A U.S. government investigation and related traceback of a foodborne illness outbreak linked to romaine lettuce from the Yuma, Arizona region earlier this year raised new questions from fresh produce industry members about traceability and the Produce Traceability Initiative (PTI). Those conversations yielded these FAQs.

**What is the difference between an outbreak investigation and a recall?**

Once a food is suspected of being associated with a foodborne illness outbreak, in the United States the Food and Drug Administration (FDA) and states try to determine where the ill persons purchased that food. Records are collected from retailers, restaurants, etc. where that food was likely purchased/consumed. The supply chain paths for several ill people are explored in the hope that those paths converge at a common processor, grower etc. where contamination could have occurred. At this point, the lot numbers of suspect product is not known; in fact, the traceback attempts to identify what lot(s) may be problematic. This is in contrast to a product recall, where a supplier identifies the scope of an issue and recalls the lot number(s) associated with a problem. Both traceback (aka outbreak investigations) and recalls rely on good recordkeeping across the supply chain, but the information is used to answer very different questions.

**Would better traceability have identified the grower associated with the romaine outbreak in the Yuma region?**

Based on this investigation’s traceback, it appears that there is *not* a single point of convergence. Separate “legs” of the traceback – that is, supply chain pathways from ill people to the source(s) of the product – suggest that contamination may have been widespread, impacting product from several companies. Traceability alone would not have solved this outbreak. However, better traceability capability would have expedited the investigation.

**Then why is better traceability needed?**

When a traceback investigation is unable to find a point of convergence, as has been the case of the Yuma region romaine outbreak, the next best step is to establish confidence that the entities indicated by the traceback were actually involved in the issue and not “innocent bystanders”. If a retailer can’t definitively say that product offered for sale came from supplier A, not supplier B, or a processor can’t differentiate grower X’s product from grower Y’s, the traceback diagram will be unable to identify entities that were and weren’t involved in the issue. If the traceback can be limited to only those links across the chain supplying potentially contaminated product, that can help focus investigators on where to look to try to determine what these firms had in common (e.g., a common water source).

**Which parts of the supply chain need to do better?**

All parts of the supply chain can, and must, do better. FDA begins a traceback investigation at the point of sale/service. This is sometimes referred to as the “last mile”. When adequate records are lacking at this point, the investigation stops or is substantially hindered. “Adequate records” would include knowing what lot numbers of product were sold in a given timeframe. While this kind of detailed information is not required to be kept by law, its absence delays and sometimes prevents a traceback investigation. At other points in the supply chain, traceability can be limited by factors including the
inability to differentiate lot numbers shipped in mixed pallets, the inability to demonstrate which case went to which customer, the lack of adequate record keeping across the supply, and the commingling of raw and finished product.

If product is going to be commingled (at processors, at retail, etc.) then why bother keeping records? Even when product is commingled, it is imperative to capture the lot numbers of the input products and the output finished goods. When product is commingled, recording of the input lot numbers and the corresponding output lot numbers will speed up the investigation and ensure that product not involved in the recall is not implicated.

What is the current status of traceability regulations?
- In the United States: The Bioterrorism Act of 2002 and its implementing regulations of 2005 require one up, one down recordkeeping. Implementing regulations have not yet been proposed for the Food Safety Modernization Act’s traceability requirement. FDA does now have authority to require additional records be kept for “high risk foods” (which have not yet been defined).
- In Canada: The new Safe Food for Canadians Regulations will come into force starting January 2019, and include traceability requirements relative to lot numbers, record keeping and labelling.

What is the produce supply chain currently doing to improve traceability?
- Implementation of the Produce Traceability Initiative continues across the supply chain.
- Industry leaders continue to work with regulators, standards bodies, consumer groups and other stakeholders to ensure efficacious traceability for industry.
- Produce industry associations continue to work globally to ensure that common solutions for traceability are implemented regardless of the country or region of origin.
- Global Food Traceability Center continues to educate regulators, industries and companies on traceability best practices.
- Blockchain traceability and transparency pilots now underway with Walmart, Kroger, Wegmans, Dole, Driscoll’s and IBM are based on PTI, and demonstrate the value of whole chain traceability.

PTI is unique to fresh produce, doesn’t it present challenges to distributors, retailers and restaurants who handle all types of foods?
PTI is based on GS1 Standards and is aligned with all food traceability solutions. In fact, other fresh-food industries are using PTI as the model for their traceability initiatives.

What is the current adoption rate of PTI?
The majority of major grower shippers of fresh produce have implemented PTI. There is less adoption on the buy side of the supply chain.

Is blockchain going to make PTI obsolete?
No, in fact the traceability/transparency blockchain pilots underway now are based on PTI and GS1 Standards, and require PTI case labeling.

What should I do?
- If you’ve not already done so, implement PTI and ensure there is a commitment to traceability within your organization. For more information and implementation resources and tools are available at www.productraceability.org.
- Review the PTI Guidance Document for Sharing Traceback Data to ensure your company can provide the required data when required:
  

- Familiarize yourself with the traceability regulations in all countries that you ship product to.

*Prepared by:*