IFT GFTC Global Food Traceability Center

IFT's Tech-Enabled Traceability Insights Based on the FDA's Low- or No-Cost Traceability Challenge Submissions

May 17, 2023

FDA non-endorsement statement

As an activity under the New Era for Smarter Food Safety blueprint, the goal of the Low- or No-Cost Tech-Enabled Traceability Challenge was to encourage development of innovative approaches for scalable, cost-effective food traceability solutions to advance widespread implementation of tech-enabled traceability systems throughout the supply chain. This report documents these efforts. The Challenge was not related to, nor was FDA seeking solutions that pertained to, FDA's Food Traceability Rule. Reference to any commercial products, services, manufacturers, or companies does not constitute an endorsement by the U.S. government, including the FDA.

For more information about the Food Traceability Rule, please visit: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods

About the Institute of Food Technologists

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 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.

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Background on FDA's Low- or No-Cost Traceability Challenge

Beginning in 2020, under the FDA New Era of Smarter Food Safety blueprint—a collaborative policy initiative that outlined the FDA's food safety goals for the upcoming decade—the FDA stimulated renewed discussion surrounding tech-enabled traceability's role in helping to create a more digital, transparent, efficient, and safe food system. For these reasons, FDA's Office of Food Policy and Response (OFPR) hosted the Low- or No-Cost Tech-Enabled Traceability Challenge in 2021, with administrative support from precisionFDA, which spurred global engagement with participants submitting innovative technologies from nearly a dozen countries.

The Challenge had two main goals. The primary goal was to encourage stakeholders—including technology providers, public health advocates, entrepreneurs, and innovators from all disciplines—to develop traceability hardware, software, or data analytics platforms that were low-cost or no-cost to the end user. The secondary goal of the Challenge was to promote innovation throughout the private sector. Under the FDA New Era of Smarter Food Safety blueprint, the agency hoped to enable food producers of all sizes to participate in tech-enabled traceability in a scalable, cost-effective way. While it is an important factor, data security and privacy were not considered as part of the challenge.

Once the challenge concluded and the winners were announced, IFT used the FDA's Low- or No-Cost Traceability Challenge submissions to benchmark the tech-enabled traceability community's progress in executing against best practices related to interoperability, support and infrastructure, usability, and cost considerations.

About this report

The U.S. Food and Drug Administration (FDA) contracted with the Institute of Food Technologists (IFT) in 2022 to develop this report on food traceability technology based on the 90 technology solutions that were submitted to the FDA's 2021 Low- or No-Cost Tech-Enabled Traceability Challenge (the Challenge). This report is intended to contribute to ongoing discussions about the role of technology in traceability and provide high-level recommendations to key stakeholders on work to be done to enable an environment for tech-enabled food traceability. After the Challenge concluded, the FDA provided IFT with critical background materials and a reporting framework, and asked IFT to evaluate the private sector traceability solutions submissions received during the Challenge by:

- Highlighting the innovative efforts of Challenge participants, using the submissions as a representative sample for the overall tech-enabled traceability landscape
- Examining submissions to evaluate fundamental themes that are critical to achieving end-to-end tech-enabled traceability.
- Developing key learnings for further enabling adoption of digital traceability technology
- Providing insights into opportunities for future stakeholder collaboration

Report Contents

Methods for Review
How IFT conducted the review of the Challenge participants

Sector Trends
What technology is being incorporated and how quickly does it change

Insights and Themes

Interoperability
Why is interoperability key to widespread adoption of tech enabled traceability

Support and Infrastructure
What else is needed to support tech enabled traceability into the future

Usability
What to consider for end users

Cost Considerations
Considerations for choosing a solution

Closing Recommendations
Opportunities for a more traceable food system

Methods for Review

Methods for Review

IFT-GFTC scientists reviewed publicly available information and materials submitted by the 90 traceability solution providers* for the FDA's Low- or No-Cost Traceability Challenge to generate an assessment based on the criteria below. While the examples in this report primarily reflect the assessment criteria, qualitative categorization was considered throughout the review.

Qualitative Categorization	
Criteria	**Description/Example**
Target Supply Chain Stage	Producer, manufacturer, distributor, retailer
Target Commodity or Category	Fresh produce, leafy greens, grains
Solution Purpose – Primary & Secondary	Product traceability, data analysis, data storage, product testing
Technology Elements	Blockchain, cloud-based, software, hardware

Assessment	
Criteria	**Factors Considered**
Interoperability	Data formatting, data sharing mechanisms, use of existing data standards
Support/Infrastructure	Cost of data collection/interpretation, training needs, devices/license/other costs borne by ancillary actors
Usability	Number of available languages for user interface, target commodities, supply chain segments
Cost Considerations	Cost of acquisition, implementation, operation/maintenance, hardware, server capacity, other licensing costs

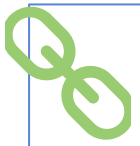
*Solution providers were not directly contacted for this review & assessment exercise.

Sector Trends

Technology and Innovation

Types of Technology

There are numerous types of technology that can be deployed in a traceability system. To highlight this point, the variety of technologies utilized by the challenge submissions ranged from cloud-based blockchain applications that could integrate with internet connected sensors and other hardware to record data automatically, on one end of the spectrum, to spreadsheet-based programs designed for farming operations. **These examples are not intended to state that one is better than another, but to illustrate how important it is to use different technologies depending on the intended outcomes.**

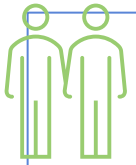


Blockchain or a distributed ledger technology are data ledgers shared by multiple entities operating on a distributed network.

Cloud Computing is on-demand access, via the internet, to computing resources hosted at a remote data center.

Mobile Apps are software applications that can be accessed on wireless computing devices.

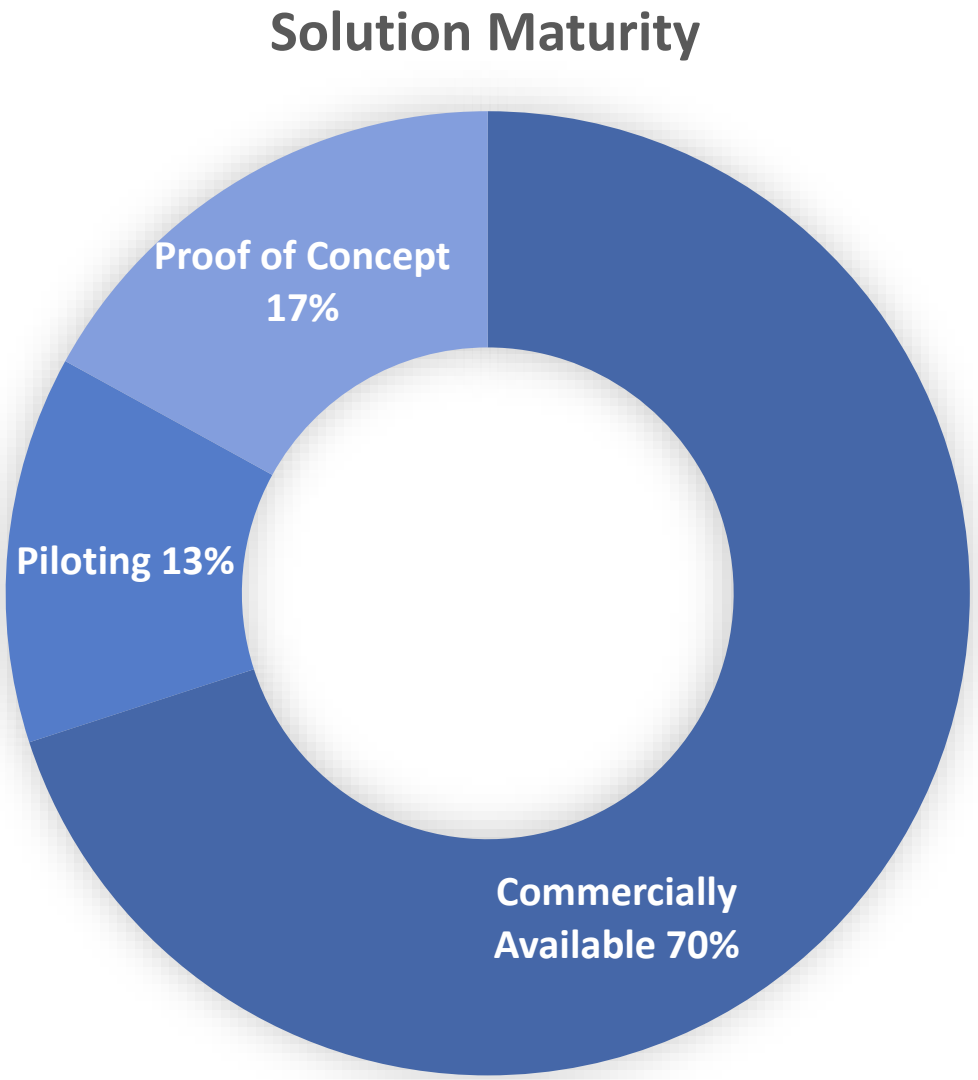
Internet of Things (IoT) refers to devices that have the capacity to automatically collect and share data such as location or environmental conditions through an internet connection.



Digital Twins are a virtual representation of real-world entities and processes, synchronized at a specified frequency.

Artificial Intelligence & Machine Learning allow computer programs to analyze and “learn” from large data sets.

Data Carriers, such as QR codes, barcodes, or RFID tags, help efficiently transfer data about a product.



Solution Innovation

In addition to new technologies being developed, the variety of submissions also made it clear that there are countless configurations of piecing together technologies and their associated functionality. Of the 90 submissions, 30% were in concept or pilot phases and not yet commercially available. **This could indicate the pressure on software providers to innovate and find new ways to relate to their customers' needs and present new ideas to the market.**

Insights and Themes

Interoperability, Support and Infrastructure, Usability, Cost Considerations

Interoperability

- **What is interoperability?**
  - Interoperability is the ability of software systems to exchange and interpret data without the need for human intervention.
- **Why is interoperability important?**
  - Interoperability is a critical component of scalability, both internally and with external partners. No single traceability solution will meet the needs of everyone, and without a basic set of rules, solutions will not be able to create efficiencies great enough to incentivize implementation. Interoperability also reduces system wide costs by:
    - Eliminating the need for custom integration between software solutions
    - Reducing the administrative burden and input errors associated with manually inputting shared data
- **How is interoperability achieved?**
  - Seamless data exchange and interpretation requires three levels of standardization:
    - Standardization of the data that is collected
    - Standardization of the data format
    - Standardization of the communications protocol that allow software to transfer information between them

Interoperability

Scoring Interoperability

Although over half of the submissions scored a 2 or 3 for interoperability it is important to note that even if two solutions scored a 3, it doesn't necessarily mean that they are interoperable with each other. Because there are multiple data formats and communications protocols that they could have aligned with, if both didn't align with the same standards, they would not be interoperable.

While further alignment around a standardized data format and communications protocol is needed, it is encouraging to see that most solutions utilized an existing data standard. This indicates a collective understanding for increasing data sharing efficiency between systems.

Key Takeaway

The FDA's Food Traceability Rule is a step towards interoperability in that it defines CTEs and KDEs. However, this model could be further standardized by stakeholders through defining data elements, formats, and communications protocols that account for other industry priorities such as waste, climate, nutrition, and other regulations.

Solution Scoring for Interoperability	
Performance Level	**Criteria**
High (3)	Does not require custom integration to communicate with other platforms, information capture AND sharing aligns with existing data standards
Medium (2)	Enables information sharing via custom integration with other platforms, information capture/sharing aligns with existing data standards
Low (1)	Enables information sharing via custom integration with other platforms, information capture/sharing does not align with existing data standards
Not Present (0)	Cannot be integrated with other platforms, information capture/sharing does not align with existing data standards

	Solution Scores			
Evaluation Category	**0**	**1**	**2**	**3**
Interoperability	2%	38%	47%	14%

Solutions' Support & Infrastructure Needs

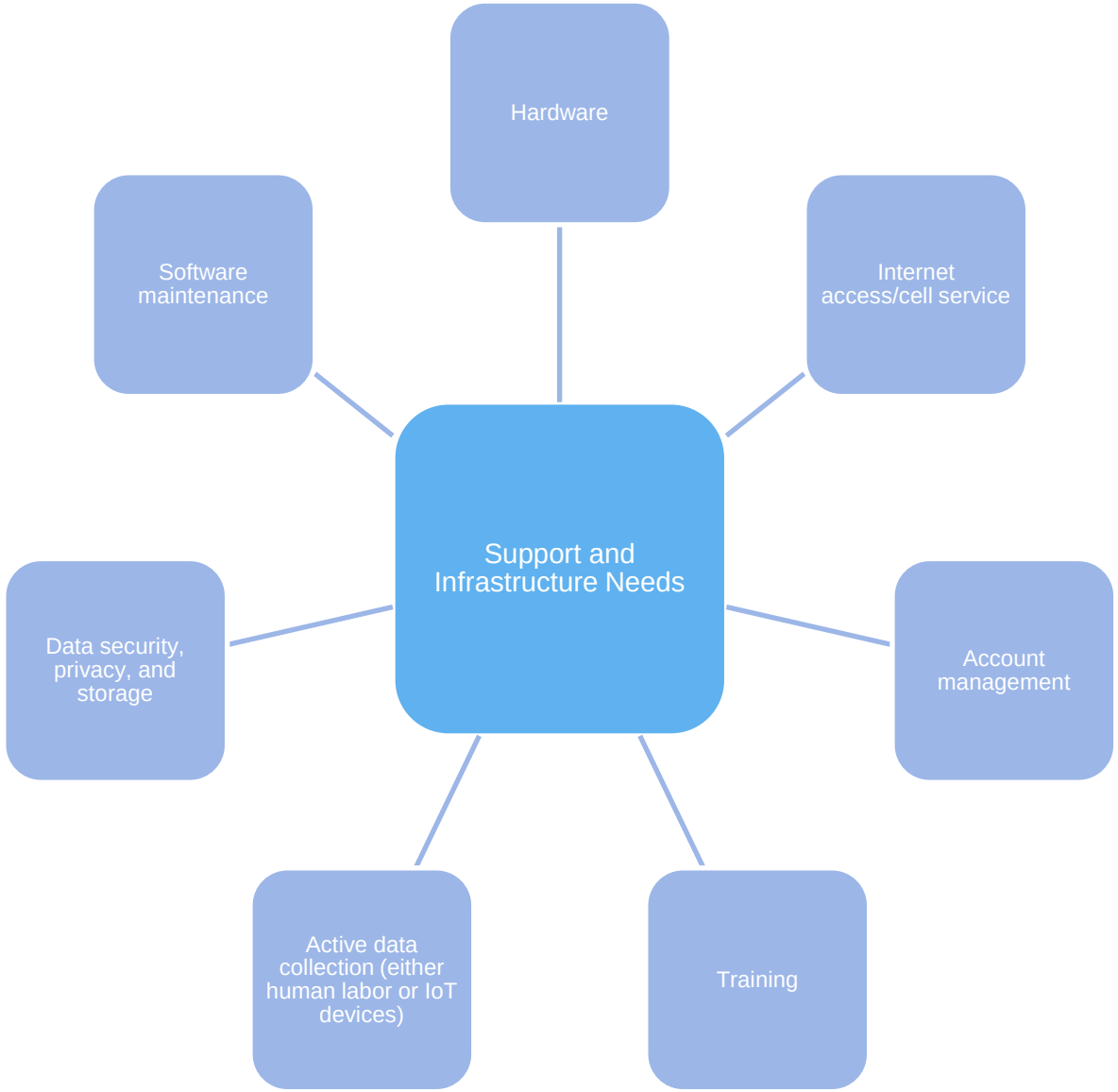
Evaluation Category	Solution Scores 0	1	2	3
Support/Infrastructure	7%	*76%*	16%	0%

Although the challenge called for low- or no-cost traceability solutions, few submissions received high scores for support/infrastructure needs. This does not necessarily indicate inadequate solutions, but reflects the costs inherent to implementing, scaling, and maintaining digital traceability systems. However, investments in digital transformation can provide benefits beyond traceability including improved supply chain visibility and efficiency, reduced recall costs, enhanced regulatory compliance, and improved risk assessments.

Solution Scoring for Support/ Infrastructure needs	
Performance Level	**Criteria**
High (3)	Low data collection/interpretation cost, low training cost
Medium (2)	Moderate data collection/interpretation cost, moderate training cost
Low (1)	Moderate data collection/interpretation cost, high training cost, requires device purchase, software licenses, other costs
Not Present (0)	High data collection/interpretation cost, high training cost, requires device purchase, software license, other costs

Solutions' Support & Infrastructure Needs

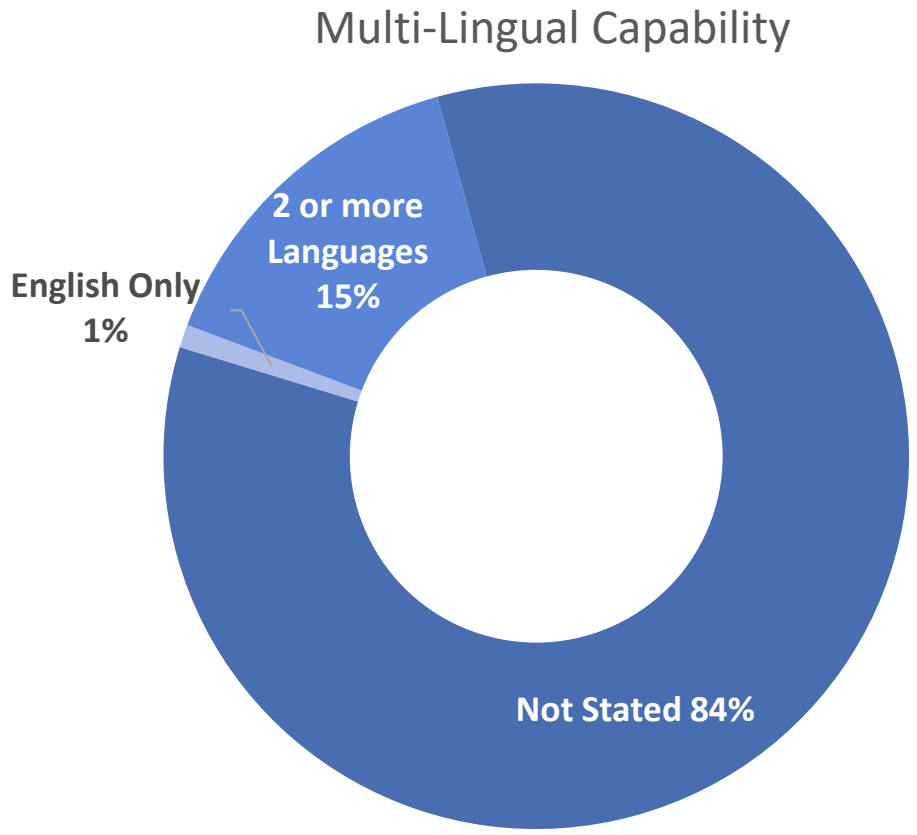
While it is important to consider the internal capacity needed to support tech enabled traceability, it is equally as important to consider the realities that may be outside of the control of a company. A primary example is internet connectivity, which can be a major concern to certain sections of the supply chain. **Therefore, it is important for solution providers to consider the support and infrastructure realities of food systems when designing products.**



Usability

Experience with different technologies for users is inconsistent and work environments may not be suitable for traditional data entry methods. Developing and designing a product that is intuitive to all levels of experience is critical and utilizing technologies such as IoT devices, natural language processing, and other AI tools could be used to increase usability.

A clear opportunity for improvement is in multi-lingual capabilities, only 15% of solutions stated they support more than one language. **In addition to language, it is important for solution providers to consider all factors that could be a barrier to usability such as working conditions, technical skills, and applicability to supply chain segments or specific commodities.**



Cost Considerations Beyond the Sticker Price

Solution purchase is only a portion of the initial traceability investment cost; users must consider the **long-term costs** of **system implementation** *and* **maintenance.**

Software License & Subscription	**Custom Software Updates**	**Data Collection**	**User Training**	**Data storage**	**Installation & Configuration**
Customization	**Integration**	**Data Migration**	**Hardware (purchase + maintenance)**	**IT Support**	**Tech Infrastructure***

*Indirect Cost

Similarly, to Support and Infrastructure costs, these apply to a general digital transformation of a business and provide company-wide benefits beyond increased traceability.

Closing Recommendations

Bridging the Gap –

Getting to end-to-end traceability throughout the food system

Interoperability

Progress still needs to be made in expanding traceability for food safety, environmental, climate, nutrition, and labor purposes and aligning tech solutions around data, formatting, and communications standards.

Support and Infrastructure

Investing in infrastructure and support is critical for participation, therefore it is important that investment in the digital transformation is equitably distributed amongst all stakeholders that stand to gain from it.

Usability

Food systems employ a wide variety of people with different language skills, experience with technology, and/or working in settings not conducive for data entry. It is important to creatively design solutions with these end users in mind to ensure valuable data is captured correctly and consistently.

Cost Considerations

Transparency and due diligence around expectations for technology life-cycle costs will help investors evaluate risk and plan for the future. It is also important that cost effective solutions continue to be developed for all user types.

Tech-enabled traceability and progress towards end-to-end traceability

Food supply chains are designed to move product to people as cost effectively as possible. However, as the food system has been optimized for cost and profitability, it has globalized and lengthened, and its ability to move information about products has not kept up with the pace of change. This has put a strain on the ability to pinpoint the who, what, when, and where a product was produced. To remedy the data issue, the private sector looked to technology. As of a decade ago, the tech sector had developed many tech-enabled, cloud-based, commodity-specific solutions to support industry actors in addressing their internal data collection needs. However, timely and accurate traceability data sharing between trading partners, or between private sector entities and regulatory bodies remained challenging.

Over the past decade, there has been an even greater proliferation of private sector solutions, with advances in methodologies and diversification of use cases with solutions leveraging technologies like blockchain, mobile apps, and others. However, in the US, there have also been profound shifts in the structure and sourcing of our food supply, with marked shifts in production of foods to other countries. These shifts highlight the importance of creating solutions that are accessible to a diverse set of users and capable of supporting accurate transmission of data between multiple supply chain segments and regulatory partners to achieve timely, end-to-end traceability.

Today, using the Traceability Challenge as the barometer, solution providers are taking steps in the right direction, but continue to chase the everchanging food system. However, there are clear opportunities for future-proofing against these changes to achieve digital, interoperable traceability in food supply chains. The technology needed to achieve this is available and solutions are adapting to the requirements of their customers. Further action should be taken to clearly define the shared goals for traceability as well as costs associated with the life-cycle of investing in a systems. Support and infrastructure is still lacking in certain geographies and programs should be designed to ensure that digital traceability is accessible regardless of supply chain segment, commodity, or size of operation. The FDA's Traceability Rule provides the industry with a starting point by defining the critical tracking events and key data elements related to food safety, but this should be expanded, by all stakeholders, to realize the widely accepted goals for improving climate, nutrition, labor practices, and elimination of fraud and waste that are important to us all as consumers.

The knowledge, means, and technology have been developed to make end-to-end tech-enabled traceability a reality, but it will not be realized without collective action and continued innovation.

Appendix

Appendix A – Qualitative Categorization of Submitted Solutions' Target Customer Base

Figure 1. Supply Chain Segment(s) Targeted by Submitted Solutions

Supply Chain Segment	% Solutions
Full-Chain (all segments)	45%
Multiple Segments	26%
Single-Segment	29%

Figure 2. Segments Targeted by Single-Segment Solutions

Target Segment	% Solutions
Producers	44%
Manufacturers	36%
Distributors	4%
Retailers	16%

Figure 3. Commodities Targeted by Submitted Solutions

Target Commodity	% Solutions
Non-specific	59%
Produce	19%
Meat	7%
Seafood	6%
Grain	3%
Other*	7%

*Commodity-specific solutions that comprised <2% of solutions

Appendix B – Qualitative Categorization of Solution Purpose & Function

Figure 4 – Types of Submitted Solutions

Solution Type	% Solutions
Traceability Only	21%
Traceability + Additional Function(s)	50%
Traceability Adjacent/Support	29%

Figure 5 – Primary Purpose of Submitted Solutions

Purpose	% Solutions
Track & Trace	44%
Data storage/sharing/analysis	15%
Data Carriers/Physical Tracking Tag	10%
Business/Supply Chain Management	9%
Food Safety and Quality Management	9%
Product Verification/ Validation/Authentication	9%
Product Marketing/Consumer Engagement	3%
Document Management	1%
Farm/Field Management	1%

Appendix C – Qualitative Summary of References to Data Governance Among Submitted Solutions

Figure 6 – Data Standards Referenced by Submitted Solutions

Data Standard	% Solutions
No Standards	46%
GS1- Unspecified	26%
GS1 - EPCIS	24%
GS1 - Digital Link	7%
PTI Case Label	6%
GS1 Barcode Standards (General Specs)	4%
OriginTrail	2%
Other	7%

Figure 7 – Data Communication Mechanisms Used by Submitted Solutions

Data Communication Mechanism	% Solutions
Not Stated	79%
Open/Public API	11%
Custom Integration	6%
GS1 Digital Link	4%

Figure 8 – References to Data Security Among Submitted Solutions

Reference Type	% Solutions
Permissioned Access	13%
Data Security	12%
Data Privacy	7%

Appendix D – Supplementary Explanations: Cost Considerations for Traceability Solution Users

Software License & Subscription	Includes recurring subscription fees and/or licensing fee required to access the software and any updates published by the solution provider.
Custom Software Updates	Includes expenses related to development and maintenance of custom software products created specifically for the user.
Data Collection	Includes expenses associated with the resources (e.g., human labor, IoT devices) required to collect and process data.
User Training	Includes expenses associated with training personnel responsible for data collection; data verification, validation & analysis; data management & security; and digital system maintenance.
Data Storage	Includes expenses associated with cloud and/or on-premises storage and maintenance of digital data.
Installation & Configuration	Includes expenses associated with setting up software, configuring its settings, and ensuring compatibility with necessary hardware for a specific user(s) system.
Customization	Includes expenses related to modifications made to existing “off-the-shelf” software products to better fit the needs of software users.
Integration	Includes expenses associated with development and maintenance of mechanisms (e.g., APIs) that ensure the user’s software system can “talk” to other necessary software systems (e.g., trading partner’s systems, internal CRM system, data analysis software).
Data Migration	Includes expenses associated with moving data between storage systems, data formats, or applications.
Hardware	Includes expenses associated with the initial purchase and ongoing maintenance of hardware (e.g., computers, scanners, printers, smartphones) needed to use a software system.
IT Support	Includes expenses associated with personnel that manage technical assistance or maintenance services (e.g., user setup, system updates/repairs, security measures) for software users.
Tech Infrastructure	Includes direct and indirect expenses associated with access to and upkeep of the technological infrastructure required to use a specific software (e.g., internet connectivity, cellular service).

Appendix E – Supplementary Explanations: System-Wide Support and Infrastructure Costs

Hardware	Includes the development of physical equipment needed to measure, record, and transmit data
Internet Access/Cell Service	Includes the need for consistent access to the internet regardless of geographic location.
Account Management	Includes user account managers as well as a software provider's account manager that oversees that the needs of the user are being met.
Training	Includes generalized training related to industry, policy-makers, regulators, software developers, and other stakeholders on traceability concepts and best practices.
Active data collection	Includes development of scalable data collection methods to help reduce the burden on individual stakeholders.
Data Security, privacy, and storage	Includes the software industry's collective effort to maintain best practices concerning protection of supply chain data stored and shared between systems.
Software Maintenance	Includes industry best practices for clearly communicating software maintenance and life-cycle costs