Requirements for Additional Traceability Records for Certain Foods

WHO IS SUBJECT TO THE RULE?

1. 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
   - No
   - You are NOT subject to the rule.

2. Are you a shell egg producer with <3,000 laying hens at a particular farm?
   - Yes
   - No
   - You are NOT subject to the rule.

3. 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
   - No
   - You are NOT subject to the rule.

4. Are you a transporter of food?
   - Yes
   - No
   - You are NOT subject to the rule.

5. Are you a nonprofit food establishment?
   - Yes
   - No
   - You are NOT subject to the rule.

6. Do you manufacture, process, pack, or hold food for personal consumption?
   - Yes
   - No
   - You are NOT subject to the rule.

7. Do you hold food on behalf of specific individual consumers, AND:
   - You are not party to the transaction involving the food you hold;
   - You are not in the business of distributing food?
   - Yes
   - No
   - You are NOT subject to the rule.

8. Do you produce and package food on a farm, AND:
   - The packaging of the food remains in place until the food reaches the consumer;
   - The packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product; AND
   - Labeling of the food includes the name, complete address, and business phone number of the farm?
   - Yes
   - No
   - You are NOT subject to the rule.

9. Do you produce food on your farm (including food that is also packaged on your farm) AND sell it directly to a consumer?
   - Yes
   - No
   - You are NOT subject to the rule with respect to the food that meets these conditions.

10. 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
       - No
       - You are NOT subject to the rule with respect to the RCR food.

11. Do you produce a food that is listed as rarely consumed raw in 21 CFR §112.2(a)(117)?
    - Yes
    - No

12. 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
       - No
       - You are NOT subject to the rule with respect to the FTL food.

13. 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
    - No
    - You are exempted, EXCEPT:

14. Are you a farm-to-school or farm-to-institution program that purchases food produced on a farm?
    - Yes
    - No
    - You are exempted, EXCEPT:

15. Are you the owner, operator or agent in charge of a fishing vessel?
    - Yes
    - No
    - You are exempted, EXCEPT:

Partial Exemptions

- 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)(11)
- 21 CFR §112.2(b)
- 21 CFR §118.3
- 21 CFR Part 1, subpart H