

Requirements for Additional Traceability Records for Certain Foods

WHO IS SUBJECT TO THE RULE?



U.S. FOOD & DRUG
ADMINISTRATION

Are YOU subject to the rule?

Do you manufacture, process, pack or hold foods that appear on the Food Traceability List?

No



You are NOT subject to the rule.

Yes

Are you a farm or farm mixed-type facility that is not subject to the Produce Safety Rule because annual produce sales are \$25,000 or less?

Yes

You are NOT subject to the rule with respect to the produce you grow.

No

Are you a shell egg producer with <3,000 laying hens at a particular farm?

Yes

You are NOT subject to the rule with respect to the shell eggs you produce at that farm.

No

Are you any other originator of food with average annual monetary value of food sold during the previous 3-year period of no more than \$25,000 adjusted for inflation?

Yes



You are NOT subject to the rule.

No

Are you a transporter of food?

Yes



You are NOT subject to the rule.

No

Are you a nonprofit food establishment?

Yes



You are NOT subject to the rule.

No

Do you manufacture, process, pack, or hold food for personal consumption?

Yes



You are NOT subject to the rule.

No

Do you hold food on behalf of specific individual consumers, **AND**

- You are not party to the transaction involving the food you hold; **AND**
- You are not in the business of distributing food?

Yes



You are NOT subject to the rule.

No

Do you produce and package food on a farm, **AND**:

1. The packaging of the food remains in place until the food reaches the consumer; **AND**
2. The packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product; **AND**
3. Labeling of the food includes the name, complete address, and business phone number of the farm?

Yes

You are NOT subject to the rule with respect to the food that meets these conditions.

No

Do you produce food on your farm (including food that is also packaged on your farm) **AND** sell it directly to a consumer?

Yes

You are NOT subject to the rule with respect to the food sold directly to consumers.

No

Do you produce food that meets one of the following conditions?

1. Produce that receives commercial processing and that meets the conditions in 21 CFR §112.2(b); OR
2. Shell eggs produced at a farm where all eggs receive a treatment as defined in 21 CFR §118.3?

Yes

You are NOT subject to the rule with respect to the food that meets the condition(s).

No

Do you produce a food that is listed as rarely consumed raw in 21 CFR §112.2(a)(1)?

Yes

You are NOT subject to the rule with respect to the RCR food.

No

Do you produce an FTL food that is a commingled raw agricultural commodity that is NOT a type of produce covered by the Produce Safety Rule (i.e., eggs), and:

1. The commodity is combined or mixed with food from different farms; **AND**
2. Such combining/mixing happens after harvesting but before processing?

Yes

You are exempted **EXCEPT** that, **IF** you are required to register with FDA under 21 CFR Part 1, subpart H, **THEN**:

You must maintain records (for 2 years) identifying the immediate previous source and the immediate subsequent recipient of the food.

No

Are you a retail food establishment that purchases food produced on a farm directly from the owner, operator or agent in charge of that farm?

Yes

You are exempted, **EXCEPT**:

You must establish and maintain (for 180 days) a record documenting the name and address of the farm that was the source of the food.

No

Are you a farm-to-school or farm-to-institution program that purchases food produced on a farm?

Yes

You are exempted, **EXCEPT**:

The school food authority or relevant food procurement entity must establish and maintain (for 180 days) a record documenting the name and address of the farm that was the source of the food.

No

Are you the owner, operator or agent in charge of a fishing vessel?

Yes

You are exempted **EXCEPT** that, **IF** you are required to register with FDA under 21 CFR Part 1, subpart H, **THEN**:

You must maintain records (for 2 years) identifying the immediate previous source and the immediate subsequent recipient of the food.

No

You are subject to the Food Traceability Proposed Rule

* In addition, we are offering two proposals for how this rule would apply to small retail food establishments (RFEs):

Option 1 Full exemption: RFEs that employ 10 or fewer full-time equivalent employees (FTEs) would be exempt from the requirements of the rule.

Option 2 Partial exemption: RFEs that employ 10 or fewer FTEs would be exempt from the requirement to provide FDA, under specified circumstances, with an electronic sortable spreadsheet containing certain traceability information; however, they would be required to comply with all other aspects of the rule.

CFR - Code of Federal Regulations Title 21 documents referenced in chart:

[21 CFR §112.2\(a\)\(1\)](#)

[21 CFR §112.2\(b\)](#)

[21 CFR §118.3](#)

[21 CFR Part 1, subpart H](#)