July 20, 2020

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


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 Federal Register, Volume 85, Number 35, pages 10107-1011.

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 including barcode, RFID, RTLS, IoT, etc. AIM North America 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. With an uncompromised reputation as a global authority for nearly 50 years, AIM, Inc. takes pride in its proven value as an unbiased resource and industry leader. AIM, Inc. acts as the administrator of the U.S. Technical Advisory Group (TAG) to ISO/IEC JTC 1/SC31 for all standardization in AIDC. See Appendix A. Most barcode and RFID standards in ISO today originated in or were contributed by AIM.

AIM North America is an 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) Notice in the above-captioned docket, seeking comment on the agency’s approach to the modernization of food safety, including development of the anticipated Blueprint for a New Era of Smarter Food Safety.

Sincerely yours,

Jeanne Duckett
AIM North America Board & Food Supply Chain Chair

Debangana Mukherjee
AIM North America Board Chair
INTRODUCTION AND SUMMARY

Consumers have long been interested in finding easier ways to identify healthful foods by looking at the labels when food shopping. Claims are quick signals for consumers about what benefits a food or beverage they choose might have, and they can also encourage the food industry to reformulate products to improve their healthy qualities.

The goals of food standards modernization are to:

- Protect consumers against economic adulteration;
- Maintain the basic nature, essential characteristics and nutritional integrity of food; and
- Promote industry innovation by giving manufacturers the flexibility to produce healthier foods.

At the public meeting on the Nutrition Innovation Strategy, held in July 2018, and in comments submitted to the public meeting docket, stakeholders expressed general support for the FDA and the USDA continuing their work to finalize the proposed rule. However, due to changes that have occurred in manufacturing, food technology, market trends, nutrition science and technology the FDA is soliciting comments for this effort.

To meet the FDA’s objective of protecting consumers against economic adulteration and promoting healthier food choices it is paramount that consumers have confidence in the integrity of their food and access to complete nutritional information.

We would like to refer the FDA and USDA to FMI & Label Insights study from consumers in 2018. Their key findings

- Transparency Valued: Almost all consumers (93 percent) continue to say it is important for brands and manufacturers to provide detailed information about what is in food and how it’s made, compared to 94 percent in the 2016 Label Insight study. In addition, the vast majority of shoppers in 2018 (74 percent compared to 39 percent) say they would switch from the brand they usually buy to another brand that provides more in-depth product information, beyond what is on the physical label.
- Consumer Confusion: About two-thirds of shoppers sometimes or always find themselves confused about the ingredients listed on a package, despite saying they are informed after reading a product label.
AIM North America strongly believes that the manner to address these concerns in through standards adoption and leveraging new technologies. AIM North America supports FDA’s focus on technology-driven food traceability and the connection to the digital supply chain to provide the consumer will access to accurate reliable data to support the nutrition facts panel and agency claims such as organic or non GMO.

As far as selecting a healthier diet per a study completed by Albert Heijn¹ the crucial ingredient our nutrition labels lack is transparency and traceability. Many of us strive to eat a healthy diet, but we are missing quality information about where our food comes from. In this study oranges were traced from Brazil to the consumers connecting the famers directly with the consumers. This provided a bridge to where the food was sourced from and the actual ingredients in the juice. Our globalized food system allows food to be grown anywhere that has the right climate, before it is then picked, packed, shipped and finally trucked to wherever customers want to buy it. To get juice that tastes the same from one week to the next, a company might mix oranges from different farms and harvests to achieve a precise sweet/sour balance. The modern food system gives us access to unprecedented variety, but also, when we prefer it, exceptional sameness.

The downside is that long and convoluted food chains can obscure where produce comes from to the point where diners may not know which fish or animal species they are actually eating.

“That single package of ground beef can be coming from hundreds of different sources,” says Alexis Bateman, the director of the Responsible Supply Chain Lab at the MIT Center for Transportation and Logistics. “In the seafood industry, there’s a lot of actual fraud…so people want to make sure it’s the right fish.” ²

Recently, people have been realizing there is something lacking from their diets: quality information. Tech Enabled Traceability can bridge this gap between sourcing and consumers.

As a global organization dedicated to developing interoperable technical guidance and ISO standards, we support the collaborative standards development process. To that end, we feel that the FDA must specify the following minimum elements required for traceability.

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• To enable the consumer transparency that a food safety culture is built on, multiple data carriers on a pack should be converged, that is, reducing the number of on-pack symbols. The proliferation of barcodes and other methods of identification on products and things causes confusion to consumers and trading partners, who expect a seamless experience of connecting products and things to relevant experiences in the digital world.

• Provide supply chain security from point of origin to point of consumption enabling consumer trust in their product selection by collecting critical tracking events from production and tying product certifications such as organic or sustainably caught directly to the item.

• Provide seamless access to expanded digital product master data containing product content, nutritional information and allergens.

AIM North America encourages FDA to adopt policies to facilitate the use of technology to address these challenges by requiring or incentivizing the use of global unique identifiers that can be used to trace each end-consumption item; specifying the minimum content to be tied to global unique identifiers; requiring the use of technology to electronically and easily capture and share required information; and connecting to the digital twin containing product master data. With enhanced, technology-driven data management and automation, we can greatly improve the quality and availability of data in the supply chain, action food safety issues quicker and with more precision, reduce food waste, and build more transparency between trading partners and end consumers.

Food Safety

Increasingly globalized, complex supply chains have resulted in less visibility into food sourcing for customers and regulators. These trends are driving the need for digital transformation through the adoption of technology to bring automation, integrity and data management solutions to supply chain traceability. Digital and sensor technology can enhance the ability to identify, respond to, and prevent food safety issues such as outbreaks. For example, the time it takes to identify the source of a contaminated food product can be drastically reduced compared to the status quo processes for recalls. Given recent food incidents, the use of digital technology has become even more needed, as it can help to make full product data accessible throughout every stage of the food supply chain in the event of a recall.

Currently this level of sophistication is not reflected in the relevant global standards. 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. ISO 22000 Food Management Systems, Harmonized Gap, Codex all contain a similar level of detail.

Power of Connected Supply Chain

COMMENTS

A. Ubiquitous Global Food Traceability

The federal government should adopt standards to set the baseline content – or data points – needed to facilitate a food supply chain that is both visible and actionable. These standards should require such baseline content to be physically tied to each item entering the food supply chain in a manner that can be digitally captured. By establishing universal baseline requirements, each supply chain participant should be able to collect and share the same information (e.g. unique identifier, lot/batch, etc.) regardless of the technology or platform used.

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) FDA/USDA data elements required to recall a product 2) Globally Unique Identification 3) Common data carrier attributes 4) Core set of events to be tracked with minimum viable data elements 5) Global access to interoperable data repositories 6) Digitally signed data carriers

1) FDA/USDA data elements required for traceability

Regulatory agencies need to decide what data elements are required to identify an item in the supply chain, this requirement will normalize the identification across data carriers. An example could be Global Trade Item Number (GTIN), Lot/Batch Number, Serial Number and Relevant date code. We encourage the FDA to set this requirement as soon as feasible as it will provide a guidepost for solution developers.
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, 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 the use of varying data carriers including GS1-128, U.P.C., GS1 DataMatrix, ITF14, GS1 Databar, QR code, and digital watermarking.

AIM North America recommends the alignment 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, or Lot/Batch or Serial Number and/or Expiration Date (or another relevant date). Standardization of the data attributes is critical to successfully locating products in the supply chain for recall or other purposes. Co-location of different data contained in data carriers on the package for the same purpose can introduce complexity and errors in the system. For instance, the Drug Supply Chain Security Act (DSCSA) compels a DataMatrix be contained on the package containing GTIN, Lot, Expiry Date and SN. Another data carrier containing a GTIN and SN for the purposes of traceability introduces complexity and errors. If the standardized minimal data elements are not present in the data carrier some means outside the normal process flow will be needed to acquire them adding friction and cost into the supply chain.

As an alternate approach, a globally unique identifier could be contained in the data carrier with all sub classifying data attributes. Below is a table illustrating this point – the left column
specifies the business objective and the next 2 columns compare a data rich data carrier with a GTIN.

<table>
<thead>
<tr>
<th>Feature</th>
<th>GTIN</th>
<th>GTIN+LOT, Serial Number, &amp; Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traceable</td>
<td>Not without other manual intervention</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Data required beyond GTIN</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Product Recall</td>
<td>Not without other manual intervention</td>
<td>Lot/Batch or Serial Number</td>
</tr>
<tr>
<td>Anti-Counterfeit Measures</td>
<td>Not without other measures</td>
<td>Yes</td>
</tr>
<tr>
<td>FIFO Inventory Management</td>
<td>Not without other measures</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Data Carrier</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.P.C.-A/EAN/Databar/ITF14</td>
<td>Contains GTIN only – not recommended for traceability since the item is identified only at the class level</td>
</tr>
<tr>
<td>QR Code, GS1 DataMatrix, GS1-128</td>
<td>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</td>
</tr>
<tr>
<td>Digital Watermarking</td>
<td>GTIN+ serial number and/or Batch/Lot and Expiration Date</td>
</tr>
<tr>
<td>RFID</td>
<td>GTIN+ serial number in base memory and Lot/Batch and Expiration Date in user memory as needed</td>
</tr>
</tbody>
</table>

4) Core set of events
AIM North America recognizes the GS1 EPCIS, which has also been published as: ISO/IEC 19987 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.

In order to address this situation, AIM North American 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. If the FDA establishes that they require the trace back data within a few seconds that will compel industry to develop electronic path for the data transfer.

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.
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

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

http://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 will retrieve the GS1 EPCIS data for this item.

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 consistent internet access), consumers are demanding far more information than can be stored on a label or packaging. It is clear that 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 compelled to be on the package contain the same data attributes for the same application.

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. Both the GS1 and ISO organizations have developed approved standards for digitally signed carriers.

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

B. Ensuring Extensibility and Scalability

Without interoperability, a vast amount of critical food supply chain data remains siloed, preventing a visible supply chain. The producers and growers at the start of the food supply chain tend to be small businesses, particularly as compared to the large distributors and retailers participating down the line. Supply chain participants can be asked to comply with multiple different/conflicting transparency and traceability demands, which can be burdensome to meet, particularly in the aggregate. Industry collaboration driven by interoperable standards is necessary to lower the technological and financial barriers to adoption and participation, particularly for smaller players. Standardization will also reduce the need for customization allowing for a more seamless and scalable onboarding processes for participants deploying transparency and traceability solutions.

FDA November 2016 document on FDA Does not have an Efficient and Effective Food Recall Process called out that, “Weaknesses in the current system have been identified by the Health and Human Services' Office of the Inspector General (OIG) and that FDA did not have an efficient and effective food recall initiation process that helps ensure the safety of the Nation’s food supply.. In a 2009 report, OIG auditors attempted to trace 40 food products from retail sale back to the farm and only five food products were fully traceable. Problems identified in tracing the food by the OIG included failure by firms to maintain lot-specific information and the co-mingling of products from many farms.

AIM North America recommends conducting additional National/International Food recall simulations at the following intervals.

1. Q1, 2022 Benchmark current state of food trace back
2. Q1, 2023 Interim Report on Progress of Smarter Food Supply Chain
3. Q1, 2024 Report out of Smarter Food Supply Chain and recommendations for next steps

B. 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 reductions. But when selecting an ingredient for a transformation event in a small foodservice, a direct line of sight 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.

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.

CONCLUSION

The General Principles for Food Standards Modernization must focus on the adoption of technology to bring automation, integrity and data management solutions to supply chain traceability. The role of government is to establish minimum standards that will facilitate the use of technology allowing them to work seamlessly.

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.
Standards Organizations

International Standards Organization (ISO)

Technical Committee (TC) 122 (Packaging)

ISO TC122 Work Group (WG) 4 (Package Labeling)

National Body (NB) Technical Advisory Groups (TAG)

ISO/IEC Joint Technical Committee 1 (JTC 1) - IT

ISO/IEC JTC 1 Subcommittee 31 (ADC)

Secretariat

WG 1 Optical Data Carrier

U.S. TAG Administrator (NB)

Shipping Labels

Product Package Marking

Dimensions & Layout

Symbology Recommendations (Linear & 2D)

Print Quality Level

Label Materials

License Plate Recommendations

Database / EDI Issues

RFID Applications

WG 2 Data Structure

WG 3 Applications

WG 4 RF

WG 5 Applications

WG 6 Applications

WG 7 Applications

WG 8 Applications

US National Body (NB) Technical Advisory Group (TAG)
Some Key IoT Standards Developers

Some IoT Standards Developers

ISO
IEC
IEC/TC 1
Information Technology

IEEE
IETF
3GPP
ETSI
ITU-T

INTERNATIONAL

W3C
IETF
W3C
HTTP
Others

US Counterparts

ANSI (US Member = IEC)

INCITS Executive Board (US TAG, INCITS)

SE 25, TAG 11
SE 31, TAG 12, 21
SE 31, TAG 21, 31
SE 28, TAG 21, 31
SE 31, TAG 21, 31
SE 28, TAG 21, 31
SE 31, TAG 21, 31

Department of State
(US Member = BIS)

Key:
T = Technical Advisory Group
† = private sector, national member-based international standards body
@ = IN agency, member state-based international standards body
‡ = private sector, international standards developer (e.g., consortium, industry association, professional society)

Food Standards; General Principles and Food Standards Modernization

-15-
APPENDIX B

AIM Contributed ISO Standards
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 15459


ISO/IEC 15459-8:2009 Information technology — unique identifiers — Part 8: Grouping of transport units

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<td>ISO/IEC 15459-6</td>
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<td>ISO/IEC 15459-4</td>
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<td>ISO/IEC 19988</td>
<td>GS1 Core Business Vocabulary (CBV)</td>
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**Food Supply Chain Management**

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<tr>
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<tr>
<td>REPORT TO CONGRESS ON ENHANCING TRACKING AND TRACING OF GOOF AND RECORDKEEPING</td>
<td>SUBMITTED PURSUANT TO SECTION 204 OF THE FDA FOOD SAFETY MODERNIZATION ACT, PUBLIC LAW 111-353 submitted by US DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION NOV 11, 2016</td>
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<td>FOOD TRACEABILITY FROM BINDERS TO BLOCKCHAIN EDITED BY DR JENNIFER MCENTIRE AND ANDREW KENNEDY</td>
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<td>ROMAINE TASK FORCE FINAL REPORT AND RECOMMENDATIONS, SEPTEMBER 2019</td>
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<td>THE TRANSPARENCY IMPERATIVE- PRODUCT LABELING FROM THE CONSUMER PRESPECTIVE</td>
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<td>ISO 9001 QUALITY MANAGEMENT SYSTEMS — REQUIREMENTS</td>
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<td>CODEX CAC/GL 60-2006 - PRINCIPLES FOR TRACEABILITY/PRODUCT TRACING AS A TOOL WITHIN A FOOD INSPECTION AND CERTIFICATION SYSTEM</td>
<td>USDA HARMONIZED GOOD AGRICULTURAL PRACTICES (GAP) REQUIREMENTS FOR TRACEABILITY</td>
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<td>FOUNDATION FOOD SAFETY SYSTEM CERTIFICATION 22000 (FSSC 22000)</td>
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