

# FAQ

## Frequently Asked Questions

Question	Answer
<b>Q: What is the purpose of the FSMA Traceability Rule?</b>	A: FSMA Traceability Rule aims to harmonize traceability essential record keeping throughout the food chain.
<b>Q: What are the benefits that are foreseen with the application of the Rule?</b>	A: The benefits to be achieved with the implementation of the Regulation are: <ul style="list-style-type: none"> <li>• Establish faster, connectors between the elements of the food chain.</li> <li>• Align with current industry best practices.</li> <li>• Limit the scope and minimize the negative effects of recalls and contamination events.</li> <li>• Faster and effective response for tracking of food products in the event of a recall or an outbreak.</li> <li>• Strengthen the ability to perform more effective root cause analysis to identify and apply lessons learned.</li> </ul>
<b>Q: Who is under the scope of the Traceability Rule?</b>	A: Companies that manufacture, process, pack or handle food on the Food Traceability List are under the scope of the Rule. Domestic and foreign companies.
<b>Q: Which foods are covered by the FSMA Traceability Rule?</b>	A: The Traceability Rule focuses on foods included in the Food Traceability List FTL, which were defined using a risk assessment model associated with different foods. The FTL includes fruits and vegetables, seafood, dairy products, and other ready-to-eat foods.
<b>Q: What is the Risk-Ranking Model for Food Tracing (RRM-FT)?</b>	A: The Risk-Ranking Model for Food Tracing (RRM-FT)FDA is a model developed by the Project Advisory Group (FDA-CDC) and its objective was to rank the risks associated with different foods. The model took into account chemical and biological hazards and was reviewed by groups of experts and adjusted it and generate the FTL that is now available on the FDA website.
<b>Q: What type of information fed the model that generated the FTL?</b>	A: The information sources that fed the model were: <ul style="list-style-type: none"> <li>• Outbreak Data</li> <li>• FDA Recall Data</li> <li>• Reportable Food Registry Annual Reports</li> <li>• Microbiological Data Program, MDP-USDA</li> <li>• Diet and food habits studies</li> <li>• Manufacturing and process control data and information</li> <li>• Databases: National Health and Nutrition Examination Survey (NHANES) What We Eat in America</li> <li>• Literature and technical reports</li> <li>• Subject matter expert knowledge</li> </ul>
<b>Q: What is a Critical Tracking Events (CTE)?</b>	A: CTE are events throughout the supply chain that are essential for achieving food traceability and supply chain visibility. The Critical Tracking Events in the final rule are harvesting; cooling (before initial packing); initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel; first land-based receiving of a food obtained from a fishing vessel; shipping; receiving; and transformation of the food.
<b>Q: What is a Key Data Element (KDE)?</b>	A: Key Data Elements (KDEs) are specific pieces of information that must be documented and maintained at critical points in the supply chain under the FSMA (Food Safety Modernization Act) Traceability Rule. These elements are essential for effective traceability of food products in the event of a foodborne illness outbreak or other safety concerns. KDEs include information such as the names and addresses of entities involved, food descriptions, lot or code numbers, dates and times of events, and quantities of food, and are specific for each CTE.

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<b>Q: What are the Critical Tracking Events (CTEs) identified in the rule?</b>	A: The final Traceability Rule identifies 7 CTE: <ul style="list-style-type: none"><li>• Harvesting</li><li>• Cooling (before initial packing)</li><li>• Initial packing</li><li>• First Land-Based Receiver</li><li>• Shipping</li><li>• Receiving</li><li>• Transformation</li></ul>
<b>Q: Are there exemptions to the FSMA Traceability Rule?</b>	A: Yes, certain exemptions exist based on factors like facility size, food type, and direct-to-consumer sales. It's essential to review the specific criteria outlined in the rule.
<b>Q: What are important dates to remember related to the FSMA Traceability Rule?</b>	A: Publication: November 21, 2022 Effective date: January 20, 2023 Compliance date: January 20, 2026
<b>Q: What are the consequences of non-compliance with the FSMA Traceability Rule?</b>	A: Non-compliance may result in regulatory actions, including recalls, facility inspections, and potential legal consequences.