>The proposed rule is restricted to listed foods, which creates one standard of record keeping to those foods and leaving remaining foods in ambiguity. While we commend FDA for recommending adopting end-to-end digital traceability systems for all foods, we recognize they are statutorily restricted from requiring traceability for foods beyond those with a demonstrated history of causing food borne illnesses. Pilot participants UNANIMOUSLY supported “trac[ing] all food product categories in the supply chain, regardless of the risk they are perceived to have...” IFT has recommended and has found in subsequent traceability initiatives that defined data fields and code lists of KDEs further enhances the accuracy and speed of collection and transmission.</i>
<i>Maintain CTEs and KDEs</i>	<i>Accuracy</i>	<i>Y</i>	<i>We commend the FDA on the dedication to the CTE/KDE framework. We recognize the effort to curtail the burden of record keeping by focusing on first receivers but believe this adds complexity to application of the CTE/KDE framework, which could be avoided by starting at harvest.</i>

<sup>8</sup> [https://www.ift.org/-/media/gftc/pdfs/ift\\_fda\\_producttracingpilotsfinalreport.pdf?la=en&hash=0C3519FD083651860AF89835E1A517AC413C6AF0](https://www.ift.org/-/media/gftc/pdfs/ift_fda_producttracingpilotsfinalreport.pdf?la=en&hash=0C3519FD083651860AF89835E1A517AC413C6AF0)



<i>Require industry traceback response plans</i>	Accuracy and Speed	N	<i>This is more of a recommendation for implementation support, but this remains critical to successful implementation of the proposed rule.</i>
<i>Support industry-led initiatives</i>	Speed	N	<i>IFT commends the FDA's ongoing work with the leafy greens industry and encourages similar work with the seafood, shell egg, and dairy/cheese industries.</i>
<i>Communicate needed information</i>	Accuracy	Y	<i>Section PROPOSED § 1.1335 clearly outlines required records</i>
<i>Develop standardized electronic reporting templates</i>	Accuracy and Speed	Intended (expected)	<i>Provision of spreadsheet templates is critical for conceptualizing the rule's requirements and would enhance clarity of the proposed rule's requirements. From the public meetings, this template is expected, but release of the templates prior to rule finalization to allow an opportunity for industry to comment on their utility would be appreciated.</i>
<i>Accept CTEs and KDEs in summary form</i>	Speed	Y	<i>This is consistent with the sortable spreadsheet requirement. Additionally, the 24-hour requirement for producing the sortable spreadsheet is consistent with the findings of the pilot project in 2012, further emphasizing the appropriateness of that timeline.</i>
<i>Request more than one up one back</i>	Speed	Y	<i>While the proposed rule stops short of the recommendations for end-to-end traceability, it does move the needle forward from one-up-one-back traceability</i>
<i>Use technology to share and analyze data</i>	Accuracy and Speed	N	<i>While being overly prescriptive in the proposed rule could be an impediment to evolution and eventual efficiency with which the rule is implemented, providing additional guidance on options for appropriate digital solutions could ease the burden of compliance and assure successful implementation.</i>
<i>Coordinate with state and local counterparts use industry subject matter experts as appropriate</i>	Accuracy and Speed	Y	<i>FDA has continued to support this recommendation through the CORE Network. Ensuring appropriate subject matter experts are identified for each food and engaging them in developing and disseminating implementation guidance will be critical to the proposed rule's success.</i>

The FDA's greatest deviation from the recommendation lies in the limitation of the scope of the proposed rule and trepidation in offering standardized reporting templates. Of these deviations, we believe it is more critical to address the lack of electronic reporting templates. There have been significant advances in broadband access and IoT devices since 2012 or even 2014, easing the burden of data capture and transmission, even on farms in rural areas. Acknowledging this reality and incorporating it into guidance on the practical implementation of traceability, will not only ease the burden of implementation, but also make it more likely that the ultimate objectives of the proposed rule are achieved.

*We recommend the FDA develop additional guidance that acknowledges our current digital reality, particularly with how it pertains to guidance on what it means to "establish and maintain records."*



## We support the methodology used to construct the Food Traceability List

Comprised of 23 categories of foods, the process for developing the food traceability list as well as its composition are consistent with the requirements of FSMA section 204(d)(2)(A). The team led by Dr. Chen engaged in exhaustive, transparent, and rigorous process to develop the list, which included extensive historical data collection (all outbreaks 1999 through 2019), model development and testing, followed by multiple rounds of peer review<sup>9,10</sup>. In addition to considering the frequency and severity of historical foodborne disease outbreaks, the team also considered food characteristics (e.g., pH) and manufacturing processes (contamination risks and kill steps) that could also influence the likelihood of an outbreak, its impact on public health, and its costs. We commend the FDA on this process and believe the resulting semi-quantitative risk-ranking model and tool are consistent with the requirements set forth in FSMA section 204(d)(2)(A), yet also limit the scope of the list significantly from the nearly 50 categories considered. This narrower, targeted list, where a risk score can be calculated and considered for each food-hazard pair constitutes a robust, scientifically grounded, and understandable framework for the public<sup>11</sup>.

The FTL does not completely address hazards related to chemical contamination, of particular concern in seafood as identified by the risk ranking model. Specifically, the kill step exemption makes sense for microbial pathogen mitigation however, some categories of foods on the FTL list, such as seafood have been subject to contamination with certain toxins and/or heavy metals. Rather than mitigate contamination concerns, a kill step could further concentrate these hazards or create a false sense of security for downstream actors in the supply chain.

Reliance on historical outbreak data as required by statute for inclusion/exclusion from the list resulted in some seemingly arbitrary designations. One such example is the inclusion of peanut and tree nut butters, but exclusion of soy and seed butters. We believe the high-profile outbreaks related to peanut butter were related to negligence and gross violation of basic GMPs. This is reflected in the results of the risk ranking model results for nut butters, which puts the contamination risk score low at 10, but the frequency of consumption, number of outbreaks and the severity of resulting outbreaks were all scored much higher at 90. We believe exclusion of seed butters may be an oversight that ignores emerging trends in consumption driven by the more than 3 million Americans who are allergic to peanuts<sup>12</sup>. These consumers, particularly children, as reflected by the shift in the school lunch program, are shifting from peanut butter to soy or sunflower seed butter, which may justify its inclusion on the list given similar industry risk and consumption. We do not see sufficient differences between the supply chains and material handling and processing for peanut, tree nut, and seed butters to support exclusion of seed butters. Additionally, an outbreak related to soy-nut butter and insufficient traceability to related products in 2017 is cited within the “Need for the regulation” section further underscores the value of including all seed and nut butters on the FTL.

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<sup>9</sup> Chen et al. 2020. Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223). Available from: <https://www.fda.gov/media/142247/download>

<sup>10</sup> <https://www.fda.gov/media/142247/download>

<sup>11</sup> <https://www.cfsanappsexternal.fda.gov/scripts/FDARiskRankingModelforFoodTracing/>

<sup>12</sup> [https://www.ars.usda.gov/ARSUserFiles/80400525/Articles/ADA10\\_SunflowerAlmondButter.pdf](https://www.ars.usda.gov/ARSUserFiles/80400525/Articles/ADA10_SunflowerAlmondButter.pdf)



*Overall, IFT supports the structure and contents of the FTL, but believes there are some artifacts of the methodology used to build it that should be re-evaluated prior to adding any more items to the list.*

### Benefits and Drawbacks of the Risk-Ranking Model relative to a Root Cause Approach

The risk-ranking model approach to designation of the foods as “high-risk” has benefits and drawbacks. Largely driven by the directive set forth in FSMA, this model is a primarily retrospective, data-driven approach to risk identification and regulatory prevention. While the 7 criteria considered in the approach do include an “industry intervention” criterion that is a semi-quantitative scoring matrix of the probability of contamination during the manufacturing process, and the strength of steps taken to prevent or mitigate contamination by the industry. While each commodity was given a score for this criterion, the scores themselves derive from interviews with “three external expert panels.” This process is subjective and the result or score could be subject to change through time as industry modifies their manufacturing processes to better manage risk. This is also still a score of outcomes, rather than root cause. Drawing upon the 2009 Salmonella outbreak associated with peanut butter, its magnitude in economic and public health damages were contingent on its previous status as a “low-risk” food and its incorporation in a diverse number of products (sometimes referred to as a “stealth” ingredient). It is conceivable that this phenomenon will occur in other previously deemed low-risk foods, especially those without kill steps.

Shifting from risk-ranking to root cause, or at least adding a root cause lens to the process used to list and/or de-list foods also calls into question the breadth of categories on the list. Some categories seem arbitrarily narrow, while others may be excessively broad. The distinction between peanut/tree nut butters and soy/seed butters is an example of a case where the category definition seems arbitrarily narrow and the similarity between supply chains, manufacturing procedures, and product suitability to microbial contamination/growth would support lumping of those two groups. Conversely, more narrowly defining the deli salad category to one that was explicitly deli salads formulated without antimicrobials/ Listeria inhibitors is an example of a case where a category of listed foods may be excessively broad.

*We recommend further identifying the root cause of outbreaks for listed foods to better delineate listing categories and enable industry to avoid future outbreaks, rather than just limit their scope via enhanced traceability and shortened response times.*

### Digital Template for Submissions is needed

For ease of compliance with this rule, it is critical that the FDA release spreadsheet templates modeling acceptable data submissions. It would be most helpful for these templates to include examples of supply chains of different lengths and levels of complexity. IFT has found that KDEs and CTEs, when structured together, can be represented by matrices, and displayed through spreadsheets. However, traceability data is not usually 2-dimensional, but rather multidimensional, meaning that spreadsheets can “flatten” and confuse the supply chain webs being examined. Because of the ubiquity of Comma Separated Value (CSV) files in many enterprise software platforms, among other reasons, spreadsheets have widespread utilization in industry and regulatory bodies. This ubiquity makes spreadsheets a natural electronic mechanism for requesting data from stakeholders and for collection efforts by both federal and state



officials. IFT understands FDA’s desire to utilize spreadsheet templates for collection of traceability data by investigators but foresees that an official template issued by FDA will influence software and business process design. For instance, the design of the spreadsheet template may influence ERP and traceability solution system design or the approach that companies take to sourcing and procurement practices.

Seeing examples for each food category on the list would also be valuable to industry, as the supply chain realities for cantaloupes would be quite different than deli salads or finfish. We would like to see the FDA’s examples of data in a template that clearly demonstrates how traceability lot codes are preserved alongside other adjacent business-relevant coding that may still be required for the effective operation of certain supply chains. Third-party logistics companies’ role in the capture and conveyance of this data is another where we believe templates and examples will be quite valuable to stakeholders.

The recently completed Leafy Greens Pilot further demonstrated the critical importance of template review and stakeholder education to maximize efficacy. In the pilots, guidance for filling out the template was provided in a separate user guide. This was ineffective for instructing stakeholders, particularly those who were not the original contacts and thus only received the template and not the user guide. The learning from the pilot was to integrate use instructions, including easy to follow visuals, into the template to make user guidance easier to follow. Additional modifications to make the templates more user friendly and less cumbersome, include re-arranging the data fields and narrowing the fields to just those relevant to each stage in the supply chain (e.g., have a different version for retailers vs. distributors vs. packers). Finally, these pilots also revealed the importance of certain data not included in the templates, such as purchase/sales dates and inventory data for narrowing the scope of the recall and ultimately identifying the source of impacted lots. Integrating these learnings or executing similar exercises with the templates for listed foods may further substantiate these findings and refine the structure and format of templates to be most effective for achieving FDA’s stated objective for this proposed rule, which is shortening the time required to identify the source of contaminated foods.

*IFT recommends FDA release the digital spreadsheet templates for review and comment.*

### **Some definitions require additional clarification or revision.**

#### **The definition of “farm” needs revision to enable implementation.**

The current definition of farm is unclear and excessively focused on ownership as opposed to activity. We believe the proposed rule would benefit from shifting to focusing on the activities critical to traceability of listed foods: growing, harvesting, and packing. Consistent with ongoing recommendations from other produce industry associations, we urge the FDA to align the definition of “farm” with the official title of the Produce Safety Rule and the corresponding section of FSMA. This clarifies that “farm” is the set of activities that includes the growing, harvesting, packing, and holding of produce, regardless of ownership structure.

*We recommend that FDA have a united and consistent farm definition location for definition of farm to reduce confusion.*



### The definition of kill step is insufficient and requires additional clarity.

The definition for ‘Kill Step’ is insufficient for practicable application of the rule and departs from the definitions and expectations stemming from other FSMA-derived regulations. The FTR defines kill step as “... processing that significantly minimizes pathogens in a food.” and lists examples including “cooking, pasteurization, heat treatment, high-pressure processing, and irradiation.” As is discussed later in these comments, kill steps represent the transition of product from a product necessary to have required enhanced recordkeeping to one where it is not required, essentially “high” risk to “low” risk. “Kill Steps” from the perspective of FDA regulations are understood to be preventative controls (§ 507.34) under “Hazard Analysis and Risk-Based Preventative Controls” (HARPC). Preventative controls include “process controls” ((c)(1)), which comprise of the control of parameters that may constitute “kill step” methods. Included within these regulations are verification and validation of process controls which mark a scientifically justified log reduction in microbial load (§ 507.3).<sup>13</sup>

*IFT recommends that the FTR explicitly reference the HARPC regulation which serves as a component in a facilities’ food safety plan, so that persons subject to the rule know how the recordkeeping requirements pertaining to preventive controls relate to other regulations.*

### Traceability Lot Code concept requires education and training to implement.

Lot codes are one of the most key data elements, if not the most important data element in recalls and traceback investigations. Proper lot code stewardship through the supply chain can effectively shorten investigations in food emergencies, limiting the negative impacts to public health and commerce that motivate implementation of this rule. Therefore, we commend FDA for their focus on this code and concept in the proposed rule.

Unfortunately, proper lot code stewardship through the supply chain, which includes limiting or restricting the CTEs where new lot codes may be assigned, is a departure from current business practices that will require targeted education and training to achieve. While we agree that new traceability lot codes should only be assigned at origination, creation, or transformation; it is currently a common business practice for mid-supply chain actors like logistics providers and distributors or other actors managing product in warehouses to assign new master codes (which they call “lot codes”) to pallets or shipments that are not originated, transformed, or created by those actors. While those codes may or may not hold the original TLC, downstream recipients of these shipments commonly lack visibility to the original TLC. Remedying this situation by mandating preservation and/or access to the original code is important and valuable from a traceability perspective for public health use. However, there exist other business-relevant reasons why mid-stream actors may assign new lot codes to aid in their product management, which may include guiding the physical movement of product through facilities or to end customers. Thus, we suggest preserving this concept, but adjusting terminology to focus on the traceability aspect of this code and removing reference to lot to reduce the likelihood that the concept of the TLC is misinterpreted. Finally, based on our recent experience with the Leafy Greens Pilot, we urge the FDA to consider issuing additional guidance to link the traceability code with ultimate point of consumption data, like shopper cards or credit card information. We found being able to link lot

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<sup>13</sup> <https://www.k-state.edu/research/industry/company/petfood/events/docs/2017/Kantha.pdf>



with customer information to be very useful in limiting the scope of recalls, believe it is feasible given current common practices, and would further protect public health by hastening and improving the efficacy of impacted party notification.

*IFT is supportive of the special definition of TLC but recognizes there will need to be significant industry support to change production and inventory management practices to meet it. IFT cautions that FDA's word choice, specifically the use of "lot", could result in misinterpretation of the proposed rule.*

**FDA's designation of government mandated CTEs (Creation) that diverge from standard traceability science and current implementation by businesses could be problematic.**

Critical Tracking Events have been broadly defined by the FDA in the proposed rule and mostly complement existing practices in supply chain visibility standards. However, FDA should further clarify that transformation and creation are functionally the same CTE and any differentiation is based solely on inclusion/exclusion on the food traceability list.

IFT recognizes that FDA intends to demarcate the CTE wherein a listed food begins receiving enhanced traceability management with the term "transformation". We appreciate the definition of transformation as "an event in a food's supply chain that involves changing a food on the Food Traceability List, its package, and/or its label (regarding the traceability lot code or traceability product identifier), such as by combining ingredients or processing a food (e.g., by cutting, cooking, commingling, repacking, or repackaging)." Potentially the requirement for TLC assignment and linkage could become complex for processors who have multiple transformation steps within their facilities which result in different products from initial inputs. It is unclear what role internal traceability has on recordkeeping requirements. Does FDA need to be able to tie products to the specific production line or does it need to tie the given lot number to a facility? IFT recommends tailoring the transformation definition so that it encompasses all transformation events within a given facility, since the regulator's need is in the ability to quickly and easily deduce the pedigree of a given product.

*IFT recommends that FDA recognize that creation and transformation are essentially the same and explicitly call that out in the finalized rule and related guidance. The diverting definitions/terminology could result in parallel approaches to traceability, which would be inferior to a united, integrated approach afforded by a clear understanding that the two terms differ only in their relation to the proposed rule.*

## **Roles, Functions, and Responsibilities**

**Upstream Actors are important generators of KDEs required in the proposed rule.**

The proposed rule envisions robust recordkeeping from origination through to retail. There is significant remaining uncertainty around the roles and responsibilities of upstream actors that needs resolution prior to effective and successful rule implementation. This lack of clarity is most marked for the functional implementation of the rule in the produce sector, which make up almost 50% of the items on the FTL, along with the seafood sector. In the former category (produce), the rule places the responsibility for record keeping downstream of where the needed records (key data elements) would be generated. This omission of originating critical tracking events (growing, packing, shipping) from the

rule, but requirement for key data elements from those events (e.g., harvest date, harvest location, grower) is potentially confusing and not well aligned with functional realities of produce supply chains and actors upstream of the USDA’s first receiver role. Resolving this issue would require the FDA to shift the focus of the rule from business entities and ownership to performers of critical activities and who is generating key data. IFT believes the introduction of the first receiver concept in the proposed rule is highly problematic. Upstream actors, like farms or fishing vessels are the sites of pertinent critical tracking events (CTEs) to public health and generators of key data elements that the first receiver is charged with the responsibility of establishing and maintaining (Figure 1, 2). This puts the first receiver in the difficult position of being responsible for establishing and maintaining records of data they did not generate, which brings forward questions on who is responsible for KDE veracity/accuracy. To comply with the rule, the first receivers will have to force the farms to transmit key data elements to them, which results in an indirect regulatory burden on farms that first receivers will be responsible for improving. Due to the provision that 1<sup>st</sup> receivers own *and* physically possess the food products, the 1<sup>st</sup> receiver may actually be fairly far downstream of origination as the below diagrams illustrate. The 1<sup>st</sup> receiver CTE is then capturing KDEs of multiple previous CTEs. This is a departure from existing industry event-based traceability practices. KDEs ideally should be associated to the CTEs where they were collected.

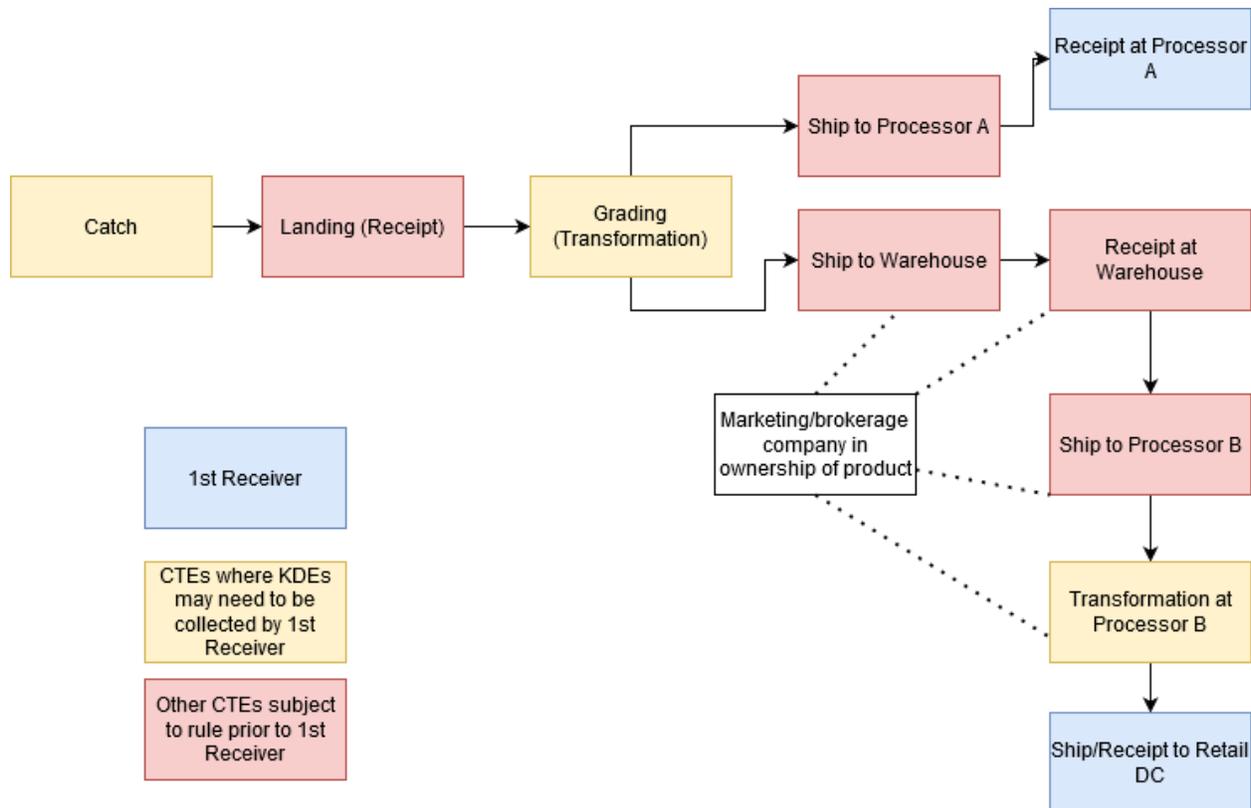


Figure 2. The first receiver concept is also problematic in the seafood sector where it would be more ideal to designate fishing vessels responsible for generating KDEs.



*IFT recommends revisions to the proposed rule to focus on the critical activities and key data elements that must be captured to provide much enhanced clarity and eliminate the problematic first receiver concept. This can preserve the prevailing event-based traceability approach which industry is accustomed to while providing flexibility in data capture and sharing relationships.*

#### **The First Receiver concept is complicated and difficult for impacted entities to implement.**

We believe the first receiver concept is unfortunate and results in undue complication in the proposed rule. First receivers of food products are denoted as being non-transporters and non-farms, who physically possess and own the food products, a set of attributes that may characterize various actors in supply chains in an inconsistent way. For example, an e-commerce retailer may receive a listed food like spinach in bulk bins directly from a grower and be responsible for that product as first receiver. They may also purchase bulk spinach through a broker, and find themselves as first receiver, despite not purchasing directly from a farm. Finally, they may receive pre-packed spinach from a co-packer they contracted to portion and bag the spinach. Depending on the procurement arrangement, they may or may not be considered the first receiver in this last case.

First receiver also creates challenges in the seafood category. First receiver appears to accommodate the partial exemption of fishing vessels or similar challenges in other raw agricultural commodities to which the rule could apply. However, as represented in the proposed rule this is at least two CTEs captured in one (Figure 2). If specific information is required for public health emergencies, such as transporter or catch area, then discrete and structured data requirements upstream may better FDA's ability to use origination data for investigation purposes. For seafood, there may be a scenario where multiple vessels catch, land, and have their harvests commingled. FDA is requiring that the 1<sup>st</sup> receiver keep records on the vessel trips and associate it with this receipt with a TLC. The purpose of this is dubious as a regulator would not be able to use this commingled lot to ascertain specific knowledge about the origination of the product.

*If the first receiver concept is retained, we recommend the FDA focus their directive on the KDEs that the first receiver must collect and maintain, e.g., immediate upstream supplier contact information. This maintains conventional traceability best practice of being able to organize data in a KDE/CTE matrix.*

#### **Broadly defining entities responsibility for KDE capture by CTE is beneficial to ensuring robust traceability.**

In its current form, the rule defines those that are subject to it as "persons", which may include individuals, cooperatives, businesses, and other conceivable legal structures. As written, we believe the rule effectively mandates within-organization traceability record keeping (generation and transmission) by tying the requirements to the physical movement and transformation of products in time and space. Recognizing that the CTEs and KDEs required by the FTL could all occur within one organization, further emphasizes how the rule places responsibility at CTE rather than static requirements, and mandates changes in the internal business practices and record keeping of certain organizations transforming, shipping, receiving, or packing items on the FTL. This is a functional reality of supply chains. IFT commends FDA for recognizing and codifying this in the proposed rule.



*IFT recommends FDA maintain the focus of recordkeeping on CTEs in the proposed rule to ensure physical movement of FTL products and their transformation within organizations is sufficiently tracked and traceable.*

### Exemptions are too broad to achieve the proposed rule’s intent.

Overall, IFT realizes that the Food Traceability Rule is restricted to constraints by the laws in which its authority was drawn from. The FDA, in this rule, has taken efforts to reduce unnecessary exemptions, prioritizing public health. FDA has included the most CTEs as can be practicable from the standpoint of FSMA, but end-to-end food traceability is best accomplished by limiting exemptions and maximizing participation by all supply chain actors wherever possible. Traceability is a shared responsibility among all supply chain actors that advances in technology and digitization have made more accessible to all but the smallest businesses.

### Small retailers should be included as full stakeholders.

The FTL currently provides partial exemption for small retailers, a category which as written includes some restaurants and food service. The threshold, fewer than 10 employees per site, is inconsistent existing business size classifications offered by the SBA<sup>14</sup> or OECD<sup>15</sup>, and may be excessively broad with the trend toward greater digitization in retail (e.g., AmazonGo). These sites may well have fewer than 10 FTEs per site but are certainly integrated components of large businesses with advanced data systems that should not be exempt from compliance with the rule. While these individual establishments may be small, they play an important role in our food system and in outbreaks of food borne illness<sup>16</sup>. Greater than 90% of retailers have receipts less than \$7.5M, the SBA threshold for small business designation, however, these retailers are also responsible for >40% of food sales.<sup>17</sup> Therefore, full exclusion of these actors from the proposed rule is inappropriate given their relevance in the food system. If FDA prefers to define the threshold by the number of FTEs, we recommend aligning with the OECD threshold, which is fewer than 49 FTEs across all sites of the business. However, regardless of which threshold FDA selects, these small retailers are the very stakeholders who need regulatory reinforcement to support adoption of better practices by their suppliers. Without regulatory support, these stakeholders do not have sufficient market leverage to demand better traceability of listed foods from their suppliers. Full inclusion of these important stakeholders would benefit public health and the liability burden of food borne illness on small actors.

*IFT supports re-defining small retailers based on existing SBA criteria (<\$7.5M receipts per year) regardless of the number of sites. IFT further advocates for inclusion of small retailers as full participants*

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<sup>14</sup> P. 24 Food and Beverage Stores, Subsector 445. Available from: [https://www.sba.gov/sites/default/files/Size\\_Standards\\_Table.pdf](https://www.sba.gov/sites/default/files/Size_Standards_Table.pdf)

<sup>15</sup> Enterprises by business size. Available from: [https://data.oecd.org/entrepreneur/enterprises-by-business-size.htm#:~:text=of%20people%20employed,-,In%20small%20and%20medium%2D-sized%20enterprises%20\(SMEs\)%20employ%20fewer,employ%20250%20or%20more%20people.](https://data.oecd.org/entrepreneur/enterprises-by-business-size.htm#:~:text=of%20people%20employed,-,In%20small%20and%20medium%2D-sized%20enterprises%20(SMEs)%20employ%20fewer,employ%20250%20or%20more%20people.)

<sup>16</sup> Figure 52. Retail Segment Characteristics, “Distribution of firms and associated receipts, by size” p. 308 [https://www.iftevent.org/-/media/gftc/pdfs/ift\\_fda\\_producttracingpilotsfinalreport.pdf](https://www.iftevent.org/-/media/gftc/pdfs/ift_fda_producttracingpilotsfinalreport.pdf)



*in the proposed rule to provide them with the necessary regulatory backup to encourage traceability in their supplier networks. This is most consistent with option 2 of § 1.1305(g).*

**The Kill Step is a partial exemption that needs further clarification and downstream record-keeping.**

As is talked about elsewhere in this document, “kill steps” exempting subsequent CTE recordkeeping, while reducing overall economic burden and acknowledging the reduction of risk by that food, is complicated and not straightforward to implement on a practical basis. Those downstream of kill steps would need documentation tied by TLC to ensure they are not subject to enhanced recordkeeping requirements of their CTEs regarding that product. Therefore, some traceability to the TLC level is still necessary, but with perhaps fewer KDEs.

*We recommend that the FDA explicitly require actors downstream of a kill step to maintain lot-based traceability capable of linking back to the CTE where the kill step occurred to alleviate potential confusion and liability for downstream supply chain actors.*

## **Recommendations for Education, Training, and Support to Facilitate Implementation**

**Traceability Program Recordkeeping Requirements will require public-private partnerships to develop functional interoperability in impacted sectors.**

Recordkeeping requirements put forth in the proposed FTL are less extensive than those put forth in the Nonbinding Recommendations<sup>17</sup> put forth by the FDA in 2019 related to the Produce Safety Rule, and less extensive than those put forth by IFT’s category-specific CTE-KDE matrices<sup>18</sup>. The FTL’s requirements may be less extensive to try to lessen the burden of implementation on impacted businesses. However, deviation from full, supply chain-wide CTE-KDE frameworks does create some complication and/or leave some gaps in achieving the proposed rule’s objective of end-to-end traceability within 24-hours for rapid recall. To overcome this challenge and achieve industry-wide compliance with the rule, businesses will need to create, maintain, and share data they have never shared before. Businesses will need convening events to develop interoperable industry standards for data sharing. A key focus of these convenings will need to be resolving interoperability challenges with upstream business partners currently exempted from the proposed rule. Developing commodity-specific dos and don’ts as outputs of these convenings will enable industry partners to achieve the new level of data and information sharing mandated by this rule in the least burdensome and onerous way possible. Data privacy issues are a significant barrier to broader adoption and implementation of digital traceability solutions. IFT has extensive experience working across supply chains and industries to navigate and overcome these concerns through facilitated dialogue and convenings of key stakeholders.

Beyond convening dialogue, we envision supply chain mapping, and piloting will be necessary over the next 2 years with impacted industries to ensure everyone is ready and comfortable to launch on the proposed timeline. IFT’s GFTC has deep expertise in mapping supply chains to determine where Critical

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<sup>17</sup> <https://www.fda.gov/media/126868/download>

<sup>18</sup> <https://doi.org/10.1111/1541-4337.12103>



Tracking Events (CTEs) occur through food science and traceability. As an external expert, IFT is well-equipped to facilitate this as a neutral technical leader in the field. IFT's experience with piloting and supporting beta implementation of interoperable sustainability with the dozens of Global Dialogue on Seafood Traceability participants serves as demonstration of their ongoing leadership in guiding the industry forward in this space. Industries with frequent Class 1 recall challenges, i.e., poultry, ground beef, and leafy greens, represent a critical constituency for advancing adoption of interoperable systems. The emergent issues in seafood traceability often center on aggregation processes in the supply chain that occur during primary and secondary processing. With the IFT's CTE/KDE framework and modern tech, it is possible to empower key industry actors to successfully transmit key traceability information through these challenging nodes to maintain system wide smarter food safety.

Furthermore, pilots provide the best means of identifying areas where there are data quality and/or compatibility issues. This will be particularly important for FTL items like cucumbers that have received less targeted development, support, and attention than others like leafy greens.

*IFT recommends the FDA support convening of public-private partnerships to develop interoperability in impacted sectors, particularly those on the FTL with less well-developed baseline traceability.*

**Impacted industries need education on the traceability principles undergirding this rule, how they apply to their internal business processes and practices, and how they will govern or impact their interactions and data sharing with external business partners in their supply chains.**

In addition to 2-way dialogue and convenings to develop standardized, cross-industry business practices to support this rule, there is also a need for additional curriculum and traceability education to aid adoption of those critical practices. Much like the Produce Safety Alliance that has supported critical educational delivery for the FSMA Produce Safety Rule, we believe formation and facilitation of education through a Traceability Alliance facilitated in partnership with land grant institutions and their extension services would be beneficial to ensuring all stakeholders have an appropriate level of education related to the why and how of traceability to achieve successful implementation within their organizations<sup>19</sup>.

*IFT recommends the FDA collaborate with non-governmental partners, industry associations, and neutral, non-profit, technical organizations to assess industry educational needs and develop educational content to support rule implementation.*

**The proposed rule creates needs for new training and data infrastructure to enable business partners to capture and exchange data that deviates from historic practices.**

IFT sees that the proposed rule as a complex, multi-stakeholder, and systemic change in potentially both business practices and information management. The changes represented in this rule will require cooperation across the supply chain and among varied business types including technology companies. Because multiple disciplines are involved in imparting changes in response to this rule, training will be essential to ensuring its widescale success. Food system participants need to have universally

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<sup>19</sup> <https://producesafetyalliance.cornell.edu/food-safety-modernization-act/produce-safety-rule/>



understood and applied foundational concepts in food traceability, such as KDEs, CTEs, and lot-based unique identification of products.

For larger businesses subject to this rule, existing ERP and MRP software alongside supplier management platforms will provide sufficient infrastructure to provide compliance in a non-burdensome way. While there may need to be some slight adjustments of data fields, creation and conveyance of the critical traceability lot code data will fall well within the realm of existing standard business processes. For smaller businesses, e.g., those with \$25,000-\$250,000 in annual sales, there will be a need for low- or no-cost software solutions to support the timelines required by this rule (e.g., provision of a spreadsheet within 24 hours of a request). Identification of these solutions, and adaptation of these solutions to the needs of smaller-scale supply chain actors will be necessary to support their compliance with this rule in a way that is not excessively burdensome. A focus on digital, open access, interoperable solutions is needed, alongside interactive, participatory training sessions to support adoption and implementation.

*IFT recommends the FDA partner with neutral, trusted industry experts to assess current practices, infrastructure, and needs. Training and development of low-cost, flexible solutions will be necessary to achieve the intent of the proposed rule and facilitate its broader adoption for non-FTL foods.*

#### Unique identification requires articulation of acceptable tactical pathways to compliance.

The proposed rule requires uniquely identifying item and lot codes, but in end-to-end traceability should further specify that identifiers need to be *globally* unique. There are primarily two methods of ensuring unique identity, through registries and through algorithms. Globally unique assets employed registries because of their ability to incorporate other information into the identifier by the means of its construction, persistence, and common registration (i.e., only one identifier is associated with a particular location/object). Global standards, such as GS1, use “prefixes” to construct such styled identifiers. In GFTC’s work in seafood traceability, we found utilizing standards put forward by the Internet Engineering Task Force can also ensure globally unique identification, especially among upstream supply chain roles. Utilizing URLs, commonly referred to as web addresses, in which identity is represented by a unique company address in which strings which identify the product type and/or lot code are affixed and used for asset identification purposes, has been an alternative approach when working with different supply chain roles and technology vendors who may be more familiar with IETF standards rather than GS1 standards. Additionally, algorithmically generated identifiers (e.g., UUIDs), another standard promulgated by IETF, can have application, especially in scenarios where upstream supply chain actors have limited means for using a registry-based identifier.

*IFT recommends the FDA revise the proposed rule to specify “globally unique” identification as a requirement for FTL food traceability recordkeeping and develop additional guidance for industry stakeholders on implementation of various options for unique identification such as GS1 identifiers (e.g., GLNs and GTINs), URLs, and UUIDs. We believe the power of commonly utilized identifier standards that are ubiquitous to digital and physical assets are particularly important for new business models and non-CPG items, which have more rapidly changing product portfolios that require greater flexibility.*



The proposed rule intersects with several other regulations, creating areas where additional attention may be needed to avoid conflict or duplication.

Food traceability has more application than food safety, though food safety is often the primary motivator. IFT has seen food traceability be used for sustainability, assessing legality, and maintaining international trade regulatory requirements. Because of the breadth of the proposed rule, there are intersections with other domestic and global regulations and enforcement of food safety and traceability data.

Collecting CTEs proposed in this rule conflicts with terms of the EU’s General Data Protection Regulation.

The food system is global, and domestic regulations become relevant internationally. The proposed rule is no different in that it expands regulation of certain goods to jurisdictions throughout the world. To better protect public health, this is a necessary consideration. The General Data Protection Regulation (GDPR), promulgated by the European Union, is a sweeping data privacy provision which gives natural persons certain rights on their data. These rights pertain to any EU national, regardless of the location of the given records. The data under GDPR include personal identifiable information, such as name, address, and other contact information. Precisely these types of data are required under CTEs in the proposed rule. This means for products originating or transformed in Europe, this regulation mandates supply chain systems be compliant with GDPR. IFT does not discourage the use of these data for recordkeeping requirements but would like to highlight the impact of the recordkeeping.

*IFT recommends consultation with EU stakeholders to ensure data capture regulated by this proposed rule does not conflict with the GDPR.*

FDA’s proposed implementation timeline is consistent with the timelines of other regulatory changes and achievable given the age and availability of practices codified by this rule.

The FDA’s proposed 2-year implementation timeline from finalization of this proposed rule is shorter in absolute terms than the 10-year implementation timeline the FDA allotted to the pharmaceutical industry for implementation of the Drug Quality Supply Act<sup>20</sup>. However, the practices codified by this proposed rule are not new and have been articulated as best practices for food handling and traceability for nearly a decade (since 2012). So, while they were not mandated in the original FSMA rule, these practices are consistent, if not more lenient than the best practices recommended based on the IFT pilots conducted 2010-2014. Therefore, we believe the implementation timeline is comparable to the decade allotted to the pharmaceutical industry. Standards, tools, and solutions for carrying out traceability have advanced beyond the minimum necessary to be compliant with the proposed rule.

*IFT recommends that FDA maintain the implementation timeline but continue working towards larger goals articulated in the New Era of Smarter Food Safety around developing low-cost solutions appropriate for digitized supply chains.*

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<sup>20</sup> <https://www.fda.gov/drugs/drug-supply-chain-security-act-dcsca/are-you-ready-drug-supply-chain-security-act>



**Additional development of codes clarifying FDA-to-state-and-local-authority and USDA-to-FDA responsibilities and cooperative processes are necessary to avoid redundancy and achieve efficacy.**

Due to the cooperative relationship between all levels of food safety regulation in the United States, traceback investigations are not arbitrated exclusively by federal officials. Crucial, localized tracebacks and subsequent trace-forwards are performed by state and local officials. In a food safety emergency, the progression of response often starts by laboratory and epidemiologic findings by local/state authorities. Findings from these initial investigations then get handed to CDC/FDA CORE with subsequent coordination and response done in concert back with state authorities. Implementation of the enhanced recordkeeping requirements may entail additional state-based codes to assist with enforcement and oversight by state regulators.

*IFT recommends organizing convenings of state and federal authorities as well as between the USDA and FDA to identify and develop additional codes to clarify inter-agency handoff for maximum efficiency.*

**Seafood traceability is already regulated for environmental and economic reasons by the US and other governments. Practices and CTE-KDE structure developed for these other applications should be adopted and further supported by the FTL, rather than replaced or creating an additional framework.**

Traceability of seafood products regulatory requirements extend beyond food safety both domestically and internationally. There are environmental considerations for seafood harvesting regulated by both national governments and international bodies. Fishing vessel, fishery, and water registrations and regulations are critical for maintaining fishery stocks and ensuring the future seafood harvests. For these reasons, the US and other national governments have implemented Illegal, Unreported, and Unregulated (IUU) fishing regulations. The Seafood Import Monitoring Program (SIMP) requires continual collection and input of KDEs in support of these regulations.

*IFT recommends FDA utilize the existing framework for seafood traceability, the GDST Standard, and simply emphasize CTEs and KDEs within the GDST that are necessary for compliance from a food safety-driven traceability perspective.*

## **Conclusion**

IFT welcomes the advance in food traceability adoption and standardization supported by this proposed rule. We support the methodology used to construct the food traceability list, finding it to be evidence-based and rigorous, yet not over-reaching. Public health and liability costs related to insufficient traceability and acute food safety outbreaks justify inclusion of listed items, as well as the 24-hour timeframe and sortable spreadsheet requirements put forth by the FDA. IFT also commends FDA on their conceptualization of traceability lot codes as a key data element from a traceability perspective. We believe additional refinement of the terminology used to describe the code, such as “traceability code” could bolster clarity for stakeholders and ease implementation and efficacy of the final rule. There are a few areas where we perceive additional modifications will be necessary to achieve successful implementation: 1) development and review of listed item-specific templates, 2) further clarification on what constitutes unique identification and available options, 3) revision of the first receiver concept and approach to one that is an easily recognizable, familiar and consistent point in the supply chain, and 5) our evolving realities of data and record keeping and what an appropriate conceptualization of record



establishment and maintenance means in the digital age. Finally, throughout the rule, we urge the FDA to avoid overly prescriptive approaches to record keeping and instead focus on clarifying the outcome that impacted parties must achieve (provision of information necessary to traceback to source in <24 hours). We look forward to supporting the FDA and industry in successful resolution of these remaining issues and in implementation of the ultimate rule. We thank you in advance for your consideration of our comments. Please contact Bryan Hitchcock, Senior Director Food Chain & Executive Director Global Food Traceability Center ([bhitchcock@ift.org](mailto:bhitchcock@ift.org), 312-604-0225) if IFT may provide further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Noel Anderson'.

Noel Anderson

President, 2020-2021

A handwritten signature in black ink, appearing to read 'Christie Tarantino-Dean'.

Christie Tarantino-Dean, FASAE, CAE

IFT Chief Executive Officer

## About IFT

The Institute of Food Technologists (IFT) is a non-profit, membership-based scientific institute whose mission is to advance the science of food and its applications across the global food system, to ensure sustainable, safe, and nutritious food for all. Established in 1939, IFT has more than 13,000 individual members in over 100 countries from across industry, academia, government, and non-profit organizations. Organized around the core values of community, integrity, passion, progress, and respect, IFT's members and 68 staff create and uphold a scientifically sound society focused on overcoming barriers to feed our future safely. IFT's Global Food Traceability Center (GFTC) provides the global food industry resources and solutions to help improve food safety, diminish risk, avert devastating health consequences and economic loss to the food system. GFTC works throughout the food industry to develop next generation solutions that enable strategic commercialization across the food chain with benefits for the Ag/Food system, consumers, and the environment.