



## FDA FSMA Food Traceability Final Rule

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

Watch on <https://youtu.be/OwnSiC5xqqs>

[Slide] The Food Traceability Rule requires persons who manufacture, process, pack, or hold foods on the Food Traceability List (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 is a soft cheese supply chain. **Soft cheese** is on the Food Traceability List, so all the entities that handle the cheese 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] Milk and the other ingredients – salt, cultures, and rennet – that are used to produce the soft cheese are not foods on the Food Traceability List. So the farm that produces the milk and the supplier who provides the other ingredients are not covered by the rule. They do not have to maintain any records under the rule.

[Slide] The milk, salt, cultures and rennet are sent to a **Cheese Manufacturer** who makes the soft cheese. Since the milk, salt, cultures and rennet are not on the Food Traceability List, the Cheese Manufacturer does not have to maintain any Receiving KDEs for the cheese ingredients.

Making a food that is on the Food Traceability List, such as soft cheese, is a **Transformation** event. So, the Cheese Manufacturer must keep Transformation KDEs. Because none of the incoming ingredients are on the Food Traceability List, these Transformation KDEs will not include any information that relates to those incoming ingredients, such as the lot codes for those products not on the Food Traceability List. The only Transformation KDEs that are required in this situation are the Key Data Elements that relate to the soft cheese that is the output of the transformation event.

The Cheese Manufacturer must also assign a **Traceability Lot Code** or TLC to the soft cheese. 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 enables the FDA to make linkages within a firm and across a supply chain. If we know the TLC and who assigned it, we can go right to that entity during an outbreak investigation. This helps FDA 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 transform a food (as is being done in this example); when you initially pack a raw agricultural commodity; or when you perform the first land-based receiving of a food obtained from a fishing vessel. The TLC must be linked in the firm’s records with the KDEs.

Next, the Cheese Manufacturer is going to send the soft cheese to a Distribution Center for distribution to retail. So, the Cheese Manufacturer must maintain Key Data Elements related to the **Shipping** of the soft cheese to the next point in the supply chain, the Distribution Center. The Cheese Manufacturer must also send many of these KDEs to the Distribution Center.

[Slide] The Distribution Center or DC receives the soft cheese from the Cheese Manufacturer, and the DC must keep **Receiving** KDEs of the soft cheese that they receive. Most of the information that the DC needs for these Receiving KDEs will be sent to them by the Cheese Manufacturer. Unlike the Cheese Manufacturer, the DC is not a TLC Source and therefore must not assign a new TLC to the food.

Next, the DC plans to ship the cheese to a retail store, so they must maintain Key Data Elements related to the **Shipping** of the cheese to the next point in the supply chain, the Retail Food Establishment. They also must send many of these Key Data Elements to the Retail Food Establishment.

[Slide] The Retail Food Establishment receives the soft cheese from the Distribution Center, and therefore the Retail Food Establishment must keep **Receiving** KDEs of the cheese that they receive. Most of the information that the RFE needs for these Receiving KDEs will be sent to them by the DC.

[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 FDA understand a 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 FTL that you manufacture, process, pack, or hold;
- A description of how you assign traceability lot codes, if applicable; and
- A point of contact for questions regarding your traceability plan and records.

The Traceability Plan has additional requirements if you grow or raise a food on the FTL (other than eggs), but those requirements are not relevant to anyone in this supply chain.

[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, FDA is able to 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 to avoid additional illness and to potentially save lives.

Additional information about the requirements in the final rule are available on our website at [www.fda.gov](http://www.fda.gov).