

## **Romaine Task Force Dallas, TX, February 13-14, 2019 Meeting Notes/Summary**

The Romaine Task Force and its four working groups, comprising over 100 industry leaders, regulatory professionals and academic scientists, met in Dallas, TX on February 13-14, 2019 to review progress to date and work together in-person to build on that progress. The four working groups: Science & Prevention, Provenance Labeling, Traceability and Investigations met in break-out rooms to advance their thinking and present recommendations to the steering committee. This document summarizes the status of each workgroup, recommendations and next steps.

### **Executive Summary**

Following presentations by each of the four working groups, the Steering Committee discussed recommendations from each group, prioritized work goals, and agreed upon the following recommendations:

#### **1. Science/ Prevention Group Recommendations**

- Support current efforts to develop a science and risk-based model for evaluating and managing agricultural water, based on the source of water and its use.
- Develop guidance for produce industry-specific Root Cause Analysis to assist growers, processors, regulators and other stakeholders in assessing the cause of a pathogen in the event of positive environmental or product samples.
- Explore ways to provide more in-depth auditing of validation and verification procedures.
- Work with FDA Produce Safety team to relay FDA's research priorities to the Center for Produce Safety for consideration.

#### **2. Traceability Group Recommendations**

- Embrace a bold vision for traceability that can capture, retain and link information through the supply chain.
- Support use of the language of PTI and urge PTI labeling of all cases/packs of leafy green products.
- Develop systems and approaches that identify and narrow the scope of possible lots/suppliers of leafy greens at any given retail or foodservice establishment at any given time, and retain that information for immediate use in a traceback investigation.
- Gather feedback from FDA to refine a template industry can use to standardize the way traceback data are shared.

#### **3. Labeling Group Recommendations**

- Articulate that the mission is to provide consumers easy access to information about growing regions associated with romaine products.
- Publish and disseminate a revised Labeling Q&A that provides guidance on how to label consumer packaging of romaine to include standardized terminology for growing regions.

- For bulk, unpackaged product, or product destined for foodservice use, operations should refer to information on cases to determine if a product is subject to an advisory.
- The vision is that this is an interim step until better traceback mechanisms are in place.

#### **4. Investigation Group Recommendations**

- Engage FDA/CDC leadership to evaluate legal options to facilitate government/industry collaboration to accelerate and narrow outbreak investigations.
- Evaluate needs and opportunities for increased funding to FDA, CDC and states to accelerate and narrow outbreak investigations.
- Work with CDC and states to ensure the most current population consumption data of fresh produce items is used in epidemiological investigations.
- Consider potential value/methodology of a voluntary blinded industry database of pathogen testing (environmental, raw product, finished product) which could enhance knowledge and inform prevention strategies.
- Determine the value of trialing a voluntary database of harvest dates and shipping information that would support a rapid “trace-forward” in the event of an outbreak.

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## Full Report

### Science & Prevention Working Group

#### ***Ag Water***

A group of growers/processors have been working with facilitation from Western Growers to develop risk-based ag water metrics to address water safety and integrity. This effort is leading to the development of a proposal to LGMA for consideration. This is essentially a two-pronged approach to determine what cross contamination risks might be presented by various sources of ag water, and then evaluate how the ag water is to be used and delivered (overhead, furrow, drip irrigation, dust abatement, pesticide mixing, etc.). Water sources such as deep wells or municipal water are not likely to be contaminated by human pathogens and therefore would likely not require treatment or application restrictions. Open water sources, such as canals, ponds, rivers, etc. may be more likely to be contaminated with human pathogens and therefore growers would need to take precautions depending upon how the water might be used. For example, a grower would need to employ a validated water disinfection process if the water contacts the edible portion of the crop or use specific water delivery systems that avoid water/crop surface contact. The Task Force strongly supports continued to work on the development of this ag water approach.

#### ***Recommendation:***

- Review current efforts to develop a science and risk-based model for evaluating and managing agricultural water, based on the source of water and its use. It is important the model reflect the best science available and describe preventive controls and microbial metrics that growers can use to make ag water use decisions.

#### ***Timeline:***

- Feb 28: Webinar to introduce the risk-based approach to all stakeholders.
- April 1: Review final metrics document presented to the LGMA Board (March 28, 2019) and develop recommendation to Task Force.
- May 1: If adopted by LGMAs and the Romaine Task Force, Task Force to recommend to romaine buyers to require growers who are not part of LGMA to follow the risk-based water standard.

#### ***Root Cause Analysis***

Root cause analysis is a process to investigate the source of contamination when a contamination event has been discovered. Today, a positive test result or an observation of a hazard leads to the expedient action of bypassing that lot and moving on to other available product sources in order to make orders. However, by failing to go back and determine why a test was positive or why that hazard was observed, we fail to understand the issue and the result is that it may happen again. Pew Charitable Trusts has been working on guidance for conducting root cause analysis in the food industry and shared their draft document with the working group. This guidance is largely focused on food manufacturing, but the group has an opportunity to build on this work to include produce examples and/or develop a derivative that is produce specific. A small group of volunteers from the working group has taken on the task of reviewing the document and working on the development of tools that can be used by producers to conduct root cause analysis or alternatively, have the background to ask the right questions and bring in experts to assist in this complex task.

*Recommendation:*

- Develop guidance for produce industry-specific Root Cause Analysis to assist growers, processors, regulators and other stakeholders in assessing the cause of a pathogen in the event of positive environmental or product samples.

*Timeline:*

- April 15: The workgroup will draft 1-2 case studies illustrating how RCA can be used in the fresh produce environment. These will highlight (1) what circumstances should motivate a root cause analysis, (2) what mechanisms might be put in place to facilitate RCA's for producers.
- June 1: The workgroup will make recommendations regarding (1) how data might be collected and protected and (2) how results might be shared as educational opportunities.
- July 1: The workgroup will make recommendations for a detailed approach to systematic implementation of RCA by a trained team of experts.

***Audit Validation and Verification***

Although auditing reflects a snapshot in time, it does provide an opportunity to assess how validation and verification of processes have been conducted.

*Recommendation:*

Continue group discussions and create sample documents that illustrate how auditing could assess validation and verification of preventive controls that address risk factors present in the growing environment.

*Timeline:*

- March 30: Subgroup formed to explore this issue.
- May 15: Draft examples of how document to be available on how an audit could evaluate that validation and verification of ag water was appropriately conducted.
- June 15: Determine next steps, e.g., outreach to food safety standard owners?

**Traceability Working Group**

The working group and Task Force have embraced a vision and suggests that companies handling leafy greens will sign on to the vision and goals of a supply chain-wide traceability system. Specifically, the group seeks industrywide support to adopt systems and approaches that capture and maintain the GTIN and lot number of a product 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 that 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 A.

*Recommendations:*

- Adopt the following 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.”*
- Urge all leafy green packers or repackers to track and provide PTI labeling (i.e., GS1-128 scannable barcodes) on cases.
- 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).
- Encourage that key data elements are recorded for processed, commingled and/or repacked leafy greens and associated with the finished product lot.
- Upon request from a regulator, provide key data elements electronically in an established template.

*Timeline:*

- March 15: Define “leafy greens” that would be covered by the vision and stages. The LGMA definitions can be a starting point.
- March 31: Publish the vision and strategies and seek broad stakeholder input
- May 1: Work group to recommend additional stages of implementation (and associated timeframes) that move toward the vision.
- May 15: Finalize and disseminate a recommended template that can be used to electronically submit traceback data to regulators upon request.
- Jan 2020: Expect industry to label all cases of leafy greens with a PTI label.
- Sept 2020: Expect all retail and foodservice establishments to know, or be able to provide via their distributors, a definite range of GTINs and lot numbers of leafy greens possibly offered for sale in a given timeframe, within 2 hours of a request.

### **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 efficient as possible. This included discussion of standardizing locations and nomenclature for date labeling (although a harvest date is no longer a necessary element). However, it has become clear that this specific labeling approach is secondary to true traceability that can be useful in investigations. FDA has characterized this current provenance labeling as an “interim step” and urged the task force to put our highest energy into traceability.

*Recommendations:*

- To enable consumers to understand the applicability of an advisory to packaged product 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).
- Recommend the industry adopt the following standardized regions for labeling harvest location. Maps will be distributed 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.

*Timeline:*

- March 4: Post an updated Q&A document based on this current draft recommendation.
- March 31: Seek broad industry input on regions and other elements of the Q&A  
The draft Q&A is included as Appendix B.
- April 15: Post updated Q&A that reflects a final industry consensus approved by the steering committee. Begin industry communication process.
- May 1: Sunset this workgroup and fold into traceability group.

### **Investigations Working Group**

The investigation process consists of two basic parts: (1) epidemiological investigation that identifies an outbreak is underway and potential food vehicles involved and (2) traceback investigation that works back from where the ill consumers contacted the food to the source of that food. It is a complex process with many steps and involves local, state and federal public health officials. The working group recognized that we have an opportunity to make recommendations for change that might not have

been considered realistic before, including policy and legal change or new federal funding to build federal and state capacity.

*Recommendations:*

- Engage FDA/CDC leadership to establish an ongoing mechanism for communications and information exchanges to accelerate and narrow outbreak investigations.
- Evaluate needs and opportunities for increased funding to FDA, CDC and states to accelerate and narrow outbreak investigations.
- Work with CDC and states to ensure the most current population consumption data of fresh produce items is used in epi investigations.
- Consider potential value/methodology of a voluntary blinded industry database of pathogen testing (environmental, raw product, finished product) which could enhance knowledge and inform prevention strategies.
- Determine the value of trialing a voluntary database of harvest dates and shipping information that would support a rapid “trace-forward” in the event of an outbreak.

*Timeline:*

- March 15: Begin review of legal barriers to government/industry collaboration and information sharing during an FDA investigation, including evaluating existing CDC/industry collaboration process. [subgroup]
- April 1: Begin review of CDC’s current data on romaine/leafy green consumption and assist in supplementing current data if needed. [subgroup]
- April 15: Subgroup to review information on leafy greens as a public health product identification tool in a Wiki developed by the University of Colorado. [subgroup]
- June 1: Develop concepts and recommendations to support state and local public health resources
- June 15: Subgroup of 5-6 companies to collaborate on a trace-forward process to determine its efficacy in narrowing outbreak investigations more quickly.
- June 15: Develop recommendation and structure for industry pathogen data base.

## Appendix A. Draft Recommendations of Traceability Workgroup 4/1/2019

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:

1. 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).
2. Utilize [GS1 international standards](#) to identify, capture and share [Key Data Elements](#) as required or requested by FDA
3. 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
- Consider including GTIN/Lot information with the invoice or bill of lading.
- 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 to request technical input from FDA in the development of a standardized traceback data template by 5/1/19
- Leafy green suppliers to record and share Key Data Elements 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 (range of Lots/GTINs or specific lots), 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.
- 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.
- Supply chain members 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.

Future drafts will include a graphic that illustrates how each part of the supply chain evolves in each of the three phases.

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Appendix B. Provenance Labeling Draft Q&A

**Questions & Answers on Voluntary Romaine Growing Region Labeling  
March 25, 2019**

\*\*\*\* this is a draft; additional updates will be available and industry comment will be sought before this document is finalized\*\*\*\*

This questions and answer document, originally drafted by PMA and United Fresh using the information available from FDA ([commissioner statement](#) and [update](#)) and [CDC](#) , has been updated as an outcome of a discussion with a cross-section of the fresh produce industry charged with providing industry guidance for this voluntary program.

***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.***

1. **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.
2. **Does the labeling program apply to other leafy greens?** Not at this time.
3. **Is this a new regulation from FDA?** No, the use of this new label is a voluntary but is encouraged by FDA.
4. **What should the label (for both field packed and processed romaine) say?**
  - a. Romaine: (region(s))
    - i. See Question 10 for recommended regions
  - b. For indoor growers, the information in (a) should be preceded by the phrase: Indoor grown
5. **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.
6. **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.

7. **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.
8. **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)”
9. **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.
10. **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:

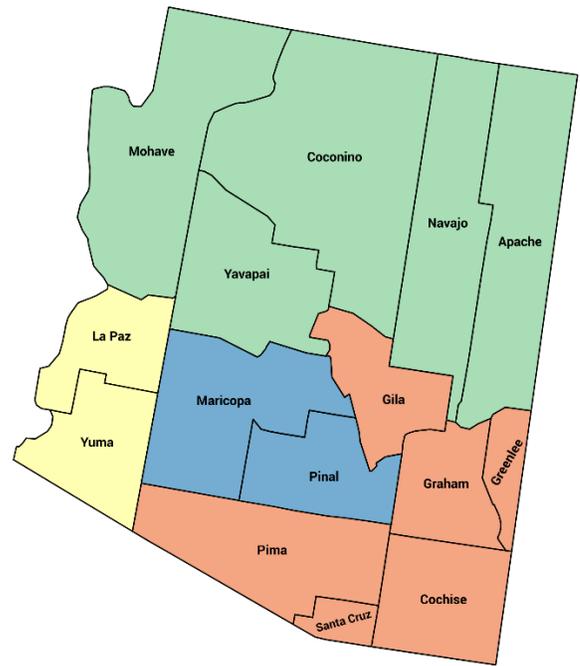
<u>Growing Region</u>	<u>Abbreviation</u>
Yuma*	Yuma
Phoenix	Phoenix
Southern Arizona	South AZ
Northern Arizona	North AZ
Northern California	North CA
Salinas	Salinas
Santa Maria	Santa Maria
Southern California	South CA
Imperial Valley	Imperial Vly
Coachella	Coachella
Central Valley	Central Vly
Northern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



11. **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.
12. **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.
13. **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.”
14. **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.
15. **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.
16. **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.
17. **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.
18. **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.

19. **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.
20. **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.
21. **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).
22. **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.
23. **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.

Example labels will be included in future drafts