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FDA Traceability Rule for the Seafood Industry

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Introduction

The Food Traceability Rule, published by the U.S. Food and Drug Administration (FDA 2022a), will take effect on Jan. 20, 2026. The goal is to help trace food products through the supply chain, with a particular focus on foods on the FDA's Food Traceability List (https://bit.ly/fdafoodtraceabilitylist). The new rule is part of the Food Safety Modernization Act and is designed to help the FDA and industry stakeholders more quickly and effectively identify recipients of potentially contaminated food to prevent or mitigate foodborne illness outbreaks. The rule establishes a standardized approach to traceability recordkeeping, paving the way for more efficient tracing of food products through the supply chain. This publication focuses on the traceability rule for Virginia's seafood industry.

Key Concepts

Before establishing procedures to comply with the Food Traceability Rule, it is helpful to become familiar with its terms and overall concepts.

Supply Chain Roles and Terms

First Land-Based Receiver: The person or entity taking possession of a food product for the first time on land directly from a fishing vessel. This role is crucial in initiating the traceability documentation process for seafood products.

Fishing Vessel: Any vessel, boat, ship, or other craft used for, equipped for, or typically used for fishing or assisting vessels at sea in fishing-related activities. This includes preparation, supply, storage, refrigeration, transportation, or processing activities as defined by the Magnuson-Stevens Fishery Conservation and Management Act (downloadable at https://www.govinfo.gov/content/pkg/COMPS-1678/pdf/COMPS-1678.pdf).

Note that fishing vessels have specific exemptions from certain recordkeeping requirements under the FTR.

Food Traceability List

The FDA's Food Traceability List contains several seafood products that require additional traceability records:

- Finfish (fresh and frozen).
- Smoked finfish.
- Crustaceans.
- Molluscan shellfish, except scallop adductor muscle (FDA 2023).
- Bivalves (fresh, frozen, and previously frozen).

Important exemptions include raw bivalve mollusks inspected under the National Shellfish Sanitation Program. While not all seafood products appear on the FTL, many seafood businesses must comply with the rule due to their handling of listed products. For the complete list, see the FDA's Food Traceability List (https://bit.ly/fdafoodtraceabilitylist).

Critical Tracking Events

Critical Tracking Events are activities in the supply chain where recordkeeping of Key Data Elements (see below) is required. For seafood, examples of CTEs include:

1. Harvesting: The initial capture or collection of seafood.
2. First Land-Based Receiver: The initial onshore location that receives seafood after harvest.
3. Shipping: Each instance of shipping FTL foods to another entity.

4. Receiving: Each instance of receiving FTL foods from another entity.

5. Transformation: Activities that change the form of the food (for example, cutting, cooking, or mixing ingredients).

Traceability Lot Code

A Traceability Lot Code is a unique combination of either numbers or letters that will generate a code to identify a traceability lot. TLCs are assigned by a company depending on the critical tracking event:

- When receiving seafood as a first land-based receiver.
- When transforming a food into a product on the FTL.
- When combining or mixing listed foods.

If the traceability lot remains unchanged during these events (for example, during a simple shipment from one facility to another without transforming the product), the same TLC can be used across multiple Critical Tracking Events (such as shipping and receiving events). If the product is transformed (for example, repackaging, processing, or combining different traceability lots into a new product), a new TLC must be assigned at the transformation event.

Key Data Elements

Key Data Elements are specific pieces of information that must be recorded for each CTE. These might include:

1. Traceability Lot Code (TLC).

2. Location information (e.g., location name, address).

3. Date and time of the event.

4. Quantity and units of measurement.

5. Item description.

6. Business name of the immediate previous source and immediate subsequent recipient.

7. Reference document type and number (for example, purchase order number, bill of lading number).

The specific Key Data Element will vary depending on the Critical Tracking Event and the role of the entity in the supply chain.

Traceability Plan

Any entity covered by the FTL needs to write and implement a traceability plan, which must include the following information:

1. Procedures to maintain the records for the rule compliance, including the format and location of where to find the records.

2. Procedures that are used to identify which foods on the FTL are included in the traceability plan (manufacturing, processing, packing, or holding).

3. Procedures followed to assign traceability lot codes (if applicable to the operation).

4. Contact information for the person or office that can answer any traceability compliance questions.

5. For aquaculture farms, a map of the area where the food listed on the FTL is produced, including the location and name of each pond, pool, tank, cage, etc., used to raise the seafood, including geographic coordinates.

An example of a Traceability Plan for Farms can be downloaded at https://bit.ly/farmtraceabilityplanexamplePDF.

Traceability Rule Example: Virginia Blue Crab Supply Chain

The following example illustrates how the traceability rule applies to Virginia's blue crab industry, a significant local seafood sector. The example is based on an FDA presentation focusing on wild-caught tuna (2022b); the key steps are similar.

1. Harvesting (Partial Exemption for Vessels)

- The vessel records key harvest data: date, location, and quantity caught.
- Basic records are maintained on the vessel, with full documentation beginning at first land-based receiver.
- Partial exemption for fishing vessels: Fishing vessels do not need to keep traceability records if they only harvest and deliver raw seafood. If a fishing vessel also processes seafood onboard (for example, cutting, cooking, repackaging), it may be required to comply with traceability rules.

2. First Land-Based Receiving

- The processor/dealer receives the catch and generates the initial Traceability Lot Code. The TL must be unique and traceable throughout the supply chain, which generally includes the company identifier, harvest date or receipt date, fishing vessel identifier, species or product type. An example TLC format would be "FLBR123-20240226-TUNA001," in which FLBR123 represents the facility ID of the first receiver; 20240226 represents the date of receipt (YYYYMMDD); and TUNA001 refers to the species and lot number.
- The entity also records comprehensive Key Data Elements: reception date/time, quantity, vessel ID, location details.
- This stage initiates the formal traceability documentation.

3. Processing

- For picked crab meat or other processed products, this step should record transformation details, including the Traceability Lot Codes for inputs and outputs.
- Documents should include processing date, location, quantity, and product specifications.

4. Distribution

- Shipping: The entity records outbound Traceability Lot Codes, date/time, quantity, and destination.
- Receiving: The entity documents inbound TLCs, date/time, quantity, and source.

End consumers include retail markets, restaurants, and direct consumers, each requiring appropriate traceability documentation through the final sale point.

Implications for Seafood Businesses

The Food Traceability Rule has a number of implications for businesses that produce, process, distribute or otherwise handle seafood. To prepare to comply with the rule, managers should focus on key elements in their operations.

1. Recordkeeping

- Implement systems to capture and maintain required Key Data Elements for each Critical Tracking Event.
- Institute a plan to maintain FTR records for two years from the date of their creation.
- Be prepared to provide the FDA with sortable electronic spreadsheets containing relevant traceability information within 24 hours of a request.

2. Supply Chain Communication

- Ensure Key Data Elements are shared with subsequent recipients in the supply chain.
- Develop protocols for efficiently communicating traceability information both upstream and downstream.

3. Traceability Lot Codes

- Develop a system for assigning and tracking traceability lot codes throughout the operation.
- Ensure the TLC system can link Key Data Elements for all relevant Critical Tracking Events.

4. Training

- Educate staff on new recordkeeping requirements and procedures.
- Conduct regular refresher training sessions to ensure ongoing compliance.

5. Technology

- Consider adopting or upgrading technology solutions to facilitate efficient data capture and sharing.
- Explore options such as blockchain, cloud-based traceability systems, or specialized food traceability software.

6. Compliance Assessment

- Conduct a thorough review of current traceability practices.
- Identify gaps between current practices and rule requirements.
- Develop and implement a plan to address any identified gaps.

7. Supply Chain Partnerships

- Engage with suppliers and customers to ensure alignment on traceability practices.

- Consider conducting mock traceability exercises with supply chain partners to test system effectiveness.

Benefits of Enhanced Traceability

Enhanced traceability systems provide significant operational and market advantages.

1. Improved Food Safety Response

- Rapid identification of product sources and distribution.
- Enhanced capability for targeted recalls.
- Reduced scope and impact of safety incidents.

2. Market Differentiation

- Enhanced product verification capabilities.
- Increased consumer confidence.
- Potential access to premium markets.

3. Operational Efficiency

- Improved inventory management.
- Enhanced supply chain visibility.
- Reduced waste and improved resource allocation.

4. Risk Management

- Better documentation for liability protection.
- Improved insurance positioning.
- Enhanced regulatory compliance.

Conclusion

The FDA's Food Traceability Rule represents a significant advancement in seafood industry safety and transparency. Although implementing the rule will demand careful planning and resource allocation, the resulting improvements in traceability systems offer substantial benefits beyond regulatory compliance. As the January 2026 compliance date approaches, seafood businesses should begin preparing their systems and staff for these new requirements. For additional information and updates, visit the FDA's Food Safety Modernization Act website at https://www.fda.gov/fsma. Seafood businesses are encouraged to consult with food safety experts or legal counsel to ensure full understanding and compliance with the rule as it applies to their specific operations.

References

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