June 24, 2024

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-2024-N-1744
Data and Technology in the New Era of Smarter Food Safety

To Whom It May Concern:

AIM North America's Food Supply Chain Work Group (subject matter experts of the design and application of automatic identification and data collection technologies), are pleased to submit the enclosed comments regarding the Docket No. FDA-2024-N-1744 seeking comments on the agency's approach to Data and Technology in the New Era of Smarter Food Safety.

AIM North America is a chapter of AIM Global, founded in 1973. AIM Global 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. Our technology expertise is primarily centered around asset tracking and tracing technologies, including Barcodes (1D & 2D Symbols), Radio Frequency Identification (RFID), Real Time Location System (RTLS), Internet of Things (IoT), and other supportive technologies and software.

AIM Global 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 (AIDC) and their associated devices utilized in inter-industry applications and international business interchange. Please see Appendix A for AIM Standards Activities.

AIM's mission is to advocate, educate, and coordinate with other subject matters experts including the FDA, GS1, MHI, AIAG, and others, to further the adoption of AIDC usage in industry. Please see Appendix B for information on industry focus and partnerships.

AIM North America will be happy to respond to any technical support requests from the FDA about the value of standards, answer any technical questions regarding AIDC technologies, and/or provide demonstrations of AIDC technology.

Sincerely yours,

Jeanne Duckett
AIM North America Board Chair

Julie McGill
AIM NA Food Supply Chain Work Group Chair

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INTRODUCTION AND SUMMARY

AIM North America, as an industry advocate for standards development and AIDC technologies, appreciates this opportunity to submit comments in response to the Food and Drug Administration's (FDA) Comments Notice for Data and Technology in the New Era of Smarter Food Safety Request for Comments, Docket No. FDA-2024-N-1744.

The public comments provided during the FDA public meeting on April 24, 2024, made it clear that it is essential for a safer, more resilient, and sustainable interoperable digital supply chain.

Our intention with sharing these comments is to demonstrate how globally ubiquitous, interoperable traceability technologies, based on international consensus-based standards, can enable meeting the objectives of the FDA in ensuring ways to leverage data and technology to exponentially advance food safety under the New Era of Smarter Food Safety.

AIM North America advocates for the adoption of voluntary consensus-based standards in the pursuit of enhanced food safety and we ask that the FDA harness the power of technology to usher in a new era of smarter food safety and supply chain management.

We respectfully submit comments on the following areas for your consideration:

- Tech-Enabled Traceability
- Predictive Analytics
- Whole Genome Sequencing
- Ways to Use Technology to Monitor and Gather Data

It is our intention to share our industry expertise regarding AIDC technologies throughout our comments. With over 50+ years of being "the voice" for the AIDC industry, we have assisted, supported, and witnessed multiple industries and businesses around the globe have proven success with broad-scale implementation when they provide the following to stakeholders:

- Common language/unified data structures and standardization procedures in place for interoperability
- Education and tools on technologies for stakeholders
- Partnerships and collaboration with industry pipeline
- Sharing of inherent benefits for individual companies and the overall food supply chain

TECH-ENABLED TRACEABILITY

Tech-enabled companies are organizations that leverage technology extensively to optimize their operations, customer interactions, and overall business model. The New Era of Smarter Food Safety has made significant progress in standardizing the data collected by the industry, providing tools to harmonize Critical Tracking Events (CTEs) and Key Data Elements (KDEs) at their facilities.

However, this is just the initial step. The next challenge the FDA needs to address is the sharing of these CTEs and KDEs. Achieving interoperability is crucial for a safe food supply chain, as it allows supply chain partners to share data easily and efficiently. To promote this, we suggest that the FDA should collaborate with technology partners to develop:

1. ***What additional steps can FDA, industry, and other stakeholders take to enable and enhance traceability across the global food supply chain?***
    - GS1 standards such as EPCIS, unique identification, and data carriers can ensure a common language to promote communications and alignment for interoperability across the supply chain.
    - Promote communication and alignment on which data carriers are going to be used within a specific network so recipients can ingest the data downstream.
    - Standardized Electronic Data Exchange (EDE) protocols to ensure consistent data transfer and exchange between businesses.
    - Use X12 standards like EDI 856 for transactional data sharing.

2. ***How can FDA help promote collaboration and information sharing between technology providers and food supply chain entities to support low- or no-cost traceability solutions?***

    The cornerstone to collaboration and information sharing is a unified data format for all business partners to use. For instance, the Global Dialogue on Seafood Traceability mandates that all partners use GS1 EPCIS TDS 2.0 (ISO/IEC 19987:2024) this ensures that all systems in the supply chain communicate in the same language.

    The FDA's greatest challenge is educating the industry to understand that adopting new technologies and automation can provide positive ROI to shareholders, stakeholders, and customers. Effective technology solutions should not hinder what a company already does, but rather, enhance business processes, augment efficiencies, streamline operations, and improve bottom-line costs.

    Some suggested approaches that the FDA can take to provide this type of education and support for the industry would include the following:

    - Identify supply chain partner conduits, such as non-profit organizations, industry trade associations, farm co-ops, etc., to help educate and raise awareness, provide technical guidance, and share needed resources and support.

- Work directly and in cooperation with FSMA 204 collaboration/industry groups and partners, such as GS1, IFT, FMI, PTI, AIM, etc.
- Help create tools (perhaps in conjunction with some of the industry partners) to help users justify traceability and technology investments, such as ROI calculators.
- The FDA often conducts pilot programs and publishes case studies demonstrating the benefits and practical implementation of new technologies. These real-world examples help businesses see the value and feasibility of adopting FSMA 204.
- FDA encourage the USDA (United States Department of Agriculture) to adopt interoperable traceability as a requirement for USDA funded school lunch programs.

3. ***What are the greatest challenges to creating a more digital, traceable global food supply, and how can FDA and stakeholders work together to approach this in a manner that creates shared value for all participants?***

   For the global food industry to recognize the shared value in a traceable supply chain, the challenge involves effectively incentivizing the economic benefits that link traceability to business success. This requires demonstrating how traceability can enhance both profitability and societal benefits.

   The FDA should consider providing economic incentives that can promote financial benefits, such as tax breaks, subsidies, or grants for companies investing in traceable supply chains. Another consideration might be to establish a Technology and Innovation Support Program that lends support for the adoption of new technologies by providing resources, training, and partnerships with technology companies to assist in this transition.

   FDA can also help on global education for small-medium businesses by sharing case studies and other resources on how to calculate the benefits of traceability.

   And, lastly, the FDA could work with countries who export to the US and their associations to help educate and bring awareness.

4. ***How can FDA best work with the food industry and State, Local, Tribal, and Territorial (SLTT) regulatory partners in testing FDA's internal Product Tracing System (PTS)?***

   - Identify and prioritize the highest impact groups.
   - Invite and encourage SLTT partners to participate/join public-private partnership(s) to document activities and help influence outcomes.
   - For the FDA's PTS program to be a success collaboration with technology companies is essential.
     - For example, a solution provider has been working with Marine Stewardship Council to test their Traceability Exchange Protocol (TEP) which facilitates the exchange of traceability data.
     - This is done in an EPCIS Query interface and a GS1 Digital Link Resolver.

    - Verifiable CTEs and KDEs are requested through a digital link to confirm the safety and authenticity of a product. The FDA can utilize a similar paradigm to assess existing foodborne outbreaks and responses.
- FDA Food Code should be updated to encourage digital HACCP records and electronic traceability. Once the data is uploaded, the PTS (Product Tracing System) will automatically process the information into a supply chain visibility data standard called EPCIS External Link Disclaimer (Electronic Product Code Information Services). This data standard is intended to promote data interoperability within FDA's PTS. While this openly accessible data standard is one option available for use by industry to promote interoperability across their supply chains, it is not a requirement to comply with the Food Traceability Rule and it is not a requirement to send FDA food traceability data in EPCIS format.

5. ***What are the most promising use-cases for deploying Artificial Intelligence (AI) or other emerging tools to advance food traceability across the food industry sector?***

Using AI can help reduce food waste, ensure product freshness and availability. Generative AI can help supply chains in several ways: AI predictions, simulations, and recommendations can support automation and improve efficiency. But it is important to think of this technology as a collaborator. It is meant to enhance the valuable work done by people in the supply chain. In that light, generative AI shows potential in the following areas:

- Global communication – language translation
- Data Quality – flag anomalies
- Management – forecasting, supply, and demand planning
- Resilience – enable companies to have contingency plans ready by testing disruption scenarios, such as weather or supply chain disruptions.

GS1 standards can help provide consistent data across systems and supply chains. They serve as a foundation to build transactional and event data that provides full supply chain visibility. For more information, visit here.

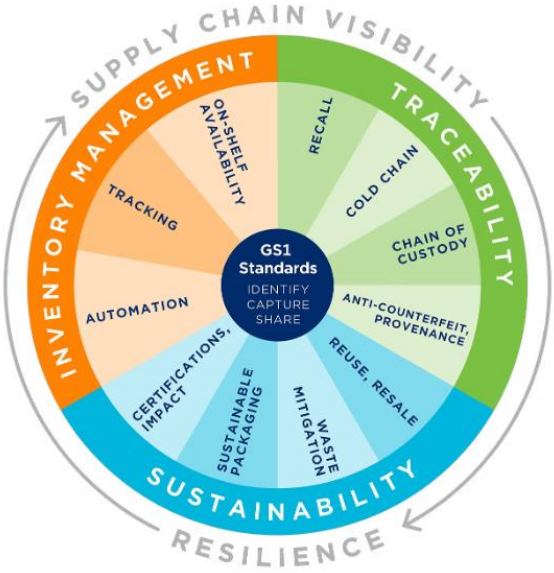
6. ***Beyond food safety, where else can tech-enabled traceability create value for the food industry?***

By using a common data language, such as GS1 Standards, and implementing AIDC technologies to meet regulatory requirements companies will be able to gain the following:

- Reduction of food waste.
- Prevention of food fraud.
- Increase on-shelf life and availability
- Maintain truck load optimization.
- Reduce the risk of mislabeling
- Greatly simplifies inspections

- Enable operational efficiency.
- Visibility for crisis contingency plans (such as weather, labor shortages, targeted recalls, etc.).
- Gain end-to-end Supply Chain Visibility for improved inventory management, traceability, and sustainability as shown in the wheel below.

Graphic provided by GS1 US



PREDICTIVE ANALYTICS

As stated in the FDA docket, predictive analytics are an emerging tool that will bring value across the stakeholder community while also enabling traceability.

Predictive analytics, a subset of data analytics, can significantly enhance traceability by leveraging historical data, machine learning algorithms, and statistical techniques to forecast future events and outcomes/trends within the supply chain.

Predictive analytics enables traceability by providing actionable insights that help companies anticipate and address potential issues before they become problems. By integrating predictive analytics with real-time data capture and advanced technologies, companies can achieve a more resilient, transparent, and efficient supply chain. This not only enhances product safety and quality, but also ensures compliance with regulatory standards and meets consumer expectations.

Data analytics plays a pivotal role in achieving this visibility by integrating data from various sources, such as IoT devices, RFID tags, GPS systems, machine learning (ML), voice recognition or natural language

processing (NLP), and enterprise resource planning (ERP) systems. Here's how predictive analytics enables traceability:

1. **Early Detection of Issues**

'Digital food safety' is integral to food safety at Nestle's.[1] Predictive analytics can identify patterns and anomalies in real-time data, allowing for the early detection of potential issues such as contamination, spoilage, or disruptions in the supply chain. Nestle has developed artificial intelligence tools that use 'big data' in real time from a variety of sources. They are exploring digital tools for use in agriculture, to help farmers manage inputs and ensure food safety. By predicting these issues before they occur, companies can take proactive measures to prevent them, ensuring the safety and integrity of food products.

2. **Enhanced Inventory Management**

By analyzing historical data and predicting future demand, predictive analytics helps optimize inventory levels. This ensures that the right amount of product is available at the right time, reducing the risk of stockouts or overstock situations. Improved inventory management directly impacts traceability by ensuring that products are tracked accurately throughout their lifecycle. Kroger leveraged machine learning to create a task-based flow to optimize efficiency[2]. Kroger can measure its success by pallets—or rather, the absence of them on store floors. By creating innovative experiences driven by data and technology, Kroger improves the customer experience and expands access to fresh, affordable food across the country.

3. **Supply Chain Optimization**

Predictive analytics can forecast potential disruptions in the supply chain, such as delays in shipping, changes in supplier reliability, or fluctuations in demand. This enables companies to adjust their supply chain strategies proactively, ensuring continuous traceability and minimizing the impact of unforeseen events.[3] FleetPride modeled three years of historical shipping data to predict the number of in- and outbound shipping orders per warehouse, over daily, weekly, and monthly horizons. As a result, they were able to reduce errors and accurately predict staffing needs.

4. **Quality Control and Compliance**

By predicting potential quality control issues, predictive analytics help maintain high standards throughout the supply chain. For example, it can forecast when equipment is likely to fail or when environmental conditions might compromise product quality. This ensures that products remain within specified quality parameters, enhancing traceability and compliance with regulatory requirements.

5. **Risk Management**

Predictive analytics allows companies to assess and manage risks more effectively. By analyzing data from various sources, it can predict potential risks related to suppliers, logistics, and market conditions. This enables companies to develop contingency plans and mitigate risks, ensuring that traceability is maintained even under challenging circumstances. Nestle's developed a digital warehouse of the future. Developed in partnership with XPO logistics[4], this state-of-the-art 638,000-square-foot distribution center will feature advanced sorting systems and robotics co-developed with Swisslog Logistics Automation. Powered by predictive analytics and intelligent machines, this digital warehouse will be used to accelerate the distribution and delivery of Nestle products as well as function as a testbed environment for XPO technology prototypes prior to global release. The digital warehouse enables Nestles to manage the risks of a global supply chain.

6. **Customer Insights and Feedback**

Analyzing customer feedback and behavior patterns helps companies predict future trends and preferences. This information can be used to adjust production and supply chain strategies, ensuring that products meet customer expectations and regulatory standards. Enhanced understanding of customer needs also supports traceability by aligning supply chain practices with market demand. For instance, Compass Group Australia believed there also could be an opportunity to support healthcare staff while improving the experiences and health outcomes of residents' nutritional needs.[5] The Meal Vision Scanning Unit includes a high-resolution camera, radio frequency identification (RFID), and a LIDAR scanner for measuring the food. At the start of a meal, an RFID tag attached to a plate enables the unit to detect which resident a particular plate belongs to; then, the unit's camera scans the plate to identify the food and calculate its volumes. The process is repeated when the resident returns the plate after eating. Data captured at both touchpoints feed into

an AI cloud-based platform that is shared with staff and clinicians who can use these real-time insights to track the total percentage consumed and food categories to identify patterns in the residents' behaviors, and determine which residents require adjustments in their meals.

Nestle developed KitKat's Chocolatory experience leveraging Machine Learning (ML) and NLP "natural language processing" to connect with customers who customize and purchase uniquely flavored candy bars.[6] This provides Nestle with a wealth of knowledge pertaining to their customer base and the changing tastes of the next, digitally native cohort of consumers.

7. **Integration with Advanced Technologies**

Predictive analytics works synergistically with other advanced technologies like IoT, blockchain, and AI. For instance, IoT devices can provide real-time data on product conditions, which predictive analytics can use to forecast potential issues. Sharing data by leveraging global standards, i.e. GS1 EPCIS 2.0, can ensure the correctness of the data and the ability to seamlessly share it.

8. **Anomaly Detection**

Understanding trends and using detailed analysis of POS and shrink data can lead to improved loss prevention for retailers. AI systems can be trained to automatically identify patterns within data that do not conform to expected behavior. Unlike traditional EBR (Exception Based Reporting), anomaly detection methods rely on predefined rules and thresholds. AI anomaly detection utilizes machine learning and statistical algorithms to learn from data over time, becoming increasingly adept at spotting irregularities.[7] AI provides insights into more complex data sets that allows for more real-time decision making.

9. **Food Waste and Greenhouse Gas Emissions Reduction**

Predictive analytics can forecast spoilage rates based on environmental data (temperature, humidity) collected during transportation and storage. This helps in planning the distribution and ensuring that products reach consumers before they spoil, reducing food waste and greenhouse gas emissions. General Article of Interest: Please see the National Library of Medicine, National Center for Biotechnology Information's article on The Application of Artificial Intelligence and Big Data in the Food Industry.[9]

Footnote Links for Information for Predictive Analytics:

- [1]https://www.nestle.com/about/research-development/food-safety-quality
- [2]https://www2.deloitte.com/us/en/pages/about-deloitte/articles/a-new-day-for-the-night-shift.html
- [3]https://www.ibm.com/case-studies/fleetpride
- [4]https://www.aidataanalytics.network/business-analytics/articles/how-nestle-optimized-the-data-to-ai-pipeline
- [5]https://www2.deloitte.com/us/en/pages/about-deloitte/articles/bringing-ai-to-the-forefront-of-a-tech-driven-food-revolution.html
- [6]https://www.aidataanalytics.network/business-analytics/articles/how-nestle-optimized-the-data-to-ai-pipeline
- [7]https://www.zebra.com/us/en/blog/posts/2024/ai-is-eating-exception-based-reporting-tools.html
- [8]https://www.grocerydive.com/spons/leveraging-data-analytics-for-enhanced-food-traceability-and-waste-reductio/692938/
- [9]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10742996/#B28-foods-12-04511

WHOLE GENOME SEQUENCING

As the FDA has recognized, Whole Genome Sequencing (WGS) is essential to determine illnesses that may cause an outbreak, to isolate specific ingredients in multi-ingredient foods, to identify geographic regions of ingredients or facility processing sites, and to identify different sources of contamination. WGS and Automatic Identification and Data Capture (AIDC) systems can be integrated to enhance the efficiency, accuracy, and utility of genomic data in various applications, such as healthcare, research, bioinformatics, and the food supply. Here's how they tie into each other:

1. **Data Collection and Management**:

    - Sample Tracking: AIDC technologies, such as barcodes and RFID tags, can be used to track biological samples through various stages of WGS, ensuring that samples are accurately labeled and managed throughout the sequencing process.
    - Automated Data Entry: AIDC can automate the capture and entry of sample information into databases, reducing the likelihood of human error and ensuring consistent data entry, which is critical for the integrity of genomic data.

2. **Process Efficiency**:

    - Streamlining Workflows: AIDC can streamline the workflows in laboratories by automating the identification and handling of samples. For example, robotic systems equipped with barcode readers can sort and process samples based on their unique identifiers.
    - Real-Time Monitoring: RFID tags can provide real-time tracking and monitoring of samples, allowing for timely updates on the status and location of samples within the sequencing pipeline.

3. **Data Integration and Analysis**:

- Linking Genomic Data: AIDC systems can link physical samples to their corresponding digital genomic data. This ensures that each sample's sequencing data can be easily retrieved and analyzed in the context of the sample's metadata.
- Enhanced Data Accuracy: The precision of AIDC in identifying and capturing data minimizes discrepancies between the physical samples and their digital records, which is essential for accurate genomic analysis.

4. **Quality Control**:

- Verification Processes: AIDC technologies can be used to verify sample identities at multiple points in the sequencing process, enhancing quality control and reducing the risk of sample mix-ups.
- Audit Trails: The use of AIDC can create detailed audit trails that document every interaction with a sample, from collection to sequencing, which is important for regulatory compliance and traceability.

5. **Scalability**:

- Handling Large Volumes: As the volume of sequencing data grows, AIDC systems can efficiently manage and track large numbers of samples, facilitating scalability in WGS projects.
- Integration with Other Systems: AIDC can integrate with laboratory information management systems (LIMS) and other bioinformatics tools, enabling seamless data flow and management across different platforms.

By integrating AIDC with WGS, laboratories and research institutions can achieve higher levels of accuracy, efficiency, and scalability in their genomic studies. This integration also supports accurate data management, quality control, and compliance with regulatory standards.

WAYS TO USE TECHNOLOGY TO MONITOR AND GATHER DATA

24. ***How can FDA, industry, and SLTT partners use technology to monitor and gather data on sales of foods through E-commerce?***

AIDC technology encompasses a range of tools beyond RFID and barcodes, including QR codes, digital watermarks, NFC (Near Field Communication), active and passive Bluetooth Low Energy (BLE) beacons and solutions, and biometric identification. Below are some ways the FDA, industry, and SLTT partners can utilize AIDC technology specifically for monitoring and gathering data on food sales through e-commerce. Many of these technologies are already used by major food

suppliers providing a circle of information flow and fosters connections along the demand chain. The data that is scanned or read is the foundation of the information chain for B2B and B2C e-commerce.

B2C E-commerce Applications:

- **QR Codes for Product Information and Consumer Engagement**: QR codes with GS1 digital link can be printed on food packaging, linking to detailed product information such as ingredients, nutritional content, allergens, and sourcing. Consumers can scan these codes with their smartphones to access relevant data, empowering them to make informed purchasing decisions.
- **NFC for Authentication and Traceability**: Near Field Communication (NFC) technology allows for short-range wireless communication between devices. NFC tags embedded in food packaging can store unique identifiers and authentication data, enabling quick verification of product authenticity.
- **Authentication and Anti-Counterfeiting**: Barcodes and RFID tags can be used to verify the authenticity of food products. By scanning these identifiers, consumers, retailers, and regulatory authorities can confirm that a product is genuine and has not been tampered with. Biometric identification methods such as fingerprint or facial recognition can be integrated into E-commerce platforms to enhance security and prevent unauthorized access to sensitive data, including payment information and personal health records.
- **Data Analytics and Predictive Modeling**: By leveraging AIDC data combined with advanced analytics techniques, stakeholders can gain valuable insights into consumer behavior, market trends, and supply chain dynamics. Predictive modeling algorithms can forecast demand, optimize inventory levels, and mitigate supply chain risks.

B2B E-commerce Applications:

- **Product Traceability**: AIDC data carriers such as RFID tags and barcodes compliant with international standards identification can be affixed to food products and cases at the point of manufacture or packaging. These tags contain globally unique identifiers that can be scanned throughout the supply chain, allowing for precise tracking of products from production to point of sale.
- **Real-Time Inventory Management**: RFID technology enables real-time monitoring of inventory levels. By integrating RFID readers with E-commerce platforms, retailers can automatically update their inventory systems as products are sold, reducing the risk of stockouts or overstocks.
- **Real-Time Data Capture**: AIDC technologies enable real-time data capture and transmission, providing stakeholders with up-to-date information on food sales, inventory levels, and consumer preferences. This data can be analyzed to identify trends, optimize supply chain logistics, and improve business decision-making.

- **Geolocation Tracking**: AIDC technology can incorporate geolocation tracking capabilities, allowing stakeholders to monitor the movement of food products from distribution centers to delivery locations. Geotagged data can help detect anomalies, track delivery routes, and ensure compliance with regulatory requirements.
- **Integration with E-commerce Platforms**: AIDC solutions can be seamlessly integrated with e-commerce platforms, enabling automatic data capture and synchronization across online sales channels. This integration streamlines inventory management, order fulfillment, and customer service processes, enhancing the overall e-commerce experience.
- **Batch and Lot Tracking**: RFID and barcode technology facilitates batch and lot tracking, allowing stakeholders to quickly identify and recall specific products in the event of a food safety issue or contamination outbreak.
- **Environmental Monitoring**: RFID and BLE based sensor solutions monitor temperature, humidity, vibration and shock for real-time indicators of potential exposure or damage to food products, allowing partners to quickly identify and isolate potential food safety risks.

In summary, AIDC technologies offers diverse applications for data accuracy for monitoring and gathering data on food sales through e-commerce, enabling stakeholders to enhance transparency, traceability, and regulatory compliance across the entire supply chain ecosystem.

25. ***What data and research can be collected in partnership with stakeholders to help assess existing regulatory framework in place domestically and internationally for food sold through e-commerce?***

The use of AIDC technologies that leverage international standards allows stakeholders to collaborate in multiple ways to collect data and conduct research in support of existing regulatory frameworks.

C2A and B2A E-commerce:

- **Regulatory Compliance and Auditing**: AIDC data can support regulatory compliance efforts by providing auditable records of food sales transactions, product recalls, and quality control measures. Regulatory agencies can use RFID and barcode data to monitor compliance with food safety regulations, track the distribution of recalled products, and identify trends or patterns that may indicate emerging food safety risks and can leverage this data to verify compliance with food safety standards and investigate potential violations.
- **Supply Chain Transparency**: By collecting data from RFID and barcode scans, stakeholders can gain insights into the movement of food products through the supply chain. This transparency helps identify inefficiencies, reduce waste, and ensure compliance with regulations.
- **Collaboration and Information Sharing**: By standardizing RFID and barcode systems and data formats, industry stakeholders and SLTT partners can facilitate collaboration and

information sharing across the food supply chain, enabling more effective responses to food safety threats and emergencies.

26. ***Are there current ambiguities related to sales of food through e-commerce that could pose risks to consumers? What actions could FDA and partners take?***

We recognize the use of AIDC technology in the sale of food through e-commerce. However, e-commerce food supply chain is even more opaque than the retail or food service supply chains. The FDA needs to encourage the adoption of consensus-based standards throughout the e-commerce food supply chain.

AIM believes the use of proper AIDC technologies will ultimately prove to be the most efficient regulatory compliance solution for the food industry. Beyond compliance, AIM also believes the use of AIDC technologies will drive greater overall accuracy, safety and efficiency in the food supply chain, reducing waste which ultimately will improve overall profitability of the food industry.

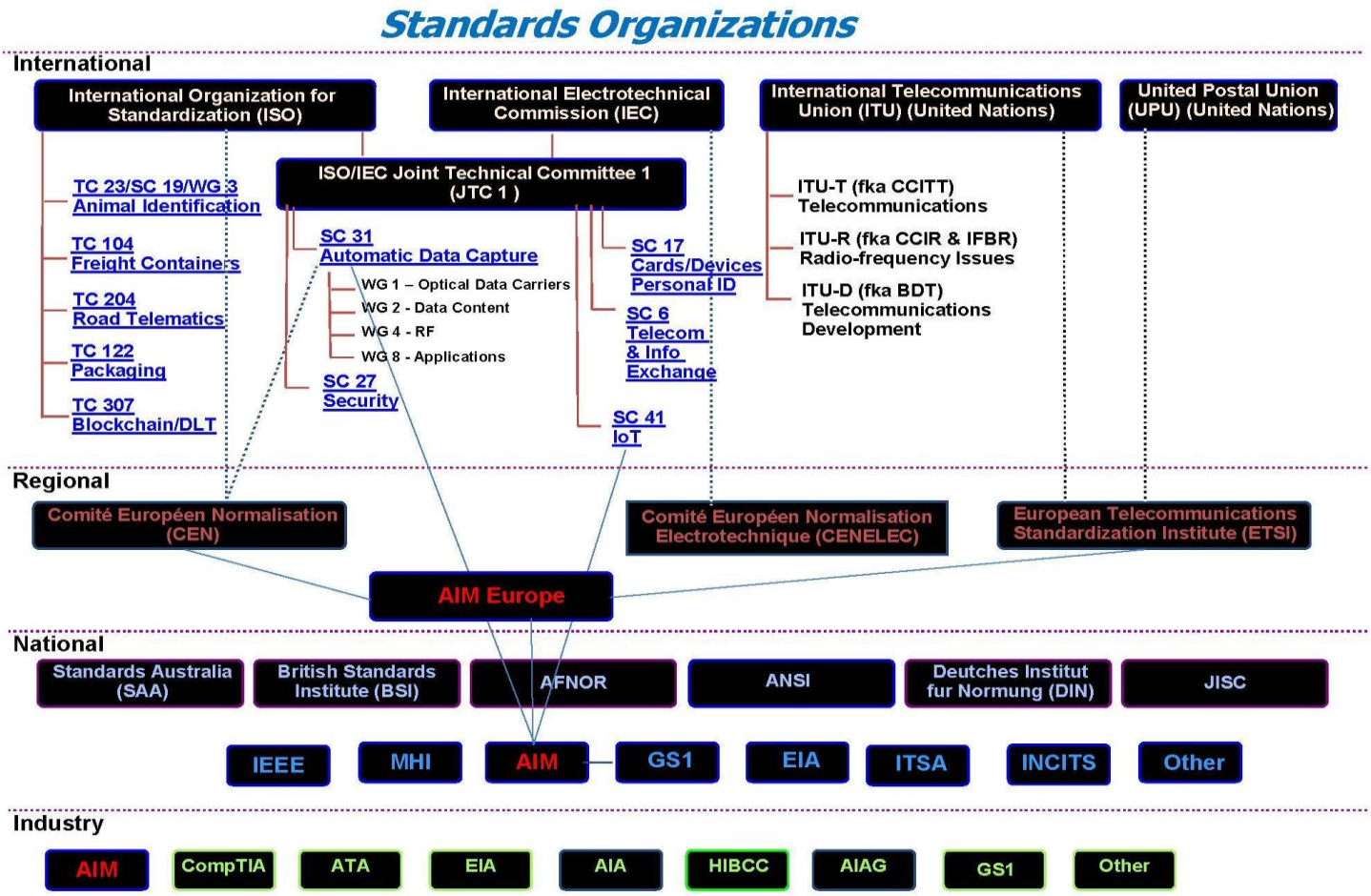
There is always an upfront cost for an industry to develop/implement new technologies. Once properly implemented, however, technology enables new ways of doing business which leads to higher quality and more cost-efficient products and solutions. FDA leadership, with AIM's support, can drive education of how the food industry can implement, use, and benefit from AIDC technologies.

CONCLUSION

A modernized approach to recalls for FDA-related commodities must focus on the adoption of standards-based technology to bring automation, integrity, and data management solutions to the food supply chain. The next step FDA should take is to complete a process flow map with industry experts through the workflows of concern. This process map will illustrate the business requirements needed to achieve the objectives.

AIM North America thanks the FDA for this very useful effort, and for consideration of our comments. If we can provide additional information or answer any questions, please do not hesitate to contact Mary Lou Bosko, CEO, AIM North America, marylou@aimglobal.org, 724-742-4473.

APPENDIX A


Standards Organizations
International
International Organization for Standardization (ISO)
International Electrotechnical Commission (IEC)
International Telecommunications Union (ITU) (United Nations)
United Postal Union (UPU) (United Nations)
TC 23/SC 19/WG 3 Animal Identification
TC 104 Freight Containers
TC 204 Road Telematics
TC 122 Packaging
TC 307 Blockchain/DLT
ISO/IEC Joint Technical Committee 1 (JTC 1)
SC 31 Automatic Data Capture
WG 1 – Optical Data Carriers
WG 2 - Data Content
WG 4 - RF
WG 8 - Applications
SC 27 Security
SC 17 Cards/Devices Personal ID
SC 6 Telecom & Info Exchange
SC 41 IoT
ITU-T (fka CCITT) Telecommunications
ITU-R (fka CCIR & IFBR) Radio-frequency Issues
ITU-D (fka BDT) Telecommunications Development
Regional
Comité Européen Normalisation (CEN)
Comité Européen Normalisation Electrotechnique (CENELEC)
European Telecommunications Standardization Institute (ETSI)
AIM Europe
National
Standards Australia (SAA)
British Standards Institute (BSI)
AFNOR
ANSI
Deutches Institut fur Normung (DIN)
JISC
IEEE
MHI
AIM
GS1
EIA
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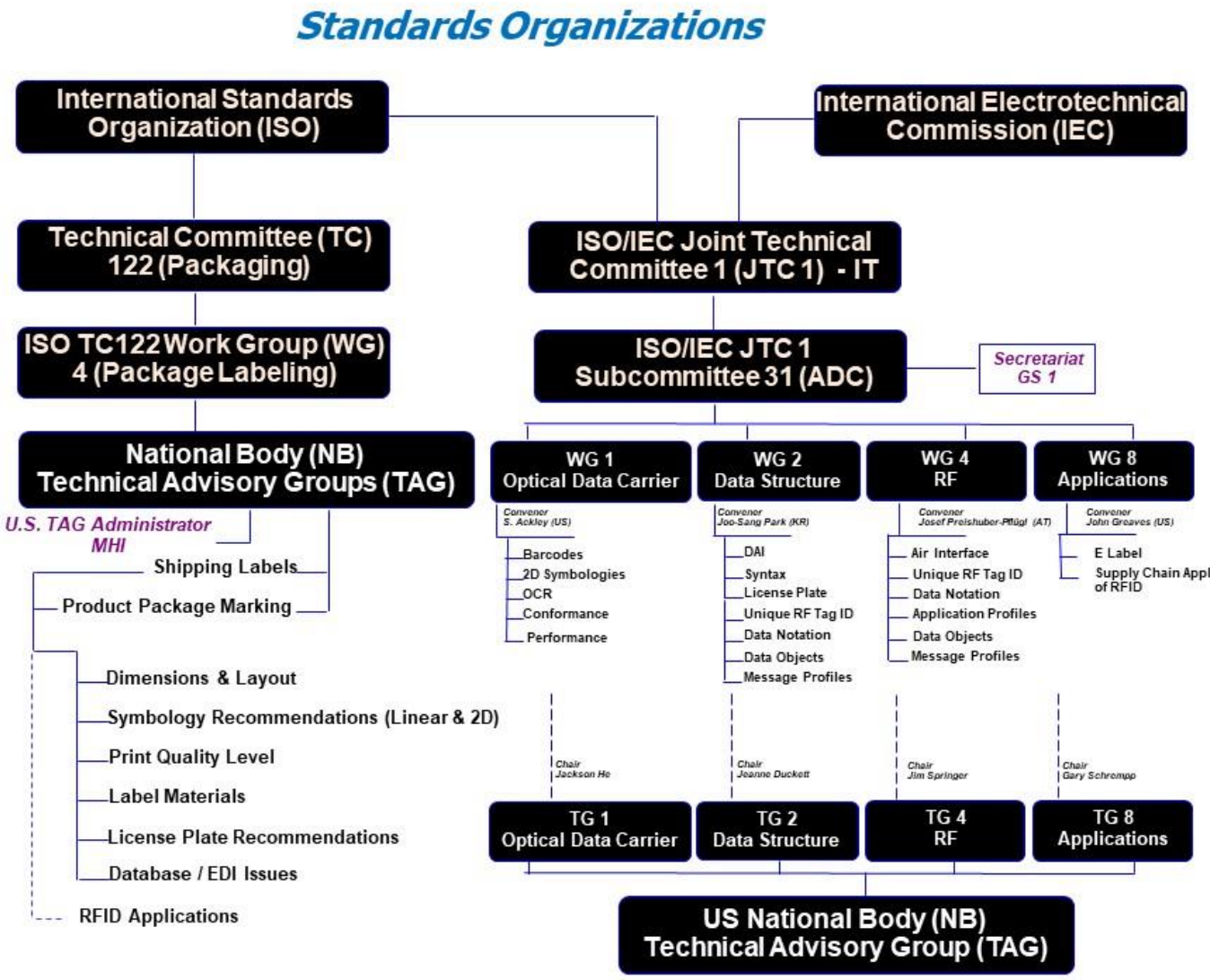
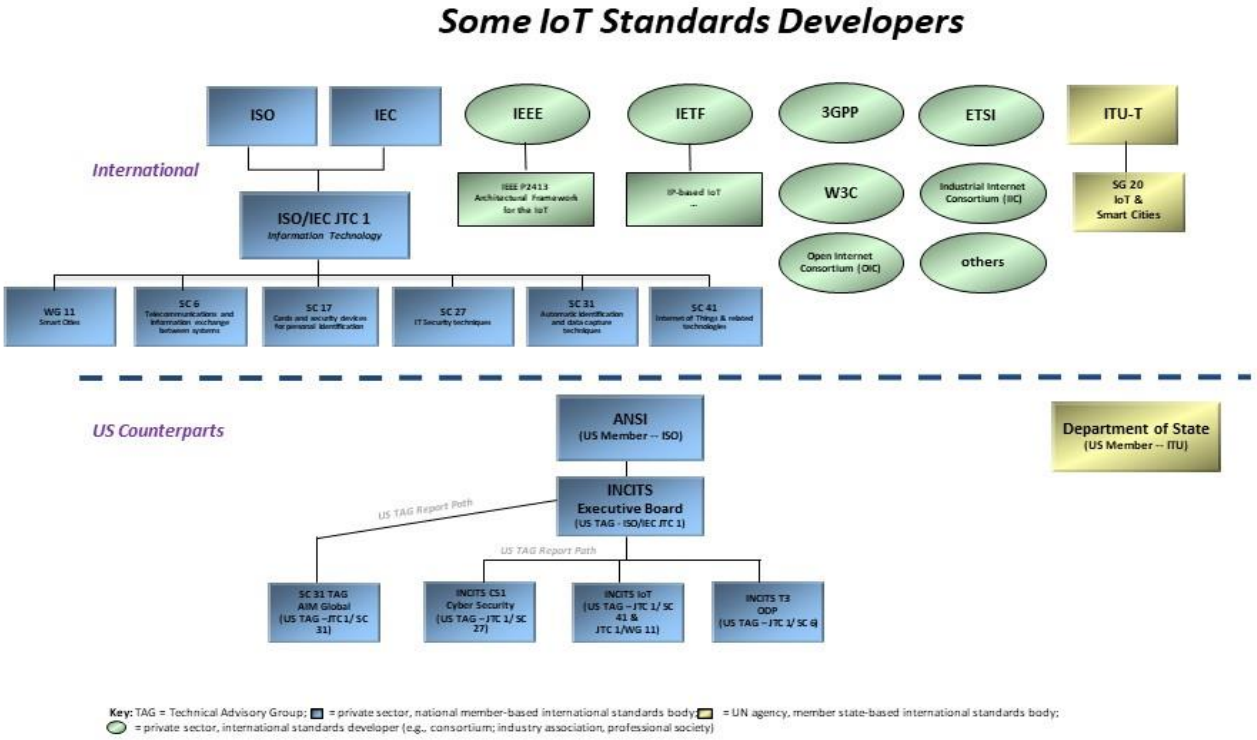
INCITS
Other
Industry
AIM
CompTIA
ATA
EIA
AIA
HIBCC
AIAG
GS1
Other


Standards Organizations
International Standards Organization (ISO)
International Electrotechnical Commission (IEC)
Technical Committee (TC) 122 (Packaging)
ISO/IEC Joint Technical Committee 1 (JTC 1) - IT
ISO TC122 Work Group (WG) 4 (Package Labeling)
ISO/IEC JTC 1 Subcommittee 31 (ADC)
Secretariat GS 1
National Body (NB) Technical Advisory Groups (TAG)
WG 1 Optical Data Carrier
WG 2 Data Structure
WG 4 RF
WG 8 Applications
Convener S. Ackley (US)
Convener Joo-Sang Park (KR)
Convener Josef Preishuber-Pflügl (AT)
Convener John Greaves (US)
U.S. TAG Administrator MHI
Shipping Labels
Product Package Marking
Barcodes
2D Symbologies
OCR
Conformance
Performance
DAI
Syntax
License Plate
Unique RF Tag ID
Data Notation
Data Objects
Message Profiles
Air Interface
Unique RF Tag ID
Data Notation
Application Profiles
Data Objects
Message Profiles
E Label
Supply Chain Applications of RFID
Dimensions & Layout
Symbology Recommendations (Linear & 2D)
Print Quality Level
Label Materials
License Plate Recommendations
Database / EDI Issues
RFID Applications
Chair Jackson He
Chair Jeanne Duckett
Chair Jim Springer
Chair Gary Schrempp
TG 1 Optical Data Carrier
TG 2 Data Structure
TG 4 RF
TG 8 Applications
US National Body (NB) Technical Advisory Group (TAG)

Some Key IoT Standards Developers



AIM/ISO Standards List

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

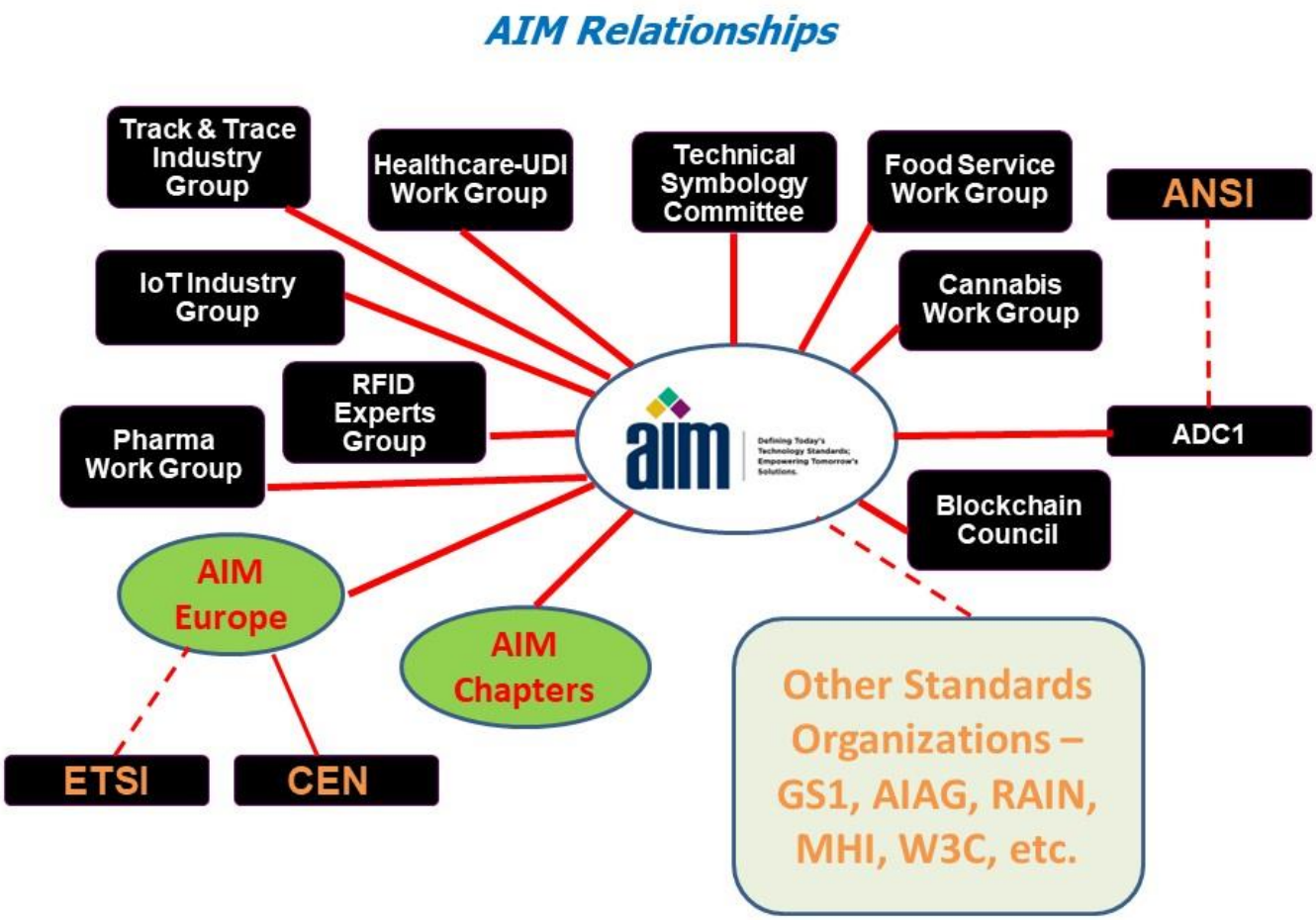
ISO/IEC 15961 - Information Technology - Data Protocol for Radio Frequency Identification (RFID) for Item Management

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/ICE 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, Confguration, and Initialization (DCI)
ISO/IEC 19987	EPC Information Services
ISO/IEC 19988	GS1 Core Business Vocabulary (CBV)

APPENDIX B


AIM Relationships
Track & Trace Industry Group
Healthcare-UDI Work Group
Technical Symbology Committee
Food Service Work Group
ANSI
IoT Industry Group
Cannabis Work Group
RFID Experts Group
Pharma Work Group
aim
ADC1
Blockchain Council
AIM Europe
AIM Chapters
Other Standards Organizations – GS1, AIAG, RAIN, MHI, W3C, etc.
ETSI
CEN