



September 12, 2024

Food and Drug Administration,
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: **International Fresh Produce Association (IFPA) Proposal for FSMA 204 Waiver**

To Whom It May Concern:

We are writing to express our collective concerns regarding the proposal to allow the calculation of Traceability Lot Codes (TLC) from business system data to comply with the FDA's FSMA 204 Food Traceability Rule. While we understand the industry's challenges in achieving compliance, we believe this proposal undermines the rule's core objective: ensuring reliable and accurate traceability of food products throughout the supply chain.

If approved, this proposal would revert us to pre-FSMA 204 processes, like those used since the Bioterrorism Act of 2002. This "current state" is characterized by fragmented systems and standards due to the lack of standardization. Without a unified system for traceability, companies often use varying methods and technologies, leading to inconsistencies and gaps in traceability data. Limited traceability capabilities slow the identification and isolation of contaminated products during recalls, increasing public health risks.

For example, during the romaine lettuce recall in November 2019, the inability to quickly identify the contamination source led the FDA to issue a "do not consume" warning right before Thanksgiving. This was not the first-time romaine lettuce was implicated in an E. coli outbreak, with similar incidents occurring in 2018 and earlier in 2019. The recall process was hampered by insufficient traceability data, making it difficult to track the contaminated lettuce from farm to consumer. Previous E. coli outbreaks linked to romaine lettuce, such as in 2018, resulted in losses exceeding \$350 million. The 2019 recall likely incurred comparable losses, impacting public safety, consumer confidence, and business profitability.

In 2024, we are five years into the New Era of Smarter Food Safety, emphasizing tech-enabled traceability. The AIM Global community of solution providers is finding that many customers already have most of the data required by the new rule. Some retailers, like Costco, now require suppliers to provide traceability within two hours and undergo bi-annual audits for compliance.

Inherent Flaws in Calculated TLCs

Accuracy and Reliability: Calculating TLCs based on business system data introduces significant potential for error. This method relies on probability rather than certainty, leading to incorrect traceability information. Probabilistic traceability does not meet the stringent requirements necessary for food safety and consumer protection.

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Complexity and Data Integrity: The proposed method increases complexity by requiring warehouses to document and share the probability associated with each TLC. This added complexity can lead to confusion and data misinterpretation, jeopardizing traceability. Ensuring the integrity of such calculated data across multiple systems and stakeholders is challenging and prone to errors. Currently, few solutions leverage this approach. The design, deployment, and debugging cycle required for this IT upgrade will impede its implementation. For major retailers, FSMA 204 compliance requires uniformity, which probability-based lot codes are unlikely to provide.

Practical Challenges in Implementation

Labor and Operational Costs: While the industry estimates significant labor costs for scanning, the proposed calculation method does not necessarily reduce operational burdens. Implementing a system to accurately calculate, document, and share probabilities involves additional training, system upgrades, auditing, and meticulous record-keeping, which can be equally, if not more, resource intensive.

Trust and Transparency: Calculated TLCs lack the transparency and trust provided by direct data capture technologies. The food industry and consumers alike depend on the certainty that comes from precise, captured traceability data. Any deviation from this standard can erode confidence in the traceability system and the safety of the food supply.

Alternative Solutions

Improving Scanning Efficiency: Instead of shifting to a calculation-based approach, efforts should focus on enhancing the efficiency and reliability of scanning processes. This includes standardizing labeling practices, investing in more advanced scanning technology, and improving training for warehouse staff.

Advanced Data Capture Techniques: Utilizing advanced data capture techniques such as RFID, passive Bluetooth, 2D barcodes, and vision systems can significantly reduce the burden of scanning. These technologies offer more efficient and accurate ways to capture traceability data, minimizing manual labor and the potential for human error. Implementing such advanced solutions can streamline the process and ensure compliance with traceability requirements without compromising accuracy.

Aggregation of Pallets: IT systems can aggregate cases to pallets and then track the pallets through the supply chain, minimizing the need to scan individual cases. EPCIS enables the aggregation of all unique cases to a pallet. Scanning the pallet ID captures the case data as the pallet moves through the supply chain, with cases only needing to be scanned when the pallet is broken apart.

EDI Traceability of Shipping and Receiving Events: EDI (Electronic Data Interchange) can serve as a robust solution for capturing shipping and receiving events in a standardized format. By utilizing EDI 214 (Transportation Carrier Shipment Status Message) and EDI 856 (Ship Notice/Manifest) transactions, companies can achieve real-time tracking and verification of products as they move through the supply chain. These standardized EDI transactions can be integrated with EPCIS to ensure that traceability data is consistently captured, shared, and stored across all stakeholders in the supply chain. This approach not only streamlines operations but also enhances data accuracy and reduces the likelihood of human error.

Global Interoperability and Consensus-Based Standards: Enabling global interoperability based on consensus-based standards is crucial for seamless supply chain operations. Standardized practices ensure effective communication and sharing of traceability information among all stakeholders, leading to a more integrated and resilient supply chain. Adopting globally recognized standards enhances traceability, improves efficiency, and reduces the risk of errors and inconsistencies. This proposal lacks the backing of consensus-based standards, with neither ISO nor GS1 endorsing this methodology.

The Value of Full Chain Transparency

Supply chain visibility includes three distinct pillars that ensure the tracking, availability, and safety of products. Each pillar plays a crucial role in transporting food and protecting products from piracy and counterfeiting, contributing to greater supply chain resilience.

Traceability: Traceability means tracking the entire journey of a product as it reaches the customer. This insight is crucial for safety in the food supply chain, especially for time-sensitive items like foods subject to spoilage and expiration.

Inventory Management: Effective inventory management provides a clear view of available products at any given time, helping avoid delays and ensuring timely fulfillment of orders. It also tracks returned products and those in shipment or production, enhancing overall supply chain efficiency.

Sustainability: Building a more sustainable supply chain reduces a company's carbon footprint and increases efficiency. Sustainable practices, such as optimizing packaging size for shipping or converting carrier fleets to electric power, benefit the planet and positively impact a company's bottom line.

Conclusion

In conclusion, allowing the calculation of Traceability Lot Codes from business system data is a flawed approach that does not achieve the necessary traceability standards set by the FSMA 204 Food Traceability Rule. It introduces significant risks related to accuracy, complexity, and trust. We strongly urge the FDA to reject this proposal and instead support initiatives that enhance the reliability and efficiency of data capturing processes. By investing in advanced data capture techniques, fostering global interoperability based on consensus-based standards, and promoting full chain transparency, we can ensure that the food traceability system remains robust, transparent, and capable of protecting public health.

Thank you for considering this perspective. We look forward to continued collaboration to achieve our shared goal of a safe and traceable food supply.

Sincerely yours,



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