FDA U.S. FOOD & DRUG ADMINISTRATION

FDA FSMA Food Traceability Final Rule
Video Presentation: How the Food Traceability Rule works: Seafood Supply Chain Example

Watch on https://youtu.be/RCT86_Nhwmc

[Slide] The Food Traceability Rule requires people 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 tuna which is sold at a restaurant as tuna steaks. **Tuna** is a **Finfish** and is on the Food Traceability List; therefore, all entities in this tuna 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] In this example, tuna is caught at sea by a **fishing vessel.** Fishing vessels are largely exempt from the rule. If the owner, operator or agent in charge of the fishing vessel is NOT required to register under section 415 of the Food Drug & Cosmetic Act as part of FDA's food facility registration requirements, then the fishing vessel is completely exempt, and the owner does not have to keep records under the final rule. If they ARE required to register under section 415, then the owner, operator, or agent in charge of the fishing vessel must maintain records identifying the immediate previous source and immediate subsequent recipient of the food. However, they do not have to retain other records under the rule.

[Slide] The tuna arrives at port and is sold to a seafood company who will sort the fish and send them on to be processed. This seafood company is the **First Land-based Receiver**, since they are the person taking possession of the food for the first time on land directly from a fishing vessel. As the First Land-Based Receiver, the seafood company must maintain Key Data Elements specifically related to their first land-based receiving of the tuna. This includes the harvest date range and locations for the trip during which the tuna was caught, information the seafood company may need to obtain from the fishing vessel. The Rule does not specify *how* that information must be obtained, to provide flexibility for a variety of supply chains and operations.

The First Land-based Receiver must also assign a **Traceability Lot Code** or TLC to the fresh tuna. 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 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 perform the first land-based receiving of a food obtained from a fishing vessel (as shown in the example); initially pack a raw agricultural commodity; or when you transform a food on the Food Traceability List. The TLC must be linked in the firm's records with the Key Data Elements associated with that lot of food.

Now that the tuna has been received on land, the seafood company is going to send it to a fish processor who will turn it into tuna steaks for sale at a restaurant . The seafood company must maintain Key Data Elements related to the **Shipping** of the tuna to the next point in the supply chain -- the Seafood Processor. The seafood company must also send many of these KDEs to the Seafood Processor.

[Slide] The Seafood Processor receives the tuna from the seafood company and therefore, they must keep **Receiving** KDEs of the tuna that they receive. Most of the information that they need for these Receiving KDEs will be sent to them by the seafood company.

In this example, the Seafood Processor is going to transform the tuna from whole fish into tuna steaks for sale at a restaurant. This is a **Transformation** event. The Seafood Processor is a TLC Source and must assign a TLC to the tuna steaks. The Seafood Processor must also keep transformation KDEs. As part of these Transformation KDEs, they must maintain records containing the incoming traceability lot codes for the tuna and link that information with the traceability lot code that they assign to the new lot of tuna steaks.

Next, the Seafood Processor is going to send the tuna steaks to a Distributor for distribution to a restaurant. The Seafood Processor must maintain Key Data Elements related to the **Shipping** of the tuna steaks to the next point in the supply chain -- the Distributor. They must also send many of these KDEs to the Distributor.

[Slide] The Distributor receives the tuna steaks from the Seafood Processor. Therefore, the Distributor must keep **Receiving** KDEs of the tuna steaks that they receive. Most of the information they need for these Receiving KDEs will be sent to them by the Seafood Processor. Unlike the First Land-based Receiver or the Seafood Processor, the DC is not a TLC Source and therefore must <u>not</u> assign a new TLC to the food.

Because the Distributor is shipping the tuna steaks to a restaurant, the Distributor must maintain Key Data Elements related to the **Shipping** of the tuna steaks to the next point in the supply chain -- the Restaurant. The Distributor must also send many of the KDEs to the Restaurant.

[Slide] The Restaurant receives the repacked tuna steaks from the Distributor. So, the Restaurant must keep **Receiving** KDEs of the tuna steaks that they receive. Most of the information they need for these Receiving KDEs will be sent to them by the Distributor.

[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 Food Traceability List - other than eggs. However, 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, avoiding additional illnesses and potentially saving lives.

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