



Food Safety Modernization Act (FSMA) Food Traceability Rule

Supply Chain Examples

June 2023

Supply Chain Examples



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.

The following examples will walk through the Critical Tracking Events in a supply chain where Key Data Elements are required.

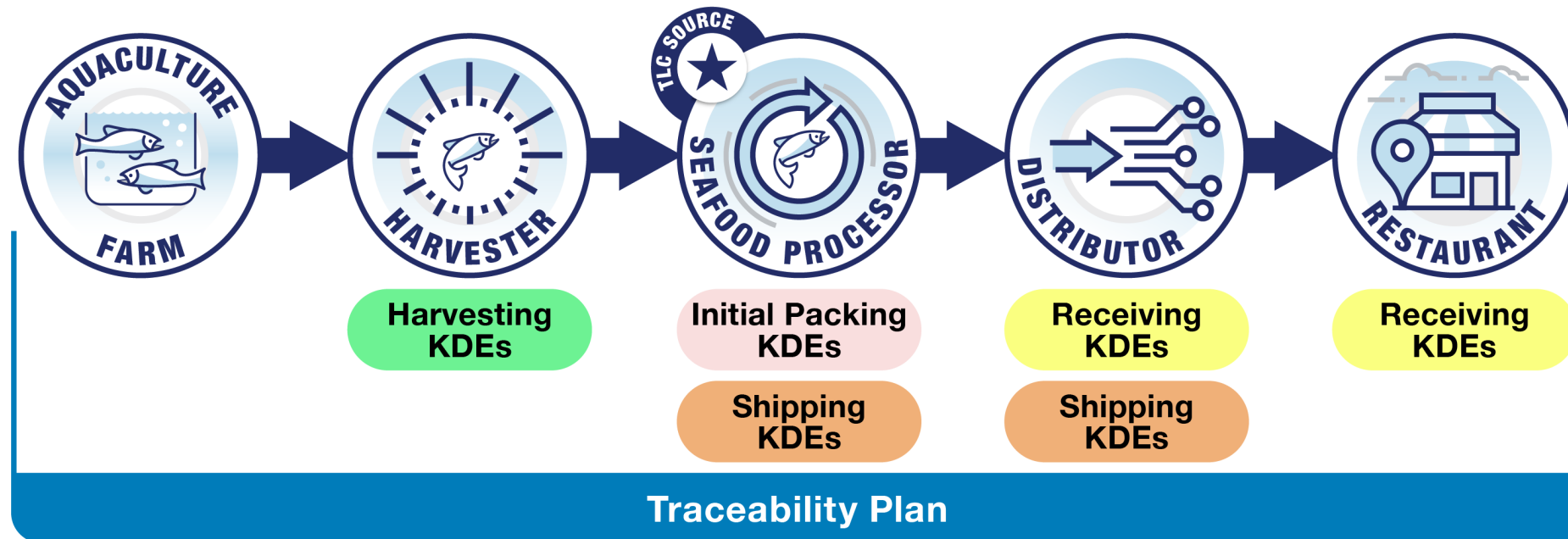
Abbreviations used:

- Key Data Elements or KDEs
- Critical Tracking Events or CTEs
- Food Traceability List or FTL
- Traceability Lot Code or TLC
- Raw Agricultural Commodities or RACs

Supply Chain Example: Aquacultured tilapia

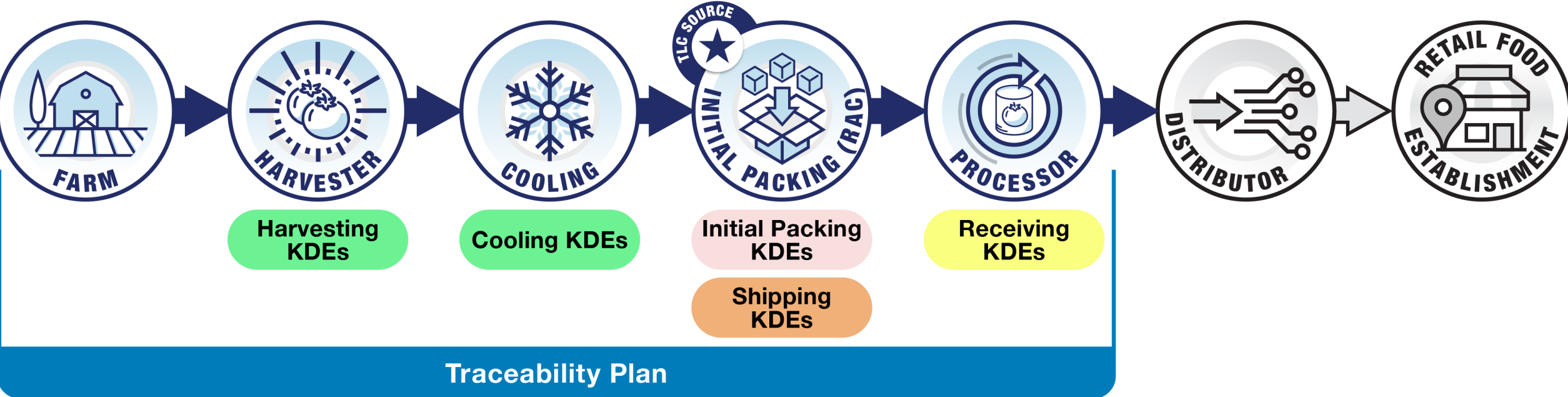


In this scenario, aquacultured tilapia is transformed from live fish into filets by the seafood processor for sale at retail. Since the seafood processor is transforming a raw agricultural commodity (RAC) that was not initially packed prior to transformation, the processor would refer to 21 CFR 1.1350(b), which specifies that rather than transformation Key Data Elements (KDEs), the processor must maintain initial packing KDEs (21 CFR 1.1330). KDEs are required for the fresh tilapia at the points indicated in the graphic. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs.



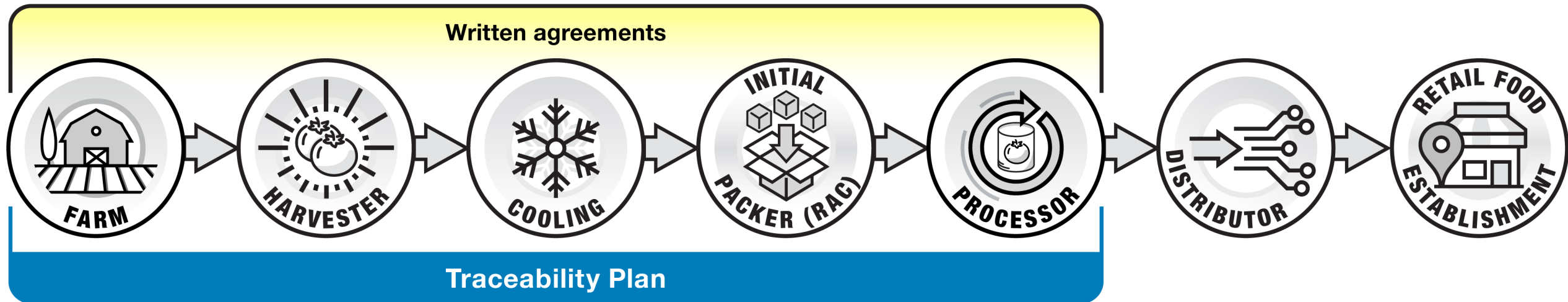
Supply Chain Example: Canned tomatoes

In this scenario, the produce processor is canning fresh tomatoes. Key Data Elements (KDEs) are required for the fresh tomatoes at the points indicated in the graphic. The produce processor must maintain receiving KDEs for the fresh tomatoes. Since the produce processor is changing the fresh tomatoes to a form that is not on the FTL (i.e., canned tomatoes), the produce processor does not need to maintain shipping records. Any subsequent receivers of the canned tomatoes would not be subject to the requirements of the final rule. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs.



Supply Chain Example: Canned tomatoes

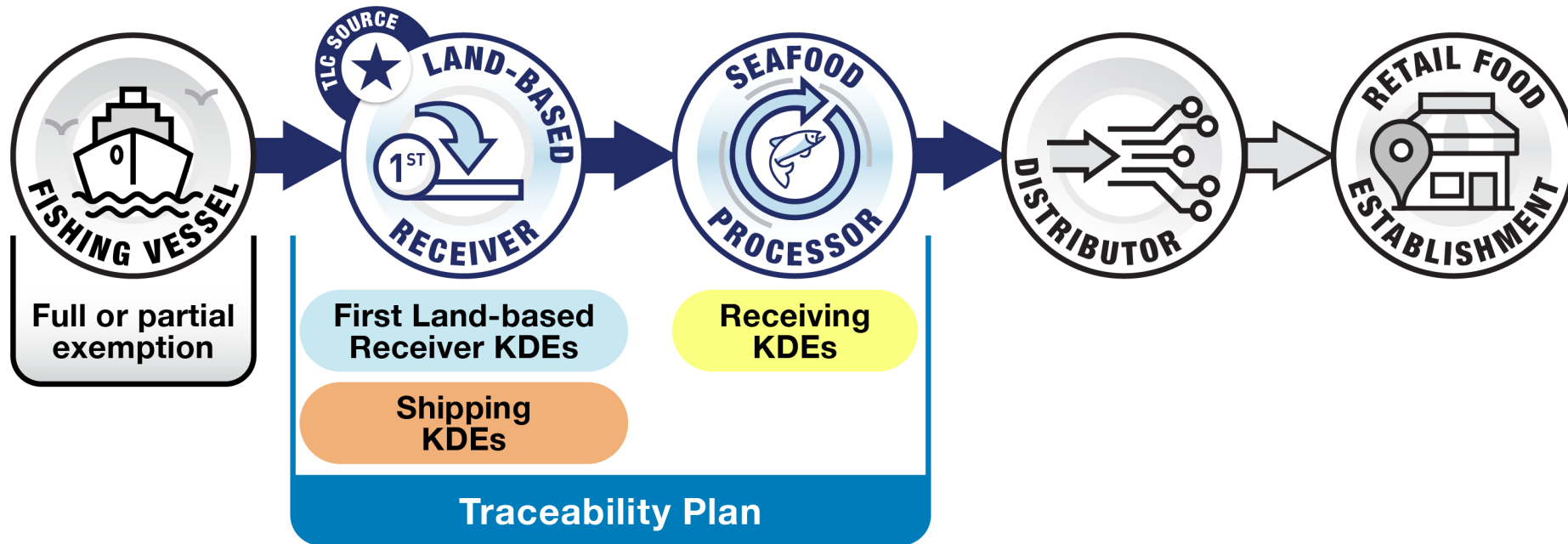
In this scenario, the produce processor is canning fresh tomatoes and written agreements are in place throughout the supply chain stating that the tomatoes are going to be canned, as described in § 1.1305(d)(6). Since the entities have written agreements in place, they do not need to maintain KDEs for the fresh tomatoes. Since the produce processor is changing the fresh tomatoes to a form that is not on the FTL (i.e., canned tomatoes), any subsequent receivers of the canned tomatoes would not be subject to the requirements of the final rule. Since § 1.1305(d)(6) is only a partial exemption, all entities which have written agreements in place must also maintain a Traceability Plan.



Supply Chain Example: Canned salmon



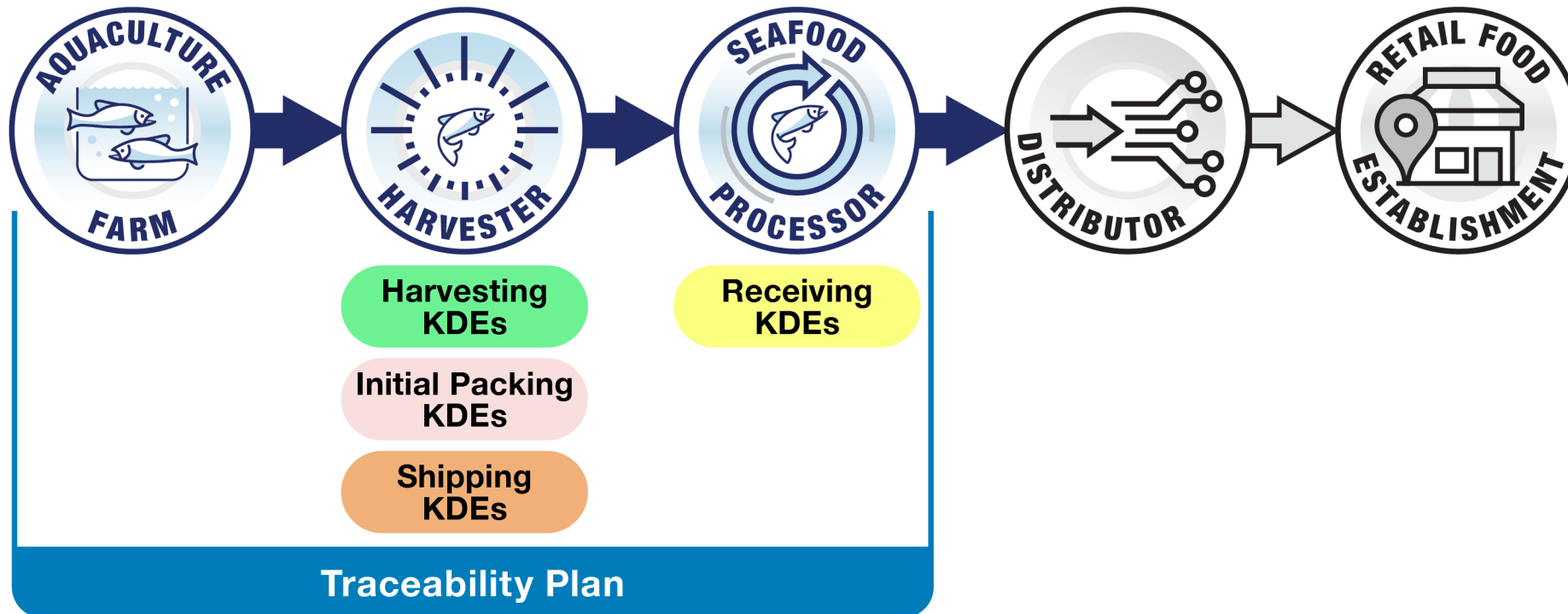
In this scenario, the seafood processor is canning wild-caught salmon. Key Data Elements (KDEs) are required for the fresh salmon at the points indicated in the graphic. (Unless written agreements are in place, as described in § 1.1305(d)(6)). The seafood processor must maintain receiving KDEs for the fresh salmon. Since the seafood processor is changing the fresh salmon to a form that is not on the FTL (i.e., canned salmon), the seafood processor does not need to maintain shipping records. Any subsequent receivers of the canned salmon would not be subject to the requirements of the final rule. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs.



Supply Chain Example: Aquacultured canned salmon

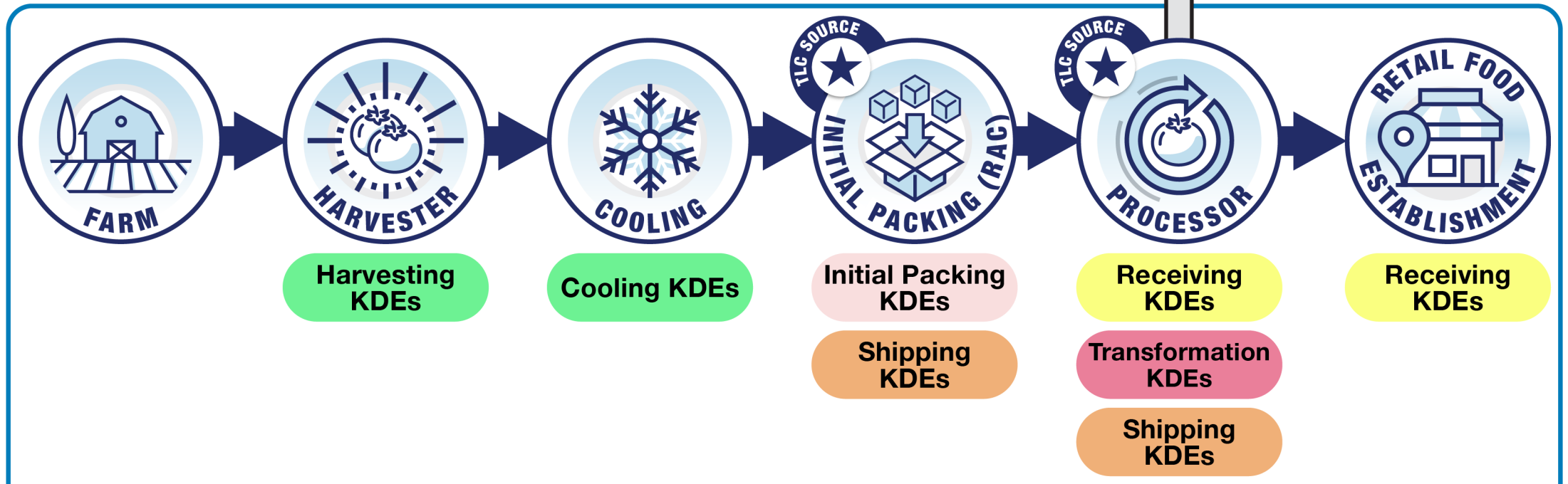


In this scenario, the seafood processor is canning salmon. Key Data Elements (KDEs) are required for the fresh salmon at the points indicated in the graphic. (Unless written agreements are in place, as described in § 1.1305(d)(6)). The harvester of the salmon also initially packs the salmon. The seafood processor must maintain receiving KDEs for the fresh salmon. Since the seafood processor is changing the fresh salmon to a form that is not on the FTL (i.e., canned salmon), the seafood processor does not need to maintain shipping records. Any subsequent receivers of the canned salmon would not be subject to the requirements of the final rule. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs.



Supply chain example: fresh tomatoes sent to retail and meal kits

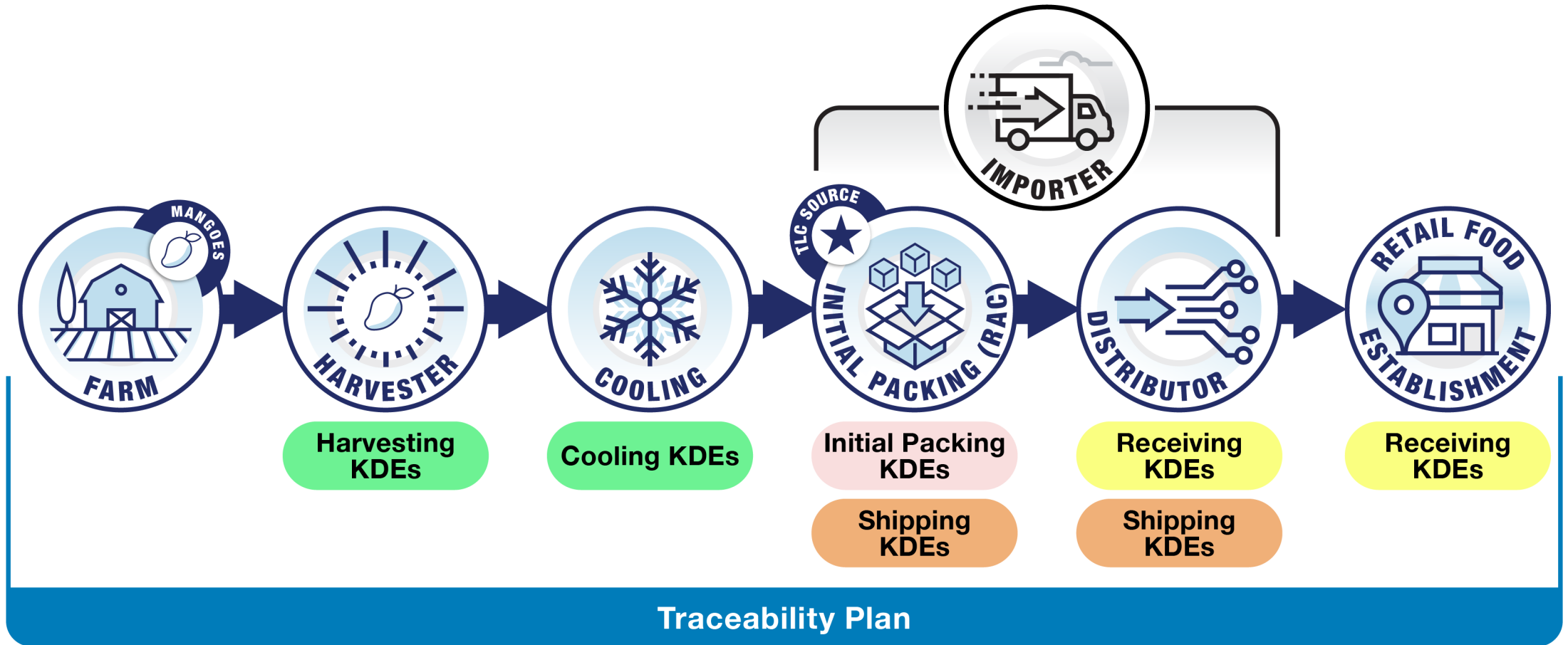
In this scenario, the processor is including fresh sliced tomatoes in pre-packaged sandwich wraps sold at retail, as well as whole fresh tomatoes in meal kits sold directly to consumers. Key Data Elements (KDEs) are required for the fresh tomatoes at the points indicated in the graphic. The processor must maintain receiving KDEs for all of the fresh tomatoes. For the pre-packaged sandwich, the processor must also maintain transformation KDEs (because the tomatoes are sliced and added to sandwiches) and shipping KDEs. The processor becomes the new TLC source for the tomatoes that are transformed. For the meal kits, the whole tomatoes are not transformed and the processor does not need to maintain shipping KDEs since the meal kits are being shipped directly to consumers. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs.



Supply Chain Example: Imported Mangos

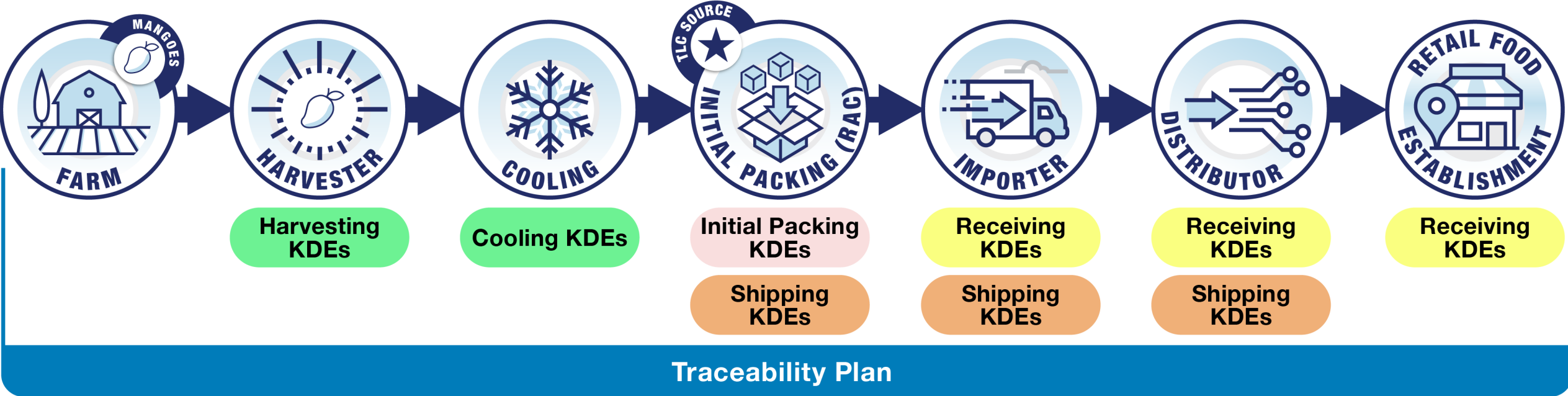


In this scenario, the importer/wholesaler is importing fresh mangos. The importer facilitates the importation of the mangos but does not take physical possession of the mangos they are importing. So the importer is not covered by the rule and does not need to maintain any KDEs. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs.



Supply Chain Example: Imported Mangoes (Importer holds the food)

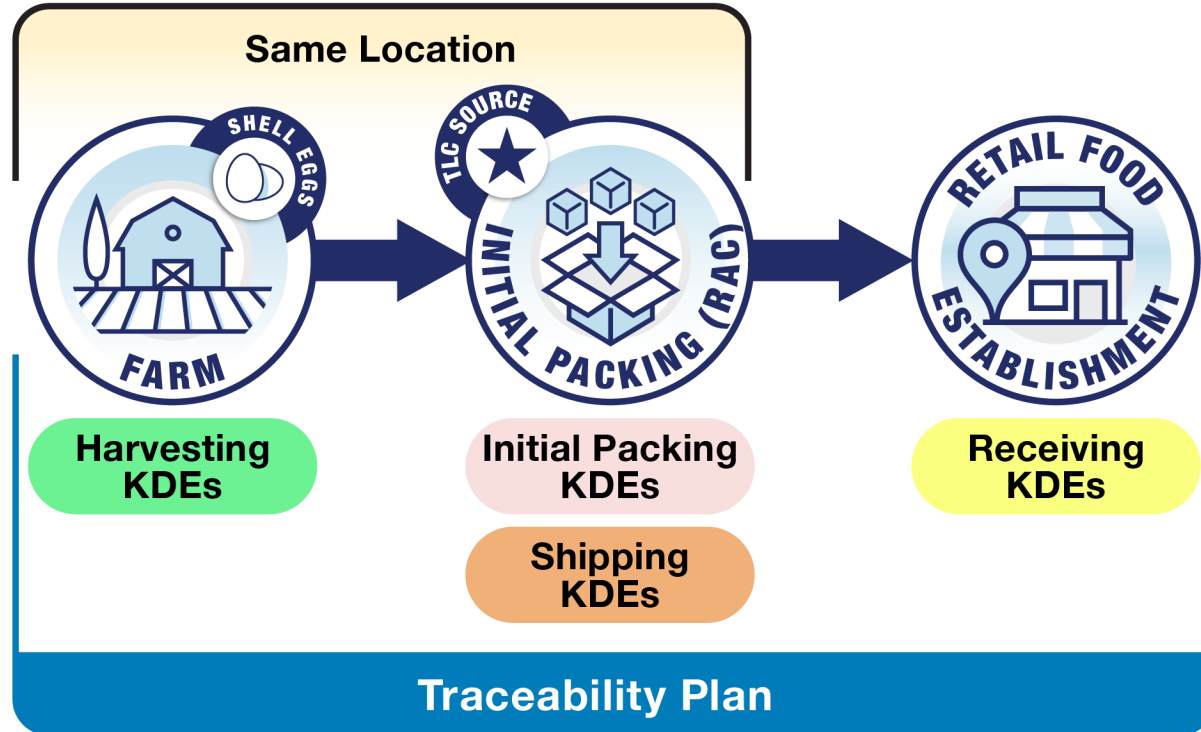
In this scenario, the importer/wholesaler is importing fresh mangos. The importer takes physical possession of the mangos they are importing, so they are covered by the rule, and must maintain receiving and shipping KDEs. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs.



Supply Chain Example: In-line shell egg production operation



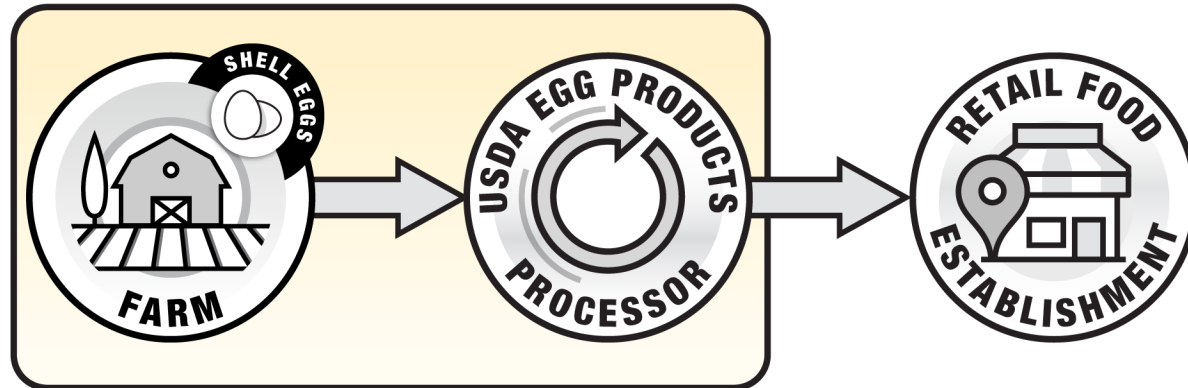
In this example, the farm is an in-line shell egg production operation where packing of the eggs occurs at the same location that they are laid (represented by the yellow box). The operation does not commingle its eggs with eggs from other farms. The eggs are cooled after initial packing. The farm ships its eggs directly to the retail food establishment. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs.



Supply Chain Example: In-line egg further processor



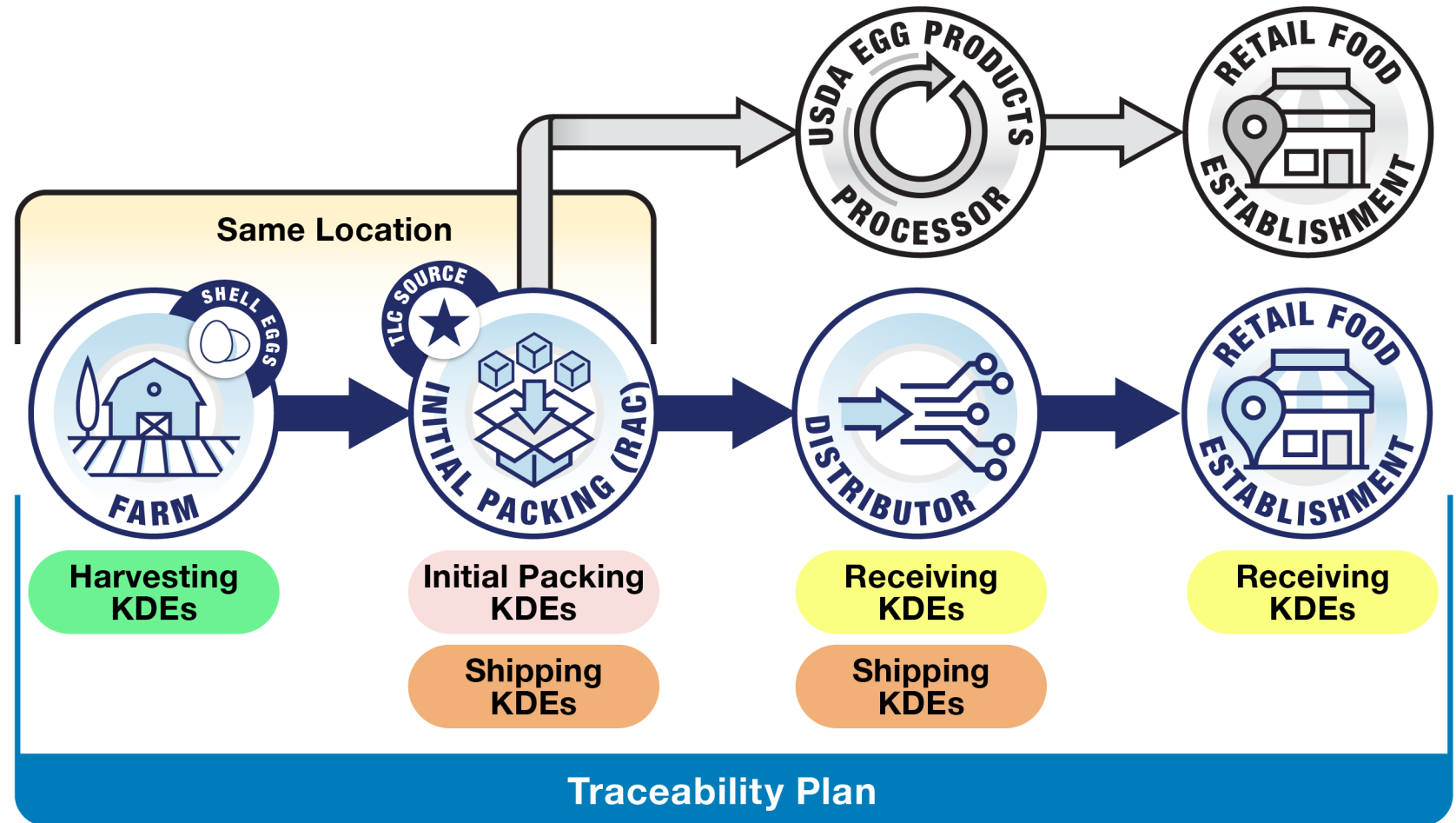
In this example, the farm is an in-line shell egg production operation (represented by the yellow box) that includes an on-site USDA egg products plant. All of the farm's eggs are processed by the egg products plant. The egg products plant ships the egg products to retail. Since all of the eggs produced at the farm receive a treatment at the USDA plant, the eggs are exempt from the rule per § 1.1305(d)(2).



Supply Chain Example: Off-line egg further processor



In this example, the farm is an in-line shell egg production operation where packing of the eggs occurs at the same location that they are laid (represented by the yellow box). The operation sends some but not all of its eggs to an off-line egg products processor (or egg products plant). Since the egg products plant is regulated solely by USDA, the plant is not covered by the final rule and subsequent receivers of the egg products would also not be covered under § 1.1305(g). For the other eggs, which are sent to the table market, KDEs would be required. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs.





Visit <https://www.fda.gov/fsma> for additional information.