



FDA FSMA Food Traceability Final Rule

Video Presentation: How the Food Traceability Rule works: Produce Supply Chain Example

Watch on <https://youtu.be/ZcSBvLQ6p6M>

[Slide] The Food Traceability Rule requires persons who manufacture, process, pack, or hold foods on the Food Traceability List or FTL, to maintain and provide to their supply chain partners, specific information— called Key Data Elements or KDEs – for certain Critical Tracking Events or CTEs, in the food’s supply chain. This framework forms the foundation for effective and efficient tracing of food.

[Slide] This example shows a supply chain for fresh cucumbers which will be sold at retail. **Fresh cucumbers** are on the Food Traceability List, so all of the entities in this supply chain are covered by the Food Traceability Rule. Next, we will walk through the Critical Tracking Events in this supply chain where Key Data Elements are required.

[Slide] The farm in this example grows cucumbers, but does not harvest, cool or pack them. Therefore, the farmer does not need to maintain Key Data Elements related to growing the cucumbers.

[Slide] The person who harvests the cucumbers, a contract **harvester** in this example, must maintain Key Data Elements related to the harvesting of the cucumbers. They must also provide certain Key Data Elements to the initial packer of the cucumbers, either directly or through the supply chain.

[Slide] Then the cucumbers are sent to an off-site **cooler**. The cooler must maintain Key Data Elements related to the cooling of the cucumbers, and they also must send certain Key Data Elements to the initial packer. These Key Data Elements are only required for FTL foods that are cooled before they are packed. This is not always the case. For example, some farms field-pack their produce, in which case the produce is not cooled before it is packed. In this situation, Key Data Elements for Cooling would not be required.

[Slide] Next, the cucumbers are sent to a packinghouse to be packed. This is the first time the cucumbers will be packed, so the packinghouse is considered the **Initial Packer**. As the Initial Packer, the packinghouse must maintain Key Data Elements related to their packing of the cucumbers. These KDEs include information about the harvesting and cooling of the cucumbers. The packinghouse will have that information because it was sent by the harvester and cooler, as discussed on the previous slide.

The Initial Packer must also assign a **Traceability Lot Code** or TLC to the fresh cucumbers. The TLC is a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the firm’s records. The place where the food is assigned a traceability lot code is known as the Traceability Lot Code Source. The TLC makes it possible for the FDA to make linkages within a firm and across a supply chain. If the FDA knows the TLC and who assigned it, we can go right to that entity during an outbreak investigation. This helps us to identify the contaminated food more quickly; and it may help to mitigate additional illness, and potentially save lives.

There are only a few activities in the supply chain during which a TLC can be assigned – when you initially pack a raw agricultural commodity (as shown in the example); when you perform the first land-based receiving of a food obtained from a fishing vessel; or when you transform a food on the Food Traceability List. The Traceability Lot Code must be linked in the firm’s records with the Key Data Elements associated with that lot of food.

Now that the cucumbers have been packed and a TLC has been assigned, the packinghouse is going to send them to a Produce Processor who will repack them for sale at retail. The packinghouse must maintain Key Data Elements related to the **Shipping** of the fresh cucumbers to the next point in the supply chain -- the Produce Processor. The packinghouse must also send many of these Key Data Elements to the Produce Processor.

[Slide] The Produce Processor receives the fresh cucumbers from the packinghouse. The Produce Processor must keep **Receiving** KDEs for the fresh cucumbers they receive. Most of the information that they need for these Receiving records will be sent to them by the packinghouse.

In this example, the Produce Processor is going to repack the cucumbers for sale at retail. Repacking is a **Transformation** event for which the Produce Processor must keep transformation KDEs. Since this is a transformation event, the Produce Processor is a TLC Source and must assign a TLC to the repacked cucumbers. The Produce Processor must maintain records which contain the incoming traceability lot codes for the cucumbers that they are going to repack. The Produce Processor must link those records with the TLC that they assign to the new lot of repacked cucumbers. This is important since repacking has historically been a place where traceability breaks down.

Now that the cucumbers have been repacked, the Produce Processor is going to send them to a Distribution Center for distribution to retail. The Produce Processor must maintain Key Data Elements related to the **Shipping** of the fresh cucumbers to the Distribution Center and send many of these KDEs to the Distribution Center.

[Slide] The Distribution Center receives the repacked fresh cucumbers from the Produce Processor. Therefore, the Distribution Center must keep **Receiving** KDEs of the fresh cucumbers that they receive. Most of the information they need for these Receiving KDEs will be sent to them by the Produce Processor. Unlike the initial packer or Produce Processor, the DC is not a TLC Source and therefore must not assign a new TLC to the food.

Since the Distribution Center (or DC) will be shipping the cucumbers to a retail store, the DC must maintain Key Data Elements related to the **Shipping** of the cucumbers to the next point in the supply chain -- the Retail Food Establishment. The DC must also send many of these KDEs to the Retail Food Establishment.

[Slide] The Retail Food Establishment receives the repacked fresh cucumbers from the Distribution Center. The Retail Food Establishment must keep **Receiving** KDEs of the fresh cucumbers they receive. Most of the information they need for these Receiving KDEs will be sent to them by the Distribution Center.

[Slide] Additionally, all entities covered by the Rule are required to maintain a **Traceability Plan**. During an inspection or in the case of an outbreak investigation, the Traceability Plan will help the FDA understand the firm’s traceability records. The Traceability Plan must include:

- A description of the procedures used to maintain the records required by the rule;
- A description of the procedures used to identify foods on the Food Traceability List that you manufacture, process, pack, or hold. For farms, this includes any foods on the Food Traceability List that you grow.
- A description of how you assign traceability lot codes to foods on the FTL, if applicable.
- A point of contact for questions regarding your traceability plan and records; and
- a farm map showing the areas where you grow or raise foods on the FTL.

In this example, because the farmer grows cucumbers, the farmer's traceability plan must include a **farm map** that shows the location and name of each of their cucumber fields. The farmer does not have to share this farm map with anyone else in the supply chain. But the farmer must make it available to FDA during an investigation.

[Slide] Maintaining these Key Data Elements at each critical tracking event in the supply chain is essential and is a requirement of the rule. This will ensure that, if an outbreak does occur, the FDA can quickly and efficiently trace the contaminated food through the supply chain. The FDA can provide critical information to the public more quickly, and work with the affected firms to remove any contaminated product from the marketplace, avoiding additional illnesses and potentially saving lives.

Additional information about the requirements in the final rule are available on the FDA's website at www.fda.gov.