



November 19, 2021

Division of Dockets Management (HFA-305)  
Food and Drug Administration,  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: **Initial Comments** of AIM North America on:  
**Docket No. FDA-2021-N-0929**  
**New Era of Smarter Food Safety Summit on E-Commerce; Public Meeting; Request for Comments**  
Federal Register, Volume 86, Number 170, pages 50130 - 50132

To Whom It May Concern:

We are pleased to submit the enclosed comments regarding the above referenced docket and regulatory information number which appeared in Federal Register, Volume 86, Number 170, pages 50130 - 50132.

These comments were prepared by members of the AIM North America Food Safety Committee, all of whom are subject matter experts of the design and application on automatic identification technology. Founded in 1970, AIM is an industry trade association that represents the providers and users of technologies, systems, and services that capture, manage, and integrate accurate data into larger information systems that improve processes enterprise-wide. AIM North America is a chapter of AIM, Inc. In this role we advocate, educate, and coordinate with other subject matters experts including the FDA, GS1, MHI, AIAG to further the adoption of AIDC usage in industry.

AIM serves as the secretariat for the U.S. Technical Advisory Group (TAG) ISO/IEC JTC 1/SC 31 | Automatic Identification and Data Capture Techniques. This group formulates the U.S. position on all work related to the standardization of data formats, syntaxes, structures, and encoding, along with capture technologies for automatic identification and data capture and their associated devices utilized in inter-industry applications and international business interchange.

AIM North America appreciates this opportunity to submit comments in response to the Food and Drug Administration's (FDA) Notice in the above-captioned docket, seeking comment on the agency's approach to New Era of Smarter Food Safety Summit on E-Commerce.

As subject matter experts in asset tracking technologies including Barcodes (1D & 2D Symbols), Radio Frequency Identification (RFID), Real Time Location System (RTLS), Internet of Things (IoT), and other technologies. AIM North America will be happy to respond to any technical support requests from the FDA about the value of standards or the implementation of the rule.

Sincerely yours,

A handwritten signature in black ink that reads "Jeanne Duckett".

Jeanne Duckett  
AIM North America Board Chair  
Chair, AIM North America Food Safety Committee

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## INTRODUCTION AND SUMMARY

AIM North America, as an industry recognized advocate for standards development and advocacy of AIDC technologies appreciates this opportunity to submit comments in response to the Food and Drug Administration's (FDA) Comments Notice for New Era of Smarter Food Safety Summit on E-Commerce Docket No. FDA-2021-N-0929.

Thank you for allowing AIM NA to provide written comments for the FDA New Retail Business Models and e-Commerce in food. The COVID -19 pandemic has made clear how essential the actions outlined in the Blueprint for Smarter Food Safety released in the Summer of 2020 are for a safer, more resilient, and sustainable interoperable digital food supply chain.

In this paper we are going to review the 4 pillars of the New Era of Smarter Food Safety: Tech enabled Traceability, Smarter Tools and Approaches for Outbreak Response, New Business Models and Retail Modernization, and Food Safety Culture.

It is the aim of this paper to demonstrate how globally ubiquitous, interoperable traceability based on international standards can enable meeting the objectives of the FDA in ensuring food safety for e-commerce. Traceability, by itself cannot solve food safety incursions, but when combine with sensors, vision, and other tools it can put a spotlight on them.

Challenges remain before achieving actionable and reliable farm to fork supply chain information including adherence to food safety guidelines. AIM NA supports collaborative standards development and we ask that the FDA specify the following for the e-commerce food supply chain.

- Clearly defined critical tracking events required. The work completed for FSMA 204 can be built upon by food safety professionals to map out critical events to be captured and shared. These tracking events along with the key data elements defined with data type and length, will enable 3rd party validation suite, a key milestone to achieving interoperability
- Clearly defined attributes that need to be captured and the relevant data carriers including: 2D barcode, RFID, Bluetooth among others. These attributes could be as straight forward as a produce id and serial number which would enable the creation of a unique “digital twin” of the products. Since technology evolves faster than regulations AIM North America recommends against specifying the specific data carriers to be used and whether the defined attributes might be encoded on the data carriers. We encourage the FDA to remain open to emerging data carriers and methods to capture and share the defined attributes.
- Food supply chain information has two important attributes: information secrecy (or confidentiality) and information integrity. There is a applicable international security standard: [ISO/IEC-29167](#) Information technology — Automatic identification and data capture techniques Part 13: Crypto Suite Grain-Security Services For Air Interface Communications that should be considered.
- Clearly defined protocol and data content for product recall and how is this data going to be transmitted to all stakeholders such as consumers, retailers, foodservice, packagers, processors, and producers.

### Traceability Stack

To illustrate the path to achieving interoperability we have developed the traceability stack. When driving towards interoperability people often overlook the most critical layer, the application layer. Driving requirements and consensus across business value chain will break down the existing data silos that today’s opaque supply chain.

<b>Application</b>	Define the requirements to meet the regulatory or business need – what objects need to be identified, to what granularity and what points need to be captured.
<b>Access</b>	Security & Permission access to the data
<b>Network</b>	Interaction of the whole network from end to end, what does the path look like from field to consumer. How does one data repository locate the next
<b>Data Link</b>	Bring the data from the physical layer to an understandable meaning in an interoperable data format
<b>Physical</b>	Includes – technical data carrier specifications, sensors, cameras

Increasingly globalized, complex supply chains have resulted in less visibility into food supply chains for supply chain partners, customers, and regulators. The growing demand for e-commerce in food has exacerbated the situation blurring the lines of responsibility. These trends are driving the need for digital transformation through the adoption of technology to bring automation, integrity, and data management solutions to the food supply chain through to the consumer. Digital and sensor technology can enhance the ability to identify, respond to, and prevent food safety issues such as outbreaks.

As a global standards organization, we regularly develop standards for the physical, data link, network, and access layers from the traceability stack. The key to achieving the FDA’s objectives rest with the technologists working with both food safety professionally and supply chain partners to develop a common vision for the application requirements. Once the application standard is developed it should be released as an ISO specification putting in under revision and review control of the international community.

The current level of definition residing in applicable ISO standards is insufficient to meet this need. When performing a survey of ISO Food Standards as well as other standardization groups one finds the following as an example of the current requirements: [ISO 22005:2007](#) (confirmed 2016) Traceability in the feed and food chain defines, “Traceability systems should be able to document the history of the product and/or locate a product in the feed and food chain. Traceability systems contribute to the search for the cause of nonconformity and the ability to withdraw and/or recall products if necessary. Traceability systems can improve appropriate use and reliability of information, effectiveness and productivity of the organization.” While this is good sound advice, it is not a sufficient technical basis on which to build a ubiquitous, interoperable food traceability system which is why one doesn’t exist. [ISO 22000](#) Food Management Systems, HarmonizedGap, Codex all contain a similar level of detail.

There is also a lack of guidance from the Federal Level on E-Commerce in food. State legislation is beginning to catch up with the passage of California AB3336 with requirements covering 3<sup>rd</sup> party delivery companies. AIM NA looks forward to the output from the FDA on the Summit for E-Commerce as platform to move forward with in development of standards and community education outreach.

## COMMENTS

In the following sections we will illustrate how automatic identification and data capture standards (AIDC) can enable the FDA’s objectives with e-commerce. “If you can't measure it, you can't manage it,” is a famous quote from Peter Drucker. An axiom to this quote could be, “If you can’t identify it, you can’t measure it.”

### I. Adapting to New Business Models & Retail Food Safety

For the purposes of this paper, we are defining “New Business Models and Retail Modernization”, as ensuring the “safety of food produced or delivered” using e-commerce model. These models include 3<sup>rd</sup> party delivery service, online and traditional delivery services such as the USPS and “ghost kitchens.” Ghost kitchens are food prep operations with no waiters, no dining room, and no parking lot – really, no public presence whatsoever but they are accessible by third party apps. An emerging food safety concern from ghost kitchens is cross contamination. “Ghost Kitchens” are developing to support multiple brands. For instance, a ghost kitchen under one roof could be: Pizza Delivery, Vegan restaurant, and Organic Salad Greens. It is easy to see that without careful protocols in place, cross contamination could occur.

The challenge for communal kitchens and 3rd party delivery is proving the chain of custody, [ISO 22095:2020 Chain of custody](#). Simply put, the chain of custody is the unbroken path a product takes from the first stage in the supply chain to the end customer, including raw commodity materials, conversion, transformation, distribution, and logistics. Note in ecommerce the physical product holder can be different from the product owner. For instance, today a customer uses a web portal or app to purchase home delivery of food and assumes immediate ownership without the ability to perform an visual inspection and acceptance of the product. Current 3rd party apps have proprietary methods of capturing this data, but this new era pillar is enabled through common access to the data through enabling electronic traceability.

Techniques to enhance navigating the last mile will include the AIDC connection making the physical food item “intelligent” and traceable and ensuring an unbroken chain of custody as defined in [ISO 22095:2020, Chain of custody — General terminology and models](#). Also, the availability of low-cost sensors to connect the status of the food as “fit for use” are both areas the AIM association members develop. These sensors will be critical to validate the HACCP points currently being developed by food safety professionals.

The GS1 has an emerging standard called [GS1 Digital Link Standard](#) that combines barcodes and other data carriers with the power of the web. This initiative may provide valuable in providing transparency into the last mile. Now that we have discussed last mile let’s return to the first mile as we examine the next New Era pillar, Tech Enabled Traceability.

## II. Tech-enabled End-to-end Traceability throughout the Food Safety System

In a report, commissioned by Lloyd's Register Foundation, RS Standards looked at the impact of traceability on the safety of food. The evidence that improved traceability leads to safer food systems is commonly accepted. However, the review found only a few examples of supply chains with full traceability, typically covering high dollar items with simply supply chains.<sup>1</sup>

A critical first step is to define the critical tracking events with agreed upon key data elements which will enable end-to-end traceability. A single repository for globally holding and sharing such information is not feasible or desirable. Accordingly, interoperability is necessary to create a traceable food supply chain.

AIM North America believes interoperability requires FDA-backed global ISO based standards for both physical and digital identities are needed to facilitate a system that allows supply chain participant's flexibility of approach in capturing and sharing universally recognized content. Such standards must support and encourage the use of technology [and automated collection], be designed to accommodate various levels of stakeholder technical capabilities/readiness as well as facilitate the adoption of emerging technologies. A standards-based approach is necessary for achieving scalability, lowering adoption costs, and preventing the exclusion or elimination of smaller supply chain participants.

In the [November 11, 2016 FDA report to congress](#) the following gaps were identified in the Institute of Food Technologist pilots.

1. Lack of coverage of all establishments (e.g., farms and restaurants are excluded)
2. Lack of uniform data and record requirements
3. Inability to link incoming with outgoing product within a firm and from one point in the supply chain to the next
4. Inadequate mechanisms to rapidly capture, receive, and analyze tracing information (electronic and technology applications).

It is the opinion of AIM that it is feasible to enable global food transparency through a cooperation with regulatory bodies, standards organizations, and user communities if some deficiencies / gaps in the current standards are addressed.

Continuing the work of FSMA 204 by developing food process flow steps for the new business models including e-commerce. By establishing universal baseline requirements, each supply chain participant should be able to collect and share the same information. It is important to recognize that as a product moves through the supply chain it will have different data requirements enabling this transparency. A tote of bulk lettuce may have a product id, lot number and harvest date by the time it reaches the consumer in a delivered salad it will have a different product id with a serial number uniquely identifying it.

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<sup>1</sup> Lloyd's Register Foundation, The Impact of Improved Traceability on the safety of Food, 19 October 2021, <https://www.lrfoundation.org.uk/en/news/impact-traceability-food-safety/>  
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AIM North America has had a long partnership with GS1 and several of the GS1 specifications have been vetted through the ISO standardization process which ensure global collaboration. AIM North America recommends that the FDA ensures Food Traceability is backed by ISO specifications that are more likely to be adopted by the global community. See Appendix B.

AIM North America recommends that the FDA addresses the following issues in laying the foundation for ubiquitous traceability:

1) New Era of Smarter Food Safety Product identification

Regulatory agencies need to decide what level of granularity they desire to be impacted. This ultimately determines how standards are developed and solutions implemented. Since this paper is discussing consumer e-commerce it is reasonable to assume that we are discussing individual units. Industry identifies individual units by product id and serial number.

2) Globally Unique Identification

The [ISO/IEC 15459](#) standard establishes a common framework for the identification of assets in the supply chain including the method whereas entities can apply to be issuing agencies.

Data carriers are encoded in such a way that you can identify the numbering authority used to interpret the data. Per the specification data carriers, either optical or RF, have a code that indicates that the data following should be interpreted by the issuing agency rules. For example, UPC-A, EAN, Databar are always interpreted by GS1 standards. In addition to the GS1, the European Health Industry, Universal Postal Union, RAIN Alliance, and Dun and Bradstreet are examples of other [issuing agencies](#).

AIM North America's recommendation to the FDA that any issuing organization in the global traceability be a registered numbering authority. An example of a non-unique numbering authority would be some of the state cattle associations. They issue a number to farmers to sell their beef under and that number is recorded when the beef is sold at auction. However, since there is no requirement for uniqueness Iowa numbers could be duplicated with Indiana numbers making it difficult to identify original source.

3) Common Data Carriers attributes

Today there are a number of voluntary industry guidelines; i.e. Produce Traceability Initiative, GS1 US Foodservice Traceability Initiative, calling out a variety of data carriers including GS1-128, U.P.C., GS1 DataMatrix, ITF14, GS1 Databar, and QR code. AIM North America recommends the standardization of minimum set of data attributes to be contained within the data carrier, ideally this set would be aligned with the data elements required to withdraw a product from market; for instance: GTIN, Lot/Batch and/or a Serial Number and Expiration Date (or another relevant date). Key in deciding data elements is standardization in the determination and calculation of relevant date codes, particularly food Expiration Dates. FDA consideration should also be given in determining whether the relevant date code should be a safety or quality end of life date—given that the end-of-life date represents a brand's best estimate of the time and temperature expected to be encountered by the

product from product labeling to end of life. Below is a table illustrating options – the left column specifies the business objective, and the next 2 columns compare a data rich data carrier with a GTIN.

It is important for the FDA to be aware of industry initiative as well. GS1 US has set a sunrise date of [2027 for 2D carriers](#) to be scanned across POS with enhanced data attributes which could include lot number and a date<sup>2</sup>.

Table outlining features that are enabled with enhanced item attributes

Feature	GTIN	GTIN+LOT, Serial Number, & Expiry Date
<b>Traceable</b>	Not without other manual intervention	Yes
<b>Additional Data required beyond GTIN</b>		Yes
<b>Product Recall</b>	Not without other manual intervention	Yes
<b>Anti-Counterfeit Measures</b>	Not without other measures	Yes
<b>FIFO Inventory Management</b>	Not without other measures	Yes

Next you need to examine the data capacity of current data carriers. For instance, if an example GS1-128 case label was generated per the GS1US Foodservice Case Label Guidance a data carrier that could contain the data elements (or to use the GS1US term - application identifiers) - that can meet the requirement are listed in the table below.

Data Carrier	Comments
<b>U.P.C.-A/EAN/Databar/ITF14</b>	Contains GTIN only – not recommended for traceability since the item is identified only at the class level
<b>QR Code, GS1 DataMatrix, GS1-128</b>	GS1-128 is limited in size to 48 characters so the combination of elements cannot exceed that size / QR Code, GS1 DataMatrix can contain all needed data elements

<sup>2</sup> GS1 Digital Link for Retailers, <https://www.gs1us.org/industries/emerging-topics/gs1-digital-link/gs1-digital-link-for-retailers>  
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<b>RFID</b>	GTIN+ serial number in base memory and Lot/Batch and Expiration Date in user memory as needed
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4) Critical Tracking Events and Key Data Elements

AIM North America recognizes the GS1 EPCIS, published as: ISO/IEC 19987:2015 Information technology — EPC Information services — Specification, as the leading standard for event data capture and recommend its global adoption.

The GS1 EPCIS specifies the syntax that the data can be exchanged. The key data elements (KDE) or critical tracking events (CTE) required to meet the global traceability initiative is beyond the scope of this document. The minimal supply chain events that are captured in the food supply chains can and does vary today among solution partners. This limits supply chain interoperability and could add unnecessary cost / friction into the globally ubiquitous traceability of food.

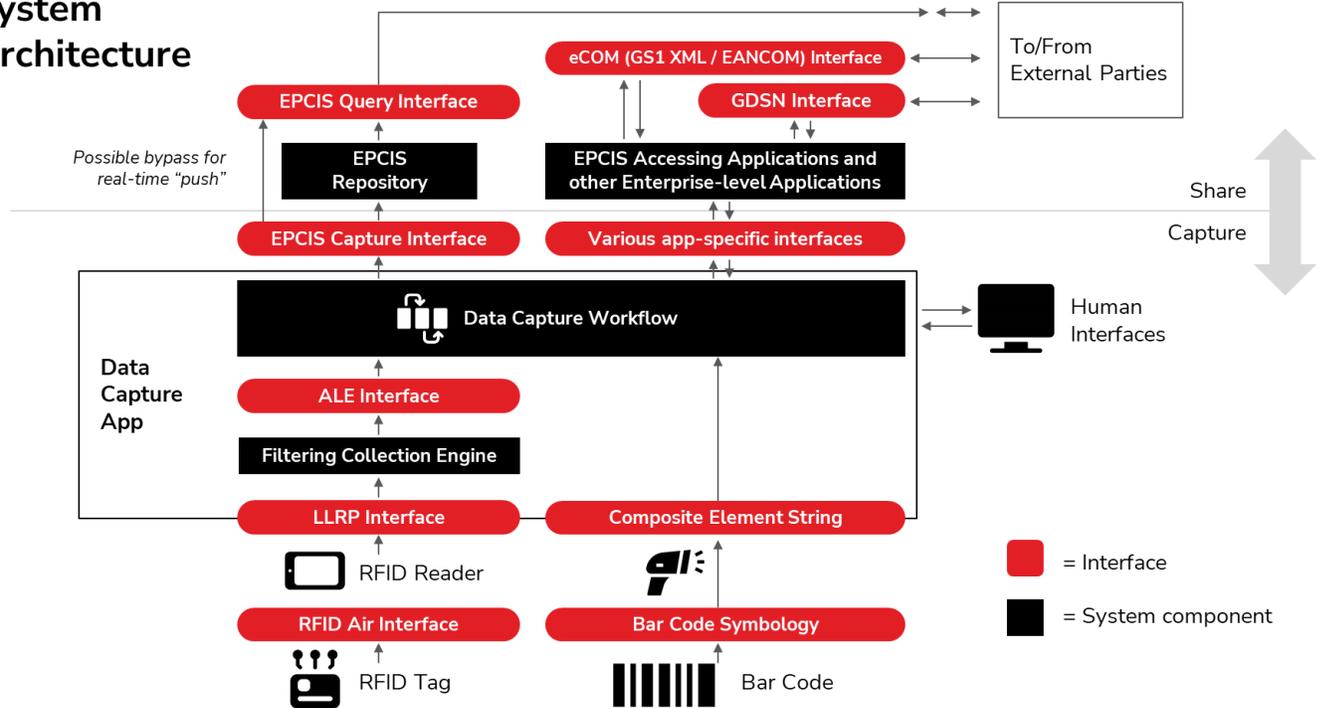
To address this situation, AIM North America recommends that the FDA set the minimal level set of supply chain events and the key data elements that are required to ensure interoperability at the base level.

5) Global access to interoperable data repositories

The FDA needs to consider the time span required for a trace back. Current paper processes time varies dramatically from a few days to a few months. The FDA in FSMA 204 has established a target of providing the FDA the required data within 24 hours of the data being requested.

GS1 EPCIS Query Interface is diagramed below to provide an example of a potential method of meeting the trace back data retrieval times by accessing one or more EPCIS repositories. In the typical scenario of a trace back from multiple start points through one or more middle points to the source it is a certainty that more than one data repository will be involved.

# System Architecture



Another emerging GS1 standard – GS1 Digital Link may provide another method of walking back the chain. The [GS1 Digital Link Standard](#) example could be enabled for authenticated access of EPCIS data for the GTIN, lot/batch, serial number, expiration date.

## GS1 Digital Link Example

<https://id.example.com/gtin/02388060103489/lot/1234/ser/001?expdate=991231 linktype=EPCIS>

<https://id.example.com/gtin/02388060103489>



When a GS1 Digital Link is interpreted the Global Trade Item Number is recognized as the class of items the link refers to

[/lot/1234/ser/001?expdate=991231](https://id.example.com/gtin/02388060103489/lot/1234/ser/001?expdate=991231 linktype=EPCIS)



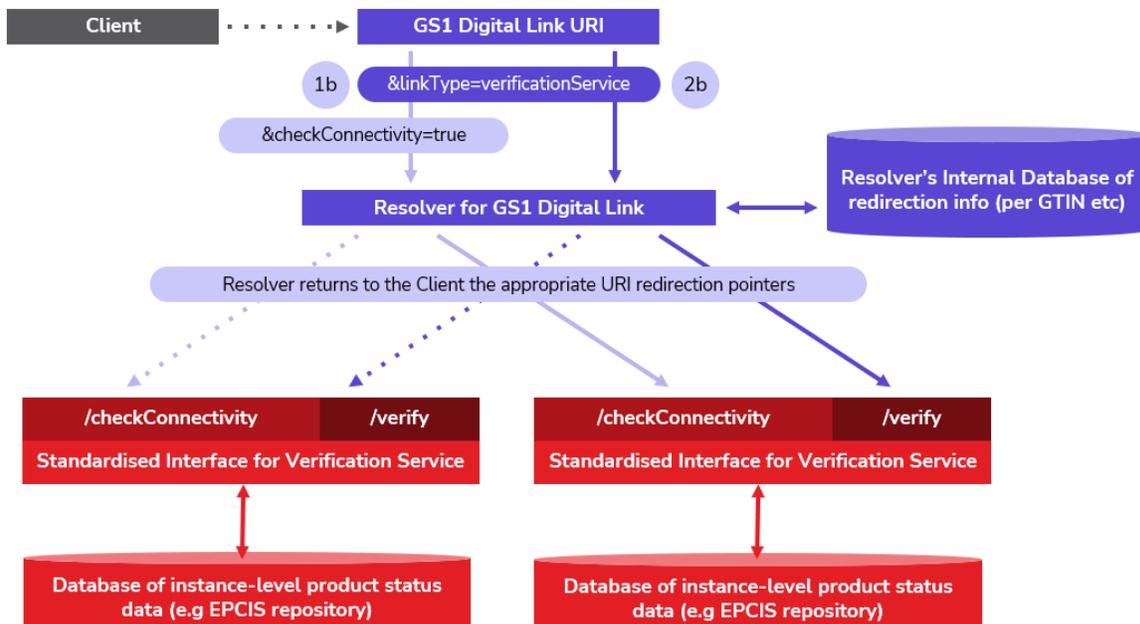
This section identifies the specific instance of product by using the lot/ batch, serial number and expiration date of Dec 31, 2099

[&linktype=EPCIS](https://id.example.com/gtin/02388060103489/lot/1234/ser/001?expdate=991231 linktype=EPCIS)



Linktype=EPCIS will retrieve the GS1 EPCIS data for this item.

The reference architecture could appear as following. This model is already being followed in the United States for the Drug Supply Chain Security Act (DSCSA) and in other countries for food. This model enables the data owner (primary producer or supply chain actor) control over their data.



A significant part of the business case – or incentive – for investing in traceability technology is responding to rapidly growing consumer demand for greater product information. Combined with advances in consumer technology (i.e., smart phones and constant internet access), consumers are demanding far more information than can be stored on a label or packaging. Intelligent connected labels are the way of the future. To ensure regulations do not become obsolete before they can even be implemented, and to allow interested parties to maximize the benefits of deploying traceability solutions, FDA should ensure that its regulations specify the minimum data attributes on the package.

#### 6) Digitally signed data carriers

As the use of global food traceability increases it will be prudent to enable a method of generating verified symbols that can be authenticated either in an online connected manner or in a stand-alone application.

[ISO/IEC 20248](#) specifies a method whereby data stored within a barcode and/or RFID tag is structured and digitally signed. The purpose of the standard is to provide an open and interoperable method, between services and data carriers, to verify data originality and data integrity in an offline use case. The [ISO/IEC 20248](#) data structure is also called a "DigSig" which refers to a small, in bit count, digital signature.

[ISO/IEC 20248](#) also provides an effective and interoperable method to exchange data messages in the Internet of Things [IoT] and machine to machine [M2M] services allowing intelligent agents in such services to authenticate data messages and detect data tampering.

### III. Food Safety Culture

Traceability is a fundamental cornerstone of any robust food system, underpinning the claims and labelling on the product. In the context of food safety, traceability has been introduced to enable the food industry to meet regulatory requirements and provide food assurance, as well as having effective systems in place to enable prompt product recalls if required. The public simultaneously stands to benefit from investment in a traceable food supply chain through improved outbreak prevention and response, reductions in food waste, optimization of inventory and consumer protection.

#### A. Food Process Map for Ghost Kitchens and 3<sup>rd</sup> party delivery services

The first step will be to work with food safety specialist to develop a HACCP food process flow map. This map will identify the critical tracking points to be captured. By continuing the traceability from the food service location through consensus-based standards combined with digital verification points will continue the chain of custody of the product. The current release of EPCIS enables documents (i.e. picture verification, certificate claims or sensor data) to be attached to items traveling through the supply chain to the final destination, the consumer. Also, through AI the picture required at each point can alert the driver and/or brand owner that the food handling procedures are not correct and provide remediation steps. The following safety concerns can be enabled and validated:

##### 1. Safe Temperatures for Delivery

Food should be delivered as quickly as possible, to avoid the potential of the food danger zone. Some companies make use of insulated thermal liners or refrigerants to deliver TCS foods (foods that need time and temperature control for safety). Once TCS foods go out of these temperature zones, there's a risk for foodborne bacteria to grow. This is where insulated delivery bags and coolers become useful to maintain safe temperatures.

##### 2. Packaging

Besides insulated delivery boxes, it's a good idea to make use of tertiary packaging to keep food upright and avoid spillage during transportation. This will also prevent physical damage and environmental contamination. Unlike primary packaging used by the retail food establishment or restaurant, the tertiary packing should be cleanable to be reused.

##### 3. Clean vehicles

Many food delivery drivers use their own vehicles for delivery. It's important that all vehicles used in the transportation of food are kept clean and free from odors, animal hair, and other debris. It's the delivery company's responsibility to make sure that the drivers have guidelines on how to properly clean and maintain their vehicles.

## B. Inventory Management & Food Waste

By making every product visible in a business's electronic inventory management system, companies can have greater efficiency and agility of operations, substantially reducing understocking and overstocking. In the retail context, electronic product tracking can provide detailed data on demand for individual products in specific stores and regions, enabling more efficient ordering, planning, and pricing. In many cases, the savings from reduced labor costs would offset the investment in such technology. FDA should consider the emerging use of returnable packaging and the potential cross contamination of food that the process of container reuse introduces into the food stream. Identification and electronic tracking ensure proper handling and sterilization processes are performed on these returnable packaging which is critical.

Every year, approximately 1.3 billion tons of food are lost or wasted around the world—an amount that could feed almost half of the world's population, according to a report from the [North American Initiatives on Food and Organic Waste study completed in 2018](#)<sup>3</sup>.

ECRLoss Institute in Europe has shown that accurate management of inventory has a tremendous impact on food waste. Waste is not a given, if you increase product's shelf life by one day you can reduce waste by 42.8% for high moving inventory categories.<sup>4</sup>

## C. Brand Power & Consumer Demand

Direct digital interactivity between the consumer and the product is becoming a key means of encouraging brand loyalty and re-purchasing. In 2018, 75% of consumers would be willing to switch brands if another offered them more in-depth product information beyond the label, up from 39% in 2016 as reported by [FMI and Label Insights report, "Transparency Imperative"](#). Similarly, consumers are increasingly demanding information about sustainability. More than ever, consumers are willing to engage with businesses that invest in food safety technology. Meeting this demand for ingredients and process transparency requires information to be collected, stored, and shared throughout each step of the supply chain. Enhanced data carriers, such as RFID and 2D barcodes, can identify a specific product throughout the supply chain. One data carrier may not be sufficient in meeting the needs throughout the supply chain. For instance, when receiving product or taking inventory, RFID may enable labor required. But when selecting an ingredient for a transformation event in a small foodservice, a direct line of site data carrier may be better suited. If the data carriers on pack contained the same data elements, they could be used interchangeably throughout the supply chain.

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<sup>3</sup> CEC, 2017, Characterization and Management of Organic Waste in North America – Foundation Report, Montreal, Canada: Commission for Environmental Cooperation. 260pp.

<sup>4</sup> Managing Retail Food Waste & Markdowns Increasing sales and reducing waste in the fresh supply chain <https://www.ecrloss.com/research/sell-more-waste-less>

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Traceability should not require customized solutions. If the same solution can satisfy regulatory requirements and enable businesses to connect with consumers, there is likely to be less resistance to adopting compliance measures. Additionally, investing in technology-driven traceability helps to create a food safety culture of trust and transparency.

#### IV. Smarter Tools & Approaches

FDA should collaborate with industry to develop resources and identify venues for educating retailers, foodservice and other supply chain members on the traceback process and information needed by FDA, State, and local government officials to conduct a traceback of a food which has been linked to foodborne illness outbreak.

Data Analytics and Artificial Intelligence (AI) are current technology trends. Emerging data mining technology can help identify hot spots, analysis trend analysis and help uncover root cause. Good data analytics is driven by data that is captured from supply chain items and requires automatic identification and data capture techniques.

Emerging sensor technology in the new era of smarter food safety includes sensing environmental and other food quality conditions such as temperature, humidity, brix, and CO<sub>2</sub>. By storing and transmitting environmental conditions in a cryptographically-secure way to make the data actionable in the supply chain by associating to the food item (GTIN). Critical to the use of sensors in traceability of the food supply is the accuracy of the tag's sensors and real time clock as well as the regularity and granularity of the sensing interval. Time and temperature calibration accuracy data, and preferably whether calibration methods are in compliance with National Institute of Standards and Testing (NIST) or other national standards should be documented and available to the user(s) of the sensor data. When expiration and other relevant end of life dates are included in sensor traceability data, these dates should be set by the product brand owner. As with current paper-based expiration dates, the calculation of the end-of-life dates should reflect quality and potency of the product's ingredients, packaging, shelf-life extenders and general care expected by the brand owner. Preferably this data should be digitally signed by the brand owner.

FDA should focus on making regulations as evergreen as possible allowing for the adoption of emerging technologies.

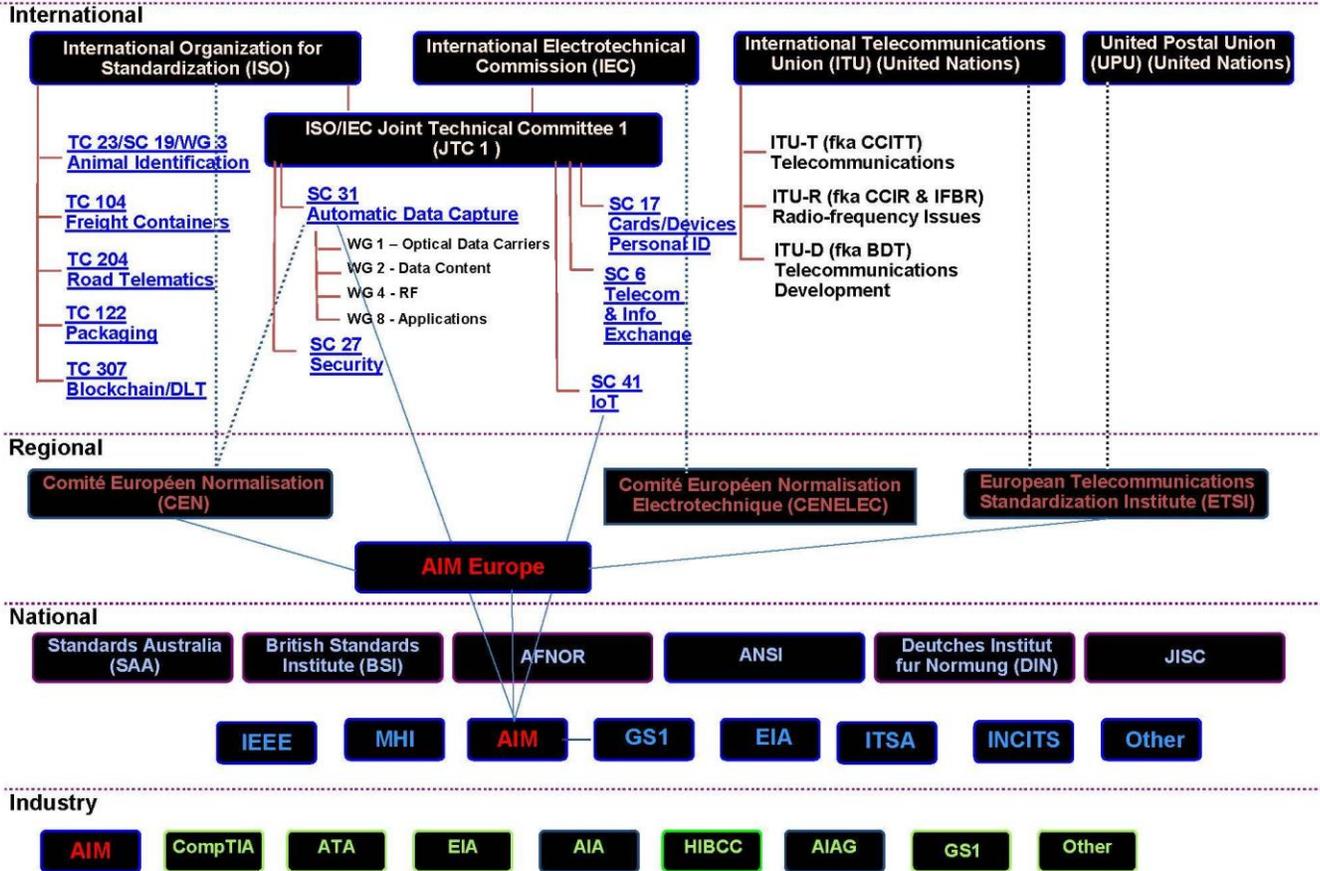
#### CONCLUSION

A New Era of Smarter Food Safety must focus on the adoption of technology to bring automation, integrity, and data management solutions to the food supply chain. The first step FDA should take is to complete a food process flow map with industry experts through the workflows of concern, ghost kitchens and 3<sup>rd</sup> party delivery. This food process map will illustrate the business requirements need to achieve the objectives.

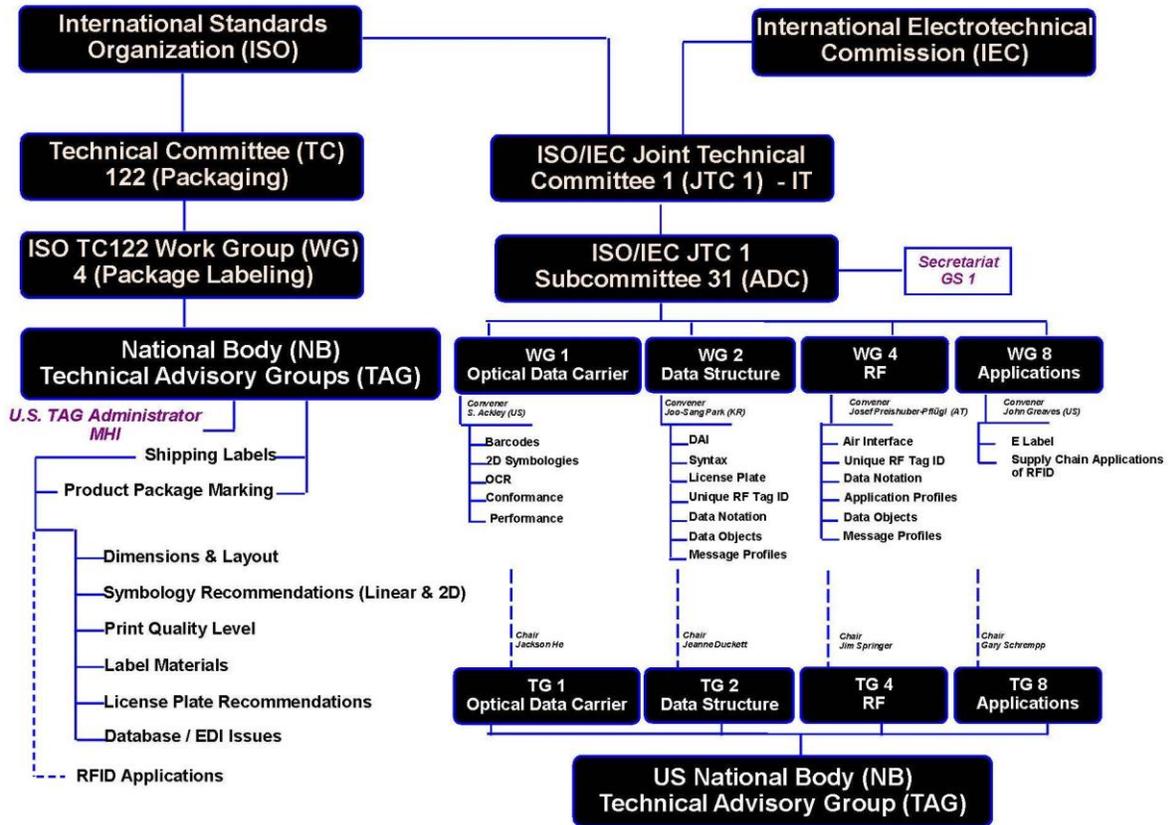
AIM North America thanks the FDA for this very useful effort, and for its consideration of our comments. If we can provide additional information or answer any questions, please do not hesitate to contact the undersigned.

# APPENDIX A

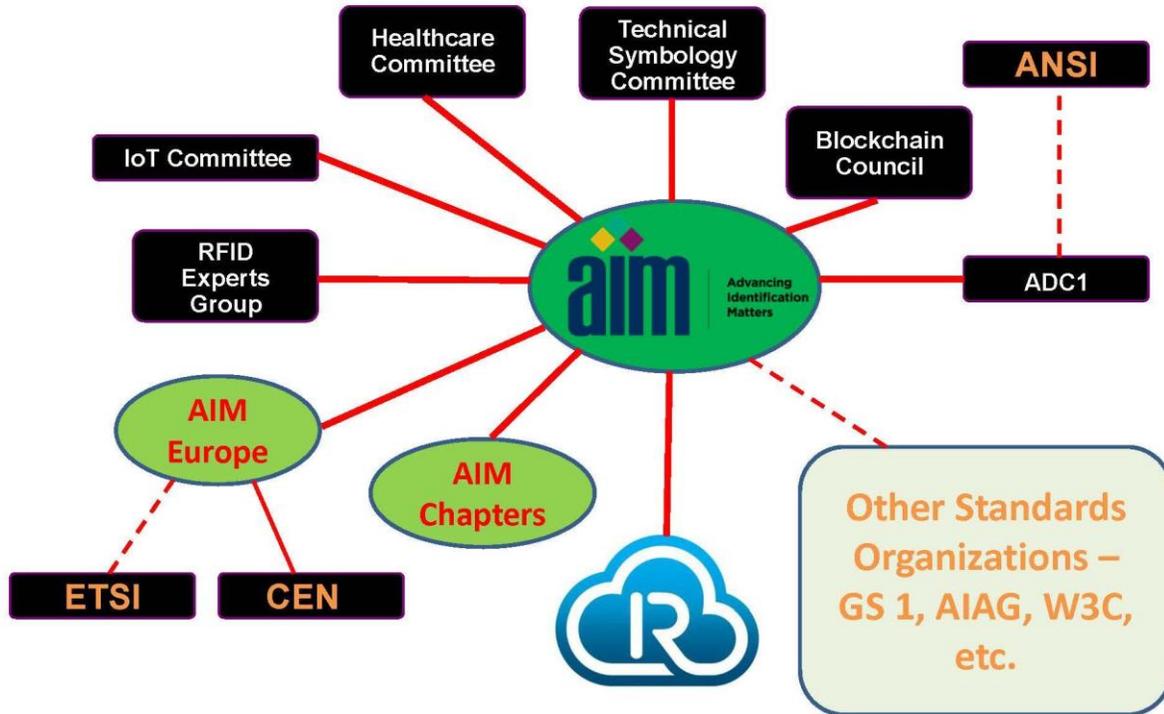
## Standards Organizations



## Standards Organizations

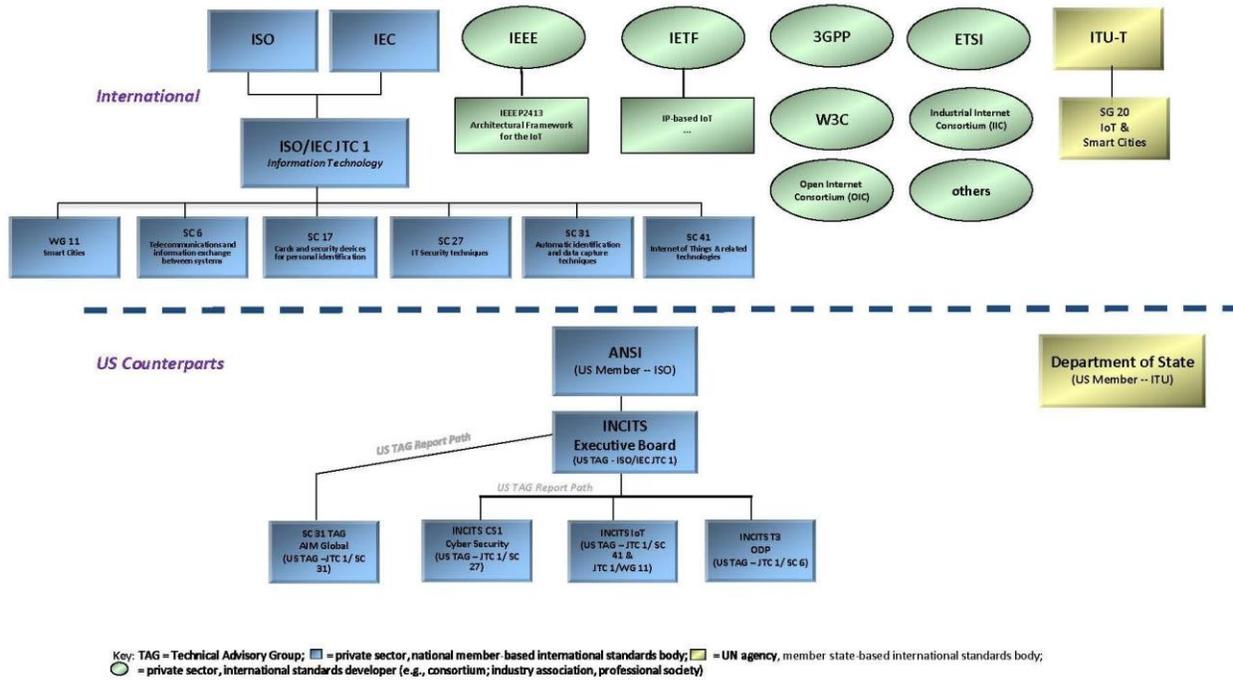


## AIM Relationships



# Some Key IoT Standards Developers

## Some IoT Standards Developers



## APPENDIX B

AIM Ultracode International Symbology Standard

AIM 7351731 Medical Electrical Equipment & Sys Electro Immunity Test for RFID Readers

AIM ISS DotCode Symbology Specification

[Global Numeric Code Issuing Agencies](#) in accordance with ISO/IEC 15459.

ISO/IEC 15459-1:2014 Information Technology - Automatic Identification And Data Capture Techniques - Unique Identification - Part 1: Individual Transport Units

ISO/IEC 15459-2:2015 Information Technology — Automatic Identification and Data Capture Techniques — Unique Identification — Part 2: Registration Procedures

ISO/IEC 15459-3:2014 Information technology — Automatic Identification and Data Capture Techniques — Unique Identification — Part 3: Common Rules

ISO/IEC 15459-4:2014 Information Technology - Automatic Identification and Data Capture Techniques - Unique Identification - Part 4: Individual Products and Product Packages

ISO/IEC 15459-5:2014 Information technology — Automatic Identification and Data Capture Techniques — Unique Identification — Part 5: Individual Returnable Transport Items (RTIs)

ISO/IEC 15459-6:2014 Information technology — Automatic Identification and Data Capture Techniques — Unique Identification — Part 6: Groupings

ISO/IEC 15459-8:2009 Information Technology — Unique Identifiers — Part 8: Grouping of Transport Units

ISO/IEC 15961 - Information Technology - Data Protocol for Radio Frequency Identification (RFID) for Item Management

[ISO/IEC 15961 – Data Constructs Register](#)

### GS1/ ISO Standards list

ISO Standard	GS1 Component
ISO/IEC 15459-6	GTIN (Global Trade Item Number)
ISO/IEC 15459-4	SGTIN (Serialized Global Trade Item Number)
ISO/IEC 6523	GLN (Global Location Number)
ISO/IEC 15459-1	SSCC (Serial Shipping Container Code)
ISO/IEC 15459-4 & 5	GIAI (Global Individual Asset Identifier)
ISO/IEC 15459-5	GRAI (Global Returnable Asset Identifier)
ISO/IEC 15418	GSRN (Global Service Relationship Number)
ISO/IEC 15418	GDTI (Global Document Type Identifier)

ISO/IEC 15418	GINC (Global Identification Number for Consignments)
ISO/IEC 15459-6	GSIN (Global Shipment Identification Number)
ISO/IEC 15418	GCN (Global Coupon Number)
ISO/IEC 15418	CPID (Component / Part Identifier)
ISO/IEC 15418	Application Identifiers
ISO 22274	Global Product Classification (GPC)
IETF RFC 3986	EPC URI Syntax
ISO 9735	EANCOM syntax
UN/CEFACT UNSMs	EANCOM content
W3C XML	GS1 XML syntax
W3C XML	GS1 XML content
ISO/IEC 15424	Symbology identifiers
ISO/IEC 15420	EAN/UPC
ISO/IEC 16390	ITF-14
ISO/IEC 15417	GS1-128
ISO/IEC 24724	GS1 DataBar
ISO/IEC 16022	GS1 DataMatrix
ISO/IEC 24723	GS1 Composite
ISO/IEC 18004	GS1 QR Code
ISO/IEC 18000-63	UHF Class 1 Gen 2 /IEC 18000-63
ISO/IEC 18000-3	HF Class 1 Gen 2
ISO/IEC 15962	EPC Tag Data Standard
ISO/IEC 24791-5	Low-level Reader Protocol (LLRP)
ISO/IEC 24791-2	Application Level Events (ALE)
ISO/IEC 24791-3	Reader Management (RM)
ISO/IEC 24791-3	Discovery, Configuration, and Initialization (DCI)
ISO/IEC 19987	EPC Information Services
ISO/IEC 19988	GS1 Core Business Vocabulary (CBV)