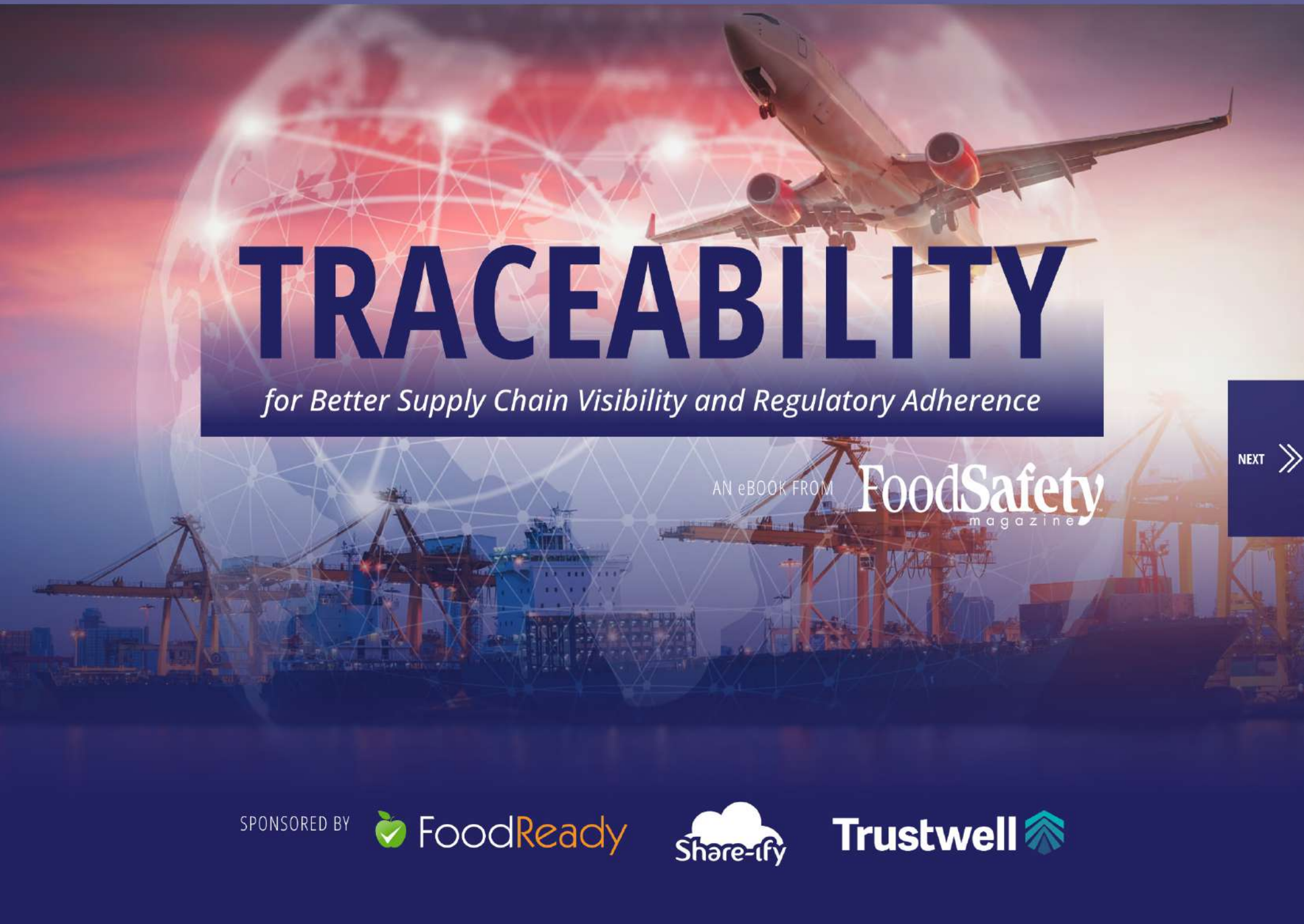

TRACEABILITY

for Better Supply Chain Visibility and Regulatory Adherence

AN eBOOK FROM FoodSafety magazine

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Global Food Chain Traceability—Reflections on the Past, Present, and Insights into Future Directions

Traceability is developing and maturing, but much remains to be tackled

By John G. Keogh, Founder and Managing Principal, Shantalla Inc. and Professor of Practice, McGill University (MCCHE); Steve Simske, Ph.D., Professor of Systems Engineering, Colorado State University; and Louise Manning, Ph.D., Professor of Sustainable Agri-Food Systems, University of Lincoln

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Traceability determines how materials, packaging, products, processing aids, and so forth have moved through the supply chain. Often broken down into two aspects, *track* and *trace*, traceability systems underpin food safety, food quality, sustainability claims, and transactional mechanisms to prevent food fraud and food defense incidents.

Tracing is the ability to follow a product backward from the retail shelf to the manufacturer, the ingredient supplier, and their suppliers. *Tracking* involves following

material from suppliers, such as a spice, through to the spice mix and then all the finished products and their destinations where the spice mix was used as an ingredient and/or dusting material. The granularity of traceability is also essential—i.e., the level of detail in which we can determine traceability. Granularity reflects the time element of the traceable unit—e.g., production for one week, one day, one shift, the product produced between the last two quality control checks, and the distance element over which the traceability operates from "one step forward, one step back" (SFSB) through to entire "field to fork" (F2F) traceability. Traceability underpins information sharing in supply chains and characteristics of the data and the systems developed. The characteristics discussed in this article include visibility, transparency, and trust.

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Global Drivers for Traceability

Figure 1 captures the many drivers of traceability in today's global food supply chains. Of note, the GS1 standards organization does incredible work to facilitate product traceability and recall generically and specifically for different food industry segments. For example, the GS1 Traceability Standard[1] is an invaluable resource for organizations, and implementation guidance documents are available for beef, fish, poultry, pork, fresh fruit and vegetables, eggs, wine, and more. The traceability standard also details examples of the fast-evolving need for organizations to understand critical tracking events (CTEs) and key data elements (KDEs). For example, the latest U.S. Food and Drug Administration (FDA) Final Food Traceability Rule[2] articulates the need for CTEs and KDEs for certain products, with full compliance scheduled for January 20, 2026. The final rule is part of the FDA's New Era of Smarter Food Safety blueprint and implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA).

Figure 1. Global Traceability Drivers

Food Traceability and Consumer Privacy

Over the past two decades, our understanding of food traceability has grown dramatically. Just like any other emerging field of study or practice, however, it can be shaped and reshaped in different directions until the concept settles and matures. It also differs in how it is applied in practice. Traceability is developing and maturing, but much remains to be tackled. For instance, F2F traceability is frequently discussed and, in some supply chains, has been achieved through analog, paper-based systems. While transitioning to digital traceability approaches has been proposed, there are challenges in collating and open sharing of all information in supply chains (supply chain visibility).

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Allergen management is one area where such systems have direct public health implications. A key point not often discussed in F2F traceability is privacy laws, which prevent consumer transactions from being tracked without consent. After all, if organizations or government agencies knew every food item bought and consumed in a household, would people feel this was an invasion of their privacy? Using customer loyalty cards with rewards points in return for providing purchase information is an embedded consumer practice, or purchasing food online and engaging with features such as "your shopping list." However, these data-driven loyalty programs and online algorithms do not give a picture of the totality of food purchases, food waste, and consumption for a given household.

Personally identifiable information (PII) is legally collected when you purchase goods from member-based retailers like Costco, through retailer loyalty programs, or through e-commerce channels. In these opt-in programs, PII is legally captured and may enable the "fork" dimension of proper F2F traceability. If something goes wrong in the supply chain, then these retailers can notify their customers directly of a product recall. If PII is not captured, then only the *product* identification is known, and the other two "Ps" needed for traceability—the *party* (consumer name) and *premises* (consumer's home address)—are unknown and, thus, traceability stops at the retail shelf.

Even if we are aware of and comprehend the goals of F2F traceability, perhaps F2F transparency would be a better framework to approach the topic. We argue that bringing food to market may involve many trading parties and complex supply chains, and business-to-business (B2B) interoperability between these systems is frequently lacking. Apart from short or local supply chains (e.g., a farmer's meat sold at a farmers' market, their farm shop, or vending machines), often called business-to-consumer (B2C) transactions, a customer typically has no access to the information about the many

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parties engaged in bringing a product to market. Suppose a consumer scans a 2D or 3D barcode on a food item. In that case, they may have limited access to a form of "fork-to-farm" traceback, often accessing only static marketing information about the brand or farm on a website, but receiving little to no data on the route to market (the actual F2F traceability).

Of course, a consumer scan is not the same degree of traceback that a food company might perform in a product recall scenario. Still, it can provide a semblance of trust. Providing consumers with static data (e.g., brand details, supplier location, farm location) on the food source lacks granularity. It is an oversimplification of the intricacies involved in end-to-end food chain traceability.

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> *The highest frequency of fraudulent USDA organic certifications reported was found in the U.S.*

Transparency and Trust

From an organizational perspective, transparency should be seen as a fundamentally important tool for addressing stakeholder and customer mistrust while improving and proving (a process known as nonrepudiation) an organization's responsible management practices.[3] In the food industry, we discuss creating a culture of food safety. With his excellent books and briefings, pioneers like Frank Yiannas helped pave the way. Is it now time for executives at large food companies to consider creating and enforcing a culture of transparency? What would that mean for their internal

operations, and what does that mean for their shareholders and customers? There is little doubt that the pressures on food companies to deliver safe, affordable, and nutrient-dense foods to market are increasing amid disruptions and conflict.

More specifically for the food industry, product-related transparency was first discussed with consumer safety, environmental politics, and sustainability concerns in mind. Transparency refers to the availability and visibility of data among the parties involved in food supply chains and extending pertinent data to consumers to permit more informed purchasing decisions. Information about the brand owner, the geographic origin or provenance of the raw materials and ingredients, the growing and harvesting practices, the manufacturing processes, working conditions, and environmental effects could be part of specific product information made transparent (visible) for consumers. Providing this information across the supply chain and to consumers can help maintain product identity (preventing fraud and counterfeiting, and thus engaging more governmental and customs support), preserve food quality (verify harvest/best before dates, etc.), food safety (food safety advice, rapid recall notifications of unsafe food), and reduce risk to brand value, among other things.[4,5,6]

Information on the credentialing procedure for product or process claims, including kosher, halal, and U.S. Department of Agriculture (USDA) organic, to name a few, is conceptualized as a crucial element in transparency data. For example, USDA recently announced[7] stricter rules and enforcement actions for USDA organic claims on January 18, 2023, to signal "A significant increase in oversight and enforcement authority to reinforce the trust of consumers, farmers, and those transitioning to organic production." USDA provides a website where a consumer can verify if a particular food company and product are certified to their organic standard. This is a critically important move by USDA, as its organic logo sends a strong signal to consumers and

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acts as a proxy for trust, especially as it is a governmental scheme with rigorous enforcement.

However, this strong signal of trust is still vulnerable to bad actors that fraudulently claim to have USDA organic certification, but do not. When we checked USDA's website for a list of fraudulent certification claims[8] in late January 2023, we found 166 records, consistent with previous years. The highest frequency of fraudulent USDA organic certifications reported was found in the U.S. (31 recorded fraudulent certifications), followed by China (23), South Africa (17), Thailand (14), Mexico (12), and India (9). In Europe, similar instances of fraud with organic products are found—e.g., selling conventionally produced eggs as organic in the UK and Germany, dilution of organic pistachios with the conventionally grown product identified in Spain, and the Italian "Puss-in-Boots" incident with cereals, a highly sophisticated organized crime group network spanning multiple countries and legal jurisdictions.[9] With credence-based foods, it is a daunting task to manage a global certification scheme and deliver effective market surveillance. Regulators must encourage an online presence where consumers can verify these product claims.

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Supply Chain Visibility

Visibility means that specific data and information are readily accessible for those who wish to use it (both inside and outside the organization) for validation, monitoring, surveillance, and verification of business operations, food product history,[10] and to understand both upstream (e.g., suppliers) and downstream (e.g., organizations involved from the business to end user) activities. Supply chain visibility has been described as "traceability and transparency of [the] supply chain process"[11] or the "identity, location, and status of entities transiting the supply chain, captured in timely

messages about events, along with the planned and actual dates/times for these events."[12]

Visibility extends beyond traceability's passive, transactional aspects.[13] Traceability allows organizations to follow a product or its components forward and backward through a supply chain. Visibility provides information about what happened at each stage—along with the people, processes, equipment, and materials involved—and as a result, the likely food safety impact. For example, in the event of a food product recall for glass contamination, traceability allows an organization to identify the batch size that needs to be recalled, where its ingredients came from, and where the product went and to which customers. Visibility utilizes information beyond traceability documentation to determine what happened at each stage, what preventive measures were or were not in place, and if they had been implemented. The process of visualizing food traceability systems has also been considered in recent research to minimize data loss using material and information flow modeling techniques.[14] Still, this aspect of food safety management has yet to take off within business. Information loss can occur at any point in a supply chain where there is a failure or incomplete transfer of traceability data. Minimizing information loss generally drives better supply chain performance, specifically regarding food safety and the potential risk of product recalls.[14]

Traceability and visibility are only two elements of transparency, as disclosure plays an essential role in delivering transparency.[15] Transparency extends beyond the provision of information alone. Transparency provides visibility of how and why decisions were made, what information was used to make those decisions, and who made decisions on behalf of others, e.g., consumers. For example, during a food safety risk assessment, an organization will determine the acceptable level of a food safety hazard that is deemed

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appropriate (e.g., the limit of detection of the monitoring equipment); however, is this acceptable for a consumer? While a wealth of technologies are now being used in food supply chains to enable digitalization and more real-time sharing of data, if the technologies themselves lack transparency and explainability, this may cause consumers to be concerned about what has been disclosed by an organization and also what has not.[15] Trust is built on the foundations of traceability, visibility, and transparency. Roy (2021) summarizes that while traceability maps logistical interrelationships between products and their component parts, supply chain visibility seeks to integrate information sharing across the supply chain to build governance structures and maximize coordination, productivity, and performance.[16]

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The Future Food Supply Chain and the Growing Importance of Sustainability

Sustainability is usually viewed as an attribute of a practice that impacts the use and application of resources in such a way as to allow any foreseeable future generation to be able to employ such resources to meet their needs effectively. To be meaningful, a definition of sustainable practice requires an understanding of the following:

1. The social, economic, and environmental resources required for the practice
2. The factors that may limit those resources
3. The factors that may grow those resources
4. Alternatives to those resources.

Because sustainability includes social attributes, it is an important (perhaps the most important) part of ensuring equity in a food supply chain. The farmers, seasonal workers, and distributors involved in sourcing for the food supply chain must be sustained with just as much care as the soil, water sources, and pest remediation necessary to bring the foodstuffs to harvestability. Economic sustainability must include sufficient resiliency so that the workers relevant to food production are not readily enticed to seek other activities and employment when the opportunity arises.

The economic aspects of sustainability require careful consideration of how both net profits and insurance-based protection for safeguarding future net profitability are distributed from the farmer through to consumers. Based on recent work, sustainability can be modeled economically with a combination of persuasion and operant conditioning incentives (ethos and positive reinforcement), with traditional willingness-to-pay/marginal cost (WTP-MC) curves, and with sensitivity analysis-enabling Likert surveys.[17] Incentivization and persuasion must adapt to the realities of the food supply chain, as for any other form of sustainability. Based on this, sustainability in the food supply chain is conditional to the current state of knowledge of the resource requirements of this supply chain and the impact the logistics of this chain place on the resources required for the practice. Sustainability is an innately mutable state, and preparing for that fact will aid in designing supply chain processes that are preadapted to change with the exigencies of each supply chain. Two key organizational resilience attributes are agility and buffer capacity.[18]

The environmental resources associated with a food supply chain are, on the surface, the most obvious aspect of a sustainability plan. However, most plans are relatively superficial, focusing on the suppliers with which the logistics network (procurement, distribution, warehousing, and retail) has direct interactions. Since sustainability must

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be concerned with factors that may limit or grow the resources required by these suppliers, a resilient sustainability plan must include secondary and even tertiary suppliers to ensure that the primary suppliers have multiple sources for their supplies, including seed and feed, pest remediation, irrigation, transportation, and seasonal access to labor and logistics support. No one can plan a contingency for every potential vulnerability. Still, there is an increased need to add layers to the sustainability plan to provide a faster, more effective response to exploiting strategies for these climate, geopolitical, and pricing vulnerabilities, as well as other crises. Insurance companies are already involved in protection strategies for weather uncertainties and climate change risk mitigation;[19] they are undoubtedly to become more involved in sustainability and supply resiliency planning in the future as part of strategies to lower their exposure to risk.

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Emerging Technologies

The growing fields of systems engineering and developing circular rather than linear economics combine to provide emerging technologies and practices for more broadly establishing sustainability in food supply chains and providing improved and transparent means of modeling and evaluating them. Sophisticated modeling techniques such as lifecycle analysis (LCA), technical-economic analysis (TEA), and agent-based modeling (ABM) allow sustainability to be modeled on a farm-to-farm level, affording a bottom-up basis for an accurate overall picture of total resource use in a complete supply chain.

Additionally, multiple forms of economic modeling, such as the WTP-MC curves mentioned previously, enable a top-down approach to be simultaneously employed. From the comparison of bottom-up and top-down models, anomalies in the alignment

of these two or more modeled networks help identify the locations most likely to deviate from the models. In these locations, extra attention can be paid to refine the models locally and also to adjust the models overall. This type of multi-network anomaly detection can be used for sustainability along adjacent (and equally important) topics of cyber-physical security, IoT, and other sensing, analytics, and identification of potential illicit trade and human trafficking.[20]

From the perspective of putting a broad program in place, sustainability starts with using what is already available; e.g., asset inertia or "sunk costs." Recognizing, for example, that the manufacturing sector has invested trillions of dollars in existing equipment and processes means that sustainability experts will look at ways to migrate these existing resources to improved resources without incurring higher costs (to the social, economic, and environmental aspects of sustainability cost modeling). Where possible, sustainability can be adopted from the ground up; for example, in creating carbon-negative infrastructure materials.[21,22] Also, the approach of trying to employ sustainability in the most difficult of environments (e.g., spaceflight) and then being able to "back off" the solution to the more mundane applications is attracting adherents.[23] It is essential for businesses to consider both offsetting strategies and also insetting, making processes and activities more efficient and, as a result, reducing their environmental impact.

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The Services Chain

In terms of delivering transparency, the services involved in getting food products to market is an area that we believe is underdeveloped and receives little attention. The research division of the Asia-Pacific Economic Cooperation (APEC) examined Chile's services industries for wine and fresh cherries in 2015.[24] It was remarkable to learn that

both sectors needed considerable services for a single-ingredient product. In the wine industry, for instance, "a total of 70 services can be identified in this value chain; 33 of which are more directly related to the wine production phase, while 23 relate to the agriculture phase; an additional 14 services are transversal operations that support all stages of the value chain."[24]

The cherry value chain consisted of 88 different services. Orchard establishment included seven services across research and development for variety development, preparation and planting, and irrigation installation. Cherry production included 20 services (agronomy, pest control, certification, equipment and transportation, labor); packing included 19 services (certification, packaging, labor, information technology); marketing, distribution, and sales included 12 services; and transversal services included 13 services (finance, accounting, legal, human resources, etc.).

How can the sustainability and credence credentials of the service providers be checked and verified? How can we be sure they are licensed, certified, or authorized, and that their personnel are properly trained and competent? How do we know they followed regulations in both the country of production and the countries to which they are exporting, and used the proper treatments and chemicals? We strongly advise businesses to look into the services needed to bring their products to market. It is crucial to be able to rapidly identify all the services that went into bringing an unsafe product to market when a food recall is necessary and a forensic investigation is required. One particular aspect of note is software as a service (SaaS) and robotics as a service (RaaS) with particular focus on cyber security and vulnerability to cyber-attacks, particularly ransomware.

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Verifiable Credentials

Verifiable credentials include many possibilities other than blockchain, which is a specific form of a distributed ledger. Distributed ledgers are multi-party means of providing consensus through a distributed, synchronized, shared record of digital data. Sequential digital signing by each sender/receiver pair in a supply chain has been available for decades by providers and standards bodies such as GS1. Credentials can also be readily provided through the use of digital signing (this can be used for any digital record, from code signing to document signing). Public key signatures (PKI), distributed ledgers tied to transaction signatures, encryption within encryption, and chains of nonces are additional sources of verifiable credentials.

Blockchain provides some non-equitable outcomes. For example, mining the next valid chain in a blockchain is innately susceptible to resource (computing power) asymmetry, thus allowing much of the chain sequencing to fall into the hands of those with the most computing power. Blockchain and bitcoin are also estimated to have the equivalent carbon emissions footprint as the country of Sri Lanka, perhaps double that if all cryptocurrencies are included. Given these facts, we recommend in general to keep credentialling both simple and sustainable: use multi-factor authentication (which also helps in forensic analysis of cyberattacks since the attackers leave their footprint on two or more networks simultaneously), and use tried-and-true PKI for authentication access control and non-repudiation tasks in the food supply chain. Certification scheme holders in the food industry who provide credence verification should investigate using the W3C "Verifiable Credentials Data Model v1.1" to facilitate digital verification of credence claims.[25]

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Summary

Pressure to make sure that the world's food ecosystems are resilient, sustainable, and compliant with environmental and human rights laws is growing. Embedding traceability, transparency, and trust in food supply chains is also essential. The new German supply chain due diligence act,[26] which went into force on January 1, 2023, is proof of this. The act mandates necessary steps to be taken by companies in Germany with 3,000 or more employees in order to maintain human rights and environmental protection across their entire global supply chains. The act establishes rigorous standards and promotes increased transparency. The actions and behaviors required to get food sown, grown, harvested, processed, and distributed are largely unobservable by the buyers, unless they have a constant local presence or engage in regular unannounced audits; therefore, companies will undoubtedly face significant compliance challenges and increased transaction costs. Audits, however, have their limitations because they only offer proof for a certain moment in time.

There is little doubt that transparency and trust are essential to the success of future food supply ecosystems; however, the delivery of these criteria in practice remains the subject of much debate.

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Revolutionizing FSMA 204 Compliance: The Ultimate Guide with FoodReady

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Revolutionizing FSMA 204 Compliance: The Ultimate Guide with FoodReady

FSMA Section 204 has emerged as a pivotal regulation, making the integration of advanced food safety traceability software a necessity for staying competitive and compliant

By *FoodReady*

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In an industry where safety and compliance are not just priorities but also necessities, the introduction of *Food Safety Modernization Act* (FSMA) Section 204 has set new benchmarks. As the deadline of January 2026 inches closer, the need for a comprehensive and effective approach to achieving compliance is paramount. Enter FoodReady—your ultimate partner in not just meeting, but also excelling, in FSMA 204 compliance.

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The Role of Automation and Electronic Data Management

The U.S. Food and Drug Administration (FDA), while not prescribing specific methods for traceability, implicitly suggests that automation and electronic data management are vital. Manual systems are increasingly seen as antiquated and inefficient in an industry where real-time data and accuracy are paramount. Advanced traceability software offers an elegant solution, seamlessly integrating into existing systems and simplifying compliance with FSMA 204.

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Exploring Traceability Technologies

Options such as barcodes, RFID, and QR codes offer viable traceability solutions. However, these technologies demand program oversight and an additional labor force to ensure efficacy. Advanced traceability software can integrate these technologies, providing a streamlined, user-friendly interface that minimizes the need for extensive additional labor.

The Broad Benefits of Enhanced Traceability Systems

Implementing comprehensive traceability systems offers multifaceted benefits:

1. *Improved Quality Metrics:* Enhanced traceability ensures higher standards of quality and safety, vital for consumer trust
2. *Optimized Transportation and Logistics:* Real-time tracking of products enhances logistical efficiency, reducing delays and spoilage
3. *Cost Reduction:* Efficient traceability can significantly reduce the costs associated with recalls and waste
4. *Waste Reduction:* Accurate tracking minimizes spoilage and waste, contributing to more sustainable practices
5. *New Market Opportunities:* Demonstrable compliance with global safety standards opens doors to international markets.

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Addressing Challenges for Food Businesses Trying to Figure Out Next Steps for FSMA 204 Readiness

Food manufacturers and distributors face unique challenges under FSMA 204, especially those that are ineligible for exemptions. Limited resources may necessitate reliance on manual methods like paper records or spreadsheets, which are labor-intensive and less scalable. Foodservice companies also confront the need to implement new processes with constrained resources. This scenario underscores the importance of scalable, affordable traceability solutions that can cater to the needs of businesses of all sizes.

The FSMA 204 Readiness Roadmap: A Tailored Approach

FoodReady offers a unique FSMA 204 Readiness Roadmap, a comprehensive Who, What, Where, When, How Guide to Compliance. This roadmap is not just a checklist; it is also a strategic allocation of resources to assess gaps and help determine and implement the necessary processes for compliance. With FoodReady, your journey from day one to full compliance by January 2026 is meticulously planned and executed.

Structured and Scheduled Task Management

The journey to compliance is a series of well-defined steps:

1. *Create a FSMA 204 Compliance Team:* FoodReady assists in assembling a dedicated team, ensuring that all necessary roles and responsibilities are clearly defined

2. *Clarify Implementation Scope:* Understanding the specific needs of your organization is crucial, and FoodReady helps clarify the extent and depth of implementation required
3. *Assess Traceability and Data Compatibility:* With FoodReady's expertise, assess your current traceability capabilities and data compatibility within your supply chain
4. *Internal Gap Assessment:* Identify the gaps in your current system against FSMA 204 requirements
5. *Implementation Plan:* Utilize industry best practices and state-of-the-art tools like IoT and hardware, curated by FoodReady, to establish an effective implementation plan
6. *Assign and Track Tasks:* From creating procedures to integrating them into business processes and training team members, FoodReady's platform allows for seamless task assignment and tracking.

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FoodReady: More Than Just Software

FoodReady is not merely a software provider; it is a comprehensive FSMA compliance management system. It validates and verifies data accuracy continuously as it manages critical data elements (KDEs), critical tracking events (CTEs), and inventory. The software is equipped with a master data management system, an item barcode generator, and a sophisticated inventory management system. This system allows for easy, practical capturing and tracking of lot codes, quantities, manufacture dates, locations, and reference numbers both on the web and mobile.

Enhancing Team Collaboration and Customization

FoodReady believes in an organization-wide effort, supporting cross-functional and cross-departmental team task management. The platform's framework allows for customization of weekly, monthly, and quarterly tasks based on your gap assessment and resource availability. This customization ensures that your organization remains on track, identifies bottlenecks, and directs attention where it is most needed to meet scheduled goals.

Data Management and Traceability Plan Templates

With FoodReady, data management becomes effortless, providing quick and easy access to validated data. Moreover, the platform offers traceability plan templates specifically designed to meet FSMA 204 requirements. This feature is complemented by a recall management module equipped with forms, letters, and log templates, ensuring efficient internal and external communication.

The FoodReady Team: Your Guide and Support

Embarking on this journey with FoodReady means having a team of experts at your disposal. From software onboarding and setup guidance to providing resources and expert support on FSMA 204 requirements, the FoodReady team is there to ensure that your organization is set on the right track from the get-go.

In the dynamic world of food production and distribution, FSMA Section 204 has emerged as a pivotal regulation, urging companies toward greater transparency and safety in their supply chains. As food safety compliance managers at leading food companies evaluate their strategies, the integration of advanced food safety traceability

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software becomes not just an option, but a necessity for staying competitive and compliant.

Conclusion

FoodReady is not just a tool; it is your partner in achieving FSMA 204 compliance. With its comprehensive and customizable approach, state-of-the-art technology, and expert support, FoodReady ensures that your organization does not just meet the FSMA 204 requirements, but also sets a new standard in food safety and traceability. FoodReady is also scalable from small farmer/manufacturer to larger manufacturing operations.

FoodReady brings technology that can be easily integrated into the current food safety/manufacturing culture and will ease the burdens of food safety compliance. Embrace the future of food safety with FoodReady, and transform the challenge of compliance into an opportunity for excellence.

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How FDA's Traceability Lot Code Requirements Advance Food Traceability

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How FDA's Traceability Lot Code Requirements Advance Food Traceability

The Traceability Lot Code serves as a breadcrumb trail, highlighting every step a product takes through the supply chain

By Sara Bratager, Food Traceability and Food Safety Scientist, Global Food Traceability Center, Institute of Food Technologists

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Since the November 2022 release of the U.S. Food and Drug Administration's (FDA's) final rule on Requirements for Additional Traceability Records for Certain Foods, food industry actors have been working to interpret the rule requirements in preparation for compliance in January 2026. Although each component of the rule will drive impactful changes in the food industry, one component stands out—the Traceability Lot Code (TLC).

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A code used to identify a specific "lot" or "batch" of product, the TLC is the most important Key Data Element (KDE) required by the rule because it links a food product to each of the events in its supply chain. The limited circumstances under which TLCs can be assigned and the persistent connection to the TLC Source (the entity that assigned the TLC) are key components of the TLC requirements. These requirements aim to enable more efficient outbreak investigations and product containment efforts. Several comments on the draft rule suggested that the TLC requirement is unnecessary given that PO numbers, BOLs, and other commonly used reference documents provide sufficient documentation to link products back to their point of harvest, creation, or transformation.

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However, the frequency and size of recalls[1] that have plagued the U.S. food supply with consumer illness and product loss over recent years demonstrate that what is sufficient is not necessarily effective in reducing the burden of foodborne illness. FDA countered dissenting comments, stating that, "Requiring documentation of traceability lot codes and related information at different stages of production and distribution will enable us to skip steps in the supply chain, link a food to the firms that have handled it, and ultimately lead us back to the source of the food."[2] The increasing length and complexity of global food chains further highlights the critical need for updated practices that allow investigators to "skip" past low-risk handling and storage stages and quickly pinpoint the growing, packing, or processing locations where contamination is more likely to occur.

Expansion Upon the Traditional Lot Code

FDA defines the TLC as "a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the firm that assigned the traceability lot code."[2]

This definition closely aligns with industry's widespread use of lot codes, but unique identification takes on new meaning given the end-to-end scope of the rule. While traditional lot codes are used to uniquely identify lots within an organization, the TLC must uniquely identify lots within the food system.

Several comments on the draft rule recommended that FDA standardize the format for the TLC. FDA declined the recommendation in favor of providing entities with the flexibility to select a lot coding approach that best suits their operation. This allows those subjected to the rule to define a "lot" with appropriate granularity for their process and then select a lot code format that meets their needs. However, the desire for flexibility conflicts with the unique identification requirement, as it is difficult to ensure universal uniqueness without a standard format that guarantees differentiation. Some processors simply use the production date to assign lot codes; for example, "030623" may be the lot code for a food product created on March 6th, 2023. Given the volume and variety of foods produced daily, the likelihood of unrelated products with identical date-based lot codes is high, especially for downstream actors like distributors and retailers that receive goods from multiple suppliers.

To avoid such situations, FDA encouraged actors to adhere to "several food industry-supported traceability initiatives [that] offer best practices and standards for uniquely identifying a food using a combination of a globally unique product identifier, firm-assigned internal lot code, and standard date code. This information, taken together, could be used as a traceability lot code, provided it meets the definition of "traceability lot code" in § 1.1310 of the final rule."[2] This guidance highlights that while the lot codes currently used by industry actors may be used to construct a TLC, most cannot stand alone and meet the definition of a TLC without enhancement.

Lot codes are an integral part of internal traceability protocols among supply chain actors. Comments to the draft rule suggested that to replace current lot coding practice with the more restrictive TLC practice would hamper internal traceability efforts. FDA recognizes that many firms use lot codes for functions outside the scope of the rule and affirms that entities are free to continue using internal lot codes in addition to the required TLC. Although the use of tandem lot codes may prevent disruption of internal tracing efforts, products labeled with multiple lot codes are likely to cause confusion for downstream actors if it is not abundantly clear which lot code is the TLC.

> *While the degree of change required may seem daunting, it is important to note that the food industry has the fundamental systems and technology needed to ensure compliance.*

Selective TLC Usage Drives Process Changes

Industry actors are accustomed to having flexibility around if and when to assign a lot code, and while this flexibility remains for internal lot coding practices, the final rule sets forth more restrictive guidelines for the assignment of TLCs. The rule requires that actors assign a TLC only during the initial packing of raw agricultural commodities (RACs), first land-based receiving of wild-caught seafood products, and at transformation events for all commodities on the Food Traceability List (FTL).

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Once a TLC has been assigned, the KDEs required at each Critical Tracking Event (CTE) must be linked to the TLC. While this will drive an operational shift for many industry actors, it will have the biggest impact on those performing transformations, as the TLCs of transformation inputs (FTL ingredients) must be linked to the new TLC of the transformed product. A physical transformation through manufacturing or processing often comes to mind at the mention of "transformation," but transformation events also include those that change a food product's packaging. Linking input lot codes to output lot codes through transformation events like commingling or repacking will likely require process changes for many actors in the middle of the supply chain.

The requirement that the TLC be preserved across trading partners that do not perform transformations will impact product handlers (e.g., distributors) most significantly. Actors who ship and receive food must capture and maintain previously assigned TLCs for the products they handle—a change from their current practice of assigning new lot codes upon receipt. Although process changes may cause temporary strain, this change, specifically, will enable investigators to "skip" product handling steps in the supply chain to more quickly identify the source of potentially harmful products in the event of an outbreak or recall.

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The TLC Source

Among the KDEs that must be linked to each TLC, the most notable may be the TLC Source. The TLC Source identifies the place where a food was assigned a TLC, which is most often where it was manufactured or transformed—and, thus, where contamination is most likely to occur. Although this data point is critical for outbreak investigation, many industry actors expressed concern over sharing the TLC source with subsequent recipients, as the identity of upstream trading partners and suppliers is

often trade-sensitive and closely guarded.

To address these concerns, FDA allows those subjected to the rule to use a TLC Source Reference in place of a TLC Source. This reference provides an alternative method for allowing FDA access to the location of the TLC Source without explicitly revealing that information to other trading partners. It can take the form of an FDA Food Facility Registration Number, a web address, or another unique identifier that can be linked to a location description for the TLC source. By offering this alternative, FDA hopes to balance the industry's data privacy concerns with the critical need to share traceability data.

Collaboration for Success

Those subject to the Traceability Final Rule will benefit from adhering to pre-competitive, collaborative efforts to adopt best practices and standards for unique product identification. GS1, best known for its barcoding system, provides standards for globally unique identification of objects, entities, and locations that could be used to create TLC Source References and universally unique TLCs. Following the TLC structure referenced in FDA commentary and GS1's FSMA 204 Guideline,[3] a firm could construct a TLC using a GS1 Global Trade Item Number (GTIN) and an internal lot code. The near-ubiquitous use of GTINs in global retail makes a GS1-based approach to lot coding a practical choice for downstream actors.

Those that do not use GS1 standards may choose to use a URL or a Universally Unique Identifier (UUID) to achieve a unique TLC. UUIDs do not depend on a central registry to guarantee uniqueness. So, although duplication is technically a possibility, the standard, algorithmic approaches to generating UUIDs ensure that the chances of duplication are

so low as to be negligible. The absence of central registration authority makes UUIDs a more accessible option for supply chain actors, particularly upstream actors, that may find registry-based methods to be cost-prohibitive.

Supply chain actors and solutions providers need to communicate openly to ensure that they can exchange TLCs digitally. One comment on the draft rule suggested that "because supply chain systems are not fully interoperable, a TLC designated at the beginning of the supply chain may not be compatible with downstream systems."[2] While true, interoperability is not strictly necessary to exchange TLC information. Those covered by the rule will need to work collaboratively with their supply chains and solutions providers to ensure that they can receive, record, and interpret all trading partners' TLCs.

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TLC Requirements Support Traceability Advancement

Of all the key features of FDA's Traceability Final Rule, the TLC stands out for its criticality and understated complexity. This crucial code serves as a breadcrumb trail, highlighting every step a product takes through the supply chain. To meet the TLC requirements, industry actors will need to make significant modifications to current lot coding practices. While the degree of change required may seem daunting, it is important to note that the food industry has the fundamental systems and technology needed to ensure compliance. Implementing these updated lot coding practices with the other components of the traceability rule will advance traceability practices across industry, saving lives and businesses.

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coding practices. While the degree of change required may seem daunting, it is important to note that the food industry has the fundamental systems and technology needed to ensure compliance. Implementing these updated lot coding practices with the other components of the traceability rule will advance traceability practices across industry, saving lives and businesses.

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Sara Bratager *is a Food Traceability and Food Safety Scientist at the Global Food Traceability Center (GFTC) at the Institute of Food Technologists (IFT). She enjoys applying years of traceability and food safety management experience in manufacturing toward GFTC's efforts to engage food system stakeholders in their traceability journey through applied research, capacity building, advocacy, system design, and implementation. Ms. Bratager and the GFTC team continue to support industry actors in their FSMA 204 compliance journey.*

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Share-ify Launches Into 2024 after Stellar 2023 Results

Share-ify offers supplier management, product specification management, product recall, product quality inspections, and production control systems to assist companies in adopting more robust processes for FSQA

By *Share-ify*

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Ales-A/iStock / Getty Images Plus via Getty Images

Share-ify, the industry-leading, secure, private network for trading partners and customers to share business information, has announced its 2023 results with a 35 percent increase in sales year over year and a forecast that 2024 will be even better.

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"I am proud of our amazing team that is all based in the U.S. We have a lot to be thankful for," stated Ernesto Nardone, CEO of Share-ify. "We have the best staff on earth, and they take great strides to make sure our customers are happy. Our results demonstrate how important that is."

Share-ify's platform includes over 17,000 companies across 59 countries, including 50 percent of the top four distributors in the U.S. and many of the top 100 restaurant chains in the industry.

"We have built this company brick by brick on the premise that service must come first. Our customers see that and stay with us as a result," says Mr. Nardone.

Mr. Nardone has been CEO of Share-ify since 2017, when Share-ify was spun out to become its own company. He spent 22 years at IBM and now puts to use all he learned from his Fortune 100 company experience. "I am grateful for my time with such an industry-leading company, but now my time is spent helping address the challenges of a very complex food supply chain."

After joining Share-ify, Mr. Nardone assembled an executive team of eight individuals across every segment of the supply chain: from growers/packers/shippers to distributors to restaurants and retail. Share-ify executives have worked among the Fortune 500 all the way to small growers/packers/shippers, and, on average, have over 25 years of industry experience.

FSMA 204 and the Need for Affordable Solutions

With the highly anticipated compliance date of January 20, 2026 fast approaching, FSMA 204 is driving companies to adopt industry standards for traceability. Produce industry

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supply chains members are focused on creating and implementing their FSMA 204 plans.

A long list of designated foods will have new recordkeeping requirements, along with food tracing recordkeeping requirements. Fresh produce affected items includes leafy greens, tomatoes, cucumbers, peppers, herbs, melons, sprouts, tropical fruits (mango, papaya, mamey, guava, lychee, jackfruit, and starfruit), and fresh-cut fruits and vegetables.

To satisfy the FSMA 204 federal requirement, a total solution needs to address four elements (depending on the type of Critical Tracking Event):

- Master data management
- Data collection (API/EDI or scanning)
- Data publishing
- Label printing.

Share-ify can help with one, some, or all of these needs for FSMA 204 compliance.

Data publishing is a key hurdle for many. Share-ify is now marketing its FSMA 204 offering, which includes an affordable price tag for small businesses.

"Our goal was to create a solution that is cheaper than a cell phone for small businesses," stated Angela Nardone, Chief Operating Officer and Head of Product Management. "Traceability is clearly important, and only possible if we can make solutions easy to implement and affordable for everyone, especially small businesses that make up over 80 percent or more of the supply chain."

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Mrs. Nardone explained the need for small companies with limited infrastructure to have an affordable option to send and receive information electronically with larger companies. "When we work with our largest customers, their issue is often getting the data from supply chain partners with minimal need to scan cases. With our smallest customers, the goal is to help them get all of the data electronically to submit to their trading partners quickly and easily. We cannot just solve the problem of one party and not the other, and hope to have traceability."

Companies that are finding the most difficult time addressing FSMA 204 often have deferred the implementation of other needed infrastructure and systems that would undoubtedly help with FSMA 204 rollout.

"Share-ify offers supplier management, product specification management, product recall, product quality inspections, and production control systems to assist companies that are trying to adopt more robust processes for food safety and quality assurance," explains Mrs. Nardone.

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Share-ify Solutions

Share-ify's solutions include:

Supplier and Vendor Management. Share-ify provides a private, online, professional network for maintaining all the details and documents related to Supplier and Vendor Management and Customer Relationship Management (CRM). Share-ify subscribers can now manage regulatory compliance, quality assurance, quality control, occupational hazard, supply chain management, food safety, and regulatory standards all in one place, with both customers and suppliers.

Ver-ify. A solution that assists Quality Control, Sales, and Purchasing teams to effectively evaluate product quality and communicate in real time. The Ver-ify system allows companies to integrate with trading partners more fully throughout the supply chain with mobile product inspections. Using a tablet device, companies can take pictures and evaluate attributes based on the specific products. Each inspection can be tailored to a company's exact requirements and be based on industry or government standards programs.

Alert-ify. A product recall and market withdrawal solution to help effectively remove product from the supply chain in hours or minutes (as opposed to days or weeks), with substantially less resources.

Work-ify (QFSM). Work-ify enables companies to more effectively manage production controls. Work-ify helps transition companies to paperless production logs for quality assurance, food safety, maintenance, and other prerequisite programs (PRPs). QFSM helps both large and small companies take traditionally paper-based systems for food safety and quality assurance logs and transition to a mobile data collection and cloud-based management platform for HACCP and similar programs. QFSM helps companies implement real-time quality assurance and food safety management so that each plant operates consistently to corporate plans.

Share-ify PLM. Product Lifecycle Management (PLM) helps align departments, teams, and vendors with complex product information, artwork, product engineering, and manufacturing workflows to efficiently bring a product to market and follow it through its lifecycle. Share-ify PLM allows companies to connect people, processes, and data across the entire product lifecycle to one safe, centralized location. Everyone in the lifecycle chain is on the same page, sharing up-to-date information.

To set up a demonstration or request more information, visit our website at www.share-ify.com.

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Digitized Supply Chains Deliver Improved Visibility, Traceability, and Happy Customers

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Digitized Supply Chains Deliver Improved Visibility, Traceability, and Happy Customers

Technology upgrades are needed to serve increasingly complex, global markets more efficiently and effectively

By Angela Fernandez, Vice President, Community Engagement, GS1 US

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In the past few years, it has become clear that the supply chains delivering everything from microchips to corn chips all over the world are stressed. Technology upgrades are needed to serve increasingly complex, global markets more efficiently and effectively and to keep up with unpredictable supply and demand, labor shortages, and other disruptions.

In some cases, companies are still moving products around the world with one foot in the past, operating supply chains using incomplete, mismatched data based on closed-loop systems to meet the needs of modern commerce. The vulnerabilities in outdated

systems came to light as the pandemic upended normal operations, contributing to widespread product and material shortages, delivery delays, backorders, and rampant uncertainty.

A lack of supply chain visibility[1] frustrates efforts to ensure food safety or improve organizational efficiency and customer satisfaction. Meeting these challenges today and into the future, in spite of volatility, requires the food industry to digitize, upgrade, and harmonize data systems so that product and supply chain information can be readily accessed and understood by all stakeholders, at all times. Key data points, such as unique product identification and location, need to be standardized and digitally encoded so that they can be automatically captured and shared up and down the supply chain, to help ensure interoperability.

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Momentum for Change

The food industry, like many others, is currently undergoing a massive transformation to address these issues, leveraging digital technology to connect suppliers and retailers across the entire supply chain so that the food supply may be better monitored and managed.

With a digital framework using common data standards, trading partners can successfully collaborate to share accurate, up-to-date information and get a clear view of product status and location along the way, from point of origin to point of sale. This visibility is especially crucial for maintaining food safety throughout the distribution of perishable items, in particular. The data that is collected, updated, and shared throughout products' journeys not only keeps trading partners apprised of status, but it also facilitates faster investigations, recalls, and withdrawals, when necessary, by

making it possible to trace back every step of the way.

Traceability is Key

Improving product traceability is the focus of the U.S. Food and Drug Administration's (FDA's) new Food Traceability Final Rule[2] under section 204 of the Food Safety Modernization Act (FSMA). The Traceability Final Rule requires additional recordkeeping for foods on the FDA's Food Traceability List (FTL)[3] that are designated as "high risk" due to their implication in foodborne illness outbreaks in the U.S. Those "high-risk" food categories include shell eggs, nut butters, leafy greens, finfish, and others. The additional documentation is intended to help improve tracebacks so that the source and scope of outbreaks can be assessed and speedily mitigated. In most instances, the Traceability Final Rule also requires information to be provided to FDA within 24 hours, upon request.

Quickly pinpointing and removing affected product from the supply chain is essential to minimize negative impacts. Zeroing in to find and locate the exact products likely to be affected (by batch/lot number, for example) not only minimizes risk, but also helps reduce waste that would be caused by casting a wider net and removing more product from the supply chain than necessary.

GS1 US recently published a new guideline, "Application of GS1 System of Standards to Support FSMA 204,"[4] explaining how all stakeholders in the food supply chain can leverage GS1 Standards to help address requirements of the Traceability Final Rule. It defines best practices for product and location identification, structured product descriptions, batch/lot codes, and the recording of key data elements (KDEs) for certain critical tracking events (CTEs) in the food supply chain.

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> *Consumer demand for transparency provides the opportunity for brands to find ways to communicate product attributes such as ingredients, production practices, sourcing, sustainability, country of origin, allergens, and more.*

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Common Language of Standards

Many of the food industry's leading companies are promoting the adoption and implementation of GS1 Standards to enable automated information exchange between trading partners, thereby increasing supply chain visibility to facilitate faster and more efficient planning and response to unexpected impacts. At the same time, the ability to share product information across the supply chain is the key to improving traceability for a safer food supply.

GS1 Standards such as Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs) for identification of products and locations, respectively, are critical to this implementation. Many food industry stakeholders have already prioritized the use of these standards to enhance traceability programs and help minimize the need for costly food recalls. Electronic Product Code Information Services (EPCIS), a standard for providing event and transactional data about a product's journey, is becoming important for its ability to not only provide the status of an item (e.g., in transit,

temperature, etc.), but also because it supports FDA's vision for electronically sharing event data like growing, receiving, transforming, creating, and shipping food products.

Combined, these standards provide a foundation for identifying, capturing, and sharing information about products; they can be used to support the recording of CTEs and KDEs, as well as Traceability Final Rule compliance.

Quality Data

This intricate web of continuous data sharing can help supply chains run more smoothly, plus deliver a tremendous load of additional benefits, from improved food safety and product recalls to happier customers, and much more.

However, a messy or incomplete collection of "dirty data"—i.e., improper syntax, duplicates, mismatched item numbers, outdated product identification, etc.—will throw off everything. A fully digitized supply chain tracking system can only deliver benefits when every organization's data is "clean," meaning it is up to date, accurate, and properly formatted for coherent inter-organizational communication. Every trading partner's ability to correctly and consistently identify products, locations, and supply chain events (shipping, receiving, etc.) relies on it.

Therefore, it is important for companies to prepare their data systems and update the master data contained therein. To this end, GS1 Standards can be used for product and location identification to ensure interoperability between organizations. This act of data management is a continuous process. Without accurate, up-to-date, standardized data, a variety of information can be misinterpreted.

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That said, building the quality data and digital infrastructure to enable full traceability takes time and resources. All supply chain partners must coordinate and harmonize their data systems, and smaller organizations that are less technologically advanced or integrated may need extra help. Resources from GS1 US can support these digital transformation efforts.

Transparency

Trading partners need supply chain visibility and transparency to move products effectively and safely; however, transparency is also increasingly important to consumers. This group is seeking different types of information, such as specifics about the products they buy, use, and consume, especially when it comes to food. One survey revealed that nearly three in four consumers (74 percent) said that transparent communication has become more important after the COVID-19 pandemic.[5]

Consumer demand for transparency provides the opportunity for brands to find ways to communicate product attributes such as ingredients, production practices, sourcing, sustainability, country of origin, allergens, and more. Providing digital access to this information and making it easy for consumers to find is the way of the future. As with everything else in today's society, digital technology has irrevocably changed the relationship between brands and buyers.

Providing that instantaneous information access raises new data management issues. Labeling and marketing claims must be considered, of course, but the digital piece may be the heavier lift for some companies, especially those lagging behind in the digital revolution or in data management practices. All companies can benefit from the use of higher-tech data carriers that can accommodate deeper product information, combined with standards to ensure that the information can be readily conveyed and exchanged.

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Advanced Data Carriers

The retail industry has been scanning barcodes for half a century as a means of digitally capturing price and item information at checkout. Today, a more advanced barcode is available that has virtually unlimited data capacity, and it can carry infinitely more information than the traditional, linear (UPC) barcode. This opens a new world of possibilities for brands to provide the transparency that consumers demand. Product information such as ingredients, nutritional information, batch/lot numbers, country or place of origin, and expiration dates can be encoded in a 2D barcode, such as a QR code, that leverages the GS1 Digital Link standard. This standard allows 2D barcodes to be web-enabled, providing connections to many types of business-to-business and business-to-consumer information. This is a game-changer for industry.

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To unlock these benefits and provide true transparency and traceability, the retail industry has committed to becoming capable of implementing and scanning 2D barcodes at point of sale within the next four years, in a GS1 US-led initiative called Sunrise 2027.[6]

Additionally, radio-frequency identification (RFID) has come a long way in the past several years, to the point where it is now considered a viable option for tracking food products throughout the supply chain. The technology has advanced to enable longer read ranges and better accuracy than earlier iterations. Reader infrastructure has expanded, and the tags themselves are now available in a range of sizes and sensitivities, as well. At the same time, costs for tags have been decreasing, and global usage is projected to reach $18.45 billion USD in 2023.[7]

An RFID tag can be used in the same way as a barcode to carry unique product identification and serialized data. Automation enabled by RFID not only offers inventory

visibility, but also supports critical supply chain processes including withdrawals, product safety holds, return logistics, and more.

A new guideline developed by the GS1 US foodservice workgroup has been published to help clarify how suppliers should encode GS1 Standards in RAIN RFID tags and to provide a roadmap for adoption. The new "GS1 US RFID Foodservice Implementation Guideline"[8] provides case/carton requirements for foodservice suppliers to minimize disparate supplier tagging requirements. For food products and consumer-facing food packaging, the guideline specifies tag encoding, tag marking, and tag placement. It is designed to guide companies with implementing open, interoperable GS1 Standards to enable more efficient tracking, management, and traceability of products throughout the supply chain. Information is provided to help distributors learn how to integrate RFID technology within their systems to ensure compliance with new standards, and end users can benefit from understanding the available data and the access provided by this enhanced method of data capture.

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Deadlines on the Horizon

Opportunities to deliver the next level of consumer engagement, improve backend operations, and ultimately help curb foodborne illness are here, now. With the looming Traceability Final Rule compliance deadline in January 2026 and Sunrise 2027 less than four years away, there is no better time to up your traceability and supply chain visibility game.

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Angela Fernandez *is the Vice President of Community Engagement at GS1 US, where she is responsible for driving broader adoption of GS1 Standards to help industry achieve their goals for improved product traceability, product information transparency, and data quality. Since joining GS1 US more than 15 years ago, Angela has collaborated with a diverse range of industry stakeholders to identify how the use of GS1 Standards can improve supply chain business processes and e-commerce operations, as well as address regulatory requirements to deliver safe products to patients and consumers. Angela is a frequent guest speaker at industry events, including the Council of Supply Chain Management Professionals (CSCMP) Edge and the National Restaurant Association Show. Angela holds a B.S. degree in Business Administration from Drexel University.*

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The Road to FSMA 204 Readiness

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The Road to FSMA 204 Readiness

Trustwell's integrated approach to food safety and traceability helps food businesses achieve FSMA 204 compliance

By *Trustwell*

bluecinema/E+ via Getty Images

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In the dynamic landscape of the food supply chain, regulatory compliance is not just a legal necessity; it is a cornerstone of consumer trust and brand integrity. The *Food Safety Modernization Act* (FSMA) Rule 204, known as the Food Traceability Final Rule, marks a significant step forward in ensuring transparency and safety in the food industry. For businesses grappling with the complexities of FSMA 204, Trustwell emerges as a guiding force, offering unmatched expertise and solutions for the food supply chain.

FSMA 204: What Is It?

In summary, the Food Traceability Rule mandates that businesses involved in manufacturing, processing, packing, or holding foods on the Food Traceability List (FTL) maintain records with key data elements (KDEs) for specific supply chain activities, which the U.S. Food and Drug Administration (FDA) has defined as critical tracking events (CTEs). This information must be captured, stored, and maintained for 24 months, and event data must be made available to FDA within 24 hours, upon request. Additionally, lot-level shipping event data must be shared with supply chain partners.

The Traceability Rule also requires that businesses establish and maintain a traceability plan that outlines procedures for record maintenance under the new requirements, identifies FTL foods handled, and assigns traceability lot codes to FTL foods.

Key Components of Planning and Implementation

With the January 20, 2026, compliance deadline now less than two years away, it is crucial for companies and professionals in the food industry to start preparing accordingly. This includes having the necessary procedures and protocols documented,

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employee and supplier training programs developed, and the proper tools and software systems implemented. As businesses think about their FSMA 204 journey, it is important to consider the following elements.

Strategic Planning. The cornerstone of successful FSMA 204 implementation is comprehensive planning. This encompasses all aspects of traceability and recordkeeping. Key activities in the planning phase include:

- **Responsibility Identification:** Assigning accountable individuals or teams is crucial for oversight and execution of FSMA 204-related tasks. materials, processing, packaging, and storage.
- **Traceability Plan Formulation:** Businesses must craft a traceability plan that complies with FSMA 204, detailing recordkeeping, identification methods for FTL items, assignment of traceability lot codes (TLCs), contacts for plan inquiries, and, where applicable, farm maps for producers of listed foods.
- **TLC Creation:** The introduction of a unique TLC, integrating a Global Trade Item Number (GTIN) with the product lot code, is the industry's recommendation to achieve distinct traceability within a firm's records.
- **Solution Provider Partnership:** Choosing a solution provider that offers tech-enabled traceability solutions is about forming a partnership that aligns with the organization's strategic compliance needs.

*Implementation.*Collaborating with solution providers to put the traceability plan into action is a key step. Key activities in the implementation phase include:

- **Enhanced Training:** Developing and executing a continuous training program is imperative to ensure that all supply chain participants comprehend their roles and responsibilities within the FSMA 204 framework.

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- **Data Capture:** Companies need to ensure the capability to capture and store the required KDEs for the traceability events they manage. Additionally, companies must be able to receive traceability data from their suppliers. When it comes to shipping products, coordination with trading partners is crucial to understanding their system capabilities, enabling the seamless sharing of shipping CTEs.
- **Documentation Updates:** Revising related food safety plans and protocols (e.g., supplier approval programs, recall plans, training protocols, etc.) is necessary to integrate the new traceability elements.
- **Compliance Testing:** Conducting mock recalls and traceability exercises is essential to validate the functionality of the FSMA 204 program and readiness of the team.

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Leveraging Technology for Compliance and Beyond

While software is not a requirement for the implementation of FSMA 204, adopting tech-enabled traceability solutions can streamline compliance with FSMA 204's rigorous tracking and reporting requirements. When evaluating traceability solution providers, stakeholders should consider the following:

- **End-to-End Traceability:** It should provide complete traceability from the point of origin (like farms or fisheries) to the end consumers. This includes tracking the production, processing, packaging, and distribution phases. Although this is not required for FSMA 204, many companies are implementing beyond the basic requirements to meet their brand promise for a transparent supply chain.

- **Data Integration and Sharing:** Adopt platforms that facilitate seamless data integration and sharing across different stakeholders in the supply chain. This ensures that all parties, from suppliers and distributors to grocers and foodservice operators, are able to capture, store, and share FSMA 204-compliant traceability data, promoting transparency and accountability.
- **Mobile Compatibility:** Mobile compatibility allows for tracking and managing the supply chain with a native app or integration into your existing mobile tools, enhancing flexibility and responsiveness.
- **Customization and Flexibility:** The software should be customizable to fit the specific needs and workflows of different businesses.
- **Robust Reporting and Analytics:** The ability to generate comprehensive reports and analytics is vital for insights into supply chain operations, identifying trends and anomalies, and making informed decisions.
- **Scalability:** The software should be scalable to accommodate business growth and changes in supply chain operations.
- **Mock Recalls:** It should have features that allow for simulated recall exercises to test the traceability system, showing your traceability plan in action.

Leveraging such technologies can help businesses not only comply with FSMA 204, but also improve overall supply chain efficiency and food safety.

Trustwell's Role in FSMA 204 Compliance

Trustwell, leveraging its deep-rooted knowledge and innovative tools like FoodLogiQ Traceability, offers an integrated approach to comply with FSMA 204's new traceability

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recordkeeping requirements. Trustwell's heritage in the pilots and development of FSMA 204, through to the enhanced traceability functionality in the FoodLogiQ platform, underscores its expertise in traceability and food safety compliance.

In collaboration with FDA and GS1 US, Trustwell participated in pilot programs employing the FoodLogiQ software to demonstrate the practical application of traceability standards. These programs have helped shape regulatory expectations and provided Trustwell with unique insights into the operationalization of FSMA 204 compliance measures.

Educational Resources, Tailored Consulting, Trusted Partnership

Understanding FSMA 204 is crucial for effective compliance. Trustwell offers comprehensive educational resources, including detailed analysis and guidelines on the Food Traceability Final Rule, accessible through its website. These resources demystify the requirements of FSMA 204, making it easier for businesses to align their operations with the new regulations.

"Our mission at Trustwell is to empower businesses to not just meet, but exceed FSMA 204 requirements," states Julie McGill, Vice President of Supply Chain Strategies and Insights at Trustwell. "We provide the tools and expertise needed to build a robust traceability plan that enhances food safety and quality across the supply chain."

In addition, Trustwell's FSMA 204 consulting services provide personalized support. From FSMA 204 education and supply chain assessments to the implementation of traceability systems, Trustwell's experts work closely with businesses to develop and refine strategies that meet the unique needs of each entity in the fresh food supply chain.

Ready to Take the Next Step?

For businesses eager to embrace FSMA 204 and enhance their traceability capabilities, Trustwell invites you to arrange a discovery call. This initial conversation is a step toward personalized support, ensuring that your business not only meets, but thrives under the new regulatory landscape.

To learn more about Trustwell's FSMA 204 consulting services or to arrange a discovery call, visit Trustwell's FSMA 204 Consulting Page.

For a deeper understanding of FSMA 204 and how Trustwell can guide your compliance journey, explore Trustwell's FSMA 204 Resources.

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Trustwell

Tackle FSMA 204 Compliance With Confidence

Using FoodLogiQ Traceability by Trustwell

Why Trustwell for Traceability?

Our team of regulatory experts and professionals helped shape traceability policy at the national level, participating in FDA pilots that led to FSMA 204. We used that knowledge and expertise to enhance our FoodLogiQ Traceability software, where you can monitor, share, and capture critical event data at the batch-lot level, visualizing your entire supply chain.

Visualize at the Batch-Lot Level

Capture and Share CTE Data

Improve Recall Readiness

www.trustwell.com

VISIT OUR WEBSITE TO GET STARTED

How the Food Traceability Rule will Impact Food Processors

What are food processors doing to prepare for compliance with the FDA Food Traceability Rule in 2026, and how do they see it affecting their businesses?

By Bob Ferguson, President, Strategic Consulting Inc.

SDI Productions/E+ via Getty Images

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In November 2022, the U.S. Food and Drug Administration (FDA) published its Final Food Traceability Rule, *Requirements for Additional Traceability Records for Certain Foods*,[1] as mandated by Congress under FSMA Section 204.

As stated in the rulemaking announcement released by FDA, the Traceability Rule requires companies that manufacture, process, pack, or hold foods listed on the Food Traceability List (FTL) to maintain detailed records on their supply chain and suppliers, including "Key Data Elements" (KDEs) about how those supplies are handled and processed. The Traceability Rule regulates processors of foods on the FTL, which include fresh-cut fruits and vegetables, shell eggs, nut butters, ready-to-eat deli salads, cheeses, and seafood products. The Traceability Rule applies to foods on the FTL, but a further stated aim of the rule is to encourage the voluntary adoption of these tracing records for all food products.

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It is easy to see that the Traceability Rule will have a wide-reaching impact on those food companies that produce foods listed on the FTL. However, the Rule will also have a significant impact on many other companies, regardless of whether they produce foods on the FTL, due to supply chain conformity or the imposition of commercial requirements from their customers.

For this issue's column, we wanted to find out more about food processors' thoughts on the Food Traceability Rule, the impact it will have on their businesses, and what they are doing to prepare for current expectations and for eventual full compliance with the Traceability Rule by the three-year deadline.

To find out the answers to these questions, we conducted a survey and interviews with approximately 100 companies within the U.S., Canada, and 13 other countries across eight major processing categories. Of the companies that were part of our investigation, roughly two thirds—73 percent in North America and 67 percent international—said

that they are FDA-regulated facilities (Figure 1). Of those in North America, 88 percent said they are aware of the changes proposed by the Rule (Figure 2). We found a lower level of awareness among international companies, with fewer than 50 percent saying they are familiar with the requirements, at the time of the survey.

Figure 1. Are You an FDA-Regulated Facility?

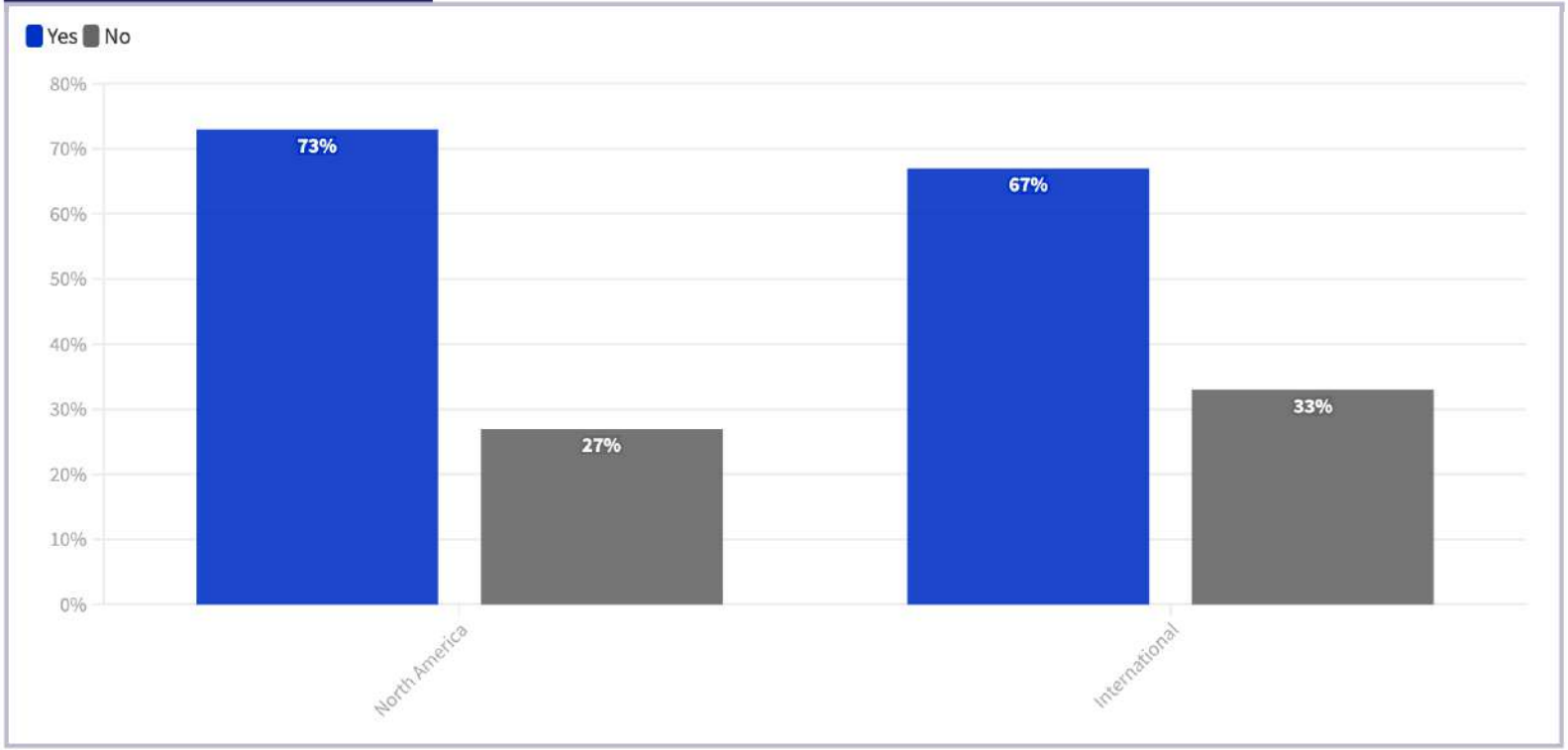

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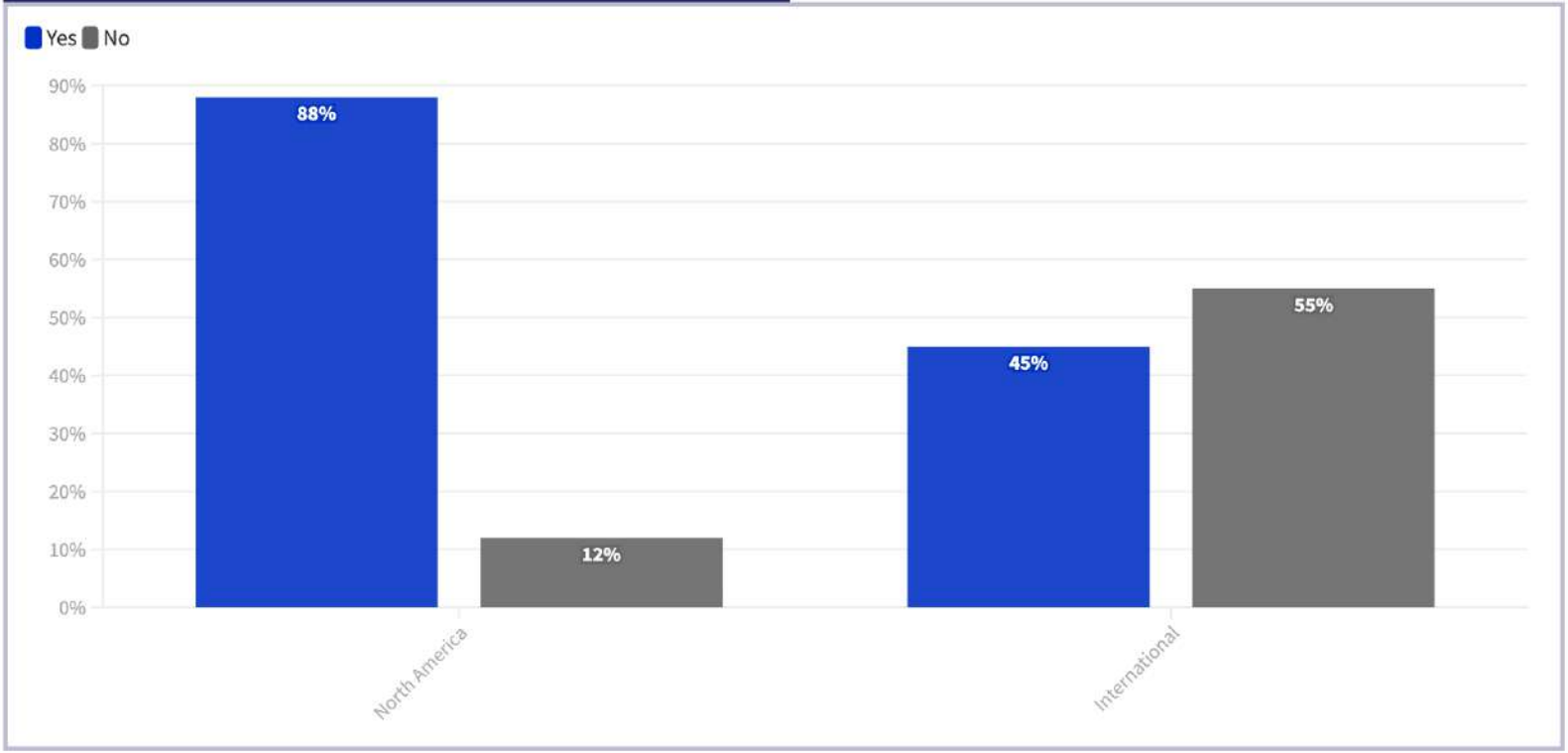
Figure 2. Are You Aware of the Changes Proposed by the FDA Food Traceability Rule?



Roughly one third of all facilities (Figure 3) said they produce products on the FTL (although this may be underreported, as about the same percentage said they did not know), and 57 percent said they thought the Traceability Rule would eventually apply to other foods not listed on the FTL.

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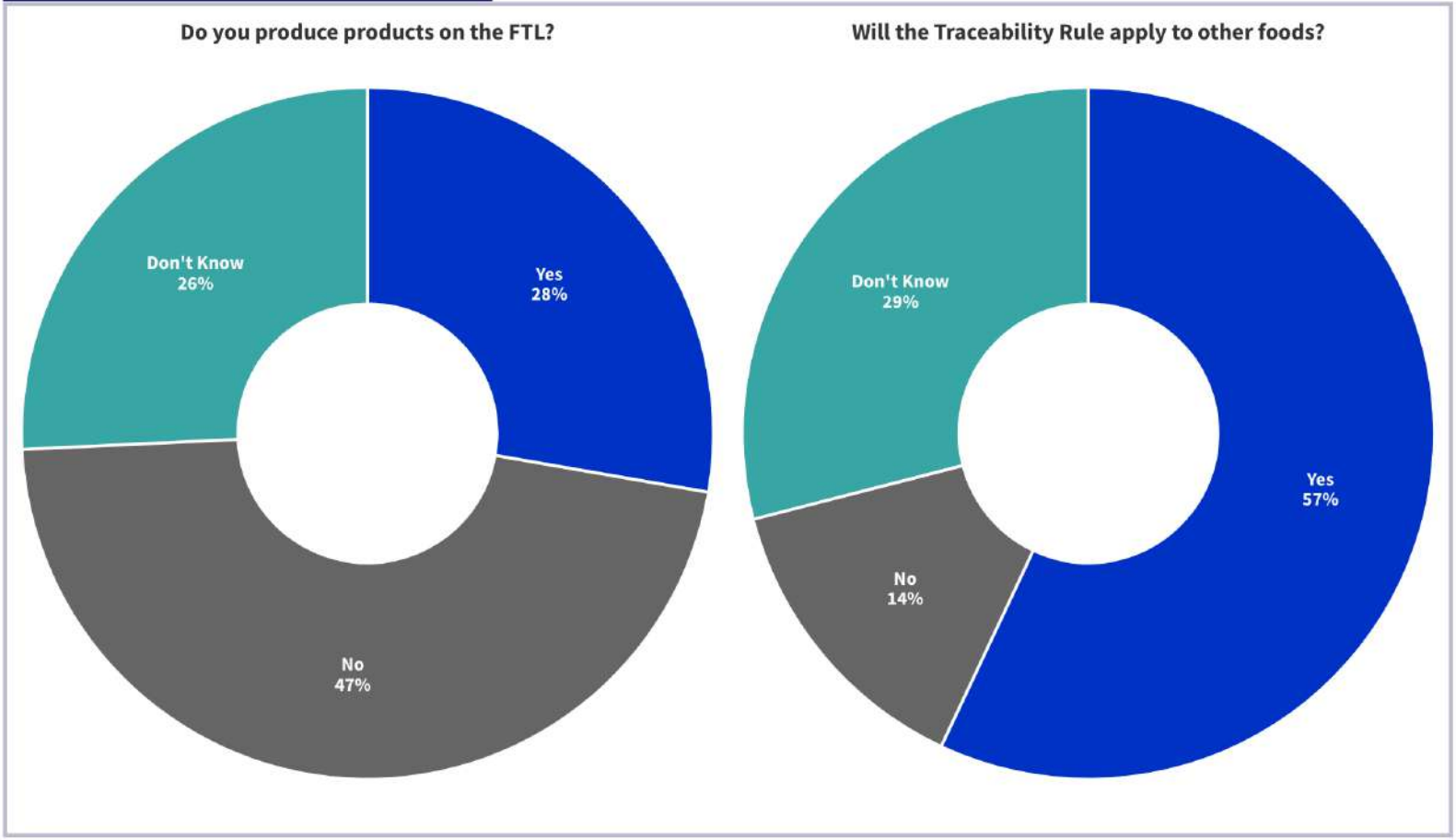
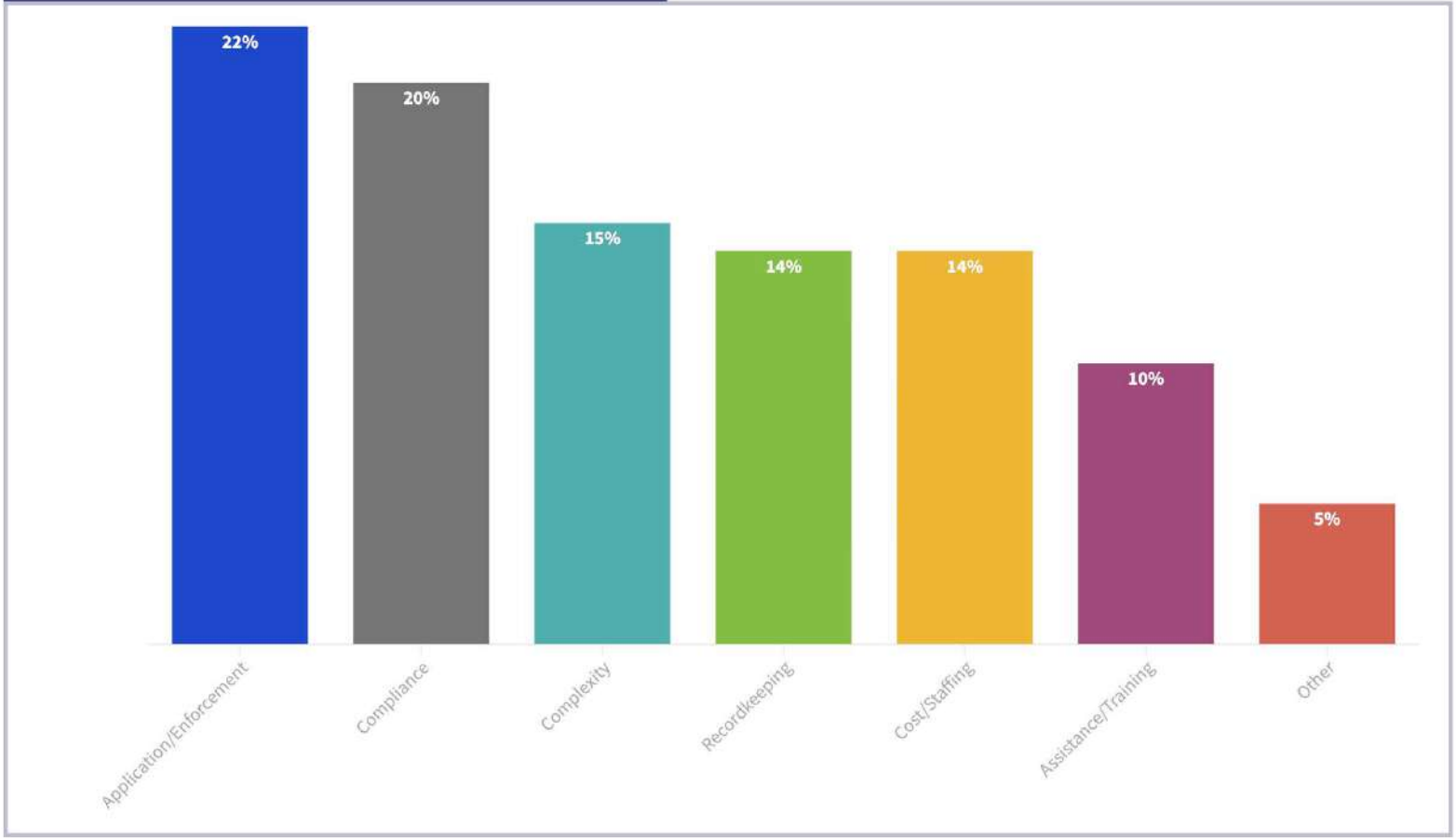
Figure 3. Does the Food Traceability Rule Apply to You?



We also wanted to find out processors' top concerns about the Traceability Rule and the responsibilities it will impose for compliance (Figure 4). Of those companies indicating that they are familiar with the rule, their top concerns are around application and enforcement. The comments in this category mainly concerned which foods fall under the Traceability Rule and how FDA will approach enforcement for products that appear to be covered under the FTL but are not precisely defined in the text of the Rule.

Figure 4. What are Your Top Concerns about the FDA Food Traceability Rule?



As stated earlier, the Traceability Rule covers a number of high-risk foods listed on the FTL. These foods can be ingredients or final products, and can exist in the supply and processing chain in a number of forms. Many survey respondents questioned which foods are specifically addressed by the Rule and what happens when a food or ingredient is potentially covered in one form but may be changed during processing to a form that is potentially not covered. Are these foods still "high-risk," according to the spirit of the Rule, in the way that these processors are using them? How will FDA define

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these products when they are used in another way, other than the exact form as described in the Rule?

One processor commented, "We are unsure when the foods are sufficiently changed to no longer match what is described on the FTL and at what point are foods not considered 'fresh.'" Another added color to the topic by mentioning, "In our processes, we often use both whole and diced tomatoes and sometimes switch between both in a single production batch. The Rule doesn't take into account that during the manufacturing process, the whole tomatoes break down and become indistinguishable from diced tomatoes, essentially making the ingredient description irrelevant."

Another processor questioned the applicability of the Traceability Rule to its specific operation. The Rule defines applicability to include "...companies that manufacture, process, pack, or hold foods listed on the FTL..." This respondent said, "We are a nonprofit food bank distribution center. Does this Rule apply to us?" Another asked, "We are a distribution center only, and we do not change or process the food while in our possession. How does this Rule apply to us?"

The Rule also makes provisions for facilities to apply for an exemption. Several companies, especially distributors in a similar situation to the one referenced above, asked, "What will be the process to prove and maintain an exemption if one is allowed?" These types of questions about the applicability of the Traceability Rule run hand-in-hand with those directly related to enforcement in terms of who is required to do what, the type and intensity of enforcement to be expected, and how companies should prepare before the 2026 compliance dates.

Another theme that emerged from the enforcement questions was asking for help from FDA. Companies are eager for help in getting suppliers to understand and comply with the requirements of the Rule so that processors, especially smaller ones, are not put in

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the position of being responsible for educating several layers of their supply chain in compliance requirements of the Rule, or face penalties. If FDA implements strict levels of enforcement for suppliers and producers of end products, then end-product producers can be more confident that getting the data they need from their supply chain will be easier and the responsibility for education, awareness, and enforcement of the Rule will not fall on their shoulders. As such, many companies are looking for a high degree of outreach and education from FDA for everyone in the supply chain, so that all are aware of the Traceability Rule and understand its requirements.

The second most-cited concern has to do with compliance requirements. This series of comments can be simplified to, "What, specifically, needs to be done in my situation, and how do we get it done?" Many mentioned that without further clarity of all the steps required, it will be difficult to perform a gap analysis between current practices and Traceability Rule compliance. One processor wants to know, "Are our current practices not sufficient enough to match some of the KDEs being maintained?" Another asked, "What requirements for our suppliers are different from the requirements for our third-party auditors?"

The main topics within processors' remaining major concerns can be characterized as elements of the execution of their eventual plan, concerns about the complexity of the programs and recordkeeping needed, and important considerations on additional staffing and costs required to comply with the Traceability Rule.

Only 5 percent of processors said they had "no concerns" about the Rule.

As anxiety-producing as these questions and concerns may sound, 87 percent of companies said that a three-year compliance timeframe was reasonable (Figure 5), with only 11 percent indicating "maybe or not sure" on the timeframe. Of the 87 percent who agreed, many said that they believed they had many of the necessary pieces already in

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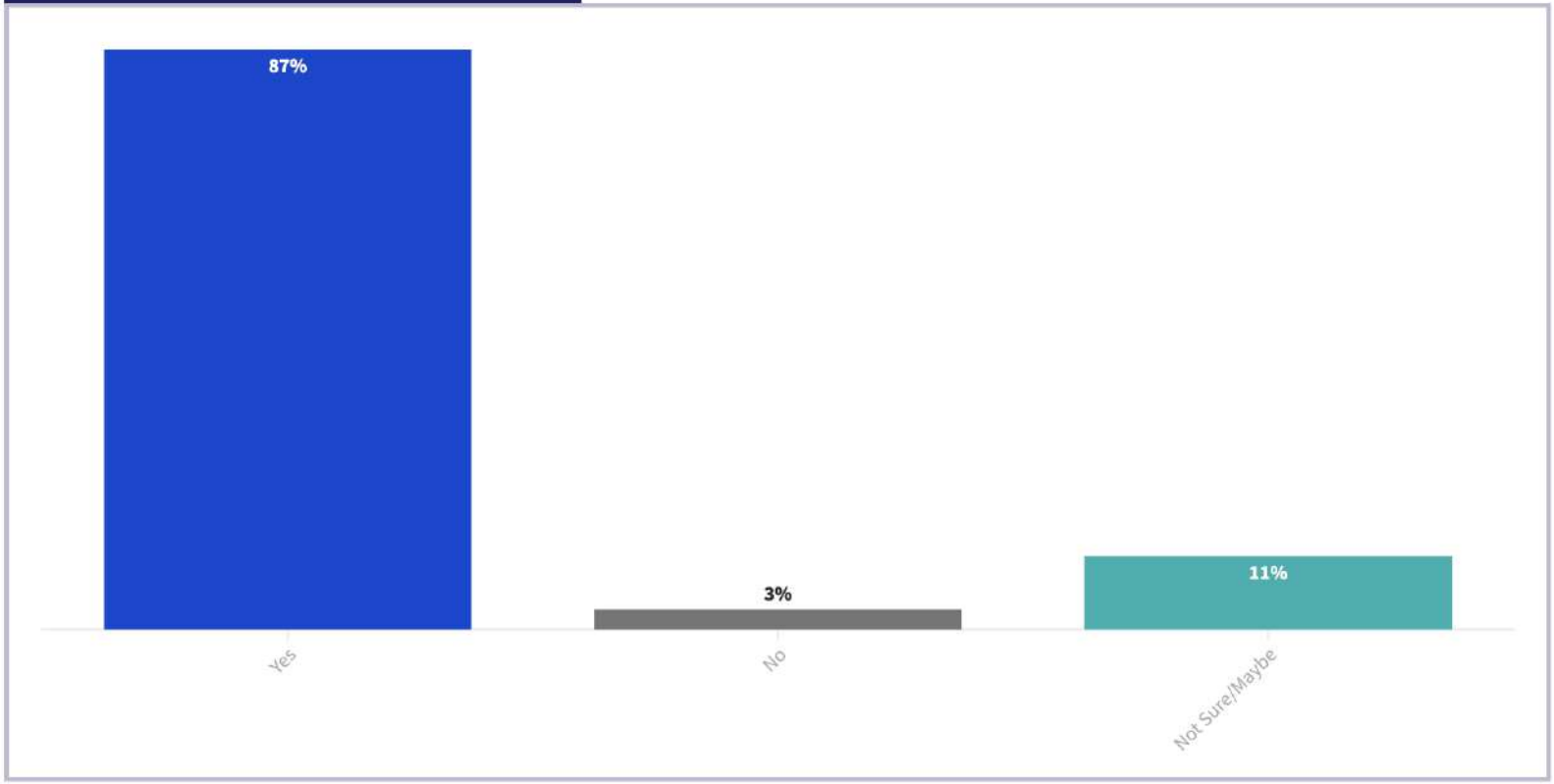
place. One vegetable processor mentioned, "Three years is reasonable... most growers have already implemented the Rule." An infant formula producer said, "Yes, I believe we are already compliant; if anything, it will require minor changes."

Figure 5. Is the Three-Year Compliance Timeline Reasonable?



Others seemed to be comfortable with the three-year timeline, but added caveats to their answers. "It depends on the technology that is needed to assist in this process," said a quality assurance/control manager at a ready-to-eat meal producer, while a quality assurance/control manager at a dietary supplement manufacturer opined, "Three years is typically enough time to update a procedure."

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A food safety specialist at a fruit and vegetable processor was less convinced that the three-year compliance deadline was reasonable, saying that FDA will have a big role to play in the achievement of this deadline. "I'm not sure," he said. "The FDA has not been clear about what is included in the final rule. They need to 'educate before they regulate.' FDA should hold educational sessions that clearly lay out the expectations of the law."

Many of the comments and questions we received around the Traceability Rule were largely along the lines of, "Exactly what does this mean for us, and what will we have to do to comply?" Due to the uncertainty of what exactly is required, we also heard many comments related to what help might be available for processors to better understand the requirements, as well as FDA's expectations and how we can hear those answers directly from the FDA. Processors want to know, "What is the impact on my company and my operations?"

Anticipating these comments, we also asked in our survey, "What do you wish the FDA understood about the impact of the Food Traceability Rule?" (Figure 6).

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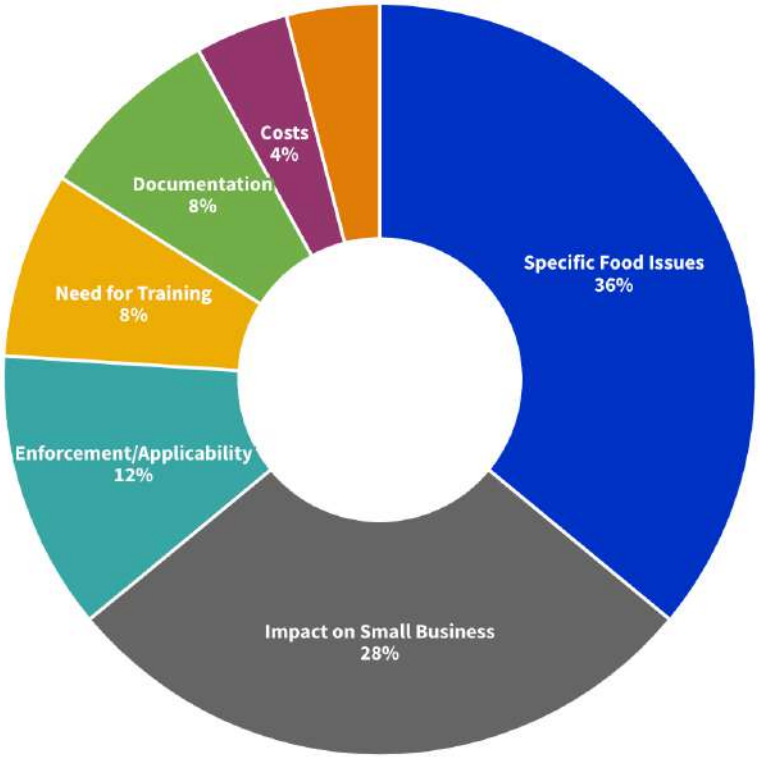
Figure 6. What Do You Wish FDA Better Understood about the Impact of the Final Food Traceability Rule?



In the direct answer to our question, roughly one-third of respondents mentioned that they had specific food processing issues that would arise or be impacted by the Rule (Figure 6). Twenty-eight percent said the agency needed to consider the impact of the Rule on small businesses, and the remaining one-third had questions for FDA about the agency's enforcement position, the training that may be needed, what resources and training assistance will be available from the agency, how the documentation requirements will work, and similar issues.

As to the first issue of specific food processing segments impacted, a food safety specialist at a fresh produce packager mentioned, "Most fresh produce products fall

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under the FTL, yet FDA does not have a solid grasp on how fresh produce is traced. In the proposed Rule, they seemed to be looking for case-level traceability, which is not doable."

Another packaging company director of quality mentioned the complexities when dealing with multiple suppliers in a production process. He said, "Supply chain availability can sometimes require a manufacturer to pivot to a different supplier. Subtle differences, like diced tomatoes versus whole tomatoes, often prevent us from being able to do so because the ingredient deck of the finished product must specify the tomato's form. Oftentimes, whole and diced are both used, and so both must be listed accordingly. It doesn't consider that during the manufacturing process, the whole tomatoes break down and become indistinguishable from the diced, essentially making the ingredient description irrelevant, not to mention misleading. Allowing for 'tomatoes' to be listed without identifying the form would allow more flexibility and keep production lines moving. Downtime often comes when we are waiting on ingredients."

Another quality assurance/quality control manager in a processed food facility echoed this complexity, saying, "Mixed production facilities such as ours use the same products across multiple streams in large quantities and need to have several suppliers for some production runs."

The impact on small businesses is another area where processors wish FDA had a better understanding. Many people indicated this concern with a concise, "We wish they understood the impact this will have on small businesses; we are already struggling to comply with existing requirements."

A key element of the Rule is for processors to have the ability to produce lot traceability records within 24 hours of a request for those records from FDA. Survey responses on readiness to comply with this element may be an indication of processors' confidence in

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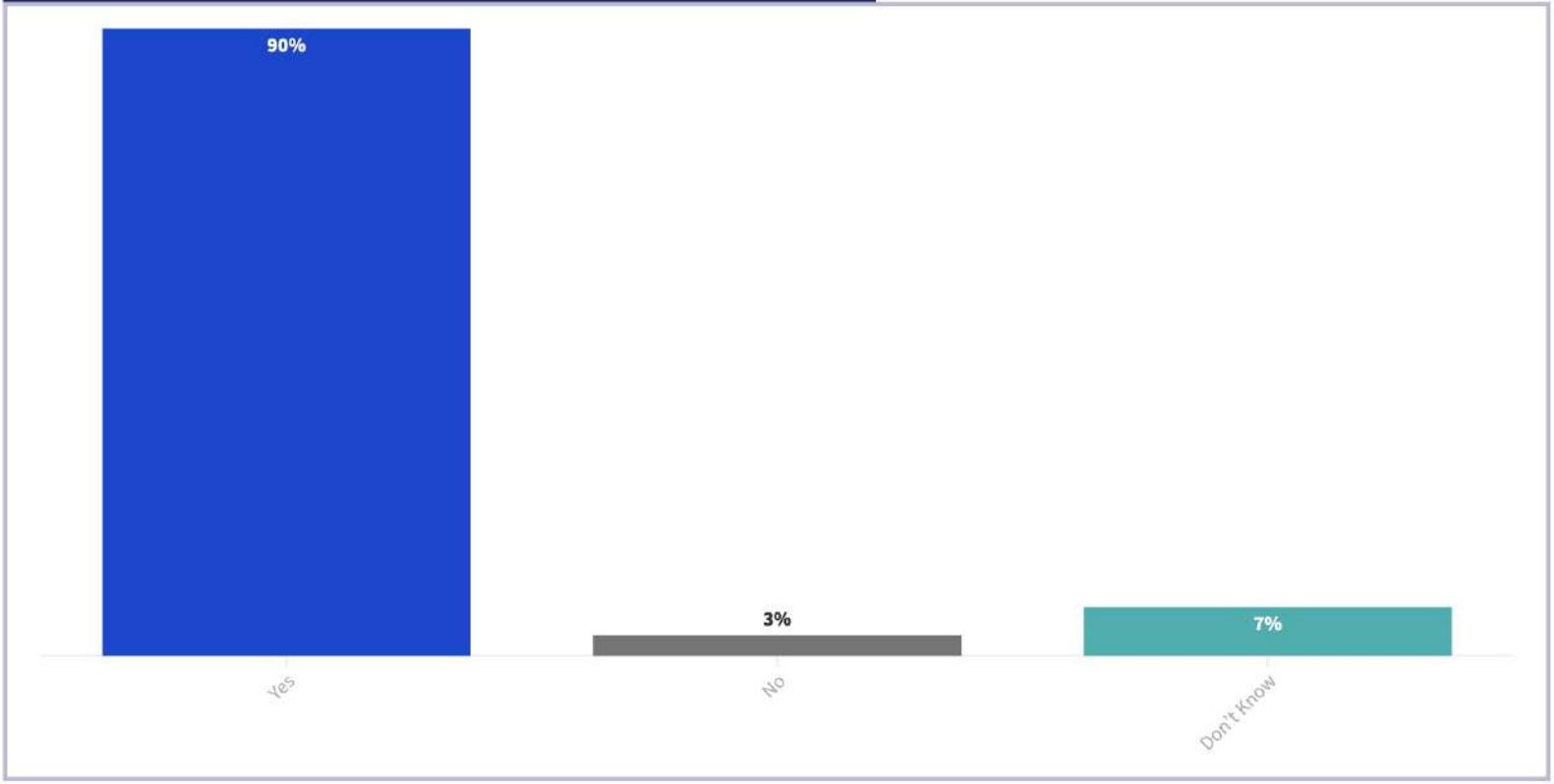
their current abilities, with 90 percent of survey respondents saying they have that capability now (Figure 7).

Figure 7. If requested, Can you Produce Supply and Product Traceability Data Within 24 Hours?

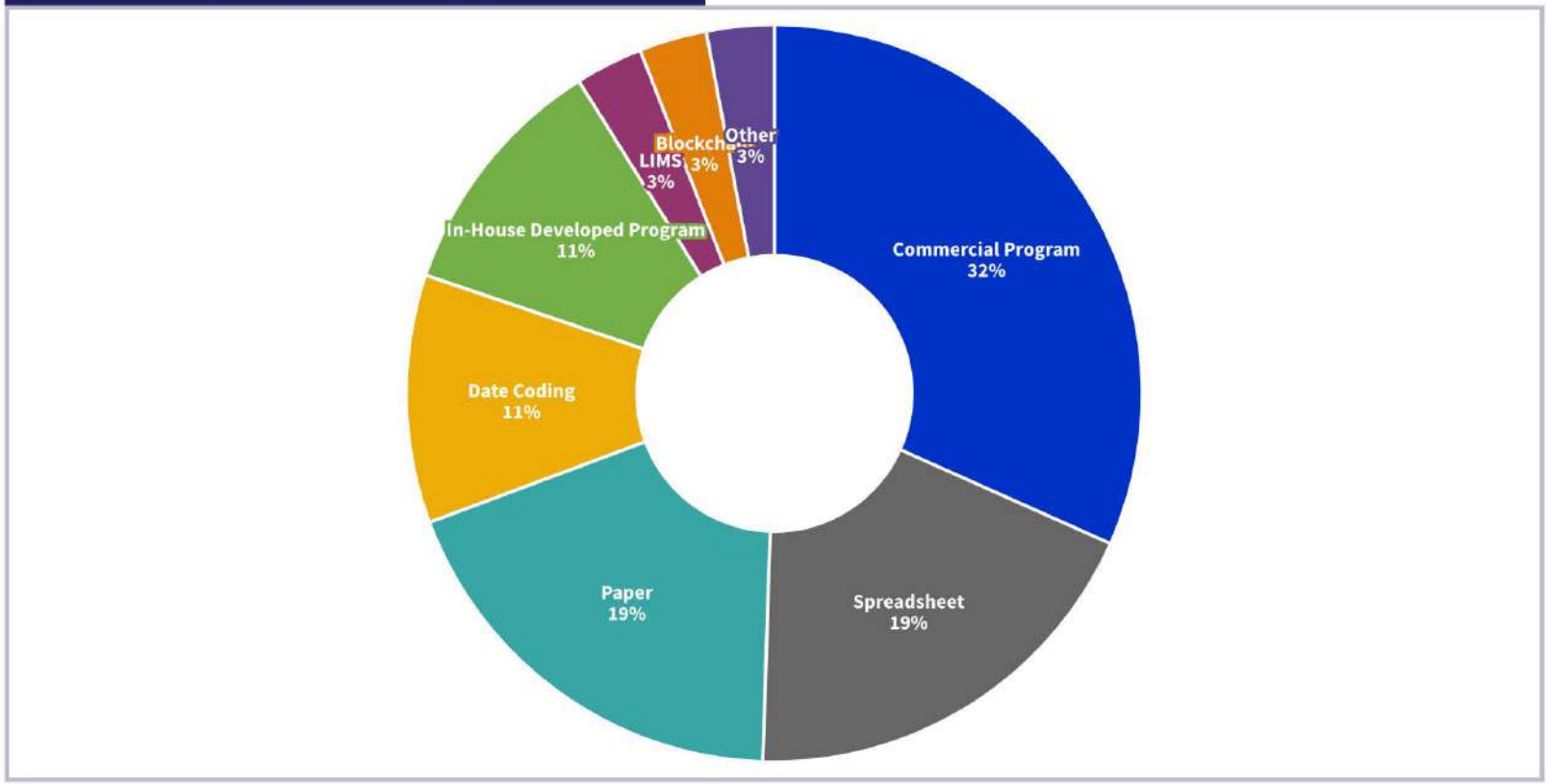


One dairy quality assurance/quality control manager added, "I imagine, for some companies, meeting the new requirements in three years could be difficult to achieve. Some small companies might have trouble [affording the] software that would make traceability more efficient..." Another comment, also from a dairy specialist, reinforced this idea: "It will be difficult for smaller companies to produce required documentation."

So, what are companies using to gain this capability? We asked that too, of course!

Roughly one-third said they were using a commercial software program or an off-the-shelf module for their current enterprise resource planning (ERP) system (Figure 8). The next two responses saw 19 percent reporting that they were using spreadsheets, and 19 percent saying they had their records on paper. Together, these two categories of relatively "manual" recordkeeping accounted for the largest subset of systems reported being used.

Figure 8. What Supply Chain Tracking/Traceability System Do You Use Now?



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One quality assurance/quality control manager of a dietary supplement contract manufacturer said that they would have no trouble tracking their raw materials and ingredients to their origin with their existing systems and programs. "We looked at existing systems and programs, and we found that each had gaps in what we needed. So, we worked with an independent design company, and we built our own system to meet our needs." Once that system is ready, he indicated that tracking their products back to the source would be possible even within the 24-hour time target set by the Rule. "We even purchase certain ingredients from domestic brokers, but we get all of the tracking data from them on the origin of the products." The main issue to overcome in their situation arises when they sell it to their customer—the brand owner. "The data on the distribution from our customer to the store and then to the end customer is not available to us," the manager noted.

Another director of quality assurance at a contract manufacturer mentioned that all of their current records are still on paper. "We have looked at a number of the commercially available options, and we think one of those—especially those that are a 'bolt-on' to our current ERP system—may work well for us." The issue he mentioned that is holding them up from fully implementing the new module is its cost. "Our issue is the not only the outright cost of the software and installation itself, but those costs combined with the continuing high costs we are facing in other areas—such as supply chain shortages and the high prices we are continuing to pay for logistics—makes it difficult to take on anything else. We keep waiting for our supply and logistics costs to return to normal, but it seems that once these costs went up during the supply chain crisis, there has been no incentive to reduce costs since, and that takes resources from other projects."

Other companies that have already implemented traceability systems and new software programs commented about the lack of standardization of the software packages and

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the form of reports expected by FDA. Although the specific requirements of the Final Food Traceability Rule are not yet in force, several said that they have had issues with explaining what their systems collected in terms of supply chain data and how some inspectors had trouble accepting the format of the reports they produced. This lack of standardization may make communication and meeting expectations of the Rule more difficult during an inspection.

These are just a few examples of what companies are doing to prepare for compliance. This still leaves open the question of "Am I covered by the Rule, and *do* I have to comply?" Recall that about one-third were not sure if the Rule applied to them. Furthermore, more than one-half expected that the Rule will ultimately apply to foods other than those on the FTL, expanding the applicability of the Rule and potentially impacting more processors than expected.

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As part of its outreach and education on the requirements of the Rule, FDA has released a decision-tree tool on its Food Traceability Website that allows companies to go through a series of questions to determine if they are entitled to an exemption to the Rule. Using what I learned in my interviews, I decided to try out this program. Now, certainly a caveat is in order. I took the information I was given in the interviews and applied that to the decision tool. I understand that what I learned in a 30-minute interview does not make me well versed with the particulars of any processor's or distributor's operations. In many cases, I had to estimate the correct input for the tool. These examples should be viewed as an illustration of the use of the decision tool and not as a definitive answer for anyone's particular situation. Nonetheless, this exercise was an interesting experience.

In the case of the processor mentioned earlier that works with both whole and diced tomatoes, they reported that they used a validated thermal process to treat the incoming product. Assuming that their validated process meets the Rule's requirement

to comply with 21 CFR 112.2(b) to reduce the presence of microorganisms, and that process is used on all of their products, the FDA decision-tree tool seems to suggest that they should qualify for an exemption because of this kill step. This does not solve their labeling issue, but it may offer the possibility of a simpler option for compliance with the Rule.

Recall that we also discussed the case of a nonprofit food bank distributor. In describing their operation, they said, "We are a nonprofit food bank distribution center... and we do not change or process the food while in our possession."

In running this case through the decision tool, it takes about five steps to arrive at the answer that this nonprofit distributor may not qualify for an exemption if they distribute any products on the FTL. Since they "take physical possession" of the food and it is for distribution and not "personal consumption," the decision tool reports that they are *not* qualified for an exemption under "personal consumption, holding food for specific consumers." On the other hand, the distributor may be eligible for an exemption if all of the foods that they distribute are "rarely consumed raw," as defined in the Rule. This illustrates another of the complications of determining whether an entity qualifies for an exemption—there may be multiple paths to explore.

This exercise was used only as an illustration of how many questions may arise in determining which companies are subject to the Rule and much will depend on their specific situations. It does, however, illustrate that you will need to do your homework on your own, using all of the details of your specific operation to find out what you will be required to do to comply.

It is probably a good thing that we have several years.

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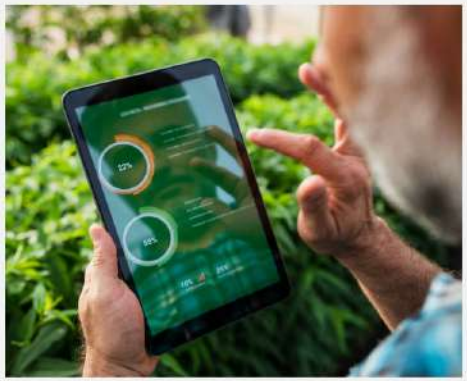

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Digital Transformation of Supply Chains to Meet Foreign Supplier Verification Program Requirements

A move toward digitalizing supply chains may offer solutions to some of the challenges of FSVP compliance management

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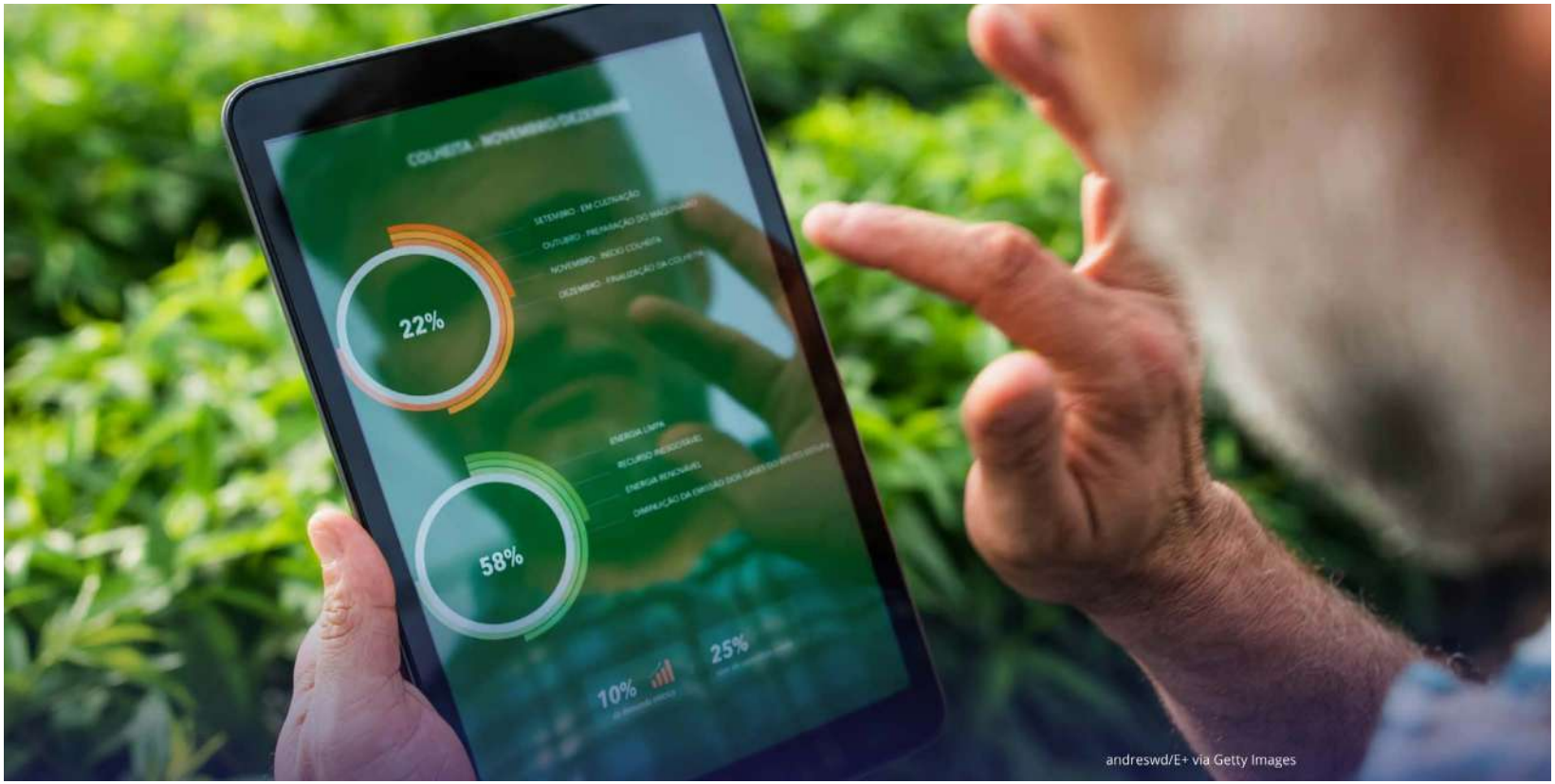

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"Food safety in supply chains is of utmost importance. As the food product changes hands from raw material to finished product, it goes through several touchpoints, including production, transportation,[1] storage, and packaging, increasing the risk of contamination and fraudulent activities. The more complex the supply chain, the higher the probability of such risks. Without accountability and transparency among different stakeholders, including the tier 1 and tier 2 suppliers, it becomes challenging to avoid or respond to food safety incidents. The risk has increased significantly with greater offshoring to different markets, including developed and emerging markets.

Accordingly, to enable higher accountability and traceability in the food supply chain, the U.S. Food and Drug Administration (FDA) enacted the Foreign Supplier Verification Program (FSVP)[2] via the Food Safety Modernization Act (FSMA) in 2016. Through the FSVP requirements, food importers are now liable for their foreign-based suppliers. According to FDA, they must ensure that the "...foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventive controls or produce safety regulations." Importers are now responsible for hazard assessments, risk evaluation, supplier audits, supplier performance assessments, and the development of written procedures, along with extensive recordkeeping.

Accordingly, how do U.S.-based firms deal with such increased responsibilities? Also, how do they enable themselves to reduce adverse consequences for themselves, public health, and the general economy? As per the blueprint of FDA's New Era for Smarter Food Safety initiative,[3] one of the core principles of modern-day food safety will be "technology enabled." According to FDA, "The world is rapidly becoming more digital. Advances in artificial intelligence, the Internet of Things, sensor technologies, and blockchain are improving business processes. New digital technologies offer the potential to help us predict and prevent food safety problems and better detect and respond to problems when they do occur." Accordingly, through this article, we assess how the move toward digitalizing supply chains may help food firms achieve FSVP compliance.

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What are Digital Supply Chains?

Digital supply chains utilize digital technologies and data analytics to shape the decision-making process, enhance performance, and promptly respond to rapidly changing conditions.[4] Digital technologies offer an array of tools to modernize supply chain operations, revolutionizing the way companies have been managing their supply

chains traditionally. It not only provides an opportunity to update existing supply chain networks, but it also forms basic building blocks for future technologies. Recent estimates suggest that the digital supply chain market is expected to reach $13.7 billion USD by 2030 from a $3.9-billion-USD valuation in 2020.[5]

It is high time that companies committed to operational excellence in supply chain execution should move toward a long-term and short-term digital strategy. With ongoing uncertainties caused by the recent U.S.-China trade war, the Russo-Ukrainian war, the COVID-19 pandemic, and other events, spending on digital supply chain technologies could pay off in building a resilient supply chain network.

While many industries have embraced the digital supply chain and reaped its benefits, the food industry, unfortunately, has lagged in leveraging these technologies. This has been due to several factors, outlined below.

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Complexity of Regulations

According to one estimate, it takes more than 200,000 regulatory restrictions from farm to fork to produce one ounce of beef in the U.S. (as of 2021), compared to fewer than 50,000 restrictions in 1970.[6] These restrictions impact not only farm production but also the processing, transportation, storage, and retail of food products. The burden of such regulatory restrictions is a double-edged sword that can accelerate and impede the pace of technology adoption among food supply chains.

Consumer Activism

Heightened consumer awareness and sensitivity to food-related safety incidents have impacted how food firms respond to technology adoption. Consumer activism challenges the practices of food businesses to change corporate practices for good. This increased social pressure from food activists lead to a different dynamism within the

food industry. This level of scrutiny affects the ability of food firms to experiment with such technologies.

Low Gross Profit Margins

The increased costs of transportation, storage, and procurement of perishable products, along with high labor costs (especially in cold chains), as well as the associated regulatory burdens, have decreased the profit margins of the food industry significantly. To maintain competitiveness, food firms constantly compromise on margins. According to one estimate, the food industry experienced a gross profit margin of about 22 percent in 2019, compared to approximately 49 percent for the rest of the market.[7]

Perishable Nature of Goods

The food industry deals with perishable goods that have a limited shelf life. This poses challenges in maintaining product quality, managing inventory, and ensuring timely delivery. The complexity of handling perishable items adds a layer of difficulty in implementing digital solutions effectively. The need for such procedures extends beyond the FSVP. For example, the lengthy customs clearance process and economic impact caused by perishable products have led many countries to use a single-window system, where digital information is shared to facilitate the prompt trade of perishable goods.

Fragmented Supply Chain

Food supply chains are often broken into several small and informal value chains, including several small players. This fragmentation results in various complex layers that can make it hard to trace the products from their place of origin to the end consumers. Primarily, food supply chains in emerging economies are entangled, often

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resulting in silos that are difficult to integrate into the mainstream digital ecosystem. Digitization requires considerable time, money, and effort, making it challenging for small firms to achieve.

Resource Constraints

Most businesses in the food industry are small- and medium-sized enterprises struggling to keep up with large firms. As discussed, they are already working to keep afloat and face resource limitations in budgeting, retaining, and attracting qualified employees, which makes their technology learning curves much steeper. These firms also need help accessing loans, insurance, and other investments. Moreover, technology adoption is a function of economies of scale, limiting food firms from multiplying the impact of technology assimilation.

Despite these challenges, the benefits outweigh the costs. Digital technologies are playing a significant role in shaping the landscape of food supply chains, especially compliance with FSVP. These technologies enable food firms to achieve transparency, traceability, and accountability at the heart of FSVP requirements. The digital supply chain toolkit comprises several technologies; this article focuses on some of the major ones, discussed below.

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> *Digital supply chains hold great promise for FSVP compliance. They have the potential to strengthen the foundations of food firms by helping them build transparency, traceability, and accountability.*

Digital Supply Chain Solutions for Complying with the FSVP

Blockchain

Blockchains are shared and immutable ledgers that are used to record business transactions. They are linked to peer-to-peer networks where each transaction is uniquely recorded. Blockchain has some unique properties, such as once data is recorded, it is almost impossible to change it. Each block has data information, a unique code, and a code of its previous block. Data stored inside the blockchain depends on the type of blockchain. Once a code has been generated, changing any information will change the foundation of the block and disrupt its chain of information.[8]

Blockchains allow for improved visibility and traceability[9] across the supply chain, essential for FSVP compliance. As a result of improved access to accurate information, tamper-proof storage of digital records, and digital access to this information, blockchains enhance the traceability of products from their origin to the consumer with verifiable proofs. This helps increase the bargaining power of firms, improve the credibility of information-sharing, and negotiate transparent contracts. Transparent

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access to reliable information helps firms better manage their inventory.

One of blockchain's most important benefits for fulfilling FSVP requirements is that it provides end-to-end data encryption. This helps firms avoid food fraud and safeguard their supply chains from counterfeit products. Once generated, it is tough to alter these information blocks, and any alteration triggers a new blockchain, keeping the original information intact. Furthermore, since this is a peer-to-peer open network system, the data on the blockchain is stored across a network of computers, making it impossible to alter any information via cyberattack.

Blockchains eliminate the use of intermediaries, thereby significantly increasing the rate of information gathering, flow, and access. They help digitize the record and eliminate any manual processing of information. For example, in case of a recall or a food safety incident, a firm can trace the problem to its source of origin in seconds. The speed of information access within the supply chain decreases information asymmetry among the firm and its suppliers, leading to more confident transactions. Firms can safely meet the regulatory requirements of recordkeeping and monitor suppliers more accurately using blockchains.

Overall, blockchain can help firms improve transparency and traceability. They can better rely on auditable information. Blockchain also helps increase stakeholder confidence and trust in the mutual relationship. The immutable nature, decentralized approach, and increased privacy of blockchain make it an intelligent choice for FSVP compliance.

Artificial Intelligence (AI) and Machine Learning (ML)

Artificial intelligence (AI), in simple words, is machine intelligence used to mimic human intelligence. On the other hand, machine learning (ML) is a sub-field of AI that

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comprises models that train themselves without being programmed by humans.[10] These capabilities have already found significant applications in the areas such as natural language processing, machine vision, speech recognition, etc. For example, the rise of ChatGPT[11] as an AI chatbot that can synthesize existing information on the internet and intelligently interact with its user is a testament to the potential of AI models. Responsible use of these models can help firms comply with the requirements of FSVP in several ways.

In the 21st century, the problem is not the need for more data, but rather over-information. With technology, firms are generating or collecting a huge amount of data without knowing how to drive actionable insights from it. Managers in the food industry face the challenge of accessing the correct information at the right time. AI and ML models can help make sense of large data streams by helping identify patterns, highlighting critical information, and pinpointing data inaccuracies and duplications. For example, AI and ML models can be used to understand legacy databases, help process certification records, streamline written procedures, and help optimize supply chains for FSVP compliance.

Furthermore, AI and ML models can be trained to use historical data points and help understand patterns to make predictions. These forecasts can be much more precise than the comparable alternatives. AI and ML have vast potential in inventory optimization and procurement decision-making, especially with perishable products. These tools can help warn supply chain managers of potential glitches in the value chain that can help them develop mitigation plans. AI and ML can also help with strategic sourcing decisions such as multi-sourcing, nearshoring, offshoring, insourcing, or co-sourcing arrangements for FSVP compliance. They can also help firms pre-emptively evaluate existing and potential suppliers by assisting them in understanding the risks to food safety and quality.

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In addition, AI and ML tools can help augment human judgment on quality inspections. For example, machine vision models enabled by AI and ML can precisely detect bacterial colonies[12] in food. This is a much faster and more efficient way of pathogen detection compared to more expensive and time-consuming laboratory procedures. Machine vision can also identify different types of bacteria and tell them apart based on their features. Such optical capabilities can aid in understanding the patterns of food composition and help increase the confidence of both consumers and producers in the food supply chain.

In summary, AI and ML models have enormous potential to process vast data streams and detect anomalies during food inspections. These models hold great promise in augmenting human judgment by helping them process accurate information more efficiently.

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Customer Relationship Management (CRM) Tools and Automation Software

Customer Relationship Management (CRM)[13] tools help firms manage their customer interactions and relationships with clients, as well as manage end-to-end supply chains by focusing on upstream and downstream stakeholders. This technology can also optimize the sales experience by enhancing visibility into customer data and improving the efficiency of contract management and performance. There are several advantages of using CRM tools for FSVP compliance, including streamlining the flow of information, creating a central repository of information, and efficient task management.

CRM tools help integrate several information channels.[14] They enable effective follow-up on potential leads by profiling customers and suppliers. They also integrate website information, telephone, chats, and social media data points. CRM tools can help employees with external-facing roles to be more effective in relationship management by providing intelligent insights. They also help with better data organization and act as

a centralized database for supplier information.

Furthermore, CRM tools make sharing information with internal and external stakeholders much more convenient by giving them access to this central repository of information and helping them improve team collaboration. This enhanced collaboration leads to better coordination among employees and suppliers and effective FSVP compliance. It enhances communication with the stakeholders by automating reminders, task follow-ups, and email generation. Such automation not only takes away non-value-added tasks from employees, but it also creates more accurate follow-up and helps generate automated reports on supplier and customer communication, thereby improving the visibility and efficiency of reporting.

Overall, CRM tools are an effective way to automate redundant tasks while managing relationships with external stakeholders. They help communicate effectively with suppliers and customers, improving coordination among partners and leading to efficient compliance with FSVP requirements.

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Robotic Process Automation (RPA)

Robotic process automation (RPA)[15] is a software technology that can be used by businesses to create "bots" that can replicate human efforts, especially for rule-based, mundane tasks. RPA can help food safety managers automate data entry processes for digital recordkeeping, update written procedures in real time, and generate reports for audits and inspections.

One of the best uses of RPA for FSVP compliance can be to automate data entry tasks that humans otherwise carry out. One of the requirements of FSVP is enhanced recordkeeping. Firms must maintain data records for all business transactions and activities. These recordkeeping requirements could include data on supplier audits,

supplier performance, inventory levels, warehouse temperatures, incoming material details, etc. For example, RPA can automate data entry tasks by enabling bots to scan bill of lading paperwork, extracting required information such as the type and volume of products being transported and shipper information.

RPA bots can also update written procedures required for production. For example, in a production unit, due to demand and supply uncertainty, RPA bots can automatically adjust recipes based on these daily production plans. The operators would not need to manually adjust the quantity order for each sub-unit of ingredients that go into the final product. The RPA bots can also communicate with the equipment to adjust temperature, pressure, and humidity requirements for the quantity of products produced.

Finally, RPA bots can help generate real-time reports for audits and inspections. For example, during a surprise visit, a consumer safety officer may ask for a summary of food safety performance over the past few weeks. Instead of grappling with the information, an RPA bot can generate real-time performance reports for the inspector. The RPA-generated pieces can have pre-populated fields connected to multiple databases to help gather, append, clean, and analyze data to produce insightful reports in seconds.

In summary, RPA is a powerful technology to automate several mundane yet rule-based tasks. It can help bring efficiency to otherwise non-value-added tasks and help operators and managers focus on more value-added activities. Beyond food safety, the RPA bot can automate procurement order generation, inventory management, and many other tasks.

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Internet of Things (IoT) Solutions

IoT solutions[16] comprise physical devices, such as sensors, actuators, and vision systems, that gather information from the real world and transmit that information to the digital world via the internet. These sensors are the eyes and ears of the digital world in the real world. They are feedback loops through which the digital ecosystem adapts its responses. They enable FSVP compliance by helping firms increase real-time visibility into critical parameters of their products and processes.

One of the most significant advantages of IoT devices is that they can gather real-time information from products and processes. For example, milk containers can be installed with temperature and humidity sensors to monitor the variation in these two parameters from the farm to the processing plants. These IoT devices can log information locally and push the data online. Users can program these devices to adjust the frequency of data collection. Such information can be used to ensure product integrity and delineate potential deviations in the process. This can help firms take appropriate remedial or proactive actions, as required.

Furthermore, these IoT devices can ensure protection against food fraud and economically motivated adulteration. For example, these devices can be used as door alert sensors to record the times and duration for which the storage room door was accessed. Similarly, other sensors, such as vibration sensors, can record the transportation conditions of the food and create a data log for recordkeeping. Another example is IoT devices for odor and gas monitoring in warehouses and production units. These sensors can alert operators and managers about potential risks to products and processes.

IoT devices combined with IoT platforms can gather, compile, and visualize data in real time. Integration with IoT platforms can enable firms to develop data dashboards to

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monitor performance across critical control points. Such data can be used for compliance, audit reporting, and supplier monitoring. Overall, they can help comply with FSVP requirements by assisting firms to monitor suppliers and their activities from anywhere and anytime.

Augmented Reality (AR)/Virtual Reality (VR) and Digital Twins

Augmented Reality (AR) is an experience that combines real-world content with virtual content generated with the help of computers. AR can help improve the real-world experiences of humans by augmenting reality with different sensory experiences, such as visual or olfactory. On the other hand, in Virtual Reality (VR), a human is immersed in a simulated environment using headsets or other wearable technology.[17] Furthermore, digital twins are a virtual representation of real-world objects or systems that are updated in real time throughout their lifetimes. Coupled with digital twins, AR and VR can help improve human efficiency.

AR technology can be used for the repair and maintenance of machines. Using headsets or intelligent devices such as smartphones, operators can overlay schematics and drawings on the machines to troubleshoot them efficiently. It can also help technicians refer to the service manuals in real time. This can reduce production downtime and help operators avoid errors. Moreover, using live feed, equipment service providers can generate precise instructions by guiding the in-house operators to conduct efficient repairs.

The disruption of the COVID-19 pandemic accelerated the use of virtual inspections and auditing. Remote audits and inspections can be significantly improved via AR/VR technologies. Inspectors can use AR/VR headgear or smartphone applications to digitally enter and assess buildings, storage spaces, and vehicles. AR headsets can help

remote inspectors provide exact directions to the operator on the ground for a comprehensive assessment. Although virtual inspections are not intended to replace in-person inspections, they can help increase monitoring of suppliers.

VR headsets can be used to train new employees in a virtual environment where they can experience the machines and processes. They can also be used to conduct simulations to ensure compliance with safe operating procedures, and they can help in identifying potential risks and developing mitigation plans. Simulation of emergency response plans can help prepare employees for high-risk, low-probability events. VR headsets can also be used to simulate regulatory inspection experiences.

In summary, AR and VR technologies and digital twins can help humans experience the world more efficiently. Regarding FVSP requirements, AR and VR technology can aid in auditing suppliers remotely, as well as allow access to expert technicians and service providers remotely.

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Summary

In a nutshell, digital supply chains hold great promise for FSVP compliance. They have the potential to strengthen the foundations of food firms by helping them build transparency, traceability, and accountability. Technologies like AI and ML can help firms improve risk evaluation by using legacy data to pre-empt issues. Blockchain, with the use of tamper-proof ledgers, can help generate more confidence in the supply chains. AR and VR can help with remote supplier audits. Technologies such as RPA can automate mundane recordkeeping tasks and document written procedures. IoT devices can help generate real-time information, leading to enhanced visibility across the internal and external stakeholders. These benefits far outweigh the costs of assimilating these technologies. Digital supply chains are a win-win solution for FSVP compliance and beyond.

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