

Proposed Rule: Requirements for Additional Traceability Records for Certain Foods (FSMA Section 204)

Scope and Exemptions

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Who Is Covered?

- Rule applies to persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL)
 - FTL includes foods specifically listed and foods that contain listed foods as ingredients
- Includes entities throughout the supply chain: from farms and manufacturers, through distributors and wholesalers, to retail food establishments
- Includes domestic and foreign entities



Overview of Exemptions

Statutory Exemptions	Statutory Partial Exemptions
Farms selling food directly to consumers	Certain commingled RACs (not fruits & vegetables)
Food produced/packaged/labeled on farm	Fishing vessels
	Farm-to-school/institution programs

Additional Proposed Exemptions	Additional Proposed Partial Exemptions
Very small farms	Retail food establishments receiving food directly from a farm (expanded from “grocery stores”)
Produce and shell eggs that receive certain processing	
Produce on FDA’s “rarely consumed raw” list	
Transporters of food	
Non-profits, personal consumption	

In addition, traceability records would not be required after a kill step is applied. Record of kill step application would have to be maintained by the person who applied the kill step.



Exemptions for Small Originators of Foods

- *Produce farms*: Farms or farm activities of farm mixed-type facilities with respect to produce they grow, when the farm is not a covered farm under the produce safety regulation in accordance with 21 CFR 112.4(a)
- *Shell egg producers*: Shell egg producers with fewer than 3,000 laying hens at a particular farm (as to the shell eggs produced there)
- *Other originators of food*: Originators of food with an average annual monetary value of food sold during previous 3-year period of no more than \$25,000 (on a rolling basis)



Exemption for Farms When Food Is Sold Directly to Consumers

- Exemption applies to a farm with respect to food produced on the farm (including food that is also packaged there) that is sold directly to a consumer by the owner, operator, or agent in charge of the farm
- Includes applicable sales at farmers' markets, roadside stands, over the internet, and through community-supported agriculture programs



Certain Food Produced and Packaged on a Farm

- The rule would not apply to food produced and packaged on a farm provided
 - The food's packaging remains in place until the food reaches the consumer, and the packaging maintains the integrity of the product and prevents subsequent contamination or alteration
 - The food's labeling that reaches the consumer includes the name, complete address, and business phone number of the farm
- FDA would waive requirement to include business phone number to accommodate a religious belief of a farm owner



Foods Receiving Certain Types of Processing

- *Produce*: the rule would not apply to produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the requirements in 21 CFR 112.2(b) are met
 - Exemption would apply to all who manufacture, process, pack, or hold such produce, not just the farm that grew it, and would apply both before and after the processing takes place
- *Shell eggs*: the rule would not apply to shell eggs when all eggs produced at a farm receive a treatment (as defined in 21 CFR 118.3) in accordance with § 118.1(a)(2)



Produce Rarely Consumed Raw

- The rule would not apply to produce listed as rarely consumed raw in § 112.2(a)(1) in the produce safety regulation



Partial Exemption for Commingled Raw Agricultural Commodities (RACs)

- The rule generally would not apply to a “commingled raw agricultural commodity” –
 - Defined as any commodity combined or mixed after harvesting but before processing
 - But does *not* include fruits or vegetables that are RACs subject to the produce safety regulation
 - Shell eggs are **an example of a** ~~the only~~ potentially commingled RAC on the proposed FTL
- However, if a person who manufactures, processes, packs, or holds such a commingled RAC must register with FDA as a food facility (with respect to that RAC), the person would have to keep records identifying the immediate previous source and immediate subsequent recipient of such RAC (in accordance with §§ 1.337 and 1.345 of the existing 21 CFR Part 1, Subpart J, traceability requirements)
 - Some of these facilities are already subject to the Subpart J traceability requirements
 - Those who aren't would now need to keep “one-up, one-back” records



Exemption for Small Retail Food Establishments (RFEs): Co-Proposal

- Two proposed options for how the rule would apply to small RFEs (10 or fewer full-time equivalent employees)
 - Option 1: Full exemption from the rule
 - Option 2: Exemption from requirement to make available to FDA, in certain circumstances, an electronic sortable spreadsheet containing requested traceability information (for specified foods and date ranges)
- We request comment on which option (or an alternative approach) FDA should select for small RFEs



Partial Exemption for Retail Food Establishments

- The rule generally would not apply to RFEs regarding food produced on a farm (including food produced and packaged on a farm) and sold directly to the RFE by the farm's owner, operator, or agent in charge
- However, the RFE would have to keep a record (for 180 days) of the name and address of the farm that was the source of the food



Farm to School & Farm to Institution Programs: Partial Exemption

- The rule generally would not apply to an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Sec. 4 of the Child Nutrition Act of 1966, or any other entity conducting a farm to school or farm to institution program, regarding food produced on a farm sold directly to the school or institution
- However, the school food authority or relevant food procurement entity would have to keep a record (for 180 days) of the name and address of the farm that was the source of the food



Food Produced Through Use of Fishing Vessels: Partial Exemption

- The rule generally would not apply to the owner, operator, or agent in charge of a fishing vessel with respect to food that is produced through the use of the vessel
- However, if such an owner, operator, or agent in charge must register with FDA as a food facility with respect to the food produced through use of the fishing vessel, the person would have to keep records identifying the immediate previous source and immediate subsequent recipient of such food (in accordance with §§ 1.337 and 1.345)



Other Exemptions

- Transporters
- Nonprofit food establishments
- Persons who manufacture, process, pack, or hold food for personal consumption
- Persons who hold food on behalf of individual consumers if:
 - Not party to the transaction involving the food they hold
 - Not in business of distributing food

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