



December 2, 2019

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

Submitted via electronic mail: www.regulations.gov

Re: New Era of Smarter Food Safety; Public Meeting, Request for Comments; Docket No. FDA-2019-N-4187 (September 18, 2019)

Dear Sir or Madam,

The Institute of Food Technologists (IFT) is a non-profit, scientific institute whose mission is to advance the science of food and its applications across the global food system. IFT's vision is a world where science and innovation are universally accepted as essential to a safe, nutritious, and sustainable food supply for everyone. Established in 1939 by MIT and headquartered in Chicago, IL, IFT has more than 15,000 individual members in over 100 countries, approximately 80% US based.

IFT appreciates the opportunity to provide input on the New Era of Smarter Food Safety. We commend efforts to leverage digital and physical technologies to enhance the safety of the food supply and the efficacy of the food system.

IFT has a long history of active engagement in food safety, and partnership with the FDA. Key domains of expertise have been leveraged to address several topics and issues within food safety and including traceability, and food processing, to name a few. During the past 20 years, IFT undertook several contractual task orders for the FDA, addressing microbial inactivation kinetics, preventative control measures, evaluation and definition of potentially hazardous foods, allergen-related manufacturing and labeling practices, and food defense. Further, IFT led food product tracing pilots for the FDA, as required by FSMA Section 204, to evaluate methods to improve food traceability and protect public health. IFT defined the Key Data Elements (KDE) and Critical Tracking Events (CTE) concepts and drove the development of industry-wide traceability frameworks.

Since then, IFT established the Global Food Traceability Center (GFTC), created and executed domestic and international traceability pilots through the Global Dialogue on Seafood Traceability (GDST), and delivered effective education integrating traceability concepts into food safety. IFT has also been active in other areas, such as involvement in Codex Alimentarius, publishing a variety of scientific documents, and conveying round tables. Examples include: a Whole Genome Sequencing roundtable in 2018 with JISAN; engaging in activities and publishing on the issue of antimicrobial resistance; publishing a review

of the role of date labeling in food waste which addresses food safety and quality and the advantages of smart packaging.

Evolving food safety is not an option, but an on-going mandate. Breakthrough technologies are driving digitalization of food chains and ecosystems. We encourage the FDA to build a regulatory framework that is flexible and anticipates a digital and data-based future.

IFT is pleased to provide detailed comments focused on building effective traceability systems beginning with the IFT led FDA pilot completed in 2012 and concluding with current status. We believe this aligns closely with FDA's requested topic areas:

1. Tech-enabled Traceability and Foodborne Outbreak Response
2. Smarter Tools and Approaches for Prevention
3. New Business Models and Retail Modernization
4. Food Safety Culture

IFT FDA Traceability Pilot Outputs Summary & Insights

In collaboration with academic, industry, government, and industry stakeholders, IFT completed in 2012 an extensive pilot program and provided specific recommendations to the FDA on key next steps to drive traceability forward to widespread implementation. As the FDA builds the "Blueprint" for a "New Era of Smarter Food Safety," we recommend revisiting the original recommendations, as they present a solid foundation. The recommendations and conclusions are reiterated below. The full report can be found at [IFT-FDA 2012 Traceability Report](#).

Excerpts from IFT-FDA 2012 Traceability Pilot Project Report

Recommendations

Upon completion of the task, IFT determined that costs associated with implementing a product tracing system can vary widely as determined by numerous factors: the size of the firm/facility, the method of product tracing already in use (i.e., manual or electronic), and the range of each firm's capabilities to implement or improve its product tracing system, to name a few. Nevertheless, IFT is confident that a product tracing system incorporating its recommendations would greatly benefit the FDA as well as other state and federal partners, the food industry, and consumers. The recommendations are as follows:

1. From an overarching perspective, IFT recommends that FDA establish a uniform set of recordkeeping requirements for all FDA-regulated foods and not permit exemptions to recordkeeping requirements based on risk classification.
2. FDA should require firms that manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain records of CTEs and KDEs as determined by FDA.
3. Each member of the food supply chain should be required to develop, document, and exercise a product tracing plan.

4. FDA should encourage current industry-led initiatives and issue an Advance Notice of Proposed Rulemaking or use other similar mechanisms to seek stakeholder input.
5. FDA should clearly and more consistently articulate and communicate to industry the information it needs to conduct product tracing investigations.
6. FDA should develop standardized electronic mechanisms for the reporting and acquiring of CTEs and KDEs during product tracing investigations.
7. FDA should accept summarized CTE and KDE data that are submitted through standardized reporting mechanisms and initiate investigations based on such data.
8. If available, FDA should request more than one level of tracing data.
9. FDA should consider adopting a technology platform that would allow efficient aggregation and analysis of data submitted in response to a request from regulatory officials. The technology platform should be accessible to other regulatory entities.
10. FDA should coordinate traceback investigations and develop response protocols between state and local health and regulatory agencies, using existing commissioning and credentialing processes. In addition, FDA should formalize the use of industry subject matter experts in product tracing investigations.

Conclusion

In summary, IFT found that there are several areas (such as uniformity and standardization, improved recordkeeping, enhanced planning and preparedness, better coordination and communication, and the use of technology) in which industry improvements and enhancements to FDA's processes would enable tracebacks and traceforwards to occur more rapidly. There was a range of costs associated with improving product tracing capabilities for certain sectors of the industry based on the specific technologies used to achieve the data capture and communication objectives. Case studies demonstrated the range of public health benefits from reduction in illnesses from improved product tracing. The recommendations outlined in this final report will enable FDA to conduct more rapid and effective investigations during foodborne illness outbreaks and other product tracing investigations, significantly enhancing protection of public health.

Traceability Current State and What Remains to be Done?

As we reflect on the recommendations and conclusions, there has been significant progress made. Key highlights:

- Consumer interest and awareness of the where their food comes from and how it is manufactured has grown.
- Traceability technology solutions have advanced in quantity and capability.
- Data collection capabilities, such as IoT devices, RFIDs, and image processing, have grown and become more cost effective.

- Investments in new technologies (such as blockchain, whole genome sequencing, and rapid microbial testing) have generated advancements and viable commercial offerings.

Yet, there is much yet to be done. We have found there are several opportunity areas as well as solid enabling tools. Through our interactions with small and large stakeholders across the value-stream, several themes resonant:

- Public-Private Partnerships
- Global Standards including interoperability
- Privacy mechanisms
- Financial investment & return
- Mechanisms to facilitate small & medium sized organizations to participate
- Food Safety Culture & Education

Public-Private Partnerships

Considering the complexity and global nature of supply chains, it is important to map out the ecosystems and actors. In our experience, global pre-competitive public-private partnerships (PPPs) are key to productive collaborations driving voluntary standards and best practices for traceability. Our experience in the Global Dialogue on Seafood Traceability (GDST) with over 70 seafood industry organizations is case in point.

The process of creating interoperable frameworks for food traceability requires a neutral convener, making PPPs an excellent vehicle for driving and accelerating change across all stakeholders. Because traceability deals with product risk, sensitive business information, and niche technical expertise, conventional food standards processes may be insufficient. Through GFTC's work in the GDST, we have brought value to the effort through our knowledge and expertise, but also as a nonprofit, technology agnostic resource. This has allowed us to navigate and understand supply chain issues from source to consumption, and enables the collaboration across producers, processors, distributors, retailers, government entities, NGOs, and software solution providers. With how dependent food traceability is on digital technologies, PPPs streamline technology adoption and helps ensure an interoperability framework keeps to food traceability use cases and remains abreast with current technology.

Global Standards Including Interoperability

Combined with interoperability principles, standards are necessary to drive efficiencies and scale up adoption.

In building effective traceability systems, we leverage a three-step standardized process: Design, Build, Deploy.

Design: The process places significant upfront emphasis on the design step, that enables organizations to create strategic, cost-effective systems tailored to their individual goals, priorities, and constraints. Many organizations overlook designing a detailed, objective driven traceability system in favor of advancing to testing and piloting. In our experience, this leads to significant rework and potentially overly complex systems.

Two critical initial steps in designing an effective system including identifying clear, concise objectives and developing core KDE/CTE lists that apply across the entire supply chain and commodities.

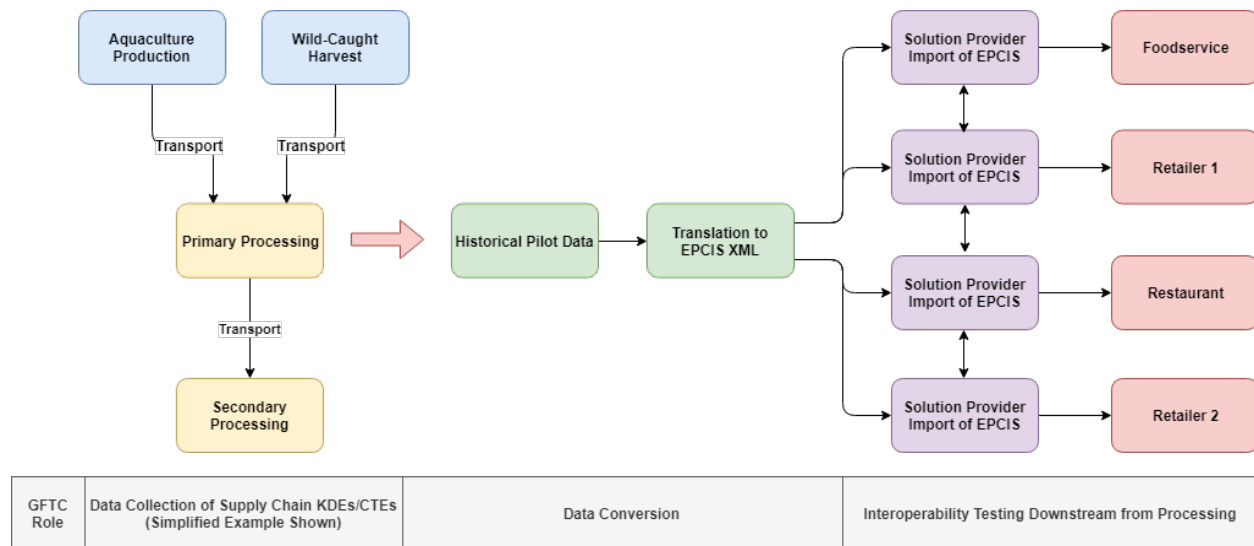
Food traceability then touches on two primary areas of standardization: logistics and information technology. To coordinate complex networks, both domains have used precompetitive standards setting processes to allow for interoperability between separate actors. Product identity standards, such as those promulgated by GS1, are key to common expectations and methods of logistical unit identification. Information technology standards ensure that linkages between computer systems are possible.

Work by standards organizations such as IEEE or Linux highlight other approaches to interoperability, namely through open source collaborative projects. We have found success marrying these two approaches by taking successful elements of both. In logistical standards bodies, there is great benefit to buy-in from industry stakeholders and technical experts, but these processes may skew the perspective of working groups developing standards, potentially alienating SME and producer needs. Conversely, collaborative, foundation-driven processes to develop open source software have unique attributes and approaches to interoperability challenges. Examples, such as the development of Kubernetes, a virtual machine-based platform for automating application deployment, and associated efforts like the Open Service Broker API to enable interoperability among cloud-native apps on Kubernetes, show how a more iterative and crowdsourced process can accelerate adoption and provide a less rigid approach to interoperability.

Build: In this step, the designed system is tested with historical data often through end-to-end or targeted pilots. Key learnings are obtained, and the traceability system is optimized.

Deploy: Once designed and built, there are several elements critical to successful deployment including a robust investment thesis, enterprise wide training, and post-launch monitoring. The food industry can learn and leverage solutions from lessons in the finance, technology, and healthcare sectors to enable interoperability and extend adaptability of global standards, both in product identity and information technology.

The graphic below provides an example of leveraging GS1 standards (in this case, EPCIS) to address use cases in seafood traceability. By working with stakeholders across the supply chain and facilitating the exchange of data, a PPP can drive towards developing comprehensive frameworks which work across the various contingencies in technology adoption, current business practices, and regulatory realities. After developing datasets in EPCIS, we were able to incubate open source solutions in hackathon competitions, generating code which may be used to enable interoperability in new and existing traceability solutions.



Privacy Mechanisms

Data privacy is a critical concern among all stakeholders. Clarity around what data needs to be visible during routine operations and during food safety events is of key concern. The FDA could enable faster and more complete investigations by creating mechanisms for submitting and housing salient data.

Traceability data inherently contains sensitive information about a food business' operations that may need to be conveyed to supply chain partners to expedite speedy utilization. Retaining appropriate data governance so that only pertinent actors have access is essential, not only to effective traceback and recall, but for institutional buy-in. However, in IFT's experience, other sectors have implemented effective solutions to these challenges which could be operationalized for the food industry. Permissioned access and tokenization of sensitive data have applications already in tech, finance, and healthcare. By bridging the development community with food industry stakeholders, gaps in understanding may be bridged and innovative solutions can be created.

Financial Investment & ROI

Without comprehensive and systematic analysis of food traceability's microeconomic impacts, digital traceability systems will have slower adoption rates. Though the benefits of digitized and standardized traceability can be clearly demonstrated, it is not as straightforward to assess these benefits on a bottom-line basis that is generalizable for the diversity of players in the food system. There are several factors which feed into the value proposition of enhanced end-to-end traceability including but not limited to labor savings, inventory and supply chain efficiency, risk mitigation, and consumer engagement. Data-enabled analytics can fuel benefits not always immediately obvious at the investment stage.

Small and Medium Organization Participation

The New Era of Smarter Food Safety will require full engagement across supply chains as well as participation from organizations small and large. Mechanisms to encourage and engage organizations

with limited people and financial resources will be critical to the success of the overall initiative. These mechanisms could include interoperability standards, clear requirements guidance, and platforms where organizations can share common resources.

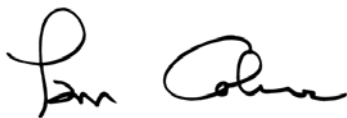
Food Safety Culture and Education

As with the creation of FSMA, education and training on digital technologies will be immensely important. Digital technologies can be intimidating and require new skills. Whether it is producers, processors, quality professionals, retailers, or consumers, awareness and new mindsets will be needed. Although technology advancements will enable progress towards a safer food system, the human element will continue to be a significant contribution. We highly encourage that communication, education and training be given careful consideration.

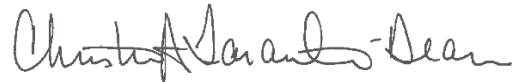
Conclusion

In conclusion, IFT appreciates the opportunity to participate in this exciting new journey towards a digitized, data-enabled future. Consumers are counting on all of us to give them great tasting, nutritious, and most importantly, safe and transparent food. IFT is committed to assisting with the New Era of Smarter Food Safety process. Through leveraging the power of convening settings, such as the Global Dialogue on Seafood Traceability, IFT has demonstrated the power of PPPs to drive and accelerate technology adoption to empower food safety. In addition to food safety, there will be numerous supply chain efficiencies and insurances realized from deploying an effective traceability system. Education and training at an enterprise level will be critical to sustained implementation. 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, 312-604-0225) if IFT may provide further assistance.

Sincerely,



Pam Coleman
President, 2019-2020



Christie Tarantino-Dean, FASAE, CAE
IFT Chief Executive Officer