FMI Traceability Implementation Guide: For the Food Retail Sector and its Supply Chain
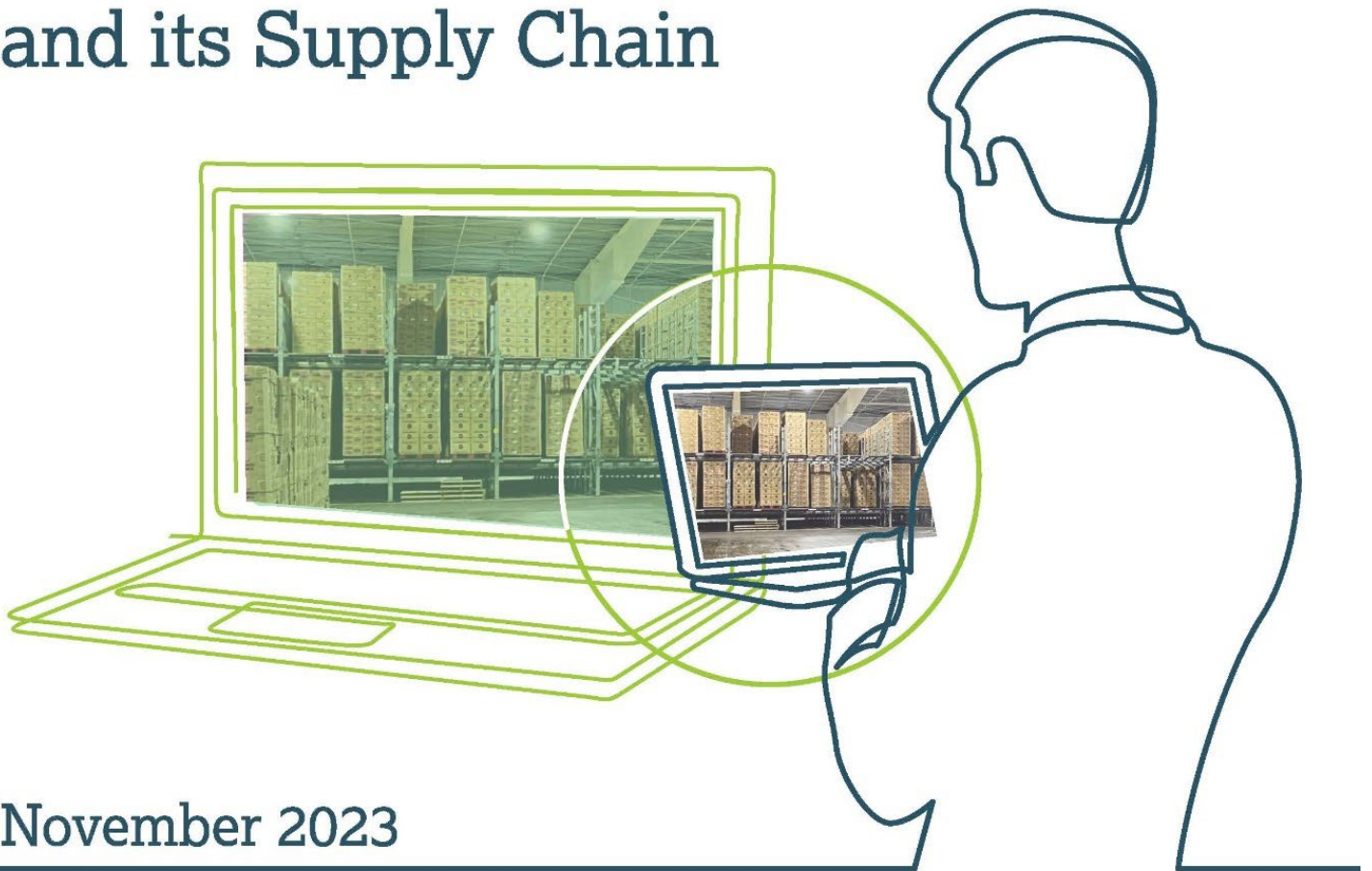
November 2023

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Users Guide

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This document was developed to help FMI members implement the FDA final traceability rule. The following individuals and communities had significant input and contributed time and expertise to this document.

Jennifer McEntire, PhD, Food Safety Strategy, LLC

FMI Food and Product Safety Team

FMI Food Protection Committee

FMI Traceability Steering Committee

GS1 US

Version 1 – Published November 2023

Quick Start Guide

1. Start now; don't wait for the official compliance date (currently January 2026). Evaluate, plan and implement changes to systems and processes to support traceability. Communicate internally and externally. Don't assume trading partners are aware of the rule.
   a. The GS1 US [FSMA 204 readiness checklist](#) provides handy guidance and links to more information.
2. Don't let perfection be the enemy of good. Make progress toward the goal of understanding, with as much granularity as possible, the manufacturer/processor/first receiver of foods on the US FDA Food Traceability List (FTL).
3. Establish a multidisciplinary team, possibly including but not limited to IT, supply chain, procurement, merchandising, compliance, legal and food safety, with a [RACI chart](#) that clarifies the roles of the many team members who will support the company's traceability efforts (those responsible, accountable, consulted and informed)
4. Rely on suppliers to determine and communicate if the food is subject to the rule requirements.
   a. Encourage suppliers to include this as part of the master data they share through the GS1 Global Data Synchronization Network (GDSN)
   b. Alternatively, consider a questionnaire to ascertain if the food is on the FTL, if the supplier is covered by the rule, if an exemption or modification applies, etc.
   c. Consider how your product master data management system can help identify and manage this information.
5. Leverage the GS1 system of standards.
   a. Supplier data elements including key data elements (KDEs) should use the GS1 system because common data sets enable different solutions to interoperate (e.g., GTIN, GLN, etc.)
6. Communicate best practices, requirements and expectations for traceability data sharing through the supply chain (e.g., use of GS1 Standards with [Electronic Product Code Information Services (EPCIS),](#) transmission of information electronically, on the distribution unit, in human readable form, machine readable, etc.)
7. Suppliers should share data elements, including KDEs, via Advance Ship Notices (ASNs) or other electronic data sharing method.
8. Pallets should bear a serial shipping container code (SSCC) that can be used to look up the pallet contents as communicated through the ASN.
9. Retailers should retain ASN transaction data and capture/associate to the inbound SSCC.
10. While not required in the regulation, cases including foods on the FTL should bear a GS1-128 barcode (or more advanced data carrier in the future) with appropriate KDEs (using GS1 Standards), along with other optional human readable information that could

be helpful to the business, such as a voice pick code to aid in inventory management and picking at distribution centers.

11. For retailers with private brand product, we recommend working with co-manufacturers and co-packers to determine responsibilities for and access to traceability information.

12. Consider how you can lean on other supply chain partners/ locations to help manage traceability requirements (e.g., a store relying on shipping records from a Distribution Center (DC) or store receiving direct store delivery (DSD) products.

13. Start small, start simple, and most importantly, align traceability requirements with your peers in a manner that is consistent with pre-existing traceability initiatives. Don't reinvent the wheel.

Starting Point for this Implementation Guide

This guide assumes that the reader's company/ operation is subject to and familiar with the FDA traceability rule. The rule, along with background information provided by FDA, can be [found on FDA's website](#). Additional background on the rule and details on compliance can be found in the [*Guide to the FDA Food Safety Modernization Act Traceability Rule*](#) (NRF and FMI, October 5, 2023). Definitions provided by FDA appear in Appendix A. This guide also references GS1 standards. Information about the standards and how they relate to the rule can be found in the [GS1 US guideline specific for traceability rule implementation for retail grocery and foodservice](#).

This guide is intended to complement and not replace the regulatory language in the rule, the compliance guide or other guidance from FDA. The primary audience for this document is retailers, wholesalers and suppliers seeking to implement the rule, recognizing that the food industry is diverse and complex including but not limited to:

- Retail stores including those that have substantial foodservice operations
- "Hub and spoke" operations; retail stores are co-located with a retail-owned or 3rd party commissary/ central kitchen that may service other stores
- Wholesalers
- Distributors
- Processing/Manufacturing

The document is also intended to aid the broader supply chain, recognizing that the associations that represent various products on the FTL may have additional guidance specific to traceability for that commodity/ product (e.g., the Produce Traceability Initiative- PTI- for produce).

It is impossible to account for every scenario. There may be instances where quickly and perfectly achieving the letter of the law is challenging. Companies should understand the *intent* of the regulation and aim to provide regulators with information that enables them to quickly ascertain the origin of a product as specifically and granularly as possible.

There are two main situations the rule intends to address:

- Recalls: can all recalled product be accounted for, including the use of the product as an ingredient?
  - In general, today's recall processes are effective. The rule may prompt some less sophisticated firms to more easily or expeditiously execute a recall, but is less likely to improve the process for more advanced operations and supply chains.
- Traceback/ outbreak investigations: what product is most likely causing illness, based on supply chain convergence? Of the items that ill persons in different locations reported eating, which product can be traced back to a single manufacturing location, field, etc.?
  - In general, the traceback process, led by regulators, is complicated. Supply chain-wide implementation of the rule is likely to improve the outbreak investigation process in the following ways:
    - If stores can specify lot numbers of products available for purchase within a given date range, regulators can focus on these lots and not waste time tracing items/ suppliers/ lots that are unlikely to be the cause of illness.
    - Consistency in the types of information provided (Key Data Elements; KDEs) will limit the guessing, assumptions, and back and forth between regulators and industry.
    - The use of standards, though not required by the rule, will enable regulators to more easily decipher and link information provided by various supply chain entities.

Outbreak (traceback)
- lot number/ product unknown
- regulatory led

Recall
- lot number/product known
- industry led
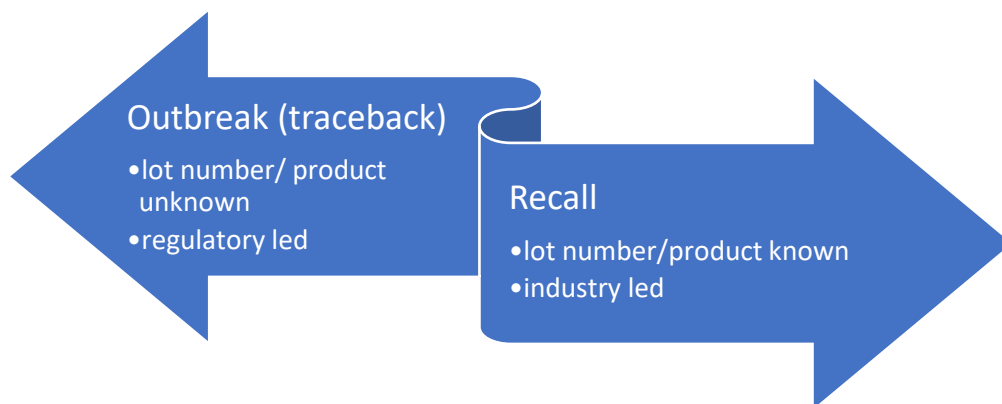
Traceability Team

Traceability is a tool that uses systems and data to understand the movement of product. Although the rule is focused on food safety related use cases (recalls and outbreaks), successful implementation of the rule will depend heavily on individuals with expert knowledge on the physical movement of product and the systems capable of tracking that movement. Roles and titles vary, but typically traceability teams are led by supply chain and/or IT teams who are

advised by food safety and regulatory professionals. The ideal traceability team will have representatives with knowledge of the following systems and processes:

- Inventory management
- Product and vendor information management
- Master data
- Warehouse management systems
- Data engineering/systems architecture
- Produce lifecycle management
- Supplier database/ vendor management
- Buyers/merchants
- Compliance programs
- Store transfer processes
- Contractual arrangements with vendors (and as applicable, customers)
- Budget management

Another way to think about the traceability team and the roles team members should play is to consider who can answer the following questions:

Related to sourcing products and receiving (including receiving ingredients to be used for transformations):

- Who understands which foods may be covered by the rule, and the internal teams that lead procurement of these products?
- Who is responsible for describing items received (e.g., assigning item numbers, nomenclature/ descriptions used in internal systems, etc.)?
- Who manages the relationship with suppliers? Who is responsible for signing the agreement?
- Who maintains contact information for suppliers/vendors, and knows where this information is stored?
    - Who is responsible for updating the product and/or vendor master data management system?
    - Who is responsible for validating data entered by suppliers?
- Who establishes requirements for suppliers?
    - Who can communicate to suppliers the information that needs to be provided electronically and on the physical product (pallet, case, etc.)?
    - Who monitors and assesses suppliers' adherence to expectations?
    - Who manages contracts for foods received directly at stores?
- Who understands system architecture and data management?
    - Where does data flow? How is data retained?
- Who establishes and maintains systems for electronic communications from suppliers?

- In which systems would information from ASNs be stored?
- Who knows how to access and query that information?
- Who understands the receiving process?
  - Who knows what information is captured upon arrival of a shipment?
  - Who understands how incoming product is identified and tracked throughout the system? (e.g., the license plate numbering process, the slotting process for the physical product, etc.)?
  - Who determines the deviation/ resolution process (e.g., product received without required traceability information e.g., missing labels)?

Related to shipping:

- Who understands how inventory is rotated?
  - Is a FIFO (first in first out) system used?
- Who understands the selection/ picking process?
  - What instructions are given to pickers? Are voice pick codes used? Are they directed to select by specific use by/ best by or other date?
- Who understands the order assembly process?
  - Who knows if orders are assembled and palletized by customer/drop off location, or if the driver selects which cases on a truck to leave with each customer?
- Who manages the information sent to customers (including internal customers, like store locations) related to the products on the shipment?
  - Who can query this information?

Related to transformation of retailer production facilities:

- Who knows how ingredient inventories are managed?
  - Is a FIFO system used, or are ingredients selected for use based on other quality factors?
- Who understands how ingredients are linked to the finished product?
  - If electronic systems are used (e.g., an ERP) who manages this system?
  - If manual processes are used, who understands what ingredient information is captured?
- Who understands the production process including:
  - How finished product lot numbers are assigned (e.g., by time, by volume, etc.)?
  - How finished product lot numbers are recorded/ captured?
- If co-manufacturers or co-packers are used, who manages those relationships and discusses compliance with the rule?

Other

- Who manages identifiers associated with the company and/ or location, including:

- o GS1 company prefix(es) and the assignment of item numbers (global trade item numbers or GTINs) for transformed/ manufactured products.
  - o Business and location identifiers such as GS1 global location numbers or GLNs, DUNS numbers, FDA facility registration numbers, etc.
- Who is the key contact for regulators who would be asking about recalls or outbreaks?
  - o Who is the company lead for executing recalls?
- Who understands how items are returned to inventory
  - o When shipments are rejected and items are returned, and/or if partial cases and mis-picks are returned?
  - o When ingredients are not used and returned from the production floor to the warehouse?
  - o When items are sent to a reclaim center?
  - o When items are removed from stock?
- Who manages the relationships with direct to store delivery providers (DSD) and in-store 3rd party vendors?
- Who is responsible for documentation, developing new SOPs and training?
- Who is responsible for management of records (maintenance, systems, storage location, storage capacity, access, protection, retention policies, etc.)?

The individuals responsible for the areas above should be aware of the role they play in the traceability system, and in some companies, the effort may warrant a full-time project lead. A RACI chart should lay out the roles each person will play in the traceability team as the company begins to plan for implementation (who is responsible, accountable, consulted and informed).

Companies that are early in the implementation stage should first map their current systems and processes to determine how data are captured and shared, both internally (intracompany) and externally. This includes an evaluation of, with respect to traceability data:

- What data is shared with you?
- What data do you share?
- What data do you collect, but not share?

The following questions can help the traceability team understand current capabilities and gaps:

- For each Critical Tracking Event (CTE), how are data elements **captured?**
  - o What data elements are missing from/ not being provided by suppliers?
  - o What data elements are provided but not captured internally?
  - o What data elements are captured in electronic systems? Which systems? How long are data retained? How easily can data be searched?
  - o What data elements are captured 'on paper' (including as pdfs, handwritten information, etc.)? Where are these stored and who has access to them?

- For each CTE, what process deviations may occur? How often do they occur, and how they are currently tracked?
- Is data verified? If so, how and by who?
  - *Note: although the rule does not require validation or verification of data shared by suppliers, many companies will want to gauge the accuracy of information so that they can provide feedback to the supply chain in the spirit of continuous improvement.*
- For each CTE, how are data elements **shared?**

Is the Food Exempt? Is the Supplier Exempt?

If you are receiving many foods from many suppliers and supply chain channels it can be difficult to determine which recordkeeping requirements apply. The rule only applies to foods on the [Food Traceability List (FTL)](). However, even for those foods, there can be exemptions or modified requirements. Some of the foods on the FTL may be ingredients in products received (e.g., nut butters can be in confections, salad kit dressings, frozen foods, health foods, bakery items, etc.). The breadth of FTL foods within a manufacturing facility, distribution center or store may extend beyond the scope of the obvious categories.

Is the Food on the FTL?

The entity that is best positioned to determine if a food is on or off the FTL is the producer, packer or harvester of that food, e.g., the one who assigns the traceability lot code. They know the ingredients in the food, whether it was subject to a kill step, etc. They may or may not be your direct supplier; either way, your supplier should be able to communicate this information to you.

There are a few ways that a supplier/producer/manufacturer can disclose that a particular food is on the FTL. In the short term, each receiver can ask the supplier for this information, as described below. Recognizing that suppliers may tire of providing similar information their many customers, another option for suppliers is to utilize the GS1 [Global Data Synchronization Network (GDSN).]() In this way food facilities may receive up to date information directly from the harvester, packer or manufacturer related to the product in real time. There are over 50 GS1 certified "data pools" worldwide that facilitate the transfer of master data (data that rarely changes, as described later in this document, including KDEs like addresses). The information flow is illustrated below.
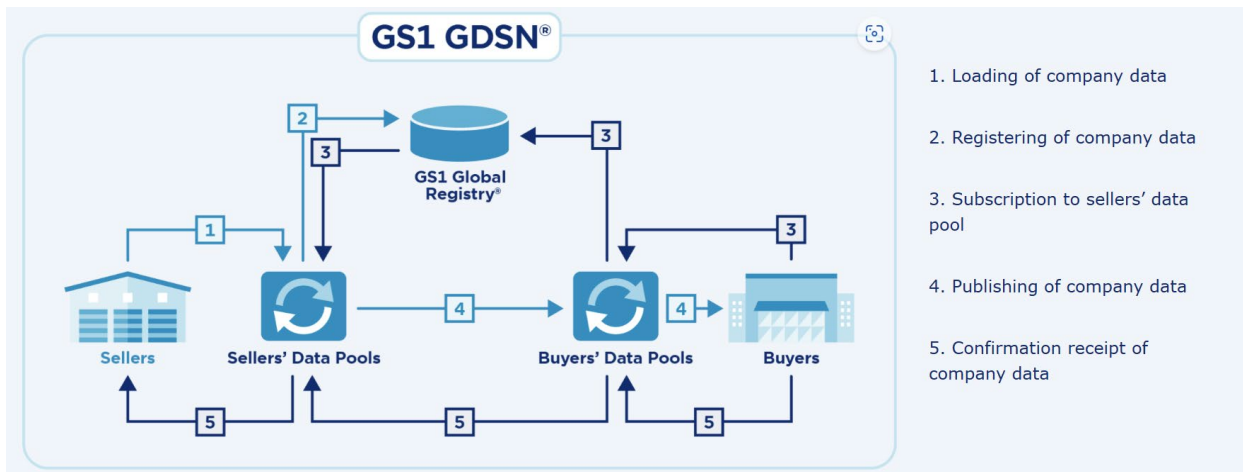
Figure 1. [How GS1 GDSN works - Services | GS1](#))

If the supplier (producer/ manufacturer) or the retailer is not currently part of the GDSN, and/or pending other business reasons, a receiver (e.g., a retailer) can also ask suppliers about the applicability of the rule via a questionnaire, for example, as part of a supplier approval survey. A model questionnaire could be structured as a drop-down menu to include the following:

- Is the item subject to the traceability requirements?
    - If not, why not?
        - There is a kill step (1.1305(d)(1), (2), or (3))
        - Food was changed (e.g., in form) so it's no longer on the FTL (1.1305(d)(4))
- Are you as a supplier required to keep records for this item as part of the traceability rule?
    - If not, why not
        - Farm with average annual sales less than $25,000 (1.305(a)(1)(i) or (ii), or (3))
        - Shell egg producer with <3,000 laying hens at a particular farm (1.1305(a)(2))
        - Produced and packed on farm with packaging integrity maintained to prevent subsequent contamination, and with labeling that reaches the consumer as specified in 1.1305(c)
            - Note: the retail food establishment does not need to keep records other than the name and address of a farm when the farm ships FTL food *directly* to the store (e.g., not the DC). However, the farm is still required to maintain records unless the packaging and consumer-level labeling applies. 1.1305(j)
    - *When the supplier is not subject to the rule, but the food is, the DC may need to assign a lot number to the food if one does not exist (additional discussion*

appears later in this document). This does not apply if the food is shipped directly to the retail food establishment.

If a questionnaire is used, the following decisions would need to be made:

- Are all suppliers required to provide traceability information for all products, or should this be limited to foods that may be on the FTL?
    - o For the latter, how would items be categorized and mapped to automate the questionnaire process? Would this mapping be based on the item GTIN or an internal item number? Would systems be able to distinguish, for example, USDA FSIS vs FDA regulated products (knowing that the former are not covered by the rule)
- Who within the company will architect the questionnaire, and in which system will it reside?
- Who within the company would communicate to suppliers the need to provide this information?
    - o How often will the information be reviewed and verified?
    - o Will suppliers be reminded to update this information if things change (e.g., a process change that no longer includes a kill step; an ingredient change; a change in supplier status)?
- When will the supplier need to provide this information relative to receiving the product?
    - o Will a system be implemented that prevents ordering until the information is provided?
    - o If not, upon receiving, how will the receiving location know if the information has been provided?
    - o What would happen if traceability information is not provided? Will the product be rejected? Will you assume the products are not on the FTL and receive the product? Who will make this decision?

Supplier Requirements

Unlike most regulations, this rule requires strong communication and information sharing between supply chain partners. Some sectors have established voluntary (to date) traceability systems. An example is the [Produce Traceability Initiative](#) within the produce sector. Although the initiative did not reach a voluntary adoption of 100% it is well enough established that it should be leveraged**; it would be disruptive and inefficient for other parts of the supply chain as a group (e.g., the retail community) or as individual companies, to impose traceability requirements of their supply chain partners that are inconsistent with current standards and approaches.**

Using Standardized Data Elements

Identifying key data elements (KDEs) using globally recognized standards is strongly recommended. While not required by the regulation, consistent application of master data standards used by the industry could facilitate communication throughout the industry and increase compliance. The use of GS1 US standards is not required by the regulation nor is the use of any specific type of data carrier or sharing standard. Use of standards is highly recommended by FMI. This is foundational to using interoperable systems and will aid in the exchange of unambiguous information. Many data elements are required KDEs by the rule for some CTEs; other data elements are recommended to aid in business processes. The GS1 system of standards for identification has the greatest global adoption and is therefore recommended. The tables below show the name of the standard as well as the associated application identifier (AI) that signals to electronic scanning systems the type of information being provided. These tables are derived from the GS1 US North American Industry Guidance for Standard Case Code Labeling [GS1 Document Type (gs1us.org)](). Therefore, many suppliers should be familiar with these expectations already.

The tables identify if the data elements should be presented in human readable form, in a data carrier such as a barcode or RFID tag on a pallet or case that can be scanned or transmitted electronically by Advance Ship Notice (ASN). These are described in more detail later in this document and summarized here:

- *Human readable:* this information provides visual cues that can help in slotting, picking, and inventory management. Human readable information could also assist with verifying information. In most cases, the human readable information serves a business purpose unrelated to compliance with the rule. For example, a voice pick code is easily seen by warehouse staff and helps them identify which product to select. Dates that indicate product age, such as use by/ expiration/ packed on can help with stock rotation. Identifying products and suppliers subject to a recall is easier when the information is human readable. Some retailers ask that PLU or UPC information appear as human readable information, and this is part of the [Harmonized PTI label]() although it is not a KDE according to the rule. Even if rule KDEs are presented as human readable information, unless they are manually captured (e.g., someone types it into a spreadsheet), the data will be discarded when the case is disposed of. **This means that KDEs required by the rule would ideally be scannable or transmitted electronically, not just as human readable information**.
- *Scan:* The data elements to be scanned are embedded in data carriers such as barcodes (the GS1-128 being the most commonly used barcode at this time) or RFID tags that are associated with the physical unit. The Application Identifiers (the numbers in parentheses, such as (10) for the batch/lot number) signal to software the nature of the data element that follows. Scanning information captures the data electronically but has

a high burden on labor and it is important that scanning be done consistently in order to capture all required KDEs.

- *ASN*: Advance Ship Notices are electronic data interchange (EDI) transactions that provide the receiving company with advance data on shipments to better plan workloads and receipt processing. These are communications between computers. In practice, the ship notice must arrive before the shipment ([ASN_856_PTI_Final_20200616.pdf (producetraceability.org)](producetraceability.org)). ASNs do not have a high reliance on labor since scanning is not required as data is sent from shipper to receiver electronically.

Decoding Using Application Identifiers

How do systems know what the characters in a barcode mean? [Application identifiers](#) (AIs) are the key. The numbers in parentheses correspond to different types of data elements, and signal this to scanning/ software systems. Although there are over 100 AIs, the list below highlights those that correspond to KDEs and other data elements most often used for traceability purposes. Some of these may be communicated using data carriers such as barcodes, and some may be communicated via ASNs:

Application Identifier	Name/ Data Element*
01	GTIN (including the brand owner company prefix and item reference number, 14 digits)
10	Batch/ lot number (traceability lot code; up to 20 digits)
11	Production date (YYMMDD)*
13	Packaging date (YYMMDD)* (interpreted by the produce industry as pack or harvest date)
15	Best before/ best by date (YYMMDD)*
16	Expiration/ use by date (YYMMDD)*
410	Ship-to Global Location Number (GLN)
414	Global Location Number
3202	Net weight in hundredths of a pound

*These data elements are not required to be shared through the supply chain (although transformers and others need to record dates of transformations)

Some industries and commodities include other AIs, such as for serialization (AI 21). For example, in the seafood industry, serialization of cases may help reduce opportunities for food fraud. However, serialization (tracking individual cases) is not required by the FDA Food Traceability Rule. Because the GS1-128 barcode has limited capacity, other AIs are prioritized, as shown below. As data carriers evolve (e.g., RFID, 2D barcodes, etc.) with expanded capacity, other attributes may be able to be conveyed. FMI strongly recommends focusing on master data and allowing for flexibility in use of data carriers as well as data sharing tools.

Product Identification Key Data Elements for Food Traceability List Items

The information in the table below is based on the [GS1 North American Industry Guidance for Standard Case Code Labeling](#). The data elements listed are an example of product information for items on the Foot Traceability List that could be captured and shared through the use of the GS1-128 barcode and associated Application Identifiers (AIs) for case labeling and the use of Advance Ship Notices (ASNs). For additional details about case labeling practices, see the [GS1 North American Industry Guidance for Standard Case Code Labeling](#).

Product Identification Data Element	Application Identifier (AI)	Scan Length GS1-128 Barcode limited to 48 characters	FTL Commodity	Variable Measure Human Readable	Variable Measure Scan	Variable Measure ASN	Fixed Measure Human Readable	Fixed Measure Scan	Fixed Measure ASN
Global Trade Item Number (GTIN)	**AI (01)**	**N2+N14**	**ALL**	✓	✓	✓	✓	✓	✓
Batch/Lot Number	**AI (10)**	**N2+X..20 (max) ****	**ALL**	✓	✓*	✓	✓	✓*	✓
Responsible Party			**ALL**	✓		✓	✓		✓
Traceability Lot Code Source GLN			**ALL**	✓		✓	✓		✓
Location Description for Immediate Previous Source GLN		**"Ship From" or URL within ASN data segment**	**ALL**			✓			✓
Reference Doc type and reference document number			**ALL**			✓			✓
Various Date(s)	Variable measure: AI (11), AI (13) Fixed Measure: AI (15), AI (16), AI (17) (11) Production Date, (13) Packaging/Harvest Date, (15) Best Before, (16) Sell By, (17) Expiration Date	N2+N6	ALL	✓	✓	✓	✓	✓	✓
Net Weight in lbs.	Cheese & Seafood: AI (3201, 3202, 3203) Last digit of this AI indicates # of digits after decimal (i.e., 1.1, 1.01, 1.001)	N4+N6	Cheese and Seafood	✓	✓	✓	✓#		
	N/A for Produce, Deli/Bakery, Shell Eggs, Nut Butters	Not used	Produce, Deli/Bakery, Shell Eggs, Nut Butters						
"Food Traceability Required"		Text	ALL	✓			✓		
UPC or PLU (for verification only)		Numerical	ALL	✓			✓		
Voice Pick Code (if used)			ALL	✓			✓		
Case-Level Product Description			ALL	✓		✓	✓		✓

Bolded Text and Fields Shaded in Green = GS1US standard to capture KDE required for FDA Traceability Rule
Human Readable = Human readable case label text
Scan = Barcoded or other scannable data carrier
ASN = Advance Ship Notice/Ship Notice Manifest
AI = Application Identifier
* AI (10) is a critical data element. Although using AI (21) Serialized Case Codes is acceptable, the AI (21) cannot replace AI (10) in the barcode.
** The maximum field length for Batch/Lot Number is 20 characters. When net weight is included in the barcode, the Batch/Lot Number character limit is reduced and should be no more than 12 characters.
# For fixed measure products, AI (3201, 3202, 3203) for net weight may be shown as (1) the total net weight of the case (i.e., net weight: 10 lbs.) or (2) the total number of inner units and the net weight of each (i.e., contains 10 units, 1 lb. each).

Master Data versus Transactional Data

Some of the information required by the rule will seldom change from shipment to shipment (e.g., the location of the supplier, product identification number/GTIN, whether or not the food is on the FTL, etc.), and is referred to as Master Data. Other information will change often (e.g., the lot number, dates, quantities etc.), and is called Transactional Data.

Master Data can be obtained directly from suppliers once (or infrequently) and stored in a retailers' system. Alternatively (and preferentially for many), a supplier can choose to share their master data with a central network such as the Global Data Synchronization Network (GDSN) via a certified data pool, and the receiver can link to this system (via the same or different certified data pool) to retrieve up-to-date master data.

Transactional data must be shared regularly and on an ongoing basis, such as for each shipment. It can be shared electronically (computer to computer, such as through EDI transactions/Advance Ship Notices and traceability solutions which leverage EPCIS to support KDEs for CTEs) as well as physically attached via data carriers to the accompanying product. For ease of compliance, it is recommended to share as much information as possible via the ASN, and link this information via the physical shipment (e.g., through a Serial Shipping Container Code, SSCC).

Data Elements

Traceability lot code: Within this document, the term "lot code" is often used as shorthand for "traceability lot code." The lot code is a key piece of information, and the data element that is least often tracked to the retail store today. Lot codes change often and should be communicated with each shipment.

As is the case today, the transformer (or initial packer or first land-based receiver) can assign lot codes at their discretion. If you are the manufacturer, you are free to use the same lot code schema you have been using. This should be described in your traceability plan (e.g., if other data elements, such as a Julian date, or facility location, are encoded in the lot code; the size or duration of a run that distinguishes one lot or batch from the next, etc.). To ensure global uniqueness of the traceability lot code, the TLC could consist of the combination of the GTIN plus the internal, producer-assigned lot code.

If FTL food is received without a lot number (e.g., from an exempt supplier), the receiving firm will need to assign a lot number. There is flexibility in how this can be constructed, such as using the PO number, BOL number, internal license plate number, or received-on date as the traceability lot code. The process should be described in the Food Traceability Plan. The approach must allow you, and regulators, to associate the traceability lot code to a defined unit of product. Additionally, the entity that assigns the lot number is now considered the traceability lot code source.

- The Traceability Lot Code is unique to the FDA Food Traceability Final Rule and does not have to be the same as the assigned lot code by the packer, processor or manufacturer. For consistency FMI recommends that the food industry, distributors and retailers use the GTIN + lot code (12-20 digits alphanumeric) in GS1 US standard.

Traceability lot code source: This conceptually new data element will aid FDA in being able to immediately contact the entity who determined and assigned the lot code (generally the last transformer/packer of a product). FDA requires that the location description for the traceability lot code source, OR the traceability lot code source reference, be shared by shippers and captured by receivers. Currently there is no GS1 application identifier (AI) to represent the traceability lot code source. There are several ways this information can be relayed through the supply chain:

- The traceability lot code source could be a separate data element that would be shared with each shipment. Until there is an easy way to encode this in a barcode or transmit it through an ASN, capturing this information would be manual.
- As described below, the Global Trade Item Number (GTIN) is a combination of three data elements: the company prefix that indicates the brand owner (publicly available through the GS1 registry), the item description associated with that number that can be used to look up (including flavor, pack size, etc.) by the manufacturer, and a check digit code via standard algorithm to ensure global uniqueness. In some cases, the company prefix alone may be sufficient as the traceability lot code source, if the brand owner only has one location at which the product is produced. In this case the GTIN would serve as a traceability lot code source reference.
  - Although the DUNS number or FDA facility registration number associated with the lot code originator could also serve as traceability lot code source references, these are not ordinarily shared due to concerns around fraudulent use. The GTIN is more likely to be transmitted through the supply chain (e.g., via ASNs and the GS1-128 barcodes) and would be the preferred number to use.
- If there are multiple locations that use the same GTIN, then the traceability lot code source could still be determined *if* the location is embedded in the lot code, allowing the brand owner to determine which location produced a certain product.
- The Global Location Number (GLN) should point directly to the location of the producing entity (which is generally the lot code source). Although the GLN can be communicated via a data carrier, the capacity of the GS1-128 barcode means that the GLN is not included. The GLN of the traceability lot code source can be communicated via ASN to the immediate subsequent recipient, but the mechanism to continue to share this information further down the supply chain is uncertain.
- An alternative way to convey the location of the traceability lot code source includes the communication of a website that contains this information. The capture of this information throughout the supply chain may be challenging.

Location: The ship-to and ship-from locations need to be tracked (note, the transporter does not need to be tracked, and cross-docking is considered part of the route and therefore does not need to be tracked).

The location description needs to include the following, which are generally considered master data and can be housed in a database (such as the GS1 US Data Hub), network such as GDSN (in other words they do not need to be shared with each shipment):

- Business name: This relates to the business name of the shipper (immediate supplier), which may or may not be the company that produced the FTL food (as noted above, the GTIN in a data carrier such as the GS1-128 barcode includes the identity of the brand owner. In some instances, however, the brand owner may not be the same as the company actually producing the FTL food)
- Phone number
- Physical location address (or geographic coordinates), including city, state and zip code
- Comparable information for foreign locations, including country

The GLN provides a ready link to the information above. Many farms, facilities and retail locations already have a GS1 Global Location Number (GLN) but traceability team members may be unaware. For example, traceability requirements in the pharmaceutical supply chain mean that retail locations with onsite pharmacies likely already have a GLN. Over 5 million North American farms have GLNs through AgGateway (housed in GS1 US Data Hub). The GLNs for the ship-from and ship-to locations can be communicated via ASN.

Product Description: The GTIN is a standardized way to describe an item. The GTIN contains up to two KDEs—the company prefix, as well as an item code assigned by the brand owner. This item code can be used to look up additional information about the product: its description, how it is packaged (weight/ volume), etc.

Quantities and units of measure: Quantities are generally shared between supply chain partners today, in part so that appropriate payment can be made. Units of measure are generally associated with the GTIN (as part of the item reference).

Recommended Data Carriers

The FDA Food Traceability Final Rule does not require use of a data carrier. The examples provided are examples of data carriers used by the industry at the current time to varying degrees of implementation. KDEs should be provided electronically as well as on the physical products distribution unit (be it pallet, case, or item). There are several ways that information can be conveyed on the physical product. Data carriers, whether they are GS1-128 barcodes, 2D barcodes, or RFID tags, can all carry the same KDEs based on GS1 US master data standards (with varying limitations based on the capacity of the data carrier).

Barcodes

The UPC or universal product code on many consumer products is a familiar barcode, but there are many types of barcodes that can carry varying amounts of information. Capturing information from barcodes requires line of sight and the hardware and software to physically scan and decipher the information contained in the barcode. The information on barcodes should match the information sent via ASNs. It is up to each receiver to evaluate their confidence in the accuracy of the information in the ASNs, and determine the additional value added by scanning barcodes, whether at the pallet or case level, upon receipt. In other words, the receiving CTE can be satisfied by *either* trusting the information on the ASN, or scanning the physical units (or both).

Pallet level: In an ideal world a pallet would contain only one lot number of only one product; it is easier to track a pallet than each case on it. Some buyers/ retailers have tried to encourage or impose this requirement, with varying (and generally limited) success. Sometimes a pallet may consist of multiple lots of the same product, and/or multiple products (each with their own lot numbers). Capturing this at the receiving stage is facilitated using the GS1-128 barcode. At the pallet level, this barcode can be used by the shipper to communicate the contents of the pallet, done through the Serial Shipping Container Code (SSCC). Each individual pallet is identified by a SSCC; this is the identifier for a specific logistic unit, akin to a tracking number on a package. The SSCC is a combination of the GS1 company prefix, plus the serial reference, and a single check digit as the last number. This number serves as the key to "unlock" additional information that was previously transmitted via an ASN about the contents of the pallet. Although other types of barcodes can encode the SSCC (such as the GS1 DataMatrix or QR code barcode – which require optical scanners), the GS1-128 barcode is currently the common data carrier for the SSCC.

Case level: At this time, the barcode most often used for traceability purposes at the case level is also the GS1-128. This is the barcode recommended by PTI at this time. With a limitation of 48 characters, the information typically communicated includes:

- The GTIN (this can be used as a "link" to additional master data)
- The batch or lot number (KDE)
- Date (Date Elements related to production, expiration, etc., *not* the shipping and receiving date that are required by the rule. The reason production or expiration dates are encoded in the barcode is to help warehouse management systems with inventory rotation).

Placing two barcodes with different information (e.g., one with the GTIN and batch, and one with the GLN and other info) is NOT recommended. To limit confusion by receivers, cases should only bear one barcode, to the extent practicable.

There is generally space on the barcode for "human readable" information (that often serves a business need and does not need to be scanned and retained). This information can help workers readily distinguish products. An example of human readable information is the "voice pick code" that signals to workers using audio pick systems which case should be selected. Another example is a date, which can help identify the oldest or newest product and aid in stock rotation.

Individual item level: Because traceability to the individual consumer is not required by FDA, traceability at the item (each) level is generally not useful or practical. There may be instances where a case is broken and individual items are sent to retail locations, for example, specialty cheeses or chocolates with nuts that are unlikely to sell at high volumes. In this situation, the traceability information on the case can be captured, along with the quantity shipped to the retail store, as part of the shipping CTE. The corresponding receiving CTE could rely on the shipper to maintain their receiving KDEs, as long as the shipper retained the date and ship-to location.

Although tracing consumer purchases is not required by the rule, it would be ideal in outbreak investigations to know exactly which lot of a product a consumer purchased. In the future, technology may enable this capability, which would exceed regulatory requirements. The aforementioned UPC barcode on products contains the GTIN (which includes the company prefix and the company's internal reference number for the item). The UPC does not convey the lot/ batch number as it is only capable of encode the unique product number, GTIN. The industry is in the process of enabling the use of 2D barcodes due to the fact they are capable of carrying substantially more information. This initiative is called [GS1 US Sunrise 2027](#) and the capability to encode 2D barcodes and read at POS is expected to occur in 2027. At this point, it is possible that the lot number would be included in the 2D barcode, and would be able to be captured at the POS. If this capability is realized, it would give more precise information to aid in outbreak investigations compared to simply knowing what was received at a store and may obviate or replace the need to capture information at the back end of the store.

Readability of barcodes: There are many reasons that a barcode may not be scannable: it may have been constructed and/or printed incorrectly, it may have been printed on a surface (such as corrugated cardboard) that lacks sufficient contrast or has a disruptive texture, or it may have gotten wet, ripped, or otherwise damaged during transportation. Buyers should ask suppliers (the traceability lot code source) to provide sample barcodes for review/ confirmation prior to the first shipment/ receipt. During the early stages of implementation, providing this feedback to supply chain members is important. Recording read rates for various suppliers and noting your correspondence with them helps demonstrate your efforts to comply with the rule. Because redundancy is built into the system, the supplier should be able to communicate what was shipped; ASNs should provide duplicative information.

RFID

Radio frequency identification (RFID) is another kind of data carrier. Although the information carried can be identical to the information carried by a barcode, a main advantage of RFID is that line of sight is generally not required for data capture. Some companies, particularly in the foodservice sector, are exploring using RFID tags to carry traceability information. Historically, the use of RFID has been limited in the food industry due to cost, as well as technological limitations (the ability of signals to transmit through dense products). As improvements continue, RFID may be a viable option with reduced labor costs. Today, there are data carriers that offer a combination of the barcode with an RFID tag.

Advance Ship Notices

Advance Ship Notices (ASNs) offer receivers a way to obtain traceability information with little to no manual labor; it is computer-to-computer communication. As the shipper (supplier) assembles a shipment for the receiver (e.g., the retail distribution center), the traceability information, including quantities and lot numbers of various products, are packaged into a digital file that is transmitted from the shipper to the receiver as an EDI transaction. GS1 application identifiers are still foundational to deciphering the message, and the same data elements communicated via barcodes can also be sent via ASN, along with additional information. For example, a pallet can bear an SSCC, as described above. The SSCC will also be referenced in the ASN, along with an indication of the product/lot number combinations of the cases on that pallet. In this way, the ASN, leveraging the SSCC, eliminates the need to scan each case in pallet upon receipt in order to determine the lot numbers: One scan of the pallet barcode (the SSCC) is sufficient to unlock the information about the contents of that pallet.

Work with suppliers to ensure that they are capable of sending ASNs. Once they are, be clear on the data elements that need to be transmitted via ASN (based on tables xx). The "advance" in ASN is important; suppliers should transmit the ASN *before* the load arrives.

Additional resources:

> ASN 856 [ASN_856_PTI_Final_20200616.pdf (producetraceability.org)](ASN_856_PTI_Final_20200616.pdf)
> ASN (general) [GS1 Document on logistics labels in conjunction with ASN](GS1).

Blockchain

Successful use of blockchain is predicated on successful implementation of the previously discussed items: clarity on key data elements (e.g., location, date, lot number), standardization of those identifiers (e.g., GTIN), data carriers that hold the data elements (e.g., barcodes), and digital sharing of the data elements (e.g., ASNs). Blockchain is then the next step, providing access and visibility to this pre-existing information. It is important to note that at the current time, there are *several* blockchains, and they are not necessarily interoperable. The rule does not require the use of blockchains or any specific software solutions. FMI recommends that

emphasis be placed on the master data and effective ways to convey and share the data required.

Common Critical Tracking Events

Some of the FDA-identified CTEs are unlikely to apply to distributors and retailers. These include harvesting a RAC (other than a food obtained from a fishing vessel) on the FTL, cooling a RAC before it is packed, initial packing of a RAC (including sprouts and/or RACs received from suppliers not subject to the rule), and serving as the first land-based receiver of a food on the FTL. Readers are referred to the appropriate trade association for more information on how to implement traceability if those CTEs apply.

The CTEs most relevant to distributors and retailers are receiving (both at the DC and at the retail food establishment, as well as the receipt of ingredients at a retailer's manufacturing location including a commissary/ central kitchen), shipping (from the manufacturing location to the DC or store, or from the DC to a store or another DC), and, in some cases, transformation (when the retailer operates their own manufacturing operations, central kitchens, etc.).

Receiving

Distributors will receive food at their DC. Retailers may receive FTL foods at their DCs, the stores, and/or their own manufacturing locations. The same basic information (KDEs) is required.
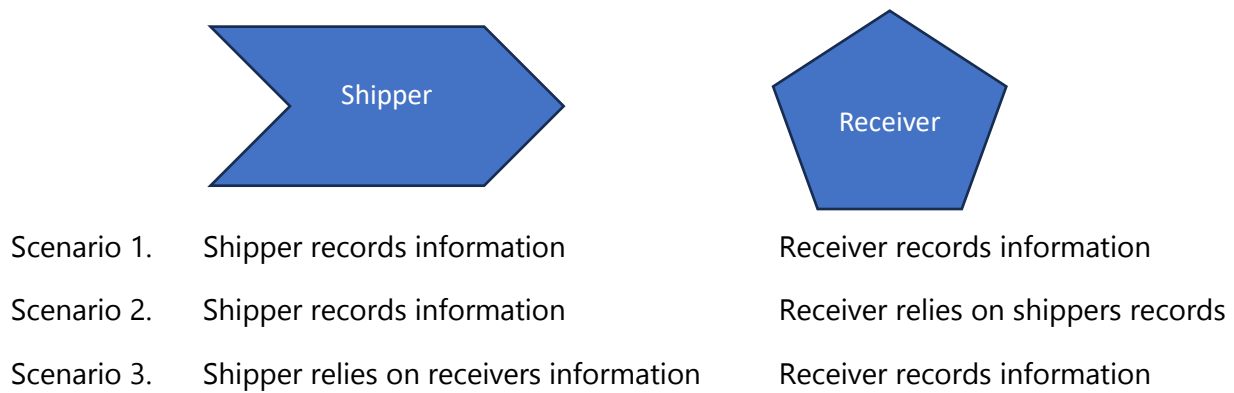
Suppliers/ shippers should provide this information through a combination of human readable information (good for ease of visual identification, but difficult to manage from a recordkeeping standpoint), as scannable information (e.g., using the GS1-128 barcode to convey the SSCC at the pallet level, and using the GS1-128 barcode on cases to carry the GTIN, lot/batch number, and date), and via ASNs (to associate the SSCCs with the details of cases on the pallet, as well as transmit other KDEs).

Receiving at the DC can be facilitated when the supplier/ shipper utilizes ASNs and SSCCs. Upon receipt, employees would scan the SSCC, and this would provide a rapid way to record the products and associated lots on that pallet. Today, many entities in the supply chain create a license plate number or other identifier that serves as an internal reference for a received shipment. Warehouse management systems may track the movement of products throughout a warehouse based on the LPN. While the LPN may be useful to help companies manage their inventory, it cannot be used as a substitute for the traceability lot code.

Whether a store is receiving FTL foods from their own distribution center or another entity (e.g., a 3rd party DC, DSD, etc.), the store can either capture the receiving information itself, or can rely on the shipper to retain this information and provide it on request (and within 24 hours, if the store needs to respond to a regulatory request). The same labor issues that make it difficult to scan each case or item upon receipt in a DC exist at the back of the store. If relying on the shippers information, the shipper (e.g., the distributor) will need to have all the information

required for the shipping CTE, as well as the additional information (store location and date of receipt) for the receiving CTE. One way to accomplish this is for the store location to display a bar code that carries location information (e.g., the GLN), which can be scanned by the shipper. (this situation is the converse of the last bullet in 'shipping', below, and is illustrated as Scenario 3 in Figure 3).

Figure 3. Shippers and Receivers Can Establish and Maintain Each Other's Records

	Shipper	Receiver
Scenario 1.	Shipper records information	Receiver records information
Scenario 2.	Shipper records information	Receiver relies on shippers records
Scenario 3.	Shipper relies on receivers information	Receiver records information

Shipping

The DCs and manufacturing operations (including commissaries and central kitchens) will generally have shipping CTEs. A retail food establishment may also be a shipper, if store-to-store transfers are a frequent event.

Associating the traceability lot codes of FTL foods with specific shipments can be challenging. Even when the incoming lot codes are captured upon receipt (e.g., via the SSCC and ASN), a pick slot may house multiple lots of the same product at a time. In some instances, there may be multiple suppliers of that product in the same pick location. There are a few ways to approach recordkeeping at shipping:

- Scan the GS1-128 barcode of each case as it is picked, or at the time a pallet is assembled
  - o This is a time-consuming process that can also be error prone. Without training and oversight workers may default to scanning one case 5 times, and then selecting 5 cases, which may or may not have the same lot number/ supplier. If there are changes in orders or if cases become damaged and are not ultimately shipped, this would need to be accounted for.
- Use the voice pick code to direct warehouse staff to pick certain lots.
  - o The use of voice pick technology is not universal and the voice pick code is not a KDE. Where it is in use, the warehouse management or other system would need

to maintain for the 2 year recordkeeping timeframe the link between the voice pick code and the associated product/ supplier/ lot number selected. Similar to scanning cases, the assumption that cases that are picked are the same as those ultimately delivered may not be 100% accurate.

- Have drivers scan each case as it is delivered to a store
    - This approach is labor intensive but has the benefit of accuracy (assuming that the store does not reject the shipment). Note that transporters are not subject to the rule. The shipper and receiver would need to ensure that the transporter agreed to serve this role and capture data on behalf of the covered entities.
- Use the stores receiving records to infer the product lot numbers that were shipped
    - Entities are permitted to rely on the data of another entity, as long as it's available within 24 hours of a request. This is the converse of the concept described in 'receiving,' above, and is illustrated as Scenario 2 in Figure 3.

Transformation (Manufacturing/ Processing)

Manufacturing and processing of an FTL food, or of a food containing an FTL ingredient that does not undergo a kill step, is a transformation CTE if that food is going to be shipped to another location (e.g., if the food is prepared in the same store in which it is sold, traceability records do *not* need to be retained, but if it will be shipped to another store, they do).

Company-owned Private Label Manufacturers: Retailers may own their manufacturing operations and produce private label products that are sent directly to their stores or to their own DCs and from there, to their stores. Each of these locations (the manufacturing facility, DC, and store) need to keep traceability records. As the manufacturer, the retailer would be responsible for determining if the finished food product is subject to rule requirements (e.g., is it an FTL food) or not.

Private Label Contract Manufacturers: When an independent company is producing a food on behalf of a retailer, the retailer should determine how traceability information will be captured and who will have access to this information. If the GTIN conveys the company prefix of the brand owner (retailer), then one can anticipate that a regulator will ask the brand owner (retailer) for traceability details, similar to what often happens today.

Commissary/ central kitchen (in store to others, or centrally located): Whether located within a retail store or as a separate location, if food covered by the rule is being prepared or assembled for distribution to multiple locations (e.g., other stores), this is considered a transformation CTE covered by the rule. The central kitchen may be owned by the retailer or may be a 3rd party co-located in a retail store, for example.

Here are some examples of how traceability can be Implemented as part of different transformation CTEs:

- Using FTL ingredients to make a new FTL food (e.g., preparing a salad at a central kitchen/commissary)
    - The receipt of the FTL ingredients needs to be tracked, whether the ingredients are received from a supplier, the retail DC, or from within the retail store (in situations where the central kitchen is co-located with a retail store). Note, ingredients that are not on the FTL do not need to be tracked; retailers should weigh the advantages and disadvantages of tracking all ingredients, considering the ability of staff to properly distinguish FTL ingredients.
    - During preparation/ processing/ manufacturing (e.g., transformation), traceability information for the FTL ingredients, including lot numbers, need to be associated with the lot number of the finished product. The finished product may contain many ingredients, each with one or more lot numbers. The "many-to-one" relationship is acceptable, as long as the raw material/ lot numbers are tracked and associated with the finished product lot.
    - Foods produced in a manufacturing facility may be more likely to have a lot number than those produced in a commissary. If prepared foods (salads, sandwiches, sushi etc.) bear a date (whether a production date or a 'use by' date), this can serve as the finished product lot number.
    - Today, invoicing needs generally necessitate the capture of the quantity and description (which can be indicated by the UPC, if applicable) of the produced food along with recipient of that food (e.g., DC or store location). The lot code is one additional piece of information that should be captured as part of the shipping CTE.
- Using non-FTL ingredients to produce an FTL food (e.g., producing peanut butter crackers)
    - Verify that none of the ingredients are on the FTL. If they are, follow the approach described immediately above.
    - The rule requires finished product lot numbers to be assigned to the new FTL food. This is typical of today's manufacturing operations.
- Using FTL ingredients to produce a non-FTL food (e.g., using fresh tomatoes to make jarred sauce, or using shell eggs and cheese to make frozen omelets)
    - In order to meet their traceability requirements, the shipper/ supplier may ask for a written agreement (at least every 3 years) stating that you, as the receiver, will indeed apply a kill step to the food or change it such that it is no longer on the FTL (1.1305(d)(6))

Data Storage, Retention, and Electronic Sortable Spreadsheets

The FDA rule requires traceability data to be stored for at least 2 years. Considering the number of foods covered by the rule and the volume of products moving through the supply chain,

massive amounts of data will need to be stored and queried. Retailers should carefully evaluate 3rd party and internal systems to understand data retention capabilities, ownership and access to data, cost to access data, and the ability to search information.

The requirement to provide requested information in an electronic, sortable spreadsheet is only triggered when there is an issue that FDA is investigating, such as an outbreak. In the event of an outbreak investigation, data may be requested for long timeframes (e.g., weeks). The ability to pull the breadth of required data into electronically sortable spreadsheets should be carefully considered. As noted earlier, during the early stages of an outbreak investigation the lot numbers of suspect products are seldom known. Because the rule requires the traceability lot code be captured upon receipt at the store, retailers can expect regulators will be requesting the lot numbers and contact information for the lot code source associated with suspect foods sold in a given timeframe.

Validating and Verifying Information

Verifying supplier information

The rule does not require receivers to verify the information provided by suppliers is correct. If a receiver decides to verify information, they should focus on the supplier/ FTL combinations that present the greatest risk. For example, verification could be focused on FTL foods that are most frequently the subject of regulatory investigations, or they can focus on suppliers that are still working to update their systems and processes.

Verifying electronic and physical inventories

The frequency of matching the information on an ASN with that of an SSCC could be based on the historical frequency of errors. As a new supplier begins providing ASNs and pallets with SSCCs, this could be done often, scaling back as the retailer gains confidence the information matches.

Verifying the information on the SSCC matches the information on the cases is a more laborious process. This may be worthwhile to conduct occasionally as a means of system verification. Routinely scanning barcodes on incoming cases is rarely efficient.

Synergies with other Business Needs

In order to comply with the rule and meet their business needs, many companies will make changes to their systems and processes. The interdisciplinary team mentioned earlier in this document can look for opportunities to improve other business functions as a result of these changes, and consider leveraging existing systems to achieve the desired outcome. In addition to capturing KDEs at CTEs, some companies look for other business benefits. The list below is not exhaustive and is intended to encourage companies to think about potential business

benefits that may help defray the costs associated with compliance. The applicability and extent of the benefit will be company specific:

- Reduction in mis-picks and errors, improved order accuracy and efficiency
- Improved inventory management and rotation, decreasing food waste/ shrink and supporting sustainability
- Authentication of claims: organic, ethically sourced, sustainable, etc.
- Streamlined interactions with regulators during a recall or outbreak

Special Cases

Cross Docking

FDA has indicated that cross-docking is a stop along the distribution route, and FTL food would not be considered "received" if it is not the intended destination of the food. However, factors such as the time at the cross dock location, whether or not it was taken into inventory at the cross dock location, and whether the food was held under the same temperature as during transportation (as applicable) would be considered by the agency.

Direct to Store Delivery

Retailers will want to determine the responsibility for the maintenance of records with their DSD provider. Often the DSD provider has the most information about the products on display at the retail location.

Shipments between Distribution Centers

When a DC transfers product to a sister DC, these are considered shipping and receiving events.

Intra-Store Purchases

If one retail food establishment sells food to a sister store on an *ad hoc* basis, outside of the normal purchasing practice, then the retail food establishment that makes the purchase must have a record of the product purchased, date of purchase, and name and address of the place of purchase. In this case, the lot code does not need to be captured. Retailers should use caution and limit circumstances where FTL foods are being shipped between stores. If this happens on a regular basis, it could be difficult to argue that it is an *ad hoc* event and not part of normal business practices.

Returns from Store to DC

The traceability plan should identify the circumstances under which product is returned from a store to the DC, if ever. If these returned items are FTL foods and they are returned to the DC, this would qualify as a CTE, with the store shipping and the DC receiving.

Reclaim Centers

Reclaim centers can receive product back from retail stores because these items are discontinued, recalled, damaged, out of code, store resets, etc. Retailers should assess which FTL foods are sent to reclaim centers, and the frequency with which they enter the reclaim system. Typically, frozen and perishable items are not part of the reclaim process, whereas shelf stable items containing nut butters may be more likely sent to reclaim centers. Since for most retailers a minority of FTL food enters the reclaim process, this could be considered an ad hoc event in some instances.

Often reclaimed products will be donated and/or discarded making them exempt from the rule. In other situations products can be resold into the food supply chain. These products typically come back to reclaim as individual retail units and have no reference to original traceability information on the ASN, master shipping case, etc. Store inventory systems should be assessed to determine if they currently track the volume of specific items that go to reclaim (even if the store inventory system does not capture the lot number). Lot numbers on the consumer level unit would need to be captured or deduced based on the lot numbers likely in store inventory. Retailers should consider how they would be able to trace the item forward to its final destination if it is recalled.

e-Commerce Fulfillment Centers

Deliveries of FTL foods to an e-commerce fulfillment center, whether from a DC or from suppliers, are CTEs. If the e-commerce fulfillment centers provide food directly to end consumers, they are likely categorized as retail food establishments. Tracing to the consumer level is not required.

Retail Sales to Local Commercial Operations

Local restaurants or purveyors may purchase items from retail stores alongside consumers, unbeknownst to the retailer. If this is done on an *ad hoc* basis (e.g., to "fill in" product, outside the purchaser's usual purchasing practice), the retail store does not need to maintain KDEs for a 'shipping' KDE, and the purchaser has a limited set of information they need to retain. The information available on the store receipt (product name, date, name and address of the retailer) is generally sufficient. The retailer does not need to capture any information.

Donations

According to the rule, donations to not-for-profit organizations do not need to be tracked.

In-Store Preparation

As long as food prepared in the retail location is sold only in that location, the rule does not apply. However, capturing traceability information for the ingredients used in the recipe to the extent practicable is a best practice. If the food prepared in one store is shipped to other stores

(or DCs), then the preparation is considered a transformation CTE, and the KDEs associated with the shipping and receiving KDEs also need to be recorded, as described above.

FAQs

- **What if I don't know if the food I'm receiving is on the FTL or not? For example, I may not know if a food containing an FTL ingredient was subject to a kill step.**
  - The supplier questionnaire should help you understand if the food you are receiving is subject to the requirements of the rule or not, and if not, why not. Because of the exemptions and modified requirements, the transformer of the food is in the best position to determine if the food is on the FTL and subject to the requirements.
- **What if I don't receive the required traceability information from my supplier?**
  - If your supplier has indicated the food being shipped is subject to the rule requirements but is not providing the information required, the supplier should be alerted to this in writing. Ultimately, as the receiver you can only capture the information provided to you. Having a record of outreach and requests for traceability information could be helpful. Capture the information that is provided.
- **How can I be sure the information provided by my supplier is accurate?**
  - Each supply chain entity is responsible for the information they provide. A widely adopted data verification system is not currently in place. Once the supply chain is accustomed to receiving and providing the information required by the rule, a logical next step would be to begin assessing the accuracy of the information.
- **Individual stores don't have the labor or systems to scan cases at the store level. Is it possible for the distributor (whether self-distributing or another company) to retain traceability records of their shipment, that would suffice?**
  - Yes, the rule allows for a 3rd party to retain traceability records as long as the covered firm (in this case the retail store) can provide them within 24 hours of a request from FDA. In addition to the distributor retaining records for their compliance, they would also need to retain a few additional pieces of information regarding the receiving at the store level, namely location and date of receipt.
- **Is traceability required at the case level?**
  - Not necessarily. The rule requires tracking a traceability lot code through the supply chain. In many cases, products are packed in a case and the lot number is associated with the product in that case. However, in some cases an entire pallet may contain the same lot number. In that instance, tracking the pallet would be suitable. At times, the case may be broken and individual units (generally of small volume/ low turn items, for example chocolates containing nuts, or specialty cheeses) may be shipped. Tracking lot numbers in this instance could be the most

challenging. In other industries, "case level tracking" pertains to serialization (distinguishing case 1 from case 2) and that is not required by the rule.

- **Do donations need to be tracked?**
  - No, the rule does not require that donations be tracked.
- **Do ad hoc store-to-store transfers need to be tracked?**
  - Occasional, *ad hoc* transfers between retail food establishments do not need to be tracked, as long as they are indeed occasional and outside the normal purchasing practices. To the extent practicable, it would be a best practice to maintain some record of a transfer, if only for accounting and inventory purposes. These systems should be explored to determine if additional traceability information can be included.
- **Is there a checklist for compliance that can aid in an inspection? How will I know I am in compliance?**
  - The best checklist is the FMI/GS1 US spreadsheet that lists the CTEs required for each KDE. Additional requirements include the traceability plan. The FMI compliance guide should be referenced to help determine compliance.
- **If a 3rd party vendor sells items in my store, who is responsible for compliance?**
  - Contract language should specify this. Often the entity that would be responsible for executing a recall would be in the best position to also be responsible for traceability information.
- **Do foreign suppliers have to provide traceability information? If so, do they know this?**
  - The rule does not exclude or exempt foreign suppliers of FTL foods. It could take some time before the full supply chain (domestic and foreign) is aware of the rule, understands the requirements, and is able to meet the requirements. Receivers should communicate this information to their suppliers, domestic and foreign, and work to support their understanding.
- **I source from brokers. How can this be addressed?**
  - The intent of the rule is to be able to re-create the physical flow of product, regardless of ownership and business transactions. If a broker does not take physical possession of the FTL food, no CTEs apply—they are not shipping, receiving, etc. The rule requires that the ship-from and ship-to locations be recorded, even if a broker is the one responsible for the sale.
- **Is there an exemption for local produce?**
  - It depends. First, the requirements only apply to foods on the FTL (not all fresh produce). If the produce is on the FTL:
    - The **farm** may have an exemption if:
      - The produce is produced and packaged on the farm, with packaging integrity maintained to the point of the consumer, and

bearing some information about the farm on the consumer-level packaging

- The farm meets the definition of a very small farm
  - The **retailer** may have an exemption if:
    - The produce is shipped directly from the farm to the retail food establishment (not the DC), and the retail food establishment maintains records of the name and address of the farm

Continuous Improvement

As companies strive to comply with the rule they should not lose sight of the intent and objective of traceability: determine the source/ origin of a potentially contaminated food, and, once identified, be able to rapidly pull it from the distribution system. Achieving this objective requires participation of the full supply chain, with each company doing their part to understand product flow through their internal systems. Implementation may be easier for some sectors than others; some companies may be able to meet the requirements more quickly than others. As technology and supply chains change, the approaches to traceability may change.

Additional Resources

FMI Food Safety Modernization Act Resource Center- Traceability

Appendix A – Key Terms Used in the Food Traceability Rule[1]

Term	Definition
Critical Tracking Event (CTE)	Event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity (RAC) other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.
Food Traceability List (FTL)	The list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d)(2) of the FSMA. The term FTL includes both the foods specifically listed and foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list.
Key Data Element (KDE)	Information associated with a CTE for which a record must be maintained and/or provided.
Kill step	Lethality processing that significantly minimizes pathogens in a food.
Location description	Key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country.
Traceability Lot	A batch or lot of food that has been initially packed (for raw agricultural commodities other than food obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.
Traceability Lot Code (TLC)	A descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source
Traceability Lot Code Source	The place where a food was assigned a TLC.
Traceability Lot Code Source Reference	An alternative method for providing FDA with access to the location description for the traceability lot code source as required under this subpart. Examples of a traceability lot code source reference include, but are not limited to, the FDA Food Facility Registration Number for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source.

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[1] Definitions taken from the Small Entity Compliance Guide: Requirements for Additional Traceability Records for Certain Foods: What You Need to Know About the FDA Regulation (May 2023)

Appendix B – Product Identification Key Data Elements

The information in the tables below is based on the [GS1 North American Industry Guidance for Standard Case Code Labeling](). The data elements listed are an example of product information for items on the Foot Traceability List that could be captured and shared through the use of the GS1-128 barcode and associated Application Identifiers (AIs) for case labeling and the use of Advance Ship Notices (ASNs). For additional details about case labeling practices, see the [GS1 North American Industry Guidance for Standard Case Code Labeling]().

Table 1. Product Identification Key Data Elements for Food Traceability List (FTL) Items

Product Identification Data Element	Application Identifier (AI)	Scan Length GS1-128 Barcode limited to 48 characters	FTL Commodity	Variable Measure			Fixed Measure		
				Human Readable	Scan	ASN	Human Readable	Scan	ASN
Global Trade Item Number (GTIN)	**AI (01)**	**N2+N14**	**ALL**	✓	✓	✓	✓	✓	✓
Batch/Lot Number	**AI (10)**	**N2+X..20 (max) ****	**ALL**	✓	✓*	✓	✓	✓*	✓
Responsible Party			**ALL**	✓		✓	✓		✓
Traceability Lot Code Source GLN			**ALL**	✓		✓	✓		✓
Location Description for Immediate Previous Source GLN		*"Ship From" or URL within ASN data segment*	**ALL**			✓			✓
Reference Doc type and reference document number			**ALL**			✓			✓
Various Date(s)	Variable measure: AI (11), AI (13) Fixed Measure: AI (15), AI (16), AI (17) (11) Production Date, (13) Packaging/Harvest Date, (15) Best Before, (16) Sell By, (17) Expiration Date	N2+N6	ALL	✓	✓	✓	✓	✓	✓
Net Weight in lbs.	Cheese & Seafood: AI (3201, 3202, 3203) Last digit of this AI indicates # of digits after decimal (i.e., 1.1, 1.01, 1.001)	N4+N6	Cheese and Seafood	✓	✓	✓	✓#		
	N/A for Produce, Deli/Bakery, Shell Eggs, Nut Butters	Not used	Produce, Deli/Bakery, Shell Eggs, Nut Butters						
"Food Traceability Required"		Text	ALL	✓			✓		
UPC or PLU (for verification only)		Numerical	ALL	✓			✓		
Voice Pick Code (if used)			ALL	✓			✓		
Case-Level Product Description			ALL	✓		✓	✓		✓

Bolded Text and Fields Shaded in Green = GS1US standard to capture KDE required for FDA Traceability Rule
Human Readable = Human readable case label text
Scan = Barcoded or other scannable data carrier
ASN = Advance Ship Notice/Ship Notice Manifest
AI = Application Identifier
* AI (10) is a critical data element. Although using AI (21) Serialized Case Codes is acceptable, the AI (21) cannot replace AI (10) in the barcode.
** The maximum field length for Batch/Lot Number is 20 characters. When net weight is included in the barcode, the Batch/Lot Number character limit is reduced and should be no more than 12 characters.
# For fixed measure products, AI (3201, 3202, 3203) for net weight may be shown as (1) the total net weight of the case (i.e., net weight: 10 lbs.) or (2) the total number of inner units and the net weight of each (i.e., contains 10 units, 1 lb. each).

Table 2. Product Identification Key Data Elements for FTL items (excluding Seafood) *- variable measure*

Data Element	Application Identifier (AI)	FTL Commodity	Scan Length GS1-128 Barcode limited to 48 characters	Variable Measure		
				Human Readable	Scan	ASN
Global Trade Item Number (GTIN)	**AI (01)**	**ALL**	**N2+N14**	✓	✓	✓
Batch/Lot Number	**AI (10)**	**ALL**	**N2+X..20 (max)****	✓	✓	✓
Responsible Party		**ALL**		✓		✓
Traceability Lot Code Source GLN		**ALL**		✓		✓
Location Description for Immediate Previous Source GLN		**ALL**	*"Ship From" or URL within ASN data segment*			✓
Reference Doc type and reference document number		**ALL**				✓
Various Date(s)	**Variable measure: AI (11), AI (13)** (11) Production Date, (13) Packaging/Harvest Date	ALL	N2+N6	✓	✓	✓
Net Weight in lbs	**Cheese: AI (3201, 3202, 3203)** Last digit of this AI indicates # of digits after decimal (i.e., 1.1, 1.01, 1.001)	Cheese	N4+N6	✓	✓	✓
	N/A for Produce, Deli/Bakery, Shell Eggs, Nut Butters	Produce, Deli/Bakery, Shell Eggs, Nut Butters	Not used			
"Food Traceability"		ALL	Text	✓		
UPC or PLU (for verification only)		ALL	Numerical	✓		
Voice Pick Code		ALL		✓		
Case-Level Product Description		ALL		✓		✓

Bolded Text and Fields Shaded in Green = GS1US standard to capture KDE in FDA Traceability Rule

Human Readable = Human readable label text

Scan = Barcoded or other scannable data carrier

ASN = Advance Ship Notice/Ship Notice Manifest

AI = Application Identifier

** The maximum field length for Batch/Lot Number is 20 characters. When net weight is included in the barcode, the Batch/Lot Number character limit is reduced and should be no more than 12 characters.

\# For fixed measure products, AI (3201, 3202, 3203) for net weight may be shown as (1) the total net weight of the case (i.e., net weight: 10 lbs.) or (2) the total number of inner units and the net weight of each (i.e., contains 10 units, 1 lb. each).

Table 3. Product Identification Key Data Elements (KDEs) for *seafood* FTL items - *variable measure*

Data Element	Application Identifier (AI)	FTL Commodity	Scan Length GS1-128 Barcode limited to 48 characters	Variable Measure Human Readable	Scan	ASN
Global Trade Item Number (GTIN)	**AI (01)**	Seafood	N2+N14	✓	✓	✓
Batch/Lot Number	**AI (10)**	Seafood	N2+X..20 (max) **	✓	✓*	✓
Responsible Party		Seafood		✓		✓
Traceability Lot Code Source GLN		Seafood		✓		✓
Location Description for Immediate Previous Source GLN		Seafood	*"Ship From" or URL within ASN data segment*			✓
Reference Doc type and reference document number		Seafood				✓
Various Date(s)	**Variable measure: AI (11), AI (13)**	Seafood	N2+N6	✓	✓	✓
Net Weight in lbs	AI (3201, 3202, 3203) Last digit of this AI indicates # of digits after decimal (i.e., 1.1, 1.01, 1.001)	Seafood	N4+N6	✓	✓	✓
"Food Traceability"		Seafood	Text	✓		
UPC (for verification only)		Seafood	Numerical	✓		
Voice Pick Code		Seafood		✓		
Case-Level Product Description		Seafood		✓		✓

Bolded Text and Fields Shaded in Green = GS1US standard to capture KDE in FDA Traceability Rule

Human Readable = Human readable label text

Scan = Barcoded or other scannable data carrier

ASN = Advance Ship Notice/Ship Notice Manifest

AI = Application Identifier

* AI (10) is a critical data element. Although using AI (21) Serialized Case Codes is acceptable, the AI (21) cannot replace AI (10) in the barcode.

** The maximum field length for Batch/Lot Number is 20 characters. When net weight is included in the barcode, the Batch/Lot Number character limit is reduced and should be no more than 12 characters.

For fixed measure products, AI (3202) for net weight may be shown as (1) the total net weight of the case (i.e., net weight: 10 lbs.) or (2) the total number of inner units and the net weight of each (i.e., contains 10 units, 1 lb. each).

Table 4. Product Identification Key data elements for FTL items (excluding Seafood) - *fixed measure*

Data Element	Application Identifier (AI)	FTL Commodity	Scan Length GS1-128 Barcode limited to 48 characters	Fixed Measure Human Readable	Fixed Measure Scan	Fixed Measure ASN
Global Trade Item Number (GTIN)	**AI (01)**	**ALL**	**N2+N14**	✓	✓	✓
Batch/Lot Number	**AI (10)**	**ALL**	**N2+X..20 (max) ****	✓	✓	✓
Responsible Party		**ALL**		✓		✓
Traceability Lot Code Source GLN		**ALL**		✓		✓
Location Description for Immediate Previous Source GLN		**ALL**	*"Ship From" or URL within ASN data segment*			✓
Reference Doc type and reference document number		**ALL**				✓
Various Date(s)	Fixed Measure: AI (15), AI (16), AI (17) (15) Best Before (16) Sell By (17) Expiration Date	ALL	N2+N6	✓	✓	✓
"Food Traceability"		ALL	Text	✓		
UPC or PLU (for verification only)		ALL	Numerical	✓		
Voice Pick Code		ALL		✓		
Case-Level Product Description		ALL		✓		✓

Bolded Text and Fields Shaded in Green = GS1US standard to capture KDE in FDA Traceability Rule

Human Readable = Human readable label text

Scan = Barcoded or other scannable data carrier

ASN = Advance Ship Notice/Ship Notice Manifest

AI = Application Identifier

**Batch/Lot should be no more than 12 digits when net weight is needed. When there is not a net weight, the field can go up to 20 digits.

\# For fixed measure products, AI (3201, 3202, 3203) for net weight may be shown as (1) the total net weight of the case (i.e., net weight: 10 lbs.) or (2) the total number of inner units and the net weight of each (i.e., contains 10 units, 1 lb. each).

Table 5. Product Identification Key Data Elements (KDEs) for seafood FTL items - *fixed measure*

Data Element	Application Identifier (AI)	FTL Commodity	Scan Length GS1-128 Barcode limited to 48 characters	Fixed Measure Human Readable	Scan	ASN
Global Trade Item Number (GTIN)	**AI (01)**	**Seafood**	**N2+N14**	✓	✓	✓
Batch/Lot Number	**AI (10)**	**Seafood**	**N2+X..20 (max) ****	✓	✓*	✓
Responsible Party		**Seafood**		✓		✓
Traceability Lot Code Source GLN		**Seafood**		✓		✓
Location Description for Immediate Previous Source GLN		**Seafood**	*"Ship From" or URL within ASN data segment*			✓
Reference Doc type and reference document number		**Seafood**				✓
Various Date(s)	Fixed Measure: AI (15), AI (16), AI (17) (15) Best Before (16) Sell By (17) Expiration Date	Seafood	N2+N6	✓	✓	✓
Net Weight in lbs	AI (3201, 3202, 3203) Last digit of this AI indicates # of digits after decimal (i.e., 1.1, 1.01, 1.001)	Seafood	N4+N6	✓#		
"Food Traceability"		Seafood	Text	✓		
UPC (for verification only)		Seafood	Numerical	✓		
Voice Pick Code		Seafood		✓		
Case-Level Product Description		Seafood		✓		✓

Bolded Text and Fields Shaded in Green = GS1US standard to capture KDE in FDA Traceability Rule

Human Readable = Human readable label text

Scan = Barcoded or other scannable data carrier

ASN = Advance Ship Notice/Ship Notice Manifest

AI = Application Identifier

* AI (10) is a critical data element. Although using AI (21) Serialized Case Codes is acceptable, the AI (21) cannot replace AI (10) in the barcode.

** The maximum field length for Batch/Lot Number is 20 characters. When net weight is included in the barcode, the Batch/Lot Number character limit is reduced and should be no more than 12 characters.

For fixed measure products, AI (3202) for net weight may be shown as (1) the total net weight of the case (i.e., net weight: 10 lbs.) or (2) the total number of inner units and the net weight of each (i.e., contains 10 units, 1 lb. each).

*[i]Appendix C – Draft Language for Agreements

THESE TEMPLATES ARE FOR GENERAL INFORMATION ONLY AND ARE NEITHER INTENDED AS NOR DOES IT CONSTITUTE LEGAL ADVICE. Competent legal counsel should be consulted regarding any member's compliance with the FDA's Final Rule, and the information herein should not be used or relied upon in regard to any particular facts or circumstances. These are recommendations, every company will need to evaluate their current systems, processes, and capabilities and make their own business decisions.

Template 1: [Traceability Addendum](#)

Template 2: [Traceability Compliance Agreement](#)

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