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WHITEPAPER

CLEAN DATA MATTERS

The FDA's FSMA Rule 204 and major retailers' stricter data requirements underscore the need for robust data validation and cleansing to mitigate risks, ensure compliance and enhance supply chain efficiency.

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Executive Summary

With the Food Safety Modernization Act (FSMA) Rule 204, the FDA has intensified its focus on enhanced traceability in food supply chains. Concurrently, major retailers like Kroger, Walmart, Costco, Albertsons and Target are imposing stricter data requirements on its suppliers and distributors to improve supply chain efficiency and compliance. However, the persistence of unvalidated, erroneous, or incomplete data presents systemic risks. These hamper traceability, increase costs and create operational friction. This is particularly true for a distributor, where a large plurality of the data it must pass to its customers is sourced from the original supplier.

This brief explores the importance of “clean” data and the implications of unvalidated data. It underscores the necessity of robust data validation, cleansing and correction mechanisms from suppliers/distributors through to its customers to ensure regulatory alignment and streamline supply chain processes.

The Challenge of Unvalidated Data

Supply chain participants often exchange data without validation, leading to inconsistencies and inaccuracies in key product attributes, lot codes, shipment details and timestamps. While traceability is still a new operating discipline, there is a rich enough data set available to begin to report out results and metrics.

Key Findings

80 **Types of errors that have been experienced** within data fields and files.

45% Of data elements are **sourced from the supplier**. Most are transactional, meaning they change with each shipment

30% Of data files have **missing or incorrect data** in required fields

20% Only 20% of suppliers have a zero percent error rate (many are small suppliers with only a few shipments). If we remove the small suppliers from this data set **only 7% of suppliers have an error rate 5% or less.**

70% Data errors occur across suppliers of all sizes and types: **70% of the largest suppliers sharing data have error rates above 30%!**



Data errors result in:

Regulatory Non-Compliance:

FSMA Rule 204 mandates that Critical Tracking Events (CTEs) and Key Data Elements (KDEs) must be captured accurately. Unvalidated data compromises compliance efforts and increases the risk of FDA enforcement actions.

Traceability Gaps:

Without clean data, tracking food products through complex supply chains becomes difficult, impeding rapid response during recalls and foodborne illness investigations.

Retailer Rejections and Penalties:

Leading retailers require suppliers to adhere to stringent data accuracy standards. Inconsistent or erroneous data can result in chargebacks, shipment rejections, and strained relationships with key retail partners.

Operational Inefficiencies:

Inaccurate data propagates downstream inefficiencies, leading to manual reconciliation efforts, time and delivery delays, and elevated supply chain costs.

Retailer Data Requirements:

Retail giants have raised the bar for suppliers, demanding standardized, validated, and enriched data to ensure product integrity and supply chain visibility. Key expectations include:

Enhanced Traceability Data:

Retailers require suppliers to provide complete, structured data on product origins, transformations, and movements to comply with FSMA Rule 204.

System Interoperability:

Data must be structured in a way that aligns with retailers' traceability platforms, enabling seamless integration and real-time tracking.

Data Accuracy and Consistency:

Suppliers must ensure that lot codes, product descriptions, and other KDEs are correct across all transactions to avoid penalties and disruptions.

The Path Forward: Validating, Cleansing, and Correcting Data

To mitigate systemic friction and meet regulatory and retailer expectations, companies must implement a structured approach to data validation:

- **Automated Data Validation:** Deploy AI-driven or rule-based validation systems to detect discrepancies before data is shared with trading partners.
- **Data Cleansing Protocols:** Establish workflows that continuously correct and standardize product attributes, timestamps, and batch codes.
- **Collaborative Data Governance:** Strengthen industry-wide efforts to establish uniform data exchange standards and enforce compliance measures.

Conclusion

FSMA Rule 204 and heightened retailer expectations necessitate a disciplined approach to data management. By validating, cleansing, and correcting data at every touchpoint, companies can ensure regulatory compliance, enhance traceability, and reduce inefficiencies across supply chains. The imperative is clear—businesses that proactively invest in data integrity will not only mitigate risks but also gain competitive advantages in an increasingly regulated and data-driven marketplace.

