Traceability Frequently Asked Questions – August 2018

- What is the difference between an outbreak investigation and a recall?
    - Once a food is suspected of being associated with an outbreak, FDA and states try to determine where the ill person 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 hopes that they converge at a common processor, grower etc. where contamination could have occurred. Lot numbers are not known; in fact, the traceback attempts to identify what lot(s) may be problematic. This is in contrast to a recall, where a supplier identifies the scope of an issue and recalls the lot number(s) associated with it. Both tracebacks (outbreak investigations) and recalls rely on recordkeeping, but the information is used to answer very different questions.
- Would better traceability have identified the grower associated with the romaine outbreak in Yuma region?
    - Based on the current traceback, it appears that there is *not* a single point of convergence. Separate "legs" of the traceback (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 would have expedited the investigation.
- Then why is better traceability needed?
    - When a traceback diagram is unable to find a point of convergence, as in the case of the Yuma region Romaine outbreak, the next best possibility is confidence that the entities indicated in 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 in the supply chain of potentially contaminated product, it 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 the producer's lot numbers associated with product 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 an investigation. At other points in the supply chain, the inability to differentiate lot numbers on 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 that occurs all limit traceability.

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- If product is going to be commingled (at processors, at retail, etc.) then why bother keeping records?
    - Even when product is comingled, it is imperative to capture the input and output lot numbers. When product is comingled, 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?
    - US – One up, one down recordkeeping requirements were finalized by FDA in 2005 based on authority under the Bioterrorism Act. There are no new FSMA-related traceability regulations yet although FDA does have authority to require additional records be kept for "high risk foods" (which have not yet been defined).
    - 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?
    - PTI implementation continues
    - Industry continues to work with regulators, standards bodies, consumer groups and other stakeholders to ensure efficacious traceability for industry
    - Produce Associations continue to work globally to ensure that common solutions for traceability are implemented regardless of the country or region.
    - Global Food Traceability Center continues to educate regulators, industries and companies on traceability best practices
    - The Blockchain traceability and transparency pilots underway with Walmart, Kroger, Wegmans, Dole, Driscoll's and IBM are based on PTI implementation and demonstrating the value of whole chain traceability.
- If PTI is unique to produce, won't this present challenges to distributors, retailers, and restaurants who handle all types of products?
    - PTI is based on GS1 standards and is aligned with all food traceability solutions.
- What is the current adoption of PTI?
    - The majority of major grower shippers have implemented PTI. There is less adoption in the buy side of the supply chain.
- Is blockchain going to make PTI obsolete?
    - No, the traceability/transparency Blockchain pilots 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 commitment to traceability within your organization.
    - Review the PTI Guidance Document for Sharing Traceback Data to ensure your company can provide the required data when required
        - https://www.producetraceability.org/documents/Guidance_Document_for_Sharing_Traceback_Data_R1.0_Sept2015.pdf
    - Familiarize yourself with the traceability regulations in all countries you ship product to.

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