GS1 US® COMMENT

to the

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

regarding

Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA to Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food

Docket No. FDA-2012-N-1153

GS1 US® appreciates the opportunity to provide this comment to the Food and Drug Administration (FDA) as it prepares its report to Congress regarding the findings of the Institute of Food Technologists (IFT) pilot projects and the FDA's own recommendations for improving the tracking and tracing of food.

GS1 US participated in the pilot program, and was pleased to support IFT in this important work. In preparing our comments, GS1 US reviewed the IFT Report to the FDA (entitled *Pilot Projects for Improving Product Tracing along the Food Supply System*), as well as the background information provided in the Request for Comments (RFC). We offer comments to the IFT report, and to various questions posed by the FDA in the Request for Comments. In addition, we offer recommendations for next steps. These comments are intended to support the FDA in forming its own recommendations and preparing its report to Congress.

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INTRODUCTION

GS1 US commends the IFT for its hard work and dedication in conducting the product tracing pilots and preparing the detailed pilot report. We support the recommendations contained in the IFT Report, and provide the clarifications and comments contained herein in order to expand upon and supplement IFT's work. One of the great successes of this project was the analysis of FDA's investigative methods and needs within the context of industry's capabilities and business processes. As was noted in the report, both parties had a lot to learn about each other, and the opportunity to communicate directly during the analysis injected insight and enthusiasm about what was possible. Another great success was the identification and definition of the Key Data Elements (KDEs) that the FDA needs to conduct traceback and traceforward investigations. As is discussed further in our comments, this has the potential to be a major turning point for food safety.

Traceback and traceforward investigations are collaborative efforts between the FDA and industry that rely on supply chain information. In explaining what it takes to enable that kind of collaboration, the IFT Report introduced supply chain standards and described how various standards are used by industry. As a supply chain standards organization, GS1 US has a unique perspective and level of expertise on these topics, enabling us to offer an industry standards-based and relevant business process perspective to the challenges and opportunities that lie ahead. GS1 US is pleased to support the FDA in this important work.

WHO IS GS1 US?

GS1 US is a not-for-profit standards organization established over 40 years ago by the grocery industry to administer and manage Universal Product Codes, also known as U.P.C.'s. The U.P.C. remains one of the most successful standards in history – with billions of barcodes scanned daily worldwide. This method of identifying products and capturing product data has evolved into what is now known as the GS1 System, the world's most widely used supply chain standards, which include:

- globally-unique numbering formats (identification numbers) standards for **identifying** supply chain objects;
- barcodes and radio frequency identification (RFID) standards for **capturing** identification numbers; and
- data synchronization and electronic information exchange standards for **sharing** data.

GS1 US is an information standards organization that brings industry communities together to solve supply chain problems through the adoption and implementation of GS1 Standards. More than 300,000 businesses in the United States and 2 million businesses globally in 25 industries rely on GS1 for trading partner collaboration and for maximizing the cost-effectiveness, speed, visibility, security and sustainability of their business processes using GS1 Standards. GS1 US also manages the United Nations Standard Products and Services Code (UNSPSC). Some of the world's largest corporations participate in our boards and work groups, motivated by the knowledge that GS1 Standards help their companies reduce costs and increase both the visibility and security of their supply chains.

GS1 US is not:

- a software provider
- a hardware provider
- a commercial solutions provider
- a technology company
- a trade organization
- a government agency

GS1 US is one of 111 Member Organizations of GS1 that serve 150 countries, and is a voluntary, consensus standards body as described in OMB Circular A-119. As such, GS1 US works with and actively supports numerous federal government entities, including:

Department of Agriculture (USDA)
Department of Commerce (DOC)
Department of Defense (DOD)
Department of Homeland Security (DHS)
Department of State
Department of the Treasury (DOT)
Department of Veteran Affairs (VA)
Commodity Futures Trading Commission (CFTC)
Consumer Product Safety Commission (CPSC)
Customs & Border Protection (CPB)
Federal Communications Commission (FCC)
Federal Reserve Bank
Federal Trade Commission (FTC)
Food and Drug Administration (FDA)
Securities & Exchange Commission (SEC)
United States Postal Service (USPS)
National Institute of Standards & Technology (NIST)
United States Congress
United States Trade Representative (USTR)

COMMENTS TO THE IFT REPORT

GS1 US agrees with the recommendations put forth in the IFT Report, and offers the following comments in an effort to expand upon and support IFT's work.

IDENTIFYING STANDARDS-RELATED CONCEPTS

Supply chains are heavily dependent upon industry standards to achieve greater interoperability and scale, which is why the use of supply chain standards is so prevalent across numerous industries. However, based on its experience, GS1 US has come to understand that concepts related to standards can be complicated and subtle. In fact, on page 220 of the report, IFT noted that, "'The concept of 'standardization' means different things to different people." Unfortunately, GS1 US has found this to be true, and notes that this lack of consistency can sometimes confuse the ability to identify standards-related issues and leverage existing standards-based solutions to resolve them. GS1 US seeks to assist the FDA in leveraging the investments industry has already made.

To that end, GS1 US notes three high-level areas of clarification in the IFT Report:

1) **Instances where the word "standard" was not used correctly**
(e.g., page 217 in the Barriers discussion where the heading "Lack of Standards Results in Fragmented Requirements" is actually discussing issues related to the lack of a uniform data set);

2) **Instances where issues related to standards (or the lack thereof) should be recognized**
(e.g., page 100 in the "Data Manipulation" section where the bullet point "Nomenclature turned out to be a big challenge, especially because technology cannot easily distinguish or identify different names being used by different trading partners for the exact same product…" is actually an issue caused by the lack of identification standards);

3) **Instances where opportunities to use standards to respond to problems should be identified**
(e.g., page 100 and other locations where time spent to "understand data" and time spent to "feed data" should be connected to the opportunity to significantly reduce if not eliminate these time delays by using identification standards and data standards)

Throughout the remainder of this section, we will specifically address some of the key opportunities in these areas. In addition, we will examine various issues and challenges identified in the report, and discuss how standards can be (or are being) used to improve or resolve them.

DEFINING HOW STANDARDS AND TECHNOLOGY AID THE FOOD INDUSTRY & REGULATORS

Similar to our comments above, IFT offered the following "Next Step" recommendation discussing the need to develop the concept of a "collaboration platform" (page 221 under the heading "*Distinguish and Define How Technology Aids the Food Industry and Regulators*"):

"The pilots suggest that the term 'collaboration platform' does not properly define what is needed to execute food product tracing queries and investigations. 'Collaboration' needs to be separated into what is needed for data producers and data consumers. Supply chain participants produce data and health officials/regulators consume data. Producers need tools to collect, secure, and store data, and to make data available as they choose to do so in terms

of access/transmit permissions, etc. Investigators need systems capable of querying, receiving, and making sense of distributed data. Future pilots should seek to focus attention on these different needs…"

Although GS1 US agrees with the recommendation on the concept of a collaboration platform, there are certain aspects of this description that need to be refined. Data producers (i.e., supply chain participants) will be collecting key data as part of their everyday business processes (e.g., shipping, receiving, invoicing, etc.), and then storing and sharing that data as needed. The data consumer (i.e., the FDA) will be receiving and analyzing data during investigations. A standards-based "collaboration platform" is what ties the two sides together. GS1 US believes the FDA should expand its definition of a "collaboration platform" within the context of what is needed to support the collection, recording, and exchange of information.

The pilots examined track and trace software solutions that were available in the marketplace to support the FDA as the data consumer. The pilots did not examine the tools and solutions available to support data producers as it was beyond the scope. We believe that this is an important next step. Industry has long been applying the concepts of a "collaboration platform" and using the associated tools to support their business processes and enable collaboration with one another. GS1 US encourages the FDA to work with industry and their years of experience to leverage the benefits and value of the work that has been done and the groundwork that has been laid.

Going forward, GS1 US believes it is essential that the FDA seek further insight into what is needed to support data capture, data storage, data sharing, and data analysis – and to learn more about the various options that currently exist in these areas. There are numerous tools available at different levels of complexity and cost, and technological advancements of recent years have extended the options even further. For example, barcode scanning can now be accomplished via cell phone or other mobile device and "apps" can be used to record or look-up information associated with that barcode. Common use of "barcode apps" can be found in supermarkets where *consumers* can be found scanning barcodes to access nutritional and allergen information while shopping. Considering the diversity across the food industry (e.g., large, multi-national corporations; small, independent farm; local bakery; supermarket chain; corner market; etc.), it is essential to understand the breadth and depth of the options available. This will enable the FDA to leverage those capabilities, like current data sharing models observed in the pilots where participants were able to provide more than "one up" and "one back." This will also enable the FDA to evaluate creative, cost-effective options for small business enterprises (SBEs).

SAVING TIME MEANS SAVING LIVES

In the event of a foodborne illness and other food-related emergencies, time is of the essence. Considering the amount of time lost due to poor data quality, it is absolutely imperative that these data quality issues be addressed. Fortunately, industry understands data quality issues, and has worked together with their standards organizations and technology providers to develop tools and approaches to resolve them. Therefore, GS1 US recommends that the FDA should work with these supply chain experts and standards organizations in a targeted effort to better understand the data quality issues and how they can be addressed using tools and approaches already in place across the industry. It should be noted that further analysis of the raw data from the pilots may provide additional insight as to where issues occur (i.e., which industry groups or segments). This would support the FDA in identifying vulnerable points in the supply chain and working with industry to develop creative, cost-effective solutions to help those groups improve data quality within their own business constraints.

UNDERSTANDING WHAT SLOWS INVESTIGATIVE SPEED

In describing the mock traceback results on page 22, IFT described the results, and identified a key issue (emphasis added): "Many of the collaboration platforms were able to demonstrate the flow of specific lots of product through the supply chain with minimal effort, and some were able to identify convergence. However, *while querying occurred within seconds, the collaboration platform providers reported spending between 3 - 7 days uploading the data into their systems due to the lack of a standard structure or format and the need to re-enter data*." Although this summary information alone was quite telling, IFT collected a treasure trove of time data that further illuminated the issues.

TIME LOST DURING THE INVESTIGATION

Understanding the importance of time during a food-related emergency, IFT broke down the various tasks needed to perform the investigative analysis and collected time data about how long it took to perform each task. On page 100 of the report, IFT described this process:

"Each technology company was asked to give the breakdown of the time they spent trying to understand the data (for tasks such as creating master data, linking the data to the scenarios or to ask IFT clarifying questions), time to feed the data into the system (either manual, semi-automated, or fully-automated data entry as well as error handling), and finally time to query or analyze those data for convergence (time to submit a query into the system as well as receive a meaningful response). The breakdown of time spent working with the data from five out of the nine technology providers is listed in Table 27."

Table 27. Technology Provider Analysis Data Breakdown

Technology Provider	Time to Understand Data	Time to Feed Data	Time to Query/Analyze Data	Percent of Pilot Data Used
1	3 days	4 hours	Within minutes	50%
2	2 days	8 hours	instantaneous	100%
3	7 days	3 days	5 minutes	100%
4	2 days	1 day	10 minutes	33%
5	24 hours	24 hours	Within seconds	100%

"Time to Query/Analyze Data" (Column 4) relates to the software's analytical capabilities, and illustrates how technology can enhance and expedite investigations. In contrast, "Time to Understand Data" (Column 2) and "Time to Feed Data" (Column 3) relate to the data itself, and illustrate how data issues can completely undermine investigative speed. In standards and technology circles, these issues are referred to as "data quality issues" and it is critical that the FDA recognize these data quality issues as fundamental barriers to an effective traceforward and traceback system.

UNDERSTANDING DATA QUALITY ISSUES

During the pilots, technology providers highlighted the fact that pilot data contained "significant data quality issues." To be sure, some of the data quality issues were related to business practices (e.g., re-labeling without linking; using batch/lot as an identifier; etc.). These types of problems can be addressed with best practices and education. Some of the data quality issues were related to how data was submitted (e.g., non-searchable PDFs or

scanned documents). These types of issues can be minimized with standardized interfaces (e.g., XML; GUI interface; etc.). Some of the data quality issues were due to variations in how products and parties/locations were identified (e.g., red round tomatoes being identified as "5x5 tomatoes" or "tomatoes 5x5" by different trading partners). These types of issues can be resolved by using standardized identifiers (e.g., Global Trade Item Number or GTIN and Global Location Number or GLN). And some of the data quality issues were due to inconsistent data format and/or uncertainty about what information was being conveyed. These types of issues can be resolved by using data standards.

Standards provide the common language that enables trading partners to communicate with each other, and enables their IT systems to process and manage the data they exchange. When a participant used standards, the data they submitted was usually high quality and able to be processed without further human intervention. When a participant did not use data quality standards, the data they submitted presented numerous challenges that required significant human intervention before it could be processed. IFT was unable to address these issues due to the timing requirements of FSMA, so it looked to the technology providers and software to handle the disparate datasets. Reflecting on that experience on page 31, IFT noted that, "…the utility of an FDA-managed platform for collaboration with public health partners is completely dependent on the submission of accurate, complete event data. Technology should not be expected to compensate for poor recordkeeping." GS1 US agrees.

CONCEPTS RELATED TO KEY DATA ELEMENTS (KDES)

GS1 US believes that the identification of the KDEs was one of the great successes of this pilot project. We offer two comments to IFT's discussion of KDEs.

LACK OF UNIFORM DATA REQUIREMENTS – NOT "LACK OF STANDARDS"

The IFT Report includes identification and discussion of various barriers to the implementation of its recommendations. GS1 US would like to expand upon one of the key barriers and clarify this important point. The following discussion (emphasis added) appears on page 217 of the report under the heading *Lack of Standards Results in Fragmented Requirements*:

"In considering all the data and all the stakeholder input offered, IFT believes that issues related to product tracing will remain in a state of perpetual flux until FDA provides clearer definitions for *data requirements* and begins to share with industry the Agency's vision of an effective product tracing system. Currently, there are several industry initiatives underway which seem to be working in concert (Chapter 9), but there are also numerous customer requirements that challenge food supply chain members.

With time, as adoption and capability evolve, FDA could work with industry to drive consistency with a more *unified set of product tracing requirements* across all segments of industry. It is important that the ends of the supply chain closest to consumers are not faced with needing to accommodate numerous systems with different requirements; similarly, it is important that manufacturers are not forced to provide *different types of tracing information on different products* based on the requirements of their customers, as is the case today."

The discussion in the IFT report is on point, but the heading is misleading. As described in the discussion, the barrier is lack of uniform data requirements, not lack of standards. The IFT Report presented findings about numerous industry-led food safety traceability initiatives and about how implementation efforts are being stifled by the lack of uniform data requirements. Clarification of this point is needed because not only is the lack of a uniform

data set a significant barrier, but it is also a barrier to which the FDA can easily respond with leadership and clarity (see our comment to FDA Question 2 for more information).

THE IMPORTANCE OF ONE SET OF KDES

On page 220 of the "Next Steps" discussion, IFT made the following comment: "A thorough regulatory investigation accounting for all steps in the supply chain may demand a different set of KDEs compared with those which allow for rapid identification of convergence and those needed for an effective recall." GS1 US is concerned that this statement could be misinterpreted to unintentionally contribute to the uncertainty that has stifled implementation across industry-led food safety initiatives.

In our experience with track and trace standards, the KDEs do not change or vary. Variations only occur in the events for which KDEs need to be captured (i.e., the CTEs), and/or the KDE values. For example, trading partners may capture/record different CTEs because different events are associated with different supply chain roles (e.g., manufacturers would not likely have a consumption event; retailer would likely not have shipping events; etc.). Moreover, there can also be variations in the permissible values for a certain KDE depending on supply chain role (e.g., the permissible values for *Activity Type* for manufacturers will likely be different from those for retailers due to the different types of activities they perform). However, each supply chain partner should capture the same data set for each data capture event (i.e., each CTE). Considering the chilling effect that uncertainty about data requirements has had across industry, we strongly encourage the FDA to provide clarity on this point and to avoid any messaging that could imply otherwise.

CLARIFYING THE DEFINITION OF "COLLABORATION PLATFORM"

In defining the tasks to be performed as part of the pilots, the FDA charged IFT with using a "collaboration platform" for the mock investigations so that IFT could provide insight about software solutions that could assist the FDA with traceback and traceforward data analysis. The use of the term "collaboration platform" in this context was challenging because this is not the traditional application of that term. IFT resolved this challenge by working with pilot participants to create a definition of "collaboration platform" that made sense within the context of the task at hand. However, GS1 US believes that it is essential to step back at this point and clarify terminology to distinguish between software and standards as this will be important for the work that lies ahead.

DEFINITION USED IN THE IFT REPORT

On page 21 of the report, IFT provided the following description for how the term "collaboration platform" was used during the pilots: "Ultimately, the 'collaboration platform' functioned as more of a data analysis system, which could be used by FDA (or other regulators) to share and analyze data collected from industry. Collaboration platforms were not used in this task by food industry members to submit data. Instead, industry data was collected by IFT through these pilots. IFT in turn blinded and supplied these data to the collaboration platform providers. These collaboration platforms were then used to query the data to look for convergence and conduct tracebacks." Although this is an apt description for what IFT was asked to do, it is not the traditional definition of "collaboration platform." Instead, this is actually a description of track and trace software solutions. Therefore, wherever the term "collaboration platform" appears in the IFT Report, it should be understood to be referring to track and trace software.

SUPPLY CHAIN INDUSTRY DEFINITION

So, what is a "collaboration platform"? A "collaboration platform" is actually the standards-based foundation on which collaborative supply chain solutions (like track and trace) are built. Supply chain partners need to communicate and share various types of supply chain information (i.e., product information; location information; etc.) in order to support their business processes (e.g., procure-to- pay cycle; logistics; etc.), and to enable collaborative efforts like track and trace. In order to do that, they need a common language. Standards provide the common language that enables trading partners to communicate with each other, and enables their IT systems to process and manage the data they exchange. A "collaboration platform" includes four types of standards: identification standards, data capture standards, data standards and interface standards.

Identification Standards: Identification standards ensure that each supply chain object, party and location has one and only one identifier that all trading partners use to identify that object/legal entity/physical location in all supply chain transactions, supply chain communications, and internal systems. Identifiers should be globally unique, persistent, and applied at the source.

Data Capture Standards: Data capture standards enable trading partners to capture standardized identifiers in a common way, ensuring efficiency and accuracy in recording identifiers and supply chain information. Data capture standards include data carriers (i.e., barcodes and/or EPC-enabled RFID[1] tags), human readable formats, and secondary information to be marked on products (e.g., batch/lot; expiration date; etc.).

Data Standards: Data standards specify the content and meaning of data to ensure data completeness and accuracy when data is exchanged or shared among trading partners. Data standards include data dictionaries, data formats, file formats, schema definitions, etc.

Interface Standards: Interface standards define how trading partner systems interact with each other to exchange data. Interface standards include messaging protocols, web service definitions, etc.

Together, these standards provide the foundation for the tools and applications that trading partners use to manage their supply chain and collaborate with one another—tools and applications like the track and trace software evaluated in the IFT Report. GS1 US believes that one of the critical next steps FDA should take is to expand its understanding of a "collaboration platform," including what standards are available in these areas and what industry has already adopted and utilizes today.

EXAMPLE OF AN INDUSTRY-LED COLLABORATION PLATFORM

Participants, IFT and technology providers discussed the use of GS1 Standards within the track and trace software evaluated in the pilots, and we will use the GS1 System here to illustrate the concept of a "collaboration platform."

The GS1 System is a "collaboration platform" that provides a solid foundation for visibility-driven applications like track and trace. The GS1 System is an integrated suite of global standards for identifying, capturing, and sharing information regarding products, locations, assets and services (including the identification standards, data standards, data capture standards, and interface standards discussed above). GS1 Standards are used in business practices, supply chain tools and software solutions to tie all of those pieces together. These standards ensure the quality and

[1] EPC-enabled RFID stands for "Electronic Product Code enabled Radio Frequency Identification."

amount of data for backend systems, and facilitate the communication and sharing of information across those systems and among trading partners. Table 1 (below) summarizes some of the GS1 Standards related to track and trace.

Table 1: Overview of GS1 Standards to Support Track & Trace

Type of Standard	Examples	GS1 Standard(s)
Identification Standards	**Trade Items** (e.g., selling unit; inner packs; etc.)	Global Trade Item Number (GTIN)
	Locations & Trading Partners (e.g., Ship-to; Bill-to; etc.)	Global Location Number (GLN)
	Logistics Units (e.g., cases; cartons; pallets; etc.)	Serial Shipping Container Code (SSCC)
	Fixed Assets (e.g., manufacturing equipment; etc.)	Global Individual Asset Identifier (GIAI)
	Reusable Transport Equipment (e.g., barrels; kegs; etc.)	Global Returnable Asset Identifier (GRAI)
Data Capture Standards	**Automatic Identification** (e.g., barcodes and RFID)	Universal Product Code (U.P.C.) barcode GS1-128 barcode DataMatrix 2D barcode GS1 DataBar barcode ITF-14 barcode EPC-enabled Radio Frequency Identification (RFID)
	Readable Identification (e.g., location; format; etc.)	Human Readable Interpretation (HRI) Guidelines
	Secondary Data (e.g., batch/lot; expiration date; etc.)	GS1 Application Identifiers (AIs)
Data Standards	**Data Attributes**	Global Data Dictionary Electronic Product Code Information Services (EPCIS) Core Business Vocabulary
Interface Standards	**Data Synchronization**	Global Data Synchronization Network (GDSN)
	Business Transactions	Electronic Data Interchange (EDI)
	Physical Events	EPC Information Services (EPCIS) Capture & Query

ASSESSING INDUSTRY CAPABILITIES AND OPTIONS

On page 214, IFT noted that, "The most contentious recommendation was around data requirements, and specifically, the feasibility of collecting lot/batch numbers through distribution and at retail and foodservice." Related to the batch/lot issue, IFT presented a section called "Prerequisites to Efficient Data Capture and Sharing" wherein it discussed the current state of standards implementation, issues related to industry practices, and their own thoughts as to what it would take to resolve those issues, including opinions about the cost/benefit of doing so (pages 215 – 217). GS1 US agrees that batch/lot information is vitally important as it provides a more granular level of product identification to support focused convergence investigations and targeted recalls. However, GS1 US understands that FDA must protect public safety in a way that is mindful of the cost to business.

When it comes to marking batch/lot information onto products, there are various options in terms of type or types of barcodes (e.g., GS1-128; Data Matrix; etc.), and how they can be applied to products (e.g. cases with pre-printed

barcodes; dynamic encoding on the production line; pre-printed barcodes manually applied to cases; etc.). It is essential to understand all of the different options available in order to determine the "best approach" based on a company's individual constraints and current operating environment. Otherwise, one might select an approach that is more complicated and expensive than is justified, and then have the misguided impression that the effort (as opposed to the specific approach used) is too expensive.

Program parameters and time constraints prohibited a thorough analysis of the barcoding options as part of the pilot effort. As a result, the report does not include the level of detail and insight needed to draw conclusions in this area. Because cost is a key consideration in regulatory efforts, GS1 US recommends that the FDA conduct further research about the options before drawing any conclusions.

COMMENTS TO FDA QUESTIONS

QUESTION 2

The report recommends that all foods be covered, not just high-risk foods. The rulemaking requirement in section 204(d) of FSMA only refers to high-risk foods. Should FDA pursue implementation of some or all of the report's recommendations with respect to all foods, not just high-risk foods? If so, what routes might the Agency use?

GS1 US recommends that the FDA adopt IFT's set of KDEs as the uniform data set for the FSMA additional recordkeeping requirements for high risk foods, and endorse it as the uniform data set it will use for any/all future regulatory requirements in this area. Beyond regulatory requirements, GS1 US recommends that the FDA seek any and all opportunities to use its considerable influence to promote and endorse the KDEs across food industry segments for all food products.

GS1 US understands that the FSMA requires the FDA to designate high-risk foods and establish additional record-keeping requirements exclusively for that high-risk class, and that the Act specifically excludes all food not so designated from any additional record-keeping requirements. Nonetheless, there is opportunity for the FDA to leverage the KDEs defined in the IFT Report for more than just those regulatory requirements. GS1 US strongly recommends that the FDA take the opportunity to leverage the KDEs for more than just current FSMA regulatory requirements because it has the potential to be a major turning point in the effort to enhance food safety. In fact, GS1 US believes that IFT Recommendation 1 supports this point.

IFT Recommendation 1 is discussed in two locations within the report. On page 15, Recommendation 1 is summarized as follows: "…IFT recommends that FDA establish a uniform set of recordkeeping requirements for all FDA-regulated foods and not permit exemptions to recordkeeping requirements based on risk classification." Unfortunately, this summary and use of the word "exemptions" appears to extend Recommendation 1 beyond FDA's statutory authority. However, the full discussion of Recommendation 1 provided on page 203 clarifies the recommendation as follows: "IFT recommends that FDA establish a single set of recordkeeping requirements. If FDA can only require increased recordkeeping for certain foods, IFT encourages FDA to recommend that all firms in the food supply chain meet these standards as a best practice." This fuller discussion of Recommendation 1 stays within the statutory constraints, encouraging the FDA to use the KDEs in the statutory recordkeeping requirements **and** in recommendations for industry best practices.

Page 203 of the IFT Report included the following noteworthy finding: "In a rare showing of unanimity, the pilot participants and advisors agreed … that there is a need to trace all food product categories in the supply chain, regardless of the risk they are perceived to have today." This finding is noteworthy because industry itself was acknowledging a need beyond what is circumscribed in the statute. In addition, the IFT Report discussed

impressive food safety traceability initiatives being pursued by numerous segments of the food industry [e.g., Produce Traceability Initiative (PTI) and Foodservice GS1 US Standards Initiative, in addition to industry efforts in the seafood, meat and poultry, dairy, deli and bakery industries—all supported by GS1 Standards]. Without and beyond any regulatory requirement, industry is concerned about and engaged in food safety issues. However, during its research, IFT discovered that although industry was motivated and active in these initiatives, companies were hesitant to begin wide scale implementation because they were concerned that the FDA could subsequently announce a separate and conflicting set of regulatory requirements. In other words, uncertainty about potential regulatory requirements is stifling the momentum of industry-led food safety implementation.

If the FDA endorses IFT's set of KDEs as the uniform data set it will use for all related regulatory requirements (i.e., for high risk foods per FSMA today and any other groups that may be authorized in the future), industry will then have the certainty it needs to pursue wider implementation of its own food safety traceability initiatives. During outbreaks of food-borne illness and other food-related emergencies, the FDA's ability to conduct rapid and effective investigations is completely dependent on industry's ability to provide the needed information. Promulgation of a uniform data set enables industry to better support those information needs in their everyday business processes, whether they do so pursuant to regulatory recordkeeping requirements, industry best practices, or one of the numerous food-safety initiatives being pursued by various food segments today. On page 209 of the report, IFT noted that, "FDA's support for … industry-led implementation initiatives will enable real-world adoption of improved product tracing capability at a more rapid pace than would otherwise be possible…" GS1 US agrees and believes that FDA endorsement and adoption of the KDEs would further enhance the momentum of those industry initiatives.

QUESTION 4

What additional information and data sources could be used to determine cost and benefits associated with implementing IFT's recommendations for KDEs and CTEs?

It is always a challenge to find specific resources regarding cost/benefit and return on investment (ROI). Nonetheless, the following resources provide facts and figures that may assist the FDA:

How GS1 Standards Support Critical Tracking Events
www.gs1us.org/industries/fresh-foods/tools-and-resources under White Papers

17 Billion Reasons to Say Thanks
www.gs1us.org/industries/cpg-grocery/tools-and-resources under Resources

Integrated Traceability in Fresh Foods: Ripe Opportunity for Real Results
www.gs1us.org/industries/fresh-foods/tools-and-resources

Case Studies found on the GS1 US Fresh Foods website:
www.gs1us.org/industries/fresh-foods/tools-and-resources

The Produce Traceability Initiative (PTI) website
www.producetraceability.org

GS1 US RECOMMENDATIONS FOR NEXT STEPS

Based on our comments, GS1 US recommends that the FDA take the following Next Steps:

(1) ADOPT THE KDES AS THE "UNIFORM DATA REQUIREMENTS" FOR FDA INVESTIGATIONS

Promulgation of a uniform data set enables industry to better support those information needs in their everyday business processes, whether they do so pursuant to regulatory recordkeeping requirements, industry best practices, or one of the numerous food-safety initiatives being pursued by various food segments today. In addition, it will provide the certainty that industry needs to pursue wider implementation of its own food safety traceability initiatives. GS1 US believes that this has the potential to be a major turning point for food safety.

(2) FOCUS ON DATA QUALITY ISSUES

The pilots revealed significant data quality issues that undermined investigative speed. Considering the amount of time lost due to poor data quality, addressing data quality issues must be a top priority. The FDA should work with supply chain experts and standards organizations to better understand the data quality issues revealed in the pilots, and reinforce the value of data quality in the efforts and approaches already in place across the industry.

(3) PARTICIPATE IN AND ACTIVELY SUPPORT INDUSTRY-LED FOOD SAFETY INITIATIVES

Without and beyond any regulatory requirement, industry is concerned about and engaged in food safety issues, as demonstrated in the impressive food safety traceability initiatives being pursued by numerous segments of the food industry. On page 209 of the report, IFT noted that, "FDA's support for … industry-led implementation initiatives will enable real-world adoption of improved product tracing capability at a more rapid pace than would otherwise be possible…" GS1 US recommends that the FDA leverage these resources, and take every opportunity to participate in and actively support these industry-led initiatives. With most initiatives focused on a specific target group of the food industry, these initiatives offer specialized insight into the needs and challenges of these diverse segments, and bring together industry leaders who can help the FDA develop creative, cost-effective solutions for all trading partners in the food supply chain, including lesser enabled partners (i.e., SBEs).

(4) ENGAGE WITH INDUSTRY SUPPLY CHAIN EXPERTS AND STANDARDS ORGANIZATIONS

Traceback and traceforward investigations are collaborative efforts between the FDA and industry that rely on supply chain information. On page 22, IFT noted that, "…the pilot participants appeared to have many of the tools and processes in place which are required to allow the capture and communication of critical track and trace data (i.e., KDEs) at critical points of product transfer and transformation (i.e., CTEs)." Industry has been developing and using collaborative solutions for decades, and there is so much that they can do today to support a state-of-the-art track and trace system. Nonetheless, challenges remain and there is work to be done. FDA is encouraged to view itself as a new collaboration partner in an industry that is advanced in collaboration infrastructure and tools. FDA should engage with supply chain experts and standards organizations to not only understand what is in place, but to also develop creative, cost-effective solutions for segments of the industry that are not up to speed in these areas. The knowledge base is there – the FDA only needs to seek it out.

GS1 US remains committed to helping the FDA leverage supply chain standards and solutions to improve the tracking and tracing of food as well, and looks forward to offering any further assistance we can provide. *(See page 4 for a sample list of federal government entities with whom GS1 US works.)*

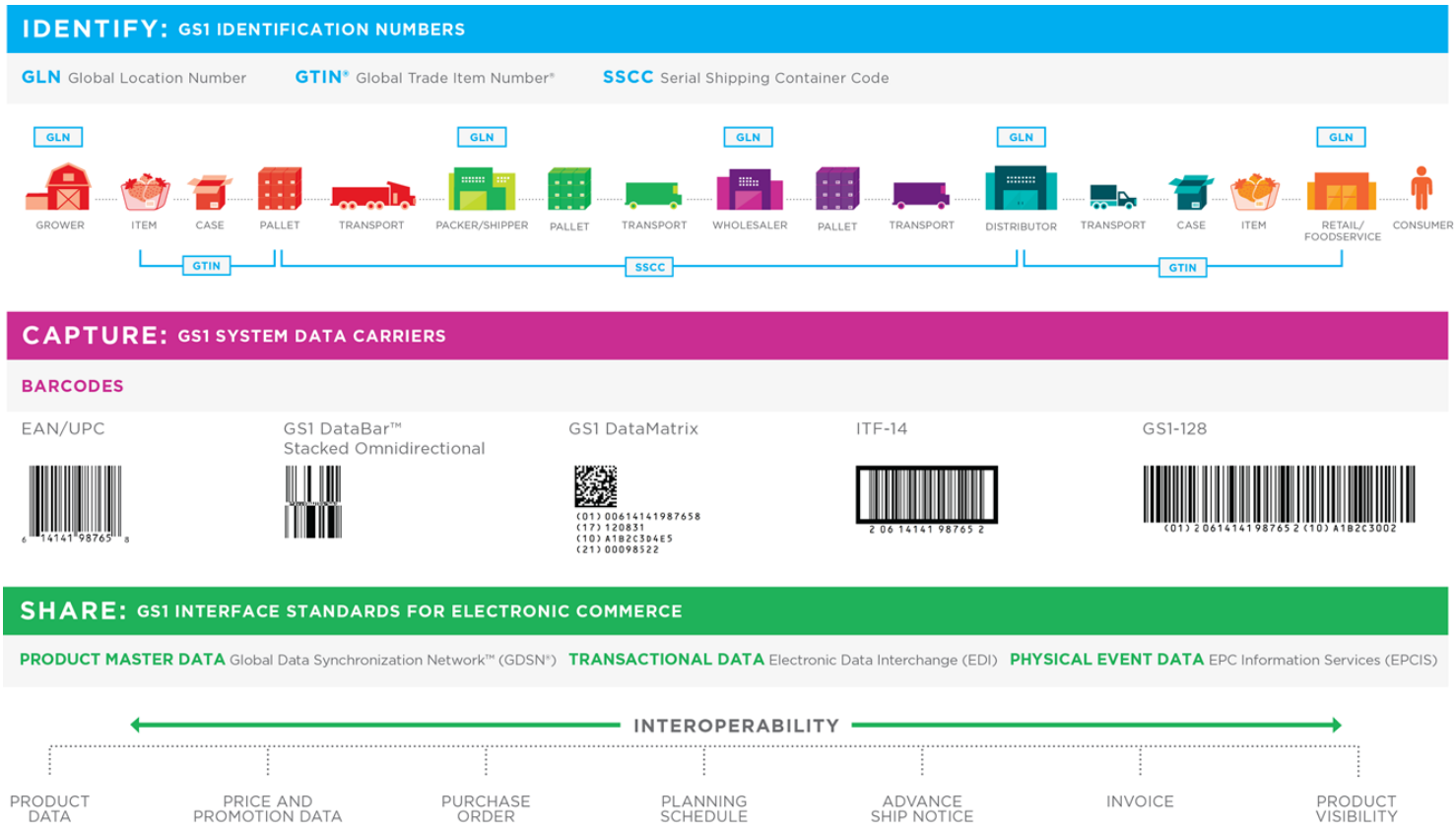
APPENDICES

ACRONYMS

FSMA	Food Safety Modernization Act
IFT	Institute of Food Technologists
RFC	Request for Comment
CTE	Critical Tracking Event
KDE	Key Data Element
SME	Subject Matter Expert
SBE	Small Business Enterprise
XML	Extensible Markup Language
GUI	Graphical User Interface

INTRODUCTION TO THE GS1 SYSTEM

The GS1 System is an integrated suite of global standards that provides supply chain visibility through the accurate identification, capturing, and sharing of information regarding products, locations, assets, and services. Using GS1 identification numbers, companies and organizations around the world are able to globally and uniquely identify physical things like trade items, physical locations, assets, and logistic units as well as logical things like corporations or a service relationship between distributor and operator. When this powerful identification system is combined with data-sharing methods, transactional messaging standards such as electronic data interchange, and/or physical event information, the connection is made between these physical or logical things and the information the supply chain needs about them.



The GS1 System is a powerful three-step process: companies must identify products and locations using a standardized product identification and standardized location identification method. Additionally, companies must capture the standardized identification in a common approach – barcodes and/or EPC-enabled RFID tags are shown in the above illustration. Finally, once companies are using a common language to identify and capture product data, the information must be shared in a standardized format, ensuring data completeness and accuracy.

Identify - Globally Unique Identification

The GS1 System provides globally accepted identification numbers to support a common language for the communication of product information from company to company. The GS1 identification number for products is the GS1 Global Trade Item Number (GTIN). Global Location Numbers (GLNs) are identification numbers for

retrieving information about locations related to the supply chain. For decades, these GS1 identification numbers have facilitated the sharing and communication of product and location information among supply chain partners. Moreover, they have provided the foundation for innovative improvements in supply chain management for many American industries, including the impressive and well-documented advances in the retail and grocery industries.

Capture Product Information

The GS1 System uses the U.P.C. and other barcode symbologies and Electronic Product Code (EPC)-enabled RFID tags to encode GS1 identification numbers. Barcodes are machine-readable, which are read by scanning. Scanning speeds data collection and eliminates manual data collection errors, e.g., illegible handwriting and data entry errors. The GS1 System enables users to design applications that automatically process GS1 data captured from approved barcode symbologies. Additional information such as best-before-dates, serial numbers, and lot numbers may also be encoded into barcodes. EPC-enabled RFID tags, which are typically applied to products during the manufacturing process, consist of a microchip attached to an antenna, allowing for wireless capture of information encoded in them. The product's EPC number incorporates a GTIN and a serial number, making it possible to track and trace an individual instance of an item with greater accuracy and intelligence.

Share Product Information

The GS1 System provides three standardized approaches for sharing information and to support the concepts of Critical Tracking Events and Key Data Elements. Companies can implement one method or a combination of all three depending on what information they want to capture and share with trading partners.

1. Master Product Data - Master product data enables „one source of truth" for specific product information. This type of data also typically exists to describe locations, and parties. The GS1 standard that supports master data is the Global Data Synchronization Network® or GDSN®. With GDSN, trading partners always have the latest information in their systems, and any changes made to one company's product database are automatically and immediately provided to all of the other companies that do business with them.
2. Transactional Data - Transactional data provides evidence of the completion of a business transaction, such as the completion of a transfer of ownership (purchase and sale) or a transfer of custody (shipping and receiving). GS1 standards that support transactional data include Electronic Data Interchange (EDI) and Extensible Mark-up Language (XML) Business Message Standards.
3. Physical Event Data – Physical events are actual observations made in the physical world of products or other assets. Each observation captures what was observed, when it was observed, where it was observed, and why it was observed (that is, what was the business context in which the observation took place). Often physical event data is generated as the result of automatic identification, such as scanning a bar code or reading an RFID tag. The GS1 standards that support physical event data are Electronic Product Code Information Services (EPCIS) and the Core Business Vocabulary (CBV).

IAPMO

In this publication, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code" which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.