

The proposed rule includes exemptions for certain types of foods and certain persons who manufacture, process, pack or hold foods on the Food Traceability List. Some of these exemptions were provided by Congress, while others reflect the FDA's current thinking about the application of this rule to certain foods and persons.

### **Exemption for Certain Types of Small Originators**

The proposed rule would exempt certain farms and other originators (i.e., persons who grow, raise, or catch listed foods, or harvesters of non-produce listed foods, such as eggs) because they produce relatively small quantities of food. Specifically, the proposed rule would **not** apply to:

- Farms (or the farm activities of farm mixed-type facilities) with respect to the produce they grow, when the farm is not subject to the Produce Safety Rule because it has no more than \$25,000 in average annual produce sales as calculated under 21 CFR 112.4(a).
- Shell egg producers with fewer than 3,000 laying hens at a particular farm, with respect to the shell eggs they produce at that farm.
- Other originators of food whose average annual monetary value of food sold during the previous 3-year period was no more than \$25,000 (on a rolling basis), adjusted for inflation.

### **Exemption for Farms That Sell Directly to Consumers**

The proposed rule would exempt farms with respect to food they produce on their farm that they sell directly to consumers. This would include sales at farmers' markets, roadside stands, over the internet, and through community-supported agriculture programs (CSAs).

### **Exemption for Certain Food Produced and Packaged on a Farm**

The proposed rule would not apply to food produced and packaged on a farm under the following conditions:

- The packaging of the food remains in place until the food reaches the consumer, the packaging maintains the integrity of the product, and it prevents subsequent contamination or alteration of the product\*; and
- The labeling of the food that reaches the consumer includes the name, complete address, and business phone number of the farm where the food was produced and packaged.

*\*Produce packed or packaged in containers such as clamshells with holes, cardboard boxes, vented crates, plastic bags with holes, or netted bags would not be eligible for this exemption because such packaging does not necessarily maintain the product's integrity and prevent subsequent contamination and alteration.*

### **Exemption for Foods that Receive Certain Types of Processing**

We propose exempting produce and shell eggs that undergo certain types of processing. Specifically, the proposed rule would exempt:

- Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions set forth for the commercial processing exemption in the Produce Safety Rule are met.
- Shell eggs when all eggs produced at the particular farm receive a treatment (as outlined in the Egg Safety Rule)

These exemptions would apply to the food throughout the supply chain, including before the processing is performed.

In addition, if a person applies a kill step to any food on the FTL, they would not be required to maintain records for their subsequent shipping of the food, as long as they maintain a record documenting the application of the kill step. Subsequent recipients of the food would not need to maintain records relating to the food.

### **Exemption for Produce that is Rarely Consumed Raw**

The proposed rule would exempt produce listed as "Rarely Consumed Raw" (RCR) in the Produce Safety Rule.

### **Partial Exemption for Commingled RACs**

The proposed rule includes a partial exemption for certain commingled raw agricultural commodities (RACs). This partial exemption would not apply to fruits and vegetables that are subject to the Produce Safety Rule. Commingling means that the commodity is combined or mixed after harvesting but before processing. An example of a commingled RAC subject to this exemption would be shell eggs that are mixed from separate farms under different management before packing.

When this exemption applies, exempt entities that are required to register through FDA's [Food Facility Registration](#) system would be required to maintain records

identifying the immediate previous source and the immediate subsequent recipient of the food, in accordance with 21 CFR §§ 1.337 and 1.345.

### ***Co-proposal for Small Retail Food Establishments***

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.

The FDA is interested in hearing from stakeholders regarding these options during the public comment period and public meetings.

### ***Partial Exemption for Retail Food Establishments***

The proposed rule includes a partial exemption for all RFEs with respect to food on the FTL that they purchase directly from the farm that produced it. In such situations, the RFE would only be required to establish and maintain for 180 days a record documenting the name and address of the farm that was the source of the food.

### ***Partial Exemption for Farm-to-School and Farm-to-Institution Programs***

We propose a partial exemption for farm-to-school and farm-to-institution programs operated under the auspices of USDA, State agencies or local jurisdictions. This partial exemption would apply to food that is produced on a farm and sold directly to the school or institution. In such situations, the school food authority or relevant food procurement entity would be required to establish and maintain for 180 days a record documenting the name and address of the farm that was the source of the food.

### ***Partial Exemption for Food from Fishing Vessels***

The proposed rule would not apply to the owner, operator or agent in charge of a fishing vessel with respect to a food that is produced through the use of the fishing vessel. Under this partial exemption, activities of fishing vessels such as harvesting, transporting, heading, eviscerating, and freezing fish would generally not be subject to the proposed recordkeeping requirements. However, if the owner, operator or agent in charge of the fishing vessel is required to register through FDA's [Food Facility Registration system](#) with respect to the manufacturing, processing, packing or holding of the applicable food, they would be required to maintain records identifying the immediate previous source and the immediate subsequent recipient of the food, in accordance with 21 CFR §§ 1.337 and 1.345.

### ***Exemption for Transporters***

The proposed rule would exempt transporters of food on the FTL.

### ***Exemption for Nonprofit Food Establishments***

The proposed rule would exempt nonprofit food establishments from the requirements of this rule. This exemption would apply to charitable entities that prepare or serve food including central food banks, soup kitchens and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code.

### ***Exemption for Personal Consumption***

The proposed rule would exempt persons who manufacture, process, pack or hold food for personal consumption. We would consider food prepared in a private home and transported for non-business purposes (e.g., to dinner with friends) to qualify for this exemption.

### ***Exemption for Certain Persons who Hold Food for Individual Consumers***

The proposed rule would exempt persons who hold food on behalf of specific individual consumers, provided that they are not parties to the transaction and are not in the business of distributing food. This exemption would cover persons such as a hotel concierge, reception desk staff in an apartment building, and staff at an office complex who may receive and store food.

### ***Special Requirements for Foods Subjected to a Kill Step***

As discussed above, under the proposal, if a person applies a kill step (i.e., processing that significantly minimizes pathogens, such as cooking or pasteurization) to a food on the FTL, they would not be required to maintain the records required by this rule for their subsequent shipping of the food, as long as they maintain a record documenting the application of the kill step. Subsequent recipients of a food on the FTL to which a kill step has been applied would not need to maintain records required by this rule.

In addition to the exemptions listed above, the proposed rule would allow the FDA, on its own initiative or in response to a citizen petition, to create modified requirements or exemptions if the FDA determines that the application of the relevant requirements to a given food or type of entity is not necessary to protect the public health. The proposed rule describes the process by which such modified requirements and exemptions can be requested. The proposed rule would also establish a process for the FDA to provide waivers when the agency determines that the application of the requirements would result in economic hardship for an individual entity or type of entity, due to the entity's unique circumstances.