CAST Issue Paper
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Food Traceability: Current Status and Future Opportunities

Food traceability describes a system that documents the history of a product through its entire production chain from primary raw materials to the final consumable products.

A food traceability system needs to be:

- fit-for-purpose, user friendly, globally accepted, and be feasibly incorporated into current industry practices and systems.
- compatible with the components of other food safety and quality management systems.

The fundamental pillars of traceability—the who, what, when, and where—must be unambiguously communicated through the supply chain.

- Key terms, like critical tracking events (CTE) and key data elements (KDE), provide the framework and foundation for an interoperable system that needs to be successfully applied by all partners in the supply chain to assure success.
- CTEs are supply chain events where data capture is necessary to achieve traceability. These are usually points of transfer or transformation like shipping, receiving, or processing.
- KDEs are the pieces of information or attributes that describe the events, the products, and the players involved at each CTE.

Global regulatory agencies have established traceability requirements to ensure the safety, security and legality of both domestically produced and imported products.

- The widespread practice of “one step forward, one step back” traceability is reflected in food regulations through the United States, the European Union, and Canada.
- The United States Food and Drug Administration (US FDA) published regulation in 2022 that pushes industry towards an “end-to-end” traceability approach with a defined set of baseline traceability requirements for certain commodities.

Traceability systems rely on good data, from trusted sources.

- The effectiveness of a traceability system directly correlates with the quality of the data collected. Comprehensive investment in system design and maintenance efforts (e.g staff training, technology, standardization) is essential for cultivating quality data.
- Emerging tools and technologies like decentralized identifiers (DIDs) and verifiable credentials offer promising opportunities to improve trust in digital data.

Our ability to track and trace food depends upon systems that enable people to share information quickly and efficiently up and down the supply chain without fraud or errors.

- Collaborative efforts to standardize what data is collected, how data is formatted, and/or how data is exchanged enable easier and more efficient traceability systems.
- The FDA’s Food Traceability Rule standardizes data collection requirements for those that manufacture, process, pack, or hold food that are on the food traceability list.
- The GS1 Digital Link is a new standard that enables simplified sharing of GS1 standard identifiers using the broadly adopted QR barcode format.

About this Publication

Food traceability has been defined as “the ability to track and trace a food product through all stages of the supply chain”. Though food traceability supports numerous use cases (e.g. supply chain optimization, sustainability efforts, and product differentiation), food safety remains one of the most critical applications. Food traceability enables corrective actions (such as a product recall) to be implemented quickly and effectively when something goes wrong. When a potential food safety problem is identified, an effective traceability system can help isolate and prevent contaminated products from reaching consumers. Food traceability not only facilitates consumer awareness of potentially harmful products but can also be used to provide desirable information about provenance.
The technology and enabling architecture of food traceability is rapidly advancing in response to demand from consumers, food producers, distributors and retailers, and food safety regulators. There have been several technological and regulatory developments that make clear that credible, functional, and impactful food traceability is likely to become a reality in the United States.

Food traceability has become an important focus both industry and government. The incidence of food borne transmission of pathogens resulting in acute and long-term adverse health impacts remains stubbornly above acceptable levels.

- The primary objective of the paper is to investigate and discuss the development and use of various technologies to enable the traceability of food products and thus enhance food safety, source transparency, and consumer confidence.
- The paper will deep dive into the technological infrastructure underlying food traceability platforms, and discuss the history of such platforms, current state of the technology, ongoing U.S. food traceability regulatory initiatives, and the likelihood of commercial scale deployment.
- This paper will also address current infrastructure limitations that may slow technology implementation, including the current state of rural broadband access.

This publication is a joint effort between CAST (Council for Agricultural Science and Technology) and IFT (Institute of Food Technologists).

About CAST

The Council for Agricultural Science and Technology (CAST) is a nonprofit organization with its membership composed of scientific and professional societies, companies, nonprofits, and individuals. Through its network of experts, CAST assembles, interprets, and communicates credible, balanced, science-based information to policymakers, the media, the private sector, and the public.

The primary work of CAST is the publication of papers highly regarded as a source of science-based information written and reviewed by volunteer scientists and subject experts from many disciplines. CAST is funded through membership dues, unrestricted financial gifts, and grants.

About IFT

Since 1939, IFT has been a forum for passionate science of food professionals and technologists to collaborate, learn, and contribute all with the goal of inspiring and transforming collective scientific knowledge into innovative solutions for the benefit of all people around the world. As a scientific community grounded in purpose, IFT feeds the minds that feed the world.

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feeding the minds that feed the world

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Food Traceability: Current Status and Future Opportunities

Effective food traceability allows food system partners to track foods and ingredients, from harvest through processing, and finally to the marketplace. (Photos from erelyuk/Shutterstock, DedMityay/Shutterstock, and Zyn Chakrapong/Shutterstock.)

Abstract

This report, *Food Traceability: Current Status and Future Opportunities*, is a joint project of the Council for Agricultural Science and Technology (CAST) and the Institute of Food Technologists (IFT). Its purpose is to provide an overview of food traceability, so readers in the food industry, academia, state and federal government agencies, production agriculture, trade associations and everyone involved in supplying and distributing food can obtain a basic understanding of this critical area. It is not intended as a comprehensive, exhaustive, review, but rather as a fundamental primer, to provide information about the history, significance, nomenclature, regulations, technology, and future of food traceability.

Food traceability has been defined as “the ability to track and trace any food through all stages of production, processing and distribution” (including importation and at retail). Though food traceability supports numerous use cases (e.g., supply chain optimization, sustainability efforts, and product differentiation), food safety remains one of the most critical applications. Food traceability enables corrective actions (such as a product recall) to be implemented quickly and effectively when something goes wrong. When a potential food safety problem is identified, an effective traceability system can help identify, isolate and prevent contaminated products from reaching consumers. Food traceability not only facilitates consumer awareness of potentially harmful products but can also be used to provide desirable information about provenance.

The technology and enabling architecture of food traceability is rapidly advancing in response to demand from consumers, food producers, distributors, retailers, the food service industry and food safety regulators. There have been several technological and regulatory developments that make clear that credible, functional, interoperable and impactful food traceability is likely to soone become a reality in the United States.

Foreword

Over the past five years, I had the honor and privilege of serving under two different administrations as the Deputy Commissioner for Food Policy and Response at the U.S. Food and Drug Administration (FDA), a position I held from 2018 to 2023, after spending 30 years in public health leadership roles for two industry giants: Walmart and the Disney Company. It’s because of these experiences, both public and private, that I’ve often said that while today’s modern

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food system is impressive, it does have an Achilles heel – a lack of food traceability.

People often talk about the food supply chain, but in reality, it isn't a chain at all. The food system today—the way we get our food from farm to table—has evolved into a complex, decentralized, and distributed network that is interdependent on many entities including farmers, processors, distributors, grocery stores, foodservice establishments, and more. And while there is no question that today's food system provides consumers with a more diverse, convenient, and economical source of food, it also presents risks and challenges.

For example, in today's food system, the output from one ingredient producer could end up in thousands of products on a grocery store shelf. We saw evidence of this during a Salmonella outbreak in 2009, caused by contaminated peanut paste produced by the Peanut Corporation of America (PCA), which lasted for months as suppliers slowly became aware that their products contained PCA's peanut paste. In the end, nearly 4,000 food items were recalled.

Yet another example, readers may recall an outbreak of E. coli 0157:H7 in the United States in 2006 that resulted in all spinach produced, regardless of source, being pulled from grocery store shelves. This outbreak served as a warning signal of the need for better traceability capabilities within the food system. Fast forward to the fall of 2018, more than a decade later, and yet again the nation was experiencing another multistate outbreak of E. coli 0157:H7 involving leafy greens, this time romaine lettuce. After the CDC and FDA issued advisories directing consumers to avoid eating romaine lettuce, regardless of source, it was clear that not much had changed in the 12 years since the spinach outbreak. Our nation's food traceability capabilities had not significantly improved or kept up with the digital modernization that has happened in the world around us.

Until recently, there has not been a widely adopted regulatory standard for what and how each segment of the food system should track and record data for food traceability purposes. Therefore, the current system has been limited to traceability capabilities that are often described as "one step forward and one step back" without much specificity.

However, things are changing. Because of these limitations, Congress included in the passage of the Food Safety Modernization Act (FSMA) a requirement for FDA to develop a Food Traceability Rule, often referred to as Section 204 (Additional Record Keeping for Certain Foods). On November 15, 2022, the FDA published the final version of its Food Traceability regulation. The rule's enforcement date is January 20, 2026.

The main elements of the rule, which you will learn about in this paper, are the establishment of Key Data Elements (KDEs), Critical Tracking Events (CTEs), a Food Traceability Lot Code, as well as a List of Foods that will require these additional data keeping requirements. I've personally described the establishment of these standards as the equivalent of creating a universal language of food traceability.

The benefits of a more traceable food system are obvious and it's more than mere containment. First, being able to trace a contaminated food to its source in the midst of an outbreak allows a culprit food to be identified earlier in an epidemic curve, allowing the food to be pulled from commerce, thus, preventing additional illnesses. This is a form of prevention, albeit secondary prevention. In addition, it enhances our ability to not needlessly affect the livelihood of food producers whose products are unaffected. Second, enhanced traceability allows public health officials to identify an affected food product involved in an outbreak sooner, thereby, allowing a more timely and relevant root cause investigation to take place that could strengthen our ability to prevent future, similar, recuring outbreaks. Again, this would also strengthen prevention. Lastly, better food traceability ultimately results in greater transparency and numerous behavioral science studies have shown how powerful a force transparency is to inhibiting undesired behaviors and influencing conformance to more desired behaviors and outcomes.

Lastly, the cost benefit analysis of FDA's final Food Traceability Rule demonstrates that there is a favorable return on investment, from a public health perspective alone, on better food traceability. When you consider other features, such as the potential to enhance supply chain efficiencies, reduce food waste, and improve sustainability, the public health and business case are undeniable.

In closing, better food traceability can't wait. Our ability to provide safe, affordable, and sustainable food for this generation and the next depends on it.

*— **Frank Yiannas**, Former U.S. Food and Drug Administration Deputy Commissioner, Food Policy and Response*

Introduction

Keeping track of one's possessions and their location has been an important human behavior of people throughout the ages. Tracking and tracing items are not new concepts and have been in place since the beginning of recorded history.

It is thought that the practice of identifying animals by the use of markings began at the beginning of civilization. Some of the earliest information about traceability dates back to 1700 BCE in the Middle East to Mesopotamian shepherds who marked animals from different owners with color dyes to distinguish them. This is believed to be the earliest form of identification used to differentiate between who owned which animals (Blancou 2001). Identification of individual, live animals with body markings has been practiced for more than 3,800 years (Code of Hammurabi) using a variety of techniques such as branding, ear incisions, other indelible markings or tags. This identification, used in many regions of the world, served as a sign of ownership, assertion of rights, and protection against loss or theft (Blancou 2001; Landais 2001). The marking of animals and then, the link to written documents often held by regulatory authorities, certifying their origin, evolved with time. This trend continued for many centuries, with traceability being used almost exclusively for very high value assets, like horses and other prized animals (Blancou 2001). During the Middle Ages, in European countries with large cattle grazing regions, branding animals with a hot iron was widely practiced.

As European powers expanded their territories during the colonial era, the practice of branding to identify cattle spread around the globe. By the middle of the 18th century in the Americas, cattle raising became a large enterprise and hot metal branding spread throughout North America (Ketchum 2017).

This practice of marking animals expanded and continued to track and trace the movement of domestic livestock as the industry grew. With advances in veterinary medicine, it was important to monitor disease control and maintain health certification standards to prevent epidemics among herd animals (Ketchum 2017). Today, a National Uniform Eartagging System (NUES) is in effect in the United States. It is a numbering system for the official identification of individual animals that provides a nationally unique identification number for each animal and enables the tracing of livestock movement interstate (USDA 2020).

Seals were an important part of identifying goods that were being traded. Stamp seals were used on products that were traded during the Bronze Age (3300 BC to 1200 BCE) in Mesopotamia (Hirst 2019). These seals were impressions that were carved into stone and pressed into moist clay. These clay seals were used to indicate product authenticity and were tied to packages and used to seal products to be traded. In an article on seals, Hirst mentions that "the impressions on the seals often listed the contents, or origin, or destination or the number of the goods in the package, or all of the above." Cylinder seals were used to form impressions that branded products, authorized transactions, and controlled the movement and storage of goods (Mark 2015). These seals were most likely one of the earliest examples of tracking goods that were traded (Hirst 2019).

Evolving from simply keeping track of and safeguarding expensive assets in early civilization, traceability now encompasses a comprehensive system that enables food companies to assure quality and safety by tracing and tracking their products and ingredients through the entire food supply chain, from beginning to end.

Supply Chain Complexity

Global trade in food commodities most likely began more than 2,000 years ago as people moved across borders and brought spices and other luxury items with them to trade. Through technological innovations and improved transportation, global trade increased during the 16th and 17th century, the scientific and industrial revolutions, and after World War II (World Economic Forum 2019). Benefitting from the second and third industrial revolutions, global food trade increased at a rapid pace (World Economic Forum 2019). Now, foods and ingredients are sourced from all over the world.

The global food supply chain is enormous, extremely complex, and dynamic, involving multiple stakeholders. According to Simpson, "Food really drives the world and apart from clean water, access to adequate food is the primary concern for most people on earth. This makes agriculture one of the largest and most significant industries in the world; agricultural productivity is important not only for a country's balance of trade but the security and health of its population as well" (Simpson 2022).

The growing, harvesting, processing, transportation, storage, distribution, preparation, and merchandising of food is most likely the world's single largest economic activity. Agriculture provided work for 866 million people in 2021 and this represented 27% of the global labor force (FAO 2022a). The total area of agricultural land represents almost 50% of its vegetated area and 38% of the earth's terrestrial surface (Gladek et al. 2017). Total food from animals exceeds 1.1 billion metric tons annually and that is derived from 31 billion animals kept as livestock (Gladek et al. 2017). The global fisheries and aquaculture sectors produced about 178 million tonnes of seafood in 2020 (FAO 2022b) and this represents a significant protein source for more than 3.3 billion people. Food produced globally from cultivated agriculture (i.e., primary crop production) was 9.3 billion tonnes in 2020 (FAO 2022a). The FAO estimates that by 2050 food production will need to

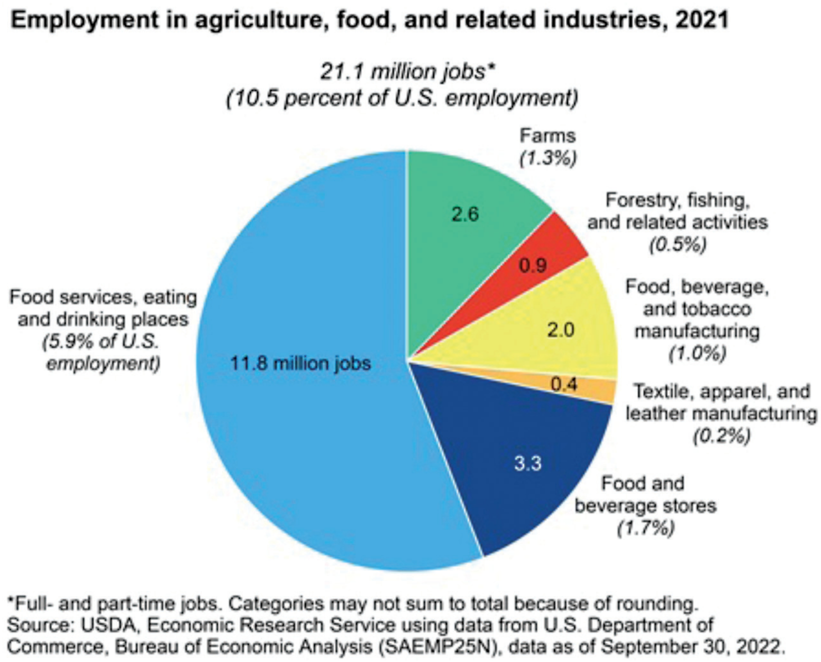

Figure 1. Employment of workers in the United States working in agriculture, food, and related industries.

increase 60–70% over the 2005 levels to meet the needs of the world's estimated 9.8 billion people (FAO 2009).

According to the USDA, as of 2022, there were more than 21 million individuals employed in the United States in agriculture, food, and related industries (USDA 2023). Of these 21 million individuals, 2.6 million were employed on farms, 2 million were employed in food, beverage, and tobacco manufacturing, 11.8 million were employed in the foodservice, restaurant, and drinking establishment workforce, and 3.3 million people worked in food and beverage stores. (Figure 1).

As of July 5, 2023, the U.S. Food and Drug Administration's (FDA) Food Facility Registry contained 88,774 domestic manufacturing facilities and 111,999 foreign facilities, for a total of 200,773 FDA-registered food manufacturing facilities registered globally (US FDA 2023b). According to the United Sates Department of Agriculture's (USDA) most recent report, in the United States food is produced on more than 2 million farms (USDA 2022b) and sold in 115,526 food stores (USDA 2022a). In 2021, the food service sector had more than one million restaurant locations in the United States. (Finances Online 2023).

These statistics convey the size, scope, and complexity of the food system in the United Stares and globally. In addition, there are many other factors that contribute to food system complexities, including social, political, economic, environmental, sustainability and demographic concerns in countries throughout the world. The sheer number of operations from production agriculture, fisheries, processors, transporters, distributors, warehouses, food retailers, food service operations and others involved in supplying food to populations throughout the world, provides the rationale for a robust food traceability system to keep track of and document food and ingredient transactions around the globe.

Tracking and tracing food products (food traceability) is a vital component of a safe, effective, efficient, and sustainable food system. But, tracking and tracing food products and ingredients through the complex, intricate and multifaceted food system described above requires a robust, well-organized, and systematic approach (Zhang and Bhatt 2014).

Foodborne Outbreaks, Product Recalls, and Traceability

Despite the increased understanding of foodborne illness causes, mandatory reporting by industry, use of more modern processing methods, enhanced food safety management systems, advances in microbiological testing and adoption of new government regulations, foodborne illness outbreaks continue to be a serious public health problem. The number of foodborne outbreaks in the United States fluctuate from year-to-year and in a 23-year span, from 1998 to 2021, ranged from a high of 1,403 outbreaks in 2000 to a low of 313 outbreaks in 2020. (Figure 2) (CDC 2023). The trend in Figure 3 illustrates that foodborne outbreaks during this period have not declined markedly until 2020 and are now showing signs of increasing.

According to the National Outbreak Reporting System (NORS) dashboard (CDC 2023a), from 1998 to 2021, there were 28,601 outbreaks, 533,847 illnesses, 23,170 hospitalizations and 606 deaths. Figure 3 illustrates the number of foodborne outbreaks by year from 2009–2021. During that time frame, almost 5,000 outbreaks were of unknown origin. The CDC noted a marked decrease in the incidence of foodborne illness outbreaks in 2020, continuing in 2021, most likely due to public health practices used to slow the spread of COVID-19 (Collins et.al. 2022; Ray et al. 2021).

Biological, chemical, and physical hazards continue to cause concerns in the food industry. Bacteria such as Salmonella, Shiga toxin–producing E. coli (STEC), Listeria, and Campylobacter, enteric viruses including Norovirus and hepatitis A, and a parasite, Cyclospora, have all been implicated in large-scale foodborne outbreaks (Scallon et al. 2011; US FDA 2023a).

Many national and international food safety incidents have highlighted the importance and challenge of being able to quickly identify, isolate, and recover unsafe foods (or ingredients) from the supply chain, prevent them from reaching the consumer to protect public health. There have been many foodborne outbreaks and product recalls over the years involving a number of pathogens and foods (Qiu et al. 2021). The multistate outbreaks shown in Table 1, illustrate the variety of microorganisms and food products involved, as well as the large number of people debili-

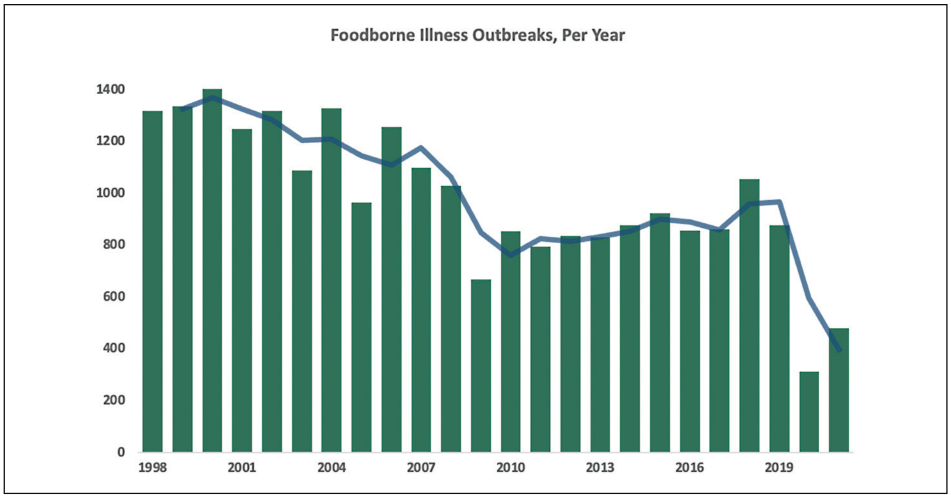

Figure 2. Number of foodborne outbreaks reported per year, along with average trendline.

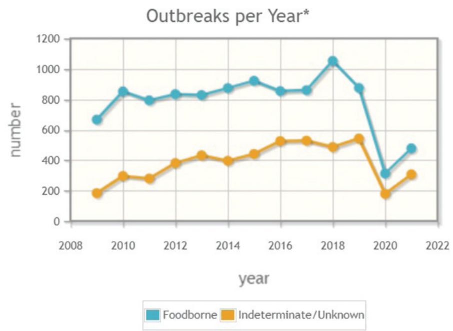

Figure 3. Foodborne Outbreaks and those outbreaks of unknown origin from the years 2009–2021. (CDC National Outbreak Reporting System (NORS), 2023

tated by these foodborne illnesses.

These multistate food product recalls have received widespread media attention and caused consumer concerns about the safety of foods. They often result in a temporary decline in purchases of the implicated foods for some time after they have occurred. The Economic Research Service (ERS) of the USDA noted that after the spinach outbreak of 2006, consumers were slow to return to their previous spinach purchases. After analyzing retail scanner data, agency researchers found that lost consumer expenditures at U.S. grocery stores totaled $60.6 million for all fresh leafy greens (spinach and lettuces) between the September 2006 outbreak and December 2007 (USDA 2013). This is one example of how the publicity from foodborne outbreaks can impact consumers and affect the sale of implicated foods.

Some highly publicized foodborne outbreaks include:

- 2008–2009: Peanut butter and peanut paste - One of the largest food recalls in U.S. history occurred in 2008–09 and was caused by Salmonella contaminated peanut butter and peanut paste (CDC 2009a; Whittenberger and Dohlman 2010). The Peanut Corporation of America (PCA) shipped peanut butter contaminated with Salmonella Typhimurium that resulted in the illness of 714 people in 46 states and one person in Canada, resulting in nine deaths. About 24% of the people affected were hospitalized (CDC 2009a). In addition to the contaminated peanut butter products being recalled, they were used in almost 4,000 food products from over 200 companies, resulting in recalls of those foods and driving some companies to bankruptcy. Recalled products, such as cakes, candy, cookies, peanut crackers, ice cream, snack mixes and even pet food, contained peanuts, peanut paste, or peanut butter produced by PCA. Since this outbreak involved so many different foods where Peanut Corporation of America peanut products were used, they were difficult to trace. This outbreak and recall underscored the need for a system to quickly identify, track, and trace food and food ingredients as they were transported from

Table 1. Selected Multistate Foodborne Illness Outbreaks from 2006–2023. (CDC 2023)

Year	Causative Agent	Food	Reported Illnesses	Reported Deaths	Citation
2006	E. coli O157:H7	Bagged Spinach	205	3	CDC 2006
2007	Clostridium botullinum	Hog Dog Chili	5	0	CDC 2007
2009	Salmonella Typhimurium	Peanut Butter Products	714	9	CDC 2009a
2009	E. coli O157:H7	Raw Cookie Dough	72	0	CDC 2009b
2010	Salmonella Enteritidis	Eggs	1939	0	CDC 2010
2011	Salmonella Heidelberg	Ground Turkey	136	1	CDC 2011
2011	L. monocytogenes	Cantaloupe	147	33	CDC 2012
2015	Salmonella Poona	Cucumbers	907	0	CDC 2016a
2016	E. coli O157:H7	Flour	63	0	CDC 2016c
2016	Hepatitis A	Frozen Strawberries	143	0	CDC 2016d
2018	E. coli O157:H7	Romaine Lettuce	210	5	CDC 2018
2020	Cyclospora	Bagged Salad Mix	701	0	CDC 2020a
2020	Salmonella Newport	Onions	1127	0	CDC 2020b
2022	L. monocytogenes	Ice Cream	28	1	CDC 2022
2023	Salmonella Saintpaul	Ground Beef	18	0	CDC 2023b
2023	Salmonella Enteritidis	Raw Cookie Dough	26	0	CDC 2023d

their source to brokers, formulators, manufacturers, distributors, and retailers.

- 2015: Mexican cucumbers - Salmonella from cucumbers imported from Mexico infected 907 people in 40 states. This outbreak resulted in the hospitalization of more than 200 persons and six deaths. The distributor of the cucumbers issued two separate recalls (CDC 2016a).
- 2015: Chipotle Mexican Grill fast food restaurant - Between October and November, an E. coli O26 outbreak with about 55 people in 11 states becoming ill, 22 reported hospitalizations and no deaths, after eating at the restaurant during the initial outbreak. In a second outbreak attributed to the restaurant, there were five illnesses from a different strain of E. coli. An investigation by regulatory officials was unable to identify a single food item or ingredient that could explain either outbreak (CDC 2016b).
- 2018: Romaine lettuce - Another notable foodborne outbreak occurred in April 2018 when illnesses were reported and then attributed to romaine lettuce grown in Yuma, Arizona. The outbreak resulted in 210 cases of E. coli O157:H7 in 36 states, with 96 hospitalizations, five deaths, and 27 people developing hemolytic uremic syndrome (HUS), a type of kidney failure (CDC 2018). Epidemiologic, laboratory, and traceback investigations linked the outbreak strain to E. coli found in water samples taken from an irrigation canal in the Yuma growing region (CDC 2018). The E. coli O157:H7 outbreak certainly highlighted traceability challenges with leafy greens, as well as the inability for foodservice operators and individual consumers to identify the regional source of their romaine lettuce (IFPA 2023). When an FDA outbreak advisory alerted consumers to discard romaine from the Yuma, Arizona growing region, many discarded all their romaine lettuce, since they did not know the regional source of the lettuce they purchased (IFPA 2023).

These highly publicized foodborne outbreaks have triggered major recalls, caused consumer concerns about the safety of foods and in at least two cases, resulted in criminal prosecution and prison time for company senior management. They often negatively impact the entire food sector they are a part of, resulting in a temporary decline in purchases of the implicated foods for some time after the outbreak has ended. While a product traceability system may not necessarily prevent a recall, it can certainly improve the response by quickly identifying contaminated ingredients or products and retrieving them quickly before they reach consumers.

In this new era of smarter food safety, it is imperative that companies in the food industry advance measures to strengthen food traceability in their organizations, as well as through supply chain partners around the world. If this is successfully carried out, the food supply will be safer, more effective, efficient and more sustainable.

Importance of Food Traceability

The term "traceability" was originally mentioned in 1994 in the International Organization for Standardization (ISO) 8402 standard that defined quality management and quality assurance terminology (ISO 1994; Walaszczyk and Galinska 2020). Traceability was defined in that standard as the ability to trace the history, application, or location of an entity by means of recorded identifications. Since the original reference to traceability in ISO 8402, food traceability has been used to describe a system that documents the history of a product through and along its entire production chain from primary raw materials to the final consumable products (Montet and Ray 2018). Simply stated, food traceability is a record keeping system designed to track the flow of product (or product attributes) through the supply chain (USDA 2004).

Since sourcing of foods and ingredients from around the world has become commonplace and the complexities of the food supply chain have increased, food traceability has received considerable attention by the international community. It has become the focus of many research projects, technical and technological innovations, and national and international legislation and regulations (Olsen and Borit 2018). This trend has resulted in many media stories, scientific publications and symposia and conferences on this important subject. A concern has been the lack of uniformity and the use of inconsistent terminology and definitions of traceability and the components of a traceability system (Olsen and Borit 2018).

To provide a scientific framework for food traceability, the FDA commissioned the Institute of Food Technologists (IFT) in 2008 to conduct an in-depth review of traceability systems and technologies used by the food industry, as well as systems used in international markets and provide recommendations. IFT assembled a team of experts and collected information from 58 food companies and more than 200 stakeholders throughout the food supply chain. In a 2009 report presented to FDA, the IFT team developed and shared a product tracing plan and first used the terms Critical Tracking Events (CTEs) and Key Data Elements (KDEs) (Mejia et al. 2010a). These important terms provide the underpinnings of a robust food traceability system and have gained broad acceptance in the food industry.

To be accepted by all stakeholders in the food supply chain, a traceability system needs to be simple, user friendly, globally accepted, and be easily incorporated into current industry practices and systems. The design of such a system should be open and interoperable, with each supply chain partner having the ability to select methods and technologies that suit their operations (IFT 2011). Traceability is an important business and food safety tool that will help a company identify the location of their products (and ingredients) through every step in the supply system, quickly determine the quantity that is available, and effectively provide an overview of inventory control. Having quick access to this information is critical on a daily basis and especially during a crisis (Thesmar 2015).

The Benefits and Costs of Food Traceability

Tracking and tracing foods through the supply chain have some distinct advantages for companies that have

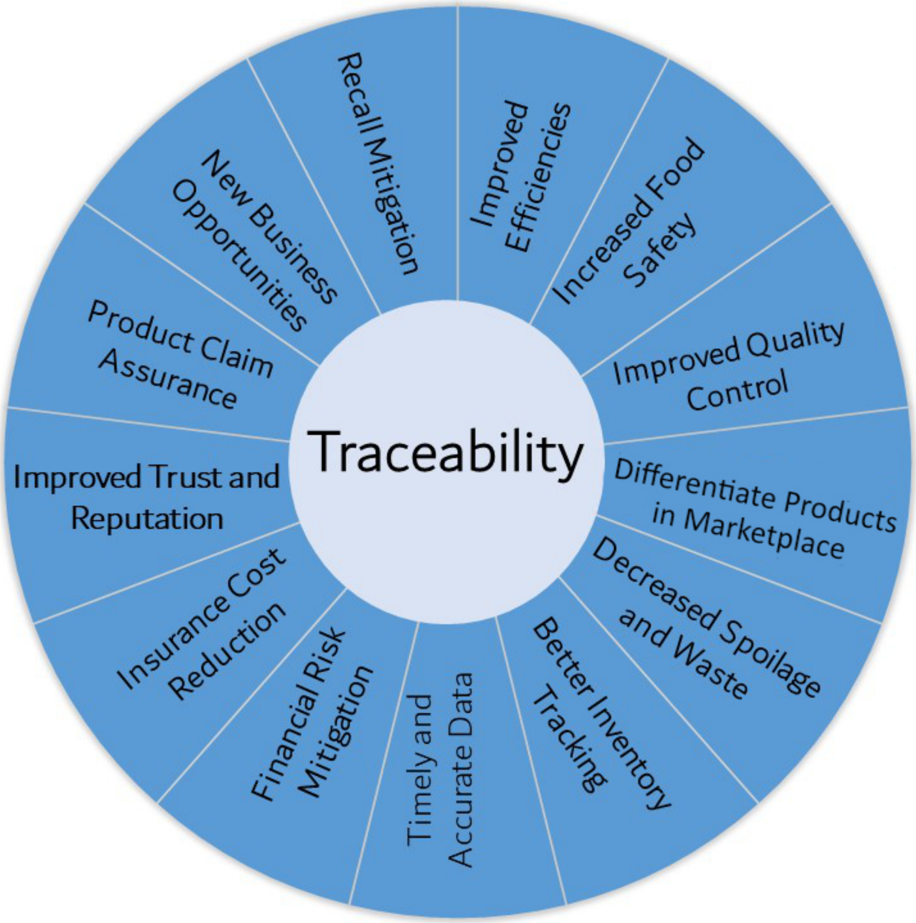

Figure 4. Investments in an effective food traceability system can improve other areas of the business such as product trust, quality control, and risk mitigation.

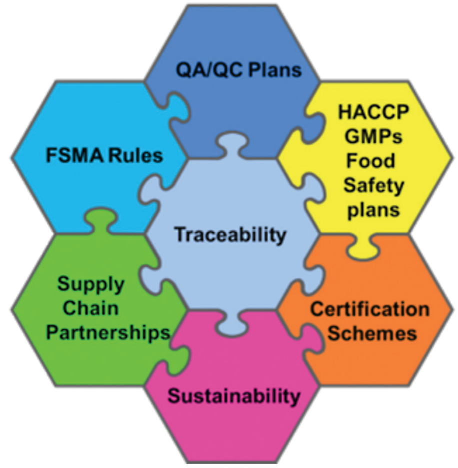

Figure 5. Compatibility of food traceability systems with other food safety and quality management systems (IFT, GFTC).

implemented and maintained robust food traceability systems. Companies with an effective traceability system often see returns in time, labor efficiency, employee productivity, cost savings, supply chain and business management improvements, enhanced communications, and business partnerships, as well as increased market opportunities (Fisher 2015; IFT GFTC 2016). In addition to the economic benefits for the companies involved, there are also benefits for customers. Companies with robust traceability systems have seen increased consumer confidence and customer loyalty, as well as improved brand reputation. Traceability also provides consumers with proof that products possess specific attributes as claimed (Fisher 2015; IFT GFTC 2016). Figure 4 provides a view of the many advantages of a food traceability system.

A food traceability system is compatible and complements the components of other food safety and quality management systems that may be implemented within a food company, and this is illustrated in Figure 5.

From a business perspective, the cost of prevention almost always outweighs the consequences and expenses involved in a food safety incident. The consequences of a foodborne outbreak and costly product recalls can be devastating to a company. In a 2011 publication, the Grocery Manufacturers Association (now the Consumer Brands Association), Covington & Burling LLP, and Ernst & Young estimated the average cost of a product recall at $10 million (Philpot 2021). That amount just covers the direct cost of recovery and disposal of the defective product, while indirect costs (such as litigation, lost sales and impact on market value and brand reputation) could reach hundreds of millions of dollars (Philpot 2021).

While a food traceability system may not prevent a recall, it can certainly improve the response to one by identifying contaminated products and retrieving those that are still in the market. It has been found that integrated traceability systems can reduce the direct costs of recalls 90% for short shelf life products and 95% for longer shelf life products (IFT 2022).

Several early reviews of costs associated with implementing traceability systems and technologies in the food industry were conducted through discussions with food companies and technology providers. (Mejia et al. 2010a; Mejia et al. 2010b). From these discussions, it was found that most firms have adopted various types of warehouse management systems and other techniques, but the product tracing information varied in breadth, depth, precision, and accessibility to supply chain partners (USDA 2004).

The Global Food Traceability Center developed a calculator to assess the costs and benefits of implementing traceability systems compliant with guidance through the Global Dialogue on Seafood Traceability. Companies can use this calculator to determine the financial benefits for their organization based on their sector, revenue, current level of traceability and other critical factors like legal costs,

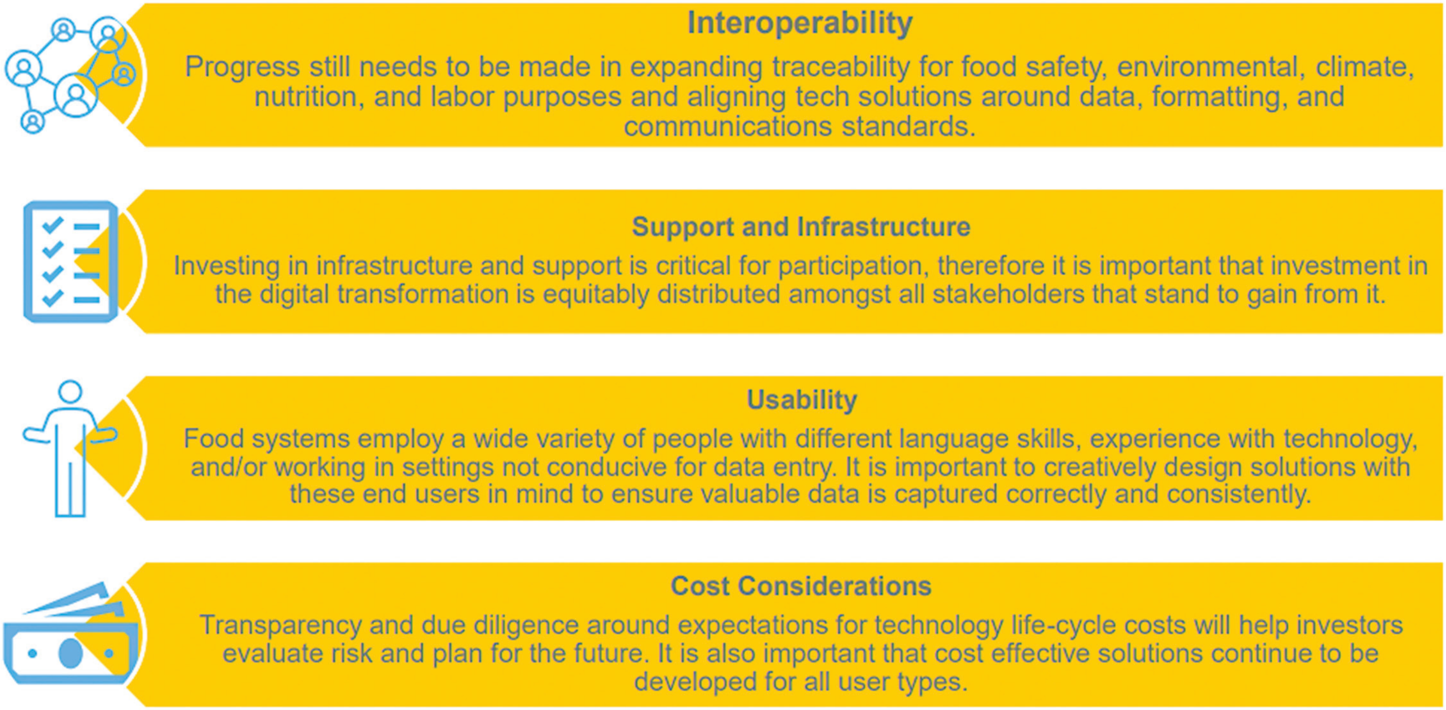

Figure 6. Achieving End-to-End Traceability in the Food System

recalls, information management, and the cost of product losses (shrink) (IFT 2022). The tool was developed with input from industry members and is available through the Global Food Traceability Center.

In 2022, through a contract with FDA, IFT reported on tech-enabled food traceability trends based on information from 90 teams that participated in the 2021 FDA Low-or No-Cost Tech -Enabled Traceability Challenge (IFT 2023). The report concluded that "the knowledge, means and technology have been developed to make end-to-end tech-enabled traceability a reality, but it will not be realized without the collective action and continued innovation among the diverse food industry community." To continue to expand traceability systems, it is crucial that low-cost traceability solutions be intuitive to all levels of experience, available in multiple languages, promote the use of data standards and data communication protocols and consider applicability to specific supply chain segments or commodities (IFT 2023). Figure 6 illustrates the areas of continued innovation and improvement in interoperability, support and infrastructure, usability and cost considerations that must be addressed as traceability solutions advance (IFT 2023)

According to FDA guidance an interoperable traceability system "encompasses the ability to exchange product tracing information accurately, efficiently, and consistently among trading partners". The term "interoperable" appears numerous times in FDA's "Traceability" regulation yet standards for interoperable exchange of traceability information is still emerging (addressed later in this paper).

Every company is unique and will encounter different costs to implement electronic tracking depending on its organization, structure, and circumstances. Variables include costs associated with designing, implementing, and maintaining an effective food traceability system that will meet Food Safety Modernization Act (FSMA) requirements (US FDA 2022b). Several other factors include the sector of the food industry, size of the company, its technological sophistication, the nature of their product(s), where they are sourced, harvested and/or packed, how they are manufactured, how they are packaged and shipped, their perishability, and whether they are used in further processed products. Costs will also depend on whether the technology is "off the shelf" or needs to be custom designed (Mejia et al. 2010b). Costs clearly go beyond the initial purchase of equipment and companies should consider the long-term costs of system implementation and maintenance (IFT 2023). Some of the fixed and variable cost components of a traceability system (IFT 2023; Mejia et al. 2010b) include:

- Capital equipment (computer systems, scanners & labeling equipment)
- Installation and configuration of equipment
- Software licenses and subscriptions
- Custom software updates
- External consultants
- Staff training
- Data collection
- Data storage
- Data migration
- Customization
- Integration
- Labor for operating the system (recordkeeping)
- Supplies and materials for operating the system
- Effects of efficiency of operations
- System maintenance and retrieval costs
- Tech infrastructure

- IT support
- Unforeseen or unidentified costs associated with the system

In the past, inadequate record keeping, inaccuracy and errors, difficulty linking records of the supply chain partners and delays in obtaining critical data and information, especially during a foodborne disease outbreak (Badia-Melis, Mishra, and Ruiz-Garcia 2015), frequently characterized food traceability systems. Today, a wide variety of innovative electronic technologies provides more efficient, secure, and faster access to product information. These technologies can be used to identify products, track inventory, keep accurate records and store data, share data about the movement of products and trace ingredients and products through the supply chain. In today's world, if a food safety incident or other triggering event occurs, companies must respond quickly and efficiently to identify, track down, recover, and remove defective or violative products from the marketplace.

Traceability Foundations

Some terms and concepts are foundational to discussing and assessing traceability systems. At the highest level, these concepts can be thought of as the way products are uniquely identified, the way this information is shared and communicated through the supply chain, and how the information is captured and stored. Because traceability is used to understand the movement of products through the supply chain, it's important that members of this chain can understand the information provided to them. Alignment around data standards and interoperability is needed to achieve efficient, effective, supply chain wide traceability.

Critical Tracking Events and Key Data Elements as a Framework for Traceability

Prior to 2010, terminology around traceability distinguished between internal and external traceability. Internal traceability referred to the ability of a company to understand how product moved within the four walls of its operation, including any manufacturing, processing, packaging, etc. that occurred (Schuitemaker and Xu 2020). Even at that time, most companies self-reported having good traceability, because they viewed traceability from a company, not supply chain perspective. Some companies expanded the concept of "internal traceability" to include the movement of product throughout their company, including transfers between locations owned by the same company. External traceability referred to the movement of product from one entity to another or one ownership to another. However, the terms internal and external traceability have been largely replaced by concepts that more simply describe traceability principles: Key Data Elements and Critical Tracking Events (Mejia et al. 2010).

Critical Tracking Events (CTEs) are "critical points of product transfer and transformation", including "points in a supply chain…where data capture is necessary to follow product movement." (McEntire and Bhatt 2012). Some CTEs relate to "external traceability" such as transportation between different locations (farms, facilities, warehouses, etc.). CTEs also encompass events internal to a company such as, commingling, processing, or manufacturing, where data need to be captured to link ingredients with a new product but may not be shared with external trading partners CTEs can also indicate the removal of a product from the supply chain through either depletion or disposal (Bhatt et al. 2013). Although both transportation and transformation are types of CTEs, a fundamental difference is that during transportation, the product, and therefore its lot number and associated identifiers are unchanged. However, the physical location of the product changes. In contrast, during transformation, the location remains the same (e.g., the transformation is occurring within one facility location), however the lot number generally changes because a new product has been formed. In both cases, information about the product pathway is changing, and that information needs to be captured. The information to be captured at each CTE is termed "Key Data Element" (KDE).

Key Data Elements are the information, or attributes, for each CTE. The determination of which data elements truly are "key" to product tracing depends on the granularity with which one wants to trace, as illustrated in Figure 7 which first appeared in the 2012 IFT traceability pilot report (McEntire and Bhatt 2012). Different use cases may require more or less granularity, and therefore may dictate which data elements are "key" for that situation.

Since these terms were introduced, several examples and resources have been developed to further describe how the CTE/KDE concepts apply to different supply chains and commodities. Early work by IFT, the originator of these terms, laid out some fundamental data elements, distinguishing between "currently required KDEs" and "linking KDEs". These essentially cover the "who", "what", "when" and "where" for each CTE (McEntire and Bhatt 2012). Subsequent IFT work (Zhang and Bhatt 2014) recommended specific CTEs and KDEs

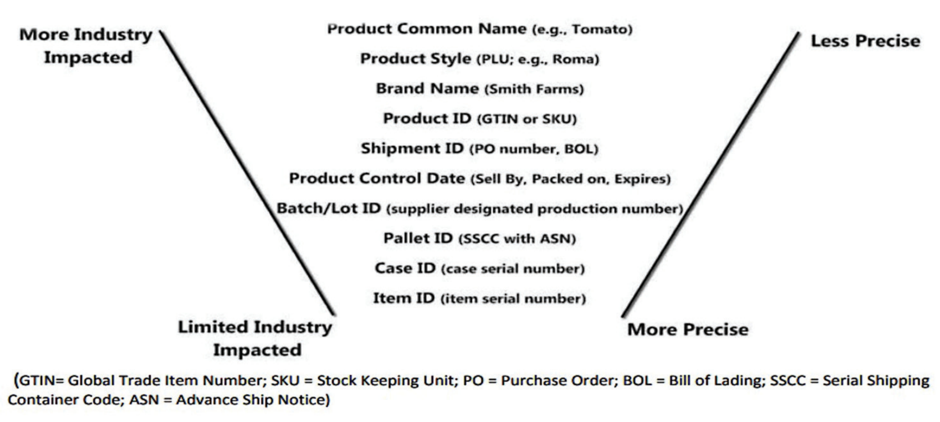

Figure 7. Specificity of information and impact to industr .

for several different food sectors, including processed foods, meat, produce, and dairy (Zhang and Bhatt 2014). The Global Dialogue on Seafood Traceability has tailored the CTE terminology to apply to the seafood industry (e.g., specifying "on vessel processing" and "landing" as CTEs), and identified industry-specific terms and processes that constitute KDEs (GDST 2020a). As discussed later, FDA has adopted the CTE/KDE framework and specified how they apply to foods covered by the traceability rule.

Standards and Interoperability Enable Traceability

If the goal of traceability is to be able to ascertain how a product moved through a supply chain, even if the physical product is long gone, these fundamental pillars of traceability—the who, what, when, and where—must be unambiguously communicated through the supply chain. A 2008 outbreak of Salmonella highlighted the difficulty regulators had in following product information from the point of sale or service back to the farm. Initially, the epidemiological investigation suggested tomatoes as a possible vehicle. Trying to determine if tomatoes in different parts legs of the traceback investigation came from a common source was complicated by the varying ways different supply chain entities described the product name. Investigators noted that: "Traceback issues such as commingling, repacking, varying degrees of product documentation throughout the supply chain, difficulty in linking incoming with outgoing shipments to the next level in the distribution chain, and the complexity of the distribution chain continue to hinder product-tracing efforts. Improvements in product-tracing systems and the ability of the systems to work together are needed for more rapid tracing of implicated products through the supply chain" (Barton Behravesh et al. 2011). The naming or identification of products is not the only area where confusion can exist. Worldwide, the expression of dates varies. For example, if a production date is indicated as 06/05/23—is that June 5 or May 6?

Standards seek to provide a common structure that harmonizes practices and decreases opportunities for confusion. Several types of standards are relevant to traceability: standards to identify KDEs and standards to convey KDEs through the supply chain both in physical form as well as electronically. The global, neutral, not-for-profit organization, GS1 collaborates with industry to develop and maintain a system of supply chain standards that support businesses processes. Many of the standards used to support traceability today leverage the GS1 system of standards. For many data elements, such as location, there are several options one can choose, and the industry continues to work to determine which should be used.

Identification Standards

Products within the supply chain can be identified with varying degrees of granularity. For example, bulk produce items are differentiated based on their Price Look Up (PLU) number. While it can distinguish a banana from an apple (the "what"), it does not provide information about the brand or grower (the "who") and does not allow the differentiation between an apple harvested at different times (the "when") or from different locations (the "where").

Many items in North America are marked with Universal Product Codes, or U.P.C, at point of sale. The U.P.C encodes the product's Global Trade Item Number or GTIN. A GTIN is a GS1 identification key that is used to identify a trade item which could be a product that you may sell or a service that you may offer in an online listing or in a brick -and-mortar store. It is a globally unique number that is used to identify a specific product or service. It identifies who owns the product (brand owner) and what the item is.

The GTIN consists of three elements: A unique GS1 Company Prefix that is licensed from GS1, a unique item reference number assigned by the brand owner, and a calculated check digit. The item reference number is unique to the type of product (variety, ingredients, etc.) as well as the way the item is packaged (quantity, count, etc.). Brand owners have the option to share information to decode the barcode via the GS1 Registry Platform.

Locations can also be communicated in a variety of ways. There are street addresses and latitudes and longitudes, which are generally decipherable, although still prone to confusion (will different systems recognize that Drive is the same as Dr.?). Food facilities that manu-facture, process, pack or hold food to be consumed in the United States must reg-ister with FDA and are assigned a non-public facility registration number. Many supply chain entities, such as farms, and retail and foodservice establishments, do not have this number. The growing areas within a farm may be a distance from the street address. Locations can also be identified using a Global Location Num-ber (GLN). Like the GTIN construct, the GLN begins with the company prefix, followed by the location reference and a check digit.

Called "the most key KDE", the lot code is currently considered to provide the appropriate level of granularity for traceability. Lot codes are highly variable in construct. There is no standard that specifies that, for example, the first three digits of a lot code must be the Julian date of production. The volume of product associated with one "lot" is also highly variable. Some producers distinguish lots based on "clean up to clean up"; others use a set time (e.g., eight hours of production); yet others use the raw material or ingredient lots to guide the size of the finished product lot number. The way that a producer differentiates one lot from another is not standardized. Lots may be very large, spanning large volumes produced over long timeframes, or could be very small. Obviously, when lots are large, there are fewer lots to track, but if there is an issue with that lot, a recall will be much larger. The characters used to identify a lot, and whether other KDEs are embedded in the lot number (e.g., indicating date, production line, facility location, etc.) are highly variable and unlikely to be standardized in the future.

Communication Standards

Together, CTEs and KDEs (Figure 8) (US FDA 2022c) establish a useful framework that can be overlaid with standards as described above. However,

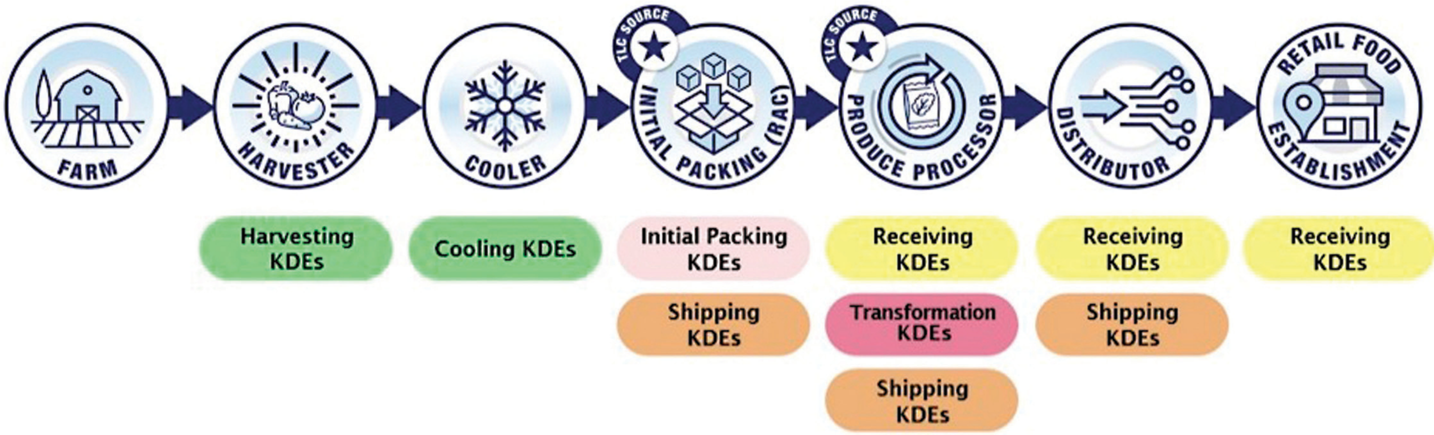

Figure 8. The relationship between CTEs and KDEs. (US FDA 2023c).

Figure 9. Harmonized PTI Label, illustrating the use of Application Identifiers in the GS1-128 barcode.

even if the data elements are standardized, additional “ingredients” are required for a functional traceability system. As described by the global standards organization, GS1, traceability requires identification (the KDEs at each CTE) as well as data capture and data sharing. Standardizing the way KDEs are identified is not enough. The information needs a mechanism to be communicated through the supply chain, ideally simply and with great accuracy.

Communication of KDEs can be done through physical vehicles that carry data, such as printed human readable information, printed scannable bar codes, or sensors such as RFID tags. Regardless of the vehicle—from rudimentary to sophisticated—the same KDEs should be communicated. A benefit of using physical vehicles is that KDEs accompany the physical product, such as a bar code on case. KDEs can be, and should be, digitized, but require varying degrees of labor. For example, although entering information manually into a database is possible, it is labor intensive and error prone. A variety of bar code options are available, with the GS1-128 bar code being utilized by most industry-driven traceability initiatives owing to its ability to carry several data elements that can be decoded via the use of application identifiers. An example of application identifiers in a GS1-128 bar code are shown in Figure 9, an illustration of the Harmonized Label for the Produce Traceability Initiative. The industry-driven group has identified that the bar code will be used to convey the following key data elements: GTIN (as indicated by the application identifiers (01)); pack date or best by date (indicated by application identifiers (13) or (15), respectively), and lot number (as indicated by the application identifiers (10)).

Scanning bar codes is faster than reading and transcribing information off a box or piece of paper, but still requires line of site with each unit to be scanned and assumes that the bar code quality enables scanning. The technology associated with RFID tags, which require even less labor, but more are more expensive in terms of infrastructure, has advanced, but questions around the ability to capture data as well as environmental consequences of used tags remain (Zuo 2022). This technology is being explored by segments of the foodservice industry in the United States.

Increasingly, there is a desire by both regulators and companies to share traceability information between supply chain partners electronically (Gemba 2020; US FDA 2023c). The standards, systems and tools that support electronic exchange of information ventures outside food safety and into the world of information technology.

Interoperability

Given the volume of data to be shared between hundreds of thousands of supply chain partners, it is critical that data is standardized and that systems are interoperable. Interoperable systems allow information to be shared in a standardized fashion between different systems. Imagine if a bank card only worked at the ATM of that bank, instead of any ATM around the world, or if a phone could only call the exact same make and model of phone. As traceability software solutions were being developed, some systems required that all traceability data be stored in one system, similar to everyone using the same bank, or having the same phone. It is extremely unlikely that the global food supply chain will agree to house all traceability data in one centralized system. This would be akin to everyone in the world having the same type of phone, same service provider and same data plan. Because different companies will want to use traceability related information in different ways (e.g., for marketing insights, to measure system inefficiencies, etc.), the marketplace must develop a variety of options for the industry that encourages innovation while facilitating interoperable communication.

To encourage the development of systems to handle traceability information in no or low-cost ways, FDA launched a challenge (US FDA 2021). An analysis by IFT found that just over half of the systems assessed were characterized as "does not require custom integration to communicate with other platforms, information capture AND sharing aligns with existing data standards" (14%) or "Enables information sharing via custom integration with other platforms, information capture/sharing aligns with existing data standards" (47%). The authors note "even if two solutions scored a 3 [most interoperable], it doesn't necessarily mean that they are interoperable with each other" (IFT 2023).

In 2021, GS1 US conducted a study in collaboration with the Global Dialogue on Seafood Traceability (GDST), Institute of Food Technologists (IFT), Beaver Street Fisheries, Bumble Bee Seafood, Chicken of the Sea, FoodLogiQ, IBM Food Trust, Insite Solutions, Norpac, ripe.io, SAP, Walmart, and Wholechain to explore the challenges associated with data sharing in the food supply chain. The solution providers all offered traceability platforms, which were powered by various blockchain, distributed ledgers, and cloud-based technologies.

A key motivator was to bring attention to the data being shared across the food system. "It's important to remember that any one solution does not inherently make the data being shared more trustworthy—bad data can be recorded on a blockchain too, for example. A single solution also does not, by itself, provide end-to-end supply chain visibility. To achieve a truly visible and traceable supply chain, the integration of internal and external business processes must occur. This means that the internal processes a company uses to track a product within its operation is integrated into a larger system of external data exchange and business processes that take place between trading partners to move the product. Therefore, to solve whatever supply chain challenge has been identified—in this case, seafood traceability—the focus must really be on the network of trading partners sharing data and then trusting in that data via the audit trail of those transactions." (Fernandez 2021)

To enable interoperability, the food industry needs to add role-based permissions not only for data access, but also for platform-to-platform data exchange. Business to business data sharing is only one part of the food ecosystem and involves known trading partners. If we are to enable sharing between disparate solutions and unknown partners, then we will need to employ new ways of verifying, validating, and routing these data requests. The technology and standards are in place to share the data, but this crucial step is not yet determined. This topic has been under discussion for many years, and references can be found in the McEntire and Bhatt's 2012 report, "Pilot Projects for Improving Product Tracing Along the Food Supply System – Final Report". The participating solution providers recommended: "Business and proprietary data can be protected with encryption and bank-level data security, but still needs to be quickly and easily accessible to the regulators in order to protect public health."

Next Steps to Build the Foundation

In July 2011, IFT convened a group of thought leaders as part of a Traceability Improvement Initiative (a predecessor to the GFTC) to envision traceability in the future. The group predicted the state of traceability in 2012, 2016 and 2021 (Newsome, Bhatt, and McEntire 2013). The degree of standardization and data sharing anticipated by 2021 has not been accomplished. Progress has been slower than anticipated, in part because much of the U.S. food industry was reluctant to evolve their systems and processes in advance of having regulatory requirements. FDA's final traceability rule provides definitions and expectations that should allow the community to evolve beyond the foundations. A team approach to traceability implementation, inclusive of food safety, regulatory, supply chain, and information technology, is required to maximize the likelihood that a traceability system will meet its intended purpose.

Government Traceability Regulations

Hazards in food such as bacteria, allergens, and foreign objects can pose a risk in everyday life. However, foodborne illnesses and injuries are never identified because of poor recordkeeping that limits or prevents traceability.

Based on several foodborne illnesses that have occurred where their cause or source could not be identified, many countries have adopted traceability legislation that requires or encourages the food industry to establish systems to identify the source of food ingredients and raw materials (one step backward) and to who their food products were sold (one step forward). If all parts of the food supply chain can effectively implement the one step backward and one step forward, then the time needed to identify food safety issues or the cause of foodborne illness can be significantly reduced and the likelihood of identifying a root cause increased, potentially saving lives, and reducing foodborne illnesses. The various technologies to trace food ingredients and raw materials backward to their source or forward to the next customer are addressed in another section of this paper.

United States Federal Government System of Food Safety and Traceability

The U.S. federal government has primary responsibility for food safety, including investigating and identifying the root cause of foodborne illnesses and deaths using epidemiology and traceability. Unlike many countries who have consolidated their food safety programs into one agency, there are a number of different U.S. federal agencies (see brief listing below) that together share this responsibility in a coordinated effort to minimize the impact of any food safety problems while sharing information to maximize the ability to trace the source of the food safety issue, either before (preventive) or after the food reaches the consuming public.

- **Food and Drug Administration (FDA)** primarily through its Center for Food Safety and Applied Nutrition (CFSAN) and Office of Regulatory Affairs (ORA) investigative field staff. Responsible for the safety of all human foods and animal feed, whether produced domestically or imported except for foods under the responsibility of USDA and beverages containing alcohol.
- **USDA Food Safety Inspection Service (FSIS)** and its approximately 6,000 resident inspectors. Responsible for regulating all meat (beef, poultry, pork), liquid egg products and Siluriformes, including catfish.
- **Environmental Protection Agency (EPA)** regulates the use of various chemicals for treating food crops, cleaning food processing equipment and any chemical considered as a pesticide. EPA works cooperatively with both FDA and FSIS on acceptable chemicals and use levels intended to be applied to food or food crops.
- **USDA Agricultural Marketing Service (AMS)** has responsibility for establishing and enforcing a voluntary grading program to designate the quality of many different types of food including meat, fruits, vegetables, eggs, raw milk and some dairy products, as well as collecting information on the level of pesticide residues in foods. AMS also administers and enforces the mandatory "Country of Origin" food labeling requirements as well as the U.S. organic foods program.
- **USDA Federal Grain Inspection Services (FGIS)** is responsible for providing testing methodologies, grade designations and enforcement of U.S. grain standards to both buyers and sellers of grain, pulses, oilseeds and related raw agricultural.
- **USDA Animal Health and Plant Inspection Service (APHIS)** is responsible for ensuring that imported live animals, plants, plant seeds and animal semen are pest and disease-free.
- **Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF)** has regulatory responsibly for foods and beverages with an alcohol content of more than 1.2% alcohol by volume (vol.). ATF works closely with FDA on some food safety and labeling issues.
- **Federal Trade Commission (FTC)** has oversight and enforcement authority to ensure that advertising of all products including food is truthful and non-deceptive.

Since the U.S. federal government responsibility for human food safety lies primarily with the FDA and USDA FSIS, we will limit our discussion related to traceability to these two agencies. Both the FDA and FSIS also have working agreements or MOUs with other federal agencies such as EPA, CDC, ATF, and various state government counterparts. Notwithstanding these understandings, both agencies always retain their federal pre-emptive food safety regulatory and enforcement authority.

Food and Drug Administration (FDA)

Starting in the first decade of the 21st Century, the United States experienced increases in some microbial-based foodborne illnesses with no sustained decrease in others (Figures 2 and 3). The cause of many of these outbreaks was never identified because of a lack of traceability records as the raw materials, food ingredients, and finished foods moved through supply chains.

FDA Food Traceability Regulation

Prelude to FDA's Traceability Regulation

Prior to the passage of the Food Safety Modernization Act (FSMA) on January 4, 2011, and implementation of its associated regulations, the FDA did have some traceability requirements for infant formula (21 CFR 106). Also, facilities required to register with FDA resulting from the 2002 Bioterrorism Act were subject to traceability recordkeeping requirements, commonly known as the "one step backward and one step forward".

FSMA's traceability requirements included:

- Establishing a product tracing system to allow FDA to effectively track and trace food consumed in the United States
- Conduct traceability pilots of produce and processed food sectors with 180 days

Before publishing any traceability regulation, in 2011 FDA commissioned a study/pilot conducted by the Institute of Food Technologists (IFT) to provide more detailed and practical insight into the U.S. food industry's use of traceability, its effectiveness and to conduct traceability pilots with different companies representing different food sectors. IFT collaborated with representatives from more than 100 organizations, including the USDA, state departments of agriculture and public health, industry, consumer groups, and not-for-profit organizations to implement the pilots. Two product tracing pilots of foods were conducted. One food pilot focused on the tracing of chicken, peanuts, and spices in processed foods; the other pilot focused on the tracing of tomatoes.

IFT conducted 14 mock tracebacks/traceforwards, ranging from simple to complex. In summary, IFT found there were several areas that required industry to make improvements, such as uniformity and standardization, improved recordkeeping, enhanced planning and preparedness, better coordination and communication, and the use of technology which if adopted, would increase the speed at which tracebacks and traceforwards could be conducted, both by FDA and the food industry.

In 2021, the FDA identified traceability of food and food ingredients as a key component as part of its new "Foodborne Outbreak Response Improvement Plan".

FDA Traceability Regulation Details

From the signing of FSMA in January 2011 until FDA's publication of the final version of its Food Traceability regulation on November 15, 2022, FDA's regulatory expectations were that each node in the supply chain needed to have the capability of tracing their food, food ingredients or raw food one step backward to their supplier and one step forward to their customer. The traceability regulation became effective 60 days after publication, but FDA established an enforcement date of January 20, 2026, when all food processors making foods on the "Food Traceability List (FTL) needed to be in full compliance. The traceability regulation contains the following sections:

- General Provisions
- Traceability Plan
- Records of Critical Tracking Events
- Procedures for Modified Requirements and Exemptions
- Waivers
- Records Maintenance and Availability
- Consequences of Failure to Comply
- Updating the Food Traceability List

FDA Food Traceability List

Of the many parts of the Food Traceability regulation, the most impactful is the "Food Traceability List" (FTL) (Table 2). This list identifies those foods that are subject to the FDA Food Traceability regulations. Food identified as a "listed" food or if the "listed food" is used as an ingredient and remains in the same form in which it appears on the list (example soft cheese such as mozzarella melted on a cheese pizza), then almost all points in the supply chain incur some responsibility for maintaining the traceability regulation record keeping requirements. If a food or food ingredient does not appear on the list, at this time, FDA will not be enforcing this regulation on these other foods.

This "list" was developed based on the following risk-ranking criteria (in no order of priority):

- Frequency of outbreaks and occurrences of illnesses
- Severity of illness
- Likelihood of contamination
- The potential for pathogen growth, with consideration of shelf life
- Manufacturing process contamination probability and industry-wide intervention
- Consumption rate and amount consumed
- Cost of illness

The written traceability plan is required to identify how FTL foods are handled, and assign traceability lot codes to all FTL foods that includes:

- A description of the procedures used to maintain the records, including format and record location.
- A description of the procedures used to identify foods on the FTL that you manufacture, process, pack or hold.
- A description of how traceability lot codes are assigned to foods on the FTL.
- Identifying a point of contact for questions regarding traceability plan and records.
- If food on the FTL is grown or raised (other than eggs), a farm map is required, showing the areas where such foods are raised, including geographic coordinates and any other information needed to identify the location of each field or growing area. For aquaculture farms, the farm map must show the location and name of each pond, pool, tank, or cage in which the seafood on the FTL is raised, including geographic coordinates and any other information needed to identify the location of each pond, pool, tank, or cage.
- Parties that grow or raise a FTL food (other than eggs) for commercial distribution or sale are required to keep a farm map identifying where the FTL food is grown or raised, including geographic coordinates for the growing/raising area.
- Harvesters and coolers of raw agricultural commodities (RACs) (not obtained from a fishing vessel) that are on the FTL must keep records of their activities and provide information to the initial packers of these RACs. These initial packers, along with the first land-based receivers of FTL foods obtained from a fishing vessel, as well as entities that transform an FTL food (by manufacturing/processing a food or by changing the food or its packaging or labeling), must assign a traceability lot code to the food to help ensure accurate identification of the food as it moves through the supply chain.
- Shippers and receivers of FTL foods must keep records of these actions, and shippers must provide the traceability lot code and other information identifying the food to the recipients of the food, including information relating to the traceability lot code source.

To avoid disclosing confidential information about their suppliers, instead of directly identifying the traceability lot code source of an FTL food, the shipper may instead choose to provide a traceability lot code source "reference," such as an FDA Food Facility Registration number or a web address (which could be configured to require authentication for access), and taken together, these fundamental requirements are intended to provide a system of traceability information for FDA to more rapidly and effectively identify the source of contamination when investigating a foodborne illness outbreak.

Exemptions: The final rule exempts certain small producers (including small produce farms, shell egg producers, and other producers of RACs) and, at the other end of the supply chain, certain small retail food establishments (RFEs) and restaurants. The rule also provides several other exemptions, including, but not limited to:

- farms when food is sold or donated directly to consumers
- food produced and packaged on a farm whose packaging maintains product integrity and prevents subsequent contamination
- foods that receive certain types of processing, including produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance
- shell eggs that receive a certain treatment
- foods that are subjected to a pathogenic kill step
- foods changed such that they are no longer on the FTL
- produce rarely consumed raw
- certain raw bivalve molluscan shellfish

Table 2. Products that are included in the FDA Food Traceability list (US FDA 2023c). See footnotes.

	Food Traceability List (FTL)	Description
Cheeses, other than hard cheeses, specifically:	Cheese (made from pasteurized milk), fresh soft or soft unripened	Includes soft unripened/fresh soft cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
	Cheese (made from pasteurized milk), soft ripened or semi-soft	Includes soft ripened/semi-soft cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
	Cheese (made from unpasteurized milk), other than hard cheese[1]	Includes all cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
	Shell eggs	Shell egg means the egg of the domesticated chicken.
	Nut butters	Includes all types of tree nut and peanut butters. Does not include soy or seed butters.
	Cucumbers (fresh)	Includes all varieties of fresh cucumbers.
	Herbs (fresh)	Includes all types of fresh herbs.
	Leafy greens (fresh)	Includes all types of fresh leafy greens. Does not include banana leaf, grape leaf, and leaves that are grown on trees.
	Leafy greens (fresh-cut)	Includes all types of fresh-cut leafy greens, including single and mixed greens.
	Melons (fresh)	Includes all types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, muskmelon, and watermelon.
	Peppers (fresh)	Includes all varieties of fresh peppers.
	Sprouts (fresh)	Includes all varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts.
	Tomatoes (fresh)	Includes all varieties of fresh tomatoes.
	Tropical tree fruits (fresh)	Includes all types of fresh tropical tree fruit. Does not include tree nuts such as coconut. Does not include pit fruits such as avocado. Does not include citrus.
	Fruits (fresh-cut)	Includes all types of fresh-cut fruits. Fruits listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
	Vegetables other than leafy greens (fresh-cut)	Includes all types of fresh-cut vegetables other than leafy greens.
Finfish (fresh and frozen), specifically:	Finfish, (histamine producing species)	Includes all histamine-producing species of finfish.
	Finfish, species potentially contaminated with ciguatoxin	Includes all finfish species potentially contaminated with ciguatoxin.
	Finfish, species not associated with histamine or ciguatoxin	Includes all species of finfish not associated with histamine or ciguatoxin.
	Smoked finfish (refrigerated and frozen)	Includes all types of smoked finfish, including cold smoked finfish and hot smoked finfish.[4]
	Crustaceans (fresh and frozen)	Includes all crustacean species. Examples include but are not limited to shrimp, crab, lobster, and crayfish.
	Molluscan shellfish, bivalves (fresh and frozen)[5]	Includes all species of bivalve mollusks.
	Ready-to-eat deli salads (refrigerated)	Includes all types of refrigerated ready-to-eat deli salads. Does not include meat salads.

[1] Hard cheese" includes hard cheeses as defined in 21 CFR 133.150, colby cheese as defined in 21 CFR 133.118 and caciocavallo siciliano as defined in 21 CFR 133.111. Examples of hard cheese include, but are not limited to, cheddar, romano, and parmesan.
[2] For a more comprehensive list, see Chapter 3 of the Fish and Fishery Products Hazards and Controls Guidance.
[3] Data for catfish were excluded from the Risk-Ranking Model because Siluriformes fish (such as catfish) are primarily regulated by the U.S. Department of Agriculture.
[4] "Smoked finfish" refers to a finfish product that meets the definition of a smoked or smoke-flavored fishery product in 21 CFR 123.3(s).
[5] Under 21 CFR 123.3(h), molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.
Note: Foods for animals are not included in our current risk-ranking model and are not included on the FTL, and therefore not covered by the final rule.

- persons who manufacture, process, pack, or hold FTL foods during or after the time when the food is within the exclusive jurisdiction of the USDA
- commingled RACs (not including fruits and vegetables subject to the produce safety regulation)
- RFEs and restaurants purchasing directly from a farm; certain ad hoc purchases by RFEs and
- restaurants from other such entities; farm to school and farm to institution programs; fishing vessels; transporters; nonprofit food establishments; and food for research or evaluation.

Any entity or company subject to the rule who manufacture, process, pack, or hold foods on the FTL, maintain records containing KDEs associated with specific CTEs is required to provide records on traceability including traceability lot codes to the FDA within 24 hours after FDA makes the request or within some reasonable time to which the FDA has agreed. The final rule applies to domestic as well as foreign firms producing food for U.S. consumption, along the entire food supply chain in the farm-to-table continuum.

Specific FDA Traceability Recordkeeping Examples

In order to know which KDEs are required for each CTE, FDA has provided an excellent interactive webpage which can be found at https://www.fda.gov/media/163132/download.

In addition, for specific food sectors, FDA has provided detailed examples to help the industry identify CTE and their associated KDEs (see bulleted list with hyperlinks below).

- Produce: https://www.fda.gov/media/163054/download
- Seafood: https://www.fda.gov/media/163055/download
- Cheese: https://www.fda.gov/media/163056/download
- Additional Supply Chain Examples including:
  - Aquacultured tilapia
  - Canned tomatoes
  - Canned salmon
  - Imported mangoes
  - Shell eggs
  - Fresh produce meant for meal kits: https://www.fda.gov/media/169511/download

U.S. Department of Agriculture Food Safety Inspection Service (FSIS)

Program Overview

The USDA Food Safety and Inspection Service (FSIS) regulates meat, shell eggs, and Siluriformes, including catfish, under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. Some foods that contain a meat and another food may be subject to "dual regulation" by both FDA and USDA. One example of this dual regulation/jurisdiction is pizza. A cheese pizza is exclusively regulated by the FDA while a pepperoni-topped pizza is regulated primarily by the USDA (pepperoni being a meat) with the FDA responsible for the nutritional information on the pepperoni pizza label.

The Federal Meat Inspection Act (FMIA) and the associated regulations have a very strong traceability requirement that requires records for traceback to the farm or ranch that supplied the live animal prior to slaughter. In addition, these regulations require all animals slaughtered for human food (e.g., beef, pork, and chicken) and sold for consumption into interstate commerce in the United States to originate from a facility that receives on-site inspection by USDA-FSIS trained and employed inspectors. These inspection personnel also conduct post-mortem inspection to ensure that the meat from the carcass and internal organs are fit for human food. Each live animal is identified by a tag or other unique identifying "mark of inspection" so any disease or other abnormality identified post-mortem can be traced back to the seller of that animal.

USDA FSIS regulations, with few exceptions, require the meat products from a slaughtering and meat processing facility receive a USDA ink stamp or mark if the facility meets applicable USDA FSIS requirements, authorizing its sale. Examples of the stamp are shown in Figure 10.

In general, the requirements on traceability enforced by USDA FSIS can be found in 9 CFR 320 and more specifically, the recordkeeping requirements (9 CFR 320.1 (b)).

Traceability of Pasteurized Eggs

The 1970 Egg Products Inspection Act (EPIA) required all liquid or dried egg products distributed for consumption or further processing be pasteurized. The USDA-FSIS has the regulatory responsibility for enforcing federal regulations on pasteurized eggs. The minimum requirement for traceability is that pasteurized egg processing facilities have the capability to identify the source(s) of the eggs they are pasteurizing and the customer(s) that the pasteurized egg (sometimes dried) are shipped to ("one step forward and one step backward").

Traceability for Shell Eggs

The U.S. federal regulatory system for shell eggs involves FDA as well as multiple USDA agencies with FDA having primary traceability authority. Each agency's responsibilities are summarized below.

- **FDA**: Shell eggs are on the FTL and therefore have to meet all of the recordkeeping requirements identified in the FSMA-based traceability regulation. In addition, the Egg Safety Rule (July 9, 2010) applies to egg producers with 50,000 or more laying hens, requiring them to implement safety standards to control risks associated with pests, rodents, and other hazards; to purchase chicks and hens from suppliers who control for Salmonella in their flocks; and to satisfy testing, cleaning, and refrigeration provi-

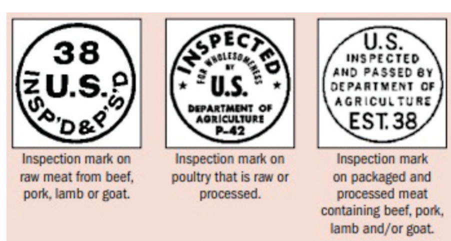

Figure 10. Examples of USDA stamps used in food production.

sions to prevent Salmonella Enteritis (SE). These facilities must register with FDA and are required to maintain written plans summarizing their safety practices including traceability recordkeeping.

- **USDA AMS** is responsible for the Shell Egg Surveillance Program to assure that eggs in the marketplace are as good as or better than U.S. Consumer Grade B quality standards. AMS conducts inspection of handlers and hatcheries four times each year to ensure conformance with these requirements. AMS also administers a voluntary egg-quality grading program for shell eggs paid for by processing plants.
- **USDA FSIS** verifies shell eggs packed for the consumer are labeled "Keep Refrigerated" and stored and transported under refrigeration and ambient temperature of no greater than 45°F.

Food Traceability Regulations in the EU

Under European Union legislation, “traceability” means the ability to track any food, feed, food-producing animal or substance that will be used for consumption, through all stages of production, processing and distribution.

On September 19, 2011, the European Commission (EC) adopted Regulation No 931/2011 that updated traceability requirements for food of animal origin (it does not apply to food containing food ingredients of both plant and animal origin). This regulation, which was effective July 1, 2012, mandating competent authorities in the EU member states apply the traceability requirements in Regulation (EC) No 178/2002 to food business operators with respect to food of animal origin. The goal of such legislation is to facilitate the withdrawal of faulty products from the market and provide consumers with accurate information.

EC No 178/2002 is the primary regulation identifying traceability requirements for unprocessed and processed products. Article 18 requires traceability at all stages of production, processing, and distribution. It also states that food business operators must provide to government authorities the identity (name and address) of their supplier as well as the party (name and address) they supplied their food to. This is very much the “one step forward and one step backward” approach. It is important to note that there is no EU-level requirement to implement internal traceability which tracks food ingredients and products as they move through the manufacturing process.

Additional EU legislation that provides the foundation for the traceability regulation includes Regulation (EC) No 852/2004 (April 29, 2004) on the hygiene of foodstuffs, Regulation (EC) No 853/2004 (April 29, 2004) laying down specific hygiene rules for food of animal origin and Regulation (EC) No 854/2004 (April 29, 2004) laying down specific rules for organizations responsible for regulating products of animal origin intended for human consumption. Other traceability requirements are listed below:

- provide additional information on the volume or quantity of the food of animal origin
- a reference identifying the lot, batch or consignment, as appropriate
- a detailed description of the food and the date of dispatch.

Article 3 of EC N 178/2022 deals specifically with traceability information requirements to be captured by records and applies to parties involved in the handling, storage, processing or packaging of food of animal origin and is to be updated daily with records stored and available until the food has been consumed. This information is to be made available to competent authorities upon request:

- an accurate description of the food
- the volume or quantity of the food
- the food business operator from which the food has been dispatched
- the name and address of the consignor (owner) if different from the food business operator from which the food has been dispatched
- the name and address of the food business operator to whom the food is dispatched
- the name and address of the consignee (owner), if different from the food business operator to whom the food is dispatched
- a reference identifying the lot, batch or consignment, as appropriate; and
- the date of dispatch.

The EC has provided several supplementary documents including the factsheet on food traceability published in 2007 and the leaflet on “Key Obligations of Food and Feed Business Operators” which covers in more detail what is expected of food and beverage businesses related to food safety and traceability.

Canada – Safe Food for Canadians Act (SFCA) and Traceability Regulations

Canada has a unified, one-agency federal food regulatory system administered by the Canadian Food Inspection Agency (CFIA).

Under the new Safe Food for Canadians Act (SFCA) and its accompanying regulations, which became effective on January 15, 2019, for food businesses that import or prepare the following food for export or to be sent across provincial or territorial borders:

- dairy products, eggs, processed egg products and processed fruit or vegetable products, fish, meat products and food animals, fresh fruit or vegetables, honey and maple products, unprocessed food used as grain, oil, pulse, sugar, or beverages.

For food additives, alcoholic beverages, and all other foods (manufactured foods) the effective date was July 15, 2020. SFCA requires federal licenses, as well as a written, preventive control programs that outline steps to address or mitigate potential risks to food safety. Specific Canadian government regulations on traceability are found in Part 5 of the SFCA regulations.

Canadian SFCA Traceability Requirements

Federal traceability regulations for food in Canada are based on the international standard established by Codex Alimentarius – tracking of food forward to the immediate customer and back to the immediate supplier. Traceability has been identified as one of the four (4) key elements of the Safe Food for Canadians

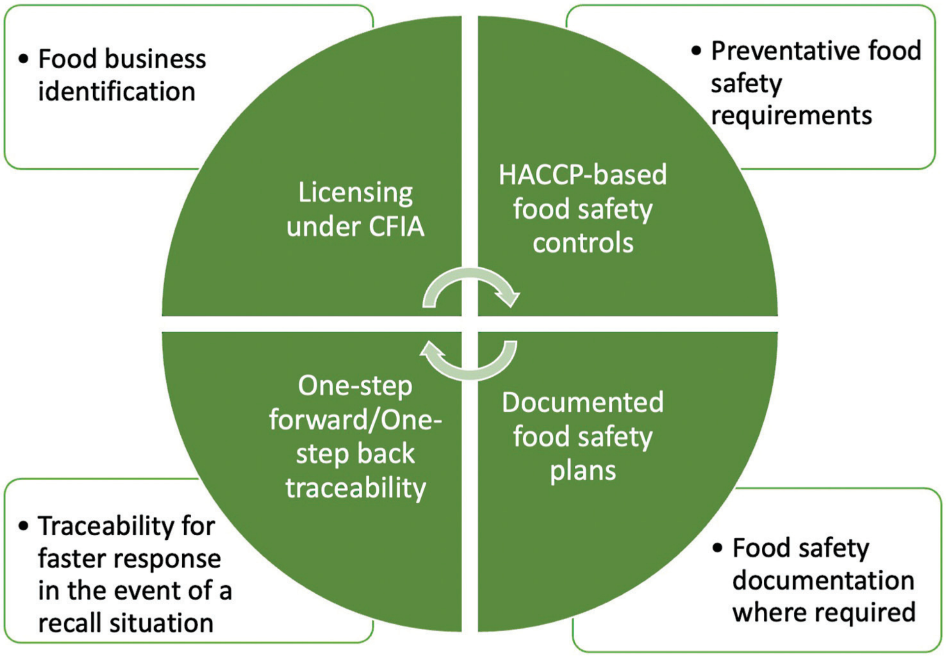

Figure 11. Diagram of CFIA traceability program. Information adapted from Government of Canada Traceability Fact Sheet (Government of Canada 2023).

Act (SFCA) and associated regulations (Figure 11).

Four Key Food Safety Elements

Food that is traded across inter-provincial borders must be identified as follows:

- common name
- lot code or another unique identifier and
- name and principal place of business of the entity by whom or for whom the food was manufactured, prepared, produced, stored, packaged or labeled.

Food businesses are expected to trace the food one step backward to the immediate supplier by indicating the date food was received and the name and address of the supplier who provided it. In addition, companies must trace food one step forward by indicating the date products were sold to a customer and name and address of the entity the food was shipped to. Traceability requirements also include foods sold at retail.

Traceability documents must be made available upon request to the Canadian Food Inspection Agency (CFIA) in English or French and within 24 hours of the CFIA making the request or within a shorter period of time if the CFIA believes there is a risk of injury to human health. CFIA's traceability interactive tool (https://na1se.voxco.com/SE/93/traceability/?&lang=en) can be used to determine which requirements apply to a specific business.

Codex Alimentarius Guidelines on Food Traceability

The joint FAO/WHO Food Standards Conference in 1962 requested that the Codex Alimentarius Commission imple-ment a joint FAO/WHO food standards program and create the Codex Alimenta-rius Secretariat to assist in the administra-tion of this work. Today, CAC has 189 Codex Members/Governments and 235 Observers (private international industry, consumers, United Nations, etc.). Together, this body is organized into 14 active committees drafts standards, guidelines, principles, and codes of practice related specifically to food, which are finalized and referred to the full CAC for official adoption. Many countries, particularly less developed countries, rely on the CAC's food standards, guidelines, principles, and code of practices as the basis for their food safety laws and regulations.

The concept of "one step backward and one step forward" is captured in a few Codex documents, with the Codex "Principles For Traceability/Product Tracing As A Tool Within A Food Inspection And Certification System (CAC/GL 60-2006)" specifically addressing traceability/product tracing to enhance existing food safety systems for the industry or for use by government and private auditors and inspectors to identify the root cause of a food safety problem or foodborne illness.

Best Practices and Case Studies

Best Practices

Food operations are incredibly unique and traceability practices are often customized to fit a specific operation or supply chain but there are best practices that apply to the science of traceability as a whole:

- **Scope and objective**: There are many use cases for traceability, but different use cases require distinct data collection and analysis efforts. For example, the data needed to meet regulatory requirements will look different from the data needed to track and reduce waste. To collect, store, analyze, and share data requires significant resources and it is easy to crush a system under the weight of over commitment. A clearly defined objective and data management practices that align with the objective are crucial for the success of a traceability system.
- **Roles and responsibilities**: Traceability requires input and effort from a diverse set of stakeholders; each stakeholder should be aware of what must be done, why it must be done, and how it will get done. It is important to define and communicate who needs to be responsible, accountable, consulted, and/or informed of the tasks required of system stakeholders.
- **Data Standardization**: System-wide alignment around what data to collect based on the defined scope and objective, and how to format and exchange that data between systems enables

- interoperability and eases the burden of traceability implementation through a supply chain.
- **Data digitization and fit for purpose technology**: Digitization allows system actors to take advantage of data analysis tools and fully reap the benefits of traceability data. The quality and availability of digitized data is heavily impacted by the technology used to collect and exchange data. It is important to choose technology that aligns with the objective of the system and meets the needs of both data collectors and data users.
- **Comprehensive investment**: Traceability requires continued investment beyond initial implementation. Traceability programs and processes should be adjusted over time to reflect the evolution of technology, market requirements, operational needs, and industry structure. Additionally, long-term investment in user training, data governance, and technology maintenance are critical for system longevity and efficacy.
- **Data security**: Supply chain actors often cite data security and data privacy concerns as a barrier to traceability. Traceability data can be trade-sensitive, and it is important to ensure that only relevant data is accessed by authorized parties. Traceability systems should utilize robust data security protocols to protect stakeholders and their sensitive data.

Noteworthy Traceability Initiatives in Recent History

Regulations across the globe continue to advance the practice of traceability. Food traceability practices have expanded significantly over the last two decades, impacting a range of commodities, geographic regions, and segments of the food supply chain.

Standard setting organizations have also played an impactful role in the adoption and implementation of traceability systems. The International Organization for Standardization (ISO) and the Global Food Safety Initiative (GFSI) have published traceability standards that have guided industry practice for many years. The suite of standards designed by GS1 to identify, capture, and share data have become an integral part of traceability practice in the global food system. Several commodity or sector-specific initiatives have utilized, customized, and expanded upon GS1's foundational standards to meet traceability needs unique to their supply chains.

Shortly after the emergence of bovine spongiform encephalopathy (BSE) catalyzed traceability efforts in the beef industry, the Meat and Poultry Business Data Standards Organization (mpXML) pioneered the use of GS1 standards in meat and poultry supply chains, aiming to simplify the flow of data between trading partners (PR Newswire 2014). A series of high-profile U.S. outbreaks linked to produce in the early 2000s set the stage for the creation of the Produce Traceability Initiative (PTI): a collaborative, industry-wide effort designed to improve traceback procedures and to develop a standardized approach to produce traceability. The PTI used GS1 standards to develop a standardized case label using the GS1-128 barcode that is widely used throughout North American produce supply chains today (Produce Traceability Initiative 2023). Traceability initiatives to combat Illegal, Unreported, and Unregulated (IUU) fishing gained steam in 2011 with the efforts of the National Fisheries Institute (NFI) and continued with the launch of the Global Dialogue on Seafood Traceability (GDST) in 2017 (GDST 2020b). The GDST facilitates voluntary, industry-led traceability standards applicable to all seafood industry actors. Rounding out the grocery staples, the International Dairy, Deli, and Bakery Association (IDDBA) worked with GS1 in 2013 to develop best practices and instructive guidance for implementing traceability fundamentals in their respective sectors (IDDBA 2013).

Each of these initiatives are connected by the overwhelming theme of standardization. While certainly critical, standardization is one of several factors – like multi-stakeholder engagement, digitization, and clear objective – that contribute to the success of a traceability system. The following are examples of initiatives that demonstrate the diversity of traceability efforts over the past two decades and their use of best practices. It is important to note that these case studies do not depict flawless traceability systems; rather, they illustrate initiatives that have achieved notable impact within the food industry.

Standards & Certifications Case Study – GFSI

The Consumer Goods Forum established the Global Food Safety Initiative (GFSI) in 2000, aiming to increase the safety of the food supply and harmonize global food safety requirements. GFSI is a benchmarking organization that sets high-level requirements for food safety standards and certification schemes (GFSI 2023). This allows standard-setting bodies to customize their standards according to sector or geography-specific needs while still reflecting a globally recognized set of core food safety elements. GFSI recognizes several standards that are widely used across North America, Europe, and Asia; some of the most prevalent include Safe Quality Food Institute (SQFI), British Retail Consortium Global Standards (BRCGS) Global Food Safety Standard (British Retail Consortium), Food Safety System Certification (FSSC 22000), and International Features Standards (IFS). GFSI requires each of their recognized schemes to incorporate a minimum level of upstream and downstream traceability requirements. Most schemes require, at minimum, that operators demonstrate the ability to track product outputs forward to the first level of distribution and trace product inputs backward to immediate suppliers. These requirements have played a significant role in the proliferation of the "one-up, one-down" traceability approach throughout the food industry as many major retailers require their upstream trading partners to adopt GFSI-recognized schemes. Outside of explicit customer demands, the opportunity to reduce 3rd party audits and consolidate customer requirements into a consistent, cohesive request, further incentivized adoption among companies in the middle of the supply chain. Since its inception, more than 15,000 international food and beverage manufacturing companies have become compliant with GFSI recognized standards (Crandall et al. 2017). GFSI regularly updates their benchmarking requirements to ensure they remain relevant and appropriate for industry.

Industry Case Study – Foodservice

GS1 US launched the Foodservice GS1 US Standards Initiative in October 2009 in partnership with the International Foodservice Distributors Association (IFDA), the International Foodservice Manufacturers Association (IFMA), and the National Restaurant Association, along with 55 leading manufacturer, distributor, and operator companies (Restaurant Business 2009). The initiative aims to improve reliable product information to increase efficiencies throughout the supply chain while enhancing food safety for consumers and transparency for industry. The scope of this initiative focuses on two of the fundamental pillars of traceability: product and premises identification. Foodservice organizations are encouraged to use GS1 Identifiers for product, premises, and party identification (Global Trade Item Numbers, GTINs and Global Location Numbers, GLNs) in tandem with the GS1 Global Data Synchronization Network (GDSN): an standardized, global network that enables trading partners to exchange product data in real time – data created once and shared with many at one time. These essential standards facilitate traceability programs through the maintenance and exchange of complete, accurate, and standardized product data. The global standards enable interoperability across solutions – so supply chain partners can utilize their own systems and still be able to share and receive in different systems/solutions. With improved product data, initiative members have improved track and trace processes, optimized transportation & logistics, and increased sales. Comprehensive industry engagement spurred widespread adoption within a few years of launch with 55% of manufacturers and 45% of distributors in the U.S. food service industry (percent determined by sales revenue) using the GDSN by 2012 (Restaurant Business 2011). Adoption has continued to grow with 83% of manufacturers and 65% of distributors using GDSN as of 2020 (GS1 US 2021). Current membership is comprised of more than 130 leading organizations that include a variety of companies throughout the foodservice supply chain, academia, government agencies, associations, and solution providers (GS1 US 2023). The Foodservice GS1 US Standards Initiative remains active with collaborative efforts to expand data standardization in the foodservice industry and develop standards-based guidance for FSMA Rule 204 compliance.

Commodity Case Study – Seafood

In 2011, the National Fisheries Institute (NFI), seafood industry representatives, and GS1 US collaborated to develop voluntary, industry-wide guidance for seafood traceability implementation. Filling a need for further guidance, the World Wildlife Fund (WWF) and the Institute of Food Technologists (IFT) expanded upon that work in 2017 by co-convening the Global Dialogue on Seafood Traceability (GDST) with the support of philanthropic funding. The GDST aims to address IUU fishing through the advancement of a standardized framework for interoperable and verifiable seafood traceability. The GDST Standard was created through a three-year, multi-stakeholder dialogue process in which participants collaboratively determined the data collection and exchange practices needed to achieve interoperable seafood traceability systems (GDST 2022). Built upon GS1 foundational standards, the GDST Standard defines, for the global seafood industry, what data must be captured, when it must be captured, and how that data must be formatted and exchanged. This digitized data-centered approach to traceability not only standardizes traceability practices through the supply chain but also informs seafood regulations, certifications, and traceability solution design. Grounding the standard in digital interoperable data allows the GDST to provide the seafood industry with tools to benchmark implementation efforts. The Capability Test tool, launched in 2022, verifies the ability of traceability solution software to meet the requirements of the Standard. This test provides recognition opportunities for solution providers, facilitates traceability solution selection for supply chain organizations, and eases the implementation of the GDST standard across the supply chains through interoperable systems. Regular, member-driven Standard updates ensure that the GDST Standard meets the evolving needs of seafood industry stakeholders.

Technology Case Study – Barcoding & Laser Scanning

The idea for the first barcode symbology, a series of concentric circles that could be "read" from any direction, was patented in 1952 but the lack of small computers and bright lights needed to read the code prevented practical application. The later invention of the laser and progressive downsizing of computers provided the technology needed to bring the barcode to life in the 1970's. A collaboration between Kroger and the Radio Corporation of America (RCA) produced the first working bullseye barcode and laser scanning system. Recognizing a need for standardization, a committee of industry representatives was formed to create a universal code that could be applied by manufacturers and utilized by downstream retail actors across the industry (Weightman 2015). This effort resulted in the first Universal Product Code (U.P.C.), a one dimensional (1D) linear barcode with vertical lines and spaces and a twelve-digit number. This barcode was administered by the Uniform Code Council, an organization that later expanded to become GS1.

Use of the U.P.C. generated product identification and movement data that provided unprecedented sales and production insights for food industry actors. Valuable data incentivized adoption while simultaneous development of laser scanners designed to function in the diverse environments of the food chain (e.g., sub-zero warehouses, distribution centers, retail stores) facilitated rapid implementation of barcoding technology. Just 30 years after the first barcode was scanned at retail, Fortune magazine estimated that 80–90% of fortune 500 companies were using barcodes. Though the U.P.C. and other 1D barcodes are still widely used, the industry is moving towards two dimensional (2D) barcodes, or quick response codes (QR codes) that hold far more data (7,000 characters) than their 1D counterparts with improved accessibility through cell phone scanning capabilities (GS1 US 2023). GS1 continues to develop and maintain a suite of barcodes that meet the evolving data capture needs of industry actors and their unique supply chains.

A Summary of Successful Practices in Case Studies

These case studies illustrate the diversity in traceability use cases, outcomes, and practices observed throughout the food chain, but despite the variations in approach, a set of common best practices links each of these initiatives. A clear objective and recognition of the benefits of standardization facilitated the precompetitive, multi-stakeholder alignment needed to make meaningful advancements in food traceability. Acknowledgement of opportunities to improve traceability in their respective areas has contributed to the longevity of these initiatives. Food traceability is an ongoing process, and the long-term success of any system requires adaptation to our evolving food system.

Technology Enhanced Traceability

As customer demands and food regulations have evolved, the food industry has adopted systems and solutions to address processes and activities across their supply chains. As a result, the food industry has seen an acceleration of companies moving from manual, labor intensive, error prone processes to automated data collection, digitization of records, and data sharing through complex networks and platforms. However, the technology changes have been slow, relative to other industries (Traasdahl 2020).

Food regulations now require enhanced recordkeeping for traceability, food safety, and movement of goods. The sheer volume of data, and the requirements to capture, store and share data, has precipitated the need for companies to explore technology investments in many areas of their businesses.

Technology Drivers

Drivers for technology adoption come from many different sources, including:

1. **Regulations and standards**, such as the Food Safety Modernization Act (FSMA), including Section 204, and Foreign Supplier Verification Programs (FSVP), as well as regulations from other countries and standards from international organizations.
2. **Initiatives**, such as the FDA's New Era of Smarter Food Safety, the Global Dialogue on Seafood Traceability (GDST), The Produce Traceability Initiative (PTI), IFT, and GS1 US traceability programs and resources.
3. **Customer mandates** are directing suppliers to various technologies, including blockchain and cloud-based traceability solutions, IoT sensor technology, RFID for automated data capture, and Artificial Intelligence (AI) for enhanced data insights and reporting. Many programs follow GS1 standards for traceability, using GS1-128 barcoding, electronic data interchange (EDI) and global data synchronization network (GDSN).
4. **Corporate objectives** in areas such as transparency, sustainability, and supply chain visibility are becoming center stage. "The world's major food companies, engaged in food production, trade, processing, and consumer sales around the world, play a major role in the global food system, and therefore have crucial roles to play in the transformation of sustainable food systems" (CCSI 2021).
5. **Consumer demands** are propelled by many things including environmental concerns, more sustainable business practices and products that have a lower carbon footprint. Consumers want to know more about the foods they eat, where they come from, and the people and practices behind them (Hassoun et al. 2022).

Looking Beyond Traceability Benefits

Industry research studies, such as the National Restaurant Association Supply Chain Management Executive Study Group's "Building Traceability in Foodservice Supply Chains: Insights from the Leaders" found that these traceability data sets can contain value well beyond their initial purpose. "One operator was able to show savings of $1.3 million per year through improved truckload optimization and materials handling related to its traceability efforts – and this was for just one supplier to distributor route. This came about as the operator compared product weight/dimension records between its system and that of its suppliers and distributors. The operator discovered that as many as 82% of product records were inaccurate. Correcting these discrepancies facilitated greater efficiency in shipping" (Tokar and Swink 2018).

It also minimizes the impact of product withdrawals, by potentially changing the number of products to research and pull, as well as the resources needed to pull these products from the supply chain. These benefits have been outlined in the NRA Supply Chain Management research as

- Increases speed at which bad product can be removed from the supply chain
- Minimizes time spent collecting product
- Minimizes waste associated with unnecessary removal of good product
- Eliminates unnecessary communication with unaffected distributors and restaurants
- Offers protection to brand image

Companies need to recognize that "Traceability is not a competitive space, it's a collaborative space. Everyone must participate for it to work" (Tokar and Swink 2018).

Digital Supply Chain Transformation

Digital supply chain transformation is part of a bigger event happening in the manufacturing sector today. McKinsey & Company describes this transformation as "Industry 4.0—also called the Fourth Industrial Revolution or 4IR—is the next phase in the digitization of the manufacturing sector, driven by disruptive trends including the rise of data and connectivity, analytics, human-machine interaction, and improvements in robotics" (McKinsey & Company 2022). This is not just about the technology. We also need to prepare our workforce to ensure that they are able to transition from legacy systems and standard operating procedures to more automated and frictionless processes.

The vision for the food industry is an interoperable, visible, and traceable supply chain. "To achieve a truly visible and traceable food supply chain, the integration of internal and external business processes must occur. This means that the internal processes a company uses to track a product within its operation is integrated into a larger system of external data exchange and business processes that take place between trading partners to move the product" (Center for Supply Chain Innovation 2018).

Traceability technology relies on good data, from trusted sources. Industry developed consensus-based standards will help solution providers build tools that can capture, share, interpret and use traceability data, while permissions and protocols will determine what can be shared, and with whom. Data must be digitized to realistically meet today's regulations and customer mandates, as well as provide the ability to tap into these data sources and use it to run today's complex supply chains more efficiently and effectively.

Technology-Enhanced Traceability

"The world economy is on the verge of rapid digital transformation, and that includes food processing. The global industrial automation market is predicted to be worth $297 billion by 2026, with food and beverage applications making up 11% of the market. Internet of Things (IoT) technologies, such as sensors, simulations, artificial intelligence–based autonomous systems, additive manufacturing, cloud systems, and blockchain, are projected to have the greatest impact on the food processing industry by enabling integration of physical processes, computation, and networking in cyber-physical systems.

Such digitalization and integration can offer an unprecedented opportunity for business gains. Enabling technologies are under rapid development and their transfer to the food industry will be key" (Boz 2021).

Today's food supply chains utilize a variety of technologies that enhance traceability data capture, data maintenance, and data sharing. Previously in this document, we reviewed product and location identification, as well as the data elements needed for traceability. We will now look into how and where traceability data can be stored, shared, and used for supply chain visibility and business insights.

Internet of Things (IoT)

The Internet of Things (IoT) represents a network of physical objects, or things, embedded with technologies such as sensors or software that can connect and exchange data with other systems and devices over the Internet. ISO defined IoT as "An infrastructure of interconnected objects, people, systems and information resources together with intelligent services to allow them to process information of the physical and the virtual world and react" (ISO 2015).

IoT use is varied in the food industry, including production, processing, warehousing, inventory management and logistics. "With the help of IoTs, food manufacturers can access and make use of real-time food safety data, such as carbon dioxide, heavy metals, humidity and temperature, or shipping times and storage conditions" (Foodcircle n.d).

Radio Frequency Identification (RFID)

"RFID technology is part of our daily lives and can be found in car keys, apparel security tags, highway toll tags and security access cards. RFID uses radio waves to automatically identify objects. The identification is done by the communication between the tag (a microchip that stores the unique identification code of the object along with an antenna) and the reader (an electronic interrogator that receives the stored identification information from the tag that falls within its radio frequency range)" (Delen, Hardgrave, and Sharda 2008).

RFID has great promise in the food industry, as it allows companies to move from line-of-sight barcode scanning, where staff have to scan every item, to automatic data capture as products move past RFID readers. Process efficiencies and accuracy rates are greatly increased, as RFID serialization accounts for every single product. However, this an emerging space for the food industry, and there is still work to be done to get RFID as widely accepted as their predecessors, such as barcodes, data matrix and QR codes.

A few foodservice and grocery companies are exploring, and some have implemented RFID programs in their supply chains. Their use cases are varied, from in-store pilots, end-to-end RFID applications, enhancing traceability and inventory systems, automating operations, and providing access to inventory data in real time. For most who are in production with RFID, they are utilizing a GS1-128 label as well as the RFID inlay to mark cases and pallets of products.

RFID Next Steps

RFID tags use a serial number to identify products. However, these serialization schemes are varied, and there are many proprietary solutions in the market today. This adds complexity and cost, as users may need access to third party databases to retrieve key product information. The food industry needs to come together to agree on consensus standards, that can be universally understood and decoded. In 2020, stakeholders came together to create GS1 US TDS 2.0, which supports the encoding of additional data, beyond the serial number, including lot information, so users can immediately retrieve key information when interacting with food products that have RFID tags.

Artificial Intelligence (AI

"Artificial intelligence is simply a system's ability to correctly interpret data, to learn from it, and to use those learnings to achieve specific goals and complete tasks through adaptation. In general terms, AI is great at automating the routine and repetitive. In other words, it's great at optimizing" (Michigan State University Career services Network 2019).

The FDA is investigating artificial intelligence and its applications to food safety. In their TechTalk Podcast Episode 3, they discussed AI in the New Era of Smarter Food Safety. The speakers noted that "AI is becoming increasingly embedded in the end-to-end supply chains in agriculture and food. It gives us algorithms that, when combined with conventional techniques like forecasting, can sharpen and expedite foresights and insights. And AI-powered Internet of Things (IoT) can improve efficiencies, detect defective or unsafe ingredients in food processing, and ensure that food safety protocols are adhered to in compliance with regulations" (US FDA 2022c).

The FDA is also conducting pilots with the seafood industry to utilize AI and machine learning (ML) to strengthen import screening and to ensure that foods entering the U.S are safe. ML is a type of AI that can help identify connections and patterns that people, or the FDA's screening system, cannot see. These patterns are applied to incoming supply chains to help predict the likelihood that an import shipment is potentially harmful and not compliant with FDA regulations. The ability of ML to analyze data, already generated and used by the agency, makes it well suited for addressing complex public health challenges and helping the agency to ensure the safety of imported food (US FDA 2022b).

Traceability Solutions, Data Storage, and Blockchain Technology

Many traceability systems are powered by blockchain and cloud-based technologies. This determines how data is stored, managed, validated, and accessed.

Blockchain

Blockchain is a type of shared database for recording transactions. This data is stored in "blocks", which are linked together to form a chain. Blockchains use an application layer, which contains traceability programs and solutions that allow users to connect with the blockchain.

A blockchain is a tamper-evident, shared digital ledger that records transactions in a public or private peer-to-peer network. Distributed to all member nodes in the network, the ledger permanently records, in a sequential chain of cryptographic hash-linked blocks, the history of asset exchanges that take place between the peers in the network. Each member has a copy of the ledger.

All the confirmed and validated transaction blocks are linked and chained from the beginning of the chain to the most current block, hence the name blockchain. The blockchain thus acts as a single source of truth, and members in a blockchain network can view only those transactions that are relevant to them" (Brakeville and Perepa 2018). Figure 12 details the flow of a blockchain transaction

Blockchains are:

- Immutable: These are immutable ledgers, meaning that users cannot change information. When there is an error, the user must submit the updated data, and a new block is added.
- Distributed: Network participants have access to the distributed ledger and the immutable records. This eliminates duplication of records and makes users aware when new records are added.
- Visible: Depending on the industry

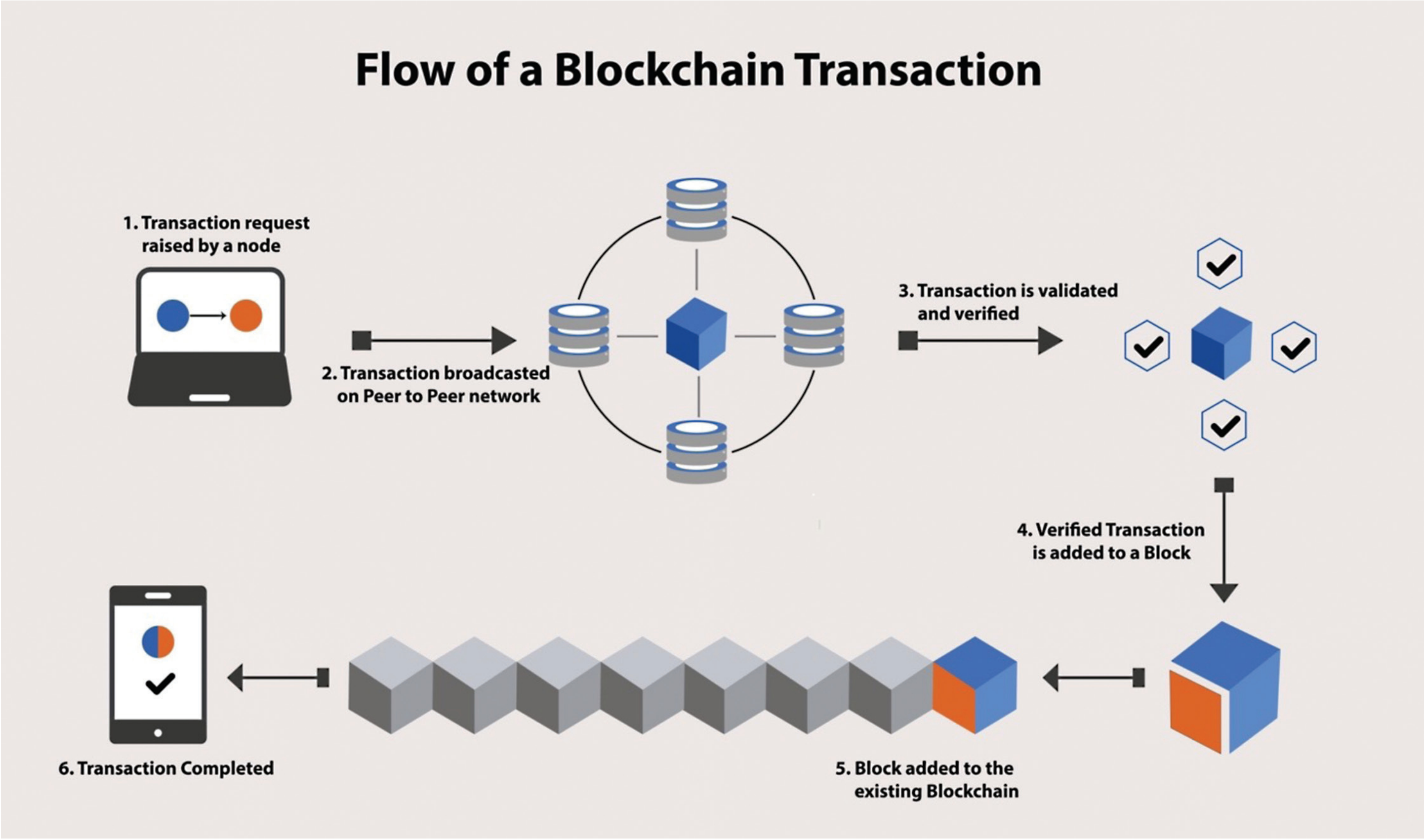

Figure 12. Source: Shutterstock https://www.shutterstock.com/image-vector/flow-blockchain-transaction-219275767

and needs, blockchains can be public, where everyone sees the data, or private, which adds a permissions layer to determine visibility to approved users.

Challenges and Opportunities for Food Supply Chain Partners

Food supply chain traceability systems in the United States are much less efficient and effective than traceability systems for packages, ride hailing, and even last mile food delivery. In the Final Regulatory Impact Analysis for the Traceability Rule, the FDA projects that the average number of days used for identifying a product source without lot codes is about 35 days and 6 days with lot codes. For consumers with instant access to the status of an ecommerce delivery or the location and anticipated arrival time of a driver, it is hard to imagine systems that measure response time in days.

Unless the food industry adopts a single data exchange system like the Society for Worldwide Interbank Financial Telecommunication (SWIFT) messaging network, our ability to track and trace food quickly and accurately depends upon interoperable, standards-based traceability systems. The primary challenges to achieving interoperability include but are not limited to: (1) the scope and scale of the global food supply chain, (2) the lack of a common language for food traceability, (3) privacy concerns about food traceability data sharing, and (4) the additional cost and complexity of traceability technology.

The FDA's Food Traceability Rule is a significant step forward in establishing a common language for food traceability in the U.S. and globally due to the amount of food imported to the United States. Based on this framework, industry-wide consortia are addressing technical and data sharing challenges through the development of best practices for the use of advanced traceable object identifiers and data carriers, traceability-specific data sharing protocols, advanced security, and privacy measures, and return on investment models. Innovative private entities are using these standards and best practices to build easier to use, cost effective, interoperable solutions to meet both the regulatory requirement and the food industry's needs for supply chain efficiency and resiliency.

Addressing the Challenges of Interoperability

The Technology Adoption Model (TAM), developed by Fred D. Davis indicates that technology adoption is driven by perceived usefulness and perceived ease of use (Kobiruzzaman 2022). Historically, food traceability systems and interoperability standards have been plagued by the twin perceptions of complexity and limited usefulness. Both perceptions will need to be addressed to encourage the adoption of interoperable traceability standards and systems.

Scope and Scale of the Food System

It is unrealistic to expect that one organization, government or technology provider can establish the semantic and technical standards to achieve interoperability for the global food supply chain. It is important for the industry to develop consensus-based standards. GS1, the International Organization for Standardization (ISO), and The United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) are examples of organizations with extensive experience and efforts in this area. These entities must work together with the food industry to develop consistent, easy to understand and beneficial to use global traceability standards. These standards need to be broadly communicated to software and hardware developers that service the global food industry.

Creating a Common Language for Food Traceability

Identifier

The diversity of ways foods may be packaged represents significant barriers to easy, interoperable identification. Mesh onion bags, wooden crates containing sweet corn, clamshells of berries, wheels of cheese, and large fish delivered on pallets offer unique challenges for tagging and tracking.

Traditionally, buyers and sellers used a variety of proprietary and standards-based identifiers to facilitate trade. Identifiers were not specifically developed for interoperable traceability across the whole supply chain.

The FDA Food Traceability Rule does not specify an identification method or technology but does require a Traceability Lot Code (TLC) be assigned and shared between trading partners unless the product is transformed. Therefore, the food industry can decide the best way to identify foods and share information about those foods. How this is accomplished will have a significant impact on adoption and interoperability.

The Opportunities Related to identifier

GS1 Digital Link

The GS1 Digital Link standard extends the flexibility of GS1 identifiers by making them part of the web. Where a URL typically points to a single, specific website, GS1 Digital Link enables connections to all types of business-to-business and business-to-consumer information. It starts with the item and points to one or more places where there is information about it. The fundamental aim of GS1 Digital Link is to enable anyone to find answers to their questions about the thing in front of them. GS1 Digital Link URL can be encoded into a 2D data carrier that has the capacity to hold more information than an UPC. From an interoperability perspective, this technology will enable traceability systems to dynamically find and query other traceability systems. This stands in contrast to traditional data exchange protocols that require significant setup, testing, monitoring, and maintenance.

Sunrise 2027, 2D Barcodes and Digital Receipts

The EAN/U.P.C. barcode has offered price lookup functionality for decades at point of sale. However, this and other 1D barcodes are no longer keeping up with today's growing demands for greater product information transparency, traceability, and authentication. Due to this, industry is moving toward two-dimensional (2D) barcodes that are able to carry more dynamic data and information. 2D barcodes allow for a single, standardized way to meet both supply chain needs and evolving consumer requirements. Industry has agreed that by 2027, retail point of sale systems will have the capability to read and interpret at minimum, the GTIN in a 2D data carrier. Product and lot or date code information combined with a consumer's mobile phone or loyalty card number could be a game changer for traceability and transparency – enabling quicker outbreak investigations and recalls while providing consumers with detailed information about products' origins on their printed or digital receipt without the need for them to scan the QR code.

Describing Food Traceability Events

The concepts of traceability outlined by IFT and GS1 were useful in developing discrete traceability systems for specific commodities (e.g., Global Dialogue on Seafood Traceability), retail and foodservice organizations, and solution providers (e.g., IBM Food Trust EPCIS Events). However, prior to FDA's Food Traceability Rule, there was no global consensus of what critical tracking events and key data elements should be required.

With the incorporation of specific Critical Tracking Events and Key Data Elements into FDA's Food Traceability Rule, the basic language of food traceability in the United States was established. Given the large number of global food companies and foreign suppliers that will be covered by FDA's Food Traceability Rule, one cannot overstate the impact.

Confidentiality of Food Supply Chain Data

Food traceability system developers must balance the need to facilitate traceability and transparency while respecting the privacy of the many participants in the food supply chain. The FDA Food Traceability Rule requires that the source of a TLC be provided to FDA so that outbreak investigations may quickly contact the organization with access to the related traceability records. The challenge was how to share that from the source to the retail food establishment or restaurant in a confidential manner. The alternative provided by the FDA is the Traceability Lot Code Source Reference (TLCSR).

The TLCSR could be a location identifier that may be used to lookup location and contact information from a database, or it may be a web address that provides the required information to authorized individuals. Additionally, the FDA Traceability Rule does not require that the pedigree of the food be shared from farm to store or restaurant. Instead, each entity is responsible for their own records. Covered entities must only share shipping key data elements, including the TLC and TLCSR, to their trading partners. Most of this information is already shared as part of commercial transactions.

Generally, if this model is followed, it will provide the food industry with quick and accurate traceability both backward and forward while minimizing the risk of exposing sensitive information such as farm and supplier locations, product formulations, customers, and financial transactions.

Cost of Supply Chain Traceability Systems

We are comfortable with the idea that the cost of an airline ticket changes minute to minute based on availability and demand. We are also familiar with the declining cost of technology as it is widely adopted and producers reach economies of scale. Traceability technology is no different. Regulations such as FDA's Final Traceability Rule will create increased demand for traceability technology. Initially, costs may be high, but as producers scale up and generate more and easier to use products with valuable add-on features, the return on investment (ROI) in these systems will increase. The perception of increased ROI will drive higher rates of adoption, leading to lower costs for food supply chain traceability.

Conclusion

It is clear and apparent that as the global food supply continues to increase in size, scope, and complexity, and as more countries expand their export of products, the need for an effective, efficient, robust and interoperable food traceability system, is vital to determining where foods and ingredients come from, how they are transformed, where they are going and where they end up. In short, the tracking and tracing of foods through their product cycle is critical to assuring the quality, safety, national origin, authenticity, and sustainability of foods that are grown, harvested, processed, transported, distributed, and prepared in multiple facilities and venues throughout their life cycle. The case for an improved worldwide food traceability system has been made by each author in this report and it needs to be done using a universal language and agreement between and among everyone involved in the production and distribution of food and ingredients. It is also essential for food industry partners to recognize that this type of system will make companies stronger and consumers more trusting of the foods that they purchase. It will also enable regulators to identify and companies to quickly retrieve products that are contaminated or defective and may cause harm to consumers.

A few best practices, defined and explained in this report, can be applied to the science of traceability and should be used when developing and implementing a comprehensive food traceability system. Those best practices including the role and responsibility of stakeholders, data standardization, digitization, and security are vital to the effective development of food traceability systems.

It is only through cooperation and collaboration and the keen recognition that this type of system needs to evolve and expand as the technology significantly improves through artificial intelligence, machine learning, big data analysis, data sharing, blockchain and the internet of things (IoT). While this task is certainly not easy and there are many complicated and thorny challenges that need to be addressed and resolved, the food industry and its many components will need to rally and move from simple, paper-based systems to sophisticated electronic technologies to track and trace the movement and transformation of foods and ingredients.

We have already seen countries around

the world that have espoused the concept and are working within their regulatory processes to move forward through a variety of regulations. We also have several food organizations that have developed standards and practices for traceability. The challenge is to make sure that the international regulations and standards are compatible with each other, not so restrictive, but harmonized with universal terminology to allow companies to operate effectively and efficiently with each other, across borders, with the common goal of assuring and even perhaps of improving the quality and safety of foods.

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