

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

**** this is a draft that is still being reviewed by the Romaine Task Force, as reflected by the inclusion of “comments” highlighting some areas of continued discussion; 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 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:

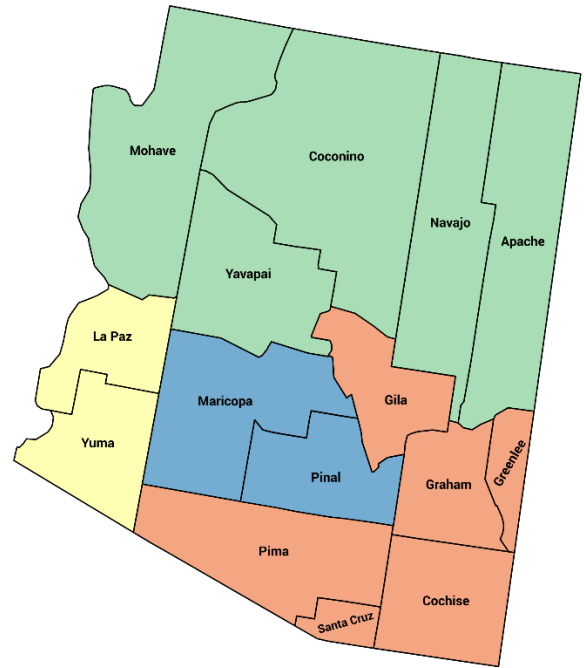
<u>Growing Region</u>	<u>Abbreviation</u>
Yuma*	Yuma
Phoenix	Phoenix
Southern Arizona	South AZ
Northern Arizona	North AZ
Northern California	North CA
Salinas	Salinas
Santa Maria	Santa Maria
Southern California	South CA
Imperial Valley	Imperial Vly
Coachella	Coachella
Central Valley	Central Vly
Northern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