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Step-by-Step Guide to the FDA's Traceability Rule

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Introduction

The FDA is requiring all companies that hold, pack, distribute, or sell foods to keep detailed records for a specific list of foods. Food companies must supply the FDA with these records in a sortable spreadsheet within 24 hours upon request.

The most basic elements of this rule are as follows:

- ◆ The compliance deadline is January 20, 2026.
- ◆ Each food on the FDA's Food Traceability List must be assigned a Traceability Lot Code and several Key Data Elements that must be shared at each Critical Tracking Event.
- ◆ The rule applies to any company that owns the food actually or virtually including growers, manufacturers, distributors, warehouses, retailers, and restaurants with very few exceptions.
- ◆ This rule also applies when you transform a food such as making a salad for the deli case and transporting it to a second location.
- ◆ Every company must have a Traceability Plan with procedures for all recordkeeping.
- ◆ The FDA or local food safety authorities can reach out by phone or email to request records that must be supplied within 24 hours.

This guide is designed to assist food retailers and distributors in complying with this rule and includes a special section for companies that transform foods. Each section of the document will include the following information as needed:

1. **Background:** An overview of how the FDA and food industry are thinking about the rule.
2. **Requirements and Definitions:** What the rule says and what it means.
3. **Step-by-step Compliance:** Options for how to become compliant with the rule.
4. **Resource Links:** Templates and guides for creating required documentation.

We will start with the foundational concepts of the rule and then move to step-by-step compliance.

Critical Tracking Event: Food Shipped

Key Data Elements Required

- ◆ The Traceability Lot Code for the food.
- ◆ The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds).
- ◆ The product description for the food.
- ◆ The location description for the immediate subsequent recipient (other than a transporter) of the food.
- ◆ The location description for the location from which you shipped the food.
- ◆ The date you shipped the food.
- ◆ The location description for the Traceability Lot Code source, or the Traceability Lot Code source reference.
- ◆ The reference document type and reference document number.

Critical Tracking Event: Transformed Food

Key Data Elements Required

- ◆ New Traceability Lot Code you assign
- ◆ The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds).
- ◆ The product description for the food.
- ◆ The location description for the immediate previous source (other than a transporter) for the food.
- ◆ The location description for where the food was received (i.e., the Traceability Lot Code source), and (if applicable) the Traceability Lot Code source reference.
- ◆ The date you received the food.
- ◆ The reference document type and reference document number.

Critical Tracking Event: Food Received without a Traceability Lot Code

Key Data Elements Required

- ◆ The Traceability Lot Code for the food, which you must assign if one has not been assigned.
 - Does not apply to retailers selling directly to consumers.
- ◆ The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds).
- ◆ The product description for the food.
- ◆ The location description for the immediate previous source (other than a transporter) for the food.
- ◆ The location description for where the food was received (i.e., the Traceability Lot Code source), and (if applicable) the Traceability Lot Code source reference.
- ◆ The date you received the food.
- ◆ The reference document type and reference document number.

Figure 8 – Traceability Lot Code Flow Chart for Picking, Packing, and Shipping

