FEED THE FUTURE
The U.S. Government's Global Hunger & Food Security Initiative

FEED THE FUTURE ENABLING ENVIRONMENT FOR FOOD SECURITY PROJECT

THE ENABLING ENVIRONMENT FOR FOOD TRACEABILITY SYSTEM SUCCESS:

ASSESSING FACTORS THAT SUPPORT FOOD SAFETY, QUALITY, AND INTEGRITY

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FROM THE AMERICAN PEOPLE

CONTENTS

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ACRONYM LIST

ANVISA	Brazilian Health Regulatory Agency
AU	African Union
BANA	Feed the Future Bangladesh Aquaculture and Nutrition Activity
BRC	British Retail Consortium
BSE	Bovine Spongiform Encephalopathy
CTE	Critical tracking event
DLT	Distributed Ledger Technology
EFSA	European Food Safety Authority
ERP	Enterprise resource planning
ESE	eServices Everywhere
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FMIA	Federal Meat Inspection Act
FSMA	Food Safety Modernization Act
FTL	Food Traceability List
FTS	Food traceability system
GFSI	Global Food Safety Initiative
GINC	Global Identification Number for Consignment
GLN	Global Location Number
GTIN	Global Trade Item Number
HACCP	Hazard Analysis and Critical Control Points
ICT	Information and communications technology
IFS	International Featured Standard
IFSSP	Improving Food Safety Systems Project
IP	Implementing Partners
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
ISPMs	International Standards for Phytosanitary Measures
IUU	Illegal, unreported, and unregulated
KDE	Key data element
LDC	Less-developed countries
MAPA	Brazilian Ministry of Agriculture, Livestock and Food Supply
NGO	Non-governmental organization
OIE	World Organisation for Animal Health
QR	Quick response (code)
RASFF	Rapid Alert System for Food and Feed
RFID	Radio frequency identification
SGTIN	Serialized GTIN
SPS	Sanitary and Phytosanitary
SQF	Safe Quality Food
SQFI	Safe Quality Food Institute
TBT	Technical Barriers to Trade
TRACES	Trade Control and Expert System
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wide Fund for Nature

I. EXECUTIVE SUMMARY

Widespread adoption of food traceability systems (FTS) holds the potential to provide several benefits for agricultural market systems, including mitigating food safety risks, improving market access, and increasing productivity gains. Improvements in supply chain transparency from FTS adoption can also lead to an expansion of mutually beneficial trade between countries.

While the uptake of FTS is relatively ubiquitous in developed countries and globally integrated supply chains, adoption among developing country food operators continues to lag. This places developing country food operators, including those in Feed the Future countries, at a competitive disadvantage in market channels that increasingly require traceability, and raises the risks of food contamination and fraud for consumers. These risks pose not only public health implications, but also significant economic costs.

Developing country food systems would particularly benefit from the adoption of FTS, as these countries bear a significant share of the global burden of foodborne illnesses, and rely heavily on the competitiveness of their food operators for employment, smallholder supplier income, and foreign exchange generation. By supporting the introduction, adoption, and implementation of FTS in developing countries, USAID and its implementing partners (IPs) can advance several U.S. Government (USG) development priorities.

For instance, **The USG Global Food Security Strategy (GFSS)** calls for "investing to link producers and other agribusinesses in the food system to end markets" (IR2) and "building capacity to improve food safety policies, guidelines, and enforcement" (IR5).[1] The **United States Agency for International Development's (USAID) Multi-sectoral Nutrition Strategy** highlights the need to "strengthen food supply chain…capacity to ensure high-quality, safe food," and to "promote…transparency within the national food systems and enforcement of global standards."[2] **USAID's Digital Strategy** calls to "strengthen the critical components of digital ecosystems…a sound enabling environment and policy commitment; robust and resilient digital infrastructure; capable digital service providers and workforce; and, ultimately, empowered end-users of digitally enabled services."[3]

To advance these strategies, it is first necessary to understand the factors that drive adoption and successful implementation of FTS. This report finds that the low level of FTS adoption by food operators in developing country market systems is in part a function of the following four factors:

- **Operator incentives** include the role of mandatory regulations — driven by public policy objectives and enforcement capacity – as well as voluntary market standards — driven by increased consumer demand for verifiable food safety, quality, integrity, and origin.
- **Operator capacity** includes the knowledge and skills to implement a FTS properly, as well as the access to financial resources to put one in place.
- **Operator access to technology** includes the local availability of a user-friendly platform to meet objectives/requirements, as well as information and communication technology (ICT) infrastructure, which influences rural connectivity, reliability, and speed.
- **Supply chain coordination** includes the willingness of vertical partners to agree on a shared FTS technology or different technologies capable of sharing information up and down the chain as required by prevailing regulations and/or standards.

Where USAID and its IPs endeavor to support the uptake of FTS in developing countries, these enabling environment factors should be examined closely. For instance, reviewing the prevailing regulations and/or voluntary standards within a given market channel will present the specific traceability requirements (or

[1] "U.S. Government Global Food Security Strategy FY 2017-2021" September 2016. https://www.usaid.gov/sites/default/files/documents/1867/USG-Global-Food-Security-Strategy-2016.pdf.
[2] USAID, "USAID Multi-Sectoral Nutrition Strategy 20214-2024," https://www.usaid.gov/sites/default/files/documents/1867/USAID_Nutrition_Strategy_5-09_508.pdf.
[3] USAID, "USAID Digital Strategy 2020-2024," https://www.usaid.gov/sites/default/files/documents/15396/USAID_Digital_Strategy.pdf.

absence thereof) which operators must follow to be in compliance. These requirements will inform the necessary functionality of a FTS, and therefore the appropriate technology platform to support it.

This study presents the specific traceability requirements according to the existing regulatory regimes of the U.S., EU, and Japan for the following reasons:

- To illustrate different regulatory models/approaches for developing countries to improve their food safety and traceability rules.
- To demonstrate how consumer concerns and food operator interests often shape regulatory reforms related to food safety and traceability.
- To provide practical guidance for food operators on the traceability requirements to access these high-value end markets.

The report also presents the specific traceability requirements of several private voluntary standard systems, including Global Food Safety Initiative (GFSI), GLOBALG.A.P., BRC Global Standards, International Featured Standard (IFS), Safe Quality Food Institute (SQFI), and the GS1 Global Traceability Standard. In addition, the report presents the traceability requirements of several reference standards and/or guidelines provided by international organizations, including the World Trade Organization (WTO), Food and Agriculture Organization of the United Nations (FAO), Codex Alimentarius, International Plant Protection Convention (IPPC), and the World Organisation for Animal Health (OIE).

The traceability requirements across various regulation, standards, and guidelines demonstrate the importance of customizing FTS design solutions based on the target market channel. FTS designs should consider at least four critical dimensions: **data entry method, data granularity, distance data travels, and data storage**. These four dimensions are discussed in detail, and examples of different designs are presented according to the operator objectives, market requirements, operator capacity, access to technology, and degree of supply chain coordination.

Distributed ledger technologies (DLTs), such as blockchain, have been attracting significant interest recently, given their potential to disrupt and transform how transactions are made, recorded, and shared between suppliers and buyers. While DLTs offer certain advantages over other digitally enabled traceability systems, including strengthening the integrity and reliability of data storage, these technologies may not be appropriate, or necessary, depending on the enabling environment factors within a target market system. Where DLTs are found to be inappropriate or unnecessary given the enabling environment context, then alternative digitally enabled technologies can be capable of delivering the data granularity, data sharing, and data storage requirements necessary to be in compliance with prevailing regulations and/or standards.

In market systems where food operator incentives, capacity, access to technology, and supply chain coordination remains weak, the uptake and successful implementation of FTS by food operators is expected to be low. In these contexts, USAID and IPs should consider foundational investments to improve these enabling environment factors prior to, or in tandem with, the introduction of FTS. To demonstrate this importance, this study presents several short case studies from across developing country market systems, summarizing factors that enabled or inhibited the uptake of FTS.

By first conducting a comprehensive analysis of the enabling environment for traceability in a given country and market channel, USAID and its IPs will uncover the investments needed to improve FTS uptake. This study presents in detail these various factors influencing FTS uptake to inform analysis prior to FTS investment. These investments may include not only an appropriate technology platform, but also national regulatory reforms, enterprise-level technical capacity building, consumer awareness campaigns, rural ICT infrastructure expansion, and industry association strengthening to promote information sharing between vertical supply chain partners.

For readers seeking background learning and basic concepts related to food traceability, please also refer to Annex 1.

2. THE EMERGENCE AND EVOLUTION OF FOOD TRACEABILITY

Traceability systems have evolved throughout the history of global food production and trade. The features of food traceability systems across this evolution have been shaped in parallel with an increasing understanding of risk, technological capacity, consumer expectations, the role of the private sector, and the ability and willingness of authorities to respond with appropriately targeted regulations.

In today's food systems, a food operator's ability to comply with food traceability requirements will affect its access to markets both at home and abroad. Border control measures typically require certification of the origin of the imported product, along with additional information confirming that the place of origin is certified as safe, that exports of relevant animals have disease-free status,[4] and that exports of relevant plants exported are free of contamination or infestation. Each country's regulatory agencies will have differences in their food traceability requirements for both imports and domestically produced goods. In addition, the private sector has played a leading role in shaping voluntary standards in response to increasing consumer awareness of food safety, environmental, and ethical concerns.

In the early stages of global food trade systems, food products were primarily derived from local food supplies, and therefore the origin of products was well known by food operators and consumers. As the world became increasingly connected and the transport of perishable goods could reach much larger distances, the sense of origin became more important. While this shift led to a greater variety of products,[5] it also led to an increased risk of pests, diseases, and other contaminants being introduced from outside a local food system.

Arguably, one of the earliest forms of government-required tracing systems, trade tariffs, dates back at least 2,500 years.[9] As the complexity of global food supply chains grew and foodborne diseases spread, food traceability initiatives expanded and became more sophisticated. By the mid-1950s, several technological advancements enabled an increased sophistication of food traceability systems, such as barcodes and Radio Frequency Identification (RFID).

What is a Food Traceability System (FTS)?

An FTS is a tool that allows food operators to track food ingredients and/or finished food products throughout their entire lifecycle, using captured and stored records including key data elements (KDEs) and critical tracking events (CTEs).[6] KDEs record the who, what, where, when at each step of the chain, and CTEs record the completion of a step in the supply chain.[7]

What is a Food Operator?

A for-profit or not-for-profit entity involved in the production, processing, packaging, trading, distribution, and/or sale at any stage of the food chain.[8] According to many national regulations around the world, the food operator has the primary role and responsibility for managing the food safety of their products and for complying with related regulatory requirements. While the EU Food Law and other regulations/standards may use the term "food business operator," this study uses the term "food operator."

For more background and key concepts on FTS, See Annex 1: Key Questions and Answers on FTS

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[4] Quote: "Establishing and Maintaining a Disease-Free Status Throughout the Country Should Be the Final Goal for Member Countries." from OIE, "Terrestrial Animal Health Code — Chapter 4.4. Application of Compartmentalisation." Accessed November 18, 2020. https://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/2018/en_chapitre_application_compartment.htm.

[5] Behnkea, Kay, M.F.W.H.A. Janssen (Marijn), "Boundary Conditions for Traceability in Food Supply Chains Using Blockchain Technology," International Journal of Information Management 52, no. 2 (2020): 101969. https://doi.org/10.1016/j.ijinfomgt.2019.05.025.

[6] IFT, "About the Global Food Traceability Center and FAQs." https://www.ift.org/global-food-traceabilitycenter/about-gftc.

[7] GS1, "GS1 Global Traceability Standard," https://www.gs1.org/standards/gs1-global-traceability-standard#3-Traceability-data-and-traceability-systems+3-1-Traceability-data-within-an-organisation.

[8] Gardner, Sherwin, "Consumers and Food Safety: A Food Industry Perspective," http://www.fao.org/3/v2890t/v2890t05.htm.

[9] Michel, Cécile. "The Assyrian Textile Trade in Anatolia (19th century BCE): From Traded Goods to Prestigious Gifts." in Textile Trade and Distribution in Antiquity, ed. Kerstin Dross-Krüpe, 14. Textilhandel und -distribution in der Antike, Harrassowitz Verlag, 2014.

In 1987, the International Standards Organization (ISO) defined traceability as **"the ability to retrieve history, use or location of an entity, activity, a process, a product, an organization or a person by means of recorded identifications,"** which later informed the ISO 8402:1994 standard.[10]

By this time, the demand for food traceability had grown as consumers in developed countries became increasingly aware of food safety issues. In 1996, the discussion on food traceability regulation came into focus in Europe. The Bovine Spongiform Encephalopathy (BSE) crisis led the European Union (EU) to enact the General Food Law 178/2002 which became active in 2005.[15] Europe's food traceability initiative covered all imported and exported foods and feed, and therefore had a significant impact on global food trade and demonstrated the weaknesses of existing food traceability systems in the global supply chain.

Many other developed countries have advanced their own policy initiatives to address safe global food trade, including the U.S. Food Modernization and Safety Act (FSMA, 2011); the U.S. Bioterrorism Act (2001, H.R. 3448); South Korea's Full Beef traceability system (GAIN Report N° KS1033. 2010); and Canada's National Agriculture and Food Traceability system (Center for food in Canada 2012),[16] among others.[17]

Understanding Food Protection

The food protection system includes food quality, food safety, food fraud, and food defense.[11]

Food safety refers to all hazards that make food injurious to the consumer's health. It is not negotiable.

Food quality "includes all other attributes that influence a product's value to the consumer,"[12] including origin, color, flavor, texture, spoilage, cleanliness, odor, etc.

Food fraud refers to "economically motivated intentional adulteration that may or may not make the food injurious to health."[13]

Food defense can be defined as "intentional adulteration from acts intended to cause wide-scale harm to public health."[14]

In parallel to enhanced regulations and consumer awareness in developed economies, global food supply chains increased in specialization and complexity. These changes spurred the development and broad uptake of new digital technologies, such as Quick Response (QR) codes, and more recently DLT as a means of enabling more sophisticated and trustworthy food traceability. Many national regulations and private voluntary standards came to require seamless information exchange between supply chain partners which functionally requires the adoption of more advanced digital technologies.

These regulatory and demand-side changes in developed countries provided an incentive, or requirement, for global supply chain actors — including export-oriented food operators in developing countries — to comply by adopting modern, digitally enabled traceability systems. Nonetheless, while many global food operators have adapted to these changes, traceability is rarely a feature of domestic food markets in least developed countries, apart from an emerging supermarket segment in primarily urban areas experiencing middle-class consumer growth.

The challenges of traceability remain far higher in developing country market contexts, given supply chain dynamics as well as weak investment incentives. Structural characteristics and relationship dynamics in

[10] Ene, Corina. "The Relevance of Traceability in the Food Chain," *Economics of Agriculture* 2 (2013): 287-297. https://ageconsearch.umn.edu/record/152808/files/6%20-%20Ene.pdf.

[11] Spink, John and Douglas C. Moyer, "Defining the Public Health Threat of Food Fraud," *Concise Reviews in Food Science* 76, no. 9 (2011): 157, https://doi.org/10.1111/j.1750-3841.2011.02417.x.

[12] Food and Agriculture Organization of the United Nations and the World Health Organization, "Important Food Issues" in *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control System*, Food and Nutrition Paper 76. Rome: 2003. http://www.fao.org/3/y8705e/y8705e03.htm#bm03.1.

[13] Ibid.

[14] U.S. Food and Drug Administration, "FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration." Last modified October 21, 2020. https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-mitigation-strategies-protect-food-against-intentional-adulteration.

[15] Montet, Didier and Gargi Dey, "History of Food Traceability," in *Food Traceability and Authenticity: Analytical Techniques*, eds. Didier Montet and Ramesh C. Ray, 15. CRC Press, Taylor &Francis Group, 2018.

[16] Ibid. 9.

[17] See Section 6: The Role of Laws/Regulations for a detailed explanation of the traceability requirements in key legislative initiatives in the U.S. and EU.

less developed country market systems play a key role, including a disaggregated primary producer supply base, and a typically low-trust environment inhibiting supply chain cooperation. The incentives for FTS adoption in developing market channels are weak in part because of limited consumer awareness, demand, and/or purchasing power for traceable foods.

In developing countries where consumer demand for foods that meet safety, environmental, and/or social objectives remains low, retailers place fewer (if any) traceability burdens on their suppliers. Similarly, policymakers may place less emphasis on stronger regulations and/or regulatory enforcement in fear of upward pressure on food prices. Where supply chain requirements for traceability remain low, operators rarely adopt FTS unilaterally, given the perceived absence of benefits for doing so and/or disincentives for failing to do so.

2.1 CHALLENGES FOR FOOD TRACEABILITY SYSTEMS: SUPPLY CHAIN COMPLEXITY

The increased connectivity between global food markets plays an important role in providing a wide range of products to expand consumer access to diverse foods; however, that has also led to a more complex and integrated global food system. According to the First FAO/World Health Organization (WHO)/AU International Food Safety Conference "it is not uncommon for a food product to be produced in China, packaged in the USA and sold in Sweden, all under license to a UK firm that is African owned."[18]

A traditional supply chain comprises linear steps: (i) Primary production; (ii) Processing; (iii) Distribution; (iv) Retailing; (v) Consumption. However, in today's global food system, these simplified stages are only valid for a small portion of products and markets, with an increasing number of actors and source origins involved in a supply chain.[19,20]

The dairy industry is a good example of this complexity. In a large-scale milk production factory, raw milk may come from thousands of farmers then be distributed to hundreds of locations for wholesale and/or retail. Instead of a linear food chain, we find a pattern more resembling a lattice. Consider the various industries globally which utilize dairy products as ingredients, and therefore rely on milk production. When any of these numerous channels faces a contamination problem, they need to be able to trace the origin of each product and its inputs backward to their source and forward to their consumers.

Each step forward and backward throughout these complex food channels must be traceable. As a result, both suppliers and buyers all along these chains face challenges in keeping accurate and accessible records to ensure the protection of food in all its pillars (food quality, food safety, food fraud, and food defense).

Additionally, these actors must adhere to a web of regulations emanating from several countries while often abiding by internationally accepted voluntary standards. This increasingly complex market context reinforces the need for **digitally enabled technologies** to address these challenges. Food operators and regulators in Feed the Future countries and other least developed countries have a particularly challenging road ahead to expand international market access and improve domestic food safety for both economic growth and nutritional objectives.

2.2 GENERAL APPROACHES TO TRACEABILITY

Just as important as ***what*** that should be traced, is ***how*** traceability systems should trace required information. Special care should be made in designing and implementing a traceability system that can meet

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[18] Manning, Louise and Jan Mei Soon, "Food Safety, Food Fraud, and Food Defense: A Fast Evolving Literature," *Journal of Food Science* 81, no. 4 (2016): 158. https://doi.org/10.1111/1750-3841.13256.

[19] Kamilaris, Andreas et al. "The Rise of Blockchain Technology in Agriculture and Food Supply Chains," https://arxiv.org/ftp/arxiv/papers/1908/1908.07391.pdf.

[20] Kay Behnkea, M.F.W.H.A. Janssen (Marijn), "Boundary Conditions for Traceability in Food Supply Chains Using Blockchain Technology," *International Journal of Information Management* 52, (June 2020): 2. https://doi.org/10.1016/j.ijinfomgt.2019.05.025.

stated objectives with the speed, reliability, and effort commensurate with the risks posed; the technical capacity of the user; and the resources available (including access to finance and technological infrastructure). There are five general approaches, or models, for traceability in today's global food system according to the GS1 Global Traceability Standard, as summarized in Table 1 below.[21]

Table 1: GS1's Five Traceability Approaches

Traceability System Models	Description
One-Up, One-Down[22]	Actors involved in the food chain keep records identifying immediate recipients ("one-up") and immediate suppliers ("one-down"), so that authorities may quickly access needed information, particularly when public health is threatened. This model is the one most commonly accepted in national legislation, multilateral trade agreements, instruments of international food organizations, and border control documentation requirements.
Centralized	All relevant parties share traceability data in a central database. All actors in the supply chain, and government authorities have access to the data stored. The EU's TRACES System and other single window systems are examples of the centralized model.
Networked Model	Each actor maintains its own database, and all actors throughout the supply chain (not only immediate suppliers and recipients) have access to the data.
Cumulative Scenario	A food actor maintains comprehensive records of all the inputs joining the supply chain stretching back to initial production, and then passes this information forward to the next recipient in the supply chain. The system consolidates all the data from previously collected in the supply chain and sends it forward.
Fully Decentralized and Replicated	DLT-enabled (including blockchain) systems where all traceability data is systematically entered by supply chain partners in the network and accessible to others. This model is considered a mix of the cumulative model and the networked model.

3. OBJECTIVES AND MOTIVATIONS OF FOOD TRACEABILITY

An effective FTS can achieve several objectives for food operators and regulators. The motivation for private food operators and/or public sector regulators to adopt these systems will vary based on specific enabling environment factors including market dynamics, consumer demand, regulatory requirements, and industry standards.

Achieving the objectives will depend on the type/model of FTS utilized, which was briefly introduced in the previous Section 2, and will be discussed in greater detail in the following Section 4. Table 2 below details potential objectives and motivations for the adoption of an FTS, and contextual considerations for the successful implementation of an FTS.

Table 2: Objectives, Motivations, and Context for FTS Investment

Objective	Motivation	Context
Mitigate food safety risks	– Minimize number/scale and cost of recalls. – Protect public health. – Mitigate brand risks. – Increase consumer trust.	The responsibility for protecting consumers from contaminated or adulterated food ultimately falls on the food operator (producer, processor, distributor, etc.). The consequences will vary across countries depending on legal responsibilities (penalties, charges) and consumer response. The potential consequences however are clear, including

[21] David Buckley. "GS1 Global Traceability Standard" GS1, December 18, 2019. https://www.gs1.org/standards/gs1-global-traceability-standard#3-Traceability-data-and-traceability-systems+3-3-Managing-traceability-data.

[22] Also sometimes referred to as "one-up, one-back" system and/or the "one-up, one-down" system.

Table 2: Objectives, Motivations, and Context for FTS Investment

Objective	Motivation	Context
	– Identify problems before production or distribution.	impact on public health, financial loss, criminal charges, and/or mistrust from consumers and trade partners.
Meet regulatory requirements	– Authorization to bring your products into market	Developed countries have strict traceability rules and require a high level of control and monitoring from food operators. In low-income countries, local regulation might not be sufficient to drive this objective. Where this is the case, this objective is most relevant to food operators that aim to export to markets with strong regulatory regimes or to domestic market channels where consumers are increasingly discerning.
Meet consumer demands	– Market position – Revenue increase – Enhance brand and market value – Increase consumer trust	Depends on the consumer awareness, expectations, purchasing power, and demand feedback loop (will they alter their consumption decisions based on improved food safety, ethics, etc.). In emerging and developing countries, there is a growing segment of consumers able to afford and prioritize the choice of foods that deliver the aspects they value most.
Meet supply chain partner requirements	– Ensure quality/safety – Integrity of data across supply chain – Enhanced trust among supply chain actors – Expand market opportunity	The standards required of a supplier are directly related to the motivations of the next operator in the chain, including regulatory compliance and meeting consumer requirements and their own brand image. As a consequence, supply chain coordination is more prevalent in developed country food systems, whereas systems in lower-income countries may prioritize lower costs to meet consumer purchasing power.
Establish brand identity, values, and principles	– Define what the brand stands for (quality, purpose, etc.) – Establish brand loyalty – Increase market value and revenue	In high-income countries consumers are often motivated by purpose and meaning. In emerging and developing countries there are a high portion of the population at the base of the pyramid prioritizing immediate needs, although the emerging middle class is resulting in increased brand awareness and loyalty.
Comply with voluntary standards (certification schemes, etc.)	– Access new market channels – Improve consumers' perceptions	In developed countries, standards compliance (e.g., obtaining certification) may be the norm, whereas in emerging and developing countries achieving certification may differentiate from domestic competitors, or open access to export markets otherwise unavailable. However, the costs of implementing and maintaining the standards required by the certification bodies may be prohibitively expensive when operating in low-income country domestic markets. Therefore, higher value exports to developed countries is often an initial incentive to invest in standards compliance.
Optimize Production	– Companies gain insights into their process and their suppliers' process, leading to identifying opportunities for operational improvement such as reducing costs, reducing waste, and improving efficiency.	In developed countries, the use of new technologies advances the ability to connect systems and optimize processes. However, in emerging and developing countries there is a technology, infrastructure, and capacity gap for food operators to take full advantage of data to drive decisions and optimize their production.

3.1 IMPLICATIONS FOR THE ADOPTION OF DIGITAL TRACEABILITY TECHNOLOGIES

As Table 2 demonstrates, there are several different motivations for food operators to invest in FTS, many of which are driven by the enabling environment — including formal rules, such as regulations or standards, as well as informal norms, such as consumer preferences. Even the most advanced FTS designs, which include DLT such as blockchain, are also driven mostly by the same motivations; however, the operational, infrastructure, and institutional capacity requirements to successfully do so are greater. As one study posits, "blockchain implementation will be primarily driven to improve speed and fidelity of traceability to protect brands (private action) and the public (regulator action) from food safety issues."[25]

What are DLTs and Blockchain?

Distributed Ledger Technology (DLT): "a novel and fast-evolving approach to recording and sharing data across multiple data stores (or ledgers)… allows for transactions and data to be recorded, shared, and synchronized across a distributed network of different network participants."[23]

Blockchain: "a particular type of data structure used in some distributed ledgers that stores and transmits data in packages called 'blocks' connected to each other in a digital 'chain'…employs cryptographic and algorithmic methods to record and synchronize data across a network in an immutable manner."[24]

Naturally, the design of the FTS, including the technology utilized, impacts how much can be achieved in each one of the objectives discussed in Section 3. Access to, and the capacity to implement such technologies, will vary across context. Many developing countries may not have the full range of technologies available, the necessary infrastructure, or the incentives (via regulatory framework and/or market-led standards) to enable food operators to adopt and successfully implement digitally enabled food traceability systems.

Section 4 below provides a more detailed discussion of different dimensions of FTS design, the technological requirements for each, their benefits and limitations, including the requirements for success.

4. THE ROLE OF TECHNOLOGY

The design of a FTS, including the technology utilized, plays an important role in enabling food operators and regulators to achieve their objectives. Importantly, as the supply chain becomes longer and more complex, the functionality and sophistication of the FTS must increase to achieve the same objectives. The design of an FTS can be organized, or structured according to the following four dimensions, which define the potential functionality of the system:

1. **Data Entry Method:** Manual or automated data entry.
2. **Distance Data Travels:** One step back and one step forward, many steps back and one step forward, or many steps back and many steps forward.
3. **Data Granularity:** Per lot (batch) or unit.
4. **Data Storage:** Paper, central database, or DLT.

Table 3 below presents the functionalities, benefits, limitations, and requirements of each of these four dimensions. The requirements presented are not exhaustive, but should raise awareness of factors that need to be considered. Any combination of dimensions calls for consideration of requirements of each of the dimensions to be applied. Table 4 presents several such potential combinations (e.g. designs).

[23] World Bank Group, "Distributed Ledger Technology (DLT) and Blockchain," FinTech Note, no.1 (2017): IV, http://documents1.worldbank.org/curated/en/177911513714062215/pdf/122140-WP-PUBLIC-Distributed-Ledger-Technology-and-Blockchain-Fintech-Notes.pdf.
[24] Ibid.
[25] Pearsona, Simon et al. "Are Distributed Ledger Technologies the Panacea for Food Traceability?" *Global Food Security* 20, (2020):149. https://doi.org/10.1016/j.gfs.2019.02.002.

Table 3: Four Dimensions of Food Traceability Technology

Dimension	Functionality	Benefit	Limitation	Requirements
1. Data Entry Method	Manual	Easy to implement	– Human error, limited amount of info, data can be manipulated	Data entry training
	Automated	Less prone to errors, fast, allows more detailed data, rapid response when issue observed	– Time and cost of implementation and maintenance – Information gap if system fails, revert to manual approach if failure	Financial resources, energy and internet connectivity, access to technology
2. Distance Data Travels	One step back, One step forward (1B-1F)	Ability to trace and track in at least one level, often a regulatory requirement	– Harder to trace origin and to reach consumer if needed	Immediate supplier and immediate buyer must be using systems able to exchange information
	Many steps back, One step forward (nB-1F)	Can trace origin without contacting suppliers	– Harder to reach consumer if needed	All suppliers and immediate buyer must be using systems able to exchange information
	Many steps back, many steps forward (nB-nF)	Complete information from farm to table	– Requires significant vertical supply chain coordination with record keeping and technical capacity at all levels	All actors in the supply chain share information. The data stored needs to follow the same standard in terms of information and the format of the data (e.g., units)
3. Data Granularity	Per lot (low)	Reduced information to gather	– Harder to identify the origin of the problem; Recalls are more expensive, takes longer and wastes good product because all products from a lot must be removed	Label products according to lot organization
	Per unit (high)	Recall can be made individually: saving costs and waste, reducing time	– Need for more control in production process including all inputs used	Individual ID code for each product; Technology to save data, track and trace individually
4. Data Storage	Paper	Simple, quick to implement	– Limited amount of information can be stored; takes longer to find the right information – Data can be manipulated by bad actors; difficulty backing up info;	Large physical, climate-controlled storage capacity

Table 3: Four Dimensions of Food Traceability Technology

Dimension	Functionality	Benefit	Limitation	Requirements
			high risk of losing information; difficult to cross-check info; insufficient for many global laws/regulations and international standards on traceability	
	Central database	Stores large amounts of data; allows data backup; can access info very quickly	– Risk of cyber-attack; – Risk of unintentional data loss unless data is regularly backed up – Data can be manipulated by bad actors	Energy, connectivity, data warehouse, digital systems to prepare data for storage, user training
	DLT	Data backup is natural as the information is distributed among all participants; can access information very quickly; much harder to tamper with data	– High cost, limited technology availability at scale in developing country contexts – Data entry capacity and consistency still critical ("garbage in, garbage out") – Inability to correct errors in the blockchain. – Delays in the required synchronization of updated data in the all the distributed ledgers, due to lack of connectivity (spotty internet service), may hamper access to the most up-to-date information.	Energy, connectivity, advanced technical capacity, more extensive training

The possible combinations of these four dimensions lead to different FTS designs with distinct sets of benefits and varying ability to achieve the stated objectives. Table 4 below demonstrates four different possible FTS designs followed by a brief summary of each. While these design examples demonstrate the basic distinctions in the dimensions that form a food traceability system, there are several practical situations in which these distinctions may not be as black and white. For instance, food operators may utilize a system with some paper-based data and other data that is digital, derived directly from the production line. However, it is important to point out that a mixed approach may be more complex to manage and more difficult to obtain, locate, and provide the right information in a timely and cost-efficient manner.

Table 4: Potential Food Traceability System Designs Based on Functionality

	Data Entry Method		Distance Data Travels[26]			Data Granularity		Data Storage		
	Manual	*Auto*	*1B—1F*	*nB—1F*	*nB—nF*	*Per lot*	*Per Unit*	*Paper*	*Central*	*DLT*
1. Simple	✓		✓			✓		✓		
2. Improved	✓		✓				✓		✓	
3. Automated		✓		✓		✓			✓	
4. Distributed Ledger		✓			✓		✓			✓

[26] 1B-1F = one step back, one step forward; nB-1F = many steps back, one step forward; nB-nF = many steps back many steps forward.

1. **"Simple"** — the simplest combination of dimensions, representing the traditional requirements for food traceability and the most basic approach in dealing with these needs.
2. **"Improved"** — incremental sophistication where data is still gathered and entered manually, one step forward and one step back in the chain, but now provides more specific unit level data available in a centralized digital database.
3. **"Automated"** — a more advanced operator with increasingly automated systems managing their own digital food traceability system.
4. **"Distributed Ledger"** — most sophisticated systems adopted by agribusinesses operating in complex global food supply chains with strong vertical coordination and strong information sharing among all actors from farm to table. DLT systems strengthen the integrity of the data history.

Consumer Demand for Food Transparency

Transparency is defined as "access to non-distorted, factual, relevant, and timely information about supply chain products. There are two elements to supply chain transparency:"[27]

- ***Visibility:*** Accurately identifying and collecting data from all links in the chain.
- ***Disclosure:*** Internally and externally communicating the data collected.

Different system designs will provide different functionality toward a stated objective. The preferred system for an operator will depend on supply chain characteristics, available technical and operational capacity, available infrastructure, consumer expectations, regulatory requirements, and/or voluntary standard requirements as discussed throughout this study.

4.1 INTEROPERABILITY TO ENABLE DIGITAL TRACEABILITY TECHNOLOGY

Open and interoperable platforms increase resilience, diversification, and transparency. Their benefits are tremendous, enabling systems users to better exchange, monitor, and assess data without the need to use traditional paper-based media. This is particularly useful for firms, organizations, and government agencies in food safety, trade logistics, and inventory management. Maintaining interoperable technical standards in digital tracking systems helps operators comply with food safety laws and standards.

What is Interoperability?

"The ability of different information systems, devices, and applications to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information."[28]

Interoperability requires data standardization, the means by which data sets from one system may be compared easily with that of another, is of critical importance.[29] This entails collecting data in common formats and according to pre-set standards.

Interoperability implies the use of open standards, where vendors, academics, and other stakeholders are able to develop a consensus and agree on a common standard that is then released to the public. It also entails fulsome international regulatory cooperation to ensure greater standardization and alignment of policies. Greater interoperability also creates possible vulnerabilities. Another important enabling environment consideration is cybersecurity, as measures must be able to respond to the task of safeguarding data from corruption or erasure.

[27] Harbert, Tam, "Supply Chain Transparency, Explained," *MIT Management Sloan School*, February 20, 2020, https://mitsloan.mit.edu/ideas-made-to-matter/supply-chain-transparency-explained#:~:text=Transparency%2C%20defined&text=Visibility%3A%20Accurately%20identifying%20and%20collecting,of%20detail%20required%20or%20desired.

[28] World Health Organization, "Global strategy on digital health 2020-2015," https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf.

[29] The problem could arise when food operators in a supply chain variously use imperial (English) [avoirdupois] measures of weight versus metric measures.

5. THE ROLE OF THE CONSUMER

Consumer demand plays a significant role in driving improvements in food quality, safety, and sustainability. In fact, consumer outrage over systemic food contamination and food scandals has historically led to incremental strengthening of food safety regulations in developed country contexts. Section 6 will demonstrate how consumers have played an important role in driving reforms in the U.S., EU, and Japanese food safety regulatory regimes. Consumer awareness and regulator responsiveness to consumer concerns remains more limited in developing countries. Nonetheless, it is important to understand the outsized role that the consumer can play to appreciate consumers' potential influence over the uptake of private voluntary standards and the strengthening of public sector regulations in developing country market systems.

Consumer confidence in a food product or food producer is built on trust, and traceability provides the transparency to validate whether a food product meets expectations, thereby reinforcing trust and confidence. The adoption of new technologies to implement FTS present significant potential to meet rising demand for transparency in increasingly complex global and local food chains.

In a 2016 study of U.S. consumer habits, 94 percent of consumers indicated they find it important for food producers to be transparent about how food is made.[30] Further, The Food Industry Association and Label Insight found in 2020 that transparency is important or extremely important for 81 percent of U.S consumers.[31] The Innova Consumer Survey in 2020 also shows that 60 percent of global consumers want to learn more about the origin and story of a food product, and 50 percent consider where or how the food is produced in their purchase decisions.[32] To compete in global markets, food operators will need to improve their ability to respond to demands through improved traceability.

Consumer awareness and market demands for food safety vary widely across countries and between formal and informal markets.[33] There are at least three potential reasons why consumer influence has been more limited in developing country food markets:

What are the Costs of Adopting a Food Traceability System?

The costs of adopting and implementing an FTS is the responsibility of the food operator. It is important, however, for operators to view the costs of FTS as an investment that adds value to a core business by opening access to new markets, mitigating business risks, and improving operational efficiency. To achieve these benefits, a food operator must consider two components of outlays: 1) initial system investment and installation, and 2) implementation and maintenance. The outlays needed for each can vary greatly depending on the design of the food traceability system and the size of the food operation.

As the operational functionality and the technology utilized becomes incrementally more sophisticated, the costs will rise accordingly. Costs will rise as each FTS design variable becomes more advanced: 1) data entry method (manual vs. automatic), 2) distance the information travels between food chain actors (one step or many steps forward/backward), 3) data granularity (per lot vs. per unit), and 4) data storage (paper vs. central database vs. distributed ledger). The costs of adopting digitally enabled systems will also vary from country to country based on technology availability and ICT infrastructure.

Where the investment capital and expected return on investment are high, then development actors may consider de-risking an operator's initial investment with leveraged grant capital or other financial services.

30 Label Insight, "How Consumer Demand for Transparency is Shaping the Food Industry," (2016). https://www.labelinsight.com/hubfs/Label_Insight-Food-Revolution-Study.pdf?hsCtaTracking=fc71fa82-7e0b-4b05-b2b4-de1ade992d33%7C95a8befc-d0cc-4b8b-8102-529d937eb427.

31 "New Research from FMI and Label Insight Reveals Omnichannel Grocery Shoppers See Transparency as Essential Across In-Store and Online Shopping Channels." *Cision PR Newswire*, June 23, 2020. https://www.prnewswire.com/news-releases/new-research-from-fmi-and-label-insight-reveals-omnichannel-grocery-shoppers-see-transparency-as-essential-across-in-store-and-online-shopping-channels-301081610.html.

32 "Innova Identifies Top 10 Food and Beverage Trends to Accelerate Innovation in 2021." *Innova Market Insights*, October 21, 2020. https://www.innovamarketinsights.com/innova-identifies-top-10-food-and-beverage-trends-to-accelerate-innovation-in-2021/.

33 "Food Safety in Africa: Past Endeavors and Future Directions," *Global Food Safety Partnership*. https://www.gfsp.org/sites/gfsp/files/public/GFSP%20Report_Food%20Safety%20in%20Africa-web.pdf.

- First, consumer awareness of potential food contamination as it relates to food production processes remains relatively low.
- Second, food operators' knowledge about consumer demand for safe foods in developing countries remains low.[34]
- Third, consumer willingness to pay for improved practices remains comparatively low, so food operators are less able to pass the costs of traceability on to consumers through higher prices. While some studies found that consumers in developing countries say they are willing to pay more for safer foods, most "willingness to pay" studies have been based on *ex ante* assessments (i.e., before faced with an actual purchase choice) that may not reflect real world purchase decisions.[35,36]

Most recently, the COVID-19 crisis has increased consumer scrutiny on food safety and food transparency,[37,38] and both are expected to increase in importance in the new normal that follows the pandemic. Therefore, demand for information such as source origin, and measures that ensure safe food handling procedures may grow or persist for many developing country consumers on the other side of the pandemic.[39]

Around the world, there have been several examples of food-related incidents caused by fraud or foodborne diseases which have fostered distrust among consumers, altered food consumption patterns, resulted in public health tragedies, and/or caused significant economic losses. The financial losses food operators absorb from food contamination scandals has been a strong incentive for the adoption of standards and improved traceability, demonstrating the influence of the consumer. Additionally, consumer outrage has historically led to regulatory reforms in many developed country contexts, also a sign of the role of the consumer in driving improved food traceability. In certain regulatory contexts, food operator liability for public health incidents may also be a strong incentive for the adoption of improved FTS.

Is Blockchain Necessary for an Effective Food Traceability System?

Distributed ledger technologies (DLTs), including blockchain, provide improvements for FTS data storage and data integrity. However, DLTs are typically not explicitly required by national regulations or voluntary standards, and they may be less appropriate than other digitally enabled traceability technology platforms depending on several enabling environment factors. The emergence of cloud-based data storage, for instance, may offer food operators a more suitable improvement over central databases without requiring a distributed ledger platform.

The primary benefit of DLTs — providing an immutable record of a transaction — strengthens the integrity of data. However, DLTs still suffer from the garbage-in, garbage-out dilemma, where data capture processes remain critical. And in developing country environments, operators often lack the operational capacity and local infrastructure to effectively implement DLT platforms.

A food operator's objectives, challenges, and incentives should dictate the selection of a specific FTS design. Before designing or promoting a traceability technology platform, it is necessary to: 1) determine the necessary FTS functionality to meet regulatory and standards requirements in a target market channel, 2) assess food operator capacity to implement a FTS platform, and 3) identify the type of system being used by supply chain partners to ensure data can be shared as required.

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[34] Ortega, David L. and David L. Tschirley. "Demand for Food Safety in Emerging and Developing Countries: A Research Agenda for Asia and Sub-Saharan Africa," *Journal of Agribusiness in Developing and Emerging Economies* 7, no.1 (May 15, 2017): 21-44. https://doi.org/10.1108/JADEE-12-2014-0045.

[35] Grace, Delia. "Food Safety in Developing Countries: an Overview," (October 2015). https://assets.publishing.service.gov.uk/media/57a0897ee5274a27b20000dd/EoD_Learning_Resource_Food_Safety_Oct2015.pdf.

[36] Jabbar, Mohammad A. et al. "Demand for Livestock Products in Developing Countries with a Focus on Quality and Safety Attributes: Evidence from Asia and Africa." *ILRI*, Research Report no. 24. Nairobi: ILRI, January 2010.

[37] "Food Safety in the Covid-19 Era and Beyond," *Codex Alimentarius*, June 26, 2020. http://www.fao.org/fao-who-codexalimentarius/news-and-events/news-details/en/c/1295757/.

[38] Kleinman, Arielle et al. "Food Safety: Now More Than Ever," *Agrilinks*, May 6, 2020. https://www.agrilinks.org/post/food-safety-now-more-ever.

[39] Eliaz, Shay and Lily Murphy. "A Shock to the Food System - Lessons Learned from the COVID-19 Pandemic," Deloitte, (2020): 16, https://www2.deloitte.com/content/dam/Deloitte/br/Documents/consumer-business/Deloitte-Covid-19-shock-to-the-food-system.pdf.

Below are some practical examples of food-related incidents across both developed and developing country food systems that have led consumer outrage, increased consumer awareness, and/or consumer demand for transparency in food systems.

- **Maize in Kenya**: In 2004, maize contaminated with aflatoxin affected 317 people, killing 125. Laboratory tests indicated that the level of contamination in maize with aflatoxin was 800 hundred times higher than the accepted standard of 10 parts per billion.[40]
- **Infant formula in China**: In 2008, melamine was added to milk and infant formula to increase its apparent protein content. This led to the hospitalization of around 54,000 infants, six deaths from kidney stones and, ultimately, a number of criminal prosecutions, including two executions.[41]
- **Peanuts in the United States**: In 2008, there was a multi-state outbreak of Salmonella typhimurium in peanut products produced by the Peanut Corporation of America (PCA). At least 700 people were sickened during the outbreak, and four PCA executives were charged with the intentional "introduction of adulterated food into interstate commerce with intent to defraud or mislead."[42]
- **Octopus in Cambodia**: In 2012, vegetable salad with raw octopus was responsible for the transmission of a Vibrio parahaemolyticus outbreak. The salad was served in a wedding banquet in a rural village, in Cambodia, and 52 guests were sickened.[43]
- **Meat in Europe:** In 2013, European consumers were outraged to discover that horsemeat was a key ingredient in burgers instead of beef. A major British supermarket chain selling the offending items suffered a EUR 300 million drop in market value as a result.
- **Sesame seeds in Nigeria and Sudan:** Between 2016 and 2017, an outbreak of Salmonella enterica, affected 47 people in the Czech Republic, Germany, Greece, Luxembourg, and the United Kingdom. The outbreak was linked to a sesame paste produced by a Greek manufacturer, which used sesame seed from Nigeria and Sudan.[44]
- **Processed meat in South Africa**: In 2017 and 2018, an outbreak of 1,060 confirmed listeriosis cases and 216 deaths were linked to a South African company that processed and exported ready-to-eat meat products across Africa. A total of 12 million South African rand ($810,000) was spent to handle the outbreak. This included a recall of 5,812 tons of affected foods – the largest listeriosis outbreak ever detected, according to the WHO.[45,46]
- **Apple Juice in the United States**: In 1987 the Beech-Nut Nutrition Corporation was found criminally liable and fined $2 million USD in connection with selling millions of jars of fake apple juice consisting of cheaper juices and sugar syrups.[47]

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[40] "Ohio State Food Safety Center to Research Food Safety in Kenya," *Food Safety News*, December 14, 2020. https://www.foodsafetynews.com/2020/12/ohio-state-food-safety-center-to-research-food-safety-in-kenya/.
[41] International Electrotechnical Commission and International Organization for Standardization, "Tackling counterfeit with IEC and ISO standards," (2018). https://www.iso.org/publication/PUB100207.html.
[42] U.S. Pharmacopeia Convention, "Food fraud mitigation guidance, Appendix XVII – General tests and assays," (2016): 1598. https://www.usp.org/sites/default/files/usp/document/our-work/Foods/food-fraud-mitigation-guidance.pdf.
[43] Vandy, Som et al. "Vibrio Parahaemolyticus Enteritis Outbreak Following a Wedding Banquet in a Rural Village - Kampong Speu, Cambodia, April 2012," *Western Pac Surveill Response Journal* 3, no. 4 (October 2012): 25. https://doi.org/10.5365/WPSAR.2012.3.4.004.
[44] European Centre for Disease Prevention and Control/European Food Safety Authority, "Multicountry Outbreak of New Salmonella Enterica 11:z41:e,n,z15 Infections Associated with Sesame Seeds," (June 2017): 1, https://www.doi.org/10.13140/RG.2.2.28149.99040.
[45] Whitworth, Joe, "South Africa declares end to largest ever Listeria outbreak," *Food Safety News*, September 4, 2018. https://www.foodsafetynews.com/2018/09/south-africa-declares-end-to-largest-ever-listeria-outbreak/.
[46] Ibid.
[47] Mintz, Morton, "Beechnut Guilty in Juice Fraud," *Washington Post*, November 14, 1987. https://www.washingtonpost.com/archive/politics/1987/11/14/beech-nut-guilty-in-juice-fraud/aed8287d-6c41-4e09-bb27-dd70a234074a/.

6. THE ROLE OF NATIONAL LAWS/REGULATIONS

The role of national governments in regulating food traceability cannot be overstated. Governments do so in several ways. First, by mandatory tracking of certain food products either produced, transported, or consumed in the domestic market. Second, by the mandatory extraterritorial reach of domestic legislation applicable to imports or transshipments of food products into or through the territory. Third, by trading rules adopted by national governments, whether through Free Trade Agreements or by relevant World Trade Organization agreements. Multinational bodies, like the EU, or trading blocs formed by trade agreements typically develop increasingly detailed rules in furtherance of trade facilitation.

Traceability in Trade and International Cooperation (FAO Guidance)

- Traceability systems should be no more trade-restrictive than necessary;
- Importing countries should not compel exporting countries to adopt any particular traceability system; and
- Technical assistance should be offered in cases where the requirements of the importing country cannot be met.

There are no binding international agreements requiring traceability for food safety purposes. Governmental traceability regulation, however, informs and is informed by international rules and systems developed by multinational organizations (See Section 8.2 for WTO traceability requirements). Several public international organizations have established standards, guidance, and recommendations that either directly or indirectly establish building blocks of an international traceability system (see Section 8.1-8.6 for international organization guidance and/or reference standards on traceability). Additionally, national governments also sometimes encourage producers to adopt national voluntary standards requiring food traceability (see Section 7.2).

The origins, development, and description of FTS in developed country market systems present several important lessons learned for USAID, developing country governments, and food operators. Sections 6.1-6.3 below present the regulatory requirements for food traceability in the **United States, the European Union, and Japan**. These three regulatory regimes are presented in detail for the following reasons:

- First, to provide the reader with examples of the international best practices for food traceability as implemented in three of the world's most advanced economies.
- Second, to present different models or approaches to regulating food traceability, each with the same objective of improving food safety. These regulatory approaches were developed over time and in response to contextual factors. Developing country governments can draw on these models, and adapt approaches for regulatory reform to their local context.
- Third, to show that food safety regulations are an iterative process, responding to consumer concerns, and local risks/threats. Additionally, regulators may balance their ambitions with the interests and concerns of food operators at all levels, influencing the scope/reach of traceability rules.
- Finally, many developing country food operators may seek to access these three high value market channels. The sections below provide the specific traceability requirements to comply with these national regulations. Food operators in developing countries, as well as USAID and IPs seeking to support these food operators, may draw upon these sections as detailed regulatory guidance in designing or selecting an FTS that will enable compliance and market access.

Engaging Public and Private Actors: Roles and Responsibilities for Effective Food Traceability

Several market system actors contribute to effective food traceability. Primarily, the responsibility for food traceability is on the **food operators** themselves. But they do not operate alone. National **regulators** and **private standards organizations** (e.g., GFSI, ISO, et al.) play a key role in putting the incentives in place for FTS adoption through the articulation of traceability rules/requirements. These regulatory agencies and standards organizations act in response to the demands from **consumers** and constituencies. Beyond this dynamic, food operators also rely on entrepreneurial **technology providers** to improve the local availability of traceability platforms and services. In addition, food **industry associations/networks** can play a key role in promoting the coordination and information sharing across a food supply chain needed for effective traceability.

It is important for USAID and IPs to consider the importance of the broader system that enables food traceability, and to engage these various actors to improve the incentives, infrastructure, technology, and capacity to adopt and implement FTS.

6.1 THE U.S. REGULATORY APPROACH TO FOOD TRACEABILITY

The U.S. regulatory approach to food traceability began with what today would be considered a light touch. It arose due to public outcry after learning of the conditions in which animals were slaughtered and how meat products were afterwards handled. Food tracing, at least initially, was restricted to beef, using a "positive list"[48] or sectoral approach. Record keeping was also light, requiring food operators to keep track of the suppliers and purchasers of their products — the "one up, one down" system. Significantly, farmers and end consumers were exempted from keeping such records. Over the last century, traceability rules have expanded in reach and widened in application in response to intervening events. Throughout U.S. regulatory iterations, ***food operators bear the primary responsibility for food traceability***, which is consistent with other developed country regulatory approaches, as well as international guidelines and standards.

The American food safety system was implemented over a century ago. The U.S. Congress passed the **Federal Meat Inspection Act (FMIA) of 1906**[49] following public outrage over unsanitary and cruel conditions in American slaughterhouses.[50] The FMIA, still in force, makes it illegal to adulterate or misbrand meat and meat products being sold as food. In order to ensure compliance, the FMIA requires each operator in the supply chain to keep ***"one up, one down"*** recordkeeping for beef products. Simply put, ***every operator must keep records*** identifying immediate suppliers ("one down") and immediate recipients ("one up") so that authorities may quickly access needed information, particularly when public health is threatened. Amendments to the FMIA later expanded traceability to other sectors of the food market to include pork and poultry.

The Federal Food, Drug, And Cosmetic Act of 1938[51] closed loopholes in previous legislation, giving the Food and Drug Administration (FDA) the authority to establish standards for food and to provide oversight and enforcement of such standards.

Two deadly events led to major revisions in the American food safety system. First, the September 11, 2001 terrorist attacks raised the specter of bioterrorism and food terrorism, the latter defined as the "act or threat of deliberate contamination of food for human consumption with chemical, biological or radionuclear agents for the purpose of causing injury or death to civilian populations."[52] Second was a

[48] When using a positive list, a party has to explicitly ("positively") list those sectors which are selected for coverage.
[49] 21 USC Ch. 12: Meat Inspection.
[50] Descriptions of rats, filth, and body parts contained in pickle jars were reported in Upton Sinclair's *The Jungle*, a book about Chicago's meatpacking industry published in January 1906.
[51] The Federal Food, Drug, and Cosmetic Act. (June 25, 1938, ch. 675, § 1, 52 Stat. 1040.)
[52] Administrative User, and JH Bloomberg School of Public Health. 2010. "Topic Center - Bioterrorism and Food Security." *Johns Hopkins Bloomberg School of Public Health*. January 27, 2010. https://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-public-health-preparedness/tips/topics/food_security.html.

series of deaths of British subjects from variant Creutzfeldt-Jakob Disease stemming from consuming tainted meat from cattle afflicted with bovine spongiform encephalopathy (BSE), or mad cow disease. The identification of BSE among American cattle later led to import bans which severely hurt the beef industry. The events led to further changes in the regulatory regime. The **U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act")**[53] amended the Federal Food and Cosmetic Act in several ways. It gives the FDA administrative detention authority over food items posing a threat to health or death to humans or animals. It also requires enhanced recordkeeping, requiring that "***any facility*** engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered" with the U.S. Department of Agriculture.[54] Such facilities are further required to maintain for two years records "relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location."[55]

The Bioterrorism Act made significant ***changes regarding food imports***, with important ramifications for food operators and traders. It requires that incoming food be accompanied with information identifying the manufacturer, the grower of the article, the country of origin, the country from which the article was shipped, and the anticipated port of entry. It also grants the FDA immediate administrative detention authority over food items if "there is credible evidence or information that indicates the food presents a threat of serious adverse health consequences or death to humans or animals."[56]

Following an increase in the cases of foodborne illness requiring enormously large and costly food recalls over the previous decade, **the Food Safety Modernization Act** (FSMA) was signed into law in 2011. The Act, supported by industry including the Grocery Manufacturers Association, overhauled previous food safety legislation. It marks a shift for the FDA from responding to foodborne illnesses to prevention by giving the FDA mandatory recall authority and additional regulatory powers that ***enhance traceability requirements***.[57] Using these powers, the FDA issued rules requiring covered food facilities to implement Hazard Analysis and Risk-based Preventive Controls plans and to develop recall plans for identified hazards, both of which are subject to inspection and review. It also gives the FDA greater rulemaking authority in traceability responsibilities and authorities. The U.S. FSMA is an example of sectoral regulation, as it only applies to specified articles of food and ***specifically exempts farmers and restaurants*** from meeting its requirements.

In 2015 the **Food Safety Inspection Service of the U.S. Department of Agriculture**, noting the numbers of incidents of contaminated ground beef and difficulties in responding rapidly, announced a Final Rule containing additional traceback ***procedures for retail outlets*** that grind beef products for sale. Under the rule, for each lot of ground beef, retail outlets must record all supplier lot numbers and production dates.[58]

The FDA on September 22, 2020 proposed new regulations pursuant to FSMA to address many of the foregoing concerns about the adequacy of existing traceability requirements for foods posing the greatest

[53] "Public Health Security and Bioterrorism Preparedness and Response Act of 2002." 2002. Public Law 107-188; P.L. 107-188. https://www.govinfo.gov/content/pkg/PLAW-107publ188/pdf/PLAW-107publ188.pdf.
[54] Ibid. Note: Farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer, and fishing vessels are exempted.
[55] Ibid, p.77.
[56] U.S. Food and Drug Administration, "Guidance for Industry What You Need to Know About Administrative Detention of Foods Small Entity Compliance Guide Final Guidance," October 2011; Revised March 2013. https://www.fda.gov/media/85381/download.
[57] Thatte, Dileep. "The Food Safety Modernization Act in a Nutshell." *NIST*. October 17, 2019. https://www.nist.gov/blogs/manufacturing-innovation-blog/food-safety-modernization-act-nutshell.
[58] Food Safety and Inspection Service, U.S. Department of Agriculture. *Federal Register*, vol. 80, no. 244. December 21, 2015. https://www.fsis.usda.gov/wps/wcm/connect/4900af9c-0657-4525-bb6b-225293143862/2009-0011F.htm?MOD=AJPERES.

risks in food safety. It would establish ***additional traceability recordkeeping requirements*** on foods contained on a proposed Food Traceability List[59] (FTL) to address food safety risks.[60] Under the rule, covered food facilities and ***operators would be required to keep traceability program records*** containing key data elements (KDEs) associated with different critical tracking events (CTEs) in a listed food's supply chain. CTEs include growing, receiving, transforming, creating, and shipping of listed foods. In addition to CTEs, traceability records should also include bills of lading, purchase orders, and lists containing FTL foods being shipped.[61] Although the proposed rule would cover only listed foods, the FDA designed the rule for applicability to all FDA food-regulated items that European regulations already cover.

6.2 FOOD TRACEABILITY RULES IN THE EU

The establishment of the European Union in 1992 created an opportunity to overhaul the food safety legislation of all its member states. It enacted the **General Food Law**[62] in 2002, an example of a comprehensive approach to food safety. It established food traceability requirements among all EU members and created the European Food Safety Authority (EFSA), located in Parma, Italy, to implement provisions of the Law.

EU Food Law Article 18

At minimum the following information must be recorded by food operators:

- Name, address of supplier, and identification of products supplied;
- Name, address of customer, and identification of products delivered;
- Date and, where necessary, time of transaction / delivery; and
- Volume, or quantity.

The comprehensiveness of the General Food Law can be viewed in several ways. In contrast with the "light touch" approach to regulation in the U.S., the EU drafters went in the opposite direction. Where the U.S. used a positive list approach on which foods should be traced, the EU determined that ***all foods and feed*** should be traced. Whereas U.S. laws exempt certain food operators, including farmers and restaurants, from provisions of FSMA, the General Food Law applies to ***all food operators without exception***.

The General Food Law ***prohibits food from the market if it is unsafe***, with unsafe defined as being either injurious to health or unfit for human consumption. It defines traceability as the "ability to trace and follow a food, feed, food producing animal or substance intended to be incorporated into a food or feed, through all stages of production, processing and distribution."[63] In more precise terms, the Law applies to all "food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution."

Article 18 of the General Food Law provides several important traceability requirements:

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[59] U.S. Food and Drug Administration, "Food Traceability List," January 12, 2021. https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list#List.

[60] U.S. Food and Drug Administration, "Requirements for Additional Traceability Records for Certain Foods," September 23, 2020. https://www.federalregister.gov/documents/2020/09/23/2020-20100/requirements-for-additional-traceability-records-for-certain-foods.

[61] U.S. Food and Drug Administration, "FSMA Proposed Rule for Food Traceability," January 12, 2021. https://Www.Fda.Gov/Food/Food-Safety-Modernization-Act-Fsma/Fsma-Proposed-Rule-Food-Traceability#:~:Text=The%20traceability%20lot%20code%20allows,And%20assign%20traceability%20lot%20codes.

[62] "Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety," *Official Journal L 031*, January 2, 2002. P 0001-0024. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32002R0178&from=EN.

[63] "Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety," *Official Journal L 031*, January 2, 2002. P 0001-0024. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32002R0178&rid=2.

- First, that tracing should be performed at "all stages of production, processing, and distribution" without any exemption.[64]
- Second, it requires food operators to "be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed."[65]
- Third, it requires food operators to have "systems and procedures which allow for this information to be made available to the competent authorities on demand."[66] Apart from plans and procedures to enable tracking, the Law requires that food and feed should be adequately labelled or identified to facilitate tracing.

Primary legal ***responsibility for tracking rests with the food operator***, who "is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe."[67] This feature overrules EU member state rules, underscoring the supremacy of EU laws and their role in ensuring a single market.

With respect to imports, it should be noted that the General Food Law's traceability provisions themselves do not apply extraterritorially (outside the EU), in keeping with FAO guidelines (described below). They only apply to those food operators beginning from the EU importer up to the retail level. Nonetheless, many, if not most, EU food operators use voluntary standards systems which require trading partners to follow traceability requirements beyond the "one step back-one step forward" principle.[68]

Ensuring food safety within an economic union consisting of numerous countries, each with its own food safety and animal health agencies and following their own rules, unveiled underlying weaknesses in effective coordination during an EU-wide response to the outbreak of BSE, or mad cow disease, in British herds.[69]

The EU's reaction to the BSE outbreak led to the creation of another comprehensive and mandatory tracking system called **TRACES (Trade Control and Expert System)**.[70] TRACES uses a hub-and-spoke centralized model for the sharing of Sanitary and Phytosanitary Practices (SPS) and other certificates attesting to compliance with applicable requirements related to the imports to, and movements within, the EU of animals, animal products, certain food and feed of non-animal origin and the majority of plants.

With TRACES, "***parties share traceability data in a central repository*** and send their information

TRACES: A Multinational Centralized Traceability System

TRACES is the European Commission's online platform for the EU imports, intra-EU trade, and EU exports of plants, animals, animal source foods and animal feed. More than 42,000 users from about 85 countries worldwide are using TRACES. The possibility to trace the movements of these products both forward and backward along the supply chains contributes to the mitigation of plant, animal, food-borne, and zoonotic disease risks.

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64 Unlike U.S. law where farmers and restaurants are exempt.
65 "Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety," *Official Journal L 031*, January 2, 2002. P 0001-0024. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32002R0178&rid=2.
66 Ibid.
67 "Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety," *Official Journal L 031*, January 2, 2002. P 0001-0024. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32002R0178&rid=2.
68 "Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No. 178/2002 on General Food Law. Conclusions of the Standing Committee on the Food Chain and Animal Health." January 26, 2010. https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_implementation-guidance_en.pdf.
69 Regulation (EC) No 1760/2000 of the European Parliament and of the Council of July 17, 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products.
70 European Commission Decision 2003/24/EC laid the groundwork for creation of the TRACES system.

requests to it."[71] It is a free-to-use single-window system linking the veterinary and plant health authorities of all EU member states plus several non-EU members. TRACES receives all information in ***electronic form (no paper),*** easing burdens on authorized food operators by accepting electronic veterinary and sanitary certificates (SPS certificates). TRACES links central and local authorities, border inspection posts, and food operators, allowing for the instantaneous tracking of food items in case of serious problems.

Noting that improved transparency was in order to assuage public concerns about the safety of beef and beef products, the EU adopted **Regulation (EC) No 1760/2000** (17 July 2000) "Establishing a System for the Identification and Registration of Bovine Animals and Regarding the Labelling of Beef and Beef Products." [72] This provision requires "sufficient and clear" labelling, allowing consumers to trace beef from farm to table.

Another feature of the European Union's FTS is the **Rapid Alert System for Food and Feed (RASFF)**. RASFF is a communications platform linking national food safety authorities, EFSA, and the EU Commission. Food and fraud safety incidents must be immediately reported to RASFF. Consumers can access latest information on food safety incidents through the RASFF portal.[73]

6.3 JAPAN'S FOOD TRACEABILITY RULES

Japan's food safety regime is something of an anomaly, embracing an effective yet inexact food traceability regime. It takes what might be called a ***soft glove, hard fist approach*** to food safety by placing the weight of ***responsibility on food operators*** to determine methods and practices. The legal regime — in contrast with that of the EU or even the U.S. — lacks specificity by not imposing clear and exacting requirements. To sum up, Japan's laws essentially tell food operators to "do the right thing."[74]

With the country's reputation for exacting high food quality, and a technological know-how to match, Japan's food safety regulations, with two huge exceptions, merely mandate the one-up, one-down system.[75] This one-up, one-down rule is contained in Article 3 of the Food Sanitation Law,[76] interestingly titled "Responsibility of Food-Related Business Operators." Article 3 provides that "any business operator of food shall make a record of the list of the names of suppliers of food intended for sale, etc., or its raw materials, being attached with any other necessary information, and shall make an effort for its maintenance."

Article 2 of the Food Sanitation Law[77] also may be seen as an implicit requirement for food tracking, as:

> Food operators *"shall be responsible for appropriately taking the necessary measures to ensure food safety at each stage of the food supply process."* *It goes on to say that "This will be done according to the code of the basic principles and on the basis of the recognition that they bear the primary responsibility for ensuring food safety when conducting their business activities."*

[71] GS1, "GS1 Global Traceability Standard," https://www.gs1.org/standards/gs1-global-traceability-standard#1-Introduction+1-2-Scope.
[72] Regulation (EC) No. 1760/2000 of the European Parliament and of the Council of 17 July 2000 — Establishing a System for the Identification and Registration of Bovine Animals and Regarding the Labelling of Beef and Beef Products and Repealing Council Regulation (EC) No 820/97. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02000R1760-20141213&from=EN.
[73] European Commission, "RASFF – Food and Feed Safety Alerts," https://ec.europa.eu/food/safety/rasff_en.
[74] Quote: "In the relatively homogeneous Japanese society, social status carries heavy obligations, and community pressure is extremely powerful." See https://www.britannica.com/topic/Japanese-law.
[75] Although the legal regime on traceability is a basic one, food operators may ascribe to voluntary systems or codes of conduct established by local producer councils. See two Japanese case studies describing the roles of producer councils at https://www.econstor.eu/bitstream/10419/53743/1/604642695.pdf, pp. 9-15.
[76] Law No. 233 of 1947.
[77] Law No. 233 of 1947.

Yet another example of this approach is contained in Article 8 of the Food Basic Law of 2003, requiring:

> Food operators *"shall, in conducting their business activities, make efforts to provide accurate and appropriate information concerning food and other articles related to their own business activities on the code of the basic principles."*

But exactly what is "accurate and appropriate information?" It is not defined, leaving it to the food operator to understand what is expected of him or her to access the Japanese market.

The discovery of the BSE contagion in a five-year-old Holstein cow, and later in other cattle, led to a major shakeup in the food safety system, and with it the first exception to the one-up, one-down rule in Japanese regulations. The realization that all Japanese beef was potentially unsafe led the Japanese government to reorganize its food safety regime in 2003.[78] The Japanese government passed emergency legislation in the form of the "Special Measures Law on Management and Transmission of Information for Individual Recognition of Cattle,"[79] which established ***traceability requirements for beef from farm to retail*** and adopted a new Food Basic Law, which among other things reorganized and elevated the Food Safety Commission. That Commission also promoted the adoption of voluntary traceability systems, driving their development, funding their rollout, and issuing a handbook[80] to help food operators implement an FTS.[81],[82],[83]

Japan's beef traceability system uses a unique ten-digit identification number embossed on an ear tag for each newborn calf. The number follows through final sale to the end consumer. This was an ***industry-led initiative to provide assurance to consumers*** regarding the safety of their product. Much like the EU's labelling system, consumers can track the beef from farm to table.

The second exception to one-up, one-down system relates to the inspection, labelling, and sale of edible rice following the Osenmai Scandal. From 1942, the Japanese Food Agency assumed control of the rice market through the Food Control Act. Without the agency's certification, a rice farmer's harvest could not be sold to rice traders and enter the consumer market. Subsequent liberalization efforts eliminated the Food Agency's exclusive role in mandatory rice inspections, allowing private companies to do the same beginning in 2001. The Food Agency, along with the requirement to inspect rice, was altogether eliminated in 2003. Private inspection firms, however, continued to operate, with their certified rice labelled as "inspected rice."

In 2008 authorities discovered that several firms had, with apparent intention, procured 5,000 tons of inedible and contaminated rice, and marketed it to the public as "not inspected rice." The public outrage led to the passage of the **Rice Traceability Act of 2009**. According to the Ministry of Agriculture, Forestry, and Fisheries, the act aims to:

[78] Law No. 48 of 2003. Translation from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3242078/.
[79] Food Safety Commission, "Measures against Bovine Spongiform Encephalopathy (BSE) in Japan (Interim report)," September 2004, https://www.fsc.go.jp/sonota/measure_bse_injapan.pdf.
[80] Food Marketing Research and Information Center, "Handbook for Introduction of Food Traceability Systems," 2008. https://www.maff.go.jp/j/syouan/seisaku/trace/pdf/handbook_en.pdf.
[81] Setboonsarng, Sununtar; Sakai, Jun; Vancura, Lucia, "Food safety and ICT traceability systems: Lessons from Japan for Developing Countries," ADBI Working Paper, No. 139, Asian Development Bank Institute, 2009. https://www.econstor.eu/bitstream/10419/53743/1/604642695.pdf.
[82] Food Marketing Research and Information Center, "Handbook for Introduction of Food Traceability Systems," 2008. https://www.maff.go.jp/j/syouan/seisaku/trace/attach/pdf/index-67.pdf.
[83] Jin, Shaosheng and Lin Zhou, "Consumer Interest in Information Provided By Food Traceability Systems in Japan," *Food Quality and Preference*, 36. (September 2014). https://www.doi.org/10.1016/j.foodqual.2014.04.005.

> *"ensure that the actors involved in the production, distribution and sale stages of rice and rice products keep and preserve records of transactions so as to allow early identification of the distribution route in the case of the occurrence of problems; and [to] provide businesses and consumers with information on places of origin of rice."*[84]

The Act and its implementing regulations have precise tracking and labelling requirements regarding the sale of rice and rice products. Nonetheless, it should be noted that it still maintains a one-up, one-down system apart from the country of harvest requirement. ***Seven types of information are to be recorded by food operators***:

1. *The name of the rice or rice commodity*
2. *Country of harvest*
3. *Quantity*
4. *Date of purchase or sale*
5. *Name of the seller or buyer*
6. *Storage location*
7. *Limitation on use (meaning whether for food, feed, or industrial use).*

The information is to be recorded either in paper or digital format and retained for three years. Restaurants, furthermore, are required to inform patrons of the country where the rice was harvested, and, if harvested domestically, may choose to indicate the prefecture or municipality.[85]

Japan's food traceability rules provide several key takeaways for developing country policymakers and food operators. For operators, these requirements must be met to access Japan's food market. For policymakers, the rules demonstrate that the simplicity of one-up, one-down can achieve a lot in terms of food safety assurances, but that these systems are not fail-safe, and high-profile cases of food contamination can lead to demands for more stringent regulatory requirements to foster trust among consumers and constituents.

7. THE ROLE OF VOLUNTARY STANDARDS

Standards are a critical compliance mechanism for buyers to ensure that food operators meet a desired process or product attribute. Food traceability is a fundamental component in monitoring compliance; the specific form that an FTS takes varies according to the specific requirements established under a specific standard.

While standard adoption is most often voluntary, when buyers or importers require compliance with a particular standard and when a food operator aspires to access this market channel, the standard effectively becomes mandatory. Food operators seeking to comply with a specific standard must be certified by an accredited body (typically a private firm) through regular audits. Audits require on-site inspections of locations managed by food operators, reviews of records, and testing of the quality control and traceability systems. Additional challenge arises for food operators where buyers in the supply chain may require compliance with multiple voluntary standards, adding complexity and costs to traceability efforts. Implementing a functionally appropriate, digitally enabled FTS can help address these complexity challenges.

[84] "Traceability System," *Ministry of Agriculture, Forestry, and Fisheries of Japan*, https://www.maff.go.jp/e/policies/food_safety/Traceability.html.
[85] Godo, Yoshihisa, "Traceability and Food Labeling of Rice in Japan *FFTC Agricultural Policy Platform,* (May, 8, 2017), https://ap.fftc.org.tw/article/1181

Voluntary standards are generally organized into two classes:

- **Private Standards:** Those that have been developed by private standards organizations, businesses, nonprofit organizations, and/or industry networks. Compliance with private standards is not legally required by national governments or international agreements. Instead, the adoption of these standards is driven by the business decisions of food operators who aspire to supply a particular market channel in which the standard is required. Many private standards are designed to access particular national or regional markets, while others are designed to meet a particular consumer demand.
- **Government Standards:** Those that have been developed by and/or administered by government agencies. Typically, government standards are created to establish a national product brand. A government agency controls the standard for purposes of building international and/or domestic consumer trust and expanding market access. Most often, government standard uptake is made by a voluntary business decision of a food operator. In some cases, however, government regulations have embedded within them voluntary standards, in which case they are mandatory. A private buyer may or may not choose to require a supplier to comply with a government standard, however, any use of a national standard label or mark would require compliance.

What are Standards? Are They Voluntary or Mandatory?

"A document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which **compliance is not mandatory**. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."*

Standards can be developed and administered by either private sector or public sector entities focusing on characteristics of the food product and/or production process desired within a particular market channel. Standards require adherence to processes that promote certain priorities including food safety, good animal husbandry, ethical working conditions, and/or environmental sustainability.

*See: *Department of Trade and Industry, Standards and Conformance Portal, Bureau of Philippine Standards*.

7.1 PRIVATE VOLUNTARY STANDARDS

Global Food Safety Initiative[86]

The GFSI was created in 2003 by the Consumer Goods Forum. It does not provide food safety standards; rather, it provides benchmarks by which private standards are assessed and certified. GFSI aims to improve efficiency and promote mutual acceptance of GFSI-based certifications across national jurisdictions based on a system of benchmarking requirements — a sort of meta-standard. Among the private food standards the GFSI recognizes are GLOBALG.A.P., SQFI, and BRC Global Standards.[87]

GFSI's benchmarking requirements do not establish a food safety standard; instead they set high-level requirements on food safety. Those requirements, and the specific data to be recorded and traced, varies according to the category of food product covered, e.g., animals, fish, plants, grains/pulses, and animal conversion. This variation recognizes that different categories of food carry their own special food safety issues.[88] These categories are called scopes of recognition, each having a benchmarking category code.[89]

[86] "Overview," *MyGFSI*. Accessed November 18, 2020. https://mygfsi.com/who-we-are/overview/.
[87] Garen, Donna, "Global Food Safety Initiative and Traceability." https://www.fsis.usda.gov/wps/wcm/connect/d20dd79d-ab04-4444-95a2-2ad6f2c48868/Trace_Garren_121009_958.pdf?MOD=AJPERES. (PowerPoint Presentation.)
[88] For example, testing a beverage, such as wine, containing alcohol for salmonella is pointless, although Chinese authorities did have a regulatory requirement to do so. (APEC issue.)
[89] "GFSI Guidance Document (Sixth Edition 6.3)," *Global Food Safety Initiative*. https://www.mccain.com/media/1407/gfsi-guidance-document.pdf.

Traceability requirements for *all food products* (animals, fish, plants, grains/pulses, animal conversion) must capture data to ensure:

- One-up, one-down traceability, which is to be applied throughout all production processes, internal and external warehousing, and ending with the final customer;
- A record of purchaser and delivery destination for all food products supplied and delivered;
- Identification of any outsourced production, inputs or services related to food safety;
- Product identification that includes as a minimum a unique product code and manufacturer's identification logo/mark to identify the batch or individual item as required by the customer;
- A complete record of in-process material or final product and packaging throughout the production process; and
- Identification of any veterinary medication purchases and treatments.[90]

Particularly for *farmed animals and farmed fish*, traceability requirements must also capture data to ensure:

- Identification of recycled materials and any other materials, from whatever source, that may give rise to food safety issues;
- Identification of the source of raw materials and ingredients, the delivery of feed and their linkages; and
- A record of all living stock inputs and outputs, movements on and off-site, to either animal.

For animal source foods, additional traceability requirements include the provision of specific additional input product identification, including feed and feed additives, and, as a minimum, the name and address of the producer, lot or batch number, and date of production or packing. GFSI also benchmarks distribution systems and requires them to use unique product identifiers and be tested regularly.

GLOBALG.A.P.[91]

GLOBALG.A.P. is a private sector body that sets voluntary standards for the certification of agricultural products around the globe. GLOBALG.A.P. standards cover crops, livestock, and aquaculture, each divided into subcategories. Although GLOBALG.A.P. bills itself as setting the worldwide standard for good agricultural practices, it is particularly tailor made for firms covered by the EU General Food Law. Its predecessor, EurepGAP, was a common standard created in the late 1990s by several European supermarket chains.[92] Food retailers and service providers like Aldi, Lidl, Tesco, McDonalds, and Pizza Hut are among its members.[93]

Sustainable Palm Oil Traceability

Environmental sustainability is an important objective and benefit of FTS adoption. Palm oil, for example, is facing continued opposition in the EU, with a possible ban on palm oil biofuel in 2030 given its impact on deforestation.

To address these challenges, the Malaysian Palm Oil Council is investing in a blockchain traceability system provided by BloomBloc to increase production transparency and sustainability.

GLOBALG.A.P. standards aim to achieve economic viability, environmental sustainability, social acceptability, and food safety and quality. GLOBALG.A.P. standards require a high degree of traceability and resemble those of the European General Food Law by allowing a food product to be traced back to

[90] Ibid, 108.
[91] "GLOBALG.A.P. – The Worldwide Standard for Good Agricultural Practices," https://www.globalgap.org/uk_en.
[92] Wikipedia. "GLOBALG.A.P." Accessed October 3, 2020. https://en.wikipedia.org/wiki/GLOBALG.A.P.
[93] GLOBALG.A.P. "Retailers & Food Service." Accessed November 19, 2020. https://www.globalgap.org/uk_en/who-we-are/members/retailers-food-service/index.html.

the first registered farm and tracked forward to the immediate customer. As an example, GLOBALG.A.P.'s technical standard for "Livestock Sourcing, Identification & Traceability" comprises these elements:

- *All livestock must have individual or batch identification, depending on the livestock. Poultry may have a batch ID.*
- *Procedures are in place to demonstrate full traceability of livestock back to the farm of birth/hatching. Livestock are uniquely identified (poultry may have batch ID).*
- *Mechanism of identification used to identify specific livestock having received treatment at least until the withdrawal period has been completed.*

BRC Global Standards (BRCGS)[94]

The BRCGS is the rebranded name of the British Retail Consortium (BRC), a trade association in the United Kingdom. BRC first developed the BRC Technical Standard & Protocol for Companies Supplying Retailer Branded Food Products, meaning a standard for "own label" products.

BRCGS is centered on the British retail food market, and as a result its standards are a reflection of the combination of regulations observed in the United Kingdom.[95] The British Food Safety Act of 1990 and the EU General Food Law provides the basic regulatory requirements for BRCGS, found in the BRC Statement of Intent No. 3.9: which relates specifically to food traceability requirements in the standard:[96]

- *The site shall be able to trace all raw material product lots (including packaging) from its suppliers through all stages of processing and dispatch to its customers and vice versa.*
- *Identification of raw materials, including primary and any other relevant packaging, processing aids, intermediate/semi processed products, part-used materials, finished products and materials pending investigation shall be adequate to ensure traceability.*
- *The site shall test the traceability system across the range of product groups to ensure traceability can be determined from raw material including primary packaging to finished product and vice versa, including quantity check/mass balance. This shall occur at a predetermined frequency, as a minimum annually, and results shall be retained for inspection. Full traceability should be achievable within 4 hours.*
- *The company shall ensure that its suppliers of raw materials have an effective traceability system. Where a supplier has been approved based on a questionnaire, instead of certification or audit, verification of the supplier's traceability system shall be carried out on first approval and then at least every 3 years. This may be achieved by a traceability test. Where a raw material is received directly from a farm or fish farm, further verification of the farm's traceability system is not mandatory.*

BRC No. 3.5.1.2 also requires operators to monitor their suppliers' traceability processes:[97]

1. *The company shall have a documented supplier approval and ongoing monitoring procedure to ensure that all suppliers of raw materials, including packaging, effectively manage risks to raw material quality and safety and are operating effective traceability processes. The approval and monitoring procedure shall be based on risk and include one or a combination of:*
    - *Certification (e.g., to BRC Global Standards or other GFSI-recognised scheme)*
    - *Supplier audits, with a scope to include product safety, traceability, HACCP review and good manufacturing practices, undertaken by an experienced and demonstrably competent product safety auditor or, for suppliers assessed as low risk only, supplier questionnaires.*

[94] "British Retail Consortium." Accessed November 19, 2020. https://www.brc.org.uk/.
[95] UK Public General Acts, "Food Safety Act 1990," https://www.legislation.gov.uk/ukpga/1990/16/contents.
[96] BRC Global Standards, "BRC Global Standard Food Safety Preventative Controls for Human Food Rule Comparison," Issue 1 (April 2016), https://www.brcgs.com/media/63857/brctag-guidance-document.pdf.
[97] Ibid.

International Featured Standard[98]

IFS Standards are uniform food, product, and service standards that are GFSI-recognized and used for auditing food manufacturers. These originated as the International Food Standard, developed by associations representing supermarket chains in France and Germany, with Italian trade associations joining later. It was renamed International Featured Standard-Food to distinguish it from IFS's expanding coverage into retail food stores, logistics, cash and carry markets, and brokers. Certification of its standards are carried out by independent, accredited certification firms which conduct audits.

With respect to traceability, IFS's standard for food safety unsurprisingly requires that a traceability system be in place. The system should:

- Enable the identification of product lots and their relation to batches of raw materials.
- Incorporate receiving, processing, and distribution records.
- Lastly, traceability is to be ensured and documented through delivery to the customer.

Additionally, IFS Food Standard Version 7 (the latest version released) requires the following as it relates to traceability:

- Mandatory use of Global Location Numbers for companies in the European Economic Area and the United Kingdom.[99]
- Alignment with updated GFSI Benchmarking Requirements (Version 2020.1) that reflect the Food Safety Modernization Act and EU regulations.[100]

Safe Quality Food Institute

The Safe Quality Food (SQF) safety standard was first developed in Australia in 1994, and since 2003 is a division of the Food Industry Association called the Safe Quality Foods Institute (SQFI). SQFI uses a modular approach, with Module 2 providing the backbone to all Food Safety Systems covered, and is then augmented by more specific modules depending on the particular food item or industry category. [101]

Version 9 of the SQF food safety standard, to be released in May 2021, comprises nine modules: Primary Plant Production, Primary Animal Production, Aquaculture, Food Manufacturing, Pet Food Manufacturing, Animal Feed Manufacturing, Animal Product Manufacturing, Dietary Supplement Manufacturing, Storage and Distribution, Manufacture of Food Packaging, and Quality Code.

SQFI's latest standard on traceability is part of the backbone Module 2, Edition 8, at SQF Code 2.6.2.[102] Implementation guidance provides the following:

- The operator must document the traceability system's methodology, showing links to all inputs and identifying who is responsible for maintaining the system. Dispatch records must be kept, identifying the responsible employee or agent, the product name, quantity, production batch dates, and customer.

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98 International Featured Standards, "IFS Database - Home." Accessed November 19, 2020. https://www.ifs-certification.com/.
99 International Featured Standards, "Factsheet: IFS Food Standard Version 7." Accessed November 19, 2020. https://www.ifs-certification.com/images/standards/ifs_food7/documents/Fact_Sheet_IFS_Food_V7_EN.pdf.
100 Ibid.
101 Safe Quality Food Institute, "SQFI Home Page - Safe Quality Food Institute." Accessed November 19, 2020. http://www.sqfi.com/.
102 Safe Quality Food Institute. "General Guidance for Developing, Documenting, Implementing, Maintaining, and Auditing an SQF System Module 2: System Elements," 41. November 2017. https://www.sqfi.com/wp-content/uploads/2018/08/Module-2-Manufacturing-Guidance-with-cover.pdf.

- The operator must use the one-up, one-back system, tracing products, materials, packaging materials, and processing aids used that may affect food safety. The operator should check if the customer requires that it trace product beyond the first customer.
- The traceability system must be tested annually, with results to be reviewed by an auditor.
- Records of dispatched products must be maintained.[103]

GS1 Global Traceability Standard

The GS1 Global Traceability Standard embraces a number of key features for traceability systems:

- Use of an open architecture approach for the exchange of critical data.
- Use of modular design, allowing for scaling up.
- Use of automatic identification and data capture, barcodes, QR codes, and RFID tags.
- Use of globally unique identification and digital information that is widely recognized.[104]

GS1's Global Traceability Standard offers an overview of elements comprising a traceability system.[105] It serves as a foundation for more specific standards based on sector, regional and local standards, and guidelines. The standard outlines three salient components of a traceability system: traceable objects, traceability data, and interoperability.

1. **Traceable objects** are "a physical or digital object whose supply chain path can and needs to be determined."[106] The GS1 system uses ID Keys enabling organizations to assign standard identifiers to products, documents, physical locations, and documentation. Examples of GS1 keys are the Global Trade Item Number (GTIN), the Serial Shipping Container Code, and the Global Identification Number for Consignment (GINC). The following provides a summarized set of definitions provided by GS1.[107]

    - A GTIN consists of all products of a given type or class. (For example, every HP q-0236 All-in-one computer used to write this sentence has an identical GTIN.)
    - Granularity can be increased to batch/lot level by appending the GTIN (GTIN + batch/lot number), which would be the proper descriptor for all the HP q-0236 computers shipped in the same truck to my local retail outlet.
    - Granularity can be further increased to the instance level by adding the serial number (GTIN + serial number), which is specific to my own HP q-0236 computer. This combination is sometimes called the Serialised GTIN or SGTIN.

2. **Traceability Data** is generated using two concepts:

    - ***Key Data Elements* (KDE)** which are defined as "[t]hose data required to be present in a CTE to accurately represent what occurred in the step of a business

[103] Ibid., 41-42.
[104] These consist of Critical Tracking Events (CTEs), Key Data Elements (KDEs), Global Trade Item Number® (GTIN), Global Location Numbers (GLN), and Barcodes and EPC-enabled RFID tags.
[105] David. Buckley, "GS1 Global Traceability Standard," (December 18, 2019). https://www.gs1.org/standards/gs1-global-traceability-standard.
[106] Ibid.
[107] GS1, "GSI Global Traceability Standard." https://www.gs1.org/standards/gs1-global-traceability-standard#2-Traceability-and-the-importance-of-standards+2-3-The-need-for-traceability-data

process, in order to ensure traceability."[108] In simpler terms KDEs denote the following five dimensions involved in a process or activity:[109]

- ✓ *Who: Which parties are involved? Such as immediate supplier, warehouse operator, transporter, and processor.*
- ✓ *What: What is the primary object (e.g., GINC) being traced? Which related objects need to be traced? This may include commodities, varieties, species, packaging, and product.*
- ✓ *Where: Where did movements or events take place? Such as origin, location, destination.*
- ✓ *When: When did a movement or event that included that object occur?*
- ✓ *Why: Why was the object at that location? What process and transaction took place?*

- ***Critical Tracking Event (CTE)*** which is defined as a "record of completion of a step in the business process in a supply chain, that is critical to record and share, in order to ensure end-to-end traceability."[110] In simpler terms, these denote events which occur to traceable objects during their lifecycle, like acquisition, processing, and shipment. Examples include harvesting, hatching, growing, milling, batching, packaging, shipping, storing, disposing, cooking, freezing, and selling to customer.

3. **Interoperability:** The GS1 Traceability Standard contains features important for establishing interoperability in tracing:

- Standardized identifiers for business objects and locations across all supply chain partners.
- Supply chain partners' ability to capture data encoded in a data carrier (e.g., RFID, barcodes).
- "Data that can be shared using standardised semantics, in a standardised format, and using standard exchange protocols."[111]

The GS1 Global Traceability Standard includes several other system components:

- **Traceability Parties** which are firms or persons — identified with a GLN (Global Location Number) or Global Service Relation Number.
- **Traceability locations** — also identified using a GLN.
- **Transactions and documents** — using a Global Document Type Identifier.

7.2 NATIONAL VOLUNTARY STANDARDS

In addition to exercising their regulatory authority, government agencies may also establish voluntary standards to promote a national brand in the global market. Compliance with these standards is voluntary, but becomes mandatory if producers wish to use certain descriptions, marks, or labels provided in the national standard. Below are just a few examples of national voluntary standards operating across developed, emerging, and developing economies including, in the U.S., Thailand, and Kenya.

[108] David. Buckley, "GS1 Global Traceability Standard," (December 18, 2019). https://www.gs1.org/standards/gs1-global-traceability-standard.
[109] GS1, "GS1 Global Traceability Standard." https://www.gs1.org/standards/gs1-global-traceability-standard#2-Traceability-and-the-importance-of-standards+2-3-The-need-for-traceability-data.
[110] David. Buckley, "GS1 Global Traceability Standard," (December 18, 2019). https://www.gs1.org/standards/gs1-global-traceability-standard.
[111] Ibid.

USDA Organic

USDA Organic is the standard by which food must be certified as "organic" by the U.S. Department of Agriculture.[112] The USDA, just like a private voluntary standards association, authorizes third party audit firms around the world to certify farms and businesses to the USDA organic standard.

Owing to growing marketplace confusion concerning the labeling of foods as "organic," the U.S. Department of Agriculture was directed by Congress under the Organic Foods Production Act of 1990 to establish a recognized set of standards that must be met to market food as organic. The purposes mentioned were: [113]

- *to establish national standards governing the marketing of certain agricultural products as organically produced products;*
- *to assure consumers that organically produced products meet a consistent standard; and*
- *to facilitate interstate commerce in fresh and processed food that is organically produced.*

Traceability is important to certifying foods produced as organic, because the regulation sets forth strict rules on inputs, and these inputs can only be audited if they are recorded and can be traced. For example:

- Operations must use organic seeds and other planting stock when available, and
- Producers must feed livestock agricultural feed products that are 100 percent organic.[114]

Food producers must provide evidentiary records showing compliance with these rules during the regular audits required for certification purposes, therefore an effective recordkeeping and traceability system must be in place.

ThaiGAP

ThaiGAP is a national voluntary standard developed by Thailand's Board of Trade and administered by the government. Thailand's Bureau of Agricultural Commodity and Food Standards ACFS handles accreditation, and the Department of Agriculture handles certification. It is aimed at boosting food safety reliability and quality assurance, especially with regard to fresh fruits and vegetables. Other objectives include protecting workers' health, introducing Good Agricultural Practices, conserving the environment, and boosting Thai farmers' incomes.

ThaiGAP aligns its requirements with GLOBALG.A.P., thus enabling Thai farmers to gain access to European food market channels by meeting EU food safety standards. ThaiGAP certification requires that producers establish a comprehensive control and monitoring system entailing extensive documentation by all partners in the supply chain. This is particularly important, as the very same producers may be handling food destined for other chains using different food safety standards, such as the Thailand Q-GAP standard.[115] While ThaiGAP is a voluntary standard, the Thai Food and Drug Administration has considered amending rules to require fruit and vegetable suppliers to purchase products only from farmers certified under the program, which would effectively make ThaiGAP mandatory.[116]

[112] U.S. Department of Agriculture, "Organic Regulations | Agricultural Marketing Service," (2019). https://www.ams.usda.gov/rules-regulations/organic.
[113] Organic Foods Production Act of 1990. https://www.congress.gov/bill/101st-congress/senate-bill/2108/text.
[114] U.S. Department of Agriculture, "Organic Production and Handling Standards," *USDA Organic*. https://www.ams.usda.gov/sites/default/files/media/OrganicProductionandHandlingStandards.pdf.
[115] Wongsprawmas, R., et al. "Food Safety Assurance System for Fresh Produce Production in Thailand: a Review." *Quality Assurance and Safety of Crops & Foods* 7, no. 1 (April 15, 2014): 73-88. https://doi.org/10.3920/QAS2013.0255.
[116] Arunmas, Phusadee. "Primary ThaiGAP to Boost Food Safety." *Bangkok Post*, February 16, 2016. https://www.bangkokpost.com/business/866796/primary-thaigap-to-boost-food-safety.

KenyaGAP

The government of Kenya, beginning in the early 2000s, played a leading role in the creation of the KenyaGAP voluntary standard. As with the case with ThaiGAP, the impetus for KenyaGAP was to enable the country's farm producers to meet more stringent EU food safety standards. By benchmarking its products to an internationally recognized standard, in this case GLOBALG.A.P., the government sought to increase the income of its smallholder farmers, particularly in the horticultural sector, by improving the quality of their products.[117] Other benefits of observing the standard were improvements in health, safety, environmental, and social practices. Similarly, KenyaGAP aligns with the traceability requirements under GLOBALG.A.P.

8. THE ROLE OF INTERNATIONAL ORGANIZATIONS

Several private and multilateral organizations provide comprehensive guidance on the use and functionality of food traceability systems. This section discusses traceability guidance according to ISO, WTO, FAO, IPPC, and OIE instruments.

8.1 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

The ISO is an independent, non-governmental organization (NGO). Despite its nominal status as an NGO, the technical standards it develops manifest an official imprimatur as its membership comprises the national standards bodies of 164 countries.[118] It has developed over 20,000 standards in a host of fields, including food safety and traceability. Adoption of an ISO standard is considered prima facie evidence that a regulating authority is in compliance with its obligations under agreements of the WTO (see next sub-section).

The ISO system of standards addresses food safety through the lens of a quality management system. Like other quality management systems covered by ISO standards, food safety systems must conform to *ISO 9001:2015 Quality Management Systems — Requirements,*[119] which provides high-level guidance on identification and traceability. Sub Clause 8.5.2 (Identification and Traceability) provides three requirements regarding identification and traceability:[120]

- *Use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.*
- *Identify the status of outputs with respect to monitoring and measuring requirements throughout production and service provision.*
- *Control the unique identification of the outputs when traceability is a requirement, and retain documented information to enable traceability.*

These three requirements acquire more specificity in *ISO Standard 22000:2018 (Food Safety Management System – Requirements for Any Organization in the Food Chain)*[121] by providing requirements to be followed

[117] Carey, Christine. "Kenya and the KenyaGAP Standard for Good Agricultural Practice – Governmental Use of Voluntary Standards, Case Study 6," *ISEAL Alliance*. (September 2008). https://community.isealalliance.org/sites/default/files/E051_Kenya_KenyaGAP.pdf.

[118] The national standards bodies comprising the ISO's memberships include both government agencies and private non-government organizations. An example of the latter is the American National Standards Institute, which is the official U.S. representative to the ISO.

[119] "ISO 9001:2015 Quality Management Systems — Requirements." 2015. ISO. 2015. https://www.iso.org/standard/62085.html.

[120] Reference from a commercial website: "Identification and Traceability." *9000 Store*. Accessed December 4, 2020. https://the9000store.com/iso-9001-2015-requirements/iso-9001-2015-operational-requirements/identification-traceability/.

[121] ISO - International Organization for Standardization. 2018. "ISO 22000:2018 Food Safety Management Systems — Requirements for Any Organization in the Food Chain." ISO. October 15, 2018. https://www.iso.org/standard/65464.html.

by organizations in the food chain. Conformance with this standard serves to demonstrate an ability to control food safety hazards and ensure that food is safe for human consumption. It works "[t]o harmonize on a global level for businesses within the food supply chain with auditable requirements."

ISO 2200:2018 requirements combine the elements of interactive communication, system management, prerequisite programs, and hazard analysis and critical control point (HACCP) principles. Traceability is an essential component, as reflected in paragraph 7.9, which adopts the baseline one-up, one-down system. It also requires that traceability records "shall be defined and shall be in accordance with customer and regulatory requirements."

ISO requirements for traceability are further elaborated in *ISO 22005:2007*[122] *(Traceability in the Feed & Food Chain*). This technical standard "specifies the basic requirements for the design and implementation of a feed and food traceability system" that are to be applied by any organization operating at any step in the feed and food chain. Traceability has been summarized in the following way:[123]

> *The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records. The traceability system shall be able to identify incoming material from the immediate suppliers and the initial distribution route of the end product. Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. Records shall be in accordance with statutory and regulatory requirements and customer requirements and may, for example, be based on the end product lot identification.*

The abstract for the standard highlights several important considerations for the design and implementation of a FTS:[124]

- *The choice of a traceability system is influenced by regulations, product characteristics and customer expectations.*
- *The complexity of the traceability system can vary depending on the features of the product and the objectives to be achieved.*
- *The implementation by an organization of a traceability system depends on.*

Important elements of a traceability plan include:

- Mapping the flow of materials and information coming from the supplier and extending those forward to the customer.
- The establishment of operational procedures required to implement a traceability plan, including management commitment to provide resources, define responsibilities, establish a training plan, and develop key performance indicators to monitor the effectiveness of the system.

ISO cautions that a traceability system is only a technical tool that helps organizations achieve defined objectives in the Food Safety Management System. In isolation, traceability is insufficient to achieve food safety, and ISO calls for continual improvement based on management reviews and internal audits, with changes made with respect to objectives, processes, regulations, based on findings and customer feedback.

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[122] ISO 14:00-17:00. 2007. "ISO 22005:2007 Traceability in the Feed and Food Chain — General Principles and Basic Requirements for System Design and Implementation." ISO. 2007. https://www.iso.org/standard/36297.html. This standard was last reviewed and confirmed in 2016.

[123] Quoted from "FSSC 22000 V4.1 – NEW ADDITIONAL REQUIREMENTS – JANUARY 2019." 2019. https://www.dnvgl.fr/Images/DNVGL_Additional%20interpretation%20of%20FSSC%20requirements_tcm11-145388.pdf.

[124] "ISO 22005:2007(En) Traceability in the Feed and Food Chain — General Principles and Basic Requirements for System Design and Implementation." 2007. Iso.org. 2007. https://www.iso.org/obp/ui/#iso:std:iso:22005:ed-1:v1:en.

8.2 WORLD TRADE ORGANIZATION

In 1995, WTO member states signed on to two trade agreements that have specific relevance for food traceability: the Sanitary and Phytosanitary Practices (SPS) Agreement[125] and the Technical Barriers to Trade (TBT) Agreement.[126] While these agreements do not specify traceability system requirements, they do provide principles upon which they should be based.

The SPS Agreement

The SPS Agreement covers issues of food safety and animal and plant health. It has the objective of limiting the use of quarantines and food safety requirements by national governments as disguised forms of anticompetitive import protection. Traceability may be imposed as an SPS measure, but the manner and level of difficulty for compliance is limited by the terms of the SPS agreement.

Under the Agreement, SPS measures may be imposed for protection of human health or safety, animal or plant life or health, or the environment.[127] Furthermore, SPS measures may be adjusted to respond to sanitary and phytosanitary irregularities, like the prevalence of diseases or pests in the area from which the product originates and to which it will be supplied.

The SPS Agreement references the international standards, guidelines and recommendations of the following organizations — each of which provide guidance on traceability, as will be discussed in the following sub-sections: *Codex Alimentarius Commission, the World Organisation for Animal Health, and the Secretariat of the International Plant Protection Convention.*

The TBT Agreement

The TBT Agreement covers technical regulations and standards, including traceability system requirements, product labelling, quality, and packaging standards. Onerous requirements in complying with a burdensome traceability system could conflict with obligations under Article 2.2 of the TBT Agreement, which requires members not to introduce regulations which are more trade restrictive than necessary.

The Trade Facilitation Agreement: Single Window Systems

Border control authorities (including customs agencies), in partnership with the private sector have been making a gradual shift towards the electronic submission of trade documentation previously handled in paper form. This development demonstrates the importance of digital traceability systems for global trade. The WTO Trade Facilitation Agreement encourages the electronic exchange of border control documents, including SPS certificates, under "single window" systems. To this end, the "ePhyto Solutions" hub is explained under Section 8.5.

One other document, the Certificate of Origin, accompanies every export in international trade. It certifies that "goods in a particular export shipment are wholly obtained, produced, manufactured or processed in a particular country."[128] It usually provides only limited information by showing the region and country of origin and shipping details.

[125] "WTO | Sanitary and Phytosanitary Measures - Text of the Agreement." 1995. *WTO.* January 1, 1995. https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.
[126] "WTO | Legal Texts - Marrakesh Agreement." 1995. *WTO*. January 1, 1995. https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm.
[127] "WTO | Sanitary and Phytosanitary Measures - Text of the Agreement." *WTO.* 2020. https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.
[128] "Certificates of Origin." *International Chamber of Commerce*. Accessed November 18, 2020. https://iccwbo.org/resources-for-business/certificates-of-origin/.

8.3 FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS

The FAO considers that traceability systems and food recalls "are essential components of a national food control system."[129] If lacking, the FAO considers it a necessity for national authorities to develop such systems. It defines traceability *"the ability to discern, identify and follow the movement of a food or substance intended to be or expected to be incorporated into a food, through all stages of production, processing and distribution."*[130]

FAO guidance developed in partnership with the WHO underscores the two core objectives of traceability for purposes of a food recall, i.e., the one-up one-down rule and the need to keep accurate records. According to the FAO, the objectives of traceability are to:

1. *Identify uniquely a lot/batch/consignment of food in a way that allows tracing of the physical flow of the food forwards through the food chain to the immediate customer and tracing of the physical flow of raw materials backwards to the immediate supplier;*
2. *Create and maintain accurate traceability records that can be provided within a short time period when needed for recall or at the request of the competent authorities.*[131]

The FAO recommends that a traceability system should have recordkeeping processes sufficient to comply with the one-up, one-down principle, and cautions that sophisticated information technology tools need not be necessarily used.

8.4 CODEX ALIMENTARIUS[132]

In 1963 the FAO and the WHO created the Codex Alimentarius Commission. Codex is a science-based organization[133] that develops internationally agreed standards, guidelines, and codes of practice aimed at ensuring that food is safe and can be traded. Adoption of Codex standards facilitates the harmonization of food regulations among its 188 members, beneficially removing barriers to trade for a freer movement of food products among countries. Hence, Codex standards are important reference points for the WTO's dispute settlement mechanism.

In 2006 the Commission issued a policy document titled, "Principles For Traceability/Product Tracing As A Tool Within A Food Inspection And Certification System,"[134] the contents of which apply to all or specified stages of the food chain from production to distribution. It provides the most authoritative statement by Codex, and by association, the FAO, on traceability.

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[129] "Traceability & Recalls | Food Safety and Quality | Food and Agriculture Organization of the United Nations." *FAO*. Accessed November 18, 2020. http://www.fao.org/food-safety/food-control-systems/supply-chains-and-consumers/traceability-and-recalls/en/.

[130] Ibid., 4.

[131] "FAO/WHO Guide for Developing and Improving National Food Recall Systems." 2012. Rome: Food and Agriculture Organization of the United Nations and World Health Organization. 28. http://www.fao.org/3/i3006e/i3006e.pdf.

[132] "Home | Codex Alimentarius FAO-WHO." 2018. *FAO*. 2018. http://www.fao.org/fao-who-codexalimentarius/en/.

[133] By science-based, it means that the Commission's work should be based on scientific findings and should be applied only to the extent that they are necessary to protect human, animal, or plant life or health. Codex standards are based on the input of leading scientists in the field and national experts on food safety.

[134] "Codex Principles for Food Import and Export Inspection and Certification CAC/GL 60-2006." 2006. http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B60-2006%252FCXG_060e.pdf.

Reflecting again the baseline traceability standard, Codex adopts the one-up, one-down system. Importantly, it introduces the idea that traceability promotes not only food safety, but also consumer protection against deceptive marketing practices.

Unlike the FAO guidance, Codex principles provide more flexibility in whether and how traceability systems should be used. Traceability is to be done if it improves food inspection and certification. Tools for traceability should be economically viable, practical, and technically feasible. The guidance makes a particularly important point regarding traceability system implementation in developing countries. It states that importing countries should not compel exporting countries to adopt any particular traceability system, specifically:

- *It should not be mandatory for an exporting country to replicate (i.e., establish the same) the traceability/product tracing tool as used by the importing country, when applicable.* [135]
- *The application of traceability/product tracing should take into account the capabilities of developing countries. Technical assistance should be offered in cases where the requirements of the importing country cannot be met.* [136]

8.5 INTERNATIONAL PLANT PROTECTION CONVENTION

Like Codex, the IPPC[137] falls under the aegis of the FAO, and establishes standards, guidelines, and recommendations related to plant health. Its standards are contained in a regularly updated collection of best practices known as the International Standards for Phytosanitary Measures (ISPMs), which are adopted by the IPPC's governing body. A number of ISPMs highlight guidelines on traceability:

- ISPM 3 (Guidelines for The Export, Shipment, Import And Release Of Biological Control Agents And Other Beneficial Organisms [2005]) provides that "[d]ocumentation sufficient to allow trace-back of released biological control agents or other beneficial organisms should be maintained by the National Plant Protection Organization (NPPO) or other responsible authority."[138]
- ISPM 7 (Export Certification System) provides that NPPOs should retain a copy of each phytosanitary certificate for purposes of validation and "trace back." Consignments should be traceable "through all stages of production, handling and transport to the point of export."
- ISPM 10 (Requirements for The Establishment of Pest Free Places of Production and Pest Free Production Sites) provides that "[v]erification measures may be needed to maintain the identity of the product (labelling to ensure traceability to the pest free place of production) and the integrity of the consignment. The phytosanitary security of the product should be maintained after harvest." [139]

In 2019 the IPPC rolled out a revolutionary single window system called **ePhyto Solutions** for the global filing and exchange of electronic phytosanitary certificates, or "ePhytos." Developed over the course of 13 years, the system has three parts. First, a central server called the Hub handles the transmission of ePhytos between the NPPOs of participating countries. Second, a Generic ePhyto National System (GeNS) allows NPPOs lacking the ability to generate and transmit electronic phytosanitary certificates to

[135] Ibid. 2.
[136] Supporting less developed countries is also embedded in the EU's General Food Law.
[137] "IPPC - International Plant Protection Convention." *IPPC,* 2019. https://www.ippc.int/en/.
[138] "Guidelines for the Export, Shipment, Import, and Release of Biological Control Agents and Other Beneficial Organisms," *FAO and IPPC*, published 2017. https://www.ippc.int/static/media/files/publication/en/2017/05/ISPM_03_2005_En_2017-05-23_PostCPM12_InkAm.pdf
[139] "Requirements for the Establishment of Pest Free Places of Production and Pest Free Production Sites," FAO and IPPC, published 2016, http://www.fao.org/3/a-x3897e.pdf.

use a web-based alternative. The third part, labelled Harmonization, aims to ensure the interoperability required to make the system work by using harmonized international e-business standards and data sets between governments. The United Nations International Computing Centre maintains the system.

Participation in the ePhyto Solutions is voluntary but is gaining popularity. As of this writing, 91 countries have registered, with 19 countries already exchanging ePhyto certificates through the system. The transition of documentation from paper to digital format is expected to make trade cheaper, faster, and safer.

8.6 WORLD ORGANISATION FOR ANIMAL HEALTH

The Office International des Epizooties was created in 1924 as a mechanism to fight animal diseases at global level. It was renamed the World Organisation for Animal Health in 2003. The OIE "is the intergovernmental organization responsible for improving animal health worldwide,"[140] and its standards are "recognized by the World Trade Organization."[141] The OIE's general principles on animal traceability are contained in Chapter 4.2 of the regularly updated Terrestrial Animal Code,[142] or International Animal Health Code, which makes the following points:

- Traceability systems should be based on the outcomes of a risk assessment.
- Animal traceability systems should be under the authority of a Veterinary Authority, and this Veterinary Authority, "with relevant governmental agencies and in consultation with the private sector, should establish a legal framework for the implementation and enforcement of animal identification and animal traceability in the country."
- The legal framework "should include elements such as the objectives, scope, organisational arrangements including the choice of technologies used for identification and registration, obligations of all the parties involved including third parties implementing traceability systems, confidentiality, accessibility issues and the efficient exchange of information."
- Before implementing a traceability system, basic factors must be considered, such as "the legal framework, procedures, the Competent Authority, identification of establishments or owners, animal identification and animal movements."

9. PRACTICAL CASE STUDIES OF TRACEABILITY SYSTEMS

Below are five practical examples of FTS implementation in developing and emerging country contexts. Each example presents the drivers/objectives of the FTS, the prevailing regulatory context, and the technology utilized. These cases provide examples of how and why enabling environment conditions will practically influence the incentives for and implementation of an FTS, and raise the importance of considering these contextual factors before investing in FTS.

For each case presented, it is important to **consider two critical questions**:

1. Were the appropriate incentives in place for food operators to adopt FTS, including formal regulatory requirements and/or market-led standards?
2. Did the food operators have what they needed to implement FTS, including the infrastructure, technology, vertical supply chain coordination, and capacity (technical, operational, and financial)?

[140] World Organisation for Animal Health, "About Us." https://www.oie.int/about-us/.
[141] International Finance Corporation, "Improving Animal Welfare in Livestock Operations," December 2014. https://www.ifc.org/wps/wcm/connect/c39e4771-d5ae-441a-9942-dfa4add8b679/IFC+Good+Practice+Note+Animal+Welfare+2014.pdf?MOD=AJPERES&CVID=kGxNx5m.
[142] "Terrestrial Animal Health Code." Chapter 4.2. *OIE - World Organisation for Animal Health,* (2019). https://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_ident_traceability.htm.

9.1 CASE 1: DAIRY IN BRAZIL

Background

From 2007 to 2017, milk and milk-based products in Brazil suffered from adulterations.[143] Once the public became aware of the adulterations and food fraud, consumption of milk declined across the country, and not only in the brands directly associated with the adulteration.[144] In 2017, motivated by this public scandal, at least one national milk producer, Languiru, sought to implement an end-to-end digital traceability system to strengthen transparency and consumer trust in their milk product.

Regulatory Context

Brazil has a highly developed food safety regulatory system. All industries in Brazil are required to follow the general regulation about product safety contained in the Brazilian Consumer Code (Law n. 8.078/90). According to the Code, a food operator ("an industry") cannot place a product in the market that presents risks to the health and safety of consumers. If a supplier becomes aware of the existence of a defect after the insertion of its products into the marketplace, the supplier is obliged to report this immediately to the authorities and consumers. It means that the supplier will need to remove rapidly from the market the unsafe products by a recall.

Two agencies, the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and the National Agency of Sanitary Surveillance (ANVISA), are responsible for ensuring a safe food supply and regulating imports and exports. MAPA focuses on the production side, when products are from products of animal origin, fresh fruit, and vegetables, organic products, alcoholic and nonalcoholic beverages, juices, grains, seeds, and animal feed. ANVISA focuses on the regulatory framework of processed food and is also responsible for overseeing the production and registration of specific categories of foods, food additives, supplements, and packaging. It is ANVISA's responsibility to regulate all products once they are in the market.

All food operators in Brazil must comply with ANVISA's recall regulations, which requires at least the one-up, one-down approach. Whereas MAPA regulations require dairy companies to be able to trace back to the farmer who supplied each specific lot of products. In addition, FTS records may be used to communicate with the consumer by identifying where the product was sold, in case a product is identified as unsafe to consume.

The ANVISA Collegiate Board of Directors' Resolution RDC n. 24/2015 establishes criteria and procedures for a food recall. According to this regulation, product traceability must be ensured at all stages of the food supply chain in order to ensure compliance within a 48-hour window to provide information to ANVISA about the defective product. All companies in the food supply chain must maintain at least records following the one-up, one-down traceability approach.

Languiru, as a food operator handling products of animal origin, is required to follow MAPA's regulation on traceability, and also the RDC n.24/2015 from ANVISA. MAPA requires that companies must have control mechanisms to ensure the traceability of raw materials and products, with the availability of information from the entire production chain. This presented a legal issue, as Brazilian regulations — following the custom of civil code legal systems where that which is not permitted is disallowed — did not expressly provide for the use of digital records for official certification. Hence, MAPA regulatory inspectors could not accept the use of digital records.

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[143] Tibola, Casiane Salete et al. "Economically Motivated Food Fraud and Adulteration in Brazil: Incidents and Alternatives to Minimize," *Journal of Food Science* 83 (2018): 2033. https://doi.org/10.1111/1750-3841.14279.
[144] Breitenbach, Raquel et al. "Whose Fault is It? Fraud Scandal in the Milk Industry and Its Impact on Product Image and Consumption - The Case of Brazil," *Food Research International* 108 (June 2018): 475-481. https://doi.org/10.1016/j.foodres.2018.03.065.

Industries that decided to adopt digital traceability systems would keep using the paper records as the official information for MAPA inspections. In 2020, MAPA updated its regulation explicitly allowing the use of digital records.

Traceability Technology Utilized

The digital traceability solution for milk adopted by Languiru was developed by SIG Combibloc, a provider of aseptic packaging for the food and beverage industry. The FTS developed collects and stores data at every stage of the product journey, which starts at the farms where the milk is collected, goes through the production line and all of the supply chain, and ends at the supermarket shelf. It may also reach all the way to the consumers, if they choose to connect. All the information is stored in one database. The digital traceability solution includes a wide range of technologies that work together, such as sensors, scanners, mechanical handling, printing, etc.

A unique QR code with fraud-proof ink is printed on each Languiru product unit during its production. This digital solution allows Languiru to identify every single milk pack at any point in the supply chain. This new technology allows Languiru to reduce the time to identify where the faulty lot was in the retail from approximately five hours to a few seconds, and comply with ANVISA regulation on food recall.

Arising from the fact the biggest motivation for this project was the reduction in the consumers' confidence in dairy products, this solution allows consumers to immediately obtain key production data, including lab tests and other relevant data, from the web by scanning the QR code on Languiru's products.

An initial challenge of implementing the FTS was guaranteeing that all dairy farmer suppliers would have access to the internet, even in remote locations. To address this challenge, the company utilized an offline approach to supplier data entry that then uploaded data to the internet as soon as an internet connection was made available during transport.

Key Takeaways

Consumer behavior, particularly the reduction in milk purchases as a result of a food contamination scandal, was the driving incentive for the food operator to adopt a digitally enabled FTS. The regulatory regime's previous requirement for paper-based records was somewhat of a disincentive; however, this requirement eventually evolved. The FTS technology employed addressed the company's objective — increasing transparency for consumers — and it adapted to the ICT infrastructure constraints — by enabling offline data entry in rural areas with limited internet connectivity. These factors contributed to the success of the implementation of this FTS in the dairy sector in Brazil.

9.2 CASE 2: COFFEE IN COLOMBIA

Background

In early 2020, Farmer Connect, Swiss-based web platform with initial participation from several multinational corporations, and IBM unveiled the Thank my Farmer initiative, which connects U.S., Canadian, and European consumers to Colombian coffee farmers. According to Farmer Connect, there is a huge opportunity to add value along the coffee supply chain and transfer value to smallholders through data collection and effective branding to connect the consumer to the story behind each cup of coffee they are drinking.

This is a new initiative, started in 2020,[145] and it remains too early to determine what has worked and what has not worked. However, the willingness of the consumer to use a mobile app to build digital connections with the Colombian farmers is clear. The connection in this case between developed country consumers with developing country producers demonstrates a potentially valuable strategy, in the appropriate instances, to deliver the right incentives for FTS adoption in less-developed contexts.

According to Farmer Connect, Colombia has "a greater availability of smart devices and cell coverage than in some other coffee origins makes the deployment of farmer facing technologies more straightforward. The country also has proven experience that differentiated products return greater value to the producer than commoditized products."[146] Those aspects seemed to be key in enabling the use of this FTS design.

Regulatory Framework

Colombia's regulatory framework is somewhat less developed than that of Brazil. Title V of Law No. 9 of 1979 covers food sanitary measures, providing that "[f]oods or beverages altered, adulterated, counterfeit, contaminated or those which may affect the health of the consumer by other abnormal characteristics are not considered fit for human consumption."[147] Government agencies responsible for food safety are the Ministry of Health and Social Protection, the National Institute for the Surveillance of Food and Medicines, the Ministry of Agriculture and Rural Development, and the Colombian Institute for Agriculture and Livestock. Notable aspects of the regulatory regime are the categorization of food items based on risk[148] and the development of a single window system for processing food import documents.[149] Colombia employs the one-up, one-down traceability system, expressed in regulations issued by the Ministry of Health and Social Protection.[150]

Colombia's regulatory framework did not have an impact in this case study. However, according to Farmer Connect, the application may help the coffee industry to comply with additional traceability requirements within U.S. regulation. Nevertheless, it is important to keep in mind that the system was designed as a connection between consumers and farmers, so it is driven by the increased demand for transparency by consumers and by the willingness to help the farmers directly, rather than the regulatory framework itself.

Traceability Technology Utilized

Thank My Farmer is an app that can be downloaded to smartphones in which the consumer will be able to scan a QR Code in the packages of coffee producers, such as Beyers 1769 Colombian beans and 1850® Coffee 100% Colombian.[151] According to Farmer Connect:[152]

> *"The core of the platform is based on a decentralized ledger built using Hyperledger Fabric by IBM. The blockchain stores transactional information that can only be added to, not deleted or amended, providing an unbroken chain of digital custody. Further, because the blockchain is private and permissioned, individually verifying whether the user has the right to see the information uploaded by another user. In addition to the blockchain, external databases are either integrated or referred to in order to retrieve*

[145] IBM, "Farmer Connect Uses IBM Blockchain to Bridge the Gap Between Consumers and Smallholder Coffee Farmers," via *PRNewswire*, January 6, 2020. https://newsroom.ibm.com/2020-01-06-Farmer-Connect-Uses-IBM-Blockchain-to-Bridge-the-Gap-Between-Consumers-and-Smallholder-Coffee-Farmers
[146] Farmer Connect, email to authors, November 24, 2020.
[147] Government of Colombia – Article 304 (Google-provided translation January 10, 2021). https://www.funcionpublica.gov.co/eva/gestornormativo/norma.php?i=1177
[148] Resolution 2674 of 2013, issued by the Minister of Health and Social Protection.
[149] Decree 4149 of 2004 covers rules for using the Single Window for Foreign Trade (VUCE).
[150] Government of Colombia. https://www.funcionpublica.gov.co/documents/418537/604808/1962.pdf/abe38fb4-e74d-4dcc-b812-52776a9787f6.
[151] Farmer Connect, "Thank My Farmer." Accessed on December 4, 2020. https://www.thankmyfarmer.com/product.
[152] Farmer Connect, email to authors, November 24, 2020.

specific and detailed information, or information that would not be appropriate on a blockchain (Personally Identifiable Information, for example). This information is then shared with the consent of the entities or individuals involved with end consumers through a mobile application."

The information is shown in an interactive map and allows the consumer to know where the coffee they are buying is from as well as further details, such as the story behind it. Additionally, the app allows the consumers to engage the farmers or local initiatives by sending financial help.

Key Takeaways

The primary driver of FTS uptake in this case was to strengthen brand loyalty by improving farm to cup transparency for consumers in the U.S., Canada, and EU. The national regulatory regime in Colombia was not a driving incentive for FTS adoption, however, the operator saw FTS as a tool to ensure compliance with end-market (U.S.) regulatory requirements. The FTS design was appropriately customized to the objective, allowing the consumer to interact with the coffee source through digitally enabled technology.

9.3 CASE 3: AQUACULTURE IN BANGLADESH

Background

The Feed the Future Bangladesh Aquaculture and Nutrition Activity (BANA) is pursuing at least two initiatives for introducing digital traceability: one in 2016 with a pilot e-traceability system for shrimp production, and another initiative to trace carp production with DLT that began in September 2020. The latter is being developed in partnership with ByteAlly, a software technology company in India.

According to BANA, the main motivation is that the formal regulatory environment for food safety in Bangladesh is relatively weak, leading to distrust among consumers about domestically produced aquaculture. Therefore, BANA's initiatives aim at building pilot projects to understand the potential of a market-driven solution, given that additional information can increase consumers' trust and as result increase the value of aquaculture and expand both domestic and international market access. In a remote interview with the EEFS project, BANA cites two main drivers for aquaculture traceability in Bangladesh:

- A shrimp virus has restricted access for Bangladesh producers to EU markets. Good aquaculture practices with integrated disease control/management with a functional traceability system to verify compliance can help address EU SPS requirements for market entry.
- Domestic consumer awareness of impurities, particularly fears (potentially misplaced fears) of hormones used by domestic aquaculture producers presents an opportunity for producers and retailers to align and provide verified hormone-free fish as demanded by consumers.

Regulatory Framework

With the passage of the Food Safety Act of 2013,[153] Bangladesh created the Bangladesh Food Safety Authority (BFSA). Modeled on the American Food and Drug Administration,[154] the BFSA has wide-ranging authorities and positions it at the top of an inter-ministerial committee. The Act bans the use of poisonous elements, radioactive materials, and heavy metals in the production of food. It also bans the storage, marketing, or sale of food that contains such contaminants or is otherwise unfit for human consumption. Food operators are required to "keep the name, address and receipt or *challan* of all parties involved in

[153] Government of the People's Republic of Bangladesh – Ministry of Food, The Food Safety Act, 2013." October 10, 2013. https://www.dpp.gov.bd/upload_file/gazettes/16173_23175.pdf.
[154] "Editorial: Food Safety Law with Some Teeth," *The Daily Star*, July 3, 2013, https://www.thedailystar.net/news/food-safety-law-with-some-teeth.

the manufacture, import, processing, storage, distribution or sale of any article of food or food ingredient." [155]

Under Article 55 of the Act, inspectors have the authority to seize adulterated food and charge violators, with cases to be heard in special food courts established under Chapter X. But these provisions appear to be extremely weak. If the food operator is not aware that the food item in its possession was already adulterated when passed on from the previous supplier, under Article 63 gives the food operator the option — not a requirement — to cooperate with the authorities to identify the actual violator.[156]

> *If it appears beyond doubt that the food seller is not involved knowingly in any act of violation of any provision of this Act, and if the food seller is ready, if necessary, to cooperate with the Authority to identify the violator of the provision of this Act, necessary steps may be initiated to identify the actual violator instead of prosecuting the food seller under this Act.*

Noting that many of Bangladesh's food standards are outdated and not based on scientific work, BSFA in 2019 began undertaking a strategy to review existing standards and regulations with a view to harmonizing them with the standards and guidance adopted by the Codex Alimentarius Commission.[157]

As previously mentioned, the weak regulatory environment for food safety in Bangladesh has proven to be a problem when exporting aquaculture to other countries and has also led to domestic consumer mistrust. Therefore, in this case, developed country regulation for food imports plays an important role. Some producers adulterate their harvests by injecting dirty water or gelatin into the shrimp, making it unfit for consumption. Since it is extremely difficult for international buyers to trace the shrimp to its source, given the weak local regulatory framework, it is not possible to guarantee the safety and quality of their food products,[158] resulting in reduced market access for producers in Bangladesh.

Traceability Technology Utilized

Based on information provided by BANA, eServices Everywhere developed by SourceTrace was used for shrimp traceability, with one mobile application that was used by the farmers and Aquaculture for Income and Nutrition staff to gather information and one web application in which it was possible to access the data and information gathered. The application appears to utilize a central database where the information is stored, then the information is traced back to the collection centers, which then have the information on the farmers that delivered the shrimp each day.

In the case of the aforementioned carp project, which is currently under development, the application will be developed by ByteAlly using IBM Food Trust blockchain. According to TheFishSite.com, ByteAlly will develop the following components: [159]

- *Cloud-based ERP – to replace the paper-based processes and to manage the farm operations. It will act as the data source from which data will be uploaded to the blockchain.*

[155] Government of the People's Republic of Bangladesh – Ministry of Food, The Food Safety Act, 2013." October 10, 2013. https://www.dpp.gov.bd/upload_file/gazettes/16173_23175.pdf
[156] Ibid.
[157] Bangladesh Food Safety Authority Ministry of Food, Govt. of Bangladesh, "Harmonization of Bangladesh's Food Safety Standards with Codex Standards and Other International Best Practices," https://bfsa.portal.gov.bd/sites/default/files/files/bfsa.portal.gov.bd/notices/a84613c2_1de6_475f_97c9_784374431701/BFSA-Strategy-for-Harmoniztion-of-Standards-draft-V-1.pdf
[158] Aktar, Shamima and Md. Shariful Alam, "Assessment of AIN-Initiated Pilot Shrimp e-Traceability System in Khulna, Bangladesh," Dhaka, Bangladesh: WorldFish. Assessment Report: 2017.
[159] Fletcher, Rob. "Blockchain Set for Bangladesh Aquaculture Launch," *The Fish Site*, September 11, 2020, https://thefishsite.com/articles/blockchain-set-for-bangladesh-aquaculture-launch.

- *Android application - for the participating stakeholders to upload traceability information from their smartphones.*
- *GS1 EPCIS API – to format the data received from multiple sources (software systems, mobile apps, IoT, etc.) into interoperable data (GS1 EPCIS compliant). GS1 EPCIS is a standard developed by GS1 for interoperability within supply chains. IBM Food Trust Blockchain requires the uploaded data to be in GS1 EPCIS standard.*
- *IoT cloud Infrastructure – to receive data from IoT sensors and transmit them to the blockchain network.*

Key Takeaways

The regulatory regime in Bangladesh is considered relatively weak, and not a driving incentive for the adoption of FTS. The FTS system under design are donor driven, in an attempt to improve both domestic and international transparency, and ultimately trust, in aquaculture products produced in Bangladesh. Anand Sukumaran, VP of Growth at ByteAlly, stated, "This is the first large scale food traceability blockchain focusing on aquaculture in the region. It will demonstrate the ability to track the provenance of the fish and ensure food quality, thus yielding a higher selling price for the fish farmers."[160] As this technology is currently under development, it is too soon to determine its success or failure.

9.4 CASE 4: HORTICULTURE IN GHANA

Background

The European Union banned imports of Ghanaian horticultural crops from 2015 to 2017 due to the difficulty in controlling pest infestations;[161] poor export procedure enforcement; and the inability to identify, trace, and remove vegetables with harmful organisms destined for EU markets. In 2018, with the technical support of USAID's Improving Food Safety Systems Project, Ghana was able to implement a food traceability system, which allowed Ghanaian food operators to better comply with EU regulation, effectively lifting the EU ban on vegetable imports from Ghana.[162]

The most important factor in this case was arguably the engagement of USAID in supporting Ghana to design and implement a food traceability system from seed to the export depot, including Kotoka International Airport in Accra, from which most shipments to the EU depart.[163]

Regulatory Framework

Pursuant to Ghana's Public Health Act of 2012, a food operator commits an offense if it "sells or offers for sale" a food item that is poisonous, contains a harmful substance, or is unfit for human or animal consumption.[164] Chapter 97 of the Act interestingly requires the registration of foods, stating, "[a] person shall not manufacture, import, export, distribute, sell or supply food or expose food for sale unless the Authority has registered the food." Ghana adopted a Food Safety Policy in 2015, which includes the objective of "[e]nsuring traceability through effective surveillance" that it deems important for an efficient food safety system.[165]

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[160] Ibid.
[161] Feed the Future, "The Global Food Security Strategy (GFSS) Ghana Country Plan" (August 10, 2018). https://cg-281711fb-71ea-422c-b02c-ef79f539e9d2.s3.us-gov-west-1.amazonaws.com/uploads/2018/11/Ghana_Country_Plan_Public_Version_WS_Edits.pdf.
[162] "Building Confidence for Export through Traceability in Ghana," *International Executive Service Corps*, accessed December 4, 2020. https://iesc.org/building-confidence-for-export-through-traceability-in-ghana/.
[163] Ibid.
[164] Government of the Republic of Ghana, "Public Health Act, 2012." https://fdaghana.gov.gh/img/annualrep/fdaact2020.pdf
[165] Government of the Republic of Ghana, "National Food Safety Policy," Draft, My, 31, 2013. Pg. 29. https://members.wto.org/crnattachments/2014/sps/GHA/14_2014_00_e.pdf.

The initiation of the FTS in this case study was motivated by a finding from EU auditors that Ghanaian food products contained harmful organisms, suggesting that the products were not effectively inspected before export. Owing to noncompliance with EU food safety regulations, the EU placed a ban on imports. Weaknesses in the enforcement of export procedures and food safety regulations in Ghana was identified as the problem. A traceability system, coupled with improvements in the enforcement of food safety regulations and export procedures, held the potential to achieve compliance for export to the EU.

Traceability Technology Utilized

The solution was developed by Optel, who described the solution is a "user-centric traceability system that covers all the steps required for the exportation of fruits and vegetables (F&V) and includes all the operators in a multi stakeholder value chain."[166] Moreover, they mention that the solution includes:

- *Inspection of exporters, packhouses, growers and fields*
- *Crop cycle and fieldwork monitoring, including planting, plant protection and harvesting*
- *F&V traceability from field to packhouse*
- *Traceability during packing operations, including reception, lot creation (linking input and output) and evacuation*
- *Traceability from packhouse to export point (airport)*
- *Linking traceability data with phytosanitary certificate and export documentation*
- *Centralized cloud data repository for data sharing, viewing, analysis and report generation*

Key Takeaways

End market regulatory requirements (from the EU, in this case), were the driving incentive for the introduction of an FTS. The introduction of the system was donor-supported, and in tandem with domestic enforcement of food safety and export regulations, the FTS has been considered a success, as it resulted in the reestablishment of market access for Ghanaian horticulture into the EU market.

9.5 CASE 5: TUNA IN FIJI

Background

Since 2017 World Wide Fund for Nature (WWF) has partnered with ConsenSys, TraSeable, and Sea Quest Fiji Ltd. to develop a blockchain-based traceability system for tuna. According to WWF, "Illegal, unreported, and unregulated (IUU) fishing remains a persistent problem in the Pacific region and blockchain technology can help lift the veil of secrecy that hides this activity."[167] WWF saw an opportunity to utilize a DLT to improve market access for fishermen who follow good practices and operate legally. Therefore, this case is an example of a traceability initiative which was not driven by the regulatory requirements, consumers demand, or market-driven standards, but was instead driven by the environmental sustainability objectives of an external nonprofit actor.

The fishing industry largely still relies on paper-based processes, as a result digital traceability systems require digitization and need to guarantee the interoperability of information systems used in the Pacific.

Consumer demand was an important incentive — and enabler — for the adoption of this FTS, as discerning consumers are willing to pay more for sustainably caught tuna. To increase transparency for consumers, the FTS was designed to apply all along the tuna supply chain "from bait-to-plate."

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[166] Optel Group. "Case Study: Using Digital Traceability to Increase Food Safety and Regain Trust." Accessed December 10, 2020. https://www.optelgroup.com/cs_using-digital-traceability-to-increase-food-safety_ng/.

[167] World Wide Fund for Nature, "New Blockchain Project Has Potential to Revolutionize Seafood Industry." Accessed December 18, 2020. https://www.wwf.org.nz/what_we_do/marine/blockchain_tuna_project/.

Regulatory Framework

Paragraph 70(w) of the Food Safety Act of 2003, the Fijian Central Board of Health is granted authority to "*regulate proper disposal of food by prescribing ways and means including but not limited to (i) keeping of records and putting batch or lot numbers to facilitate tracing the whereabouts of food.*[168] In 2008, Fiji adopted implementing measures through the "Standard on Specific Good Hygienic Practices for Fish and Fisheries Products." Pursuant to Article 19(1) of the Standard, "appropriate records of processing, production, and distribution shall be kept [by processors] and retained for a period that exceeds the shelf life of the product."[169] Moreover, "Each container of fish, shellfish and their products intended for the final consumer or for further processing shall be clearly marked to ensure the identification of the producer and of the lot."

In spite of the robustness of the regulatory regime, the enforcement of Fijian regulations in surrounding waters is relatively weak. Most developing countries lack resources to effectively police their exclusive economic zones for poaching or for illegal fishing practices. Food fraud abounds as well, with much of the fish reaching supermarkets in developed countries being sold as more expensive varieties. This demonstrates the importance of consumer demand for verification of sustainably caught fish.

Traceability Technology Utilized

A report from the FAO presents a summary of how this traceability system operates:[170]

- *"The supply chain was mapped into Treum (previously Viant), and the needed roles and permissions were set. This created the data entry interfaces and rules to capture data.*
- *On capture aboard a longliner, each tuna was tagged with unique identifiers initially using RFID tags, and later with QR code tags. Key data about the capture event and tuna were recorded into the app. Given an Internet connection, data was transmitted in real time to the blockchain; otherwise, this was done on return to port.*
- *On landing, each tuna unloaded was likewise tracked by scanning its tag.*
- *In the processing facility, at key stages along the processing line, the tuna was tracked, and key data collected. If a tuna was transformed into other products such as loins, then each new product (loin) was given a new identity on the blockchain and tracked separately.*
- *On distribution, actors along their supply chain could participate and continue to track the tuna products through the supply chain to the consumer."*

Key Takeaways

Consumer and advocate demand for environmental sustainability were the primary drivers of FTS adoption. The high value of tuna supports an acceptable rate of return on FTS investment. WWF supported the introduction of the initiative and found that supply chain actors' coordination is critical. Additionally, offline data entry is a solution to engage suppliers where internet connectivity is low.

[168] Fiji Islands, "Food Safety Act 2003." http://extwprlegs1.fao.org/docs/pdf/fij50969.pdf.
[169] Fiji Islands, "Food Safety Regulations 2009." http://www.health.gov.fj/wp-content/uploads/2017/06/Food-Safety-Regulations-2009.pdf.
[170] Blaha, Francisco and Kenneth Katafono. "Blockchain Application in Seafood Value Chains," *FAO Fisheries and Aquaculture Circular,* no. 1207 (2020): 32. https://doi.org/10.4060/ca8751en.

10. SUMMARY OF KEY DRIVERS FOR FTS SUCCESS

Prior sections have presented the objectives, benefits, motivations, and contextual factors that drive adoption and contribute to the successful implementation of food traceability systems. The practical examples provided demonstrate that there are several successful cases of FTS adoption and implementation in emerging and developing country contexts; however, many other initiatives fail to fully achieve their goals. This section summarizes some of the important aspects, or preconditions in the enabling environment, that could lead to the successful adoption and implementation of FTS.[171,172,173]

To better understand FTS success, it is necessary to consider two critical questions.

1. Are the appropriate incentives in place for food operators to adopt FTS, including formal regulatory requirements and market-led standards?
2. Do food operators have what they need to implement FTS, including the infrastructure, technology, vertical supply chain coordination, and capacity (technical, operational and financial)?

1) Do food operators have the right incentives to adopt a FTS?

For the first question, to determine whether the appropriate incentives are in place, there are several conditions in the enabling environment that must be considered.

- ***Government Regulations:*** The existence and enforcement of a regulatory framework that places food traceability responsibility on food operators. (See Section 6 on the Role of National Laws/Regulations.)
    - Relevant regulatory agencies and rules must adapt to accept digital data to demonstrate regulatory compliance.
- ***Private Voluntary Standards:*** Where retailers and other lead firms in a chain require suppliers to meet formal market-led standards for production processes and quality, the adoption of traceability is often an explicit requirement. (See Section 7 on The Role of Voluntary Standards.)
    - Importantly, voluntary standards are effectively mandatory if a food operator wishes to supply a product into a particular market channel that requires their compliance.
- ***Consumer Awareness with Demand Feedback Loops:*** Consumers who are increasingly aware of food safety issues (and other ethical concerns along a food supply chain), and respond by reducing their consumption of a product, are a powerful driver of change for both regulators and food operators. (See Section 5 on the Role of the Consumer.)
    - Consumer demands may encourage regulators to enact or enforce food traceability rules and/or provide the market incentive for food operators to adopt FTS to respond to consumer demand, even in the absence of effective government regulation.

2) Do food operators have what they need to implement a FTS?

For the second question, to determine if the industry has what it needs to implement an FTS, there are several important enabling environment considerations.

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[171] Kay Behnkea, and M.F.W.H.A. Janssen (Marijn), "Boundary Conditions for Traceability in Food Supply Chains Using Blockchain Technology," *International Journal of Information Management* 52, (June 2020). https://doi.org/10.1016/j.ijinfomgt.2019.05.025.

[172] Tsolakis, Naoum et al. "Supply Network Design to Address United Nations Sustainable Development Goals: A Case study of Blockchain Implementation in Thai Fish Industry," *Journal of Business Research* (August 2020): 5-7. https://doi.org/10.1016/j.jbusres.2020.08.003.

[173] Duan, Yanqing et al. "A Framework for the Successful Implementation of Food Traceability Systems in China," *The Information Society* 33, 4 (June 2017): 226-242. https://doi.org/10.1080/01972243.2017.1318325.

- ***Technology Platform:*** There are many emerging technology platforms; however, many are not targeted at small-scale operators in developing countries. It is important that the technology platform meets the financial, technical, and operational capacity of small-scale operators to scale uptake across less developed countries.
    - *Local availability:* Local trustworthy suppliers for the technology platform can also be important, as international suppliers can be too expensive or take too long to respond to adjustments, particularly for rural enterprises.
    - *User-Friendliness:* Digital recordkeeping and data entry platforms should be user-friendly, as many smallholder farm suppliers may have limited literacy and/or experience with digital database technologies.
    - *Supply Chain Consensus:* Agreement across supply chain partners on a shared technology or different technologies capable of exchanging information.
    - *Functionality:* Sensors and automation will ensure data veracity throughout the chain. Information security and confidentiality are also important functional considerations.
- ***Organizational Capacity****:* Food operator staff require training to obtain knowledge and skills required to use increasingly sophisticated traceability technologies, as well as access to finance to invest in these new technologies.
- ***ICT Infrastructure:*** Rural connectivity reliability and speed are important factors in implementing digital traceability — either central database or DLT-enabled system traceability.
    - This requirement can be overcome by utilizing an offline strategy for rural suppliers that uploads data when the connectivity is available.
- ***Supply Chain Coordination:*** One food operator cannot act alone given the need to trace a product forward and backward. A successful FTS requires coordination. This is particularly important — and challenging — in market systems that rely on a network of small farmer suppliers with limited access to digital recordkeeping technologies.
    - *Standard of Information:* A critical element of coordination, in addition to shared platform(s) for information sharing, is a shared standard for the information itself. Food operators all along the chain need an accepted standard of information (KDEs and CTEs) for a mutual understanding among regulators and supply chain partners of what is being monitored.

KEY TAKEAWAYS TO GUIDE FTS INVESTMENT

Several conditions need to be met for FTS to be adopted and implemented successfully. By recognizing the importance of the incentives and requirements for operators to adopt and implement FTS, USAID, its IPs, host country governments, and other development actors can more successfully facilitate food safety and food sector competitiveness improvements. Where the incentives and requirements are not in place, supporting the introduction of an FTS may be met with limited success; therefore, building these foundational factors is a critical step.

Before supporting investment in FTS, food operators, USAID, and IPs should first assess the factors in the enabling environment for food traceability success discussed in this study. Below is a summary of key questions and considerations that will help guide decision makers toward an appropriate type of FTS platform and complementary investments to pursue in a given context.

Table 5: Key Questions and Considerations to Guide FTS Investment

Key Questions Prior to Investment	Possible Considerations	Information Needed
What is driving the push to adopt FTS?	1. To comply with national regulation?	Determine traceability requirements of relevant national regulations.
	2. To reach foreign markets?	Determine traceability requirements of relevant regulations of importing country, and/or any voluntary standard required by buyers.
	3. To gain accreditation for a social/environmental cause?	Determine traceability requirements of voluntary standard commonly used for particular cause and target market channel.
What is the appropriate FTS technology/platform to adopt?	1. What resources are available to the food operator?	Determine availability of finance for operator to invest in FTS system installation and/or costs to comply with regulations/standards.
	2. What is the operational capacity of food operator?	Identify technical and operational capacity gaps that require training and determine availability of government, industry, and/or donor extension services.
	3. What degree of industry cooperation is necessary/possible?	Determine existing platforms used in the supply chain. Determine whether a particular FTS platform or data sharing standard is required by buyers. Identify platform(s) available that will seamlessly share data forward and backward with supply chain partners' systems as required.
	4. What is the local availability of a technology platform?	Determine most appropriate platform/model, and whether ongoing technical support is necessary and available. Identify local technology providers operating in-country.

ANNEX 1: KEY QUESTIONS AND ANSWERS ON FOOD TRACEABILITY SYSTEMS

1. What is a Food Traceability System?

An FTS is a tool that allows food operators to track food ingredients and/or finished food products throughout their entire lifecycle, using captured and stored records including key data elements (KDEs) and critical tracking events (CTEs).[174] KDEs record the who, what, where, when at each step of the chain, and CTEs record the completion of a step in the supply chain.[175]

2. What is a Food Operator?

A for-profit or not-for-profit entity involved in the production, processing, purchase, and/or sale at any stage of the food chain.[176] According to many national regulations around the world, the food operator has the "primary role and responsibility for managing the food safety of their products and for complying with related regulatory requirements."[177] While the EU Food Law and other regulations/standards may use the term "food business operator," this study uses the term "food operator."

3. What are the benefits of food traceability?

The most well-known and acknowledged benefit of an FTS is the ability to manage food safety, mitigate risks of contamination along the chain, and to administer product recalls where safety breaches are identified. In addition, adopting an FTS allows a food operator to access new market channels requiring compliance with regulations and/or standards, build a brand based on quality and safety, increase loyalty among increasingly discerning consumers, and identify areas for operational efficiency improvements.

4. Who are the key actors to engage for effective food traceability?

Several market system actors contribute to the effectiveness of food traceability. First and foremost, the responsibility for food traceability is on the food operator themselves. But they don't operate alone. National regulatory agencies and private standards organizations play a key role in putting the incentives in place for FTS adoption through the articulation of traceability rules/requirements. These regulatory agencies and standards organizations act in response to the demands from consumers and constituencies. Beyond this dynamic, food operators also rely on entrepreneurial technology providers to improve the local availability of traceability technology platforms. And food industry associations can play a key role in promoting coordination and information sharing across a food supply chain.

5. Is blockchain necessary for an effective food traceability system?

Distributed ledger technologies (DLTs), including blockchain, provide improvements for FTS data storage and data integrity. However, DLTs are typically not explicitly required by national regulations or voluntary standards, and they may be less appropriate than other digitally enabled traceability technology platforms depending on several enabling environment factors. The emergence of cloud-based data storage for

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[174] IFT, "About the Global Food Traceability Center (GFTC) and FAQs." https://www.ift.org/global-food-traceability-center/about-gftc.
[175] GS1, "GS1 Global Traceability Standard." https://www.gs1.org/standards/gs1-global-traceability-standard.
[176] Food and Agriculture Organization of the United Nations, and World Health Organization, "FAO/WHO Guide for Developing and Improving National Food Recall Systems," (2012): 13. http://www.fao.org/3/i3006e/i3006e.pdf.
[177] "FAO Term Portal," Food and Agriculture Organization of the United Nations. Accessed January 10, 2021. http://www.fao.org/faoterm/viewentry/en/?entryId=173194.

instance, may offer food operators a more suitable improvement over central databases without requiring a distributed ledger platform.

The primary benefit of DLTs — providing an immutable record of a transaction — strengthens the integrity of data. However, DLTs still suffer from the "garbage-in, garbage-out" dilemma, where data capture processes remain critical. And in developing country environments, operators often lack the operational capacity and local infrastructure to effectively implement DLT platforms.

A food operator's objectives, challenges, and incentives should dictate the selection of a specific FTS design. Before designing or promoting a traceability technology platform, it is necessary to: 1) determine the necessary FTS functionality to meet regulatory and standards requirements in a target market channel, 2) assess food operator capacity to implement a FTS platform, and 3) identify the type of system being used by supply chain partners to ensure data can be shared as required.

6. What are the costs of adopting a food traceability system?

It is important to view the costs of FTS as an investment which adds value to a core business by opening access to new markets, mitigating business risks, and improving operational efficiency. To achieve these benefits, a food operator must consider two components of outlays: 1) initial system investment and installation, and 2) implementation and maintenance. The outlays needed for each can vary greatly depending on the design of the food traceability system and the size of the food operation.

As the operational functionality and the technology utilized becomes incrementally more sophisticated, then the costs will rise accordingly. Costs will rise as each FTS design variable becomes more advanced: 1) data entry method (manual versus automatic), 2) distance the information travels between food chain actors (one step or many steps forward/backward), 3) data granularity (per lot versus per unit), and 4) data storage (paper versus central database versus distributed ledger). Costs of adopting digitally enabled systems will also vary from country to country based on technology availability and ICT infrastructure.

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