National Grocers Association

February 22, 2021

Dockets and Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA–2014–N–0053 for "Requirements for Additional Traceability Records for Certain Foods," 85 Fed. Reg. 59,984 (Sept. 23, 2020); Comments on Proposed Rule

Dear Sir or Madam,

These comments are submitted on behalf of the National Grocers Association (NGA), the national trade association representing the retail and wholesale grocers that comprise the independent sector of the food distribution industry. An independent retailer is a family owned or privately held or controlled food retail company operating a variety of formats. Most independent grocers are serviced by wholesale distributors, while others may be partially or fully self- distributing. Independents are the true "entrepreneurs" of the grocery industry and dedicated to their customers, associates, and communities.

The independent grocery sector is accountable for close to one percent of the nation's overall economy and is responsible for generating $131 billion in sales in approximately 21,000 stores – representing 25% of retail grocery industry sales, 944,000 jobs, $30 billion in wages, and $27 billion in taxes. NGA members include retail and wholesale grocers, state grocers' associations, as well as manufacturers and service suppliers. For more information about NGA, visit www.nationalgrocers.org.

The independent retail and wholesale grocer members of NGA are strongly committed to food safety, security, and good nutrition, and wholeheartedly support the Food and Drug Administration's (FDA) important public health mission. Commitment to these goals is part of our members' service to their communities.

We thank FDA for the opportunity to comment on the Proposed Rule and for the many outreach activities that the agency has presented during this rulemaking. We look forward to continuing these education efforts as we all move in constant improvement to food safety systems.

While we will provide specific comments below on the Proposed Rule, it is NGA's position that the agency very well may have exceeded its authority under section 204 of the Food Safety Modernization

Act (FSMA) in promulgating the entirely new recordkeeping regime. It is not merely difficult but well-nigh impossible to envision how the proposed system could work in the absence of case-level tracking, which the agency is specifically prohibited from imposing under section 204(d)(1)(L)(iii). In addition, the requirement for a sortable electronic spreadsheet to be produced is a *de facto* imposition of an electronic recordkeeping system because it would be impossible otherwise to comply with the 24-hour production requirement in the absence of existing electronic records to populate the sortable electronic spreadsheet. This requirement would therefore violate the statutory limitations under sections 204(d)(1)(C). Moreover, by mandating this production in this form, the Proposed Rule violates section 204(d)(1)(E) by requiring a record that is overly complex, burdensome, and duplicative of other extant records.

We agree with other commenters that FDA should take care in evaluating stakeholder comments and adjusting the Proposed Rule because of the danger in finalizing the regulation in a form and with requirements that effectively deny the public the opportunity for meaningful notice and comment. We support the agency taking an approach that may necessitate a supplemental proposed rule. We acknowledge the Consent Decree mandating publication of a Final Rule by November 7, 2022,[1] but compliance with that injunction cannot be at the expense of other, applicable legal requirements, including the Administrative Procedure Act and the strictures imposed in FSMA section 204 itself.

Other specific comments follow.

I. The Proposed Rule Impermissibly Imposes Case-Level Tracking Requirements

FSMA section 204(d)(1)(L)(iii) provides that the enhanced recordkeeping requirements established by this rule shall "not require . . . product tracking to the case level." In the ordinary course, NGA wholesale and retail grocery receive products from their suppliers on pallets. Each pallet typically contains multiple cases of product, each of which could be associated with different "traceability lot codes." When receiving products, these receivers (and wholesale grocery distributors on the outbound shipment) will only be able to comply with the Proposed Rule by determining which lot codes are associated with each case in the pallets they receive, forward, or break down the pallet and forward individual cases, *i.e.*, by engaging in case-level tracking.

There could never be any guarantee that the shipment of even a single product type on a pallet will contain only a single traceability code. Consider the situation where a bagged salad producer ships a pallet of product to a wholesale grocery distributor. That pallet may very well contain different salad blends, albeit all containing leafy greens subject to the FTL. In the event of a product recall based on a single ingredient in one or more – but not all – of the salad blends, only the bagged salads with the implicated ingredient would be subject to recall. The Proposed Rule would require the distributor to maintain and send shipping Key Data Elements (KDEs) linked to the specific traceability lot codes of the products in each shipment. Either the bagged salad supplier designed its traceability lot codes without regard to defining whether an implicated product in a recall could be identified, or the traceability lot codes on the palletized shipment would have to be examined on a case-by-case basis to determine whether particular cases contained implicated product.

[1] *Center for Food Safety,* et al.*,* v. *Azar,* et al.*,* No. 4:18-cv-06299-YGR (N.D. Cal. June 7, 2019) (Consent Decree).

Moreover, as identified in the Institute of Food Technologists' (IFT) *Pilot Projects for Improving Product Tracing Along the Food Supply System* ("IFT Report"),[2] existing systems such as examination of purchase orders (POs) have been and are to this day are successfully used in product trace exercises. Use of POs would particularly identify the particular products subject to recall, resulting in effective recall and removal of the implicated product, minimizing food waste, and laying the groundwork for resolution of any commercial disputes that may follow.

II. The Proposed Rule Impermissibly Imposes Specific Technologies for the Maintenance of Records

Proposed section 1.1455(b)(3) would require persons subject to the Proposed Rule to make available, within 24 hours of request by an authorized FDA representative, an electronic sortable spreadsheet (ESS) containing the information in the records they are required to maintain under this Subpart S. Given that the breadth and amount of data that the agency will be asked to summarize on the ESS, it would very likely be difficult, if not impossible, for retail food establishments to develop such an ESS unless suppliers throughout the supply chain themselves generated and transmitted electronic records and the retail food establishments themselves had an electronic recordkeeping system capable of accepting, storing, and manipulating such records for the purpose of developing the ESS. This is a *de facto* imposition of a technological system for the maintenance of records specifically prohibited by FSMA section 204(d)(1)(C).

We also join other commenters which have noted that the drive for electronic records over all other types of systems may tend to adversely affect the small producers in the communities where independent retail grocers have traditionally been a sturdy partner in bringing those small producers' products to their shared communities. For both the small producers and the independent retail grocery, this could cause disproportionate harm to both these small businesses and should be avoided.

III. The Pharmaceutical Industry's Experience Implementing the Drug Supply Chain Security Act Is Instructive to FDA Goals and Practical Expectations During this Rulemaking

The Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act (DQSA) of 2013,[3] established requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain. Industry regulated under the DSCSA negotiated with the Congress, among themselves, and with other stakeholders for a stepwise, phased-in approach to achieve interoperable, electronic, and secure exchange of data about pharmaceutical products each time they changed ownership in order to enable tracing both back to the manufacturer and forward to the healthcare entity that acquired the pharmaceutical for dispensing or administration. It was a very similar endeavor to the present Proposed Rule for FTL products.

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[2] "Activity IDs [including purchase orders], particularly when used in conjunction with a system to analyze data, can provide meaningful information to aid in product tracing investigations when firms also maintain good internal tracing." IFT Report at 113-14. https://www.fda.gov/media/124149/download

[3] Pub. L. No. 113-54, 127 Stat. 587 (Nov. 27, 2013).

The DSCSA, however, called for a ten-year implementation, not the slightly less than two years and two months called for in this rulemaking pursuant to the Consent Decree. Beginning in 2015 pharmaceutical trading partners were required to provide, receive, and maintain transaction data about their products purchased and sold. As the DSCSA required, this information was migrated over a two-year process to either point-to-point electronic data interface (EDI) transaction or uploaded through a secure portal.

In 2017 and 2018, manufacturers and repackers were required to affix unique product identifiers to all covered products and homogenous cases of such products. The product identifier is defined in the DSCSA as a standardized graphic in human-readable and machine-readable carrier that conforms to international standards. It further includes, as assigned by the manufacturer or repackager, the product's unique standardized numerical identifier (SNI), lot number, and expiration date. Even with a plain statutory definition of what constituted a product identifier, an international standard set by GS1 Global, and years of lead-time, industry still needed an additional year to accomplish item-level serialization of all covered prescription drugs.

Interoperable, electronic, and secure systems will be communicated between trading partners beginning in 2023.

These achievements have required a specific statutory mandate, regulatory guidance, industry commitment, hundreds of millions of dollars in capital and human investment industry-wide, sophisticated information technology and systems development, changes to manufacturing, labeling, and packaging configurations and lines. Even seven years into DSCSA's implementation, for most product sales, wholesale distributors are still not required to include a product's lot number in transaction data they provide to a customer. One important reason for this is that lot numbers are not standardized or machine-readable on prescription drug packages and must be captured manually. Manual inspection and recording of lot numbers prior to the transfer of a product could not, in the absence of new tools and procedures, be accomplished in an efficient, reliable way without severely affecting the ability of pharmaceutical wholesalers to provide hundreds of thousands of units of life saving medicines that must be delivered to patients and healthcare providers on a daily basis.

The food industry is not that different.

The pharmaceutical industry will achieve lot tracing at the speed and scale required by embedding lot numbers within a unique identifier in a machine-readable format, and then capturing, storing and providing that information electronically in product transactions. The food industry, operating on different product margins than the pharmaceutical industry, will have to be clever in achieving the same goals.

IV. Exemption or Partial Exemption of Retailers by Size, *Proposed* § 1.1305(g)

NGA supports the proposed exemption for small retail establishments, subject to the comments that follow. NGA respectfully submits that the exemption level of 10 or fewer full-time employees (FTEs) is unreasonably small. Even a small, single-store independent grocery store is likely to have more than 10 FTEs if one counts the number of cashiers to staff a six- or seven-day-a-week schedule with stores open for at least twelve hours a day, specialized clerks in each of the meat, deli, and produce departments, the fish

counter, stocking clerks, and management. As originally proposed, the exemption for small retailers is set so that almost no grocery store could qualify.

We suggest that FDA consider different metrics. We note that FDA's Menu Labeling regulation exempts restaurants if they are not part of a chain with 20 or more locations. Alternatively, an appropriate level of annual sales at individual locations could be set.

Regardless of the metric used, however, the requirement for production of an electronically sortable spreadsheet would be unduly burdensome on these small retailers, and effectively require them to develop electronic records in violation of the statutory limitations on this rulemaking under FSMA section 204(d)(1)(C) and (d)(1)(E). NGA, at a minimum, strongly supports the proposal that small retailers be exempted from the electronically sortable spreadsheet requirement, as FDA has proposed under "Option 2."

With respect to the limitation of subsection (d)(1)(E), the recordkeeping requirement would not be scale-appropriate and would impermissibly require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business. Under 21 C.F.R. Subpart J, while retailers are exempt from developing and keeping records regarding subsequent transporters and recipients of products who are consumers, they are not exempt from recordkeeping regarding the non-transporter and transporter immediate prior source of the food. 21 C.F.R. § 1.337(a). In the event of a traceback investigation beginning with a consumer, this information regarding the upstream supplier can easily be provided to the agency upon request under existing authority. That non-transporter immediate prior source would then either be a distributor subject to the Proposed Rule, or a party so close to the origin of the food at issue (*e.g.*, a farm or fishing vessel) so as to completely fulfill the agency's traceback need for information.

We also respectfully suggest that agency requests for this information made to either retailers that would be subject to the Proposed Rule, or exempt from the rule under an appropriate size exemption, be in writing. We acknowledge that FDA has suggested that moving from the retailer step in a traceback to an immediate prior supplier "would likely" cause 24 – 48 hour delays in a traceback investigation.[4] We respectfully submit small retailers are capable of promptly responding to well-formed, clear inquiries from regulatory authorities, especially if the gravity of a given situation is explained.

V. The Proposed Rule Conflicts with FSMA Section 204(d)(3) Insofar as It Calls for Dissemination of Confidential Commercial Information

The "traceability lot code generator" is defined as the person who assigns a traceability lot code to a product upon the origination, transformation, or creation of the FTL product. *Proposed* section 1.130 (definitions). "The location identifier, location description, and point of contact for the traceability lot code generator" is a KDE required to be maintained by the recipient of an FTL product (*proposed* section 1.1335(f)), as well as maintained and sent to a further recipient (*proposed* section 1.1350(a)(4)). While it is easy to understand why the agency would want this information for investigative purposes, it would not appear to be necessary in order to actually trace the product using other mandated KDEs.

[4] 85 Fed. Reg. at 59,997, col. 3.

At the same time, FSMA section 204(d)(3), Protection of sensitive information, FDA is directed to "take appropriate measures to ensure that there are effective procedures to prevent unauthorized disclosure of any trade secret or confidential information." Requiring the maintenance *and transmission* of this information to subsequent recipients will disclose the entity that is the originator, transformer, or creator of the FTL product. In several different contexts, the identity of the original supplier is treated as trade secret/business confidential information exempt from disclosure under the Freedom of Information Act (FOIA). 5 U.S.C. § 552(b)(4). If in the hands of the agency such information would be considered exempt from disclosure, trading partners should not be required to affirmatively disclose this information under Subpart S. Finally, points of contact change frequently, and maintaining current point of contact information would be challenging without a corresponding definitive public health benefit. NGA also respectfully submits that point of contact information is actually not necessary to perform a tracing exercise. We respectfully submit that these affirmative disclosure requirements should be deleted from any final rule establishing Subpart S.

VI. Modified Requirements for Foods Subject to a Kill Step or Rarely Consumed Raw

A. FTL Foods Subject to a Kill Step

NGA is aware that some commenters have suggested that the modified record requirements for foods subject to a "kill step,"[5] are unworkable because a recipient of a FTL product or a food containing an FTL product as an ingredient would still be faced with the problem of determining whether the food had or had not been subjected to a validated kill step. Under this interpretation, the recipient would be faced with the choice of seeking to obtain full Subpart S documentation or documentation along the lines of a certification of the validated kill step, and those documents themselves would generate both recordkeeping and reference record generation and transmission duties. NGA shares these concerns.

While NGA's retailer members' transmission duties under the Proposed Rule would be generally limited, the Association also represents wholesale grocers and the prospect of such a needless recordkeeping obligation is sufficiently prominent that NGA submits that FDA should clarify this matter. We note that the preamble to the Proposed Rule at several points explains that, "under proposed § 1.1355(b), because the kill step had been applied, the manufacturer's customer and subsequent persons in the supply chain would not be required to maintain any records required under proposed subpart S regarding receipt, transformation, or shipment of the [FTL product]."[6] We respectfully suggest that FDA promulgate appropriate regulatory language that the recipient of an FTL product or a food containing and FTL product as an ingredient be entitled, absent contrary evidence, to rely in good faith on the absence of Subpart S records from the supplier as a sign that the exemption granted under *proposed* section 1.1355(b) is in effect. If a letter of guaranty under section 303(c)(2) of the Food, Drug, and Cosmetic Act should be in place to establish such a safe harbor, the agency should so state publicly in the record of this rulemaking.

B. Foods Rarely Consumed Raw that Contains an FTL Ingredient

Foods that contain an ingredient that is on the Food Traceability List but that are rarely, if ever, consumed raw should be exempt from the Proposed Rule's requirements. For example, a frozen pizza

[5] *Proposed* section 1.1355.
[6] 85 Fed. Reg. at 60,013, col. 2.

topped with frozen peppers would be subject to the Proposed Rule's requirements, presumably because of a purported potential microbiological hazard posed by the frozen raw agricultural commodity. While the agency in the ordinary case would assert that a rule's requirements cannot be dispensed with merely because the consumer will apply an unvalidated "kill step" by cooking the frozen product, that is exactly what FDA did in the Produce Safety Rule by exempting fruits and vegetables that are rarely consumed raw. 21 C.F.R. 112.2(a)(1) (final regulation); 78 Fed. Reg. 3,537, cols. 2-3 (Jan. 16, 2013) (proposed rule). That reasoning, including its supporting assessment on impact on the public health, is wholly appropriate here.

VI. Requirements for Entities that Receive Products from Exempt Originators or Manufacturers

As part of local, independent retail grocery in communities, many NGA retail members and their distributors support small, local food producers that would be exempt from the Proposed Rule under *proposed* section 1.1305(a). Support of local, in-season, agricultural production may mean acquisition of those otherwise FTL-covered products by either NGA's retailer members individually or by some of NGA's wholesale grocer members. Those distributors would be required to establish and maintain receiver and first receiver KDEs. At the same time, those distributors would be dependent at least on the cooperation of the exempt originator or manufacturer to obtain KDE information such as "location identification and description of the immediate previous source" and the information about harvesting, cooling, and packing dates, times, and locations under *proposed* section 1.1330.

To address these concerns and to support the viability of locally produced agriculture products in and among communities, we suggest revision of the Proposed Rule so that products from such exempt originators or manufacturers remain exempt throughout distribution. This exemption is limited, insofar as one-up/one-back traceability under Subpart J would still apply. With regard to the public health implications of this suggested revision, we respectfully point to the agency's own determination that such entities within the scope of the rule generate a relatively low volume of food and requiring them to be under the full panoply of Subpart S requirements would produce "little measurable public health benefit."[7] Moreover, the vast majority of products that would be affected here would be highly perishable products with an extremely short distribution and localized supply chain, well within the ambit of Subpart J traceability.

NGA is concerned that the imposition of KDE first receiver requirements on distributors receiving product from otherwise exempt originators will have the unfortunate effect of dissuading first receivers from working with small originators exempt under *proposed* section 1.1305(a). FDA should recognize the extreme difficulty of distributors determining when they are acting as a first receiver and make first receivers of exempt originators' products likewise exempt.

As with foods containing an FTL ingredient that has been subjected to a kill step and foods containing an FTL ingredient that are rarely consumed raw, the recipient of an FTL product or a food containing and FTL product as an ingredient should be permitted, absent contrary evidence, to rely in good faith on the absence of Subpart S records from the supplier as a sign that an exemption from Subpart S requirements is in effect. If a letter of guaranty under section 303(c)(2) of the Food, Drug, and Cosmetic

[7] 85 Fed. Reg. at 59,995, col. 2.

Act should be in place to establish such a safe harbor, the agency should so state publicly in the record of this rulemaking.

VII. Other Ordinary Business Practices Cannot Be Accommodated Under the Proposed Rule

A. Broker Sales

Among the myriad daily changes in product sourcing is the prevalence of broker sales, as is common in the produce trade, where many produce items are also FTL products. In response to market conditions, including product availability affected by weather, availability of logistics capacity, or extraordinary disruption of the supply chain by other unforeseen events, produce may be delivered to a retailer from a number of different sources, including directly from an exempt farm or a non-exempt warehouse. Even the same product from the same ultimate source may take a different route to the retailer depending on circumstances outside the control of any of the market participants on a day-to-day or week-to-week basis.

Retailers therefore cannot know in all circumstances, and brokers (being neither a source nor a receiver) cannot provide retailers with the information necessary to determine whether the retailer is receiving product as a first receiver or not. This unavailable information may include information regarding when and where a product was harvested, cooled, and packed. This very common and useful business arrangement in a market that can rapidly transform itself underscores the challenge of designating first receiving as a Critical Tracking Event (CTE). Because of the potential trade disruption and assured by continued application of Subpart J traceability, NGA respectfully suggests that FDA dispense with the differing requirements of the first receiver CTE and treat all receivers in the same manner.

B. Cross Docking

One of the common business practices that facilitate the swift and efficient distribution of food, including FTL products, is cross docking. This practice can generally be understood to occur when product, usually palletized, passes over a loading dock from one transporter to another, without being held at the cross docking facility for any appreciable time and under procedures that maintain essential transportation conditions such as temperature. Cross dock providers do not hold inventories and typically maintain activity records on paper only. They do not operate as other parties that would ordinarily be called "shippers" or "receivers" because they do not carry out the responsibilities of either. At the same time, cross dock operations do not appear to present significant food safety concerns because of the time and conditions under which the operations take place. In addition, Subpart J traceability and regulations promulgated pursuant to the Sanitary Transportation of Food Act, contained in 21 C.F.R. Part 1, Subpart O, nevertheless apply. NGA respectfully submits that additional examination of cross docking within the context of traceability should be undertaken by the agency in this or supplemental rulemaking but in the interim, should treat cross docking as an exempt activity.

C. Direct Store Deliveries

Direct Store Deliveries (DSD) is another model which does not fit into the Proposed Rule's structure of ordinary shippers and receivers. Product delivered under a DSD model are not sold to the

retailer but rather remain under the supplier's risk until sold by the retailer. The DSD supplier usually is also responsible for stocking the product at the retail store. The common practice is for the product to be described in electronic records by Global Trade Identification Number (GTIN), and invoice number, quantity, and cost. Invoices are reconciled against retailer's scanned sales data. The supplier is the last commercial entity acting as a "receiver," as the product does not enter the "inventory" of the retailer, which acts as a facilitator of the sale to the consumer. This common and useful business arrangement does not fit within the Proposed Rule's structure and requires further examination.

VIII. FDA Has Substantially Underestimated the Economic Impact of the Proposed Rule

FDA's substantial underestimating of the economic impact of the Proposed Rule starts with the notion that it would take only one individual from each respondent (meaning the regulated entity) an average of 3.3 hours to "read and understand the new recordkeeping requirements."[8] Over 50 percent of NGA's retail members are single store operators that may not have full-time staffers dedicated to reading and deciphering regulations, much less designing, making necessary capital investments for, and implementing new recordkeeping procedures. FDA published the Proposed Rule on September 23, 2020, covering 55 three-column pages. The agency has since held three public meetings, published and revised supplemental materials including as recently as January 2021, and continues to hold public events addressing issues raised in the rulemaking, most recently as January 11, 2021. The presumption that an afternoon's read will suffice to permit a single person to guide their company into designing and implementing changes to complex business practices is not credible. The estimate of one-time set up of the projected one-thousand program records at 2 minutes each betrays a misunderstanding of business processes at both large and small businesses. For single-store operators who may be the entire enterprise's founder, holder of all institutional knowledge, and primary supervisor for all operations, this Proposed Rule represents the establishment of yet another full-time job atop all of the other full-time jobs that the single store operator juggles.

As drafted, the Proposed Rule will impose both one-time and continuing costs for NGA's retail grocery and wholesale grocery members as they will be required to develop new business systems, invest in new capital improvements to information infrastructure, and train personnel to mind these new systems and respond to FDA- and industry-initiated tracing exercises.

One of the most significant efforts and expenses will be in relation to the case-level tracing regime described by the Proposed Rule – if implemented as proposed. Breaking down pallets for case-level tracking would be unavoidable, as often many cases on a pallet would not have exterior facings. Whether such case-level tracking will – or can be – implemented by machine-readable or human-readable methods, or will be required to have the capacity for both, will be a fundamental change and challenge to the efficiencies by which wholesalers are able to provide valuable services to their customers. All of this will require employee training and perhaps additional employees. The costs, individually and collectively, noted in the Preliminary Regulatory Impact Analysis (PRIA) will far exceed those described in the FDA's analysis. Again, NGA views this practical implementation of the Proposed Rule, necessitating case level tracing, to be prohibited by FSMA section 204(d)(1)(L)(iii).

[8] 85 Fed. Reg. at 60,025, Table 9.

Our members have advised us that implementation costs would include vendor solicitation, warehouse management system upgrades, and acquisition of scanning devices. Labor costs would be incurred to gather, track, and forward KDEs. NGA is aware of industry estimates that these expenditures would add at least $1 per case for every case handled. With NGA's members handling 25% of all retail grocery industry sales in the United States, and a value of $131 billion in annual sales, this is a staggering additional cost to the U.S. economy.

IX. FDA Has Characterized Improvement in Traceback Efficiencies Without Proper Context

At the same time, NGA must respectfully comment on the agency's estimates of monetized benefits from the Proposed Rule. Reference 29 to the Proposed Rule is FDA's ''Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis,'' Docket No. FDA–2014–N–0053, September 2020 (hereinafter "Traceability PRIA"). It notes that "Greater tracing speed can result in faster and more precise recalls (if the FTL product is still on the market) and other preventive actions that may reduce the number of illnesses during an outbreak."[9] Most of the products on the FTL are highly perishable, with a shelf life of weeks, at most. The agency's estimated reduction of "84% traceback time resulting from the requirements of this rule"[10] should be read in concert with the fact that traceback time is not the time limiter in effectively using product tracing to reduce illness associated with an outbreak. Epidemiology is.

Identification of a food vector in a foodborne disease outbreak can take weeks because of (1) the incubation time for the particular pathogen (between two and six weeks for listeriosis);[11] the diagnosis by a physician; the reporting of the diagnosis to state public health authorities; the transmission of reports to the Centers for Disease Control and Prevention (CDC); and the identification of an outbreak by CDC. Thereafter, the investigation of case histories of clinical cases must be carried out.

"Traceback efficiency" should not be confused with "effective recalls." There are several types of recalls and associated traceback investigations. One is a case in which an adulterated product is identified either by product testing or testing at a processing facility where the potential for product contamination is located, such as a food contact surface testing positive for a pathogen. In those cases, processors and others in the food distribution chain can be alerted within hours of confirmed test results and distributors, retailers, and foodservice operators can act on information immediately even without the requirements of the Proposed Rule.

Another and more difficult type of recall is when a foodborne disease outbreak of unknown etiology occurs, and state public health officials, the CDC, and the FDA must work furiously and cooperatively to identify potential vectors. Case histories must be performed by interviewing patients with confirmed illnesses to determine what they may have eaten that led to their unfortunate illness. While CDC investigators have highly developed skills in this endeavor, people still may simply not remember what they ate weeks before or the entity from which they purchased the food that could have led to their illness. FDA, in cooperation with the CDC and the U.S. Department of Agriculture Food Safety and Inspection

[9] Traceability PRIA at 39.
[10] 85 Fed. Reg. at 60,021, col. 2.
[11] Goulet, *et al.,* "What is the incubation period for listeriosis?" BMC Infect Dis. 2013; 13: 11, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3562139/.

Service (FSIS) recently launched websites detailing ongoing foodborne disease outbreak investigations, even when no food vector has yet been determined. These new public information sources set forth the regrettable fact that sometimes it is simply not known from where disease outbreaks normally associated with food are coming. Improvement in traceback times could be improved under the Proposed Rule but only after a food vector is identified. The same is true of whether the Proposed Rule can speed up the time required for a Root Cause Analysis of the reason for product contamination; identification of the food vector must be made first. The PRIA for the Proposed Rule does not address these facts.

X. Implementation of a Final Regulation Must Be Built from the Food's Origin to the Retail Establishment in an Organized Manner

Implementation of the rulemaking will be utterly dependent on the ability of suppliers to provide required information to their customers. A phased-in implementation, starting with primary producers will be necessary so that subsequent distributors (regardless of the number of levels of distribution), of whatever products subject to the Food Traceability List (FTL), can learn and adapt to what kinds of data they will be receiving, and how that data can be organized and stored. Only after that should retail food establishments be brought to the implementation process so that the retail segment can build upon what has been learned by the distribution segment. Enforcement discretion should be exercised throughout the phased-in implementation.

NGA respectfully suggests that the agency be guided by its experience in implementing the DSCSA, as described above. NGA stands ready to partner with FDA on educating both the agency and our members on not only what can be achieved, but how and when, as well.

NGA is appreciative of FDA's efforts on to address this important issue and together with our members, we share the same goals of ensuring the integrity and safety of our food supply chain. Given the large volume of product our members deal with day in and day out, managing product recalls is an established part of independent grocers' daily operations. NGA looks forward to continuing to work collaboratively with FDA to build on the many successful systems and practices already employed throughout the food distribution system that will allow us to achieve our shared public health goals.

Respectfully submitted,

Greg Ferrara
President and Chief Executive Officer