Convenience Distribution Association

Minnesota Wholesale Marketers Association

July 15, 2026

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

Re: Docket No. FDA-2014-N-0053 (Challenges and Solutions in Lot-Level Food Traceability; Request for Comments on FDA Discussion Paper)

Dear Food and Drug Administration Staff:

The Convenience Distribution Association (CDA) and the Minnesota Wholesale Marketers Association (MWMA) are trade organizations which represent distributors that supply convenience stores and restaurants with products ranging from candy, snacks, grocery items, foodservice, beverages, health and beauty, and general merchandise. CDA and MWMA sincerely appreciate the opportunity to submit comments on the FDA's Discussion Paper titled "Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement."

These comments provide responses to the questions raised by the FDA in the Discussion Paper regarding: (1) a reasonable range of lot codes, (2) inferred traceability lot codes, and (3) eaches. In addition, a statement from a distributor is included at the end of these comments as Addendum No. 1 that focuses on the need for GS1 data standards. This distributor statement is critically important as many distributors will likely be in a similar situation and may have no alternative other than to take certain actions in the absence of uniform data standards.

Please note that a significant majority of the responses to the FDA's questions are verbatim answers provided to CDA and MWMA by their distributor members. These answers are honest, real-world responses to the complexities that distributors will encounter in attempting to implement a reasonable range of lot codes and inferred lot codes. In addition, the distributor responses outline the significance of the "eaches" issue that will need to be adequately addressed by the agency.

Regarding the eaches issue, please recall that CDA and MWMA jointly submitted a memorandum to the FDA in advance of the June 15, 2026 FSMA Listening Session which analyzed the eaches issue in detail and proposed a new flexible option to urge food manufacturers and food processors to imprint the Traceability Lot Code (TLC), Traceability

Lot Code Source (TLC Source), and the expiration date on case labels, inner packs, and individual product packages. An updated version of this joint memorandum is included with this comment letter as Addendum No. 2.

CDA and MWMA urge the FDA to consider supporting a number of different flexible options, including the imprinting option, to provide distributors with different methods to comply with FSMA Section 204(d) as no single option may work for all distribution companies.

Below are the sections of the FDA Discussion Paper that CDA and MWMA distributors have provided answer's to the agency's questions.

Reasonable Range of Traceability Lot Codes for Distributors Shipping to Retailers.

We have heard from many in regulated industry about the challenges with lot-level tracking as a Food Traceability List (FTL) food product moves through a distribution center and is shipped to a retail location. Because FTL foods are sometimes received in mixed-lot pallets, and because further mixing of lots can occur as products move in and out of designated product holding areas (pick slots), some distribution centers have stated that they would have to scan every case to accurately track the movement of Traceability Lot Codes through their warehouses. There is a concern that this would be logistically challenging and perhaps cost-prohibitive.

Some members of regulated industry have therefore proposed that distribution centers that ship to retailers be allowed to maintain and share records that reflect a range of all possible Traceability Lot Codes (TLCs) that could reasonably be associated with a shipment to a retail store or restaurant. We have several questions for stakeholders on this potential flexibility:

1. How does industry define a "reasonable" range of TLCs? Would it be feasible to have a specified limit (e.g., a single TLC can be replaced by a range of 2 or 3 TLCs, but no more than 3?

    - I think a reasonable range should be measured or calculated over a time period, more than anything else. This would allow for multiple TLC's in the pick slot as well as product is returned and is placed back in the pick slot.
    - Adding more lot codes would dilute accuracy while limiting lot codes to no more than 3 could create supply chain issues where additional product cannot be ordered until the number of lot codes can be reduced through sales.
    - I define reasonable as precisely what was picked and shipped based on a scan from the picker (personnel).

2. What factors would be considered in establishing the limit? How would such a limit work in practice, given that many shipments contain more than one TLC? If a hard limit is not workable, how else can a "reasonable" range be defined?

- I think it should be a time period, not a specific range that allows for some variance and human error when it comes to any of it.
- The shelf life or product freshness expiration would be the only factor that would create a timeline where additional TLCs could not be added without having spoiled product somewhere in the warehouse.
- In reality, these questions are proposing to introduce misinformation on TLCs.

3. At most, how many different TLCs are likely to be on one pallet?

    - Most of the time it is more than likely to be 1, but it can be two or three depending on the product. We also do not receive a pallet of every item. We may just get multiple cases of a particular product which may have different TLCs every week.
    - Depends on the distributor and manufacturer, sometimes 20+ depending on the number of different products on the pallet and the number of cases on the pallet.
    - Unknown.

4. At most, how many different TLCs are likely to be in a pick slot at any given time?

    - Depending on the item, if we receive it from the same vendor or multiple vendors, or there are returns of the item placed back in the pick slot, there could be as many as 4 or 5 TLCs in a pick slot at any given time.
    - Depends on how the product is sold, eaches could be up to 3, cases could be a significantly higher number of TLCs.
    - I just looked at a pick slot which had 7 different TLCs of the same product.

5. How likely is it that an incoming pallet will contain multiple TLCs from the same TLC Source (the same manufacturer or supplier facility)?

    - If it is coming straight from the manufacturer, it is more than likely to have just one. If we are getting it from another distribution center such as DOT, or someone of the nature if very well could have multiple.
    - If they are performing proper freshness rotation and inventory management, no more 2.
    - It is likely that a pallet will have multiple TLCs from the same manufacturer.

6. For an outgoing shipment, do you envision that the reasonable range of TLCs would be a range from the same TLC source (the same manufacturer or processor facility), or do you envision that it might encompass a range from multiple TLC sources (more than one manufacturer or processor facility)? Would it be feasible to limit the range of TLCs to being from the same TLC source?

- I think you would have to treat it the same as incoming TLC's. I don't think that there would be anyway to limit the TLC's coming from the same source. It would be almost impossible to guarantee that.
- It's most likely the TLC Source would be the same for the exact same product. We rarely source the same item from 2 different locations, but it does happen.
- Limiting the range of TLCs to being from the same TLC Source introduces misinformation.

7. What are the fundamental best practices that distribution centers should incorporate to be confident that the range of TLCs provides accurate information and is not overly broad? If these best practices are in place, how often would you need to record a reasonable range of TLCs (as opposed to being confident about which TLCs were in a given shipment)?

    - As long as we are given the correct information from the suppliers on what is being shipped to our warehouse and we follow the first-in, first-out inventory process of what is in stock of what we have, we should be fairly confident in what we are shipping to retailers, but there is always human error that could change that.
    - Recording TLCs would occur when the product arrives, and each time the product is loaded to be picked for shipment. This would need to be a daily occurrence.
    - Why is this burden being placed on the distributor when the manufacturer can print a DataMatrix barcode and use RFID tags on the items, which would remove a vast potential for misinformation.

8. How would you communicate a range of TLCs to a retailer? For example, can advance shipping notices (ASNs) transmit a range of TLCs currently?

    - No, we would not be able to currently send a range of TLCs to our retail store accounts as TLCs are not being tracked and put into our warehouse inventory system.
    - Many customers do not have electronic data interchange systems, sometimes we only have an invoice and adding TLCs would add an extraordinary amount of paper and space to the print out. Retail customers with EDI capabilities could receive that information from our system directly similar to an ASN, but this would require additional programming on our side and theirs with the cost and time to do so unknown at this point.
    - Printed invoices and electronic invoices. Specialized reports (extra expense).

9. Would any changes or investments to your system to provide a reasonable range of TLCs also be helpful for coming into full compliance with the rule?

    - It may be possible to do, but the expense to do so is an unanswered question.

- Not especially, we already record freshness dates and when recalls do occur we have an existing process to remove product from circulation.
- No. The entire proposition is unreasonable and bound to create undue burden and expense.
- CDA and MWMA Note: It is important to acknowledge that a guiding principle of Section 204(d)(1)(G) under the FSMA law is that to the extent practicable, the FDA should not require a company to change business operating systems to comply with the food tracing requirements. This question is contrary to this guiding principle. The question should be whether distributors are able to provide a reasonable range of TLCs with their current system without upgrading or purchasing new warehouse inventory management software. Some of the answers from distributors to these questions raise this concern and inquire why this significant burden is being focused on the distribution segment when the products subject to FSMA Section 204(d) are made and processed by other companies.

10. Would any changes or investments to your system to provide a reasonable range of TLCs be prohibitively expensive or challenging to implement?

    - It could be very expensive not only to change the system, but may require extra staff and changes in our efficiency.
    - It would require additional data storage and perhaps more programming with 3rd party companies who support us with technology to run a warehouse. The cost is unknowable at this time.
    - We will have to discontinue stocking FSMA regulated products and increase pricing on necessary products which will incur extra labor and expense.

Inferred Traceability Lot Codes, with Flexibility, for Wholesale Distributors Shipping to Retailers.

Many in regulated industry have stated that distribution centers often infer or calculate which TLCs are being shipped to a retailer, rather than confirming at the time of shipment (e.g., by scanning cases or eaches) which TLCs are being shipped. This inference can be made in a variety of ways, such as through a warehouse management system that takes into account when incoming TLCs were received, how they were placed in pick slots, and the order in which employees are trained to pick (e.g., first in, first out or first to expire, first-out).

We have heard that this approach is fairly accurate, but that regulated industry is concerned that if they relied on this approach to comply with the rule, they would invariably have some errors in their data. Some in regulated industry have expressed optimism that over time, with better systems, technology, and training, this approach could become very accurate (comparable to scanning). We are interested in exploring

whether it might be possible to support the development of systems that could eventually be highly accurate at inferring lot codes, while simultaneously providing flexibility as firms work toward that goal.

As an example of this approach, if a distribution center inferred that certain TLCs were part of a shipment to a retailer (e.g., 10 boxes of TLC 5, 10 boxes of TLC 6, 10 boxes of TLC 7), they could maintain and send forward these inferred TLCs, and accompany the inferred TLCs with a statement of other TLCs that might also have been included in the shipment (e.g., TLC 4, TLC 8). The distribution center's traceability plan would explain their method for inferring which TLCs were shipped and for identifying other TLCs that might have been in the shipment. This approach could be seen as a variation of the "reasonable range of lot codes" approach, but it would more closely reflect the aspiration of full compliance with the rule, because the inferred TLCs would be presented in a manner that – if accurate – would be in full compliance with the rule.

We have several questions for wholesale distributors on this potential flexibility:

1. Would the above example (in which a distribution center could state a number of other TLCs that might have been in a shipment, in addition to the TLCs that they infer are in the shipment) be a viable way to provide flexibility to distribution centers that currently infer which TLCs are in a shipment?

    - It could be but I don't see it being anymore different than what we are currently doing by checking what we have in the picking slot now, we are just guessing without scanning everything. There is too much human error.
    - There are methods that we could use to calculate this, but again, it assumes perfection from an operations team and also could lead to mass destruction of product due to a food recall or investigation.
    - This will only work if the manufacturer is required to put a legible QR Code/DataMatrix barcode with GS1 data on all packaged items in the case. Radio frequency identification tags would be even better.

2. Are there other ways to provide flexibility for such distribution centers that could ensure similar or better accuracy? Are there some distribution centers for which this flexibility would not be helpful?

    - I can't think of any at the time.
    - I don't see flexibility making accuracy better in any situation.
    - Flexibility not needed or desired. A legible DataMatrix barcode with GS1 Data Application Identifier (10) [which is the lot code identifier] could solve the issue.

3. We anticipate that there may need to be a limit on how many additional TLCs could be stated. What factors should be considered in establishing that limit?

- I believe it would have to be a time limit of say so many weeks, months etc.
- Again, product shelf life or freshness (i.e., expiration date) is the only factor I think would be a universal approach.
- No limited required.

4. How could this flexibility serve as a steppingstone to compliance with the rule as written? It seems like this could happen in one of two ways: 1) by encouraging distribution centers to hone their ability to infer TLCs to the point where they can do so with a high degree of accuracy, or 2) by providing a temporary way to trace TLCs while more precise methods (e.g., RFID) are being developed and adopted. Do either or both of these seem likely?

    - Without scanning a barcode, it will never be one hundred percent accurate. All things have human error. I believe it could be done on the shipping side if agreement was found on a specific barcode that is scanned on picking/ shipping. We can get that info in a GS1 currently, but all manufactures don't use that or don't at all levels of the product they are selling. Also, case level scanning is not a requirement under FSMA Section 204(d).
    - The flexibility at first would help with starting the process however the full implementation of the traceability would lead to expanded costs and the less flexible the rules, the more costly they become.
    - This will only work if the items have a DataMatrix with gs1 application identifier 10. RFID would improve efficiency.

5. How would you communicate this TLC information to a retailer? For example, can Advance Ship Notices transmit other TLCs that might have also been included in a shipment (in addition to transmitting the TLCs that the shipper believes to have been included in the shipment, i.e., the inferred TLCs)?

    - The best way I can see this being done would be to be send with an electric file, email or paperwork once the product is scanned and invoiced to the retailer.
    - Many customers do not have electronic data interchange systems, sometimes we only have an invoice and adding TLCs would add an extraordinary amount of paper and space to the print out. Customers with EDI capabilities could receive that information from our system directly similar to an ASN but would require additional programming on our side and theirs.
    - Printed on invoice. Included in electronic invoices. Without DataMatrix and RFID, if an employee has to manually type in lot codes it will create a cost burden as well as introduce potential for misinformation. We already notify our customers of product recalls, typically on same day.

FDA Eaches Discussion Questions

1. FDA Observation: Our current understanding is that this circumstance [i.e., "eaches"] would only apply to a low volume of food being shipped to any one customer.

   - Eaches does not apply to only a low volume of food being shipped to any one retail store or restaurant. Rather, a significant portion of each shipment to retail convenience stores and restaurants is in the form of "eaches."

2. Is there an industry or generally understood definition of eaches?

   - There are two kinds of eaches. One kind of eaches is an inner pack, which is a box that holds a certain number of individual packages of a food product. There can be numerous inner packs inside a master cardboard case. The second kind of eaches is an individual package of a food product. For examples, see the pictures below of: (1) an inner pack box for Lance Toasty Peanut Butter Sandwich Crackers that holds 20 individual packages of the product, and (2) an individual package of Lance Toasty Peanut Butter Sandwich Crackers that is packed in an inner pack container.

3. Are there circumstances where a case may be broken up to create eaches throughout the supply chain, or does this only occur immediately prior to shipment to retail?

   - Generally, a case is usually opened to create eaches (inner packs or individual packages) only at a distributor's warehouse prior to shipment to a retail store or restaurant.

4. How common are eaches in different sectors, for example, convenience stores, grocery stores, and restaurants?

   - Eaches are very common in the convenience store segment because 60% to 90% of shipments by distributors to convenience stores contain eaches. Generally, full cases of a product, not eaches, are shipped to grocery stores. Also, more than 50% of shipments by distributors to restaurants contain eaches.

5. What additional labeling information could appear on the outside of the container in which the eaches are shipped to ensure adequate traceability as the product moves through the supply chain from distribution to retail? Are there obstacles to providing information in this way?

   - The reference to "container" in Question 5 likely refers to what the distribution industry calls a "pick tote." A pick tote is a plastic container, usually with a lid, into which eaches selected from warehouse shelves are placed for shipment to a retail store. Depending on the size of the eaches, a pick tote may hold as many as 30 different eaches products. Since a distributor empties eaches out of a pick tote at a retail store and brings the pick tote back to the warehouse, a pick tote is reused hundreds, if not thousands of times. Creating a new label listing the contents of a pick tote and affixing the label to the pick tote would be very challenging and time consuming because of the high number of eaches shipped to convenience stores and restaurants. Labeling every pick tote which contains eaches would slow down the product flow through the warehouse and increase the time it takes to fulfill an order resulting in a reduction in the number of orders that can be shipped to retail stores and restaurants on a daily basis.

6. From a distribution center perspective, approximately what percentage of outgoing inventory is shipped as eaches?

   - 60% to 90% of shipments by a distributor to convenience stores contain eaches. More than 50% of shipments by a distributor to restaurants contains eaches.

7. Are eaches created only when small quantities of a food are needed, or are there other scenarios in which they are created?

   - Eaches are created every time a retail store or restaurant orders less than a full case of a product, and such orders for eaches account for a significant majority of total orders. Generally, there are no other scenarios when eaches are created.

8. What are the traceability challenges for eaches? We have heard there are challenges to tracking the TLC and TLC Source for eaches; however, is information on other KDEs such as the product description, quantity, and supplier available (via purchase order, for example)?

   - The traceability challenges for eaches are numerous. First, a distributor routinely opens cases and places inner packs and individual product packages in a pick slot on warehouse shelves. Depending on the turnover rate for any one product (i.e., how fast a product sells requiring the replenishment of the pick slot), more eaches can be added to a pick slot daily. Since pick slots may not be completely emptied before being replenished, a pick slot can contain multiple different Traceability Lot Codes of the same product. In fact, one pick slot can contain the same product with more than three Traceability Lot Codes due to how often the pick slot is replenished. This means that the number of Traceability Lot Codes

can increase and decrease daily, which would make tracing of eaches very difficult.

Second, if a retail store returns products, and the products are not opened and able to be resold, then the returned product is placed back in the pick slot which increases the number of TLCs of the product in the pick slot.

Third, actually tracing eaches would substantially increase the amount of time and labor necessary to track every inner pack or individual package of a product. Scanning every each is not possible due to the sheer volume of eaches shipped to retail stores on a daily basis.

Fourth, shipping documents provided by a manufacturer or food product suppler such as bills of lading, advance ship notices, and purchase orders may not currently include Traceability Lot Codes nor Traceability Lot Code Source data. In the absence of these Key Data Elements in shipping documents, tracing Key Data Elements for eaches would be very challenging.

9. Would either of the two previously described flexibilities ("reasonable range of TLCs" or "inferred TLCs, with flexibility") help address the difficulties associated with eaches? If so, how? If not, why not?

- FSMA Section 204(d) does not require case level tracing nor eaches level tracing. Moreover, the FSMA Section 204(d) final rule does not contain any mention of "eaches" nor tracing individual packages of a product. The "reasonable range of TLCs" and "inferred TLCs with flexibility" option models are focused on lot level tracing, not eaches level tracing. Given the significant volume of eaches moving through a distributor warehouse daily, distributors have informed CDA and MWMA that a flexible option model based on lot level tracing would likely not be adaptable or usable to trace eaches.

The CDA and MWMA again thank the FDA for this opportunity to submit comments.

Sincerely,

Thomas A. Briant

CDA Government Policy Advisor
MWMA Executive Director

Addendum No. 1

Distributor Statement on the Need for GS1 Data Standards and the Impact of FSMA Section 204(d) in the Absence of GS1 Data Standards

Below is a statement from a distributor on its experience with GS1 data standards utilized by food manufacturers and food processors.

> I think it is critical that the FDA understand that to report the data, we must have all the Key Data Elements for each product. I am sure it is going to cost distributor a lot of money to comply with this rule. In our situation, we would have to replace our entire warehouse management software at a tremendous expense if the FDA does not create or require a uniform data standard guideline to ensure that product data is consistent. Also, we would have to start scaling back the items we sell and no longer sell FSMA regulated products for which the manufacturer does not adhere to a strict data standard guideline.
>
> For example, I inserted a program into our warehouse inventory platform to log our warehouse GS1-128 barcode scans for inspection. I am finding various manufacturers do not consistently format their GS1-128 data, which will cause the traceability lot code to not be found by a software program. Our existing warehouse management application currently only interprets the GTIN (Global Trading Identification Number), the catchweight, and the lot code. Most importantly, the software program only interprets the lot code if the alphanumeric lot code is properly formatted under GS1 data standards.
>
> There are approximately 500 GS1-128 Application Identifier codes to be interpreted. Since I will have to manually construct an interpreter, it will be virtually impossible and take years for our company to interpret all the G1 Application Identifier codes.
>
> This could be mitigated with an FDA specified format that all manufacturers must comply with a data standard like the GS1 data standards for food products regulated under FSMA Section 204(d).
>
> As our warehouse inventory system exists, it will be impossible to utilize the GS1-128 barcodes to reliably obtain the traceability lot code of FSMA Section 204(d) food products because manufacturers do not uniformly comply with the GS1-128 data standards etiquette.
>
> Ideally, for us to comply with FSMA Section 204(d) traceability lot code tracking at a minimal expense for software, hardware and system upgrades, manufacturers would have to adhere to a formal format on the GS1-128 barcode and corresponding inner pack and individual package DataMatrix barcode.

Under GS1 data standards, Application Identifier 01 corresponds to the GTIN (a 14-digit alphanumeric code identifying the company and the product), Application Identifier 11 refers to the product manufacture or production date (in a YY/MM/DD format), Application Identifier 10 is the lot or batch code (variable alphanumeric length), and Application Identifier 3202 refers to the net weight of the product in pounds to two decimal places.

This is only an example of what would work for our distribution company based on my existing exercise. This scenario would require component items to have a UPC-A converted to a GTIN for each product and each package of the product. I am finding several manufacturers are already placing a DataMatrix barcode and GS1 128 barcode on the outer case, though I have found some do not match the DataMatrix barcode data exactly with the GS1-128 data, which will cause problems.

A consideration for us would be a third-party data interpreter. However, this would create a delay for warehouse users scanning the data to be sent to the interpreter and then waiting for the interpreter to return the results of a scan. Using a third-party data interpreter would result in an added expense. Every scan would have a delay, which adds to employee hourly expenses and reduces the level of product flowing through the warehouse.

This is why it is my opinion the FDA needs to specify a formal data standard requirement that food manufacturers must comply with regarding the GS1-128 and DataMatrix and RFID technology as applicable to food products regulated by FSMA Section 204(d).

Addendum No. 2

Convenience Distribution Association

Minnesota Wholesale Marketers Association

Memorandum on "Eaches" Topic and a New Flexible Option

July 2026

Executive Summary: Section 204(d) of the Food Safety Modernization Act (FSMA) requires a new level of tracing and recordkeeping by farmers, food manufacturers, distributors, retailers, and restaurants for certain "high-risk" foods. A guiding principle of Section 204(d)(1)(G) under the FSMA law is that to the extent practicable, the FDA should not require a company to change business operating systems to comply with the food tracing requirements.

The federal rule promulgated by the U.S. Food and Drug Administration regarding Section 204(d) of the FSMA law establishes a complex food tracing and recordkeeping process involving numerous Key Data Elements (KDEs) at Critical Tracking Events (CTEs) at every level of the food supply chain from the farmer, to the manufacturing facility, to the wholesale distribution warehouse, to the retail store, and to the restaurant. Such a high level of complexity has never been required before. It is critical to approach the food traceability rule as a process improvement rather than a data capture mandate. This is the cases because in analyzing various proposed flexible options to comply capturing data under, it has become apparent that most distributors, retailers, and restaurants would need to change business operating systems and procedures to implement FSMA Section 204(d) and even then, may likely find compliance to be very challenging.

Based on our research, food traceability does not begin with a lot code. Rather, a manufacturer food recall begins when a company determines that one of its food products was contaminated at its facility. Then, an investigation is undertaken to narrow down the date and the point in the manufacturing process that the contamination occurred followed by identifying the specific lot of product that is contaminated. At that point, the manufacturer issues a food recall alert to the distribution, retail, and restaurant industries regarding the suspect product which includes the lot code for the batch of product that is contaminated.

Similarly, a food traceback investigation does not begin with the identification of a lot code. In this situation, local, state, and federal health officials are alerted to a foodborne illness outbreak because people have reported becoming sick after consuming a food product. The investigation involves interviewing those individuals who became ill to identify a common food product that all consumed leading to their illness. At that point, the availability of the food packaging may pinpoint the lot code and manufacturing or processing facility that made the product. In the absence of packaging, the investigation continues with visits to retail stores, restaurants, and distribution warehouses in a further attempt to identify the suspect food product. Once the product and lot are identified, a foodborne illness outbreak notice is issued to the public.

Based on this research, there is a possible solution that would allow a higher degree of expediting food traceability without imposing significant challenges on distributors, retailers, and restaurants. This solution involves manufacturers imprinting the Traceability Lot Code (TLC), the Traceability

Lot Code Source (TLC Source), and the expiration date on case labels, inner packs, and individual packages of FSMA Section 204(d) high-risk food products. It is important to note that this new flexible option is not a perfect solution, as no flexible option will work for every segment of the food supply chain. Moreover, this imprinting option may need to be utilized in conjunction with another flexible tracing option to ensure a higher level of implementation and compliance.

However, since food manufacturers and processors have been imprinting lot codes and expiration dates on food packaging since the 1950's, it is imperative that the food supply chain industry, in conjunction with the FDA, pursue an option which is based on imprinting these three critical KDEs on food product packaging. A flexible option to imprint the TLC, TLC Source, and expiration date on case labels, inner packs, and individual product packages should accelerate the identification and removal of a contaminated food product from the market when a manufacturer issues a food recall alert or when the FDA issues a foodborne illness outbreak alert.

On June 4, 2026, the U.S. House of Representatives passed the 2027 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations bill. The Congressional report on this bill included the following language related to FSMA Section 204(d):

"Food Traceability Rule Implementation. The Committee encourages the agency to continue working with stakeholders to ensure ***feasibility of traceability lot code requirements***, interoperability of traceability and successful implementation of the rule across the food supply chain." [Emphasis added].

As discussed in detail in this memorandum, the proposed imprinting option fulfills this "feasibility" condition and should be designated a flexible lot-level tracing option.

Background: The Convenience Distribution Association (CDA) and the Minnesota Wholesale Marketers Association (MWMA) are trade organizations which represent distributors that supply convenience stores and restaurants with products ranging from candy, snacks, grocery items, foodservice, beverages, health and beauty, and general merchandise. According to the National Association of Convenience Stores, there are approximately 152,000 convenience retail stores nationwide. While there are several large chains of convenience stores such as 7-11, Circle K, Wawa, Kwiktrip, etc., approximately 63% of all convenience stores are independently owned, with many being one, two or three store "mom and pop" businesses. This fact carries significance as explained in this memo.

For more than a year, the discussion about how businesses in the food supply chain can comply with and implement Section 204(d) of the Food Safety Modernization Act (FSMA) has included various options and processes for distributors to consider utilizing to trace Food Traceability List (FTL) food products. Since distributors purchase FTL food products from hundreds of food manufacturers and food processors, the impact of compliance with FSMA Section 204(d) will fall disproportionately on the distribution segment.

Wholesale distributor operations are optimized for logistics to rapidly and efficiently receive, inventory, and ship products to retail stores and restaurants. Unlike food manufacturers and food processors, distributors generally do not package or label food products, unless a distribution company also operates a foodservice division. This means that the responsibility for packaging and labeling food products occurs primarily at the food manufacturing and processing levels. With Traceability Lot Codes and Traceability Lot Code Source data generated at the manufacturer or

food processor facility and not in a distributor's warehouse, the real solution to food traceability begins with manufacturers and food processors. In short, traceability cannot be recreated downstream but must be engineered at the source, namely at the manufacturing and food processing levels.

Significance of Eaches. "Eaches" is a significant issue for distributors, retailers, and restaurants. This is the case because eaches are routinely included in 60% to 90% or more of shipments delivered by distributors to convenience stores.

There are two kinds of eaches. One kind of eaches is an inner pack, which is a box that holds a certain number of individual packages of a food product. The second kind of eaches is an individual package of a food product. For examples, see the pictures below of: (1) an inner pack box that holds 20 individual packages of Lance Toasty Peanut Butter Sandwich Crackers, and (2) the individual package of Lance Toasty Peanut Butter Sandwich Crackers.

Oftentimes, upon receiving a shipment, a distributor will remove inner packs or individual packages of a product from a master cardboard case and place the inner packs or individual packages on warehouse shelving or into a plastic bin on warehouse shelving to facilitate order picking. This means that the cardboard case which held the inner packs or individual packages of a product, along with the case label that contains Key Data Elements (KDEs), is then recycled or discarded and the tracing KDE information is simply gone.

Also, if a product is a very high volume, in-demand item, a distributor will oftentimes move cases of a product directly from a semi-truck to the warehouse order fulfillment pick line. In the absence of a case label or when high volume products are immediately moved to a pick line instead of being stocked on warehouse shelves, tracing Key Data Elements becomes increasingly difficult, labor intensive, and time consuming, especially at the eaches level.

In speaking with a number of distributors that are members of CDA and MWMA, their opinions about eaches are consistent. Most convenience store retailers purchase products by the "each" because the stores do not have the shelf space to display an entire case of a specific product and customer demand does not support ordering a full case. If KDEs are only imprinted on a case label and given that the cardboard master case with the label is routinely discarded, tracing products on the eaches level in a warehouse would be very problematic from a logistics point of view. To do so would significantly slow down both the product flow and daily logistic operations at a distribution warehouse.

Wholesale distributors operate on thin profit margins and rely on high product volumes to remain in operation. A slowdown in product flow throughout the receiving, stocking, order picking, and shipping process due to implementing new tracing technology at the lot-level would reduce product volume resulting in lower distributor sales and a decline in profitability. In response, a distributor would need to raise wholesale prices to maintain already slim profit margins, resulting in higher prices on not only Food Traceability List food products, but also other goods sold by the distributor. An increase in wholesale prices would lead to inflation with consumers bearing the ultimate economic impact of higher prices at convenience stores, grocery stores, and restaurants.

Distributors would also need to consider ceasing selling basic food products to low volume, independently owned convenience stores and restaurants. This means that independent convenience stores and restaurants may not be able to order basic food staples such as eggs, lettuce, certain fruit, peanut butter products, and refrigerated salads which reduces the food choices available to consumers that would otherwise purchase these products at their local convenience store. In other words, food insecurity could rise due to the inability of retailers and restaurants to purchase essential food products. In less populated areas, such food insecurity could become more pronounced and widespread.

This complexity of attempting to trace food products from a manufacturer, to a distributor, to a retailer or restaurant by lot-level, case level, or eaches level in a supply chain that does not adhere universally to a standard for labeling and shipping documents will be very challenging, especially for small to medium size distributors. A common data standard will be key to achieving traceability across the food supply chain. As CDA and MWMA have proposed to the FDA previously, GS1 data standards provide a critical foundation for food traceability between different segments of the marketplace.

Given the significant impact that FSMA Section 204(d) will have on distributors, implementation and compliance with FSMA Section 204(d) needs to focus on the food manufacturing sector. The overall solution to implementing traceability needs to focus on the food manufacturing segment because that is where food products are created, processed, packaged, and labeled.

Alternative Flexible Tracing Option: The flexible option of imprinting the TLC, the Traceability TLC Source, and the expiration date on case labels, inner packs, and individual packages is a concept that begins at the manufacturing or food processing levels and works downstream to distributors, retailers, and restaurants when a food recall notice is issued or starts at the consumer level due to a foodborne illness outbreak investigation and works back up the food supply chain.

According to a report by Michigan State University, the actual elements of this other flexible option have been utilized by food manufacturers for the past 70 years. This foundational process used for decades involves the imprinting of a lot code, the facility assembly line code, a time stamp, and the expiration date on product packaging. The imprinting flexible option would expand on this fundamental process and relieve some of the potential challenges of FTL food tracing on the distribution industry, as well as the retail and restaurant segments. Specifically, this other option involves understanding and applying the lessons learned from the investigative traceback process.

The FDA provided CDA and MWMA with links to various resources compiled by the FDA and the Centers for Disease Control which explain how government agencies conduct a foodborne

illness traceback investigation. Accompanying this memo is a thirteen-page foodborne illness tracing questionnaire used by investigators along with the FDA's "Traceback of Foodborne Illness Outbreaks" infographic. As stated above, the traceback investigation process involves interviewing people who became sick from consuming a food product to determine what they ate, where the food was consumed (at home, at a restaurant, or at an event), and where the food was purchased. An important part of consumer interviews involves an investigator reviewing grocery store receipts and surveying the food in an individual's pantry and in their refrigerator to take an inventory of food products and product packaging.

One of the primary underlying goals of the Food Safety Modernization Act is to "rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak" [FSMA Section 204(d)(1)]. This traceback investigative process, especially looking for food products in a person's pantry and refrigerator, led to the idea of a flexible option that involves food manufacturers and food processors imprinting the TLC Source), and an expiration date on case labels, inner packs, and individual product packages.

Downstream Tracing: There are two primary methods of tracing food products when a food product is contaminated. One method can be referred to as "downstream tracing," which involves a manufacturer determining that a food product is contaminated and issuing a food recall alert to distributors, retailers, and restaurants downstream in the food supply chain to inform them to remove the suspect contaminated product from warehouse shelves, store shelves, and restaurant food inventory. A food recall notice issued by a manufacturer usually contains the brand name of the recalled product, the package size of the product, the TLC, the date of manufacture, and the product expiration date.

Distributors currently use internal company procedures that they have relied on for decades to respond to a manufacturer's food product recall notice. After receiving the food recall alert with the food product TLC and expiration date, warehouse employees conduct a physical and visual inspection of food product inventory to determine if any of the product in inventory matches the TLC and the expiration date that has been provided in the manufacturer's food recall alert. This identification of recalled product is accomplished by warehouse employees relying on Human Readable Information (HRI) on product cases or product packaging (i.e., seeing the manufacture TLC and expiration date on the product case label, inner pack, or individual product package). If the recalled product with the matching TLC and expiration date is found in warehouse inventory, the product is immediately removed from inventory and the distributor follows the manufacturer's instructions for returning or disposing of the recalled product.

Physical and visual inspections are the tried and tested methods to identify whether the suspect food product is in a distributor's inventory. This method has been at the center of the foundational process of imprinting the lot code and other key data points on product packaging for seven decades. Physical and visual inspections are conducted regardless of whether the distributor's inventory software lists or does not list the suspect food product in inventory because a physical and visual inspection is the only true means to ensure whether the food product is or is not in stock.

Distributor customer service staff also check warehouse sales reports and records to determine which retailers and restaurants may have purchased the involved product and then call and/or email these retail stores and restaurants to provide them with the specific manufacturer recall data and/or

the actual recall notice so that inventory can be checked and any product with the same TLC and expiration date subject to the recall can be removed from the retail stores and restaurants.

Under downstream tracing, imprinting the TLC, the TLC Source, and the expiration date on case labels, inner packs, and individual product packages would be vitally important to allow the more expeditious identification of a recalled product and the removal of the suspect food product from the market while not at the same time requiring distributors, retailers, and restaurants to adopt new software technologies. This food recall process aligns with the requirements of the FSMA law to "minimize the number of different recordkeeping requirements for facilities that handle more than [one] type of food" [FSMA Section 204(d)(1)(F)] and "to the extent practicable, not require a facility to change business systems to comply with such requirements" [FSMA Section 204(d)(1)(G)].

Upstream Traceback: The second method of tracing can be referred to as "upstream traceback," which involves the FDA, the Centers for Disease Control, the U.S. Department of Agriculture, and local and state health departments conducting foodborne illness outbreak investigations to find a potentially contaminated food product and the source of the suspect food product. The agencies search for bacteria (salmonella, listeria, E. coli, or cyclospora), parasites, or viruses as likely causes of foodborne illnesses.

Once a suspect food product is identified by local or state health agencies and/or the CDC, the FDA is contacted to determine the source of the food product. The FDA Coordinated Outbreak Response and Evaluation Network (CORE) was created in 2011 to investigate and manage foodborne illness outbreak investigations. Under current practices, the CORE team will review shipping records from different segments of the food supply chain, inspect food processing and storage facilities, conduct a traceback procedure to attempt to determine the source of the suspect food product, and issue notices to the public about a potentially contaminated food product.

Upon receiving the foodborne illness outbreak notice, distributors, retailers, and restaurants can rely on their proven process of physically and visually inspecting inventory to determine if the suspect food is in inventory. Just as with downstream tracing, upstream traceback based on imprinted TLC, TLC Source, and expiration date elements on case labels, inner packs, and individual product packages would be critical to allow the expeditious removal of a suspect food product from the market while not at the same time requiring distributors, retailers, and restaurants to adopt new software technologies.

This imprinting model should expedite the upstream traceback process and could lead to more rapid removal of the product from warehouses, retail stores, and restaurants. In other words, the traceback process is itself a form of tracing that distributors, retailers, and restaurants already participate in and have done so for decades and can be enhanced through the adoption of the imprinting flexible option proposal.

Importance of Imprinting the TLC and TLC Source on Eaches: The TLC and TLC Source are both equally important Key Data Elements for food traceability purposes. If an inner pack or actual individual product package has the TLC and TLC Source imprinted on the packaging, identifying the contaminated product in a food recall event is simplified because a visual inspection of the product in a distributor's warehouse, a retail store, or a restaurant can lead to the expeditious

identification of the product and removal from the marketplace. Similarly, with the TLC and TLC Source imprinted on an inner pack or individual product package, a foodborne illness contamination investigation that locates the actual food product package can allow the FDA to leapfrog over the retail and distributor segments and go straight to the manufacturing facility or food processor where the food product was made and packaged. This should speed up the traceback process and allow for a more rapid removal of the contaminated product from the marketplace.

The imprinting of the TLC Source on inner packs and individual product packages would also aid in a foodborne illness traceback investigation even if the actual package from the contaminated food product is not located. How? During the interviews of individuals who became sick, investigators ask not only what food products the person consumed, but where they bought the food product. By learning what store the product was purchased at, the investigator can then visit the store and survey the same product on the store shelves. While the product on the store shelf may not have the same TLC imprinted on the label, it is very likely that the product on the store shelf would have the same TLC Source imprinted on the package because retailers routinely keep the same products offered for sale in stock. With the TLC Source information, the investigation can then leapfrog directly to the manufacturing facility or food processor plant to determine the origin point of the contamination.

To support the identification of the TLC Source, the FDA should consider establishing a registry of manufacturer and food processor TLC Source codes which contains the physical location of the actual facility or plant location that matches each TLC Source code.

Meeting the Lot-Level Tracing Requirement of FSMA Section 204(d): Imprinting the TLC, TLC Source, and expiration date on case labels, inner packs, and individual product packages should meet the requirement under FSMA Section 204(d) for lot-level tracing. Both "downstream tracing" and "upstream traceback" incorporate lot-level tracing by: (1) either the food manufacturer or the FDA informing food supply chain businesses of the TLC of a contaminated food product, (2) distributors, retailers, and restauranteurs utilizing physical and visual inspection of imprinted TLCs on case labels, inner packs, and individual product packages to determine if the specific TLC of a contaminated product matches the TLC of the same food product held in inventory, and (3) distributor review of product sales records and documentation to identify which retail stores and restaurants ordered the contaminated food product. That is, lot-level tracing at the distribution, retail, and restaurant levels is achieved through the inspection of sales records and visually inspecting inventory for the contaminated product.

Imprinting the TLC, TLC Source, and Expiration Date on Labels, Inner Packs and Eaches: The question then becomes whether food manufacturers can imprint the TLC, the TLC Source, and expiration date on inner packs and eaches. As stated above, food manufacturers have been imprinting expiration dates and lot codes on food products since the 1950s. For example, if you look at a package of cream cheese, a carton of eggs, or any other packaged food product that falls with the definition of FTL food products, many manufacturers currently imprint on each package an expiration date and alphanumeric codes which refer to the TLC and the TLC Source. The following FTL food product examples show this imprinting of the TLC and the TLC Source data.

A. Philadelphia Cream Cheese

Kraft-Heinz, the manufacturer of Philadelphia cream cheese products, confirmed that the alphanumeric codes shown on the bottom of the package in the picture below and readable as "H 002 21:05 F18" reference "the plant where [the cream cheese] is made…and the time stamp of the hour that the product was made."

B. Good and Gather Eggs

UNFI, the packager of Good and Gather brand eggs sold at Target stores, confirmed that the numbers "P1867B 111/P9" imprinted on the end of the egg carton refer to the lot code number and the packaging facility where the eggs were packed into cartons.

C. Lance Toasty Sandwich Crackers

Lance, the manufacturer of Lance Toasty Sandwich Crackers, confirmed that the alphanumeric code "CH002 B1 11 24 7" on the inner pack is a code that identifies the manufacturing facility, the manufactured date, the employee shift that the product was manufactured, the time the product was made, and the packaging line at the facility.

Without the TLC, TLC Source, and expiration date imprinted on inner packs and individual product packages, the critical KDE information needed to meet the underlying goal of FSMA Section 204(d) of more rapidly tracing back a suspect food to its origin is non-existent. That is, without these three critical KDEs imprinted on inner packs and individual product packages, both a food recall notice and foodborne illness traceback investigation will be hampered and slowed down. In short, the industry would need to rely on other tracing options which will create real world operational challenges for distributors, retailers, and restaurants, which is contrary to the requirements of the FSMA law.

The Feasibility of Imprinting the TLC, TLC Source, and Expiration Date: Since manufacturers and food processors have been imprinting lot code, assembly line, time stamp, and an expiration date information on food product packaging for 70 years, the process of imprinting such data elements meets the "feasibility" condition as stated in the U.S. House of Representatives report on the 2027 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations bill. Imprinting is not a new technology nor would it require distributors, retailers, and restaurants to adopt new business processes or upgrade software platforms to comply with. In other words, besides being currently feasible, the imprinting option is in line with the underlying principles of FSMA 204(d) that businesses should not be required to adopt new business operating systems and processes to comply with the food tracing requirements and the number of different recordkeeping requirements for businesses that sell more than one type of food should be minimized.

FSMA Section 204(d) Guidance: To support this new flexible option of imprinting the TLC, TLC Source, and expiration date on inner packs and individual product packages, the FDA should consider issuing a Guidance document which includes the imprinting model as a flexible option. In fact, the following FDA answer to public comments made about the original FSMA Section 204(d) rule indicates that the agency left the door open for the possibility of imprinting the TLC and the TLC Source along with an expiration date on inner packs and individual product packages:

> "Although the rule includes requirements to provide certain information to receiving entities in the supply chain, it does not prescribe the form in which this information must be provided. We conclude that it is not necessary for the rule to require that traceability information be placed on food labels to ensure adequate traceability of FTL foods. ***Nevertheless, firms may use product labels to provide information required under subpart S to their supply chain partners if that suits their business practices.*"** [FDA Rulemaking Response No. 524].

Conclusion: A guiding principle of FSMA Section 204(d)(1)(G) is that to the extent possible, the FDA should not require a company to change business operating systems to comply with the food tracing requirements. Since food manufacturers have been imprinting lot codes and expiration dates on food packaging since the 1950's, it is imperative that the food supply chain industry, in conjunction with the FDA, pursue an option which is based on this seven decades old foundational practice of imprinting critical tracing data on food product packaging. Imprinting the TLC, TLC Source, and expiration date on case labels, inner packs, and individual product packages should accelerate the identification and removal of a contaminated food product from the market when a manufacturer issues a food recall alert. In addition, such an imprinting requirement should lead to key evidence in a foodborne illness outbreak investigation to locate the origin of the contaminated

product, isolate the specific food product that made people sick, and allow the FDA to more rapidly issue a public notice about a contaminated food product.

In both a downstream tracing and upstream traceback scenario, imprinting the TLC, TLC Source, and expiration date strengthens the food industry's ability to more rapidly and positively respond to a food recall alert or a foodborne illness traceback notice without having to change their business practices and adopt new processes to adequately trace food products through the food supply chain.

Foodborne Illness Outbreak Investigation Process Resources

1. The FDA website homepage has several resources that explain the outbreak investigation process: https://www.fda.gov/food/outbreaks-foodborne-illness/about-core-network.

2. On the FDA website homepage, a 12-minute YouTube video goes into depth on how FDA works with CDC and local/state health authorities to determine which foods to trace based on epidemiologic evidence: https://www.youtube.com/watch?v=EeJwvAdJ-JU&t=8s

3. The CDC website explains in more depth the traceback process: https://www.cdc.gov/foodborne-outbreaks/outbreak-basics/investigation-steps.html.

4. AFDO convenes a workgroup called SHOP that supports regulators in using consumer purchase history information during outbreak investigations and provides helpful information on its website homepage: https://www.afdo.org/resources/leveraging-food-purchase-history/.

5. SHOP has a video at this website address: https://www.youtube.com/watch?v=8sQrrNLjJdY.