



October 11, 2024

Dear Valued Supplier,

**This letter contains time sensitive information and should be passed along to individuals in your company managing FSMA 204 compliance. The next immediate compliance date is October 18, 2024. Compliance dates are highlighted in yellow in this letter.**

If you have already supplied information to McLane regarding FSMA 204, please read below as **updates have not been made to the data request.**

As you know, the U.S. Food & Drug Administration (FDA) released their [Final Rule on Requirements for Additional Traceability Records for Certain Foods](#) in January 2023. This is referred to as “FSMA 204” (or section 204) and is one of many elements of the Food Safety Modernization Act or “FSMA.” This law and the related guidance essentially redefines traceability for certain foods on FDA’s Food Traceability List (FTL). For more details on this law, please visit the FDA website. Some basic information is also in the [FSMA 204](#) section in the Addendum of this letter.

FSMA 204 requires entities in the food supply chain to maintain records for Key Data Elements (KDE’s) when a Critical Tracking Event (CTE) occurs for food items listed on the Food Traceability List (FTL) as published by FDA. The food manufacturer’s lot code will need to be linked to all CTE’s collected in the supply chain.

Suppliers, manufacturers, distributors, and others handling FTL items in the supply chain will be required to assign a unique “traceability lot code” (TLC) to each FTL food item if one has been previously assigned.

As a supplier, you are required to share your shipping KDE’s for each FTL item you supply to McLane. Key Data Elements are dependent on the type of food and the type of event. In general, Shipping Key Data Elements include at least the following KDE’s:

- Ship To Location (Receiving / Immediate Subsequent Recipient)
- Ship From Location
- Product Description
- GTIN
- Product Traceability Lot Code
- Quantity and Unit of Measure
- Ship Date
- Traceability Lot Code Source (TLC) or TLC Reference

For some products, date codes may also be used as a KDE.



## McLane FSMA 204 Requirements Letter

In an effort to assist the food industry with these massive changes, GS1, a non-for-profit global standards organization, has worked with multiple industry trade associations to create a consensus around standards for FSMA 204 implementation. [Click here to read more](#). These guides assist companies in their preparedness for the deadline of January 20, 2026. Adopting a standard helps all supply chain members align so that companies are not forced to implement multiple methods and records that are dependent by customers. This saves time and money for all companies and consumers.

Some of our joint customers have begun to communicate their requirements for FSMA 204. Some customers have expanded beyond the FDA's Food Traceability List and requested all food items follow this standard. Customers have also placed deadlines for readiness.

To fulfill both FDA and customer requirements and to ensure McLane remains compliant, McLane will require all suppliers to complete the below Data Request.

**At this time, McLane is requesting that all suppliers are ready by June 30, 2025 to transmit Shipping KDE's.**

As you prepare your organization for FSMA 204, we recommend you utilize the vast resources of GS1 and visit their website, which include guidance documents for your use. To learn more, [click here](#). Scroll towards the bottom of this GS1 webpage for numerous topic-based guides.

## McLane Data Request

It is our intention at McLane to make compliance with FSMA 204 as easy as possible for you and for us. To that end, we need the following information from you:

1. Is your company subject to FSMA 204?\* (Yes or No)
2. Does your company provide any FTL items to McLane (and our joint customers)?

\*Keep in mind that your company may not be subject to FSMA 204 but still sell FTL items. McLane would still be required to keep FSMA 204 compliant traceability records in this scenario.

**To answer the above questions, [please click here](#) and scroll down the page to the section entitled "FSMA 204" and begin the form submission process.**

If you answer yes to Q2, you will be required to submit additional information. This information should be submitted through the link above.

**The information for the McLane Data request should be provided to McLane no later than Friday, October 18, 2024.**

As of January 2024, McLane has chosen Share-ify as its supplier compliance platform. The above information can be uploaded through Share-ify. You will need an active subscription to access these data upload features. For more information about how to submit this through Share-ify, see the hyperlinks at the end of this letter.



Please be aware that McLane is requiring a case label that includes a GS1- 128 barcode with all Key Data Elements. A helpful guide for formatting these labels is available here. [Click here](#).

## Transmitting KDE's to McLane

All suppliers must share their shipping KDE records for each FTL item shipped to McLane. If you are selling to our joint customer that requires more than FDA's FTL items, then you will be expected to comply with those requests. It is our expectation that you will do the following:

1. Validate that all shipping records are complete and accurate.
2. Provide the shipping KDE in electronic format via an Advanced Ship Notice (ASN) or other Application Program Interface **before the delivery date**.
3. Provide any physical paper records (such as a Bill of Lading (BOL)) at the time of delivery.
4. Each FTL food item must have
  - a. The Traceability Lot Code assigned and a standard TLC format should be used for all shipments from your company.
  - b. Each individual Key Data Element identified and a standard format used for each across all shipments from your company.
5. Assign a GS1 GTIN to each FTL item.
6. Assign a GS1 Global Location Number (GLN) to identify your corporate, production, and shipping locations and upload the list of all GLN's to Share-ify.
7. Use GS1 compliant data carriers (i.e. GS1-128 barcode labels) to encode the Traceability Lot Code Source or TLC Source reference on two adjacent sides of all packages, unless we agree to a variance based on the type of product.
8. Use GS1's SSCC-18 pallet tag that references all TLC's on a pallet and identify all mixed pallets.
9. Use a distinctive case label to denote any product that is FTL.
10. Use a distinctive pallet label for pallets with mixed lots.
11. On the Advanced Ship Notice and Bill of Lading, market the FTL product and pallets with distinctive color (using labels, color wrap, or highlighter / marker).

As McLane and industry partners work on plans and rollout, we will continue to provide updates as we have them. If you have questions, please email [FSMA204@mcclaneco.com](mailto:FSMA204@mcclaneco.com).

Thank you, for your time and attention to the above.

Sincerely,

*Terry Levee*

Terry Levee  
Senior Director  
McLane Food Safety & Quality Assurance

*Mike Rose*

Mike Rose  
Director  
McLane Food Safety & Quality Assurance



# Addendum

## Share-ify Upload

To upload information to Share-ify based on McLane's data request, [click here](#) for Share-ify instructions.

## FSMA 204

The US Food and Drug Administration's (FDA's) Final Rule on Requirements for Additional Traceability Records for Certain Foods will take effect on **January 20, 2026**. The rule requires applicable entities to maintain records containing specific "key data elements" (KDEs) when they engage in "critical tracking events" (CTEs) regarding foods listed on FDA's Food Traceability List (FTL) or foods that contain FTL foods as ingredients (collectively, FTL foods). Critical Tracking Events include the following:

- Harvest
- Cool (For Raw Agricultural commodities prior to Initial Pack)
- Initial Pack
- Shipping
- Receiving
- Transformation

Entities engaging in these activities at specified points in the supply chain will be required to record point in time information called "Key Data Elements" or KDE's.

One unique aspect of FSMA 204 (as compared to previous standards of traceability) is the inability to create lot codes for products manufactured by another company. This means that a company can only use a Manufacturer's Lot Code in traceability recordkeeping and especially when requested by FDA to provide traceability recording-keeping. For example, if ABC Company produces ABC bagged lettuce and sells that product to ZYX distributor, then ZYX distributor must use ABC Company's lot number in their traceability recordkeeping. They cannot use a lot number created by ZYX Distributor if one was previously assigned by the manufacturer.

To fulfill these requirements, and to ensure that McLane can fulfill our own regulatory obligations, we expect you to comply with the following:

**You must determine whether your operations are exempt from the Traceability Rule and must notify McLane of this determination before January 1, 2025, and then as necessary on an ongoing basis (e.g., with each shipment or as part of your master data).** If you conclude that your operations are exempt, then you must notify McLane of that conclusion and identify the basis for that conclusion in writing. We will presume that any suppliers who do not provide such notifications are subject to the rule. If you are subject to the rule, you must develop a written traceability plan and take other necessary measures to



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ensure compliance with the rule. You should take these steps well in advance so that you will be able to provide the required information to McLane by January 1, 2025. This can be uploaded through Share-ify.

**You must identify which foods you send to McLane are FTL foods.** You should provide this information to McLane **before October 18, 2024**, and then as necessary on an ongoing basis. If you determine that any of the FTL foods you supply are exempt from the rule, then you must inform McLane of that conclusion and identify the applicable exemption in writing.