United Fresh Produce Association

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


To Whom It May Concern:

On behalf of our members, we respectfully submit the following responses to FDA’s request for comments on a new era of smarter food safety [Docket No. FDA-2019-N-4187-001].

Founded in 1904, the United Fresh Produce Association brings 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. 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 the United Fresh Food Safety and Technology (FS&T) Council contemplated the questions that FDA published in the Federal Register to develop comments on behalf of the association. Below we have provided our comments. We look forward to reviewing the blueprint that FDA intends to unveil this winter, and continuing to work with the agency and our members to leverage the latest advances in research and technology that can improve the safety of fresh produce, and promote consumer health.

Our comments follow each of FDA’s questions:

A. New and Evolving Digital Technologies Will Play a Pivotal Role in Tracing the Origin of a Contaminated Food to Its Source in Minutes, or Even Seconds, Instead of Days or Weeks

1. What are the most significant actions FDA could undertake to enable industry to enhance traceability across the entire global food supply chain?

If traceability across the entire global food supply chain is the goal, FDA should strongly recommend industry utilization of globally recognized standards (GS1 standards are already serving this role) and require that the full supply chain (inclusive of the ends) maintain traceability-related information.
Investigations of foodborne illness begin with the individual. If that person no longer has the food product or its packaging, as is often the case for fresh produce, the investigation generally leads to the point where they purchased or consumed that product. These entities must be able to rapidly identify the source/producer of the product in question. The location that “opened the box” to offer product for sale should be able to identify the location that “closed the box”. Parts of the industry seek clarification from FDA on the key data elements needed to provide this rapid identification. We believe that a Global Trade Item Number (GTIN) combined with a lot number are the critical data elements that must be shared, captured, and retained. These are also the backbone of the Produce Traceability Initiative.

A clear food safety objective, performance standard, and success metrics should be included in discussions of successful or desirable traceability systems. If 100% compliance by all supply chain partners, with 100% accuracy, in a specified timeframe, is the goal, it would be helpful for FDA to articulate what those percentages and timeframes are today. Doing so will enable measurement of overall industry improvement, and also help an individual company see where they may be lagging behind their peers.

Although the current 1 up/1 down traceability system needs to be augmented and strengthened to enhance traceability, these requirements have still been in place for over a decade. As facilities fail to comply with current recordkeeping requirements, FDA should impose consequences. Without a penalty, some firms may not take the current, or any future, requirements seriously.

Based on “off the record” conversations with our broad membership, there seems to be consensus that the time for voluntary adoption of effective traceability systems has passed. After the passage of FSMA, some industry leaders paused their traceability initiatives while waiting for FDA regulation. Despite the limitations imposed by FSMA, we believe industry will pay close attention to FDA recommendations and expectations. Clear, strong guidance from FDA will give progressive industry leaders the leverage they need to sway their peers, competitors, and supply chain partners.

In addition to developing a regulation and guidance related to traceability, traceability could also be addressed in the context of each rule (e.g. FSVP) as the agencies issues final guidance.

2. How could FDA make it more likely that companies utilize new technologies to enhance the traceability of their products?

To stimulate innovation and assure rapid adoption, FDA needs to focus on potential business benefits. For example, innovations that help with field traceability may assist with yield estimates and more accurate and real-time accounting transactions. FDA should encourage safe and economical production of healthy foods.

We cannot imagine a “new technology” that would revolve around a paper-based system. Data need to be captured and shared electronically. FDA could encourage this transition by requesting data electronically (and by clarifying that a .pdf is not electronic).

If FDA establishes an aggressive traceability performance standard, this may stimulate innovation around mechanisms of achieving the performance standard. Changes in processes may need to precede the implementation of new technology. FDA should also work with federal partners to subsidize the capital investment many firms will need to make to upgrade their systems.
3. What can FDA do to facilitate and expedite outbreak-related communications between government agencies, industry, and consumers?

From our perspective, FDA currently communicates outbreak-related information in a reactive fashion. In many instances, we (produce associations) have been calling and emailing FDA for days or weeks prior to an official announcement. That is backwards. FDA should consider the approach that has long been implemented by USDA FSIS. Each month, FSIS hosts an open call with their regulated industry (in its entirety: all commodities, and including associations as well as actual company representatives). One of the standing agenda items is a brief rundown of the outbreaks that FSIS is monitoring/watching and/or investigating. This regular, proactive communication raises the level of awareness within the industry and cultivates trust and partnership resulting from this transparency.

As part of the romaine task force, United Fresh and the Produce Marketing Association submitted to FDA and CDC a proposal to facilitate communication before, during, and after a produce-associated outbreak. This proposal is attached as an appendix to these comments (Appendix A).

We continue to try to understand the specific rules and policies that limit FDA’s ability to share information during an outbreak that could enable more rapid resolution which would benefit public health. As the supply chain continues to improve specific, accurate traceback systems, we can leverage the current knowledge of supply chain pathways to begin to rule in or rule out possibilities from a trace-forward perspective.

4. Are there mechanisms FDA could employ to incentivize adoption of realtime, end-to-end food traceability throughout the food sector?

There are very few supply chains that have achieved realtime, end-to-end food traceability. Recognition, perhaps in the form of Center Director or other prestigious FDA awards, should be bestowed upon those that have and are willing to share their stories as examples for others.

5. What are the challenges to creating a more digital, traceable global food supply, and how might FDA approach this in a manner that creates shared value for all participants?

The challenges have been well described. Importantly, focusing a conversation around food safety contributes to the perception that traceability is a “cost” without a benefit. Everyone thinks they have strong traceability systems, and no one believes they will be involved in an outbreak. Therefore, the food safety argument carries little weight (especially when companies may prioritize an investment in prevention). Instead, traceability should be described as a byproduct of a strong recordkeeping system. Good recordkeeping can contribute to the bottom line through supply chain efficiencies, both within a company and through the optimization of longer supply chains. Improved supply chain management and inventory rotation, better insights into bottlenecks within a system, and identification of the factors that influence throughput are some of the benefits that companies have gained through better recordkeeping and traceability. These are the benefits most likely to motivate companies to change their systems and processes.

B. To Fully Realize a Preventive Controls System That Rapidly Incorporates New Knowledge, We Must Also Ask if We Can We Make Processes and Communications More Effective, Efficient, and in Some Cases, Simpler
1. What are the most significant actions FDA could undertake to promote and support the use of smarter tools for prevention?

FDA could support more research into “smarter” tools that are implementable by working more closely with innovative and practical groups such as the Center for Produce Safety to support rapid research and development into novel new scientific approaches. Grants and collaboration with CFSAN research scientists could help.

Those that adopt and effectively implement smarter tools for prevention should be less likely to produce contaminated product, and as such, should be subject to decreased frequency of inspections, and should be minimally impacted by sampling assignments.

2. What predictive analytical tools and data streams are best suited to helping identify a potential contamination event?

The use of retrospective models may be able to help identify the data streams that correlate (and perhaps predict) past contamination events. For example, intuitively some weather patterns may predict issues, but United Fresh has not researched the extent to which this work has already been done.

The produce industry needs simple and practical new tools that can be easily deployed to help monitor and track environmental and other risk factors in real time, in order to make more intelligent and timely mitigation responses to potential contamination events in the growing environment.

As whole genome sequence data are collected, source-tracking assumptions could be made through association with outbreak- or product-associated sequences. However, we caution an over-reliance on this until we have a clearer picture of the distribution of sequences throughout the environment. FDA’s zero tolerance policies create disincentives for collecting these data.

3. What further steps can be taken to advance the safety of domestic and foreign commodities that have been the subject of frequent contamination incidents?

We suggest that rather than limit focus to commodities that have been historically implicated in outbreaks or recalls, FDA should evaluate what practices within those industries led to contamination. The implementation of poor practices (e.g., poor control of cross contamination in wash water, uncleanable equipment, etc.) may be more prevalent in some sectors than in others, and some product characteristics may amplify levels of contaminants. However, FDA’s (and industry’s) focus should be on addressing those practices through increased awareness, education and training. We fear that taking a commodity-specific approach may inadvertently send the message to other commodities that they do not need to address these same poor practices.

4. In what ways can FDA support the use of environmental assessments and root cause analyses in industry prevention efforts?

Ideally FDA, states, and industry would co-train on how to conduct an environmental assessment and root cause analysis. This has the dual benefit of building common knowledge, and also building the relationships and the trust that is needed to manage an investigation. If industry conducts an RCA without the involvement of regulators, it would be helpful to understand what information needs to be
disclosed. For example, if industry detects a pathogen in a water source, must regulators be alerted? Will a grower’s product be subject to more frequent testing? Understanding the regulatory consequences of a good faith effort need to be understood.

FDA should also recognize that, given the resources and expertise required to conduct a thorough root cause analysis, the current system capacity is extremely limited. Providing support for training and/or execution would help the industry develop the infrastructure to conduct these assessments. Appendix B summarizes discussions that occurred within the Romaine Task Force. United Fresh and PMA intend to continue trying to address these issues, and need input from FDA in order to navigate some of the sensitivities that have thus far limited our ability to formalize a RCA process.

FDA is encouraged to recognize and support industry initiatives to promote root cause analyses. An example is the new requirement in the Leafy Greens Marketing Agreement metrics that require farms to conduct a root cause analysis in certain circumstances based on agricultural water results. The LGMAs have developed guidance and training to accompany this requirement.

5. Are there changes that FDA can and should make in the way in which it conducts environmental assessments and root cause analyses, and reports its findings to industry, to better facilitate their use in industry prevention efforts?

United Fresh appreciates the speed with which FDA published the report of the environmental assessment of a California farm associated with the fall, 2018 romaine – E. coli O157:H7 outbreak. In this example, the finding of the outbreak strain in sediment provides insight and direction to the industry overall regarding possible risks. With this knowledge, companies, individually and collectively, can begin to implement preventive measures.

FDA (and state investigators) should view industry members and other stakeholders as partners instead of suspects. The approach to an investigation should be one that is focused on truly understanding an issue, as opposed to collecting evidence.

C. Evolving Business Models Present Food Safety Challenges as Well as Novel Considerations Around Regulatory Framework and Oversight at the Federal, State, Territorial, and Local Level

United Fresh defers to our colleagues that focus on the supply chain segments that interface more closely with consumers with respect to FDA’s four specific questions. However, as a general comment we urge FDA to clarify which regulations apply to newer business models (e.g., are they required to register with FDA? Are they subject to the Food Code? Etc.). If the conversation around regulation and oversight is still evolving, we encourage FDA to rapidly develop guidance that lays out the best practices for preparing, packaging, transporting, and handling food in these situations, so that food safety (regardless of regulatory oversight) is maintained. FDA should work with and through the Partnership for Food Safety Education to provide consumer-level information on food handling as well.

D. We Want To Do More To Use and Leverage Proven Organizational Culture and Behavioral Science Principles and Techniques To Enhance Organizational and Employee Compliance With Desired Food Safety Practices and Behaviors
1. What are the most significant actions FDA could undertake to foster and support the development of food safety cultures globally?

A positive food safety culture is influenced by food safety leadership. While commitment at the top is critical, the technical competency must exist in order for the appropriate practices to permeate through an organization. Today, too few individuals are adequately qualified, both in the US and globally. We lack the “bank” of food safety leaders that are needed to foster food safety cultures. FDA and sister agencies should support the promotion of food safety as a career. “Science and Our Food Supply”, the program managed and developed by FDA, should receive increased support, and the career profiles should be updated and more broadly disseminated (they currently are listed in a pdf that takes several ‘clicks’ to access). FDA should consider translating this material for domestic as well as international use.

When considering food safety culture in a global context, FDA must recognize that parts of the world still lack adequate access to potable water and electricity (temperature control). In the US, we expect safe food as a default. This may not be the case in other countries/regions. Convincing employees that the food they produce (for the US) should be safer than the food they feed their families may be challenging. In some cases, the infrastructure to support food safety must precede the development of a food safety culture. Further, resources and education related to food safety culture need to be culturally sensitive and available in many languages.

2. How can FDA encourage and support companies in the development of food safety cultures throughout the supply chain?

Currently, most FDA inspectors ask to meet with the top food safety individual at the start of an inspection. FDA would send a clear signal to company leadership about the importance of food safety if inspectors began requesting meetings with the management (including president/CEO, as applicable) of an operation. However, this approach is only relevant to registered facilities, and possibly farms. Since restaurant and grocery store locations are generally regulated by state or local agencies, it could be more challenging for FDA to promote a food safety culture that spans the entire supply chain. Working with associations that develop training for those sectors (e.g., ServeSafe) could be an effective approach.

3. What are the obstacles to creating food safety cultures throughout the supply chain?

The food industry is not known to be quick to change. The notion that “we’ve always done it this way” and “we’ve never had a problem” is still prevalent in this industry. It’s very difficult to change people’s minds.

Food safety is often viewed as a cost. Although the industry has not historically viewed food safety as a competitive advantage, there may be ways in which creating a sense of food safety competition could help stimulate change. Otherwise, if one firm invests in food safety (sufficient numbers of qualified staff, cleanable equipment and facilities, appropriate use of chemical and physical interventions, and purchasing from suppliers who do the same), they are at a financial disadvantage if they are discouraged from comparing their systems to competitors who do not make investments and are therefore able to offer goods at a lower cost.

4. Are there changes that FDA can and should take in how it approaches food safety to place further emphasis on prevention?
FDA could implement something akin to a “safe driver program” for companies that have a good food safety track record. We believe that as our scientific tools grow more robust, it will be easier to differentiate operations that have a strong food safety record. These firms should be rewarded by having a decreased frequency of inspection, and could achieve recognition from FDA. Firms that proactively and effectively implement cutting edge preventive tools and approaches should be eligible for a Center Directors or Commissioner’s certificate/award.

Conclusion

In conclusion, we appreciate the thought FDA took in addressing the numerous issues and questions associated with this initiative. We are ready to offer additional detail or clarification and look forward to working with the Agency moving forward.

Respectfully,

[Signature]

Jennifer McEntire  
Vice President Food Safety & Technology  
United Fresh Produce Association

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Appendix A: Proposal to FDA on Industry/CDC/FDA Collaboration to Improve Investigative Efficiencies and Outbreak Communications for the Fresh Produce Industry

Objectives:

- To define mechanisms where FDA/CDC can confer with produce industry experts to gain useful contextual information to bring clarity to epidemiological and/or trace back investigations in accordance with the Federal Advisory Committee Act. Examples might be: (1) production locations and seasonality for target commodities, (2) details on production practices for target commodities, (3) descriptions of SKU’s produced from target commodities, (4) overviews of product distribution practices and regions served by specific production regions, (5) current season knowledge of weather-related or environmental issues relevant to commodity growing, harvest and packing, and (6) potential industry actions and responses to FDA/CDC actions.

- To define mechanisms where FDA/CDC can share epidemiological and investigative information with a select group of situation-specific industry experts to enable the experts to better assist FDA/CDC in identifying the causative agent in an outbreak and to trace back the source of the product to enable identification of the root cause.

- Define the mechanisms whereby the information shared between industry experts, CDC and FDA can be protected by non-disclosure agreements or other mechanisms that may already exist within FDA or CDC. If such mechanisms need to be established, identify the process to create this structure.

- Determine mechanisms to share outcomes of investigations between industry experts and FDA/CDC, both successfully concluded and those that end up inconclusive to permit development of important learnings that can be shared with industry or inform industry of potential issues.

Proposal:

The produce industry, FDA and CDC can best accomplish the objectives listed above by establishing a well-defined consultative process. CDC, as a non-regulatory agency, has already established such a process, components of which inspired the suggestions below. The characteristics of this process might be as follows:

- As produce is a global endeavor and involves hundreds of thousands of producing and buying entities and hundreds of commodity, regional and national trade associations, it is proposed that FDA/CDC leverage the two largest associations, United Fresh and PMA, to coordinate the industry expertise that might be brought to bear. United and PMA have served to coordinate industry activities for FDA FSMA webinars and the PIC Quarterly reviews so this would not be a new role. PMA and United would provide multiple points of contact for FDA and CDC so that the associations might be reached routinely. PMA and United would be willing to work under confidentiality agreements. Depending on the situation, we envision that our counterparts at FMI, National Restaurant Assn, etc. would also be willing to participate.

- Outside of crises, PMA/United Fresh would coordinate monthly meetings with FDA, CORE and CDC to review status of known illness outbreak investigations, review completed investigations for learnings that could be share with industry, identify potential research needs and confer on nascent investigations to discern where additional industry information might be beneficial.

- As needed, PMA and United would leverage existing connections to propose a working “expert” list that could be called upon on a timely basis to gather commodity specific input and answers
to questions FDA and/or CDC might pose as part of their epidemiological or traceback investigations. The “expert” list could include industry experts from all segments of the industry, such as regional trade associations and commodity groups, sales, growing, harvest/packing, processing operations, cooling and transportation, retail and foodservice as well as those involved in produce safety to provide maximum coverage for areas of inquiry. This can be done in advance of an issue; a few separate commodity-specific lists can be prepared and vetted. Alternatively, or as the need arises, PMA and United can rapidly (within hours) propose additional experts for other commodities, supply chains, etc.

- During the early phases of an epidemiological investigation, CDC can contact PMA and/or United to ask questions and gain feedback under confidentiality. United/PMA can ask CDC questions to gain clarity. If United/PMA need more depth to answer specific questions, they will coordinate outreach to their network of experts to gather that information and either share it with CDC or arrange for CDC to directly interact with the specific experts (based on CDC needs, timing and limits of confidentiality).

- As FDA and partnering states began traceback investigations once the causative vehicle is reasonably known, CORE could leverage PMA/United to assist them in accessing industry knowledge to help guide their decision making on the traceback. CORE could ask questions that might help them narrow or broaden the focus of their investigation. United and PMA can assemble general supply chain information for major players (e.g., in the instance of a localized/regional outbreak, so as to proactively identify distributors/suppliers that are national in scope that might otherwise confound a traceback). Again, if more depth were required than could be provided by either PMA or United, the associations could reach to the expert network to gather information and share it with CORE to aid the investigation.

- FDA and CDC would provide appropriate points of contact for industry within Federal and State partners to ease communications.

- During the investigation, FDA and CDC would provide timely updates on progress. One of the biggest issues during a traceback investigation is communications voids. Sometimes several days might pass between “official” FDA calls with industry and those quiet periods can be damaging to the industry. It is understood that a constant barrage of calls with industry and press can be time consuming and waste resources. Within the framework of an industry/FDA/CDC partnership in dealing with outbreaks, FDA/CDC would provide PMA and United Fresh with daily 5-10-minute updates, PMA and United could provide FDA and CDC with industry reactions and we could jointly determine what could be shared with industry members looking for information. Sometimes, “nothing new, but we expect this next…” can be very helpful.

- Post-investigation and after FDA issues their incident report, FDA/CDC commit to a review of the data (protecting any patient information or CBI) with United/PMA to extract any learnings that could impact future industry practices or lead to funding research programs. The parties would agree to the best mechanisms to jointly share the information gained.

Next Steps:

In some ways, industry and FDA or CDC have been sharing information pre-, during and post-outbreak for several years. The process has been ad hoc and inconsistently applied over time. Recent attempts to more formally establish constructive and consistent information exchange around outbreaks have been met with concerns about protecting confidential business information. We need to:
• Determine what the legal barriers are and if they are relevant to the types of information that industry and CDC/FDA need to share.
• Where confidentiality is a concern for FDA/CDC or industry, we need to determine what types of formal arrangements can be made to protect that information.
• Agree on common objectives and finalize the structure for operation.
• Jump in and use the framework and step back and assess value for all concerned and modify as needed and as information needs evolve as new technologies emerge.
Appendix B. Root Cause Analysis Infrastructure

1. Incident
   - What types?
   - Mechanism?
   - Confidentiality?

2. RCA Entity
   - What does this look like? Trust, access and confidentiality are critical.
   - Leverage existing structures. Assure training
   - Development & ongoing funding

3. Assemble RCA Team
   - Determine skill sets needed
   - Team leader
   - Define guardrails to prevent RCA drift (control focus/costs)
   - Confidentiality agreements

4. Onsite Activities
   - Inspection
   - Record review
   - Interviews
   - Sampling
   - Data collection
   - Examine practices

5. RCA Team
   - Develop conclusions
   - Identify PCs
   - Develop operating parameters
   - Confer with clients
   - Measure success

6. Information Sharing
   - Mechanisms to share key learnings – multiple vehicles
   - Modification of metrics/practices
   - Catalyst for research

Awareness/Education
   - Produce examples
   - Benefit to audience
   - Solutions available

Grower/Shipper/Processor Outreach
   - Association educational programs
   - Grower meetings
   - Website content

Training - Pool of RCA Experts
   - Ongoing training
   - Production/science expertise
   - Availability?