February 22, 2021

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
Submitted electronically

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

To Whom It May Concern:

United Fresh Produce Association ("United Fresh") respectfully submits the following comments to the proposed rule "Requirements for Additional Traceability Records for Certain Foods" [Docket No. FDA-2014-N-0053] (https://www.federalregister.gov/documents/2020/09/23/2020-20100/requirements-for-additional-traceability-records-for-certain-foods).

Founded in 1904, the United Fresh Produce Association represents the produce industry, bringing together companies across every segment of the fresh produce supply chain, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. With over 1500 members, we empower industry leaders to shape sound government policy. We deliver the resources and expertise companies need to succeed in managing complex business and technical issues. We provide the training and development individuals need to advance their careers in produce. Through these endeavors, we unite our industry with a common purpose – to build long-term value for our members and grow produce consumption.

A subset of our membership representing grower/shippers, fresh-cut processors, distributors, retailers, and trade associations representing different commodities reviewed the proposed rule and assisted in the development of comments. Our comments are also informed by the numerous questions that a diverse set of members have asked, as well as the information provided in response to inquiries to the FDA Technical Assistance Network, Food and Beverage Issue Alliance, during the three public meetings, and during various webinars.

As we reviewed the preamble to the rule finalizing Subpart J, published in 2004, we see that voluntary industry action over the past 15 years has not fully addressed the challenges the Agency continues to face, and that many of the points offered by industry and the Agency at that time continue today, despite the tremendous improvements in and availability of technology and systems that can facilitate traceability.

Although Congress recognized the need to improve traceability in authoring the Food Safety Modernization Act, FDA remained somewhat limited in authority. We are pleased to see FDA use the authority under FSMA, as well as under the US Public Health Service Act, in order to propose a framework for improved traceability. We appreciate the numerous tools that FDA has made available to support the understanding of the proposed rule. To the agency's credit, FDA has also remained very accessible and engaged with the industry during the comment period.

In the preface to the proposed rule, FDA notes several times that "tracebacks are most efficient when point-of-service entities can provide investigators with as much information as possible about the origination of the food" (III E) and that accurate and detailed data at the retail food establishments is critical for an investigation (III B). We note that this requirement was essentially proposed in May of 2003 as part of Subpart J, but was omitted in the 2004 final rule except for those who manufactured, processed, or packed food. A number of United Fresh members who operate at point-of-service have attained this capability through their supply chains. We believe that the need to have traceability information about the food at the point-of-service, which we ardently support, gets lost in the structure of the proposed rule. **We feel that FDA's clear articulation of the objective—having details, including the lot number originally assigned to the product, the brand owner for that product, and contact information for that brand owner, at the point of sale, without prescribing the mechanism by which that information is shared through the supply chain, will afford the flexibility that will facilitate adoption in the short term, and will encourage innovation consistent with the New Era of Smarter Food Safety in the longer term.** For example, if, in the future, products are tagged with sensors, molecular tags, or other methods that can emit or convey lot information and key data related to origination, creation, or transformation, and those data can be automatically captured at the point of sale (or even better, by a consumer's smart device), this could meet FDA's objective but would not comply with the rule as proposed (e.g., reference records would not exist, redundant identifiers would not be necessary, etc.). As detailed in our comments below, given that Subpart J will remain in effect, United Fresh urges FDA to use clear language and remain laser focused on the outcome, while reserving some of the "how to" details for guidance.

We encourage FDA to clearly communicate the aspects of outbreak investigations that will be improved once this rule is implemented, and those that will not be affected. Despite FDA's appropriately aggressive rule, we are concerned that it is still taking too long to identify outbreaks and collect and analyze the epidemiological information that is needed to begin the traceback process. These are factors outside FDA's control. FDA predicts that the traceback time can be reduced by 84% if this rule were in effect. We would like to understand the time (hours or days) that would be saved if this rule were implemented. We also offer that, if the traceback portion is not the rate limiting step, and given the economic impact this rule will have on the industry, investments in our public health infrastructure that would decrease the time to identify an outbreak could provide a greater benefit to consumers. We realize these considerations are outside the scope of FDA's authority, but encourage a "whole of government" approach to foodborne illness outbreak investigations.

The essence of our comment is that traceability, both backward and forward, will be more streamlined and done with greater efficiency and accuracy if FDA maintains a focus on public health: understanding, to the (traceability) lot level, the food that made a consumer ill (in the event of a traceback), and the outlets where a potentially contaminated product is available for sale (in the event of a recall/ trace forward). We perceive that the rule, as proposed, retains FDA's historic focus on establishing chain of custody for the purposes of regulatory enforcement, at the expense of being able to rapidly identify, with precision and accuracy, the point of contamination, and the ability to extract that product from the supply chain. We empathize with FDA's struggles to piece together mismatched information to reconstruct supply chain pathways. The rule, as proposed, seems to codify these approaches (e.g., use of reference records, dates, times, product descriptions, identifiers) which have proven to be imperfect and cumbersome, and which IFT, in the traceability pilot report (https://www.fda.gov/media/124149/download), identified as "conditional" data elements (e.g., back up plans when the batch/lot number was not available). Importantly, the rule proposes the maintenance of the (traceability) lot number from the point of origination, creation, or transformation, through to the retail food establishment. We believe, and pilots support, that this is the critical data element (combined with information regarding the entity responsible for the lot number and the item description). We urge FDA to emphasize this point, and we fear that the multitude of redundant, and at times confusing, additional data elements, and the requirement that all supply chain points capture these data, will discourage, complicate, and delay implementation of the rule.

Our detailed comments below expand on the following themes:

1. Foundational prerequisites, including solid epidemiology, well scoped request for records, and a clear farm definition, must be in place for the rule to have the intended benefits.
2. Additional detail and definitions are needed regarding foods proposed on the Food Traceability List. Further, parameters should be developed to determine when foods containing foods on the FTL are also subject to the rule requirements
3. Proposed exemptions and limitations generally seem appropriate but may cause confusion through the supply chain.
4. Several terms and definitions are new, subject to interpretation, and create confusion. Further, many of the "new" data elements proposed to be required provide little value to traceability and simply increase the compliance burden.
5. Based on our interpretation of terms and definitions, it appears that there is redundancy in the information required. We suggest that minimal information- namely the availability at the point of sale or point of service of the lot code and corresponding information on the product and brand owner- is required to trace foods through the supply chain, regardless of the mechanism by which that information gets there.
6. Clarity is sought regarding records and information that must be shared through the supply chain, versus kept internally and shared with FDA upon request.
7. We urge FDA to leverage existing standards and industry initiatives, and work with other agencies in the US and abroad to provide resources (both training, as well as financial resources)

that will support the changes to systems and processes that will be required to comply with the rule within the proposed timeline.

Our specific comments on the aforementioned areas are as follows:

1. Foundational issues

*Good epidemiology*. Tracebacks require some identification of the food(s) to be traced. We support FDA's concept in the preamble that better traceability will enable the agency to conduct comparative analysis of supply chains to rule in or rule out certain commodities in multi-ingredient foods. While not specifically mentioned in the rule, we expect that FDA will use traceback results to verify or challenge the assumptions of the epidemiological investigation. While outside the scope of this rule, and outside the scope of FDA's authority, the industry's ability to respond to a request for traceability records will be expedited and those records will be more useful when the food suspected of causing illness is defined as narrowly as possible. When epidemiology is unable to focus on the most likely food vehicle, additional time is needed to gather information for a multitude of foods. The industry is willing to provide product and commodity information that could help focus an investigation.

*Well-informed scope of records requested.* We encourage FDA to gather additional sales and inventory data, currently not included within the scope of this rule, that can help focus the date range of requested records. FDA, in the preamble, appropriately encourages retail food establishments to share data that can help identify consumer purchases. The industry-led leafy green traceability pilots demonstrated that varying kinds of data exist that can help narrow the scope of a records request (https://www.ift.org/-/media/gftc/pdfs/fda-leafy-green-pilot-final-report-12220.pdf). When records are requested for shipments unlikely to have been available at the time of purchase, not only does this increase the time it takes for firms to respond to a broad request for records, the "signal" (i.e., the specific contaminated product) becomes substantially diluted by the "noise", increasing the burden and time associated with the review of records by the Agency.

*Farm definition*. FDA and the industry will be unable to comply with the rule as proposed if the definition of "farm" remains unclear. The lack of clarity around "secondary activity farms" is exacerbated by FDA's definition of "first receiver", which is the first non-farm entity. For the past 5 *years* we have urged FDA to align the "farm" definition with the official title of the Produce Safety Rule and the corresponding section of FSMA, which specifies that the rule is intended for the growing, harvesting, packing and holding of produce. FDA's continued reliance on ownership rather than activity unnecessarily complicates interpretation of the produce safety rule as well as this proposed rule.

*Role of the consumer*. We agree that tracking lot numbers purchased by individual consumers is not practical at this time. However, we urge FDA to encourage the industry, both conventional and in e-commerce, to capture consumer-specific data. We encourage FDA to request the voluntary submission of this information, such as customer loyalty or credit card information, recognizing that firms that currently maintain this information should not be inadvertently penalized or disproportionately "picked on" because they have this information; this could have the unintended consequence of discouraging the industry from collecting this useful information. We are concerned that FDA's brief mention of this component of an investigation in section VC 31 substantially downplays the utility of these data, which were critical in scoping records requests in the aforementioned 2020 leafy greens traceability pilots. We further note that the cited reference highlighting the challenges in tracing to the consumer level is 18 years old. The food safety community, including regulators, should be looking toward the innovations of the future and should not continue to recycle historical limitations.

2. Food traceability list

We appreciate that FDA adhered to the intent of FSMA in identifying the list of foods to which additional recordkeeping requirements would apply. We support the use of the term "Food Traceability List" as opposed to the "high risk foods" descriptor used in the Act. The diversity of outbreaks and recalls demonstrates that practices and processes contribute to risk, rather than inherent characteristics of the food itself. The public perception of "high risk" would likely have prompted consumers to avoid foods with this designation. Given that many healthful items, including fresh fruits and vegetables, meet the criteria for inclusion established by Congress as interpreted by FDA, calling these foods "high risk" would likely have exacerbated the issues we already face in promoting consumption of these nutritious foods. However, we are concerned that the breadth of the categories on the FTL, and the broad proposal that foods that contain FTL ingredients would also be subject to the rule, results in the inclusion of foods that do not meet the criteria laid out in the Act.

As expected, many fruits and vegetables appear on the FTL. We do not object to the inclusion of the items identified in principle, and support FDA's suggestion that all foods be traceable. However for the purpose of regulatory compliance, the industry needs additional clarity, perhaps in the form of guidance (issued sufficiently in advance of the implementation date) to understand the scope and definition of each listed food. The Reportable Food Registry Commodity List is inadequate (https://www.fda.gov/media/78732/download) in achieving this clarity. For example, "leafy greens" are on the list and several examples are provided. However, these examples are *not* consistent with the leafy greens covered by the Leafy Greens Marketing Agreements in California and Arizona. Clear examples would help the industry focus resources in a risk-based manner and comply with the direction in FSMA. For example, "tropical fruits" comprises a variety of products, such as mangoes and papayas that have previously been associated with illness, and pineapples and bananas which have not and, if assessed as individual products, would be unlikely to meet the criteria as identified in the FTL methodology. In correspondence with the Food and Beverage Issue Alliance, FDA stated that bananas are considered "Tropical Fruit NEC" as opposed to "Tropical Fruit". It is unclear how one would distinguish what is "not elsewhere covered". This detail is not provided in table A-2 of the methodology (https://www.fda.gov/media/142247/download). Similarly, FDA offered in response to a TAN question that "fresh-cut" as used on the FTL is defined in FDA's "Guide to Minimize Food Safety Hazards of Fresh-cut Produce". The definitions and categorizations referenced by the FTL methodology and supporting references are inadequate to ascertain if a certain commodity or variety is included in the list. As the final FTL is published, these definitions must accompany or be clearly referenced alongside the list, and the items included in the FTL should be those that meet the criteria laid out in FSMA.

We appreciate that FDA will update the FTL. We request that FDA identify, either in the final rule or in guidance, a process whereby stakeholders can request the removal or addition of a food product (either by category, or by specific item). In the longer term we urge FDA to make the tool available as an interactive model that the public can use. Enabling stakeholders to visualize the impact of changing numbers and scores (resulting from changes in the frequency of outbreaks, recalls, interventions, etc.) will increase transparency and help the industry anticipate updates to the FTL. We interpret proposed 1.1360 and 1.1370 to mean that individual food items (e.g., for produce commodities, defined by Price Look Up -https://www.ifpsglobal.com/PLU-Codes/PLU-codes-Search -or other global standard) could be exempted from subpart S requirements, even if they are part of the broad commodity groups on the FTL. Having access to the model used to calculate FTL scores will help petitioners meet the data requirements of proposed 1.1370(c).

We also suggest that FDA reconsider how older data are used in the determination of foods on the FTL. We concur with the weighted approach used in the FLT methodology, whereby older outbreaks (16-21 years old) have a weighting of 0.4, with outbreaks in the past 11 years having a weighting of 1, and those in between having a rating of 0.7. We seek clarity around whether the model will always use the most recent 20 years worth of data, and retain the same weighting. **We suggest that data older than 20 years should not be included in the model, and further encourage FDA to recalculate the scores at least every 5 years, in recognition of commodity and sector specific food safety improvements. The continued use of old data will otherwise result in a serious misrepresentation of risk.**

We understand FDA's intent in applying this rule to foods that contain ingredients on the FTL. Peanut paste is an historical example of an ingredient-driven recall executed over the course of many months as manufactures realized that they received and used the recalled ingredient, or an ingredient containing the recalled ingredient. In section IV FDA states that risk is not diminished when an FTL food is used as an ingredient. We disagree and submit that risk may be changed based on dose response curves, including the ability of the pathogen (if microbiological) to grow, or die, in the new food product. To maintain a science and risk-based approach, the methodology developed to support this rule should be used to evaluate the risk of the new food item. We recognize the enormity of combinations that would require this evaluation, and believe this demonstrates some of the practical challenges in industry maintaining such lists and in evaluating the economic impact of the proposed rule. If FDA does not have the resources to adopt this approach, we suggest that either a threshold apply that would facilitate industry compliance while minimizing the risk to the public, or that the industry be able to use the FDA methodology to self-assess the risk.

Importantly, we **believe that the requirement that foods containing ingredients on the FTL will result in formulation/ recipe changes that will put FTL foods at a disadvantage. Since so many foods on the FTL are produce items, this could decrease the consumption of produce,** which will have a demonstrable negative impact on public health. We believe that foods will be reformulated to not contain ingredients (e.g., produce items) that will trigger the application of subpart S. In many cases, those foods, if individually subjected to the methodology developed in support of the development of the FTL, would not attain the score associated with risk.

Additionally, we seek clarity on whether the "contains" provision would apply to foods regulated by USDA FSIS. For example, would a chicken salad containing diced celery be subject to the rule? Deli salads regulated by FSIS are designated as not being subject to the rule, but in section VA, FDA uses an example of a sandwich containing leafy greens as an FTL food. We expect substantial confusion could occur if celery is not subject to the rule, diced celery is subject to the rule (as a fresh-cut produce item), chicken salad containing diced celery is not subject to the rule (because it is an FSIS regulated deli salad), but when used in a sandwich it would again be subject to the rule if it is closed (regulated by FDA) but not if it is open faced (regulated by FSIS). We seek clarity around the need for facilities regulated by USDA FSIS to track raw materials and ingredients that are on the FTL (as receivers), comply with the transformation requirements, and push this information forward as shippers. We believe that products regulated by FSIS should be required to comply with FSIS regulations. Subjecting foods regulated by FSIS to an FDA rule would exacerbate the confusion that already exists, particularly in dual jurisdiction facilities.

We have serious concerns that as a result of this rule, some items produced in commissaries and central kitchens will no longer include lettuce or tomato, while those same items prepared at a restaurant or retail food establishment will, since food prepared onsite at restaurants and retailers would not be covered by the rule, but food in commissaries would be. Unless all foods are to be tracked, the current "includes" provision, especially when combined with the exemption of foods prepared within retail food establishments, creates market disadvantages for some entities that will ultimately harm public health by further reducing produce consumption.

We are similarly concerned that some entities will stop carrying items on the food traceability list, limiting consumers access to a number of fresh fruits and vegetables. While we recognize that FSMA forced FDA to limit the rule to only certain foods, we anticipate that the recordkeeping requirements associated with FTL foods will discourage some entities from stocking and serving these items, further contributing to food deserts. We anticipate that the proposed requirements would discourage not only smaller retailers and foodservice establishments from carrying items on the FTL, it may also encourage other parts of the supply chain to limit the products they handle and/or suppliers that they source from, in order to facilitate compliance.

We appreciate that FDA recognizes that product inventory and supply may change regularly, particularly for seasonal fruits and vegetables, and that therefore maintaining the FTL may not be accurate in real time (1.1315(a)(2)). We seek additional guidance from FDA regarding the appropriate frequency with which to update the list, e.g., annually, monthly, etc.? Without such boundaries we fear that firms may inadvertently be deemed to be out of compliance, either by a regulator or by an auditor. The frequency of updates is also important because of the proposed requirement that each list be retained for 2 years *past the date of its use*. For example if a firm updates the FTL on a weekly basis, it will need to retain over 100 outdated FTLs by the end of the 2 year period. Additionally, while we disagree that all food items containing FTL ingredients should be automatically covered by this rule because they may not meet the threshold of risk as determined by the methodology, we understand the value in understanding and being able to rapidly identify which ingredients were used in which products. As written, it's not clear that the list would need to identify *which* FTL ingredient(s) caused a product to appear on the FTL, which substantially limits the value of maintaining such a list. For this reason, we believe that if FDA retains a requirement for an FTL list, this requirement should be limited to transformers because they know the relationship between the FTL ingredient and the finished product. Supply chain partners who do not transform product are still subject to subpart J requirements and would be able to take appropriate, often conservative and fail safe action in the event of a recall.

3. Proposed exemptions and limitations

United Fresh has historically opposed exemptions related to food safety. However, we feel that with few exceptions, the exemptions and limitations proposed in this rule will not substantially limit FDA's ability to trace food products but could create unintended complications for other parts of the supply chain. For example, proposed 1.1305(a)(3) would exempt certain originators of food based on size. We expect that the rest of the supply chain would still be subject to subpart S (e.g., that the exemption applies to the originator, not the food), and seek clarity from FDA regarding the affirmations required from those who are exempt under this subpart. It is not clear whether those who receive foods from exempt originators (e.g., first receivers) would still need to capture the information specified in 1.1330 if the originator was not required to provide this information. Would the first (or other) receiver be responsible for verifying that the originator was exempt?

We support that produce that is not covered under the Produce Safety Rule because it is "rarely consumed raw" should also be exempt from subpart S (proposed 1.1305(e)).

We support the alignment of 112.2(b) with this proposed rule, related to produce which has been treated to significantly minimize microbiological risk (1.1305(d)(1)). In the case of the Produce Safety Rule (PSR), this provision requires the grower to know and substantiate that the food will undergo such a process. We recognize that the paperwork associated with the disclosures for this provision, and similar elements of the preventive controls rule requiring written assurances have proved challenging. We anticipate similar challenges with respect to this rule. The upstream supply chain may not know if a product will be treated, and in this case, we anticipate that by default, the rule requirements would apply. Downstream members of the supply chain will face greater challenges in not knowing if the product was adequately treated or not. For example, if a distributor receives salsa from a manufacturer, should their application subpart S be related in any way to the written disclosure requirements of 117.136 (a)(2)(i)? When combined with the proposed requirement that foods containing FTL ingredients are also FTL foods, this becomes increasingly complicated. For example, the application of subpart S for a frozen lasagna, intended to be cooked by the consumer or by a point of service following validated cooking instructions, containing diced peppers, is unclear. As written, the product does not seem eligible for the proposed exemption, even though the risk of peppers is significantly minimized by cooking. If the rule is finalized as we interpret the proposed rule, we believe the requirement to trace lasagna containing peppers, but not lasagna not containing peppers (or another FTL food) will create confusion and market disruption.

FDA requested input on two proposed options related to subpart S requirements for small retail food establishments (1.1305(g)). In part, FDA asked if 10 full time employees reasonably defines a small retail food establishment. United Fresh Produce Association is challenged to offer a better definition but notes that some retail food establishments are highly automated (e.g., Amazon Go) and that as we realize the New Era of Smarter Food Safety, the use of FTEs may decrease. We suggest FDA consider a dollar value (annual sales) as an alternative to FTEs. With respect to option a and option b, we believe the proposal for small retail establishments to provide KDEs in an electronic sortable spreadsheet is onerous. However, we agree with FDA that these entities may be able to provide valuable data in the event of an outbreak investigation. Therefore, we believe that the full exemption suggested in option a is not appropriate. We suggest a third option as a middle ground that limits the recordkeeping burden on small retail food establishments, but enables FDA to readily access needed traceability information upon request. We suggest that small retail food establishments (whether defined by the number of FTEs or annual sales), be required to retain and be able to provide, within 24 hours, records related to the receipt of the food in question if they are unable to provide the (traceability) lot number for the product in question. These records would provide FDA with the supplier (e.g., a distributor) who, as a result of subpart S, would be able to provide FDA with lot-specific information in an electronic sortable spreadsheet. FDA notes that currently, this process results in a delay of 24-48 hours. We believe small retail establishments should be required to provide this information within 24 hours, and suggest that FDA could expedite the investigation simply by asking the small retail food establishment for contact information for the supplier (e.g., prior to receipt of specific reference records). We also note that if small retail food establishments are exempt or have modified requirements, the rule as proposed would still require their immediate supplier to provide records to them, which would serve no purpose.

We find the scope of the proposed limited requirement for produce packaged on a farm to be peculiar. While we recognize that the genesis of this requirement lies in FSMA itself, we seek additional information from FDA regarding the contamination risks (e.g., likelihood of occurrence) associated with produce packaged on a farm that contains vents (e.g. in clamshells or in bags with holes) when that produce is further protected by an outer container (e.g., cardboard case) and shipped directly to a retail food establishment. We are not aware of outbreaks caused by products that were already packaged, even when cartons and/or inner packaging was vented. The Center for Produce Safety has funded research to assess risks of environmental contamination (from *Listeria*) in distribution centers and will share the results of this research with the Agency as it is completed in the hopes that it can further inform the science-based standards of the final rule.

We recognize that Congress included this provision exempting packaged produce on a farm. However, we feel that requiring consumer level labeling with the farm information (which will likely be discarded upon consumption) provides limited value for a traceback. While this allows consumers to identify a product in the event of a recall, given the perishability of produce we are doubtful of the public health benefit. Further, FDA proposes that retailers capture the full address and date of receipt of the food produced and packaged on farm. We question the utility of this information to FDA in the absence of a lot number, and also seek clarity on the exact address that should be provided. For example, if a farm field packs in different locations, must the origination location, or the corporate office be disclosed?

Must this information be on the label, or shared with the retailer? What if the product is packaged on a farm but is sold via a shipper (e.g., would they be considered an agent of the farm, or would they be considered a third party to whom the grower could delegate responsibility)? Should the grower/shipper's information be on the label as opposed to the individual farm location and farmer? And regardless of the answers to these questions, we urge FDA to consider how this information will be used by consumers and regulators in the event of a food safety issue.

We have similar questions regarding the purchase by a retail food establishment of food on the FTL directly from a farm (1.1305(h)(1) and (2)). In addition to defining "farm", we request FDA specify if this provision applies solely to purchases by the retail food establishment, or if it applies more broadly to the retail corporation. For example, if the FTL food purchased from a farm is sent to the retail food establishment via the distribution center of the retail food establishment, does the partial exemption apply, or is it restricted only to the direct receipt by the retail food establishment of the farm product? We are also uncertain if this provision, as proposed, is intended to accommodate or deliberately exclude e-commerce models.

In proposed 1.1305(i), we suggest FDA clarify the scope of the proposed exemption. As currently written, (1) notes that the food produced on a farm must be "sold directly to the school or institution" and in (2) states that a "school or institution…purchases a food directly from a farm". However, FDA appropriately characterizes these programs, in the preamble, as including distributors. We are concerned that as currently proposed, this partial exemption will not apply to the distributors who play a critical role in implementing the farm to school/institution programs. As written, we interpret this partial exemption to also exclude food purchased, for example, by USDA in support of such feeding programs, because strictly speaking, the food is not "sold directly to the school or institution". We encourage FDA to align the proposed codified language with the explanatory text. We also suggest that FDA consider expanding this section beyond food that is sold and purchased, to include food that is donated by the farm to a school or institution operating an authorized child nutrition program.

We believe the exemption of brokers and importers who do not physically possess FTL foods will substantially complicate the successful implementation of this rule. We disagree with FDA's assertion in section IV that most importers also hold food. If FDA will require that the import entry number accompany the movement of the product throughout the supply chain (which we feel is unnecessary, as described below), then we believe that importers must abide by the rule. We note that Congress recognized the need to hold importers accountable for the safety of the foods they import, regardless of whether they took physical possession or not, when they authored the Foreign Supplier Verification Programs requirement. Importers are also subject to subpart J. We feel it is appropriate for importers to retain, and as needed share with trading partners, key traceability data, even if they do not physically possess the food. Similarly, we feel that brokers also hold key data that needs to be communicated through the supply chain in order to enable FDA to access the lot number and necessary information at the point of sale/ service. In the Sanitary Transportation of Human and Animal Food rule, freight brokers are identified as a type of "shipper" that would be subject to that rule. Because other FSMA-related rules recognize the role that importers and brokers play in food safety, we do not feel that they should be explicitly excluded from this rule.

4. Terminology and definitions

Some of the terms used are new to the regulated industry. We appreciate that at the end of each public meeting, Dr. Mayne acknowledged this and indicated that it would take time to understand the new terms and concepts. However, as discussed below, we feel that some of these terms would yield redundant information and can simply be eliminated from the final rule. We offer suggestions to some definitions to increase clarity.

We recognize that the definition of "harvesting" extends beyond the realm of produce. However, given that FDA has draft guidance that seeks to clarify and classify the activities that are considered "harvesting" under the farm/ Produce Safety Rule versus activities that are conducted as part of manufacturing/processing, we suggest that FDA reference, either in the preamble of the final rule or in guidance, this related draft guidance (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-classification-activities-harvesting-packing-holding-or ). We note that the classification guidance does not address all questions related to harvesting, such as, if broccoli florets or romaine hearts are the product of the harvesting process, is this still considered harvesting?

First receiver is defined as the first non-farm entity that both owns and takes possession of the product. As described below, we believe the information that FDA seeks related to the growing, harvesting, and cooling can be readily obtained from the entities that perform these functions, using the authority granted by the US Public Health Service Act. The first receiver definition presents several challenges:

- Because of the lack of clarity around a second activities farm, an activity such as cooling may be done by a "farm" or may be done by a registered facility (or both, if a product is re-cooled). If FDA feels that data related to cooling are critical to trace products, there should be consistency in what data are retained and shared, regardless of whether the cooler meets the farm definition or not.
- The first receiver only includes entities that both own *and* take physical possession of the product (in contrast to the criteria for a facility to register with FDA).
    - Many food items are sold on consignment. This means that the "ownership" criterion may not be met, leaving a gap in the traceability records.
    - There may also be instances where a food is owned by an entity that does not take physical possession (e.g., a broker). In this instance, the next purchaser will not be able to determine if they are the first receiver or not, since they will not have purchased the product from a farm and may not receive the declaration required in 1.1350(b)(2)(i). In some instances, it will not be obvious that they are the "first non-farm" that meets the first receiver criteria, and they may not have leverage with the farm to obtain the needed information (if they even know who the farm is), since they don't have a direct business relationship.

- “Take physical possession” has also created confusion, as some marketing firms will own the product and transport it (on their own trucks) from the farm before transferring ownership to a distribution center. FDA proposes to exempt transporters from subpart S, but in the aforementioned example it becomes unclear if the transporter, who owns and takes possession of the product, meets the first receiver definition or not. In the explanation of the proposed rule, section V C 38 notes that transported is a form of possession.

**United Fresh suggests that FDA abandon the term and concept of first receiver. Instead, each entity that generates key traceability data should bear responsibility, whether they meet the farm definition or not. Resolving the farm definition should be a priority for FDA.**

FDA uses the definition of “persons” in this rule to include corporations. While FDA states that if a “person” performs several CTEs (e.g., receiving, transforming and shipping), KDEs need to be captured for each, it is not clear if shipments/ transfers within one corporate umbrella qualify as CTEs, since “receiving” is defined as needing a “customer”. We deduce that intracompany shipments would not be subject to subpart S requirements, and feel this leaves a serious gap that could result in the lack of traceability data at the retail food establishment if the 1 up/ 1 down approach is retained in the final rule. We note that FDA distinguishes, in VB7, a retail food establishment from the entire business, and suggests that the individual retail food establishment would be subject to subpart S. However, if the retail food establishment receives an FTL food from a distribution center owned by the same “person” (corporation), and the retail food establishment does not meet the definition of receiver because they are not a “customer” (as described in VC 25), then we feel that the proposed rule lays out conflicting requirements. We suggest that these can be resolved by modifying the definition of “receiving” to clarify that a product has moved between distinct (noncontiguous) physical locations, regardless of whether those locations are owned by the same person. We believe that this definition would be consistent with the intent of “shipping” as described in VC 31, as FDA states that “shipping” does not include different locations of a farm. In general, we believe that in a 1 up/down approach, CTEs should be defined based on product movement, not product ownership.

In this rule, FDA introduces the terms “originating” and “creating”. We generally find these terms to be clear. We note, however, that the term “originating” only appears in the definitions section of the rule (as its own definition, and within the definition of creating). The recordkeeping requirements never reference originating. Instead, they reference farms (which is also problematic, as previously discussed). The term “originator” appears only in the context of the first receiver. We do not object to the concepts or the use of the terms “originator” or “originating” but note that providing a definition for “originating” without subsequent use of the term in the rule is peculiar. Proposed 1.1325 specifies records that must be kept by those who grow a food on the FTL. We seek clarity from FDA regarding whether, for produce, those that grow food are the only ones who originate the food (e.g., can a harvester originate food?).

We appreciate the concept of “creation” to identify the production of foods on the FTL from ingredients that are not on the FTL. We interpret this concept to mean that, for example, whole apples (a raw agricultural commodity), which are not on the FTL, are not subject to subpart S, but when an entity processes them to become sliced apples, the finished product KDEs of the sliced apples must be carried forward. We appreciate that FDA, in the FAQs accompanying the proposed rule, confirmed that KDEs are proposed to be generated and captured from creation forward, and that ingredients of the created food would not be subject to subpart S.

In VC25 FDA describes the point of contact as an *individual* having familiarity with an entity's procedures for traceability. Rather than require an individual name, phone number etc. we believe it will be more efficient to give firms greater flexibility in establishing this contact. For example, firms may choose to set up a generic email address, phone number, and/or title that would ensure requests were promptly addressed in the event that the main contact was on vacation, had changed positions etc., particularly given the requirement that records be maintained for 2 years. We suggest that point of contact be redefined as "an entity's designated contact that is capable of communicating the entity's procedures for traceability, including their name **or** title/position, telephone number, and, if available, email address and fax number". We believe this will provide firms the flexibility to ensure that requests from FDA are promptly addressed. Although not all entities that would be covered by this rule are required to register with FDA, we also suggest that FDA can obtain the necessary information by contacting the facility registration contact, if FDA communicated this expectation to the industry, either through guidance in support of this rule, guidance in support of facility registration renewal, or as part of the facility registration process. Currently, facility registration contacts may not be positioned to respond to an FDA records request, but we believe that this is a reasonable evolution, and would obviate the need for the supply chain to transmit the point of contact forward, since FDA already has access to facility registration information.

With respect to the act of "receiving" and "holding" we request that FDA address if the practice of "cross docking," would change the application of the rule, or if cross docking is considered a component of transportation. For example, if product is received and held for a very short period of time, not checked into inventory, not owned by the cross dock facility, and simply re-distributed, would this meet the definition of holding versus transportation, and would this food be considered "received" and therefore subject to the requirements of 1.1335? If FDA retains the word "customer" with respect to receiving, we are uncertain if this would resolve or alleviate the matter, as the cross dock facility is not the intended customer of a cross docked product. Our preference is that FDA focus on the availability of the (traceability) lot number, along with the product/ brand identification and a point of contact for the brand owner at the point of sale/service, and let the supply chain determine how to best meet those requirements.

Although FDA includes restaurants in the definition of "retail food establishment" in the description in VC 30, restaurants are omitted from the definition in the proposed codified rule. We encourage the inclusion of "restaurants" as part of the codified definition of this term, especially since restaurants are specifically excluded from subpart J. This will aid in the understanding of the scope of this rule, which is necessary since traceback investigations typically begin at the point of sale/service, including restaurants.

In this rule FDA introduces the concept of a "traceability lot." We interpret this to mean a finished product lot (whether the finished product came directly from the farm, was repacked, or was further processed). We have casually referred to this as the number assigned by the entity that "closed the box". We understand the need to differentiate this identifier from other identifiers that may be assigned to a product as it moves through the supply chain (e.g., "license plate numbers" that may be used to track inventory through distribution channels). However, we note that the rule defines "lot" as "the food **produced** during a period of time at a single physical location." We submit that this definition precludes the assignment of an alternative identifier if the food is not "produced." We believe it would be simpler and clearer for FDA to simply use the term "lot" in lieu of "traceability lot" because as currently defined, we believe the terms are synonymous. We suggest that the definition of "lot" could be improved by noting that a "lot" is the *same* food produce during a period of time, *and produced under uniform conditions* that is identified by a specific code. If FDA believes the terms represent different concepts, then we seek additional clarity from FDA. Assuming FDA intends for "traceability lot" to mean the lot number of a food produced (versus handled) then we agree that this is a key data element. While it can, in some cases, be deduced from the current systems, approaches and paperwork common today, as demonstrated through the Leafy Greens Traceability Pilots, the time and resources it takes to determine the lot number is inefficient at best, and often results in uncertainty as to the product origin. In the case of produce, the brand owner and product name could be insufficient to determine convergence, since a company would likely grow the same product in many different locations, which would be most easily determined by the internal data the company associated with the lot number. Similarly, larger companies may process or manufacture the same item in multiple locations, which could be differentiated in their internal systems using the lot number as the "key" to additional detail.

While we agree that it is critical that the (traceability) lot number be retained as the product moves along the supply chain, unless it is transformed, we suggest FDA reconsider what we interpret as a requirement that a product must receive a *new* lot number after it undergoes a transformation. We would like to understand if packing (e.g., on farm) is considered a transformation. We suggest, in accordance with the comments submitted by Northwest Horticultural Council, that in some situations it may be more appropriate for the packinghouse to assign a (traceability) lot number (as opposed to the grower). FDA notes, in the preamble, that entities covered by the rule may assign responsibilities to other entities, and we seek confirmation from FDA that the rule affords the flexibility needed to accommodate a wide variety of supply chain and business relationships, as long as the overarching objective—the ability to trace a product from the point of sale/service back to the point where contamination likely occurred—is achieved.

Repacking is identified as a type of transformation. To limit physical commingling which challenges traceability, many repackers will repack within a lot. In other words, they may take 100 boxes of tomatoes of the same lot number (e.g., grown on the same farm, harvested on the same day, but of varying shapes, sizes and quality), and sort and repack them into 4 categories. Some repackers will retain the original lot number to maintain line of sight to the grower, but will describe the products differently (e.g., based on size, color, etc.). They will also identify themselves as the repacker, and would therefore serve as the point of contact for the assignment of the lot number. We suggest that when repacking “like into like” (“like” being specific to the raw material lot number), the finished product lot number *should* in fact be the same as the raw material lot number. The product description and repacker identification, (both of which could be communicated via the GTIN) should be shared with customers, making the product easily traceable. We believe that in this example, requiring the assignment of a new, unique finished product lot number serves only to obfuscate the origin of the commodity. We recognize, however that contamination can occur during repacking and that the identification of the repacker is critical. At a higher level, our concerns can also be addressed if the final rule is less prescriptive about the process of creating and sharing data.

FDA proposes in 1.1330(c) that the first receiver also has the responsibility to assign a lot number if it hasn’t been assigned by the originator. The explanation the agency offers in VE 2c is logical (that some small originators are exempt from the rule, in which case products may lack lot numbers upon receipt by the first receiver). It would be difficult for later parts in the supply chain to know if a food on the FTL had been produced by an exempt entity. In addition we believe that the way the requirement is presented in the rule can create confusion and suggest that originators are not responsible for assigning a lot number. We suggest, as an alternative (and assuming FDA retains the concept of first receiver, which, as previously discussed, we disagree with as currently proposed), that 1.1330(c) instead state *“If you are the first receiver of a food on the Food Traceability List* ***which lacks a lot code because*** *~~to which~~ the originator of the food* ***is exempt from assigning*** *a traceability lot code, you must establish a traceability lot code for the food and maintain a record of the traceability lot code linked to the information specified in paragraph (a) or (b) of this section (as applicable to the type of food received).”* We also seek to understand if FDA has considered the situation in which an FTL food is shipped to different first receivers and is assigned different lot numbers, which would add an extra step and possibly confusion in FDA’s analysis in order to determine that the product had the same origination point, and in the event of a recall, would result in the same adulterated product in the market with a different supplier name, product description and lot code, unbeknownst to consumers.

5. Redundancy in KDEs and other requirements

In section III E of the preamble, FDA states that the proposed rule describes the *minimum* CTEs and KDEs for traceability. We disagree. We find the following data elements to be redundant or irrelevant to food traceability for the following reasons:

*Import entry number*: if FDA has access to the (traceability) lot number, the name/ description of the product (e.g., the GTIN), and a contact for the originator/creator/transformer (or their designee), then the import entry number provides no additional meaningful traceability information. Further, we foresee challenges in acquiring this information if brokers, who are not covered by the rule, will not share it.

*Location*: The location description requires the location name, and complete address of the CTE location; FDA also proposes to require a location identifier. Both are proposed required data elements, but are redundant. As shown in Table 4, an operation is referred to as “GG-AZ-02” as well as “Gary Greens;

cooler #1" as well as "789 Maple, Yuma AZ". Each of these 3 unique identifiers are referring to the same entity. They are redundant. Additionally, the receiving entity may refer to them differently, creating additional chaos by needing to capture redundant information duplicatively. We especially object to the proposed *requirement* to include a "location identifier" in addition to the other location-oriented data elements. While we agree this could be suggested as a best practice in guidance, we disagree that these are customarily used, particularly within smaller operations that will already be challenged to meet the proposed recordkeeping requirements. Instead, we suggest that FDA provide flexibility in the way that location is communicated: either by the identification of company name and physical location street address (or geographical coordinates) along with the city, state and zip code, OR the disclosure of a location identifier or unique physical location name (e.g., Global Location Number or FDA facility registration number) in lieu of the physical address (as long as the physical address can be determined, upon request, based on the location identifier). In addition to reducing redundancy in recordkeeping, this approach will increase flexibility, and will also address concerns regarding the disclosure of confidential commercial information related to co-manufacturers of private label products.

FDA, in VC 14, states that the location description and location identifiers are often already retained within purchasing systems. We urge FDA to reevaluate this assumption. Often, the contacts within purchasing systems are headquarters/ corporate locations, brokers, marketing companies, etc. and are *not* the CTE locations. Retaining thrice redundant information for CTE locations (physical location) will create an unnecessary burden on the industry.

The coverage of the proposed rule expands beyond facilities required to register with FDA. However, given that most locations that are required to submit a food facility registration will be covered by this rule, we seek FDA's perspective on the use of the FDA facility registration number, FDA Establishment Identification number, DUNS number, Global Location Number, or other pre-existing unique number that could be used to describe a physical location. The use of these numbers will add consistency and standardization to data, which is necessary for the interoperability required by a functional traceability system.

*Traceability product identifier and description*: We find most of the terms described in sections VC 32-36, including Table 5, to be confusing and unnecessary. We believe that if FDA has the lot number of the product (e.g., the traceability lot number), as well as the identification of the product (such as the Global Trade Item Number) and a contact for the entity that assigned the lot number, this should be sufficient to trace food products. We fail to see the value in the additional information required. For example, FDA specifies that the traceability product description must include a category code or term, category name and for a single ingredient product includes the "brand name [n/a for many produce RACs], commodity, variety, packaging size and packaging style." These are non-specific, non-unique items that will slow implementation and, without standardization, simply exacerbate the difficulty in matching information provided by supply chain partners.

The rule appropriately proposes the capture of more specific, granular information and we suggest that FDA should rely on these specific and unique sets of data elements (combination of the lot number, product, and contact for the brand owner), not on general descriptors. Further, since FDA notes that categories can be self- assigned we do not see that this data field would facilitate interoperability and would not address the issues FDA identifies regarding changing or varying product descriptors. Proposed 1.1335(e) would require receivers to *establish* and maintain a traceability product identifier and description, which suggests that they would *not* be capturing the identifier and description assigned by the supplier. We fail to see how, without standardization and consistency, these data elements serve any traceability function. In contrast, the (traceability) lot number associated with a specific product would be a common data element tracked through the supply chain. Traceability product identifiers and descriptions will serve only to confuse regulators who try to rely on them to follow the flow of product from different points of sale and points of service. For example, in VD 1 FDA describes how differing descriptions of iceberg lettuce as well as tuna hampered an investigation. We anticipate the same challenges could still result, and in fact, could be exacerbated, by requiring the industry to create additional data and identifiers that will not be linked, and could instead result in greater divergence in terminology. Instead, we maintain that a lot number and other minimal information should be sufficient. For example, in the case of lettuce, if FDA ignored the terminology used to describe the lettuce and instead focused on the lot number and responsible party (e.g., as indicated in the company prefix of a GTIN) and their identification of the product, the commonality could have been more readily determined. We strongly believe, and pilot studies support, that very few data elements are needed to establish product linkages through the supply chain. The data elements identified in Table 5 go above and beyond the minimal KDEs required for product tracing. We seek detailed information from FDA explaining how these data elements provide unique information that enables product traceability above and beyond what would result from the lot number and product identifier (e.g., GTIN).

*Reference records*: We understand FDA's concept and definition of reference records and the current reliance on them in establishing linkages between supply chain partners (VC 28 and 29). However, their current use is largely a consequence of the lack of availability of the (traceability) lot number to FDA when records are requested. As stated previously, we believe that this should be the focus of this rule. The IFT pilot report completed in 2012 in support of section 204 of FSMA affirmed that the maintenance and communication of the lot number was a best practice, and that "linking KDEs" including Activity Type and Activity Number (referred to as reference records in the proposed rule) only served a role *if the lot number was not available*. The report (in Table 2) further notes that the reference records would only be needed as "the industry prepares to meet a future requirement to capture lot/batch numbers." The reference record may be *one way* that lot number and other information is communicated, but the proposed requirements to retain the reference record and indicate where to find pertinent information on it prescribes the mechanism, not the outcome. Firms should have the flexibility to use whatever methods are appropriate to provide FDA with necessary information, whether using a reference record or by other means. Firms should also be required to have a process to obtain this information. However, we feel that requiring all entities to use reference records is too prescriptive, and will also limit innovation in data capture mechanisms. For example, if the shipping container of a product bears a barcode that, when scanned, provides the information required by FDA, why would a reference record necessary? In section VD 1a FDA gives an example of an invoice from a distributor containing the BOL associated with the receipt of the product by the distributor. We do *not* advocate for this approach. It is clunky and cumbersome, and counter to the outcome-oriented approach that would be achieved by simply requiring the (traceability) lot number to be associated with the product shipment, or ideally, the requirement that the lot number and product identification be available at the point of sale/service, regardless of the mechanism by which this is achieved. In section VE FDA suggests that BOLs and POs customarily contain the traceability lot number. This is generally not the case for POs (since they are issued by the purchaser, who would seldom have insight into the lot number of the purchased product), and is rarely the case for BOLs. While support the communication of lot numbers on BOLs and ASNs, we do not feel it is appropriate or necessary for a codified rule to specify the medium with which lot numbers are communicated. We suggest that this and other approaches be communicated in FDA guidance to support implementation of the rule.

Although the proposed rule provides several references to paperwork (POs, BOLs, etc.) and appropriately emphasizes the importance of (traceability) lot numbers, along with product information and a point of contact, it neglects to explain how firms should relate key data elements such as lot numbers to the physical product. FSMA prohibits FDA from requiring product tracking to the case level (i.e., serialization or other unique identification of cases). Lots may be shipped by the pallet, case, or consumer unit level. Ultimately, it is the physical movement of the specific item that must be traced. For example, proposed 1.1350(b) proposes that shippers "must send records (in electronic or other written form) containing the following information to the immediate subsequent recipient…" but does not state when this information must be provided, relative to the physical shipment of the product. We urge FDA to consider how guidance can help support implementation of the rule, once finalized.

As described below, we seek recognition from FDA that approaches such as the Produce Traceability Initiative (www.producetraceability.org), which provides for lot-level tracking through the use of a GS1-128 barcode applied to the shipping container (e.g., PTI is not case-level traceability), and ideally transmitted via an Advance Ship Notice, would meet the intent of this rule. We suggest that FDA replace proposed 1.1315(a)(1) with a broader requirement to establish and maintain records that describe the procedure and systems used to determine the (traceability) lot numbers, communicate (traceability) lot numbers with customers, and, for transformers, the approach used to link raw material lot numbers with finished product lot numbers.

We seek clarity from FDA regarding the flexibility firms will have to comply with proposed 1.1315(a)(2), maintaining a list of foods on the FTL. Currently, most firms maintain shipping records for all products. We suggest that covered entities be able to include FTL foods within existing records, as opposed to creating a separate list. As previously mentioned, we do not feel that the product identifier and traceability product description provide unique information that facilitates product tracing. Further, as noted earlier, we believe that the concept of the FTL is more relevant to transformers than other points in the supply chain, for which its main purpose is to assess regulatory compliance. We object to the creation of a new list simply to facilitate FDA's evaluation of a firm's compliance with the rule.

FDA proposes, in 1.1315(a)(3) to require firms to explain how their lot codes are assigned. While some firms choose to encode other KDEs within their lot code, this is not standard across the industry. In many cases, lot codes are instead pointers or keys to the internal systems in which these data are retained. The string of characters in a lot code may mean nothing in isolation, other than tying together items produced under similar conditions, which is one way convergence can be identified in a traceback. The lot code can unlock additional production information that can be used during an investigation after convergence has been established. We suggest FDA provide clarity on the data needed and charge the industry with providing these data, rather than requiring the industry to explain how these data are communicated (e.g., whether within the lot code itself, or within an internal system that is 'unlocked' by the lot number).

In addition to the questions and concerns we have around the definition of the first receiver, and the mechanism by which they are expected to gather the proposed data elements, we have additional questions regarding the specific requirements proposed in 1.1330. For example, we understand the utility of the dates of harvesting, and packing, and to a lesser extent, cooling (some products may be recooled and we are concerned that the rule as proposed expects simpler supply chains). We seek to better understand FDA's expectations around time- is this intended to be the time of initiation, or time of completion, of the activity? Similarly, is the time to include the entirety of a lot, or sublots? For example, if an orchard is harvested on a single day, but the product is stored and packed over a period of weeks, we are concerned that the exactness of the rule doesn't accommodate this circumstance. This in part stems from the complexity that results from the requirement that the grower assign a traceability lot number, and our interpretation that this number would not change prior to receipt by the first receiver. We support the comments submitted by Northwest Horticultural Council suggesting that the orchard, in this case, be able to designate the responsibility to assign a lot number to the packer (who would be able to identify the grower/orchard).

The rule references date and time elsewhere (e.g., throughout proposed 1.1335). Many operations work around the clock, and we seek to understand if the day and the time should correspond to the beginning or end of an activity, for example, when unloading of a truck begins, or when it is complete, especially if the unloading process occurs over the midnight hour. We understand how FDA currently relies on date and time to estimate product movement, and determine when a product could have been available for purchase or shipment. Our understanding is that this approach contributes to the current traceability challenges, and that tracebacks and traceforwards would be more precise if (traceability) lot numbers were captured along with the identification of the product. If the (traceability) lot number and product information is available at the point of sale/ purchase, as proposed in this rule, then this would obviate the current guesswork that FDA currently employs. We do not believe that date and time of receipt and shipment provides additional information that aids traceability, and we encourage FDA to remove this from the subpart S requirements. We suggest that the requirements in subpart J, combined with the requirement for the (traceability) lot number, product identification, and the point of contact proposed in this rule, will enable FDA to achieve the same goal.

We also question the value of proposed 1.1350(a)(8) and 1.1335(h) which would require the shipping firm to capture and provide, and the receiving firm to retain, the name of the transporter who transported the food, linking the traceability lot code and other KDEs to what we interpret as each shipment. If the same (traceability) lot number of a raw material is received on different days, times, and/or from different transporters, it appears that this information needs to be captured separately. While we agree this is a best practice, we do not believe that it provides substantial value from a traceability standpoint. While temperature abuse can theoretically increase the risk of foods that have already been contamination (e.g., during origination or transformation), the Sanitary Transportation Rule has been implemented to address this risk, which, FDA notes in the preamble to that rule, is already low. We are unaware of any outbreaks or recalls that have been traced to the transporter. Given that in some cases transportation may be arranged by a firm other than the company conducting transportation, and that the Department of Transportation already requires Bills of Lading, we feel that requiring receivers to associate lot numbers with transporters is an unnecessary burden that does not benefit public health.

6. KDEs shared with trading partners versus with FDA

As proposed, the rule would require a substantial amount of data to be shared with trading partners. We do not believe all data proposed to be communicated is necessary for FDA to trace products back in an outbreak situation. Because Subpart J will remain in effect, we also do not believe it is necessary to effectuate a recall.

We suggest that FDA emphasize the need for the (traceability) lot number for a specified product at the retail food establishment, and require that the input lot numbers be captured during any transformation. We support FDA's proposed requirement that a point of contact for the (traceability) lot number be available to FDA at the point of sale/service so that the agency can quickly acquire additional information about the product. This is not currently communicated within most of the produce industry, and we seek guidance from FDA on feasible options to demonstrate compliance with this proposed requirement.

As requested by FDA, the entity that assigned the lot number should be able to provide more detailed information, such as location of origination, creation, or transformation, name of the transporter, and even reference records. We do not believe it is necessary for traceability for this level of detail to be shared with trading partners for each lot of product shipped.

Proposed 1.1325 proposes that growers maintain records of the growing area coordinates. We agree that growers should be able to make this information available on request. It is unclear if this information must be shared with members of the supply chain including the first receiver. Based on discussions with and presentations by FDA, it is unclear what information must be retained, versus shared, by those that meet the farm definition. While we maintain that the rule should focus on outcomes rather than process, the expectations on the data shared between farms and first receivers seems mismatched to the specificity proposed in the rest of the rule.

We support FDA's suggestion that the agency may be able to "skip steps" (points in a supply chain that do not transform or create products, such as distributors) during an outbreak investigation. We acknowledge that this is only possible if the point of sale/ point of service can provide the agency with lot number (as assigned by the originator, transformer or creator, or designee), along with the item description and contact information for the entity responsible for that lot number. We believe that these minimal data, retained by those that originate, create, transform, and retail food establishments, will help FDA achieve its goal of improved traceability in a way that is feasible in the proposed implementation timeframe. We believe the economic burden associated with implementation of this rule can be lessened, without compromising FDA's ability to conduct a traceback, by focusing additional recordkeeping requirements at the retail food establishment and points of transformation, and not at supply chain entities who do not transform or sell/serve product directly to consumers.

We seek clarity from FDA regarding proposed 1.1455(b), which would require records to be made available "not later than 24 hours after the request." Does the 24 hour timeline begin after the receipt of a written request, or does FDA intend this to include a verbal request? We urge FDA to provide a written request that details the specific records that are requested. We also urge FDA to create a mechanism by which industry can request additional time in the event of a large, broad data request. Alternatively, we ask FDA to consider prioritizing data (e.g., "top priority" date ranges, products, etc.) that will indicate to firms the information that should be made available to FDA most quickly. As stated in the beginning of our comments, industry stands ready to assist states, CDC, and FDA in trying to narrow the scope of an investigation as early as possible.

With respect to the proposed requirement to provide data in an electronic sortable spreadsheet (proposed 1.1455(b)(3)) we suggest that FDA provide possible template spreadsheets in guidance, and offer our support in helping to develop such spreadsheets, based on our role in the recent leafy greens traceability pilot. We urge FDA to specify if there are any software requirements associated with the spreadsheet. We also encourage FDA to provide flexibility in the form of a waiver to farms that do not use computers. For example, some United Fresh members are Plain Farmers (e.g., Amish and Mennonite) and would be unable to meet the rule requirements as proposed. We believe that, given the direction in FSMA (204(d)(6)(B)(ii)) which allows the Secretary to waive the requirement for a business phone number associated with a farm based on religious beliefs, that this accommodation is consistent with Congress' intent. We request that FDA provide, in the final rule, a similar opportunity to request a waiver to provide the electronic sortable spreadsheet to accommodate a religious belief of the individual in charge of the farm, similar to proposed 1.1305(c)(2).

7. Leveraging current initiatives and standards to manage resource needs and implementation timelines

Although the economic impact of this rule is difficult to quantify, it is clear that it will be substantial. It is unclear how FDA assessed the cost to industry associated with this rule, given that FDA acknowledges the difficulty in quantifying the number of foods (and therefore entities) covered by this rule, owing largely to the inability to quantify how many foods contain ingredients listed on the proposed FTL.

Regardless of the extent to which FDA has underestimated the true cost of compliance, these costs will ultimately be passed on to the consumer. We recognize that Congress limited FDA's authority to require additional records to certain foods, based on risk. As stated earlier, we are not surprised that many produce items appear on this list. However, we hope FDA recognizes that this means that the consumer cost of produce, which health officials agree should be promoted as part of a healthful diet, will increase disproportionately to other foods that may lack the health benefits of fruits and vegetables. A 2017 meta analysis by Afshin et al. (https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0172277) quantified the impact purchase price has on the likelihood that consumers would purchase produce. A 10% reduction in price resulted in a 14% increase in consumption. We can assume that the converse will also be true—a price increase will result in decreased consumption. The produce industry will maintain a focus on preventing illness, and also recognizes the need for improved traceability. However, we hope to work with FDA to identify strategies and tactics to ensure that consumers are incentivized to consume foods such as fresh fruits and vegetables that will benefit their health. We seek support from FDA and other federal entities in order to achieve compliance and still be able to maintain an affordable, nutritious food supply.

In principle we support FDA's suggestion that data should be captured and stored electronically. However, we suggest FDA amend its suggestion (in VD 1a) that data be maintained in a *single* electronic system. We fear that the concept of a *single* system may become antiquated as data are shared in cloud based systems, and as interoperability increases.

Like much of the industry, many of our members currently apply their own identifiers to manage product in their inventory, rather than tracking the items by the (traceability) lot code. In some instances they maintain a 1:1 relationship with the (traceability) lot code; in other cases they do not. Either way, the main reason for the reassignment of identifying numbers (e.g., license plate numbers) is because of the requirements and constraints of the software systems in use. Lot numbers vary in length and format (e.g., alpha-numeric). While we appreciate that FDA will continue to allow originators, creators and transformers (or their designees) with the flexibility to assign and construct lot numbers as they wish, and to use whatever identifiers and descriptors they establish, this lack of standardization challenges the recipients who have a myriad of suppliers. Many systems cannot accommodate the variety formats for suppliers' lot numbers. We understand and support the need to retain the (traceability) lot number as the product moves through the supply chain. However, this capability may require an overhaul of the systems (ERP, WMS, etc.) in current use. The time and resources (capital investments, labor, etc.) required to make these infrastructure changes are considerable and we seek implementation support from FDA. Alternatively, buyers may prescribe lot codes or lot code formats to their suppliers, which will create additional confusion and chaos. The myriad of additional data elements proposed to be established and retained will further challenge the ability to evolve existing systems to accommodate these data elements. Implementing these changes within 2 years of a final rule will be difficult. This timeframe and implementation process would be more manageable with a smaller data set transmitted between trading partners (lot code tied to product, and contact information for that brand owner) and increased flexibility on how to reach the objective. From a practical standpoint we hope FDA recognizes that on the first day of compliance, retail food establishments will be unable to comply with the proposed requirements if they receive product that was produced or manufactured prior to the compliance date. We suggest that FDA consider exercising enforcement discretion at later points in the supply chain, particularly for products with a longer shelf life, if all entities will remain subject to the same compliance date.

FDA notes in VD1 that an entity covered by the rule can meet the recordkeeping requirements by assigning responsibility to another entity (e.g., a consultant, broker, distributor etc.), recognizing that the covered entity is still responsible for compliance. As mentioned earlier, we believe other appropriate examples include growers assigning this responsibility to packers, and brand owners serving as the point of contact for co-manufactured products. The ability for another entity to retain required traceability records is not specified in the codified rule and we suggest that this be included as the rule is finalized. If this opportunity is not specified in the codified rule, it will present additional compliance challenges, especially with proposed 1.1325, which specifies that a traceability lot code must be established “when I grow a food” on the FTL. As previously mentioned, the rule takes an overly simplistic view of produce production. Many growers farm under contract with differetn grower/shippers; for some commodities it is more appropriate for packers to assign lot numbers on behalf of their multiple growers. We firmly agree that the lot number is a critical data element but urge FDA to recraft the rule to provide flexibility, with accountability, for the generation and maintenance of the lot number. For example, the Foreign Supplier Verification Programs Rule, in 1.506(a)(2) specifies the parameters around relying on another entity to develop procedures to comply with that rule. We suggest that FDA include, in subpart S, similar recognition of the ability to rely on other entities to capture and retain required records.

We seek recognition from FDA that approaches such as the Produce Traceability Initiative, which provides for lot-level tracking through the use of a GS1-128 barcode applied to the shipping container, would meet the intent of this rule. The standardized barcode contains the Global Trade Item Number (GTIN) which conveys the brand owner and their identification of the product, as well as the lot number for that date (e.g., pack date). This approach uses globally recognized standards (GS1) that could serve as a model for other segments of the industry, although we do not advocate for FDA regulating the exact system or mechanism that should be used to comply with the final rule. As the proposed rule is finalized, United Fresh and our members would be happy to discuss specific issues with the FDA to construct a program that is feasible, meaningful, transparent and protective of public health.

## Conclusion

Our association’s and industry’s commitment to improved traceability predates the passage of FSMA. The produce industry voluntarily developed the Produce Traceability Initiative over a decade ago and we continue to believe that full, supply chain wide adoption will facilitate traceback investigations and recalls, benefitting public health. Although PTI is based on GS1 standards so that the approach can readily be adapted to the multitude of foods handled by the supply chain, we recognize that even within the produce industry, full implementation has not been achieved. We support a regulation that addresses recordkeeping gaps and loopholes, leveling the playing field so that the foods that have historically presented challenges can be traced more rapidly and accurately. We support a regulation that encourages innovation and does not inadvertently penalize early adopters. We urge FDA to carefully consider the *minimum* data required to trace products, and the points in the supply chain that are truly critical for data capture, both today and in the future. We believe that the lot number, tied to the product and accompanied by contact information for the entity responsible for the production (versus distribution) of that product is sufficient to trace products. If some of the information currently proposed to be shared between trading partners were instead required to be tied to the lot number/product and maintained by the entity responsible for creating the lot number (e.g., the originator, creator or transformer), and made available upon written request, we believe that FDA's objectives could be met at a lower cost to the industry and with improved implementation and compliance.

Lastly, I have personally been obsessed with traceability for over 12 years, having led the IFT task order that coined the terms Critical Tracking Events and Key Data Elements. I have seen the paperwork FDA (and states) receives during investigations. I have had to piece it together myself. To say it is challenging is an understatement. I can follow FDA's thinking in how this rule was constructed. But I truly believe that, with some adjustments, FDA can finalize a rule that can be more readily implemented by the industry while being clear, enforceable, and effective. Given that, by the time this rule is finalized, it will be nearly 20 years since the Subpart J requirements were proposed, it is clear that voluntary action has not achieved the desired outcome, and that regulation is necessary. I am personally committed to seeing this through, and am thankful that the United Fresh membership and leadership is just as committed. Please call on us any time. We would appreciate an opportunity to elaborate upon these comments, and address any other questions or concerns that would help FDA finalize the rule.

Respectfully,

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