GS1 US COMMENTS

to the

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION (FDA)

Docket FDA-2014-N-0053

PROPOSED RULE

regarding

"Requirements for Additional Traceability Records for Certain Foods"

GS1 US appreciates the opportunity to provide the following comments to the U.S. Food and Drug Administration (FDA).

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INTRODUCTION

GS1 US applauds publication of the Proposed Rule by the U.S. Food and Drug Administration (FDA) establishing "additional record-keeping requirements for certain foods" pursuant to the U.S. Food Safety Modernization Act (FSMA), Section 204 (hereafter, the "Proposed Rule"). Our comments to the proposed rule are below.

GS1 US Supply Chain Management and Product Traceability Expertise

GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration that optimizes their supply chains, drives cost performance and revenue growth, while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code (EPC®)-based RFID, data synchronization, and electronic information exchange.

Given this, GS1 US has an abiding interest and expertise in product and food traceability. GS1 Standards were introduced more than 45 years ago to assist food producers, processors, distributors, retailers, and foodservice establishments in identifying, capturing and sharing critical information within fast-moving supply chains. They have evolved with the industry and, today, GS1 Standards uniquely identify products and locations worldwide, facilitating the movement, visibility and tracing of food products in the United States and more than 150 countries. We bring this expertise to the recommendations offered here.

GS1 US and FDA Collaboration

As an additional preliminary note, GS1 US, industry and FDA also share a long history of collaboration. In the ten years since FSMA was enacted, GS1 US has worked with businesses, large and small, to develop and refine global standards and implementation guidance for these standards to serve the evolving needs of both the marketplace and the FDA. These standards have facilitated countless formal and informal product recalls. It is through this collaboration that FDA became familiar with GS1 Standards. In addition, GS1 US has participated in food traceability pilots with FDA to inform this and other rulemakings. We offer comments in the spirit of partnership and to advance our historic collaborative relationship with FDA.

U.S. Marketplace Validation

Finally, we note that GS1 Standards also have been validated by FDA and industry as the best and most effective tracing tools in the following marketplace studies and pilots:

1. "Traceability in Food Systems" (The Institute of Food Technologists; Volume 1 and Volume 2)
2. The Produce Traceability Initiative
3. Global Dialogue on Seafood Traceability
4. Romaine Task Force
5. Leafy Greens Task Force

GS1 US Primary Recommendation: FDA Recognition of GS1 Standards

As addressed in more detail below, given GS1 US' expertise in product traceability within supply chains, our continuous engagement with large and small food businesses, and our history working with FDA, offer the following primary recommendation to improve the Proposed Rule:

> **FDA should recognize *GS1 Standards* by name, along with other "voluntary, consensus standards" *as a means for regulated facilities to comply with FDA's final rule*.**

Lacking FDA Recognition, Marketplace Confusion, Redundancy, and Unnecessary Costs Are Likely

The reason for our primary recommendation is straightforward: without the endorsement of commonly recognized system of standards, the Proposed Rule has the potential to create unintended confusion within the regulated community. If finalized as proposed, the Proposed Rule could impede FDA from achieving its objective of reducing public health risks through the "rapid and effective" traceability and recall of food.

For example, FDA proposes to create an unintentionally similar, but not identical food traceability and recall system parallel to the one that currently operates in the marketplace (leveraging GS1 Standards). In essence, under the Proposed Rule two food traceability systems would exist—one for government and one for the marketplace. Yet, if FDA deviates from identifying, capturing, and sharing information using data standards in the final regulation, FDA would be generating potential confusion, redundancies and costs for both FDA regulated interests and users of GS1 Standards.

> **The reality is what FDA has put forward in its Proposed Rule does not exist in the marketplace today, nor does it align with what is used in the marketplace – namely GS1 Standards.**

FDA's recognition of GS1 and other standards currently used in the marketplace would help FDA avoid these consequences.

Marketplace Recognition, Accessibility to GS1 Standards

GS1 US also would like to address the misconception that obtaining a GS1 identifier is an undue burden for small businesses. GS1 US has taken numerous steps to address this misperception. In 2020, GS1 US simplified the process for obtaining an identifier and less costly for ALL businesses with the introduction of the single issuance of a Global Trade Item Number ® (GTIN). Now, large and small businesses alike are able to obtain a single GTIN for $30 with no required annual renewal, commitment or implementation know how. The single GTIN option removes some of the previous adoption hurdles and the need to license a GS1 Prefix and maintain an annual renewal. The launch of single issuance Global Location Number® (GLN) soon will follow. Additionally, GS1 US is partnering with solution providers to permit companies to seamlessly obtain a GTIN while using their solutions and services. The low cost of a

single globally-unique identifier, GTIN/GLN, offers accessible options for even micro businesses.

Additional Comments and Observations

GS1 US believes FDA can improve its Proposed Rule. To this end, we submit the following comments organized in five parts:

- **Part I** addresses our concerns over (i) potential inconsistencies in the Proposed Rule compared to GS1 Standards; (ii) the potential lack of clarity or inconsistencies of certain definitions in the Proposed Rule, and (iii) the lack of standardized data structures in the Proposed Rule.

- **Part II** provides detailed responses to specific questions raised by FDA. This section includes specific comments and recommendations with respect to various definitions as well as topics relating to Critical Tracking Events (CTEs) and Key Data Elements (KDEs), and Recordkeeping

- **Part III** lays out our request for GS1 Standards to be recognized by name in the final regulation, consistent with our Primary Recommendation, as an alternative means of compliance with the FSMA, Section 204 final rule and the statutory authorities available to FDA to do so.

- **Part IV** provides information about GS1 US, GS1 Standards, and prior collaborative efforts between GS1 US, industry stakeholders, and FDA.

- **Part V** provides an appendix for supplemental reference material.

PART I: PRINCIPAL OBSERVATIONS

GS1 US submits the following principal observations followed by detailed comments:

- **Principal Observation 1**: FDA's Proposed Rule is different from commonly recognized traceability concepts widely used and employed by U.S. and global food businesses.
- **Principal Observation 2**: FDA's Proposed Rule appears to employ definitions that lack the necessary consistency, clarity, and/or precision for rapid and effective food traceability and recall.
- **Principal Observation 3:** FDA's Proposed Rule appears not to recognize the necessary standardized data structures for rapid and effective food traceability and recall.

Principal Observation 1: FDA's Proposed Rule is different from commonly recognized traceability concepts widely used and employed by U.S. and global food businesses.

GS1 US appreciates FDA's reference to GS1 Standards in the Proposed Rule. However, there is a lack of alignment between how industry and GS1 US use these concepts and terms and how FDA uses these same concepts and terms in its Proposed Rule.

The differences are most notable in how FDA employs the foundational GS1 concepts and terms for "common language;" "unique product ID;" "data structure;" "traceability;" and "interoperability."

Below, GS1 US addresses these differences:

- **Common Language**

  Creating a common language for rapid and effective food traceability and recall requires the use of precise and consistent terminology (words) as well as the use of precise and consistent data structure or syntax (grammar). FDA's Proposed Rule does not provide this guidance.

  FDA Proposed Rule: In the Proposed Rule, FDA notes how a minimum set of critical tracking events (CTEs) and key data elements (KDEs) are necessary to provide a framework or "language" for communicating tracing information throughout supply chains. A minimum set of KDEs and CTES are better than not having any set. The KDE/CTE standardization becomes more critical for administering and unifying the approach to recordkeeping. Though the FDA is focused on improving public health, FDA should not lose sight of the importance of business systems. It should be clear that a minimum set of data alone will not provide sufficient guidance and direction to achieve FDA's desired level of interoperability and traceability. The data must have structure and capable of being shared, which FDA does not address in the Proposed Rule.

GS1 US: By comparison, the structured nature of GS1 Standards easily provide for the seamless and interoperable sharing of KDEs/CTEs allowing for complete interoperability and traceability.

> **Put differently, it is the use of clear, consistent, and well-defined terms in a structured format embodied by GS1 Standards that creates a common language spoken within U.S. and global supply chains. Industry and GS1 US have refined this approach continually over nearly five decades.**

By leveraging GS1 Standards, businesses can identify, capture and share information, enabling them to communicate and to facilitate end-to-end food traceability and recall in the marketplace today, irrespective of the systems and technologies used by individual businesses.

- **Traceability**

The International Organization for Standardization (ISO) Standard 9001-2015 defines traceability as "the ability to trace the history, application, or location of an object." When considering a product or a service, ISO goes further to note that traceability can relate to a.) the origin of materials and parts; b.) the processing history, or c.) the distribution and/or location of the product or service after delivery.

FDA Proposed Rule: In the Proposed Rule, FDA discusses the importance of a robust traceability system and how sufficient traceability information is needed to identify the source of an outbreak. FDA suggests specific types of records that could be captured and used by entities (beyond FDA alone) to improve traceability. However, a robust traceability system is more than just keeping specific records to help businesses and/or FDA manage product recalls. Traceability is about providing proper identification, visibility and sharing of information among supply chain customers and suppliers at all times to enhance accountability, food safety management and prevent food risks from arising as well as to manage food recalls.

GS1 US: By comparison, the industry's approach leveraging GS1 Standards to enable supply chain traceability is focused on the use of open standards to provide visibility and sharing of objects and data that are relevant to supply chains at all times.

GS1's definition of traceability is possible through the use of three key enablers:

1. Identification of objects, parties, and locations throughout the supply chain;

2. Capture Standards [Automatic identification and data capture (AIDC)], help bridge the physical and digital information world. By embedding a globally unique identifier in the barcode directly on a product and then directly referring to that identifier in the data shared, there is a bond formed between the data talking about the journey of the food product and the actual food itself. Before capture standards, information had to be entered manually, thereby making it vulnerable to errors. As a result, the industry adopted the barcode to eliminate these errors.

3. Sharing traceability data allows for supply chain partners to appropriately share information, which will make the "robust traceability system" more effective and easier for FDA to collect data throughout the supply chain.

- **Product Identification**
  Product identification is a number identifying any item that is priced, ordered or invoiced, and that can be used as reference where there is a need to retrieve predefined information about that item.

  FDA Proposed Rule: In the Proposed Rule, FDA creates a new term called, "Traceability Product Identifier," a unique identification code that could be, but not necessarily is, an alphanumeric code that an entity assigns to a designated food product. The lack of precision regarding what constitutes "unique identification" allows for the unrestricted use of internal coding systems created and used by individual companies. These private coding systems are not standardized by industry and can significantly restrict system interoperability between supply chain customers and partners.

  GS1 US: By comparison, one of the principles behind GS1 Standards is globally unique identification. One example of this is the GS1 Global Trade Item Number (GTIN), a globally unique, defined numeric standard widely used by industry today in the United States and globally. *Note: This is the product identifier encoded into the U.P.C. barcode we all know as consumers.*

  It is worth noting in FDA's *Investigation Report: Factors Potentially Contributing to Contamination of Romaine Lettuce Implicated in the Three Outbreaks of E. coli 0157:H7 During the Fall of 2019* stated that "because of industry voluntary labeling of harvested romaine lettuce…consumers were able to more quickly identify potentially contaminated products." In fact, the FDA recommended later in the report that to improve traceability, there needs to be an increase in digitization, interoperability and standardization of traceability records, which would expedite traceback and prevent further illnesses. With a "broader, more consistent implementation of voluntary source labeling on the packaging …consumers and retailers more readily identify product during an outbreak or recall." The GS1 Standards achieve these aims.

- **Data Structure**
  Data structure is the format, length, acceptable characters, and relationships of data elements that help prevent misalignment between expected data and the data actually shared between customer and suppliers.

  FDA Proposed Rule: In the Proposed Rule, FDA does not mention "data structure" formally, by name, but does allude to the concept when discussing the "standardization of data elements." The Proposed Rule states, "Standardization of data elements is needed to help ensure successful traceability throughout the supply chain." This standardization cannot simply be a list of minimum data elements employed by industry. It also must be about how data elements are specifically formatted or structured together.

GS1 US: By comparison, GS1 Standards provide a comprehensive set or system of standards to identify, capture and share information about food (or other objects) throughout their lifecycle, providing the foundation for interoperability and the seamless sharing of information between and among supply chain partners. Consistent with GS1 Standards, we recommend that FDA better define the need for both data *and* data structure in its final rule and acknowledge their shared importance in achieving interoperability and traceability across the supply chain.

- **Interoperability**

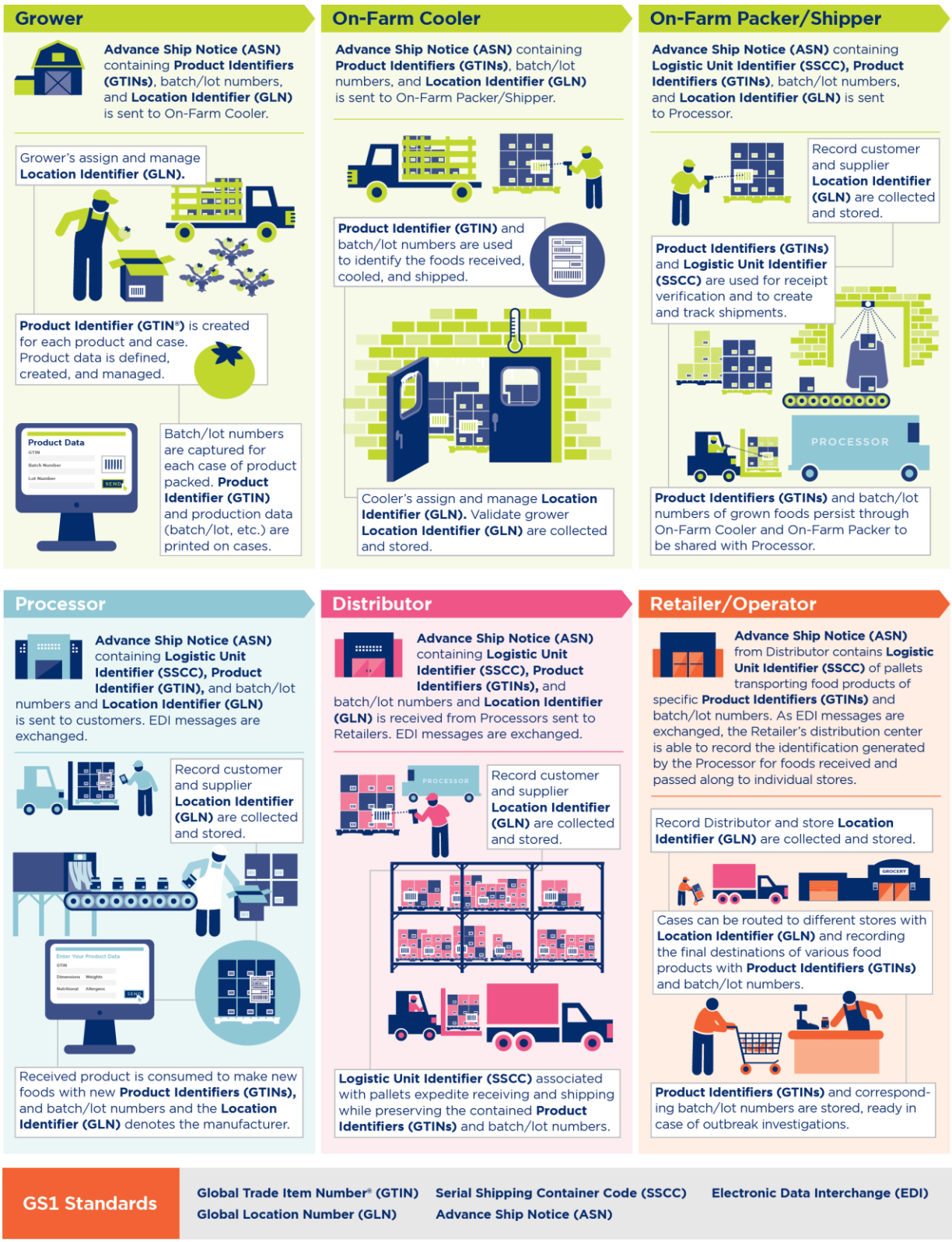
  Interoperability is made possible by identifying, capturing and sharing product/object/location data in a common language and structure so information can flow freely and efficiently between supply chain partners.

  FDA Proposed Rule: In the Proposed Rule, FDA states how information needs to be adequately understood when it comes to the terminology, methods and systems a business employs for its traceability operations and not the overall supply chain. In fact, FDA references the GS1 Global Product Classification code (GPC) as a classification scheme developed by industry. Critically, however, FDA discusses use of GPC only by individual firms rather than the many players in broader and more complex supply chains. Interoperability is about the standard classification scheme for sharing information between and among supply chain partners and not individual firms.

  GS1 US: By comparison, GS1 Standards provides a comprehensive set of standards to help different businesses in the supply chain communicate more effectively with each other, providing the core foundation for interoperability. Relevant here:

  1. Supply chain partners **identify** business products/objects and locations using standardized identifiers.
  2. Supply chain partners **capture** a product/object's identity and any additional attributes (e.g., the expiry date) that have been encoded in a standard manner in a data carrier (e.g., barcodes, RFID). This ensures the object can be read automatically and consistently throughout the supply chain.
  3. Once supply chain partners are using a common language for identification and data capture, the gathered data is refined and enhanced with business context to transform it into data that can be **shared** using standardized formats. These can include data about time (i.e., when), location (i.e., where) and other data (i.e., who and why) related to the product/object.

The following graphic further illustrates how GS1 Standards are used today by industry.



GS1 US, marketplace stakeholders, and FDA have invested 47 years in defining and establishing a strong connection between these concepts as well refining the meaning of these terms. And we are pleased to see FDA gravitating towards the use of these concepts and terms in the Proposed Rule.

However, FDA's definition and use of these concepts and terms is *not precisely aligned with how they are used by industry and supported by GS1 Standards.*

In its Proposed Rule, we recommend FDA tighten the use of these terms to align with the common usage in industry to minimize business impact as described above.

It is understandable that FDA attempts to provide regulatory flexibility given the broad cross-section of agri-food interests that would be affected by FDA's proposal. FDA's current approach is, in effect, encouraging the establishment of two traceability systems—one for government and another for the industry—generating confusion as well as operational redundancies, inefficiencies and costs for regulated food businesses.

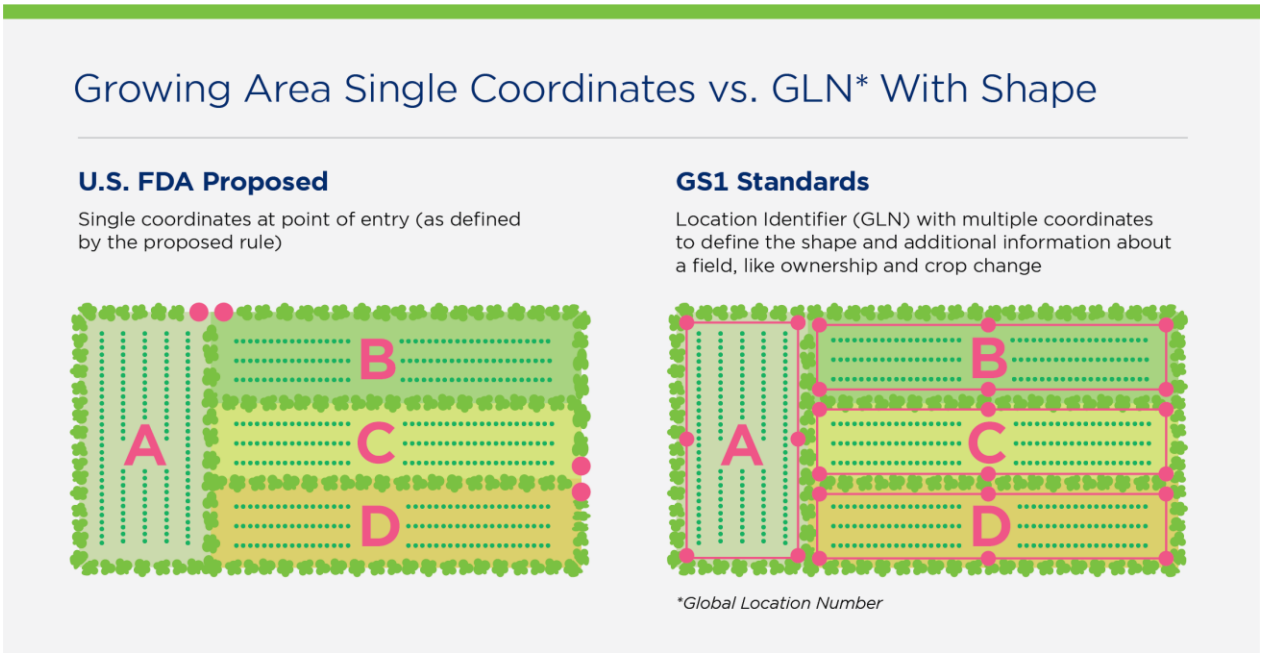
Principal Observation 2: FDA's Proposed Rule appears to employ definitions that lack the necessary consistency, clarity, and/or precision for rapid and effective food traceability and recall.

FDA's proposed definitions are central to understanding how FDA proposes to establish food traceability and recall system requirements. While many of the terms FDA proposes are aligned with those used in the marketplace, others are not and should be tightened, consolidated, or expanded. Some terms are similar and have expanded meanings while other key terms appear to have been overlooked, as explained below.

- **Need for Greater Clarity - "Growing Area Coordinates"**

FDA Proposed Rule: FDA's proposed requirement for the "growing area coordinates" for farms would require only the GPS coordinates for a specific point-of-entry to a field without further attribution. Use of a single pair of GPS coordinates would encompass sizeable geographies and fall short of what a business or FDA could use to locate a *specific* field in instances where either is trying to "rapidly and effectively" locate potential sources of foodborne contamination.

GS1 US: GS1 US recommends the use of global identification standards, such as GS1's Global Location Numbers (GLNs) to address this issue. A GLN could identify more specifically a field with a list of GPS coordinates for the whole shape of the field which, for example, would provide a more precise story of how airborne contamination from neighboring fields/pastures affected the grown food.



Per the Proposed Rule, when a field is merged with another field or there is a change in ownership, the GPS coordinates of the entry point of the physical location/field where the food was grown and harvested may be unchanged. It also should be highlighted that plots of farming land are leased and constantly redrawn, which might not be well captured with just a GPS coordinate designation as stated in the Proposed Rule. This lack of visibility into such changes could be significant in revealing how a foodborne illness occurred in a new season but not in a previous one. GLNs, with a list of GPS coordinates and other critical attributes about a location, could capture the information more efficiently for the FDA and improve the tracking of changes and updates.

- **Need for Greater Consistency - "Traceability Lot" vs "Lot"**

FDA Proposed Rule: In the Proposed Rule, FDA introduces new terms that are similar, but not identical to GS1 terms, potentially confusing regulated businesses. For example, "traceability lot" (TL) can be interpreted to be the same thing as "lot" or it can be viewed different depending on the business and supply chain. In fact, TL intends to serve the same purpose as lot code, but TL starts at the origination of the product and for the products on the Food Traceability List (FTL).

GS1 US: GS1 US recommends a simpler, clearer approach. FDA should build on the industry/GS1 Standard definition for "lot." Industry already has a working process, so FDA should consider the Produce Traceability Initiative's (PTI) – P7 Milestones to PTI Implementation. The PTI meets the requirements and needs of the Proposed Rule. Therefore, GS1 US recommends FDA draw upon existing marketplace best practices that are being applied and used successfully, such as those adopted under PTI.

Principal Observation 3: FDA's Proposed Rule appears not to recognize the necessary standardized data structures for rapid and effective food traceability and recall.

In the Proposed Rule, FDA takes a detailed, process-based approach to establishing step-by-step requirements for enabling food traceability and recall. GS1 US supports this approach.

However, we recommend FDA ***simultaneously*** take a systems-management approach, examining how these detailed requirements work together to create an operating framework that accounts for how those systems work with other systems as well.

> **This could be done through the use of standards for both globally unique product identifiers and data structures (or syntax). Once a product is uniquely identified, the data is pieced together or structured in a specific order that conveys the history of that product and how it is transformed and moves through complex supply chains, thus enabling traceability. The globally unique identification is lost if this structure or syntax is garbled just as the syntax is lost if the product lacks globally unique identification.**

On a more detailed level, GS1 US cautions FDA: **key data elements** (**KDEs) and critical tracking events (CTEs) alone are insufficient without proper data structure** (and syntax) for the data that is being requested.

Put differently, globally unique identification provides the words and data structure provides the proper grammar that, when combined, constitute the common language spoken by supply chain customers and partners.

The two components have distinct, but integrated roles. Any missing or overlooked word or garbled syntax inhibits understanding of the information that is being

conveyed and limits industry's ability to act in an adverse event. Data that does not align with a standardized data structure challenges the ability of businesses and FDA to execute food traceability and recall "rapidly and effectively." This often occurs when individual businesses incorporate company-specific data into standardized data shared across supply chains, impeding any chance of translation, or understanding.

This hybrid model of both standardized (GS1) and non-standardized (proprietary business) data is common today and would continue to occur under FDA's proposed definition.

Below is a snapshot of how GS1 Standards are already meeting the needs of industry today when it comes to complying with the FDA proposed rule. It should be noted that the comparison below is not necessarily an exact match and it is important to consider the differences between the Proposed Rule and GS1 Standards.

Example. Distributor Receiving KDEs Snapshot Comparison Between FDA Proposed Rule and GS1 Standards

US FDA Proposed Rule KDEs	GS1 global standards available and adopted/used by industry		Difference: Proposed Rule v. GS1 Standards
Immediate previous source location identifier and description	☑	Location Identifier: GS1 Global Location Number (GLN)	GLNs are globally unique; Proposed rule lacks definition of sufficient uniqueness
Entry number (if imported)		Business Transaction Type/ID	GS1 Standards do not support data format for this today, but could be discussed by the industry
Receiver location identifier and description	☑	Location Identifier: GS1 Global Location Number (GLN)	GLNs are globally unique; Proposed rule lacks definition of sufficient uniqueness
Receipt date and time	☑	Event Time	Proposed rule lacks definition of acceptable format(s) for Date & time, inhibiting interoperability
Quantity received and unit of measure	☑	Quantity and Unit of Measure	Proposed rule lacks definition of acceptable Units of Measure and data structure for Quantity, inhibiting interoperability
Traceability product identifier and description of product received	☑	Product Identifier: GS1 Global Trade Item Number (GTIN)	GTINs are globally unique; Proposed rule lacks definition of sufficient uniqueness
Traceability Lot Code	☑	Application Identifier (10) for Batch/Lot	Proposed rule lacks definition of acceptable format(s) for batch/lot; Generates confusion/redundancy with lot code as industry has currently implemented this differently than what is outlined in the proposed rule
Traceability lot code generator location identifier, description and POC	☑	Location Identifier: GS1 Global Location Number (GLN)	GLNs are globally unique; Proposed rule missing definition of sufficient uniqueness
Reference record type(s) and #(s) for documents containing Receiving KDEs	☑	Business Transaction Type/ID	GS1 Electronic Product Code Information Services (EPCIS) standard enables associating business transactions (reference records) to events
Transporter name		EPCIS Extension OR Source GLN	Not a current EPCIS field, generally recorded as an identifier with associated Name KDE

Additional Comments

1. The proposed rule necessitates trading partners repeatedly reshare attributes associated with products, locations, and business entities instead of acknowledging those attributes are populated by one or a few select parties who are responsible for that data.
2. Mandating that trading partners share the generator of Traceability Lot Codes would expose contract manufacturers or parties that suppliers would otherwise like to keep private.
3. While the proposed rule defines discrete Critical Tracking Events (CTEs), it does not require companies to indicate the CTEs in data submissions back to the FDA which could be a critical aid for interpreting the data quickly. EPCIS includes classifications of events to help users and software tools quickly interpret the structure of data contained within the event. Electronic Product Code Information Services (EPCIS) is a GS1 Standard for creating and sharing visibility event data, both across and within businesses, allowing users to gain a shared view of physical or digital objects.

PART II: SPECIFIC COMMENTS TO POINTS RAISED BY FDA

GS1 US appreciates the opportunity to comment on specific concepts, definitions, and requirements raised by FDA in the Proposed Rule. Our comments are as follows:

Specific Recommendations for Definitions

Traceability Product Identifier

FDA's proposed definition for "traceability product identifier" lacks clarity on what constitutes "unique identification," leaving the door open for regulated interests to use internal but not industry-standard product coding schemes. This is also addressed in Produce Traceability Initiative – "Practices for Preparing to Assign GTINs" and the importance of informally-standardized techniques. In discussion of the need for the regulation, FDA notes how inconsistencies in food product identification have undermined tracing during recent outbreak investigations. GS1's Global Trade Item Number® (GTIN®) already reliably serves industry as a unique identifier for products exchanged between trading partners, preventing potential confusion when internal and proprietary identifiers are applied and refencing the same food. Global uniqueness is foundational to GS1 Standards for identifying trade items that prevents confusion of food product identification.

Recommendation: GS1 US and its industry members recommend that FDA use globally unique identification (e.g., a GS1 GTIN) and restrict the use of internal product coding schemes. Globally unique identification enables a product or ingredient to be tagged accurately, and to be identified and traced backed to the source, as well as forward, as an ingredient if processed into highly refined products.

In addition, FDA should restrict the use of internal coding schemes that could impede the effectiveness and speed of any food traceability system as well as the FDA's ability to rapidly and effectively address product recalls.

- Location Identifier

FDA's proposed definition for "location identifier" lacks clarity on what constitutes "unique identification," permitting regulated interests to use internal location coding schemes for identifying their physical locations (just as they do for products). In discussing the need for the regulation, FDA notes how inconsistencies in identification of physical locations and legal entities have undermined tracing during recent outbreak investigations. GS1's Global Location Number (GLN) has served as a reliable globally unique identifier for the relevant locations and entities in the journey of food products from the grower to the point of sale/service. Global uniqueness is a key aspect of GS1 Standards for identifying locations and entities that prevents confusion in identification.

Recommendation: GS1 US and its industry members recommend that FDA restrict the use of internal location coding schemes. Unrestricted use of internal coding schemes could impede the effectiveness and speed of any food traceability system as well as the FDA's ability to rapidly and effectively address product recalls.

- Growing Area Coordinates

FDA's proposed definition for "growing area coordinates" suggests farms only require a single set of GPS coordinates of a field without further attribution. Use of a single pair of GPS coordinates would encompass sizeable geographies and fall short of what a business or FDA could use to locate a specific field in instances where either is trying to locate potential sources of foodborne contamination.

GS1 US encourages FDA to require GPS coordinates as the mandatory minimum information that regulated farms must provide FDA with a preference for use of GLNs.

Recommendation: GS1 US and its industry members and partners recommend FDA employ globally unique location identifiers, such as a GS1 Global Location Number, in any FDA guidance that may accompany the final rule to more expeditiously identify and isolate locations, particularly during food recalls.[1]

The GLN will enable the FDA to use a number of GPS coordinates to more rapidly and effectively identify a specific field that is potentially contaminated. For example, a GLN could identify a field with a list of GPS coordinates for the whole shape of the field that would tell the story more precisely of how airborne contamination from neighboring fields/pastures affected the grown food. Additionally, when a field is merged with another or changes ownership, the GPS coordinates of the entry to the field may be unchanged. The lack of visibility into such changes could be significant in revealing how a foodborne illness occurred in a new season but not in a previous one. GLNs, with a list of GPS coordinates and additional attributes, could capture what the FDA seeks. FDA's recognition of GLNs would be consistent with the statute's requirements to adopt measures that are both "practicable" and consistent with "domestic and international product tracing practices in commercial use."

- Lot

GS1 US recognizes the variation in operations among businesses and the resulting need for lot assignment tailored to those individual operations. GS1 Standards do not define overarching rules for the allocation of lots, only that in situations where multiple companies allocate lots for the same trade item, there are business processes for preventing the duplication or collision of lots assigned from different locations and entities.

Recommendation: GS1 US and its industry members recommend that FDA define the term "lot" using existing marketplace terminology that enables businesses to leverage alphanumeric code without reference to a physical location, production run or other attributes in any guidance that may accompany the final rule. In addition, FDA should consider expanding the definition of "lot" to incorporate the concept of "originated" as found in "traceability lot."

[1] GS1 US would also note that we have a partnership with AgGateway. Their membership utilizes the GLN to identify over 5 million farming locations. GS1 US assigns a GS1 Company Prefix to a member that can be utilized to identify both products (GTINs) and locations (GLNs).

- Traceability Lot

As previously mentioned, FDA's proposed definition for "traceability lot" could be viewed by regulated parties as redundant and confusing because of the use of the term "lot." The addition of "traceability lot" appears to be a recognition that assignment of a batch / lot and a unique identifier for food products can occur before food has undergone a manufacturing step.

Recommendation: GS1 US and its industry members recommend that FDA refrain from creating new terminology, such as the term, "traceability lot," and instead align with the marketplace use of the term "lot" and make further additions to that definition in any FDA guidance that may accompany the final rule.

- Traceability Lot Code

GS1 US supports FDA's use of unique, alphanumeric code to identify a specific lot. However, FDA should also recognize the importance of a consistent syntax found in the GS1 US Application Identifier AI (10), to ensure supply chain partners are speaking the same, common language. Without recognizing the importance of data structure, the interoperable exchange of traceability records tied to a Traceability Lot Code will be impossible to achieve.

Recommendation: GS1 US and its industry members recommend that FDA use GS1 Application Identifiers (AIs)—specifically AI (10) as the syntax for batch/lot identification—to enable better marketplace interoperability in any FDA guidance that may accompany the final rule. Better interoperability supports FDA's desire for industry to safely, securely and effectively exchange and use information between industry partners and the FDA.

- Traceability Product Description

GS1 US applauds FDA's recognition that food products have attributes that provide a more holistic portrayal of the product's characteristics across lots. Additionally, GS1 US applauds FDA's recognition of widely used classification standards such as the GS1 Global Product Classification code (GPC) standard and the United Nations Standard Products and Services Code® (UNSPSC®) within this definition. However, the agency's definition for the balance of KDEs as part of Traceability Product Description fails to recognize the necessary data structure and syntax that enables sound capture and exchange between parties.

Recommendation: GS1 US and its industry members recommend the FDA recognize widely used definitions and syntax for product information as defined within the GS1 Global Data Synchronization Network™ (GDSN®) standards. GDSN standards are developed by industry to reliably communicate product information between trading partners in a trusted manner, leveraging standardized meaning and data structures, and should therefore accompany the final rule.

- Location Description

GS1 US applauds FDA's recognition that physical locations have attributes, which gives a more holistic description of the location. However, FDA's definition for the attributes fails to recognize the necessary data structure and syntax that enables sound capture and exchange between parties.

Recommendation: GS1 US and its industry members recommend FDA employ widely used definitions and syntax for attributes of physical locations per GS1 Standards and restrict the use of internal coding schemes in any FDA guidance that may accompany the final rule. FDA should instead align with common locations attributes shared in existing platform definitions instead of proposing new definitions of attributes for a location.

- Reference Record

FDA's proposed definition of "reference records" that must be provided to support product traceability and recall includes records that cannot support actors in the marketplace using GS1 Standards. This undermines the statute's requirements that FDA to adopt approaches that are "practicable" and "reasonably available and appropriate."

Recommendation: GS1 US and its industry members recommend any FDA guidance that may accompany the final rule to recognize the use of electronic exchange of traceability data (e.g., The Global Data Synchronization Network™ (GDSN®), Electronic Product Code Information Services (EPCIS), Electronic Data Interchange (EDI)).

- First Receiver

FDA defines "first receiver" as the first non-farm personnel that purchases and takes physical possession of the food as well as keeps certain records that are not required for other receivers. Unfortunately, this term lacks the clarity. Individuals might not realize they are a first receiver depending on the complexity of the supply chain and there are already other means to gather the desired information today.

Recommendation: GS1 US and its members recommend FDA not introduce the term "first receivers" because it creates uncertainty as well as undue burden on certain supply chain partners. The additional information relating to growing, harvesting, and cooling can already be obtained from the entities that perform these functions, by using the authority granted by the U.S. Public Health Service Act.

Topics relating to KDEs/CTEs and Recordkeeping

- Unique Identification for Businesses

FDA's proposed definition for harvesters only defines requirements for attributes that describe the harvester. FDA does not address the unique identification of business or legal entities operating as harvesters while readily available marketplace tools exist to do so, such as GS1 Global Location Numbers (GLNs). GLNs can be used to identify any physical location and more importantly, corporate or business interests where unique identification is critical, for example, for corporate taxation, business operations or product storage.

Recommendation: GS1 US and its industry members recommend FDA employ GLNs in any FDA guidance that may accompany the final rule to more expeditiously and effectively narrow food recalls.

- Capture Standards (Use of AIDC Tools)

The Proposed Rule does not address the importance of capturing product identities physically on food products for robust food traceability in conjunction with sharing traceability data. Automatic Identification and Capture (AIDC) tools (e.g., barcodes and RFID tags) play a vital role to ensure congruence between the traceability data that is exchanged and what transpired within food supply chains. These tools capture food product identities and other pertinent data affixed to the physical object.

Recommendation: GS1 US and its industry members recommend FDA recognize AIDC standards and encourage the use of AIDC tools in any FDA guidance that may accompany the final rule. Additionally, since implementation of these tools is often cost-effective, accessible, and non-proprietary to a single solution, FDA could encourage their use without conflicting with the statutes around technology in FSMA. One example is FDA's use of the GTINs embedded in a U.P.C barcode when issuing recalls.

- Product Hierarchy

While the definition of "Traceability Product Identifier" is sufficiently broad to accommodate different levels of product hierarchy, the Proposed Rule does not address that retailers are typically ordering by the case (identified by GTIN-14), but when the food products are sold to the consumers, they are identified at the product level (GTIN-12). As a result, when a public health inspector finds the empty packaging of a contaminated food product, they will find the GTIN-12, but may not be able to quickly tie that to the GTIN-14s the retailer received. This presents an acute risk in outbreak investigations where evidence of a person who has fallen ill from an outbreak points to a consumer level item but all of the supply chain records point to a higher-level of packaging.

Recommendation: FDA should consider that food products are often a part of a product hierarchy that identifies the relationship between how a food product is identified for consumer sale/service versus how it is identified among trading partners. Specifically, GS1 US and its industry members recommend FDA recognize that the product identification employed on consumer-ready units is a lower-level packaging than the product identification for efficiently ordering and tracking between trading partners. To accurately connect outbreaks of illness with the supply chain that delivered contaminated food products, the final rule should include provisions for declaring parent/child relationships between the food product identifiers utilized on consumer-ready units and the higher levels of packaging that often bring the consumer-ready units to point of sale.

- Data Sharing

The Proposed Rule does not discuss the importance of data sharing amongst supply chain partners and focuses too narrowly on data collection between only the entity and the government. Sharing data and records in today's fast-moving agri-food and retail marketplace is most widely and commonly facilitated using digital data-sharing standards, such as: (1) GS1's Global Data Synchronization Network (GDSN) for product information (Trade Item Data); (2) Electronic Data Interchange (EDI) for transactional data; and (3) GS1's Electronic Product Code Information Services (EPCIS) for physical event data. However, these standards are not appropriately considered in the current draft rule.

Recommendation: GS1 US and its industry members recommend FDA highlight widely used marketplace standards for digital data sharing, such as GDSN, EDI, and EPCIS, in any FDA guidance that may accompany the final rule. Such standards reflect the evolution of the marketplace away from the paper-based traceability systems employed a decade ago (and which are the foundation for newer technologies), toward the digital systems being used today. In addition, since the standards are well-known, they can improve regulatory compliance from industry and reduce costs.

- Serial Shipping Container Codes (SSCC)

FDA's Proposed Rule does not mention the role of the Serial Shipping Container Codes (SSCC) to complement batch/lot level tracing of food products. This is a widely used identifier which facilities traceability of logistics units in transport and/or storage. Utilization of the SSCC aids in tracing the specific path of food product in a traceback situation, working in conjunction with batch/lot level identification and without necessitating item-level serialization. A "lot" can be split into two pallets and shipped to two different locations. SSCC will uniquely identify each pallet and make it easier to identify where each pallet is located.

Recommendations: GS1 US and its industry members recommend FDA recognize the utility of the SSCC and include SSCC in any FDA guidance that may accompany the final rule as they facilitate the process of tracing and recalling food.

- Linking Lot Code (Traceability Lot Code) and KDEs

Throughout the proposed record-keeping requirements, FDA calls for "linking the traceability lot code of the food" to the respective KDEs of the event in focus. The language could be open to multiple interpretations.

Recommendation: GS1 US and its industry members recommend that FDA clarify what is intended by "linking the traceability lot code of the food" to respective KDEs. In addition, GS1 US and its members recommend that any clarification should reference

GS1 Share Standards (Electronic Product Code Information Services (EPCIS) and Electronic Data Interchange (EDI) by name in the final FSMA, Section 204 rule. Finally, we recommend that FDA point to GS1 Standards as an example of how the Traceability Lot Code is linked to the data FDA is requesting in FDA's final rule and any accompanying guidance.

PART III: FDA RECOGNITION OF VOLUNTARY CONSENSUS STANDARDS

As discussed above, our Primary Recommendation is that GS1 Standards be identified as an alternative means of compliance with the FSMA, Section 204 final rule. As discussed below, the statutory authorities available to FDA provide sufficient authority to allow it to implement a final regulation consistent with our Primary Recommendation.

FSMA, Section 204(1)(d)(A), (E), and (G)

FDA has the statutory authority to recognize GS1 Standards in its final rule under FSMA, Section 204 itself. Section 204 encourages FDA to act in a "reasonable and practicable manner" informed by real-world pilots. For instance, with respect to record keeping requirements for high-risk foods, Section 204 requires that requirements "relate only to information that is reasonable and appropriate," "be ***scale-appropriate and practicable for facilities*** of varying sizes and capabilities," and most importantly, "***to the extent practicable, not require a facility to change business systems*** *to comply with such [recordkeeping] requirements."* *See* Section 204 (1)(d)(A), (E), and (G).

As commonly recognized standards used widely by large and small food businesses in the U.S. marketplace today, GS1 Standards meet each of these requirements.

- **GS1 Standards relate only to information that is reasonable and appropriate.** GS1 Standards are the most widely recognized and commonly used data standards for identifying, capturing, and sharing information between and among customers and trading partners in the marketplace today. This includes product safety, handling, and processing information, among other data.

- **GS1 Standards are scale-appropriate and practicable for facilities of varying sizes and capabilities.** The standards are employed by producers, processors, transporters, retailers, and restaurant operators of all sizes, large

and small, throughout all sectors of the U.S. agri-food economy, producing as well as importing food into the United States.

- **GS1 Standards do not require a facility to change business systems.** The standards are expansive and industry-defined so data attributes align with internal systems and harmonized to meet the needs of the industry.

GS1 US requests that FDA leverage these provisions, therefore, individually, and collectively, to formally recognize GS1 Standards by name in the final rule.

National Technology Transfer and Advancement Act

In addition, FDA has the statutory authority to recognize GS1 and other "voluntary consensus standards" under the National Technology Transfer and Advancement Act (P.L. 104-113) (NTTAA).

Specifically, the White House/ Office of Management and Budget (OMB) Circular A-119, written pursuant to NTTAA, recognizes that voluntary, consensus standards used by business in the marketplace today are appropriate or adaptable for U.S. Government purposes and encourages their use, specifically:

> ***OMB states that "All federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical."[2]***

OMB Circular A-119 has been employed by FDA and other agencies to recognize voluntary consensus and technical standards for over 20 years across both Democratic and Republican administrations.

Every year, the U.S. Department of Commerce issues an annual report on the U.S. Government's use of voluntary consensus standards. In its 2011 report, the Department's National Institute of Standards and Technology tracked government use of voluntary consensus standards by just 25 U.S. Government agencies and identified over 9,360 citations of standards incorporated by reference into U.S. Government regulatory documents – more than 80 percent of these were developed by the private sector, illustrating the extensive use of voluntary standards throughout the U.S. Government. [Report on Federal Agency Use of Private-Sector Standards and Conformity Assessment Activities for Fiscal Year 2010, U.S. Dept. Of Commerce, 2011; Executive Summary, page 3.]

Relevant to FDA here, GS1 Standards meet the definition of voluntary consensus standards established in OMB Circular A-119:

- OMB Circular A-119 requires "standards owner of relevant intellectual property to make that intellectual property available on a non-discriminatory, royalty-free or

[2] Circular No. A-119 Revised Feb. 10, 1998, p. 7. https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-119-1.pdf

reasonable royalty basis to all interested parties."[3] Here, the intellectual property invested into the development of the GS1 Standards is **readily available to users on a non-discriminatory, royalty free or "reasonable royalty basis" to all interested parties**, both in the United States and globally, and

- OMB Circular A-119 requires that "voluntary consensus standards bodies" are domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures." [4] Here, GS1 Standards have been and are being developed using the agreed-upon Global Standards Management Process (GSMP). GSMP is the governance model for developing and modifying standards through a development lifecycle that includes a comprehensive set of rules allowing GS1's community of stakeholders to reach consensus on user-driven standards. This process encourages the following attributes[5]:

  1. **Openness:** GS1 provides interested parties meaningful opportunities to participate in standards development on a nondiscriminatory basis. The procedures or processes for participating in standards development and improving upon the standards are transparent;

  2. **Balance:** The standards development process should be balanced. Specifically, there should be meaningful involvement from a broad range of parties, with no single interest dominating the decision-making;

  3. **Due Process:** Due process shall include documented and publicly available policies and procedures, adequate notice of meetings and standards development, sufficient time to review drafts and prepare views and objections, access to views and objections of other participants, and a fair and impartial process for resolving conflicting views;

  4. **Appeals Process:** An appeals process shall be available for the impartial handling of procedural appeals; and

  5. **Consensus:** Consensus is defined as general agreement, but not necessarily unanimity. During the development of consensus, comments and objections are considered using fair, impartial, open, and transparent processes.

- OMB Circular A-119 encourages U.S. Government agency representatives to participate in the work of voluntary consensus standards organizations to 1)

- "eliminate the necessity for development and maintenance of separate Government-unique standards" and 2) further national goals.

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[3] Circular No. A-119 Revised Feb. 10, 1998, p. 6. https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-119-1.pdf
[4] Circular No. A-119 Revised Feb. 10, 1998, p. 6. https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-119-1.pdf
[5] "Recognition and Withdrawal of Voluntary Consensus Standards – Guidance for Industry and Food and Drug Administration Staff; September 15, 2020; pages 2-3.

- OMB Circular A-119 identifies appropriate agency "support" for such organizations beyond agency participation in the standards-setting process alone, e.g., direct financial support, hosting of meetings, standards evaluation. In this case, **GS1 US has a long history of welcoming both the participation and support of not only the FDA and other U.S. Government agencies, into our standards process but also many other foreign governments and ministries. This supports the desired collaboration defined in FSMA.**

Finally, FDA established a Standards and Conformity Assessment Program and regularly employs voluntary consensus standards in its oversight of medical drugs and devices under NTTAA. FDA recognizes the use of voluntary consensus standards and their ability to "increase predictability, streamline premarket review, provide clearer regulatory expectations, facilitate market entry and to promote international harmonization."[6] This should be true for medical products, for which the Guidance was written, and it should also be true for other products regulated by FDA.

For these reasons, GS1 US kindly requests FDA recognize GS1 Standards (and others) by name in its final regulation as an alternative tool for regulated businesses to comply with its FSMA, Section 204 final rule.

[6] "Recognition and Withdrawal of Voluntary Consensus Standards- Guidance for Industry and Food & Drug Administration Staff; v September 15, 2020; page 2.

Here are the foundational concepts upon which GS1 Standards are built.

Basic elements of food traceability

Identify

Products need to be uniquely identified with Global Trade Item Numbers and Batch/Lot information for effective traceability.

Locations need to be uniquely identified with Global Location Numbers to be able to tie Key Data Elements to Critical Tracking Events along the supply chain.

Capture

Product data needs to be captured via barcodes and shared between trading partners for traceability and food safety.

Share

Product master data and location information can be shared with:

- GS1 US Data Hub®
- Global Data Synchronization Network™ (GDSN®)

Critical Tracking Events (CTEs) and Key Data Elements (KDEs) that describe what's happening to products as they travel from source to consumer can be shared with:

- Electronic Product Code Information Services (EPCIS)
- Electronic Data Interchange (EDI) transaction sets/reference documents (e.g. Advance Ship Notice)

PART IV: ABOUT GS1 US

Overview

GS1 US is a neutral, not-for-profit information standards organization with more than 300,000 members in the United States. GS1 Standards are the most widely used supply chain standards in the world. Founded in 1973 and based in Ewing, New Jersey, GS1 US administers the Universal Product Code (U.P.C.) barcode as well as other information standards and data carriers. The familiar barcode is well-known among businesses and consumers alike and is among the most-recognized standards in the world. It launched a revolution in how products are identified and transformed the way the world does business.

GS1 Standards are used in over 150 countries worldwide, providing clarity, consistency, and interoperability in the sharing of information electronically across state, regional and global supply chains. To a great extent, the use of GS1 Standards overlaps with FDA's own guidance on the handling and marketing of domestic and imported food.

In the U.S. food, foodservice, and retail grocery marketplace, GS1 Standards enable supply chain visibility while providing businesses with a much needed and demonstrated return on human and financial investment.

Over our 47-year history, the GS1 Standards' core principles of unique identification have kept pace with industry, even as technology has evolved in how our standards are used and leveraged by U.S. and global businesses.

Tomorrow's digital world will include data-sharing by utilizing blockchain, sensors, artificial intelligence, and the Internet of Things. Businesses within the fast-moving marketplace for agri-food products are investing and applying these tools to their operations. Thus, businesses need to focus on strengthening and advocating for the proven methodologies of GS1 Standards.

GS1 Standards

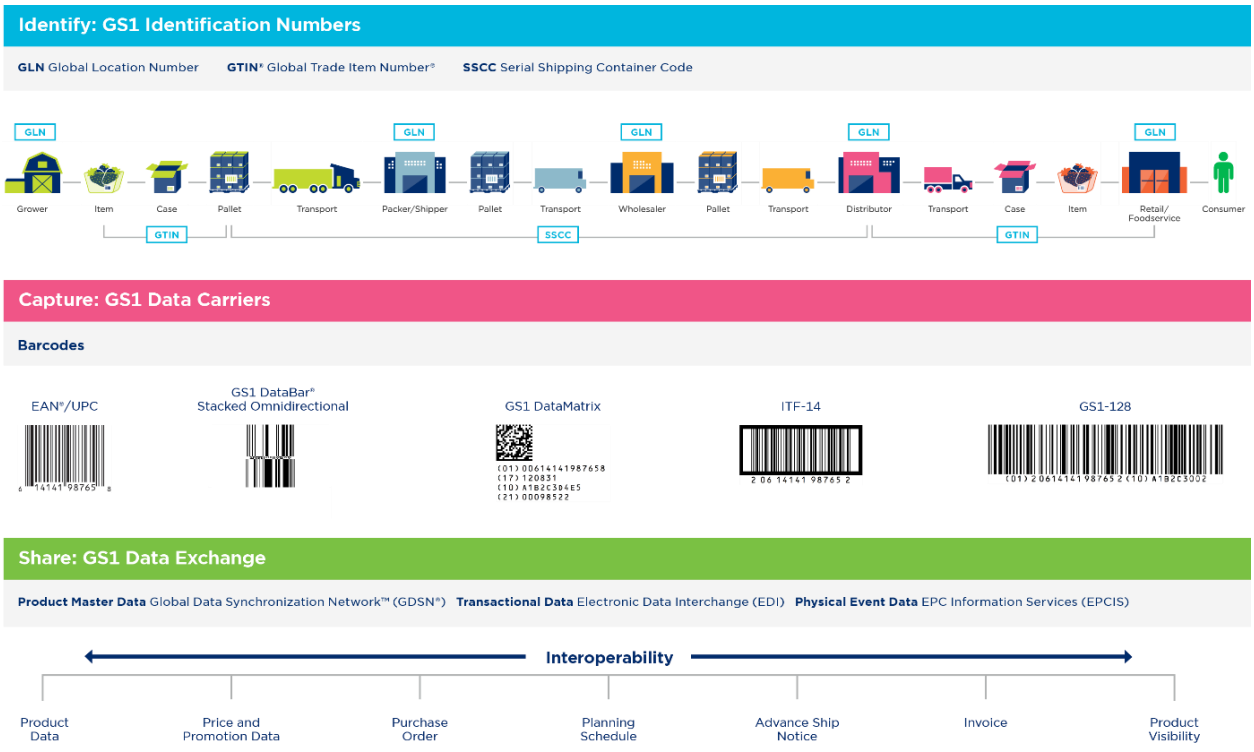
In 1974, the grocery industry came together to agree on a single, uniform method for uniquely identifying products and sharing information, to drive speed and efficiency at retail check-out by adopting the U.P.C. barcode. This cooperation marked the beginning of GS1 US and our mission to help organizations of all sizes – ranging from large multi-national corporations to small start-up businesses – uniquely and consistently identify products, assets, shipments, and physical locations throughout the global supply chain while also enabling customers and suppliers to exchange information critical to their businesses.

As the marketplace has evolved and new technologies have emerged to support the need for enhanced transparency, visibility, and efficiencies, GS1 Standards have kept pace with industry, thus providing a consistent foundation and framework to support and address these business imperatives.

Identify, Capture, and Share

This method for identifying and capturing product data has evolved into what is now known as the GS1 System of Standards, the world's most widely used supply chain standards. The GS1 System of Standards helps companies identify, capture, and share product data across the supply chain. These standards include:

- Sophisticated numbering formats for **identifying** products and locations. The most well-known and frequently used are:
  - Global Trade Item Numbers (GTINs) that identify individual products
  - Global Location Numbers (GLNs) that identify the location
  - Serial Shipping Container Codes (SSCCs) that identify the aggregation of products into larger containers for shipping and transport, e.g., pallets, totes
- A variety of barcodes and Radio Frequency Identification (RFID) tags for **capturing** information in an automated approach
- Electronic Product Code Information Services (EPCIS) enables **sharing** information with trading partners regarding the physical movement and status of products by answering the "what, when, where, and why" questions about those products. This data-sharing standard enables multiple parties to effectively use the specialized framework for sharing information about Key Data Elements (KDEs) at Critical Tracking Events (CTEs).



GS1 US Industry Initiatives

GS1 US industry initiatives bring together industry leaders to identify specific challenges and potential solutions that will lead to continuous progress toward more efficiencies, enhanced risk management, and business growth. These structured initiatives aim to help stakeholders streamline resources, and drive adoption and implementation of the industry-defined solutions leveraging GS1 Standards. GS1 US foodservice and retail grocery initiatives both engage members through workgroups in efforts around supply chain visibility, including enhanced supply chain efficiencies and processes to enable more robust food safety and traceability. The workgroups discuss industry opportunities and create guidelines, tools, roadmaps, case studies, and use metrics in an effort to facilitate the ease of adoption and implementation of GS1 Standards and ultimately enhance current operations in the entire industry community.

By the Numbers

GS1 Standards are the Global Language of Business with:

- More than **2 million companies** using GS1 Standards around the world today;
- More than **6 billion GS1 barcodes** scanned daily;
- More than **100 million products** carrying a GS1 barcode;
- More than **30 million products** registered in the GS1 Global Data Synchronization Network™ (GDSN®)
- More than **30 million products** are assigned U.P.C. barcodes in the GS1 US Data Hub®.

There are many GS1 Standards at work throughout the supply chain and understanding how they connect is critical. As illustrated below, GS1 Standards enable traceability in food supply chains by helping to ensure information flow about products matches up with the physical flow of products.

PART V: APPENDIX

White Paper: Integrated Traceability in Fresh Foods: Ripe Opportunity for Real Results

Case Study: Tyson Foods – Putting Customer and consumers first by leveraging GS1 Standards for stability and velocity

Case Study: IPC/Subway Delivering the Promise of End-to-End Traceability Throughout the Subway System

Case Study: Mother Earth Organic Mushrooms uses GS1 Standards for produce traceability and real-time inventory management

Case Study: Ocean Mist Farms

Case Study: Jem D Farms

Case Study: McLane and DineEquity (IHOP/AppleBee's)

Case Study: Oppenheimer Group

Case Study: Unified Purchasing Co-op (Taco Bell / KFC / Pizza Hut)

Video: Standards in Action – Fresh Foods

Pilot Report: Leafy Greens Action Plan Tech Enabled Traceability – 2020 Leafy Green Pilot Final Report

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IAPMO

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