What you need to know about the Food Traceability Rule: Coverage and Exemptions for Produce Farms



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 farms unless a specific exemption applies.

What produce is subject to the Food Traceability Rule?

The full Food Traceability List is available on FDA's website at https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list. The list can be changed through a process set forth in 21 CFR 1.1465. Currently the Food Traceability List includes the following produce items:

| Food Traceability List | Description |
|--|---|
| Cucumbers (fresh) | Includes all varieties of fresh cucumbers |
| Herbs (fresh) | Includes all types of fresh herbs. Examples include, but are not limited to, parsley, cilantro, and basil. Herbs listed in 21 CFR 112.2(a)(1), such as dill, are exempt from the requirements of the rule under 21 CFR 1.1305(e). |
| Leafy greens (fresh) | Includes all types of fresh leafy greens. Examples include, but are not limited to, arugula, baby leaf, butter lettuce, chard, chicory, endive, escarole, green leaf, iceberg lettuce, kale, red leaf, pak choi, Romaine, sorrel, spinach, and watercress. Does not include whole head cabbages such as green cabbage, red cabbage, or savoy cabbage. Does not include banana leaf, grape leaf, and leaves that are grown on trees. Leafy greens listed in § 112.2(a)(1), such as collards, are exempt from the requirements of the rule under § 1.1305(e). |
| Leafy greens (fresh cut) | Includes all types of fresh-cut leafy greens, including single and mixed greens. |
| Melons (fresh) | Includes all types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, muskmelon, and watermelon. |
| Peppers (fresh) | Includes all varieties of fresh peppers. |
| Sprouts (fresh) | Includes all varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts. Examples include, but are not limited to, alfalfa sprouts, allium sprouts, bean sprouts, broccoli sprouts, clover sprouts, radish sprouts, alfalfa & radish sprouts, and other fresh sprouted grains, nuts, and seeds. |
| Tomatoes (fresh) | Includes all varieties of fresh tomatoes. |
| Tropical tree fruits (fresh) | Includes all types of fresh tropical tree fruit. Examples include, but are not limited to, mango, papaya, mamey, guava, lychee, jackfruit, and starfruit. Does not include non-tree fruits such as bananas, pineapple, dates, soursop, jujube, passionfruit, Loquat, pomegranate, sapodilla, and figs. Does not include tree nuts such as coconut. Does not include pit fruits such as avocado. Does not include citrus, such as orange, clementine, tangerine, mandarins, lemon, lime, citron, grapefruit, kumquat, and pomelo. |
| Fruits (fresh-cut) | Includes all types of fresh-cut fruits. Fruits listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e). |
| Vegetables other than leafy greens (fresh-cut) | Includes all types of fresh-cut vegetables other than leafy greens. Vegetables listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e). |

What food and persons are exempt from the Food Traceability Rule?

Below is a summarized list of exemptions relevant to produce farms. See the final rule (21 CFR § 1.1305) for all of the exemptions to the Food Traceability Rule, and for full descriptions of each exemption. FDA has also developed an online, interactive tool that walks through the exemptions to the Food Traceability Rule, available here: https://collaboration.fda.gov/tefcv13/.

| Farm Exemptions | CFR |
|---|--------------------|
| Farms (or the farm activities of farm mixed-type facilities) are exempt with respect to the produce they grow when the farm is not covered by the Produce Safety Rule under § 112.4(a). | § 1.1305(a)(1)(i) |
| Produce farms are exempt when the average annual sum of the monetary value of their sales of produce and the market value of produce they manufacture, process, pack, or hold without sale (e.g., held for a fee) during the previous 3-year period is no more than \$25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment. | § 1.1305(a)(1)(ii) |
| Farms are exempt with respect to food (including produce) produced on the farm that is sold or donated directly to a consumer. | § 1.1305(b) |
| Food (including produce) is exempt when it is produced and packaged on a farm, provided that: a. The packaging of the food remains in place until the food reaches the consumer, and such packaging main-tains the integrity of the product and prevents subsequent con-tamination or alteration of the product; and b. The labeling of the food that reaches the consumer includes the name, complete address (street address, town, State, country, and zip or other postal code for a domestic farm and comparable information for a foreign farm), and business phone number of the farm on which the food was produced and packaged. FDA will waive the requirement to include a business phone number, as appropriate, to accom-modate a religious be-lief of the individual in charge of the farm. | § 1.1305(c) |
| Produce is exempt when it receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions set forth in §112.2(b) of the Produce Safety Rule are met for the produce. | § 1.1305(d)(1) |
| Food (including produce) is exempt when it will be subjected to a kill step by an entity other than a retail food establishment, restaurant, or consumer; or it will be changed by an entity other than a retail food establishment, restaurant, or consumer, such that the food will no longer be on the Food Traceability List, provided that written agreements are in place as described in § 1.1305(d)(6). | § 1.1305(d)(6) |