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Impact of FDA's Low- or No-Cost Tech-Enabled Traceability Challenge to Strengthen Traceback Investigations

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Introduction

Food traceability is a vital component of the international food supply chain, as it allows regulators, such as the U.S. Food and Drug Administration (FDA), to track individual units of food throughout the full supply chain. With this data, the FDA Coordinated Outbreak Response And Evaluation (CORE) Network can conduct more targeted traceback investigations during incidences of foodborne illness, help pull contaminated products from the market, and address the root cause source of contamination. However, traceability data received by FDA is not always consistent, detailed, or accurate, and in such instances, the speed at which traceback investigations are conducted is severely impacted. With limited traceability data, outbreak investigations can go unresolved, root cause contamination sources cannot be identified, overly broad market withdrawals can result in seemingly safe food being pulled from the market as a precautionary measure, and more consumers are at risk of contracting the illness. Figure 1 below highlights key FDA traceability activities and events to improve food traceability.

2011 — The President signed the FDA Food Safety Modernization Act (FSMA) into law to optimize the nation's food safety system for illness outbreak prevention. FSMA mandated FDA to establish enhanced traceability recordkeeping requirements for high-risk foods.

2020 — FDA developed a policy initiative called the New Era of Smarter Food Safety to outline the approach the Agency and industry stakeholders could take together throughout the next decade to leverage emerging technology to create a safer, more digital, and traceable food system.

2021 — FDA hosted a Low- or No-Cost Tech-Enabled Traceability Challenge to promote innovation and encourage a variety of stakeholders to develop hardware, software, and data analytics platforms that were low-cost or no-cost to the end user. 90 teams entered the Challenge, including from the international community.

The Challenge concluded with 12 winners announced by FDA. This Challenge demonstrated how innovative solutions could help companies overcome technological and financial barriers and support FDA in conducting more robust traceback investigations.

2022 — FDA publishes the FSMA Final Rule on Food Traceability, which requires persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) to maintain records containing Key Data Elements (KDEs) at specific Critical Tracking Events (CTEs), work with their supply chain partners to ensure data accuracy, and provide this information to FDA within 24 hours of request. FSMA required FDA to remain technology agnostic regarding how the industry maintains their traceability records. The compliance date for this rule is January 2026.

Figure 1. Timeline of key FDA traceability activities and events.

Abstract

Since 2020, the FDA New Era of Smarter Food Safety initiative has highlighted the benefits of operationalizing tech-enabled traceability among food supply chain stakeholders (see Figure 2). Throughout the Summer of 2021, the New Era Technology team and precisionFDA hosted the Low- or No-Cost Tech-Enabled Traceability Challenge, during which a diverse array of industry stakeholders across many disciplines were encouraged to showcase affordable traceability solutions that could improve the ability of regulators and companies to more easily monitor food supply chain data (see Table 1). After the Challenge concluded, the FDA published a new technology-agnostic traceability regulation to harmonize industry's traceability data requirements and the Agency has continued to collaborate with organizations to encourage adoption and innovation of software, hardware, and data analytics technologies. For example, FDA contracted with the Institute of Food Technologists (IFT) to produce an independent report analyzing the outcomes and themes from the Challenge. FDA is also currently producing a video series with Challenge participants that examine current trends and emerging innovations since the Challenge concluded. For this poster presentation, the FDA will highlight the Challenge methodologies, goals, outcomes, and benefits from the hosting the Challenge. This poster will conclude with a discussion about how industry's innovative traceability technology solutions can strengthen FDA's foodborne outbreak investigations processes while helping the industry stakeholders speak the same traceability language through data harmonization and data interoperability efforts.

Materials and Methods

The FDA created a rubric that reflected the Challenge's goal of real-time, data-driven, innovative ideas that could be applied industry-wide, and were judged on the following categories:

- **Needs-Based:** Addresses specific traceability challenge for target segment of food supply chain
- **Innovation:** Uniqueness and innovation; variety and value of additional features
- **Usability:** Use of design elements to increase utilization; ease of navigation
- **Affordability:** Whether solution is low- or no-cost to end-user
- **Scalability and Interoperability:** Potential to be adopted by, and meet needs of, target segment; enables information-sharing across data platforms and with other segments of food supply chain

Each category was equally weighted by a panel of judges from the federal government—both internal and external to FDA—with experience in the fields of technology, public health, and/or the food industry. The scores for each of the five categories were summed and the teams with the highest scores were declared winners.

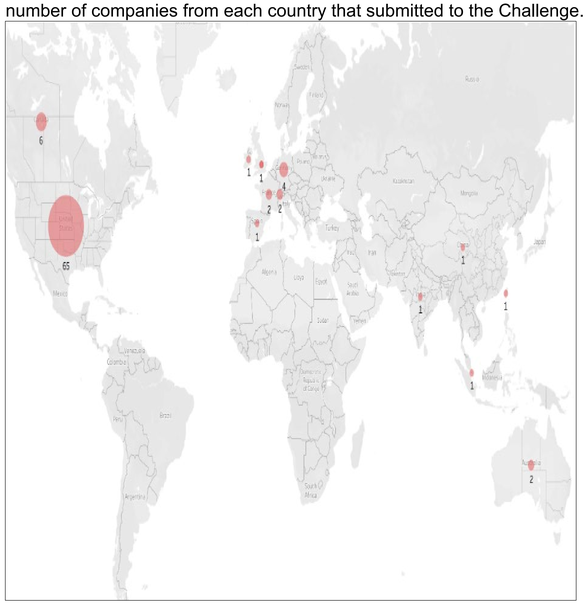
Results and Discussion

Ninety companies participated in this challenge, with 72% of submissions coming from the United States and 28% of submissions coming from companies outside of the United States, including from Canada, Germany, Ireland, England, Italy, Spain, Switzerland, India, China, Taiwan, New Zealand, and Australia (see Table 1). The Challenge allowed players from a wide range of roles within the global food supply chain to highlight their expertise and devise intelligent and feasible technological solutions to prevalent traceability issues. For example, one company created a cloud platform for assigning and managing traceability lot codes (TLCs) and a scalable blockchain solution that stores the data from the platform in a distributed ledger with an immutable chain of information that could be easily accessed by downstream supply chain partners. However, this Challenge only represented a snapshot-in-time and there are even more existing traceability solutions that could provide value to the industry beyond those who participated in the Challenge.

In the future, the FDA will be hosting a Traceability Video Series that involves numerous teams from the Challenge coming together in a moderated setting to discuss topics such as international implementation of traceability and the best methods to link the physical and digital world. The video series aims to highlight the widespread acceptance of traceability within the industry, spread awareness of the vast array of unique and low-cost solutions available, identify areas to improve data interoperability, and unite the food sector to advance traceability goals.

Figure 2. The logo of the FDA New Era of Smarter Food Safety is displayed above. It is comprised of four core elements aiming to leverage technology and new approaches to create a safer, more digital, and traceable food system. These elements include Tech-enabled Traceability, Smarter Tools and Approaches for Prevention and Outbreak Response, New Business Models and Retail Modernization, and Food Safety Culture.

Table 1. This table shows a heat map of a world with country boundaries shown. The heat map is plotted with red circles that are relative to the number of companies from each country that submitted to the Challenge.



Conclusion

The FDA Low- or No-Cost Tech-Enabled Traceability Challenge encouraged the creation and implementation of traceability solutions that navigated obstacles such as exchanging data through multiple platforms and maintaining a consistent TLC from end-to-end. The food supply industry is rapidly evolving to comply with the rule and enhance data modernization efforts, and without more robust and resilient traceability measures in place, consumers could continue to be put at risk. The Challenge highlighted a vast array of methods to improve global traceability and keep up with the varying demands of each node of the supply chain, ultimately easing the transition for operations to comply with the Food Traceability Rule. The subsequent video series will continue to promote the benefits of advancing traceability and pave the way for the industry to evolve together and embrace modernization. As a result of collective traceability advances, such solutions could be implemented industry-wide, leading to interoperability within the supply chain, more transparency, and more robust traceback investigations.