

February 22, 2021

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Division of Dockets Management (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. FDA-2014-N-0053: Requirements for Additional Traceability Records for Certain Foods

Dear Sir or Madam:

The National Retail Federation (NRF) appreciates this opportunity to comment on the Food & Drug Administration's (hereinafter, FDA or Agency) proposed rule to "establish additional traceability recordkeeping requirements for persons that manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL)." We support the Agency's goal of bringing greater speed and efficiency to its tracing responsibilities to prevent and mitigate outbreaks of foodborne illness in the U.S. food supply chain.

By way of background, the National Retail Federation, the world's largest retail trade association, passionately advocates for the people, brands, policies and ideas that help retail thrive. From its headquarters in Washington, D.C., NRF empowers the industry that powers the economy. Retail is the nation's largest private-sector employer, contributing \$3.9 trillion to annual GDP and supporting one in four U.S. jobs — 52 million working Americans. For over a century, NRF has been a voice for every retailer and every retail job, educating, inspiring, and communicating the powerful impact retail has on local communities and global economies.

As consumer-facing businesses, our members are keenly aware of the critical need to maintain the integrity of our food supply chains and to minimize the pathogen risks that are inherent with foods, particularly those foods that are more susceptible to pathogen adulteration by their very nature. Our food retail members are chain restaurant companies and nationally known grocery retailers that have professional food safety/quality assurance staff who have developed sophisticated processes and protocols over many years to ensure the safety of the food items within their restaurants and stores. The reputational risks to these brands from a single outbreak of foodborne illness can be devastating, and so they strive to ensure that the food they serve or sell to their customers is safe. Nonetheless, foodborne illness outbreaks still occasionally happen.

Traceability is challenging due to the complexity of supply chains. Moreover, there is no universal "language" for data in the industry. Barcodes are not universally used, and there are many gaps in data for produce in particular. Adding to the challenge is the fact that there are numerous growers and food manufacturers involved, a wide variety of entities involved in

product sourcing and distribution and, in a country the size of the United States, massive quantities of product moved through the supply chain. To illustrate the complexity of the food supply chain we provide the following high-level summary of a typical supply chain journey for produce from the grower to the retailer.

1. Existing Supply Chain Traceability Processes for Restaurants and Food Retailers

The typical supply chain for produce illustrates many of the most critical traceability challenges. A harvester (farm) will send bulk produce to a re-packer for packaging. A re-packer may have batches from multiple farms and locations, which may be commingled in the same packages or cases. Harvest-level data would change to new lot codes at the re-packer. From there, some items go into distribution centers, while other items are shipped directly to restaurants or retailers. Items with short shelf lives are often more likely to be shipped directly rather than channeled through distribution centers.¹

Distribution centers (DCs) do not all utilize GS1-128² traceability, although many have or could adopt such a program. When product arrives at a distribution center, it should ideally bear a pallet-level barcode denoting case-level GTIN (Global Trade Item Number which is a 14-digit unique number identifying trade items) with applicable date(s) and batch/lot numbers for products on the pallet. Although pallet-level barcodes would be ideal, many suppliers do not undertake this step because it would require a costly and time-consuming manual process - distribution centers would need to break down the pallets to record the case-level identification. Moreover, section 204(d)(1)(L)(iii) of the FSMA seems not to envision product tracking to the case level. In fact, that section of the statute specifically states the recordkeeping requirements of the proposed rule will not require case-level tracking.

Next, distribution centers scan the encoded GTIN, date and batch/lot number information into their internal Warehouse Management System (WMS). Typically, they move this product (palletized) into reserves for storage or into selection areas where it can be selected for shipment. Each case should then be scanned as it goes out for shipment. The handheld device by the selection agent often prints a custom sticker that accompanies the shipment for delivery to the retailer or restaurant with proprietary tracking information. The DC's number is linked to the GS1-128 tracking number.

Busy distribution center employees can make human errors and may occasionally fail to scan at the case level or they may scan an incorrect case. Other unavoidable errors may occur, such as label printers running low on ink or barcodes being scuffed in transit.

¹ Many restaurants and retailers also utilize grocers (e.g., Costco, Sam's Club) rather than sourcing produce through a distribution center. There is no batch-level traceability data available for these transactions, where the restaurant purchases product as if they were an individual consumer. This is an important channel for some small restaurants as a matter of budget or product availability, and for other restaurants in times of product shortages or missed deliveries.

² <https://blog.foodlogiq.com/gs1-128-barcode>

Some distributors may scan again at the time of delivery, which would be the last “critical tracking event” (CTE), as per the parlance cited by the Agency in the proposed rule. Other distributors might conduct a final scan at the time of selection at the distribution center. Perishable items such as produce are delivered to restaurants and retailers multiple times a week due to short shelf life.

We hope this summary of the typical supply chain of but one category of food – produce – highlights what we find glaringly obvious – without universal adoption of a digital traceability standard, effective traceability in the food supply chain will not be possible. We acknowledge that adoption of a universal traceability standard will cause hardship for several entities in the food supply chain, particularly small growers and even some small distributors. But we expect cost hardships will be borne across the supply chain, and that consumers will share in that cost.

2. The Need for a Single, Universally Adopted Traceability Standard

We note that in recent years many entities in the food supply chain have begun to use the GS1 Standard from GS1 US, which is a common language, expressed in barcodes, for identifying products, locations, and other data essential to moving products through a supply chain. As entities at the retail end of the food supply chain, we have observed that adoption of the GS1 Standard upstream in the supply chain is useful in promoting greater transparency and ease of traceability. In our estimation, GS1 standards have become the gold standard in foodservice traceability. We know the Agency, and the broader federal government, has a long and productive history of collaboration with GS1 US and the Agency recognizes the usefulness of the GS1 Standard in assisting with recalls. We are concerned that the Agency’s proposal seems to create a similar, but different, food traceability and recall system to the one that is on its way to more completely existing in the marketplace with the GS1 Standard, and that this will unnecessarily complicate an already complex food supply chain and serve to confuse the regulated community. We think this is not helpful and will not further the Agency’s goal to “rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded.”³

Given that the GS1 Standard, and in particular the GS1-128 barcodes which are commonly used on products in foodservice, has already established a foothold in the marketplace and continues to gain acceptance, we encourage the Agency to endorse the Standard in its final regulation and abandon the alternative language it seems to be promoting with terms like “Traceability Product Identifier” and others. We believe this more cooperative, collaborative approach will better serve the Agency’s traceability objectives mandated by the Food Safety Modernization Act (FSMA) and will bring them to fruition more quickly. Further, we think the Agency has the statutory authority to recognize GS1 Standards in its final rule, which the GS1

³ <https://www.federalregister.gov/d/2020-20100/p-3>

US organization outlines in detail in its formal comments submitted to this proposed rule. We associate ourselves with those comments and the rationale for Agency recognition of their standards which GS1 US has set forth in its comments to this proposed rule, and we incorporate them by reference here.

3. Recordkeeping at Retail/Restaurant Level

We think it would be helpful for us to briefly summarize the product data collection practices which currently exist in the restaurant and other food retail environments so that Agency reviewers can better understand how regulation can fit with real world practice.

It is important to recognize at the outset that the core business of a restaurant is hospitality and that, likewise, the core business of a food retailer such as a grocer is to present/arrange/display grocery items in a pleasant and easy-to-find format for consumers. Logistics, although necessary for any business, is not a core function for restaurants or food retail. The logistical expertise and infrastructure required to implement traceability recordkeeping (dedicated personnel, barcode scanners, label printers, Warehouse Management Systems, etc.) resides upstream from retail in the food supply chain.

When a distributor delivers product – pallets, cases, or smaller packages – to a restaurant or other food retailer, it is highly unusual for that restaurant or retailer (particularly a small business) to conduct any additional traceability data collection for those delivered products. To do so would merely duplicate that which has already been done by the distributor/supplier. Therefore, the data on the product and its delivery is held and managed solely by the supplier/distributor. Retailers and restaurants are simply not equipped to scan or manually enter data for each delivery. There would be significant cost and training needed for retailers to conduct additional incoming data collection or verification. Restaurants would need to create and update computer systems to match specific barcode systems. Many would need to buy handgun scanners to scan it into their commissaries. It would also be operationally challenging, as deliveries of FTL-listed product may come at unpredictable times of day when employees are otherwise engaged. This is a financial burden most retailers are not equipped to bear and would in practice merely duplicate data collection already conducted by distributors.

This is not to say that restaurants and food retailers should not or would not share in the cost burdens associated with implementing a traceability recordkeeping system for the food supply chain – they certainly will, and we fully expect the costs to growers, packers, distributors, and other suppliers of adopting a universal traceability system, such as the GS1-128 standard, will be borne by all entities in the supply chain. But requiring grocers and restaurants, the end of the food supply chain, to verify and duplicate traceability records that should rightly reside with distributors and other suppliers – entities with logistics as their core function and competency – would introduce unnecessary complications, inefficiencies, and additional costs to a system that will already experience higher costs from the proposed rule.

The Agency’s proposed regulation allows for a third party to be designated to maintain traceability records for a covered entity.⁴ It is possible that the Agency expects restaurants or grocers will designate distributors as responsible for maintaining traceability records, thus eliminating this duplicate data collection. We hope that is the case, and we ask that the Agency make this option clear in the final rule. However, we want to make sure the Agency understands that not all food products, including products listed on the FTL, that a restaurant prepares and sells to a consumer make their way to those restaurants via delivery by distributor or supplier. Occasionally, a restaurant will run out of, for example, tomatoes, lettuce, onions, etc., and will need to make a quick run to a nearby grocer or bulk seller to pick up a few items. For many small businesses, these grocery purchases are an economic necessity in instances where the business is not served by a food distributor, or when they may experience service interruptions. In these cases, detailed traceability documentation is not exchanged, nor is it feasible to do so.

We cannot overstate the challenges that will result if restaurants and other food retailers are required by the final rule to duplicate the traceability records that distributors and suppliers already create and maintain. A requirement for restaurants and food retailers to record and maintain “receiving KDEs” would mean that someone would need to scan or manually enter traceability records for every shipment or one-off grocery purchase, and then store that data somewhere. Foodservice staff are not trained in this type of activity, and to require it to become part of foodservice employee skill sets does not fit with the workforce as it currently exists, nor does it fit within the business model for most foodservice businesses. It would upend foodservice as we know it today, perhaps requiring the invention of an entirely new type of position in the industry; that of a “receiving-event recorder.” If this is what the Agency intends with its proposal, it must make that abundantly clear in the final regulation.

Finally, we should note that the restaurant industry has suffered tremendously during the pandemic and continues to bear disproportionate financial burdens because of lockdowns and other mitigation measures. Smaller, independent restaurants have been uniquely damaged, and the outlook for that segment of the industry is bleak. Even restaurants operating under a national brand -- the type we represent -- have suffered business declines as consumer demand has plummeted. Most chain brands operate as franchised systems, and their individual franchisees are small businesses, although the vast majority would be unlikely to qualify for the Agency’s proposed exemption for smaller businesses. We understand that the Agency is bound by the FSMA to promulgate the proposed rule on a certain timetable, but we must observe that it comes at an especially challenging time for restaurants. Moreover, it is important to recognize that most restaurants — even chains — operate on very tight margins, and the obligations envisioned by the proposed regulations, if not modified in the final rule, will stress the restaurant business model in ways that cannot be sustained.

⁴ <https://www.federalregister.gov/d/2020-20100/p-217>

4. Additional Consequences to Consider at Retail-Level

There are several problems that will result if restaurants and other food retailers are required to duplicate the digital recordkeeping obligations the rule envisions for entities in the food supply chain. We explain some situations unique to restaurants and food retailers and ask the Agency to provide clarification of the following concerns.

- Produce vendors will often divide cases of items because restaurants cannot always use an entire case, and they will repackage them for delivery to the restaurant. This is particularly common with lemons, lettuce, onions, and tomatoes. What happens when the repackaged items do not include barcodes or other traceability identifiers? Will the restaurant still be held responsible for knowing the traceability provenance of the food items that the distributor repackaged and delivered to the restaurant?
- What are the Agency’s expectations for restaurants that purchase listed food from a grocery store where traceability data is not provided? Are receipts or invoices sufficient?
- The proposed regulation states that respondents may be asked to make available an “electronic sortable spreadsheet” within 24 hours of request by an authorized FDA representative.⁵ This is not feasible in restaurant and food retail settings for a variety of reasons.
 - To the extent data is held and managed by a supplier or distributor, a restaurant or retailer may not receive a timely response to requests for information and could be late responding to the FDA because of circumstances outside of our control. Many foodborne illness events occur on weekends or after business hours, when it is most difficult to have this information retrieved and compiled. Moreover, Warehouse Management Systems often “refresh” once per day, and the information may not be up to date if a delivery has just been made or the system has not recognized recent changes.
 - The 24-hour requirement is similarly problematic for data manually gathered at a retailer or restaurant if such data collection will be required. This turnaround time would necessitate dedicated employees scanning or entering data “live” as it is delivered.
 - Regarding the 24-hour response time requirement itself, further detail and/or clarification on when the “clock officially starts” before previously noted “electronic sortable spreadsheets” are required to be submitted to an FDA representative would be appreciated. Specifically, will the official notice be delivered in the form of a phone call, email, or formal letter delivered via certified mail? To whom will the notice be delivered? Can we expect notices to be delivered to individual restaurants at any date and time or can a designated contact at corporate office be the sole recipient of notice when necessary? Depending on which is the official mode of communication and to whom the

⁵ <https://www.federalregister.gov/d/2020-20100/p-498>

notice will be directed, the realistic likelihood that the 24-hour requirement can be met is in question.

- What are the implications of incomplete traceability records due to data integrity and quality issues? As we have noted previously, human error occurs throughout the supply chain. Even where a GS1-128 barcode has been properly applied, the barcode could be scuffed or damaged, printed with low ink, or torn off in transit. Will FDA include any details about print grade requirements? Will FDA require labels on multiple sides of the case exterior?
- Retailers and restaurants are not able to verify or “police” data from our distributors. If a retailer or restaurant provides distributor-generated data to FDA, are we responsible for its accuracy? What if the barcode and scanned data held in databases do not match? Is the retailer obligated to catch discrepancies and reconcile data?

5. Do Restaurants and Grocers “Transform” Foods?

We were pleased to note that the Agency included an exemption from recordkeeping requirements in situations where a restaurant or food retailer “transforms” foods that are sold directly to a consumer. “Transforming” a food, under the Agency’s definition, is the very essence of what restaurants do – they take food ingredients and create menu items. (A similar analogy exists for delis within grocery stores.) Absent the Agency’s exemption for this activity, routine food preparation activities in a restaurant or grocery deli would trigger completely unworkable regulatory responsibilities. Kitchen staff would need to somehow record this “transformation” activity, probably either in writing or by using an electronic device, and the records would need to be kept someplace on site within the facility. Thankfully, the Agency’s apparent exemption seems to have concluded that such a requirement would be unreasonable.

However, it is not clear to us whether the exemption would apply to several situations specific to restaurants and food retail. For example, some restaurants or retailers operate “central kitchens” or commissaries, often under common ownership, which prepare food in a larger workspace for transfer (by sale or internal transfer) to nearby stores for sale to consumers. Others provide prepared food to entities such as schools or corporate cafeterias for resale to consumers. Would the commissary need to create “transformation” records for food items on the FTL that are “transformed,” such as by chopping, cutting, cooking, commingling, repacking, or repackaging?

If the answer to this question is yes, the same challenges we noted earlier will result again. Restaurant kitchens and grocery delis are wet areas and are not conducive to the creation of written records or technology-enabled printed labels, or any other such formats. Employees would need to keep track of precisely which tomatoes or lettuce or other FTL ingredients are taken from which cases/packages and, after being chopped, sliced, etc., are mixed in precisely which batches of salad dressing, chicken salad, or whatever other resulting food item is made. This would not be feasible.

6. Clarification of Obligations and Enforcement

The proposed rule is vague regarding an enforcement and penalty regime. The proposed rule states only that violations of the recordkeeping requirements of Section 204 under the FSMA is a prohibited act.⁶ We respectfully request that FDA clarify obligations and an enforcement strategy, particularly for retailers and restaurants. Rather than an added emphasis on penalties, the Agency should focus on educating suppliers, distributors, and operators so they understand tracking and traceability - why it is important and how it works. This will serve to benefit all layers of the supply chain.

We thank you for the opportunity to comment on this proposed rule, and we appreciate your consideration of our views.

Sincerely,



David French
Senior Vice President
Government Relations

⁶ <https://www.federalregister.gov/d/2020-20100/p-754>