Retail food establishments (RFEs) and restaurants:



What you need to know about the Food Traceability Rule

The Food Traceability Rule is a federal regulation that applies to persons who manufacture, process, pack or hold foods on the Food Traceability List. The rule covers retail food establishments (RFEs) and restaurants, unless a specific exemption applies.

The Food Traceability Rule has specific definitions for the following terms (see final rule for complete definitions):

"Retail food establishment" is defined as an establishment that sells food products directly to consumers as its primary function.

"Restaurant" is defined as a facility that prepares and sells food directly to consumers for immediate consumption.

"Nonprofit Food Establishment" is defined as a 501(c)(3) charitable entity that prepares or serves food directly to the consumer or otherwise provides people with food or meals.

What you need to know about the Food Traceability Rule exemptions

- The rule does not apply to RFEs and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than \$250,000 (on a rolling basis), adjusted for inflation.
- RFEs and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than \$1,000,000 (on a rolling basis), adjusted for inflation, are exempt from the requirement to provide FDA with an electronic sortable spreadsheet. However, those entities must still maintain the records required by the rule.
- The rule does not apply to RFEs and restaurants regarding food produced on a farm and both sold and shipped directly to the RFE or restaurant. However, the RFE or restaurant would have to keep a record (for 180 days) of the name and address of the farm that was the source of the food.
- The rule does not apply to either entity when an RFE or restaurant purchases food from another RFE or restaurant, if the purchase occurs on an ad hoc basis outside of the buyer's usual purchasing practice. The purchaser must keep a record (e.g., sales receipt) documenting the name of the product purchased, date of purchase, and name and address of the place of purchase.
- The rule does not apply to raw bivalve molluscan shellfish that are part of the National Shellfish Sanitation Program (NSSP). The NSSP has its own traceability requirements that must be followed when applicable. Retail food establishments and restaurants who hold molluscan shellfish may qualify for an exemption from the Food Traceability Rule, but must still follow FDA Food Code provisions for shellstock identification and maintaining identification of shellstock as referenced in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (§§3-202.18 and 3-203.12).

When do I need to comply with the Food Traceability Rule?

The compliance date for all covered entities is January 20, 2026.

You can find additional resources at our Food Traceability Final Rule page at www.fda.gov.

For additional questions:

The Technical Assistance Network (TAN) is a central source of information for questions related to the Food Safety Modernization Act (FSMA) rules, programs, and implementation strategies.

Submit Your Question Electronically:

Please <u>submit your question</u> to TAN for assistance.

Mail Your Question

If you prefer to mail in your question, please send it to the address below:

Food and Drug Administration 5001 Campus Drive Wiley Building, HFS-009 Attn: FSMA Outreach College Park, MD 20740

How TAN Works

Inquiries are answered by FDA Information Specialists or Subject Matter Experts, based on the complexity of the question. FDA will respond to inquiries received as soon as possible. However, response times may vary, due to complexity of question and the volume of inquiries we receive.

Once a question is submitted, the inquirer will receive notification of receipt and a case number to be referenced in future correspondence.