Food Traceability Rule: Overview and requirements

By Clara Diekman and Michelle Danyluk he Food Traceability Rule (FTR) is a federal regulation that establishes recordkeeping requirements for persons who manufacture, process, pack or hold foods on the Food Traceability List (FTL). The goal of this rule is to help the U.S. Food and Drug Administration (FDA) identify and remove potentially contaminated food from the market more rapidly, and ultimately reduce foodborne outbreaks and illnesses.

The FTL was created using a risk-ranking model that evaluated commodity risk based on factors such as frequency of past outbreaks, likelihood of contamination, consumption rate and the amount consumed. The FDA has indicated it intends to update this list approximately every five years to add or remove foods as necessary. Any additions to the FTL will have two years to come into compliance with the rule after the announcement of the revised list.

WHAT IS AND ISN'T INCLUDED

The FTL currently contains various produce commodities, including fresh cucumbers, herbs, leafy greens, cut leafy greens, melons, peppers, sprouts, tomatoes, tropical tree fruit and fresh cut fruits and vegetables with some exemptions [see 112.2(a)(1)]. This does not include leafy greens such as whole head cabbage, grape and banana leaf, and collards. Citrus — including but not limited to orange, clementine, tangerine, mandarin, lemon, lime, citron, grapefruit, kumquat and pomelo are *not included on the FTL*. Other foods on the FTL include shell eggs, nut butters, finfish, crustaceans, molluscan shellfish, cheeses (other than hard cheeses) and ready-to-eat deli salads. The compliance date for those subject to these record-keeping requirements is Jan. 20, 2026.

Farms that are exempt from the Produce Safety Rule based on commodity grown are also exempt from the FTR. Other exemptions from the FTR include:

- Farms with average annual sales or market value of produce manufactured, processed, packed or held without sale is no more than \$25,000, adjusted for inflation, over the last three years
- · Food sold or donated directly to the consumer
- Produce packaged on the farm in a way that maintains the integrity of the product and prevents subsequent contamination or adulteration. The label on these products must contain the name, complete address and business phone number of the farm where the food was produced and packaged.
- Produce is exempt when it undergoes commercial processing to adequately reduce the presence of microorganisms of public health significance. This includes citrus fruit grown for juice and processed under Juice Hazard Analysis Critical Control Point (HACCP).
- Food is exempt when it will be subject to a kill step or transformed in a way that the resulting product is no longer on the FTL by an entity other than a retail food establishment, restaurant or consumer.

RECORD REQUIREMENTS

Entities subject to the rule must maintain records containing Key Data Elements (KDEs) associated with specific Critical Tracking Events (CTEs) within the supply chain. CTEs for the produce industry include harvesting, cooling (before initial packing), shipping, receiving or the transformation of the food. Key players required to maintain this data within produce supply chains include the farm, the harvester (if contracted out), the initial packer, the processor (e.g., if the produce is repacked in a repacking facility or commercially processed), the distributor and the retail establishment.

An example of what this might look like, *if citrus was on the FTL*, can be seen in Figure 1 (page 16). The contract harvester would be responsible for collecting the harvest KDEs and providing those to the initial packer. The initial packer must maintain records containing KDEs for each traceability lot of the commodity packed. A traceability lot is a batch or lot of a raw agricultural commodity that has been initially packed or transformed. These lots are assigned a traceability lot code, a descriptor used to identify that specific lot

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The Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) inspections have begun. Sign up now to request a free On-Farm Readiness Review (OFRR), offered in partnership by the Florida Department of Agriculture and Consumer Services and University of Florida IFAS. The OFRR is an educational opportunity to help individual farms align practices with the PSR regulatory requirements in preparation for inspections.

For more information on FSMA and to sign up for an OFRR, visit FDACS.gov/FSMA or call (863) 578-1900.



To take full advantage of the OFRR and for PSR compliance, one farm representative should first attend a Produce Safety Alliance Grower Training. Upcoming trainings can be found at: crec.ifas.ufl.edu/extension/events

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within the records, at the traceability lot source, where the lot code was assigned. The initial packer must also maintain records of shipping KDEs for each traceability lot shipped. The distributor must keep records of receiving and shipping KDEs, and the retailer must keep records of the shipping KDEs.

An example of oranges produced for juicing can be seen in Figure 2. The farm, harvester and processor would be under the FTR. However, written agreements are in place because the processor is commercially processing the juice under Juice HACCP, which adequately reduces the presence of foodborne pathogens. The distributor and retailer would not fall under the FTR because the processor is transforming the food into a form that would no longer be on the FTL. Another requirement of the rule for covered entities is maintaining a traceability plan. The plan must be updated when necessary to ensure it reflects the current practices of the farm. Any previous version of the plan must be kept for a minimum of two years after updating. For produce farms, the information that must be included in the traceability plan is listed below.

- A description of the procedure used to maintain the required records, including the location and format of the records
- A description of the process used to identify foods that are manufactured, processed, packed or held that are on the FTL
- If applicable, a description of how traceability lot codes are assigned
- The point-of-contact individual

that can answer questions about the traceability plan and required records

 A digital or hand-drawn farm map showing where produce is grown must also include the name of each field or growing area and the location (geographic coordinates and other information needed to identify the specific location).

Visit tinyurl.com/2mj4dnsb for more information about the Food Traceability Rule requirements.

Clara Diekman is an education training specialist, and Michelle Danyluk is a professor, both at the University of Florida Institute of Food and Agricultural Sciences Citrus Research and Education Center in Lake Alfred.