

Romaine Task Force Final Report and Recommendations September 2019

Overview

United Fresh Produce Association and the Produce Marketing Association established the Romaine Task Force at the request of FDA following the November 2018 *E. coli* O157:H7 outbreak involving romaine. This outbreak came on the heels of another significant romaine related outbreak in the Spring of 2018. The pathogen strain that caused the fall outbreak had in fact been associated with outbreaks with similar distribution to the mid-western US in the two years prior.

The overall objective of the Romaine Task Force was to examine critical areas where improvements needed to be made across the romaine supply chain. In discussion with FDA, CDC and others, four areas of focus were identified: Science & Prevention, Traceability, Investigations/Collaboration and Provenance Labeling.

From the beginning, United Fresh and PMA determined that the Romaine Task Force needed to have representation from all sectors of the supply chain: growers/processors, retail, foodservice, academia, regulatory, public health, and consumer groups. The associations also retained several expert consultants to share their expertise with the Task Force. It was recognized that in order to tackle the subject matter encompassed by the Task Force objectives, very specific expertise with a wide range of experience was needed.

Therefore, four working groups corresponding to the four areas of focus for the Task Force were recruited and led by a steering committee. Together, the Task Force and the four working groups comprise roughly 100 industry and association leaders, regulatory and public health professionals and academic scientists (see Appendix A). The working groups and the Task Force met in person in Dallas, TX on February 13-14, 2019 to discuss issues and develop recommendations. The steering committee, various working groups and subgroups met numerous times between January and August 2019 via conference call to hold discussions and build recommendations for the Task Force. In some cases, the workgroup recommendations are specific to romaine lettuce (e.g., provenance labeling and agricultural water). In other cases, the workgroups felt that the recommendations were more broadly applicable (e.g., traceability and investigations/collaboration).

Romaine Task Force Goal

The goal of this report is to continue stimulating decisive action to reduce the risk of illness associated with romaine lettuce and other leafy greens by:

- Stating the principles that should govern the actions of all participants in leafy green value chains;
- Recommending near-term actions to: (1) prevent harmful contamination, and (2) improve outbreak response by government and industry, and

- Identifying the high-priority issues that need further work and recommending steps to address them.

Key Principles

Leadership – Success in ensuring the safety of romaine and other leafy greens depends on continuous improvement and strong food safety cultures throughout the value chain, which begins with clearly expressed CEO-level commitment and leadership.

Modern Best Practices – Leafy greens, whether raw agricultural commodities or fresh-cut, are ready-to-eat foods that should be handled in accordance with best practices for science- and risk-based prevention of contamination, starting on the farm and maintained throughout the entire supply chain.

Coordinated Action – Effective prevention and response to reduce the impact of outbreaks when they do occur requires concerted and coordinated action by all value chain participants, from grower to retailer and restaurant, and including government agencies.

Data Collection and Sharing – All appropriate data in the hands of government and industry should be mobilized and shared to improve both prevention and response; any legal, regulatory or commercial obstacles to data collection and sharing that are not essential to protection of personal privacy or proprietary business needs should be removed.

Standards – FDA’s Produce Safety Rule provides an essential framework and minimum standards for prevention of harmful contamination; commodity-specific standards can further promote prevention of the most significant hazards.

Task Force Recommendations

Science-Based Prevention

Water Quality

1. All romaine growers should comply with the 2019 revised CA LGMA water testing and treatment metrics for water used in overhead applications that comes in contact with the plant, unless there is a sound science-based rationale for an alternative approach.
2. It is critical that CA/AZ LGMAs address furrow irrigation applications and other application methods that potentially result in water contacting the crop. The Task Force urges the LGMAs to complete appropriate metrics by December 2019.
3. Buyers should only purchase romaine from growers following and meeting these water standards.
4. PMA and United Fresh will assemble a diverse group of representatives of the supply chain, different geographies, commodities, and practices, to evaluate which aspects of the CA/AZ

LGMA water metrics have science- and risk-based applications for other leafy greens beyond romaine and make a recommendation by March 2020.

5. The LGMAs should issue guidance for farm-level verification and validation of required water testing and treatment for all uses of ag water by December 2019.
6. The GFSI, LGMAs, and other stakeholders must continue to collaborate on standards to strengthen the rigor of audits in ensuring that key grower practices, such as for water quality and sanitation of harvest equipment, have been validated and verified.

Concentrated Animal Feeding Operations (CAFOs)

The Task Force did not specifically address risks associated with CAFOs and cattle grazing operations in the vicinity of leafy green growing areas. However, many members of the Task Force believe this is a hazard with significant potential to jeopardize the safety of romaine and other leafy greens if not managed appropriately. Under FDA's produce safety rule, growers are responsible for assessing such hazards and taking appropriate measures to prevent potentially harmful contamination, including assuring that the irrigation water they use is safe and of adequate sanitary quality for its intended use. All value chain participants, from growers to processors to retailers, share responsibility for these risks and their consequences. Generally, however, Task Force members believe current scientific knowledge is inadequate, and insufficient site-specific data are being collected, to assess the degree of risk associated with the proximity of CAFOs.

As part of the implementation phase for these recommendations, the Task Force supports further evaluation of the interface between animal and produce operations. While collaborating with existing efforts when appropriate, PMA and United Fresh will organize a group of experts and industry leaders to address risks associated with CAFOs and cattle operations. This risk evaluation will include consideration of multiple vectors (water, insects, birds and dust) that may transmit pathogenic bacteria across distances and potential variables like weather, animal density, facility operational practices, diets, shedding frequency and carriage of human pathogens. It is expected that this analysis will identify knowledge gaps that fuel needed research, and site-specific data collection that leads to best practices for setting appropriate buffer zones. The group will develop an action plan by March 2020, including milestones and timelines, that details how credible, data-driven risk assessments should guide the establishment of location-specific distances from CAFOs and other risk-reduction interventions, including what site-specific data are needed to conduct a proper risk assessment. This action plan should be based on current scientific knowledge and logical extensions of that knowledge based on real-world production environments.

Traceability

1. To support prevention strategies and contain outbreaks to further protect consumers, leaders across the leafy greens value chain must visibly and vocally commit to comprehensive implementation as soon as possible of modern, interoperable electronic traceability, allowing FDA, CDC and other public health agencies to rapidly receive lot codes and/or relevant source information for any product that was sold in a retail store or restaurant at any given point in time within the past three months.

2. By January 1, 2020, suppliers of all leafy greens should label cartons with a scannable PTI label from which the GTIN and lot number can be electronically captured. Suppliers should also work with customers to provide this information electronically (through Advance Shipment Notifications (ASNs)).
3. By September 2020, companies selling or serving a leafy greens product directly to consumers must be able to promptly (e.g., within hours) and electronically provide agencies with key data elements associated with that product that identify the lot numbers and other key data elements, including the product's original source. Such data may be captured and retained through any means, whether conveyed on PTI carton labels, consumer packaging, ASNs or other means. This data will be provided to the requesting agency in an established template.
4. Longer term, industry must enable broad implementation of modern, full value chain traceability of individual produce items back to the source as technology and systems evolve that increase the feasibility of reaching this goal. In 2020, United Fresh and PMA commit to sharing traceability success stories broadly throughout the industry to provide examples of implementation of electronic traceability systems.

Provenance Labeling

1. Until the traceability objectives above are accomplished, suppliers should label packaged romaine products with standardized regional harvest information to enable appropriate consumer action in the event of an advisory.
2. If an advisory is issued, FDA and CDC should use the terms for regions that were agreed to by the task force.

Investigations Improvement

Government-Industry Collaboration

1. To speed investigation and containment of outbreaks and better target consumer advisories, United Fresh and PMA will continue to lead a collaboration with FDA and CDC to establish on-going and sustainable mechanisms for sharing information and expertise in real time during investigations, in accordance with the requirements of federal laws and regulations.
2. The agencies and industry must identify and remove any legal obstacles to sharing information for purposes of public health protection during outbreaks.

Rapid Response Teams

1. To increase the timeliness and effectiveness of government response to produce outbreaks, FDA-supported Rapid Response Teams must be prepared to engage on produce outbreaks operating in every state, or, where more efficient, on a regional basis
2. Industry leaders should work with FDA and advocate for the removal of any current limitations on FDA funding for produce related RRT activities and advocate for adequate funding.

Root Cause Analysis

1. Root cause analysis (RCA) following significant food safety failures is a basic element of a modern, prevention-oriented food safety program and must become the norm in produce-related outbreaks. That said, RCA requires specific skill sets and technical expertise not often found within most produce companies. As a function of the implementation phase for the recommendations, United Fresh and PMA will convene romaine producers, technical experts, experienced investigators and organizations committed to RCA as a critical outbreak prevention tool to extend the work started in the Prevention working group to define how RCA might be employed across the romaine industry. This would include identifying when an RCA would or should be initiated; who would organize that effort; how experts could be mobilized; how data would be collected and under what situations it would be shared; and how growers, shippers or processors would participate and how the effort would be resourced.
2. FDA should more routinely conduct RCAs after outbreaks and share results widely with the industry to inform prevention.

Background Science/ Prevention

The Science & Prevention working group was composed of industry and academic scientists, retail and foodservice representatives and FDA/CDC. Early on as the Romaine Task Force was formed, United and PMA met with FDA and CDC to determine the scope of the subject area. Since the outbreak strain of *E. coli* O157:H7 associated with romaine in both the Spring and Fall 2018 outbreaks was found in irrigation water sources in the proximate region, the prioritization of agricultural water was a foregone conclusion. Root cause analysis or RCA is a discipline that permits the determination of the source of a pathogen contamination and identifies processes or events that occurred to permit the contamination and ultimately suggests preventive controls to manage reoccurrence in the future. RCA is the process FDA and state investigators use in outbreak investigations, and is also a consistent, rigorous practice that helps produce industry operations investigate incidents when positive tests occur. Audit depth was a term used to refer to the need to be able to move standard-based produce safety auditing to one consistently requiring evidence that the operator has conducted scientifically valid/ validation studies that its preventive measures are effective in controlling a contamination risk and that the operator verifies the process is controlled during operations at a prescribed frequency.

The Science & Prevention group quickly recognized that the three focus areas were being pursued by other groups and that romaine-focused activities would be best served by reaching out to these groups and joining forces where possible. The following are short summaries of these efforts:

Concentrated Animal Feeding Operations (CAFOs): As previously noted, the current workgroup did not address issues surrounding CAFOs because the fall 2018 outbreak did not seem to be related to CAFOs (unlike the spring 2018 outbreak, after which the LGMAs extended the set-back distance to 1,200 feet). However, the co-existence of animal agriculture and fresh produce production warrants substantial additional attention.

Recommendation to the Romaine Task Force: Through the Center for Produce Safety, the industry has provided awards to technologies that hold promise in assessing the risks associated with animals (inclusive of several species). These tools should be utilized to better characterize risk and understand the factors that impact risk. Additionally, industry should collect data, and share historical data, on risks in specific production areas where CAFOs (including large dairy operations) reside to provide granularity and context for making informed risk-based decisions on set-back distances and other mitigation strategies. By March 2020, an action plan to better manage contamination risks from CAFOs, including future research priorities, should be developed using existing data and prudent, logic-based assumptions.

Agricultural Water: Following the spring 2018 outbreak associated with romaine, the romaine industries in California and Arizona began looking at updates to their agricultural water metrics and best practices. The genesis of this effort started with leading romaine processors/producers but evolved to a CA-industry effort coordinated by Western Growers (WG) and the California Leafy Greens Marketing Agreement (CA LGMA). The Science & Prevention workgroup engaged WG and CA LGMA several times during the course of the deliberations. The workgroup received updates from WG and CA LGMA and provided in-person and written comments. The workgroup supports the CA LGMA approach of assessing the risks associated with the uses of agricultural water. On-farm decision making by examining the water source, its delivery system and its use and opportunity to contact the edible

surfaces of the plant is a sound approach. In early discussions with FDA and CDC in December, we agreed that the romaine industry needs to consider ***any open water source as potentially contaminated*** and therefore steps need to be taken to treat the water to prevent potential contaminants from contacting edible plant tissues. The working group also considered the 21-day window that the CA LGMA has adopted; i.e. if an open water source is used to irrigate romaine and contacts the edible tissues of the plant within 21-days of harvest, the water must be treated using a validated process to control any potential pathogens. While the data are limited around a 21-day window, the workgroup is supportive of this conservative timeframe for romaine given the current state of our scientific knowledge on pathogen die-off rates in CA growing environments. The Steering Committee of the Task Force recommended that a diverse group representing other commodities, other regions, and other growing practices consider the applicability of these metrics to commodities beyond romaine.

WG, CA LGMA and industry experts continue to refine guidance documents on water treatments and the validation and verification of these processes to ensure water metrics and best practices are implementable by producers. The workgroup encourages AZ LGMA to continue to work on ag water and specifically examine flood/ furrow irrigation methods in light of the recently presented Center for Produce Safety (CPS) funded research on AZ production, which is highly reliant on furrow irrigation methods. This research clearly demonstrates the potential for cross contamination to romaine when pathogens are present in furrow irrigation water. Best management practices need to be developed unless the industry opts to treat water that will be used for furrow irrigation.

Recommendation to the Romaine Task Force: The Science & Prevention working group recommends that the Romaine Task Force support the CA LGMA risk assessment approach to agricultural water use; evaluate source, delivery and use for the production of romaine. Specifically, the working group supports the concept that open water sources (e.g. canals, on-farm ponds, rivers, etc.) be considered potentially contaminated with human pathogens and therefore use of that water within 21-days of romaine harvest in California, where that water has the possibility of contact with the edible portion of the plant, should be treated to control pathogens. The Romaine Task Force calls upon the LGMAs to continue their work (metrics, guidances and education) on ag water by looking at flood/furrow irrigation and other ways that water comes in contact with the crop. These recommendations to the Task Force are limited to all forms of romaine lettuce at this time but should be evaluated for additional commodities. Lastly, the working group urges the romaine industry to maintain awareness of the emerging science on ag water contamination routes, disinfection methods, die-off rates, validation and verification measures. A critical component of this active engagement will be the recently initiated CPS regional water surveillance program and the corollary studies on water treatment practices appropriate for specific water types.

Root cause analysis: Root cause analysis (or “RCA”) is a tool that is generally employed by investigators to guide a disciplined, consistent approach to determining the cause of an incident and determine what failed that resulted in the conditions that allowed the incident to occur. The results ultimately lead to the development of prevention measures to reduce reoccurrence. FDA uses RCA when the traceback allows them to identify a physical location or operation where an outbreak originated. Some produce companies perform RCA when they uncover positive pathogen testing samples on raw or finished products or in environmental testing, but the practice is not widely applied because it requires highly trained and experienced individuals in multiple disciplines to be performed effectively. The skill set, time and resources required often render the use of RCA outside the realm of a typical produce operation. Yet, if the industry fails to employ the principles of RCA and identify the cause for repeated

pathogen positive results in product, inputs or environmental samples, then we are preordained to repeat those results and ultimately may find ourselves in the middle of yet another outbreak.

As the working group began its discussions on RCA, The Pew Charitable Trusts guide for conducting RCA, which was developed through a multi-stakeholder process, was shared with the group. This guide focused on the food industry overall and was not produce specific. The working group was invited to provide produce industry case studies of RCA that could serve as a model to others performing future investigations. An example is included as Appendix B.

A small subgroup of the Science & Prevention working group volunteered to look at how the industry might create and resource a group of experts that could perform RCA at the behest of growers, packers and processors. The concept was to have a standing team of RCA-capable individuals who might be called upon when an operation uncovered a recurrent issue that was beyond their internal capability to thoroughly investigate. We viewed this as having industry-wide applications but focused the discussions on romaine and leafy greens as a starting point. These discussions addressed the qualifications of the people that might be used to perform RCA, their immediate and ongoing training, how and when they might be deployed, mechanisms to manage and coordinate these activities, criteria that would qualify for the deployment of an RCA team, laboratory needs and capacities, protection of data generated by RCA, documentation formats, mechanisms to resource the efforts and liabilities for those doing and participating in the RCA. The deliberations suggested that there is a general unawareness around RCA in the industry, an incomplete understanding of the power of RCA to prevent future outbreaks and too many unanswered questions about the process to move forward with establishing an RCA “service” presently. In response, PMA and United Fresh are committing to furthering these discussions by assembling a group of romaine growers, technical experts, investigative professionals and like-minded groups to complete the analysis of RCA implementation; how it might be organized, resourced and deployed. PMA and United are also committed to raising awareness about RCA by providing educational content on RCA to its members through the channels they have available to them. The idea is to familiarize the industry with the importance of RCA and generate support while industry trade and commodity groups continue to address the challenges presented by a more formalized entity for RCA.

Recommendation to the Romaine Task Force: The Science & Prevention working group recommends that the industry adopt RCA as a normal exercise to evaluate failures in the system. Industry trade associations and commodity groups should provide educational content to their constituents on the concept of RCA and its importance to a prevention-based system, not only to the romaine industry, but to the produce industry as a whole to raise awareness. Further, the working group recommends that United and PMA assemble an expert group to further the discussions of the working group and address the questions raised and provide a model for how RCA could be introduced as a discipline for romaine and extended to other leafy greens and perhaps other commodities going forward. This effort would include defining when an RCA should be activated, who could be drawn on to perform the RCA, protection of confidential information, who could or should support the logistics of RCA, how information could be shared to benefit the industry, training for those who might use the tools and how RCA would be resourced. Lastly, FDA should more routinely conduct RCAs after outbreaks and share results widely with industry to inform prevention strategies.

Depth in auditing for verification and validation. The primary objective was to examine mechanisms that would introduce the requirement for operators to provide certification bodies (auditors) with evidence that the preventive measures implemented in their produce safety programs were scientifically valid, by either direct experimentation or by extension to existing scientific literature.

Additionally, audits should evaluate if the execution of the control was verified according to the operation's produce safety plan. Many of today's food safety audits are limited to determining if a preventive control exists and how it is measured without assessing if that preventive measure has been shown to accomplish its intended purpose. During our working group discussions, we were made aware of the ongoing efforts of the Global Food Safety Initiative (GFSI) to incorporate validation and verification principles into their food safety benchmarking standard. Dr. Mike Robach, the working group chair, is intimately involved with this effort. The adoption of this focus by GFSI will have a magnified effect as many of the audit programs that exist today would be revised to continue recognition by GFSI. It should be noted, specific to romaine, the CA LGMA has been working on guidance to help growers validate ag water treatment systems in conjunction with the updated ag water metrics.

Recommendation to the Romaine Task Force: The Science & Prevention working group recommends that the Romaine Task Force support efforts by GFSI to incorporate the principals of validation and verification into updated benchmarking standards. Further (and consistent with our earlier recommendations), the working group recommends that the CA and AZ LGMA's require handlers to have validation studies that demonstrate preventive measures; including those for ag water treatment and harvest equipment sanitation, are effective and that the operating parameters derived from the validation studies are monitored and verified.

Other areas of working group discussion. Though the scope of the Science & Prevention working group was purposely focused on the three key areas described in this report, our discussions frequently turned to other significant potential contamination risk factors. In part, these discussions were continuations from industry conversations after the Spring 2018 romaine-related outbreak in Arizona. Therefore, issues such as proximity of animal feeding operations, harvest equipment cleaning and sanitation, soil amendment preparation and application, weather-related events as vectors for pathogen transference and survival, and ag water sources used to mix pesticides and other on-farm uses were discussed. The romaine industry has taken some steps; e.g. increasing the distances from CAFOs to crop production to 1,200 feet as previously indicated, but the knowledge base continues to grow on these subject areas and clearly there is more room for discussion, research, and changes in practices. A consistent theme of the working group's discussion with WG and the LGMA's was that they were not "done" and were working to complete their efforts on ag water and then would move onto these other potential risk factors to seek out next generation metrics.

Recommendations to the Romaine Task Force: The Science & Prevention working group encourages the LGMA's specifically and the industry as a whole to continue work to evolve practices and metrics using existing and emerging science. Further, the working group recommends the Task Force act in an ongoing fashion to provide a forum for discussion on efforts to improve practices around the subjects raised here and to collaborate in these areas to develop risk and science-based approaches to better manage risks.

Traceability

The traceability workgroup was the largest subgroup within the task force effort, reflecting the importance of this topic and the wide range of supply chain partners that need to participate to address complicated issues. It was initially comprised primarily of retailers, foodservice outlets, and distributors, as well as representatives from their national trade associations. FDA and CDC also participated, as did growers and processors. The group grew further after the provenance labeling group was sunset, since

many of those contributors recognized that labeling is a short-term fix that can only really be addressed through better traceability.

The working group and Task Force have embraced a vision that companies handling leafy greens will commit to a common goal of a supply chain-wide traceability system. Specifically, the group seeks industrywide support to adopt systems and approaches that capture and maintain the Global Trade Item Number (GTIN), lot number, or other source identifying data for leafy greens products at retail and foodservice establishments, since the majority of contamination events resulting in large outbreaks occur prior to packing the product into a carton or bag. The packer/processor must in turn have records of the GTIN(s) and lot number(s) associated with each case, so that the origin(s) can be quickly determined. We recognize that this will be a phased in approach beginning with data availability at retail and foodservice establishments while working to eventually have electronic traceability information linked with consumer purchases. Detailed information is provided in Appendix C.

PMA and United Fresh have convened direct meetings with the retail/foodservice associations (FMI, NGA, IFDA, and National Restaurant Association) to pursue solutions, and will continue working with these industry associations and individual companies to overcome obstacles to full supply chain traceability.

Challenges include:

- Incoming cases are not labeled with scannable barcodes
 - This Task Force report strongly recommends that all shippers of Romaine provide scannable PTI labels on cases by January 1, 2020. United Fresh and PMA will urge all romaine suppliers to commit to meeting this goal, or to implement this capability as soon as possible.
 - Supplier labeling can also be accelerated by buyers requiring that cases be labeled, with suppliers labeling cases in accordance with the [“best practices for formatting case labels”](#) document.
- Scanning labels can be costly and inefficient (inbound and/or outbound)
 - Case studies have identified ongoing operational efficiencies related to shrink and inventory management
 - As alternative technologies become more cost effective, physical scanning may not be the only means of data capture (e.g. use of RFID tags). Data can also be electronically transmitted (e.g., through ASNs)
 - A proposed short-term solution is for suppliers to include lot numbers on bills of lading and/or invoices. However, carrying this information forward past the first point of receipt would be more manual and challenging than scanning bar codes

Despite the fact that few customers require Produce Traceability Initiative (PTI) labels, in general, the romaine industry can and already does implement and communicate traceability information using globally recognized standards (i.e., GS1 standards and the GS1 128 bar code, which are used by PTI). As part of the task force effort, one company, [Ocean Mist, shared their experiences which was developed as a case study](#). United Fresh and PMA, along with CPMA and GS1 US (the four organizations supporting PTI) will continue to provide information and support to romaine shippers and processors to ensure that all cases of romaine bear PTI compliant labels. As customers are increasingly scanning bar codes, opportunities to improve scanability (readability, placement) have been identified. An alternative or short-term approach for direct shipments with no repacking or handling, involves inclusion of lot codes

on the bill of lading. While imperfect, this can work as a short-term solution especially if information is available electronically.

There are several retail and foodservice operations with the capability to implement traceability within their own establishments, and an increasing number who have expressed their commitment to improve data capture and accessibility within their operations. The workgroup supports highlighting and celebrating these efforts so that others can leverage learnings and develop their own solutions.

As FDA has communicated, even if a firm's totality of paperwork contains the key data elements needed to trace a product, they are generally dispersed within several types of documents and buried amongst other types of information. Therefore, the workgroup supported the development of a template, which reflects FDA's data needs during an outbreak. FDA provided PMA and United Fresh with three redacted records requests from previous outbreaks. The data requested by FDA were converted from narrative form to an Excel spreadsheet. The purpose of the template is to submit data to FDA if requested; this would not be a system to maintain data on an ongoing basis. Rather, companies that have electronic systems could extract the data from those systems to (automatically) populate the template upon receipt of a records request from FDA (or a state). Feedback from a small but diverse group of companies has been positive, but the template needs to be more fully tested. Although FDA is restricted from endorsing the template because it has begun the rulemaking process to implement section 204 of FDA Food Safety Modernization Act (FSMA), the agency has seen the template, and asked questions that have helped yield a template that is likely to address FDA's needs.

Despite the challenges associated with capturing and retaining lot information after packaging is discarded, the workgroup recognizes that outbreak investigations would be vastly improved if the exact lot consumed by someone was captured and available in the event of an outbreak. Today, packaged products often bear an identifier, such as a lot number. However, that information is not available in a format that can be readily or automatically recorded. Achieving this capability will require numerous changes by both suppliers and buyers. While it's unrealistic to expect these changes to occur in the short term, as technology and systems advance, the supply chain should explore opportunities to bring this concept to fruition.

Several related activities, including legislative, regulatory, and voluntary initiatives, are also underway. As noted, as a result of a consent decree FDA has committed to publishing a draft list of priority foods as well as a proposed rule for additional recordkeeping requirements for those foods. This is required by September 2020, and a final rule must be published by November 2022. The restrictions contained in section 204 limit FDA's ability to require changes, although FDA believes it can effect positive change given current authority. We are aware that other groups are lobbying Congress to modify this section of the law so that FDA's authority better reflects societal needs and technological capabilities. While some workgroup members have suggested that we wait until FDA specifies through regulation which key data elements are required, the industry cannot afford to wait for final rules or statutory changes and should have traceability systems in place.

Recommendations to the Romaine Task Force:

The working group recommends the Task Force adopt the following vision -- *"In order to protect public health, the entire leafy greens supply chain commits to working together so that the source of any product available at any point in the supply chain at any given time (including after packaging has been discarded) can be readily and accurately determined and made available electronically."*

The Task Force should urge all leafy green packers or re-packers to track and provide PTI labeling (i.e., GS1-128 scannable barcodes) on cases by 1/1/2020.

The Task Force should encourage that an electronic record of the supplier-supplied information is linked with the last recipient of the case and date of receipt (or use), whether captured by wholesaler, retailer, food service distributor, or foodservice establishment (finite range of possible lots/GTINs or specific GTINs/lots received at that location) by 9/1/2020.

The Task Force should encourage that key data elements are recorded for processed, commingled and/or repacked leafy greens and associated with the finished product lot.

The Task Force supports that upon request from a regulator, an operation should be able to provide key data elements (including the lot number of the raw material or processed product; manufacturers would need to be able to identify inputs into processed products) electronically in an established template.

As a long-term objective, tracking lot information on specific items at the point of retail sale is aspirational.

Investigation/ Collaboration

The investigations/collaboration working group was composed of a mix of industry and trade association professionals and public health experts from FDA and CDC and evolved to include the participation of public health experts from the states; representatives from Colorado, California, Minnesota and Florida were asked to join the group. Specific subgroups discussed different areas given the divergent list of topics in this area. Some subject areas have been the focus of numerous government and academic studies and significant change would be dependent on a concerted, longer-term effort to realize this change. Other issues fell within the grasp of the industry to accomplish albeit providing all parties were motivated to do so. The following are the results of our working group discussions:

Collaboration with FDA/CDC on outbreaks. An industry point of concern on produce outbreaks, including the recent romaine-related advisories, is the level of communication between the agencies and the industry prior to the announcement of the incident, during the incident and then after the incident has concluded. There is an underlying feeling within the produce industry and specifically the leafy greens community that industry knowledge of production timeframes, locations, practices, supply routes, business alliances and product characteristics could aid the public health sector to move more effectively as it identifies causative vehicles and performs traceback investigations. At the same time, public health agencies need to keep industry at arms-length in some respects to avoid the perception or reality of working too closely with the industry they may be investigating and must also adhere to the requirements around the establishment of Federal Advisory Committees. Historically, CDC and FDA have reached out to industry for information, but it has been sporadic, and the utility of this effort has been hard for some to measure. In fact, recent improvements in collaboration have been the subject of Congressional criticism. CDC does employ a formal process with academic subject matter experts that can be adapted to include industry expertise. The Collaborative Food Safety Forum has developed and piloted a process for early engagement of the industry with CDC (<https://www.resolve.ngo/site-foodsafety/early-outbreak-investigations-forum.htm>). Attempts to foster agency/industry discussion on the status of investigations and learnings have been challenged by the agencies' requirements to protect confidentiality of victims and businesses that may be involved. During the working group discussions, FDA CORE and CDC provided insights into the epidemiological and traceback methods they employ. It was repeatedly emphasized that the biggest improvement that can be made in the traceback portion of the investigative process is supply chain-wide adoption of traceability strategies (see above). The

discussion of better collaboration between industry and public health was clearly relegated to an incremental improvement tool relative to traceability.

The working group determined that a proposal needed to be developed and sent to the FDA and CDC outlining what types of information the industry could share with the agencies, how that might be accomplished in an efficient way, when that sharing could occur and the benefit to public health and the produce industry. A proposal was drafted and sent to FDA and CDC (Appendix D) for review and further discussion.

Recommendation to the Romaine Task Force: The Investigations/Collaboration working group recommends that the Romaine Task Force support the initiative to create a mechanism for closer collaboration and normalize cooperation between FDA, CDC and industry prior, during and after produce safety advisories and recalls.

Whole genome sequencing database. Another area the Investigations/collaboration working group discussed was the concept of an industry-driven database housing the genomic sequences of pathogens isolated in produce production environments and the meta data associated with those isolates (type of environment, general location, season, commodity, etc.). This kind of effort has been considered by other food commodities and can be a critical resource permitting a better understanding of how pathogens move within various production environments, providing insights on how to limit movement of pathogens, identifying trends for when specific pathogens emerge near specific commodities and fuel development of more effective mitigations to protect public health. A proposal to do a whole genome sequence of environment isolates was developed and discussed with the subgroup that volunteered to take on this project (Appendix E). A number of roadblocks were identified including data protection, liabilities associated with pathogen detections on farms and handling operations, marketplace perceptions when positive tests are uncovered, data sharing/communication and costs.

Recommendation to the Romaine Task Force: The recommendation by the Investigations/Collaboration working group to the Task Force is that the proposal on creating a whole genome sequencing database be leveraged as a starting point to be socialized within the romaine and leafy greens industry and perhaps more broadly to create industry awareness on the benefits of database development and the potential to use whole genome sequencing data to enhance industry produce safety efforts. The Task Force should encourage industry trade and commodity groups to proactively provide education on this subject matter moving forward.

State Rapid Response Team Eligibility. During the working group discussions, we spent a great deal of time focused on capabilities and resources and examining communications between agencies and previous government and academic efforts to revamp outbreak investigations. The enormity of these issues and the scope of work required to accomplish significant change was seemingly out of reach for the Task Force presently. But it also became apparent that more near term improvements in outbreak investigation and response could be linked to state capabilities and resources. All outbreak investigations begin locally at a city or county level and proceed up to the state. In Dallas, during the working group discussion, CDC brought up the fact that there are over 3,600 different public health entities in the US; each with competing priorities and capabilities. It is important that the data collected and its timeliness from the states be of high quality when national or multiregional events are identified. It follows that state capabilities and resourcing are an important produce industry priority. One mechanism to accomplish this objective is to enhance states' eligibilities for rapid response team (RRT)

funding focused on building states' capacities to investigate produce-related outbreaks. A proposal has been drafted and is included as Appendix F.

Recommendation to the Romaine Task Force: The working group's recommendation to the Romaine Task Force is to assign the industry trade associations the responsibility to work with regulators and policy officials to:

- Expand the Rapid Response Team grants to include those states who hold a Produce Safety Rule (PSR) Cooperative Agreement Program (CAP) or a Manufactured Food Regulatory Program Standards (MFRPS) to be eligible applicants;
- Fund training opportunities and materials to support integration of RRTs that are managed through a manufactured foods program and RRTs that focus on fresh produce. There are a few states that have been successful in this inter-departmental integration that can serve as models.
- Develop a produce-specific component of the RRT manual.
- Identify a mechanism for additional funds specifically for after-action reviews federal/state/local partnership activities. After-action work for outbreaks, including ample debriefs and documentation of lessons learned are considerably resource intensive. States do not always have readily available resources to continue to perform months of follow up work. This could possibly be funded through the CAP or RRT.
- Provide a funding mechanism to support state-level technical assistance (this could be done through CAP or RRT mechanism). This can be used to help assist growers involved in an outbreak address both root-cause analysis as well as implement mitigation measures and on-going monitoring. This could also be accomplished in an expanded role of the Produce Safety Network working with existing RRT's and states.
- Encourage the use of CAP funding to support the development of RRTs.
- As the number of states with RRTs expands, consider adding additional support staff to FDA to manage the coordination of RRTs.

Trace forward. One of the common responses from industry during recent romaine advisories was that the industry might be able to help FDA identify the original supplier of the contaminated romaine if they knew the end point (retail or foodservice) where the consumer encountered the contaminated product. The basis for a trace forward approach is that industry professionals have knowledge of what growers/shippers/processors supply products to whom and if one knew the retail or foodservice venues involve, the scope of the investigation might be narrowed if the industry could eliminate certain suppliers based on distribution patterns during specific parts of a growing season. Trace forward would not be a replacement for traceback but a tool that could be leveraged where appropriate. This avenue of investigation was particularly appealing in the November 2018 outbreak owing to the defined distribution pattern and the time of the year for the illness outbreak. The concept received mixed results during group discussions but most of the concern revolved around the requirement for the romaine industry to create an accurate shipment database capturing shipping origins and destinations for romaine products within specified timeframes. It was not clear how or if this approach would be used when the outbreak was on a national level. Interestingly, some public health professionals familiar with the difficulties of the current traceback approach and the lack of digitized industry data viewed trace forward as a potential solution. However, trace forward also requires that FDA be able to share point of purchase information which may also represent an obstacle to this approach. Lastly, there were concerns by some in the group that trace forward might take resources away from the effort around accomplishing the main objective that can improve the speed and efficiency of investigations: developing supply chain-wide traceability.

Recommendation to the Romaine Task Force: The Investigations/Collaborations working group recommends that the Romaine Task Force table this concept for now and reinforce its support for supply chain-wide traceability.

Provenance Labeling Working Group

The group's initial work focused on how to make the current voluntary labeling of romaine with harvest date and location as effective as possible. This included discussion of standardizing locations and nomenclature for date labeling (although a harvest date is no longer a necessary element). The group was concluded after completing the update to the Q&A document, which is posted on PMA and United's websites and included as Appendix G. A webinar was also conducted in April to review the outputs of the working group and answer industry questions. Although some feedback on the draft provenance labeling Q&A recommended different geographic scopes, or variations on names for regions, the workgroup determined that the changes did not warrant interrupting the consistency and uniformity that had been achieved within the industry. The final document identifies regions and suggests a format for communicating information to consumers. Despite the fact that recommendations/Q&A document was widely vetted and communicated broadly as *final*, there are groups that have splintered off creating inconsistency and confusion in the marketplace.

During the working groups discussions by conference call and in-person in Dallas, it became clear that provenance labeling is secondary to true traceability that can be useful in investigations. FDA has characterized current provenance labeling as an "interim step" and urged the Romaine Task Force to put our highest energy into traceability.

Recommendations to the Romaine Task Force: The Task Force recommends that the final Q&A serve as the authoritative industry reference for provenance labeling owing to the representation of retailers, trade groups (including FMI, United, PMA, WG and LGMA), processors, indoor and conventional/outdoor growers, FDA, and consumer groups on the working group. More specifically the Provenance Labeling working group recommends the Romaine Task Force support the following statements:

- Provenance labeling is a voluntary program to enable consumers to understand the applicability of an FDA/CDC consumer advisory to packaged romaine products they have already purchased. Provenance labeling should be provided on consumer packs of romaine and romaine-containing items. This applies to mature and baby romaine; it does not apply to other leafy greens.
- When such packaging is not applicable (e.g., at foodservice, or bulk romaine at retail), the retail/foodservice establishment does not have to post signage indicating origin/date, but the establishment should have access to this information so that they can remove product subject to an advisory so that it's not sold to consumers. This information can be conveyed from the supplier to the buyer through a PTI label or through another mechanism.
- Labels should be applied to the front of a package, using minimum 6-point font, and be easy to read (e.g., colors contrast).

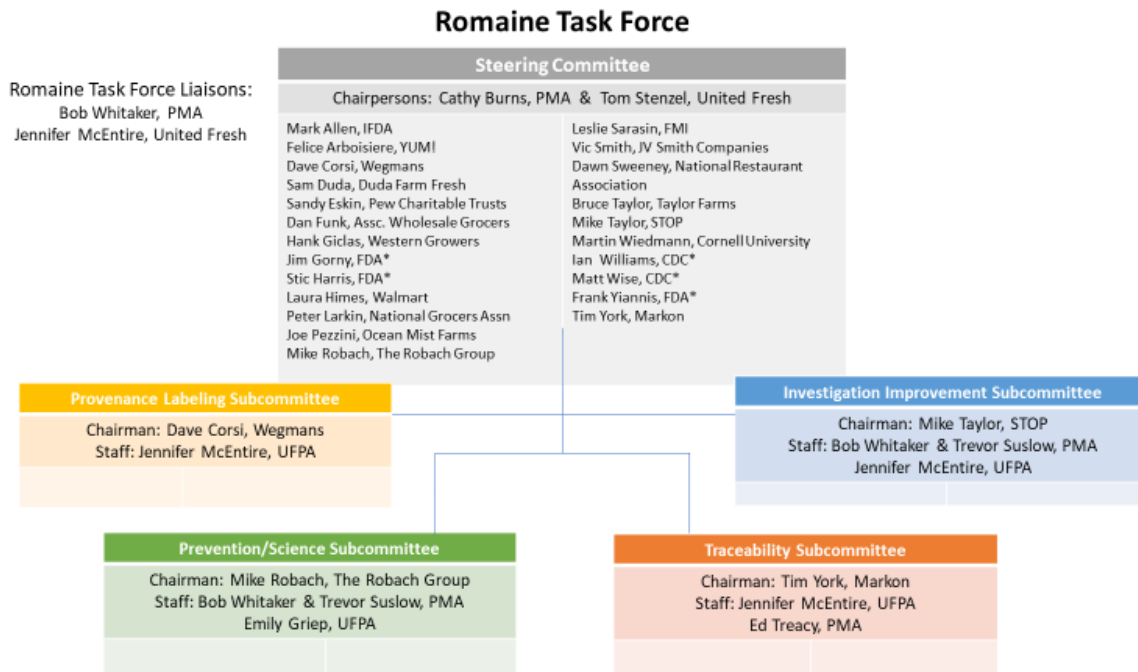
We recommend the industry adopt the following standardized regions for labeling harvest location. Maps follow so that the boundaries of each region are clear. If not listed, it is recommended to use the 2-letter state, province or territory abbreviation unless otherwise noted:

<u>Growing Region*</u>	<u>Abbreviation</u>
Yuma*	Yuma
Phoenix	Phoenix
Southern Arizona	South AZ
Northern Arizona	North AZ
Northern California	North CA
Salinas	Salinas
Santa Maria	Santa Maria
Southern California	South CA
Imperial Valley	Imperial Vly
Coachella	Coachella
Central Valley	Central Vly
Northern Mexico	North MX
Central Mexico	Central MX
Southern Mexico	South MX

* “Yuma” includes Bard and Winterhaven, CA.

The recommended format is “Romaine: (region(s))”. For product grown indoors, the phrase “Indoor grown” should precede the indication of the region.

Appendix A: Volunteer participants of the Romaine Task Force and working groups.



Prevention/Science Subcommittee	
Chairman: Mike Robach, The Robach Group Staff: Bob Whitaker & Trevor Suslow, PMA Emily Griep, UFPA	
Tony Banegas, ReadyPac Robby Barkely, Greengate Jim Brennan, SmartWash Michelle Danyluk, University of Florida Amy Duda-Kinder, Duda Farms Bonnie Fernandez-Fenaroli, CPS Hank Giclas, Western Growers Jim Gorny, FDA Bob Gravani, Cornell University Vincent Hill, CDC Jorge Hernandez, Wholesome International Scott Horsfall, CA LGMA	Amy Kahler, CDC Lianna Kelly, Markon Mike Mahovic, FDA Mark Mignogna, Sysco Gurmail Mudahar, T&A Kurt Nolte, FDA Channah Rock, University of Arizona Joan Rosen, JC Rosen Resources Don Schaffner, Rutgers University Laura Strawn, Virginia Tech Mike Taylor, STOP Angela Valadez, Publix

Traceability Subcommittee

Chairman: Tim York, Markon
Staff: Jennifer McEntire, UFPA
Ed Treacy, PMA

Lucy Angarita, Subway	Brian Kocher, Castellini
Felice Arboisiere, YUM!	Salveen Kumar, Save Mart
Tejas Bhatt, Walmart	Jason Lambros, Coastal Sunbelt
Katie Vierk Brill, FDA	Brenda Lloyd, Consultant
Tom Casas, T&A	Sherri McGarry, CDC
Jon Eisen, IFDA	Michael Muzyk, Baldor
Amber Engebretson, Chipotle	Kathy Ramos, Subway
Sandy Eskin, PEW	Kim Rice, US Foods
Mario Estrada, Chipotle	Michael Roberson, Publix
Hank Giclas, Western Growers	Shane Sampels, Sysco
Kari Irvin, FDA	Laura Strange, NGA
Michael Jantschke, PRO*ACT	Mike Taylor, STOP
Jessica Jones, Chick-Fil-A	Hilary Thesmar, FMI
Gillian Kelleher, Wegmans	Cas Tryba, Big Y
Andy Kennedy, GFTC	William Weichelt, Natl Rest Assn

Provenance Labeling Subcommittee

Chairman: Dave Corsi, Wegmans
Staff: Jennifer McEntire, UFPA

Anika Bansal, Bonduelle	Teresa Lopez, AZ LGMA
Katie Vierk Brill, FDA	Diana McClean, Ocean Mist Farms
Sandy Eskin, Pew Charitable Trusts	Marc Oshima, Aero Farms
Beth Fernandes, US Foods	Tal Shoshan, Five Star Gourmet Foods
Hank Giclas, Western Growers	Abby Taylor-Silva, GSA
John Gurrisi, Fresh Express	Hilary Thesmar, FMI
Laura Himes, Walmart	Kari Valdes, Taylor Farms
Kari Irvin, FDA	Robert Verloop, Coastline Produce
Sharan Lanini, PIM	Matt Wise, CDC
Paul Lightfoot, Bright Farms	

Investigation Improvement Subcommittee

Chairman: Mike Taylor, STOP

Staff: Bob Whitaker & Trevor Suslow, PMA

Jennifer McEntire, UFPA

John Boelts, Desert Premium Farms
Betsy Booren, GMA
De Ann Davis, Church Brothers
Natalie Dyenson, Dole
Hank Giclas, Western Growers
Laura Gieraltowski, CDC
Jack Guzewich, Consultant
Debbie Hamrick, NC Farm Bureau
Stic Harris, FDA
Craig Hedberg, University of MN
Kari Irvin, FDA

Natalie Krout-Greenberg, CDFA
Wendy Maduff, Wonderful
Drew McDonald, Taylor Farms
Glenn Morris, University of FL
Jerry Noland, Albertsons
Steve Ostroff, Consultant
Elaine Scallan, U of Colorado -Denver
Gary Van Breda, McDonalds
Craig Wilson, Costco
Matt Wise, CDC
Benson Yee, California CDC

Appendix B: Example RCA case study

Root Cause Analysis Case Study

Michelle Danyluk, Ph.D.

When an issue, food safety or otherwise, occurs, it's not uncommon that several things "went wrong" resulting in the issue. A "root cause analysis" is a systematic, detailed process that is conducted in to reveal the underlying reasons that a problem arose, so that a recurrence can be prevented. Pew convened groups of experts to discuss the process and drafted the findings into a comprehensive report.

The purpose of this case study is to demonstrate how the principles of root cause analysis can be put into practice to investigate an issue related to fresh produce. Although this case study uses avocados as an example, this case study is intended for growers and processors of any fresh produce item. Readers are encouraged to focus on the thought process used to investigate an issue, as opposed to a specific commodity, details of the situation, or "answer".

"The Problem":

As a result of an FDA sampling assignment, the same facility recalled avocados due to the presence of *Salmonella* twice within the same season.

The Approach:

A research team with extensive on-farm experience was invited to the facility to try to determine the root cause of repeat contamination.

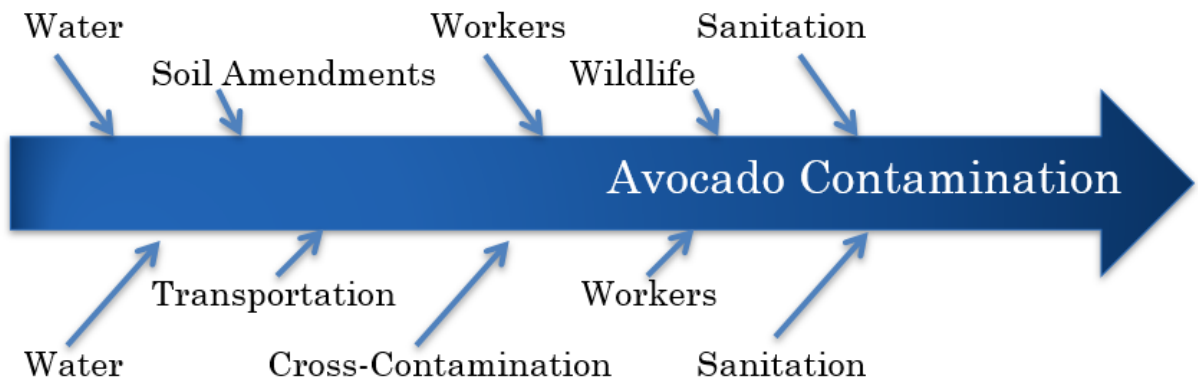
About the Team:

Conducting a root cause analysis is facilitated by having a team of individuals with different backgrounds and expertise look at the same situation, ask different questions, and build on each other's questions. There is no right number of people to involve on the team; it should be big enough to cover all necessary specialties, but not so big as that communication becomes difficult. When considering who should be on the team, consider both people very familiar with the commodity, production system, and packing, but also consider bringing in outside support not familiar with the organization, commodity, and production system, which may offer fresh eyes and new perspectives. If you plan to collect samples, the team should include a food microbiologist with laboratory expertise and experience in environmental sampling. There is no set formula for conducting a root cause analysis; there is no universal or "cookie cutter" checklist to use, so the experience of the team and their creativity, imagination, and openness to new ideas is critical to a successful root cause analysis.

The Evaluation Process:

This team used the "fishbone diagram" to visually depict the pre and postharvest inputs into avocado production. An example graphic is shown below. While these general items are applicable to a variety of fresh produce situations, an important part of the analysis is thinking about "what else" could play a role or "what have we changed or are doing differently" and should be thoroughly evaluated. Again, the illustration is not meant to serve as a checklist, although the same key starting risk-points have served the industry since the first Good Agricultural Practices document was released in 1995.

Preharvest



Postharvest

The first step in the investigation was to try to determine where exactly *Salmonella* could be found in the postharvest environment. Note, simply finding *Salmonella* and cleaning it up is *not* the root cause. How did it get there? Why did it persist? These are the additional questions that need to be answered. The team took nearly 200 swab samples in the facility in zones 1-4 *after* a full day's production. The team also asked detailed questions, and made their own observations, regarding sanitation and the control of hydrocooler water.

In the postharvest environment, *Salmonella* was found in several locations including at the hydrocooler and on the bottom of harvest bins stacked one upon another in the forced air cooler, which were visibly dirty and had already been through the hydrocooler. The sufficiency of hydrocooler antimicrobial management and clean-out, to include or exclude this as a contributor to persistent product contamination, was assessed. The team asked follow-up questions about why there was so much debris on the bottom of the harvest bins, and what practices were around their use, storage and cleaning. But where did the *Salmonella* come from? This led the team to investigate the preharvest environment.

The team visited three groves and interviewed staff to understand the production practices. Two of the groves were associated with recalled avocados; one was not but was used to store soil amendments. They again hunted for *Salmonella*, sampling soil, water (well water, sprinkler head, standing water etc.), bird feces, snails, biosolids, stored field bins, and other surfaces. The decisions on what to test was based on their own observations as well as employee interviews. The team kept an open mind regarding potential sources and vectors for *Salmonella*.

All three fields had some samples that were positive for *Salmonella*. This was not an unexpected finding, since *Salmonella* can persist in the environment. In the first field, positives were found in samples of standing water along a dirt road, as well as in a drag sample by a horse pasture and a soil sample in a different part of the field. In another field, positives were found in a fill well and a drag swab. Both of these fields had been associated with recalls. In the third field, two of three biosolid samples were positive, as was a drag swab south of the biosolid storage area.

The team learned that trees are side dressed with Class A biosolids through the year, and the process can generate dust. Multiple varieties of avocados are planted, that mature at different times, so sometimes the side dressing was applied close to the time a variety was going to be harvested. For the purpose of this investigation, the research team did not need to further investigate the process to treat Class A biosolids to understand why *Salmonella* was present in the material. For class A biosolids for unrestricted use, *Salmonella* populations must be less than three most probable number (MPN) per four grams of total solids (dry weight basis) at the time the biosolids are used or disposed. Follow up quantification of *Salmonella* populations in the biosolids indicated that they are close to, or right at the 3 MPN/4 g specified (3 MPN/ 4 g is also the *Salmonella* limit for treated compost that is specified in the Produce Safety Rule).

Resolution:

The process identified class A biosolids as the likely source of *Salmonella* and identified possible routes of contamination (dust generated close to harvest, dust and debris on bins entering the facility from the field, and no documented cleaning and sanitation program for bins). As a result of the comprehensive evaluation, the firm was able to make several changes based on understanding the source, as well as possible routes of contamination.

Appendix C: Traceability vision

7/17/19

Overarching comment: Several companies are already implementing many of the elements in this document. Changing an industry will take time, and modernizing traceability is a long-term process. The workgroup realizes that this leaves us vulnerable to additional outbreaks in which product cannot be rapidly traced. For this reason, the workgroup urges individual companies to move with expediency.

Vision:

In order to protect public health, the entire leafy green supply chain commits to working together so that the source of any product available at any point in the supply chain at any given time (including after packaging has been discarded) can be readily and accurately determined and made available electronically.

Goals:

- Enable data-driven, faster, more precise traceback investigations related to leafy greens
- Enable consumers and supply chain partners to more accurately identify affected leafy green products
- Enable faster, more precise product removal as warranted by investigation findings
- 100% compliance to the performance standards
- Elimination of all category wide withdrawals/advisories

Performance Standards:

An electronic data record identifying the origin of the case(s) and/or the last transformation point (e.g., farms, processors, repackers), is captured and provided within 2 hours of request (and is able to link back to the inputs).

An electronic data record identifying the case information and last shipping point is captured at the last point of receipt (e.g. retail store or foodservice outlet).

Utilize [GS1 international standards](#) to identify, capture and share [Key Data Elements](#) as required or requested by FDA

Use a standardized data template to exchange required data

Strategies:

Initial implementation is at case packing (grower/packer/processor) and the last point of case receiving (retail or foodservice outlet)

Pilot low, medium and high technical solutions to track and provide data

Engage service provider industry to provide low cost solutions to capture store and share traceability data.

Actively solicit commitment to the vision and goals, as well as implementation of the phases below, from key members of the leafy greens supply chain (from production through to point of sale/service)

Engage and educate leafy green stakeholders

Phases:

Stage one

Industry pilot traceability template

Leafy green suppliers to record and share PTI Key Data Elements with their customers (trading partners), and label cases with GS1-128 (PTI) barcodes by 1/1/2020

Brand owners should be able to link a case GTIN and lot number back to the individual grower(s)/ranch(es)

An electronic record of the supplier-supplied information is associated with the last recipient of the case and date of receipt (or use), whether captured by wholesaler, retailer, food service distributor, or foodservice establishment (the range of Lots/GTINs or specific lots electronically recorded), by 9/1/2020.

The key data elements are recorded for processed, commingled and/or repacked leafy greens and associated with the finished product lot

Stage Two

Each supply chain point ensures that cases bear a PTI compliant label

Label accuracy remains the responsibility of the supplier who generated and applied the label.

The inputs for processed, commingled and/or repacked leafy green products are *electronically* recorded and associated with the finished product lot

An electronic record of the supplier-supplied information, including GTINs and specific lot numbers, is associated with the last recipient of the case and date of receipt (or use), whether captured by wholesaler, retailer, food service distributor, or foodservice establishment

Stage Three

A strategy to associate the supplier lot/batch number with an individual consumer purchase is conceptualized

Additional Best Practices:

The following optional best practices may help certain companies achieve a greater supply chain efficiencies.

Elimination of the use of [generic UPCs](#) for packaged produce

While the UPC does not provide lot-specific information, it does help differentiate a consumers purchase at the brand level, which can provide useful directional information in the early stages of a trace back.

PMA will stop assigning new generic UPCs by 1/1/2020

Each touch point (Critical Tracking Event) for leafy greens is identified and traceability information is electronically captured

This enables trace back/ trace forward at other points in the supply chain, enabling other supply chain entities to identify efficiencies, control shrink, etc. Additionally, if a case is missing a label, the last point at which a label was scanned can be ascertained. This can also help target a recall (trace forward). If one entity does not scan labels upon shipment, they may need to issue a recall notice more broadly than if they definitively knew who received a recalled product.

For processed or commingled product, the number of input lots associated with one ingredient (e.g., romaine) is managed so as to limit the number of possible sources of that raw material associated with the finished product

There is a practicality and efficiency to mixing raw material lots. However, even with perfect record keeping, in the event of a trace back, the more sources of a particular raw material, the more difficult it will be to rapidly identify the potentially contaminated input.

The most efficient way to communicate PTI GTIN/Lot information is by using an Advance Shipment Notification (ASN). Supply chain members not capable of using ASNs should consider alternative approaches to communicating PTI GTIN/Lot information, for example, printing on invoices or bills of lading, or having that information accompany those types of documents in text and bar code format.

Appendix D: Proposal to FDA on Industry/CDC/FDA Collaboration to Improve Investigative Efficiencies and Outbreak Communications.

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 E: Whole Genome Sequencing Exploratory Survey

A Proposal to the Fresh Produce and Other Industries

Background:

Whole Genome Sequencing (WGS) has transformed our understanding of host: microbe interactions. In contrast to Pulsed Field Gel Electrophoresis, the preceding methodology which gives a yes/no, same/different result, WGS reveals the genetic and evolutionary relatedness between organisms. This is a powerful tool in that the relatedness between outbreak isolates, food isolates, and environmental isolates can be more definitively determined. However, without a better understanding of the inherent genetic diversity that exists in the environment, it is difficult to establish a correlation between clinical and environmental “matches” in the absence of other data. Collecting data from a breadth of sources should help reveal how microorganisms move and evolve and the rates of genetic changes among different groups, so that we can better understand the relevance of finding a particular isolate. The larger the data set is, the better our understanding of microbial diversity will be, which will lead to increased confidence in the conclusions drawn.

Objective:

Populate a comprehensive WGS dataset of isolates from agricultural “environment” origins (water, soil, plant, manure, biological soil amendments, etc.). This would not include product/ produce samples, since the objective is to paint a picture of the broader distribution of isolates in the environment.

Approach:

Begin with an evaluation of environments in which leafy greens are produced and focus on Shiga-toxin producing *E. coli*.

Rationale:

The dataset will facilitate 1) research on the prevalence, persistence and migration of STEC organisms within the greater agricultural environment; 2) development of enhanced prevention strategies for STEC in animal operations and minimally-processed/fresh foods; and 3) progression of attribution protocols for past and future potential outbreak investigations.

Basic parameters:

Database access is open to private entities involved in the US food supply; the dataset will be strongest benefit to the broader agricultural community (produce and animal-based operations) and development of inclusive (animal and produce) food safety standards for STEC prevention. Participating companies would gather samples and use their preferred laboratory to analyze samples. Isolates (or purified DNA) would be sent from a designated laboratory for WGS analysis and held for at least 6 months prior to WGS analysis. The isolate would be disposed of in accordance with an established laboratory protocol.

Each participating company would pay for the sample collection, pathogen isolation, and WGS analysis, as well as become an established client of [law firm].

Minimum “meta-data” is submitted with the isolate (as described below); additional meta-data will be held under attorney-client privilege. This information will be held for a minimum of 6 months and will not be disclosed until the WGS analysis is completed or other designated period.

The information within an industry-submitted database will not be disclosed to any public databases until 50 isolates per region have been fully sequenced and/or 12 months has elapsed since the analysis of any given isolate.

Benefits:

To Public Health and the Industry Overall

- Supports the critical need to develop science-based food safety standards (as well as potential verification/monitoring strategies) intended to minimize STEC in agricultural operations and thus the food supply.
- Allows for an appropriate time lapse between isolate submission and analysis to address concerns related to product currently in the market; encourages broader industry participation because no one company’s data will be available without either agreed collective participation and/or time frame having been met.
- Serves a model for other industry-specific WGS database development and/or future expansion to include other pathogens for fresh produce.

To Participating Companies & Overall Industry

- Provides insight into growing environments, helping to inform risk and evaluate mitigations.
- Clarifies how broadly or narrowly certain WGS patterns are seen, informing the interpretation of clinical or product matches.
- A blinded summary report will be provided to companies that submit at least 1 isolate per year, showing how their data fits into an overall picture.

Meta-Data:

submitted with Isolate:

- Isolate/ sample identification code as assigned by the submitter or through a double-blind process
- Isolate serotype or subgroup (if available)
- Sample collection date
- Isolation date
- Shipping date

Meta-Data submitted with isolate but held for longer period of time (proposed for 6 months for a survey in a leafy green production environment; if the approach is expanded to areas where crops have longer shelf lives, the delay to provide more detailed data should exceed the shelf life of the product):

- Test method for identification:
- Sample date:
- Sample source type (water, plant, soil, etc.)
- Crop related (crop type):
- Animal related (livestock type):

- Geographical region:
- Other?

Terms of Participation:

- Submit at least 1 isolate per year
- Aim to submit isolates from multiple regions
- Direct preferred laboratory to send isolates to... following the established protocol
- Retain [law firm] and bear associated fees in order to establish attorney-client privilege
- Send meta-data associated with the sample to counsel.

Appendix F: Recommendation for Rapid Response Team Expansion

Investigation Committee; Epi subgroup

May 21, 2019

Background:

FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, provides FDA with tools to better protect public health by strengthening the food safety system. It enables FDA to focus on preventing food safety problems rather than reacting to problems after they occur. It also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. These include authorities such as mandatory recall, expanded administrative detention, suspension of facility registration, enhanced product tracing abilities, and additional recordkeeping requirements for high-risk foods. FSMA also gives FDA important new tools to hold imported foods to the same standards as domestic foods.

FSMA directs FDA to build an integrated national food safety system in partnership with State and local authorities, explicitly recognizing that all food safety agencies need to work together in an integrated way to achieve national public health goals. FSMA identifies some key priorities in working with partners in areas, such as: reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities.

Developing a Food Protection Rapid Response Team (RRT)

The goal of the RRT cooperative agreements is to facilitate long-term improvements to the national integrated food safety system by unifying and coordinating federal/state/local food/feed emergency response efforts including:

- 1) Strengthening the link among epidemiology, lab and environmental health/regulatory components;
- 2) Improving States' regulatory and surveillance food/feed protection programs to include using Incident Command System (ICS)/National Incident Management System (NIMS) principles and a Unified Command structure to conduct integrated responses to all-hazards food/feed emergencies, rapidly identifying and removing tainted food from commerce, and conducting root cause investigations to inform future prevention efforts; and
- 3) Addressing supporting components, such as training, data sharing, data analysis, communications, continuous process improvement, and development of best practices and other resources to support national capacity/capability development.

This will be accomplished through the provision of funding to support development of multi-jurisdictional, multi-disciplinary Rapid Response Teams (RRTs) and will require extensive cooperation and coordination with FDA District Offices and other FDA program offices.

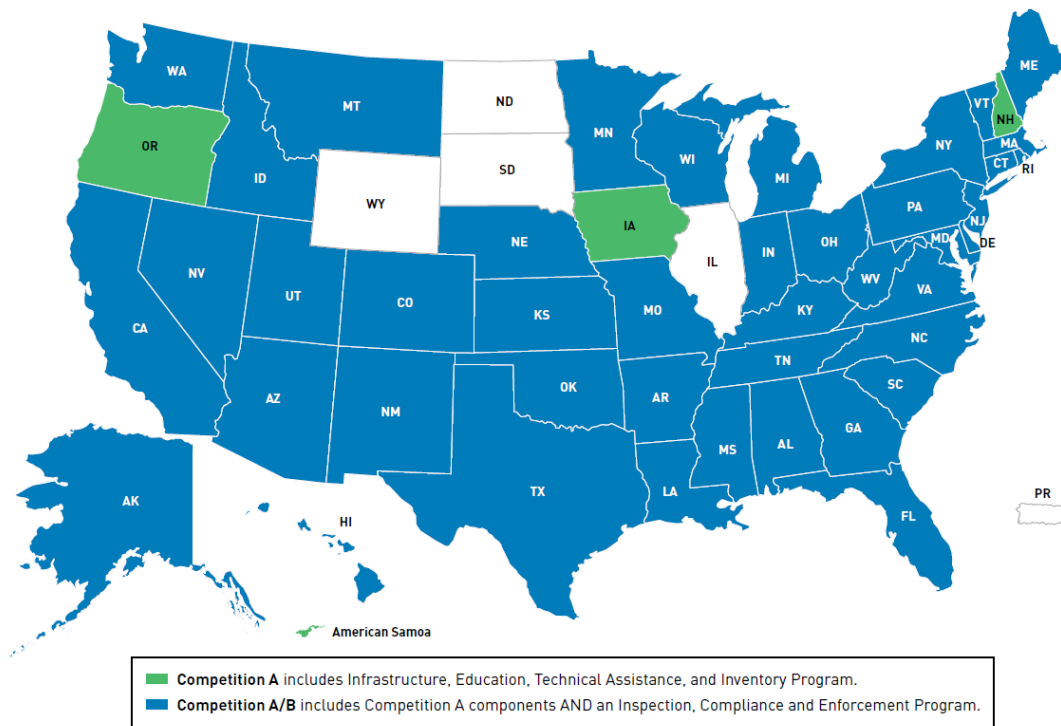
There are currently 21 states with RRTs that are funded by FDA. Funding is directed to the state agency that is responsible for the Manufactured Foods Program. Typically this is a state department of health. There are also 3 states with voluntary RRTs. Although these states don't receive funding from FDA via the RRT process, they may have a different source of funding, such as the FDA FSMA Produce Safety

Cooperative Agreement Program (CAP). The three FDA staff who manage the RRT program also manage the states with voluntary RRTs.

Problem Statement:

There are 46 states funded by the FDA FSMA (CAP). Some of these states have divided jurisdictional authority between the Department of Public Health and the Department of Food and Agriculture. States now have Produce Safety Rule (PSR) inspectors that have a role in traceback inspections. The interface with those state PSR staff and a RRT becomes critical to quickly obtain information and conduct coordinated follow up. A map of those states with a CAP agreement is below.

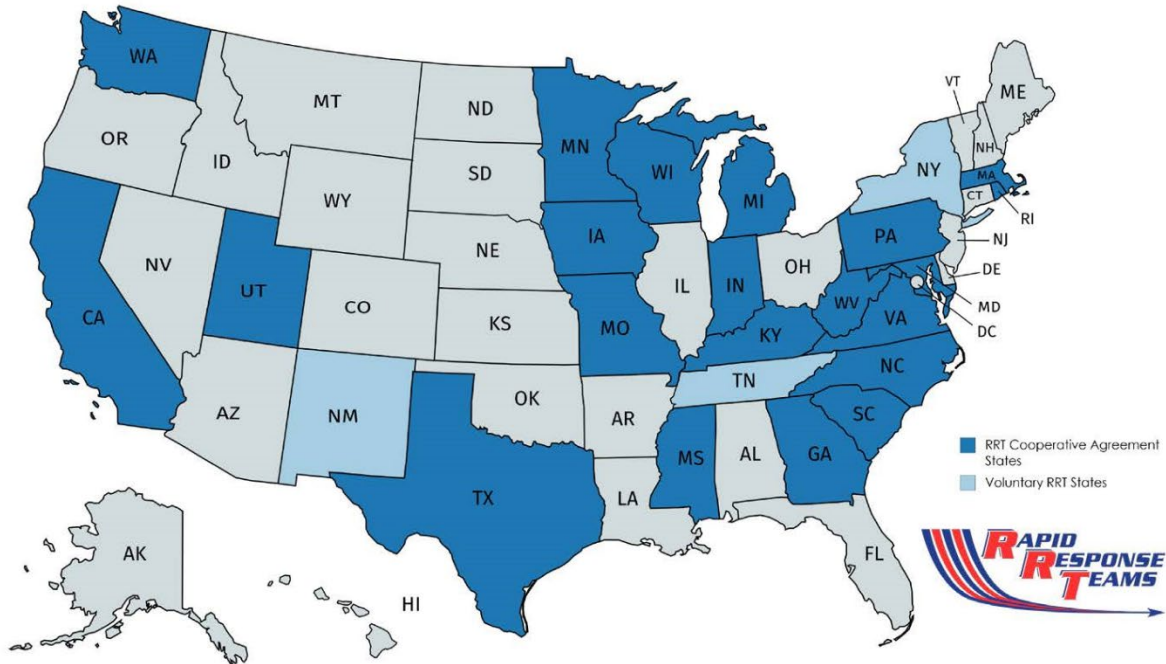
Produce Safety Cooperative Agreement Program: 2018-19 Grant Year



The RRT Structure will vary on a case-by-case basis for each state and per the grant announcement the following components must be represented on the RRT: FDA District Office; Food Program; Feed Program; Epidemiologists; Laboratory; and, Local Health Partners. There are differences in produce-related issues that warrant a different team composition. For example, the FDA point of contact may be a representative of the FDA Produce Safety Network, rather than the local FDA Emergency Response Coordinator. Most importantly, state departments of agriculture, not health, usually have jurisdiction over farms.

The following map identifies the 21 states that hold an RRT grant.

Rapid Response Teams: 2018 – 2019 Grant Year



The challenge becomes that through the expansion of the Produce Safety CAP there are now more states involved operationally. This is a benefit for the purposes of inspectional work, but when faced with an outbreak those same states performing produce inspections may not have an RRT established to lend structured support during an emergency. Furthermore, even if a state has an FDA funded RRT program, they may be jurisdictionally separated from the state agency that has authority over manufactured foods.

The RRT grant subpart b) “Food Program,” states the following as requirements to be eligible for the grant:

This should represent the grantee agency and is deemed the 'lead' state agency within the RRT. It is a requirement of eligibility for this award for the grantee to be enrolled in the Manufactured Food Regulatory Program Standards. In addition, state regulatory agencies with authority over meat and poultry, shellfish, Grade A milk and retail food establishments should also be included within the RRT. It's during times of emergency that operational preparedness can reduce the duration of an outbreak because well-qualified and trained staff meet regularly and can triage resources and engage the proper communication channels both locally and nationally. The opportunity appears ripe to find a way to engage the balance of the states in RRT efforts.

Proposed Solutions:

- Expand the Rapid Response Team grants to include those states who hold a Produce Safety Rule (PSR) Cooperative Agreement Program (CAP) or a Manufactured Food Regulatory Program Standards (MFRPS) to be eligible applicants;
- Fund training opportunities and materials to support integration of RRTs that are managed through a manufactured foods program and RRTs that focus on fresh produce. There are a few states that have been successful in this inter-departmental integration that can serve as models.
- Develop a produce-specific component of the RRT manual.
- Identify a mechanism for additional funds specifically for after-action reviews federal/state/local partnership activities.
- After-action work for outbreaks, including ample debrief and documentation of lessons learned are considerably resource intensive. States do not always have readily available resources to continue to perform months of follow up work. This could possibly be funded through the CAP or RRT.
- Provide a funding mechanism to support state-level technical assistance (this could be done through CAP or RRT mechanism). This can be used to help assist growers involved in an outbreak addressed both route-cause analysis as well as implement mitigation measures and on-going monitoring. This could also be accomplished in an expanded role of the Produce Safety Network working with existing RRT's and states.
- Encourage the use of CAP funding to support the development of RRTs.
- As the number of states with RRTs expands, consider adding additional support staff to FDA to manage the coordination of RRTs.

Additional Considerations:

The money provided to states over the years for RRT has progressed to the point where an agency cannot put together a decent program using those grant funds alone. Additional non-federal funding to support RRTs is expected, but some states just can't pull that together, especially those with limited epi staff.

The grant requirements are becoming more and more difficult to meet and often require 4 Person Years to accomplish the functions that are only funded by 1-2 PYs. If the state doesn't have any other supporting dollars, this becomes a limiting factor when trying to integrate states into the rapid response structure to get faster and better at traceback.

Appendix G: Provenance Labeling

Questions & Answers on Voluntary Romaine Growing Region Labeling

May 7, 2019

This questions and answer document, originally drafted by PMA and United Fresh, has been updated as an outcome of the Romaine Task Force labeling workgroup, comprised of a cross-section of the fresh produce industry that was charged with providing industry guidance for this voluntary program. As the industry continues to gather experience implementing provenance labeling, this information may be updated.

Mission: To provide consumers easy access to information about growing regions associated with romaine products.

Vision: This is an interim step until better traceback mechanisms are in place.

What products are covered by this label? At this time, labels should be applied to romaine lettuce including processed blends containing mature or baby romaine lettuce.

Does the labeling program apply to other leafy greens? Not at this time.

Is this a new regulation from FDA? No, the use of this new label is a voluntary but is encouraged by FDA.

What should the label (for both field packed and processed romaine) say?

Romaine: (region(s))

See Question 10 for recommended regions

For indoor growers, the information in (a) should be preceded by the phrase: Indoor grown

What if product contains romaine from multiple growing regions? If product is commingled and contains romaine harvested from multiple regions, then an “and” statement should be included or the regions should be separated by a comma; e.g. Romaine: (region), (region). Labeling should be accurate and could include the use of an “and/or” declaration if romaine from multiple growing regions is in the product.

Do we have to use the label? No, this is a voluntary effort. However, if there are outbreaks in the future associated with romaine, FDA and CDC may advise consumers that they should look for/ ask for this information when purchasing or eating romaine to ensure that the available romaine is not from growing regions that could be associated with the outbreak. In addition, they are likely to advise consumers to avoid romaine products that do not have the growing region information.

I grow and/or ship bulk romaine for regional processing. Do I have to label anything? No, the voluntary labeling initiative is aimed at communicating the growing region of the product to consumers. However, in order for your customer (the processor) to label their product with this information, it will need to be communicated to them. This can be done in several ways, based on the agreements between the

trading partners although a GS1 128 case label is that identifies grower, lot number, and growing region in human readable form is recommended.

What is the definition of “indoor grown” and how can it be labeled? It is a controlled environment for growing (not Hoop houses). We recommend that indoor growers follow the label standards and be labeled “Indoor grown” followed by the region, i.e. “Indoor Grown Romaine: (region)”

When should this be label present for consumers? Immediately and until further notice. This is an interim step until better traceback mechanisms are in place.

How should growing regions be named? A workgroup within the 2019 romaine task force suggests that growing regions be communicated on the label using the designations and abbreviations listed below that are based on the boundaries indicated in the accompanying map:

If not listed, use the 2-letter state, province or territory abbreviation unless otherwise noted:

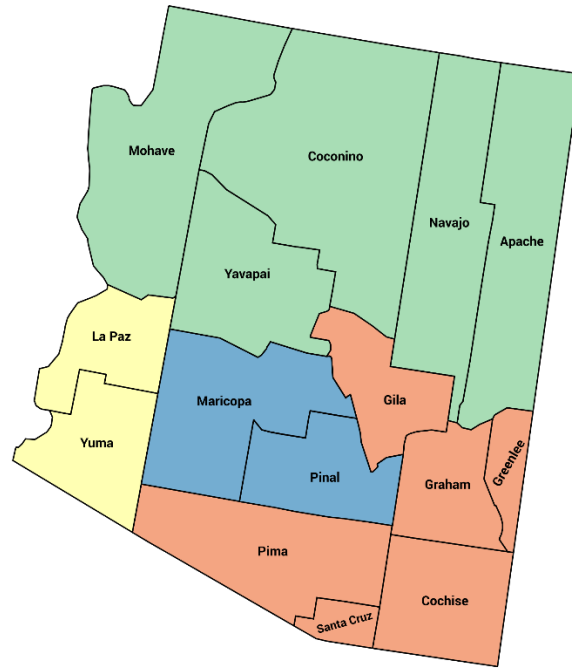
<u>Growing Region</u>	<u>Abbreviation</u>
Yuma*	Yuma
Phoenix	Phoenix
Southern Arizona	South AZ
Northern Arizona	North AZ
Northern California	North CA
Salinas	Salinas
Santa Maria	Santa Maria
Southern California	South CA
Imperial Valley	Imperial Vly
Coachella	Coachella
Central Valley	Central Vly
Northern Mexico	North MX
Central Mexico	Central MX
Southern Mexico	South MX

*note: “Yuma” includes Bard and Winterhaven, CA.

- North CA
- Central Vly
- Salinas
- Santa Maria
- South CA
- Coachella
- Imperial Vly
- Yuma



- Yuma
- North AZ
- Phoenix
- South AZ



Does a date need to be included? As long as a date of harvest can be determined using existing dates associated with the product (e.g., the “Best if used by” date or Julian date), the date of harvest does *not* need to be separately included alongside the growing region.

What kinds of label materials can be used? FDA has not provided any guidance on this but has indicated for bagged products that will be sold directly to consumers (e.g., at retail), the growing region should be printed directly on the package (e.g., ink jet). Labels can also be printed directly on cartons for salads or field-packed product or they may be printed on stickers and placed on cartons. Remember, the stickers or printed labels on cartons must be easily found by the receiver as they will need to be able to communicate with consumers directly.

For dual jurisdiction facilities, will this require a label review by USDA FSIS? At our urging, FSIS posted an [“ask FSIS” Q&A](#) that states “FSIS will permit a statement identifying the harvest location and date, consistent with FDA’s advice, on meat or poultry products that contain romaine lettuce. FSIS will also permit statements identifying that a meat or poultry product does not contain romaine lettuce, e.g., adding a sticker to a label that states, “Does Not Contain Romaine Lettuce.” The addition of these statements to labels does not require submitting the labels to FSIS for sketch or temporary approval. Both types of statements are not considered special claims and are generically approved under Title 9 of the Code of Federal Regulations (CFR), Part 412.2.”

What fonts and print sizes, color can be used? The information should be prominent, conspicuous and easy to read. While color is not specified, information is most easily read when there is visual contrast (e.g., contrast the contents or packaging graphics), upper and lower-case letters (not all upper case), and a font size no smaller than 6-point font.

Where should the label be located on the package or box? The information should be prominently displayed on the front of package; be aware of proper customer readability with the proper ink color relative to product background.

Must the growing region be printed on the PTI label? No, this information can be provided on a separate label but we advise applying a GS1 128 case label to each carton.

If a supplier chooses to include growing region information on the PTI label, is there any guidance? We suggest that this information be printed using any open space on the PTI label, with a font size consistent with other human readable information. The objective of providing the growing region on the PTI label is to ensure the information is communicated clearly through the supply chain to retailers, foodservice operations, institutions, etc.

Under what circumstances is an in-store point of sale sign needed for bulk, unpackaged romaine, and what should it say? Because retail and foodservice establishments promptly act on advisories, product under advisory should not be available for sale. Therefore, information on growing region does not need to be displayed by retailers on an ongoing basis. When there is an advisory, retailers should have a sign indicating that bulk, unpackaged romaine for sale is not implicated.

If products are transformed in-store and don’t bear a label what is suggested? CDC advised that “restaurants and retailers should check the label on bags or boxes of romaine lettuce, or ask their suppliers about the source of their romaine lettuce.” Retailers transforming product in-store (e.g.,

prepared foods) should ensure that the romaine used meets these criteria, and should be prepared to address consumer questions.

Will restaurants need to provide growing region information to consumers? Foodservice operations may field consumer questions as well as adhere to potential removal advisories. Foodservice products should include regional information on the end unit or box.

What if I ship to Canada? CFIA is not requiring any unique information for romaine at this time. If you have any questions, please contact the CFIA National Import Service Centre (NISC) from 7:00 a.m. to 3:00 a.m. (Eastern Time) at 1-800-835-4486 (Canada or USA).

Must all points in the supply chain capture growing region as part of their traceability information? The label/ sticker information is in addition to traceability information that should be captured electronically. The Key Data Elements of a robust traceability system would provide more detailed information than what is provided through this initiative.

Should the growing region be printed on the Bill of Lading? In the event of a traceback situation, this information could be useful in more quickly identifying and excluding shipments and regions that may or may not be involved in an outbreak. However, this should not be in lieu of more granular traceability information.