

FDA Traceability Rule – Common Misconceptions

[If you don't think you need to comply with the FDA Traceability Rule,](#)

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	Myth	Reality
GENERAL		
#1	My traceability program is already capable of tracing all the way to the fishing vessels/ponds; therefore, we are already in compliance with the Traceability Rule.	The Traceability Rule has requirements that are not typically covered in “sustainability” traceability programs: Traceability Lot Code (TLC) and TLC Source, and Traceability Plan just to name a few. It is important to check the details in the rule to see if you meet all the requirements.
#2	To comply with the new Traceability Rule, we must install computerized systems.	While using computer software will help reduce the burden on data and record management, it is not required by the rule.
#3	The Traceability Rule (<i>21 CFR Part 1 Subpart S - Additional Traceability Records for Certain Foods</i>) replaces all other FDA traceability requirements.	The Traceability Rule (<i>21 CFR Part 1 Subpart S - Additional Traceability Records for Certain Foods</i>) outlines <u>additional</u> traceability requirements applicable to certain foods as identified under the rule. Entities subject to the new Subpart S are also subject to the existing “one-up, one-back” rule (<i>21 CFR Part 1 Subpart J - Establishment, Maintenance, and Availability of Records</i>).
#4	We do not handle any product on the Food Traceability List; therefore we are exempt from <u>all</u> traceability requirements.	If you are currently subject to the “one-up, one-back” traceability requirements under <i>21 CFR 1 Part 1 Subpart J - Establishment, Maintenance, and Availability of Records</i> , you are required to continue to meet the Subpart J requirements.

	Myth	Reality
#5	To comply with the Traceability Rule, as a Processor / Importer / Warehouse / Distributor / Retailer / Restaurant, I need to receive and pass on to my customers all the CTE/KDE from the point of harvest.	<p>According to the Rule, the Key Data Elements (KDEs) related to a harvest Critical Tracking Events (CTEs) are not passed beyond the first receiver from the fishing vessel or the initial packer from the farm, and therefore are not required to be tracked and reported for the purpose of the Traceability Rule by the subsequent entities such as (Processor / Importer / Warehouse / Distributor / Retailer / Restaurant).</p> <p>Each entity in the supply chain is only responsible for complying with the portions of the Rule that apply to them, based on the CTEs they perform.</p>
Importer		
#1	I am an importer and therefore I am exempted by the Rule	That depends. The Rule applies to anyone who manufactures, process, packs or holds foods on the Food Traceability List (FTL). If your company physically performs any of the above activities, then you are covered by the Rule.
#2	We are an importer and do not manufacture, process, pack or hold foods on the Food Traceability List (FTL), therefore we do not need to worry about the rule.	Importers act as the conduit between foreign suppliers and the US market. It is important for importers to understand the rule so they can help their suppliers in complying with the rule. At the end of the day, if your supplier is found non-compliant by the FDA or if their product is implicated in an outbreak, it will affect your product and your sales. While not required, adding FSMA Traceability compliance to your Seafood HACCP Importer Verification Program through your specification and/or affirmative action step would be a best practice.

	Myth	Reality
#3	Traceability Lot Code (TLC) and TLC Source are between the processor, the distribution center, and the customer. As an importer, we can continue with our current internal lotting practice.	Due to the size of an ocean container, it is common for an importer to consolidate multiple products in one shipment, and sometimes with multiple lots. The current practice is to assign an internal lot for each shipment. However, with the new Traceability Rule, the importer may need to review and determine if their lotting practice aligns with the TLC requirement. Importers should work with their suppliers, cold storages, and customers to ensure proper TLC and TLC Source are received, maintained, and passed on.
Foreign Entity		
#1	We are a first land-based receiver/processor/cold storage/etc. in a foreign country and we do not ship to the US directly, therefore we do not need to follow the Food Traceability Rule.	If a product on the Food Traceability List eventually gets sold into the US market, all Critical Tracking Events (CTE) that happen in both the US and in foreign countries, are subject to the rule.
Cold Storage / Warehouse		
#1	We are a cold storage facility/warehouse for our customers. The products are not our brand and we do not own the products. Therefore, the Traceability Rule does not apply to us.	The Traceability Rule applies to persons who manufacture, process, pack or <u>hold</u> foods on the Food Traceability List. Therefore, the rule applies to Cold storage/Warehouse if the products they hold are on the Food Traceability List, even if they do not own the products or the brands.
#2	We already have a comprehensive electronic system to assign and track lots from receiving to shipping. Therefore, we do not need to be concerned with the new Traceability Rule.	The Traceability Rule has requirements not typically covered in the traditional traceability program such as the Traceability Lot Code (TLC) and TLC Source, and Traceability Plan just to name a few. It is important to check the details in the rule to see if you meet all the requirements. For example, the TLC and TLC Source cannot be changed unless a transformation event occurs at the Cold Storage/warehouse, and they must pass forward to the next receiver.

	Myth	Reality
Distributor		
#1	Distributors are not defined in the Final Rule, so this rule does not apply to me.	The rule does not define “distributors” but does define “Holding” to mean storage of food and includes activities performed as a practical necessity for the distribution of that food. The final rule is event based so if you receive and ship (both identified as Critical Tracking Events or CTEs) you must keep and pass forward the required Key Data Elements (KDEs).
NOAA SIMP		
#1	The species we import is already included in SIMP (Seafood Import Monitoring Program). SIMP already covers all the Traceability Rule requirements.	While there are similarities in record requirements between SIMP and the Traceability Rule, they are not identical. There are specific requirements in the rule that are not captured under SIMP. You don’t have to duplicate records if your SIMP records include any of the information required in the Traceability Rule. Check the NFI SIMP vs. Traceability Rule Comparison for more information (Appendix A).
National or International Standard		
#1	We are GFSI (Global Food Safety Initiative) certified and therefore already in compliance with the Traceability Rule.	The Traceability Rule has very specific requirements that are not currently covered in the GFSI benchmarked schemes (BRC, SQF, IFS, Global GAP, etc.). The Food Traceability rule seeks to standardize the data elements and information firms must establish and maintain, and the information they would need to send to the next entity in the supply chain to facilitate rapid and accurate traceability. The Traceability Rule requires additional information to provide the linkages between all steps in the supply chain to facilitate rapid and accurate traceability. This isn’t the case with the existing “one up, one back” traceability concept for foods.

	Myth	Reality
#2	All our processing plants have BRC/ FSSC 22000/etc. (<i>GFSI benchmarked certification</i>); doesn't that cover traceability?	<p>That depends. BRCGS Food Safety V9.0 (BRCGS), requires a traceability plan to meet the legal requirements of the country of sale or intended use. BRCGS encourages exporters (certified sites) to work with their importers to ensure they are keeping records of information that “may be required by their importers.” BRCGS recommends that organizations conduct a gap analysis. We infer that if the exporter [and the auditor] do not understand and properly implement the Traceability Rule, the certification decision becomes more complicated and may change in a disruptive manner. (brcgs-information-paper-fsma-traceability-rule-march-2023.pdf)</p> <p>In the 2023 Version 6 of the FSSC 22000 management system standard, “traceability” appears 3 times with reference to package claims and verification, traceability exercise and review of records. The audit guidance asks how the organization ensures traceability (“one-up, one down principle” and that it meets relevant legislative and customer requirements. The Standard expects certification bodies to be aware of “all the laws and regulations of the relevant subcategory.” Current FSSC 22000 certifications do not guarantee FSMA Traceability Rule compliance. The success of FSMA traceability compliance is heavily reliant on supply chain education and investment. Implementation of the specific FSMA requirements is not explicitly communicated within the FSSC V6 standard. One interpretation is that the task of aligning FSMA Compliance and Certification relies on communication and training from the Buyer, Importer, Exporter, and their certification bodies / advisors.</p>

	Myth	Reality
#3	The FDA is only going to audit data when an outbreak occurs, so very few people will ever get caught for non-compliance.	The major GFSI food safety certifications endeavor to check whether organizations are following relevant food safety laws. The BRC requirement that calls out traceability is a perfect example of non-regulatory auditing that will happen frequently for supply chain actors. Both Sec. 3.9.1 & 3.9.5 are sections auditors may focus on for FSMA 204 compliance as we get closer to Jan 2026. FDA may review your traceability program during inspections as well as customers requiring a written guarantee.
#4	We require suppliers to have an MSC (Marine Stewardship Council) Chain of Custody for each wild-caught species. Isn't that enough?	Principle 4 of the MSC CoC (Chain of Custody) V5.0 requires that all certified products be traceable, and volumes are recorded. Traceability records shall be able to link certified products at every stage between purchase and sale, including receipt, processing, transport, packing, storage, dispatch and/or serving. Guidance for traceability system audits (2019) did not include the specific FSMA requirement for the traceability lot codes for applicable CTEs and KDEs. This may change as the Standard is reviewed. But you may be able to use existing MSC CoC records to help meet the requirements of the Traceability Rule.
#5	We require suppliers to have an ASC / MSC CoC for all aquaculture seafood. Isn't that enough?	The new ASC COC (Chain of Custody) will launch 30 May 2023 with a new emphasis on fraud prevention with requirements for GFSI food safety certification (see #2 above), environmental, social criteria. There is mention of record-keeping and reporting laws, and others affecting traceability in the scope. The standard does not specifically reference the data requirements under the Traceability Rule, e.g., traceability lot codes for applicable CTE's and KDE's. But you may be able to use existing ASC / MSC CoC records to help meet the requirements of the Traceability Rule.

	Myth	Reality
#6	We require suppliers to have a GSA (Global Seafood Alliance) BAP (Best Aquaculture Practices) certification for all aquaculture seafood. Isn't that enough?	The GSA Wild and BAP Aquaculture (4-star traceability) SPS (Seafood Processing Standard) Processing Standard (2020), Section 9, lists the traceability data requirements and in the context of electronic traceability. A gap analysis should be prepared with the 4-star program and the FSMA Traceability rule. But you may be able to use existing GSA certification records to help meet the requirements of the Traceability Rule.
#7	"Traceability, we don't need that!" <i>As spoken by a foreign exporter, SENA 2023.</i>	Reality: They do. A sampling of personnel from exhibitors at SENA and SEG (Seafood Expo Global) yielded a caution that too many exporters are unaware of the FSMA Traceability Rule. The lack of knowledge implies that exporters are not prepared to speak about plans (road map) for compliance. This represents a challenge and opportunity for NFI and its members.



Comparison to SIMP

ONE-UP ONE-BACK

Is there a match-up with SIMP?

Information about the Entity(ies) Harvesting or Producing the Fish

SIMP	FDA Traceability / Wild Captured	FDA Traceability / Farmed
Name of harvesting vessel(s)	Not required	NA
Flag state of harvesting vessel(s)	Not required	NA
Evidence of authorization to fish; permit or license number	Not required	NA
Unique vessel identifier(s) of harvesting vessel(s) (if available)	Not required	NA
Type(s) of fishing gear used to harvest the fish	Not required	NA
Name(s) of farm or aquaculture facility	NA	Location description



Is there a match-up with SIMP?

SIMP	FDA Traceability / Wild Captured	FDA Traceability / Farmed
Species (Aquatic Sciences and Fisheries Information System (“ASFIS”) number, 3alpha species code)	Species and/or acceptable market name for unpackaged	Species and/or acceptable market name
Product form(s) at the point of first landing whether unprocessed or processed prior to landing/delivery	Product description for packaged food (i.e., packaging size and packaging style	NA
Quantity and/or weight of the product(s) as landed/delivered (on the date of the report)	Quantity and unit of measure	Quantity and unit of measure
NA	Traceability Lot Code and TLC source location description	Traceability Lot Code and TLC source location description



Is there a match-up with SIMP?

SIMP	FDA Traceability / Wild Captured	FDA Traceability / Farmed
Area(s) of wild-capture or aquaculture location;	Harvest locations for trip	“Container” name or other location information
Location of aquaculture facility;	NA	Location description of farm
Point(s) of first landing;	Location description for first land-based receiver	NA
Date(s) of first landing, transshipment or delivery;	Harvest date range Date of landing	Date of harvesting
Name of entity(ies) (processor, dealer, vessel) to which fish was landed or delivered (including telephone number and email).	Location description for first land-based receiver	Location description for initial packing location

