



U.S. FOOD & DRUG ADMINISTRATION

FREQUENTLY ASKED QUESTIONS ABOUT THE FOOD TRACEABILITY PROPOSED RULE

Following publication of the proposed rule, [“Requirements for Additional Traceability Records for Certain Foods”](#) (Food Traceability Proposed Rule) on September 23, 2020, the FDA has received a number of questions from stakeholders, including during the [public meetings](#), through the [Food Safety Modernization Act Technical Assistance Network \(FSMA TAN\)](#), and during other outreach engagements. This FAQ, which is based on the proposed rule and its references, is intended to address some of the most frequently asked questions as an aid to stakeholders who are considering providing feedback during the comment period for the proposed rule, which has been extended until February 22, 2021. Comments can be submitted at <https://www.regulations.gov/> Docket ID: [FDA-2014-N-0053](#). Those submitting comments to the proposed rule are encouraged to provide real life examples and details about specific arrangements for consideration.

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Is the proposed rule focused only on biological hazards?

The proposed rule only applies to those that manufacture, process, pack, or hold foods on the FTL. To help determine which foods should be included on the FTL, the FDA developed a risk-ranking model for food tracing (“the Model”) based on the factors that Congress identified in Section 204 of the Food Safety Modernization Act (FSMA). In developing the current version of the Model, FDA focused on biological hazards and acute chemical toxins that present an immediate public health risk and for which traceability would be necessary to rapidly identify the source of contamination and prevent additional illnesses. For more information about development of the Model, see “[Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204.](#)”

Under the proposed rule, how could foods be added to or removed from the Food Traceability List? How often will FDA review the FTL?

The proposed rule sets forth a process for FDA to update the FTL (see proposed § 1.1465). Under that proposed process, when FDA tentatively concludes that it is appropriate to revise the FTL, we would publish a notice in the *Federal Register* stating the proposed changes to the list and the reasons for these changes, and requesting information and views on the proposed changes. After considering any information and views that are submitted, FDA would publish a notice in the *Federal Register* stating whether we were revising the list and the reasons for the decision. Any deletions from the list would become effective immediately, while any additions would become effective one year after publication of the *Federal Register* notice, unless otherwise stated in that notice. We would also publish the revised list on our website.

We have not set a schedule for considering updates to the FTL, but we plan to perform a periodic review of new scientific data or other scientific information that is relevant to the factors that Congress identified in FSMA Section 204 to determine if updates would be appropriate. (See 85 FR 59984, 60019.)

Are dried spices on the FTL? What about dried vegetables?

In the [risk-ranking model for food tracing](#) that FDA used to designate the FTL, dried spices are included in the commodity “Spices,” which is not included on the proposed FTL. Therefore, dried spices would not be covered under the Food Traceability proposed rule.

Similarly, dried vegetables are included in the commodity “Vegetables (Dried),” which is not included in the proposed FTL and therefore would not be covered under the Food Traceability proposed rule.

See Table A-2 in Appendix A of FDA’s report, [Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204](#), for more information. That table lists all of the commodities that were considered for inclusion on the FTL, including commodities such as “Spices” and “Vegetables (Dried)” that are not included on the proposed FTL. Seeing the full list of commodities can be helpful in figuring out the commodity designation for a specific product.

Collards are listed as an example of leafy greens on the FTL, but they are also on the list of produce that is rarely consumed raw in the produce safety regulation (21 CFR § 112.2(a)(1)). Would collards be covered under the proposed rule?

Collards are a type of leafy green, which is why they were originally included in the description of “leafy greens” on the FTL. However, we have proposed to exempt all produce on the produce safety regulation’s [“rarely consumed raw” list](#) – which includes collards – from the requirements of the Food Traceability Rule (see proposed § 1.1305(e)). Collards would therefore not be covered under the proposed requirements. We apologize for any confusion that might have resulted from our inclusion of collards in the description of “leafy greens” on the FTL, and we have updated the description of “leafy greens” on our [Food Traceability List webpage](#) to remove collards.

Why are all finfish grouped together on the FTL when there are different hazards associated with different types of finfish?

The commodity risk score for each of three separate finfish commodities– finfish, species not associated with histamine or ciguatoxin; open ocean finfish (histamine-producing species); and reef finfish (potentially contaminated with ciguatoxin) – were each sufficient for the commodity to be included on the FTL. As a result, each of these three commodities was placed on the FTL. For convenience of communicating the foods on the FTL, we grouped them together on the list.

For more information about how commodity risk scores were determined, see [“Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204.”](#)

ORIGINATING

Would originators, such as growers of produce on the FTL, have to keep the traceability program records that are described in proposed § 1.1315?

We have proposed to require that all entities who are subject to the rule must establish and maintain the traceability program records that are described in proposed § 1.1315. This would include all originators of foods on the FTL, unless they are exempt from the rule under proposed § 1.1305.

GROWING

Would growers be required to provide the geographical coordinates of their growing areas?

Under proposed § 1.1325, growers of foods on the FTL (who are not exempt under proposed § 1.1305) would be required to establish and maintain records that link the traceability lot code of the food to the growing area coordinates. We have proposed to define “growing area coordinates” to mean the geographical coordinates (under the global positioning system or latitude/longitude) for the entry point of the physical location where the food was grown and harvested. However, please note that under proposed § 1.1350(b), growing area coordinates are not among the key data elements that farms or other entities would be required to send to the recipient of a shipment of food on the FTL. Growing area coordinates therefore would only need to be maintained as part of a firm’s own traceability records, and

to be made available to FDA upon request, as set forth in proposed § 1.1455(b); they would not need to be provided to subsequent entities in the supply chain.

FIRST RECEIVER

Why was the term “first receiver” proposed?

The proposed rule would define “first receiver” to mean the first person (other than a farm) who purchases and takes physical possession of a food on the FTL. As discussed in the preamble to the proposed rule (see 85 FR 59984, 60008), we proposed to establish this new term, and to require that first receivers keep certain records that are not required for other receivers, because we concluded that the first receiver is the person who is best positioned to maintain comprehensive information about the origination and subsequent handling of a food. On-farm activities can involve movement of a food between different entities (e.g., growers, harvesters, coolers) without sale of the food, and the relevant business relationships can be complex. In some circumstances, firms that conduct on-farm production and handling activities may not own the food and may not be well-positioned to maintain the necessary records. In order to ensure that comprehensive records relating to the origination and initial handling of the food are maintained by a single person who both owns and possesses the food, the first receiver of the food was identified as the entity who would be responsible for maintaining certain KDEs relating to originated foods (see proposed § 1.1330).

Importantly, only foods that are originated (i.e., grown, raised, caught, or, in the case of a non-produce commodity such as eggs, harvested) would have a first receiver. Listed foods that are created (such as peanut butter that is made from peanuts and salt, neither of which is on the FTL) would not have a first receiver. First receivers would be required to maintain different KDEs depending on whether the food was obtained from a fishing vessel or not. For additional information and supply chain examples, see the [First Receiver Examples \(PDF\)](#).

The proposed definition of first receiver would state that you must purchase AND take physical possession of a food on the Food Traceability List. What about brokers who do not take physical possession? What if product is sold many times before someone in the chain both purchases AND takes physical possession?

We proposed to define “first receiver” to mean the first person (other than a farm) who purchases and takes physical possession of a listed food. In a situation where food is sold multiple times before it reaches someone who meets the definition of a “first receiver,” the entities involved in such sales would be required to follow any of the proposed recordkeeping requirements that apply to them, such as requirements relating to shipping records (see proposed § 1.1350) and receiving records (see proposed § 1.1335). However, only the person who meets the definition of a first receiver would be required to follow the proposed recordkeeping requirements relating to first receivers (see proposed § 1.1330).

Note that the proposed rule would only apply to entities that manufacture, process, pack, or hold foods on the FTL. Food brokers who negotiate sales of food from producers to wholesalers, retail stores, and others, but never physically possess the food, would not be subject to the rule. See 85 FR 59984, 60000.

If a third-party cooler does not purchase the product being cooled, what information would have to be maintained?

In this situation the cooler could not be considered a “first receiver,” because we are proposing to define that term to mean the first person (other than a farm) who purchases and takes physical possession of the food. “First receiver” is the only term in the proposed rule whose definition in proposed § 1.1310 hinges on whether or not an entity is a purchaser. We propose to define “receiving” as an event in a food’s supply chain in which a food is received by a customer (other than a consumer) at a defined location after being transported (e.g., by truck or ship) from another defined location. Similarly, we propose to define “shipping” as an event in a food’s supply chain in which a food is arranged for transport (e.g., by truck or ship) from a defined location to another defined location at a different farm, a first receiver, or a subsequent receiver. A cooler would use these definitions to determine if their specific situation constituted “receiving” and “shipping.”

Note that in the preamble to the proposed rule, we state that persons subject to the proposed requirements could enter into agreements with individuals or firms to create and keep the records required under this rule on their behalf. Firms could, for example, retain consultants or other outside entities to perform some or all of their responsibilities under the proposal, or rely on their supply chain partners, such as their brokers or suppliers, to establish and maintain required records on their behalf, so long as the firm would be able to make the records available to FDA upon request, as would be required under proposed § 1.1455(b)(1)-(2). We believe that allowing firms to enter into such agreements would allow for flexibility and accommodate current business practices while ensuring that persons subject to the rule remain responsible for ensuring that these recordkeeping requirements are met. See 85 FR 59984, 60004.

If an entity purchases a food on the FTL from a grower through a broker and the broker doesn’t take physical possession, would the entity be the first receiver?

Under the proposed definition of “first receiver,” the entity would be the first receiver if they were the first non-farm entity to purchase and take physical possession of the food, even if they purchased the product through a broker.

TRANSFORMATION

Is “repacking” a transformation event that would require a new traceability lot code?

Yes. Proposed § 1.1320 would require you to establish and assign a traceability lot code when you originate, transform, or create a food on the FTL. We propose to define “transformation” to mean an event in a food’s supply chain that involves changing a food on the FTL, its package, and/or its label (regarding the traceability lot code or traceability product identifier), such as by combining ingredients or processing a food (e.g., by cutting, cooking, commingling, repacking, or repackaging). The definition would further specify that transformation does not include the initial packing of a single-ingredient food or creating a food.

CREATION

Would a person who “creates” a food on the FTL need to keep records about the ingredients used in creating the food (e.g., must information on the apples used to make sliced apples be recorded)?

We propose to define “creating” to mean making or producing a food on the FTL (e.g., through manufacturing or processing) using only ingredient(s) that are not on the FTL. Because creation of a food on the FTL would not involve the use of any listed foods as ingredients, the creator of a listed food would not be required to maintain tracing records on the ingredients used to create the listed food. Instead, the creator of the food would only have to keep records providing information on the created food, including the location and date of creation, the traceability lot code, the traceability product identifier and product description, the quantity and unit of measure for each traceability lot code, and the reference record type and number for the created food. Although such records would not by themselves provide full traceability (because the product is made from foods not on the list), they would provide the principal information needed to trace the created food through the rest of the supply chain. See 85 FR 59984, 60011.

MOVEMENT OF THE FOOD WITHIN THE SAME ORGANIZATION

Would movement of FTL foods to other locations of the same organization be regarded as “shipping” under the proposed rule?

The proposed rule would define “shipping” as an event in a food’s supply chain in which a food is arranged for transport (e.g., by truck or ship) from a defined location to another defined location at a different farm, a first receiver, or a subsequent receiver. The proposed rule would similarly define “receiving” as an event in a food’s supply chain in which a food is received by a customer (other than a consumer) at a defined location after being transported (e.g., by truck or ship) from another defined location. We recognize the wide range of business arrangements in the food industry, and we welcome comment on how these proposed definitions would fit with different types of business structures, bearing in mind the goal of efficient and effective traceability.

If a retail establishment received a created food that is on the FTL, would it be required to keep traceability records?

The proposed recordkeeping requirements would apply to persons that manufacture, process, pack, or hold foods on the FTL (see proposed § 1.1300), unless a specific exemption applies. We have proposed to define “creating” to mean making or producing a food on the FTL (e.g., through manufacturing or processing) using only ingredient(s) that are not on the FTL. We have proposed specific recordkeeping requirements on entities that create foods on the FTL (see proposed § 1.1345). Once such a food has been created, it is on the FTL, and subsequent entities in the supply chain would be required to keep records relating to that food, just as they would for any other food on the FTL.

FARMS

Would farms be covered by the rule?

Generally, farms would be subject to the requirements in the proposed rule if they manufacture, process, pack or hold foods on the FTL. We have proposed an exemption in proposed § 1.1305(a) for certain small originators (including certain produce farms and certain egg farms), and other proposed exemptions might apply to some farms. For farms that would be covered by the proposed rule, the specific requirements would depend on the activities of the farm, e.g., growing, shipping, and/or receiving.

Is the proposed definition of farm in the traceability rule aligned with other rules?

We have proposed to define “farm” as that term is defined in 21 CFR § 1.328. This is the definition that is used for the existing recordkeeping requirements in 21 CFR Part 1, subpart J, and it is the same as the definition of “farm” in other FSMA rulemakings such as the [Preventive Controls for Human Food Rule](#) (21 CFR Part 117) and the [Produce Safety Rule](#) (21 CFR Part 112). We have further proposed that for producers of shell eggs, “farm” would mean all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program. This is the same definition that is used in the shell egg regulation (21 CFR Part 118).

RETAIL FOOD ESTABLISHMENTS (RFES)

If Option 2 of the co-proposal for RFES were to be adopted, what would the small RFES need to supply, if not a sortable spreadsheet?

We have co-proposed two possible exemption options for retail food establishments (RFES) that employ 10 or fewer full-time equivalent employees. (See proposed § 1.1305(g).) Option 1 would be a full exemption for such RFES, while Option 2 would specify that the sortable spreadsheet requirement in proposed § 1.1455(b)(3) would not apply to such RFES.

More specifically, if Option 2 of the co-proposal for proposed § 1.1305(g) were adopted in the final rule, RFES with 10 or fewer full-time equivalent employees would be exempt from the requirement, in proposed § 1.1455(b)(3), to make available to FDA within 24 hours, under specified circumstances, an electronic sortable spreadsheet containing the information required to be maintained under the rule for the FTL foods and date ranges specified in FDA’s request. Under proposed 1.1455(b)(3), FDA could request such a sortable spreadsheet when necessary to help us prevent or mitigate a foodborne illness outbreak, or to assist in the implementation of a recall, or to otherwise address a threat to the public health. If Option 2 were adopted in the final rule, and RFES with 10 or fewer full-time equivalent employees were therefore exempt from proposed § 1.1455(b)(3), FDA would not require such RFES to provide the sortable spreadsheet described above. Under Option 2, all other requirements of the proposed rule would apply to RFES with 10 or fewer full-time equivalent employees, including the requirement in proposed 1.1455(b)(1) to make all required records available to an authorized FDA

representative as soon as possible but not later than 24 hours after the request. Such records could be provided as paper records.

Would restaurants be considered retail food establishment under the proposed rule?

Yes. As stated in the preamble to the proposed rule (see 85 FR 59984, 60002), we regard restaurants as a type of retail food establishment, as that term would be defined in proposed § 1.1310.

COMMINGLED RAW AGRICULTURAL COMMODITIES (RACS)

Could fish and fishery products be considered commingled raw agricultural commodities that would be partially exempt from the rule?

In some situations, yes. Proposed § 1.1305(f) would provide a partial exemption for “commingled raw agricultural commodities,” which would mean any commodity that is combined or mixed after harvesting but before processing, except that the term “commingled raw agricultural commodity” would not include any produce that is subject to the produce safety rule. This proposed partial exemption is consistent with what Congress required in section 204(d)(6)(D) of the FDA Food Safety Modernization Act. As discussed in the preamble to the proposed rule (see 85 FR 59984, 59996-59997), shell eggs are an example of a raw agricultural commodity that would be exempt from the proposed traceability recordkeeping requirements if they were commingled.

There are also fish and fishery products on the FTL that could be eligible for the exemption in proposed § 1.1305(f), provided that they are combined or mixed after harvesting but before processing. Proposed § 1.1305(f) provides that a commodity would be considered “combined or mixed” only when the combination or mixing involves food from different farms, and that the term “processing” would mean operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

Under proposed § 1.1305(f)(2), any entity that receives this partial exemption and that is 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 commingled raw agricultural commodity, in accordance with 21 CFR §§ 1.337 and 1.345. Such records would have to be maintained for 2 years.

TRACEABILITY LOT CODE

Could the traceability lot code be a lot code that a company would use already?

There are no proposed requirements regarding how a firm could create their traceability lot codes. We propose to define the term “traceability lot code” to mean a descriptor, often alphanumeric, used to identify a traceability lot. In most situations, only firms that originate, transform or create a food on the FTL would establish and assign a new traceability lot code (see proposed § 1.1320). Regardless of how a firm chooses to create their traceability lot codes, the proposed rule would require that all key data elements be linked to the traceability lot code to ensure traceability within the firm and across the

supply chain. The proposed rule would also require that a firm's traceability program records include a description of how the firm establishes and assigns their traceability lot codes, when applicable (see proposed § 1.1315(a)(3)).

Could a business establish a lot code number or other code to identify a product separate from the traceability lot code?

Once a traceability lot code has been assigned, it could only be changed when the food is transformed (see proposed § 1.1320. We recognize that there may be situations where a firm would not be permitted to assign a new traceability lot code under proposed § 1.1320, but the firm might nonetheless wish to assign their own lot code or other code that is separate from the traceability lot code. Nothing in the proposed rule would prohibit that, as long as the traceability lot code were also maintained and linked to all key data elements, as the proposed rule would require.

Would the traceability lot code have to be on the food's packaging under the proposed rule?

Under the proposed rule, firms that ship foods on the FTL would be required to send certain information, including the traceability lot code, to the receiving firm (see proposed § 1.1350(b)). The traceability lot code and the other required information would not need to be written on the packaging of the product. As discussed in the preamble to the proposed rule, we would encourage firms to send the information electronically, such as in an email to their customer or an advanced shipping notice. Shippers could also elect to send the information in other written form, such as by mailing paper documents or including the information on the documents that accompany the shipment, such as the bill of lading. (See 85 FR 59984, 60012.)

Under the proposal, would the traceability lot code stay the same as the food moves through the supply chain?

Under proposed § 1.1320, you would be required to establish and assign a traceability lot code when you originate, transform, or create a food on the FTL; and you would not be permitted to establish a new traceability lot code when you conduct other activities (except that if a food's originator did not assign a traceability lot code, for example because they are exempt, then the first receiver would be required to do so, per proposed § 1.1330(c)). In other words, the traceability lot code would be assigned when the food is first originated or created (or by the first receiver, if the originator is exempt); and a new traceability lot code would not be assigned unless the food were subsequently transformed. If the food is transformed and a new traceability lot code is therefore assigned, that new traceability lot code would not be changed unless the food underwent another, subsequent transformation. Thus, the traceability lot code would stay the same as the food moves through the supply chain, except when transformation occurs.

Would originators always have to assign a traceability lot code? In what circumstances might a first receiver assign a traceability lot code?

Under proposed § 1.1320, originators of foods on the FTL would be required to establish and assign a traceability lot code. However, under proposed § 1.1305(a), some originators would be exempt from the proposed requirements. Proposed § 1.1330(c) would provide that if the originator of a food on the FTL did not assign a traceability lot code, the first receiver must do so.

MISCELLANEOUS

For nut butters, if a kill step is applied to the nuts before they are made into nut butter, would the proposed rule still apply?

Under proposed § 1.1355(a), if you apply a kill step to a food on the FTL, the requirements of the proposed rule would not apply to your subsequent shipping of the food, provided that you maintain a record of your application of the kill step. However, there are not any nuts that are on the FTL. Therefore, application of a kill step to nuts would not trigger proposed § 1.1355(a). Thus, someone who creates a nut butter product would be subject to the requirements of the proposed rule, regardless of whether the nuts had previously received a kill step. However, because nut butters are on the FTL, application of a kill step to a nut butter product would trigger proposed § 1.1355. Under that provision, the requirements of the proposed rule would not apply to the subsequent shipping of the nut butter by the person who applied the kill step, provided they maintain a record of their application of the kill step; nor would the proposed rule's requirements apply to the subsequent movement of the nut butter through the supply chain.

What are the requirements for entities who are in the supply chain after a kill step is applied?

Under proposed § 1.1355(b), subsequent persons in the supply chain who receive a food on the FTL to which a kill step has already been applied would not be required to maintain any traceability records under the proposed rule.

When would I need to comply with the rule, if finalized?

The FDA has proposed that the compliance date for all covered entities would be two years from the date that the final rule becomes effective. We have proposed that the rule become effective 60 days after the date on which the final rule is published in the *Federal Register*.

Are there specific technologies/standards that would be required for traceability under this proposal?

In accordance with FSMA 204(d)(1)(C), this proposed rule would not prescribe specific technologies for the maintenance of records.

Why is this proposed rule needed, since subpart J already creates recordkeeping requirements?

[21 CFR Part 1, Subpart J](#), "Establishment, Maintenance, and Availability of Records," does already provide recordkeeping requirements for many persons who manufacture, process, pack, transport, distribute, receive, hold, or import food. However, as discussed in the preamble to the proposed rule (see 85 FR 59984, 59990), since implementation of the subpart J regulations more than 10 years ago,

FDA has learned that those one-up, one-back recordkeeping requirements do not capture all the information necessary to effectively and rapidly link shipments of food through each point in the supply chain. Congress recognized this when it passed the FDA Food Safety Modernization Act, which required FDA to undertake this rulemaking to establish additional recordkeeping requirements (beyond those in subpart J) for certain foods. The proposed rule would attempt to address some of the most significant gaps in the subpart J requirements, such as the lack of coverage for farms and restaurants, lack of uniform data collection, and inability to link incoming with outgoing product within a firm and from one point in the supply chain to the next. The proposed rule would also allow FDA to go, in some cases, directly to the entity within the supply chain that originated, created, or transformed the product, potentially resulting in more efficient tracing.

Would the proposed rule apply to importers?

Unless a specific exemption applies, the proposed rule would apply to all persons who manufacture, process, pack, or hold foods on the FTL, including food importers who engage in such activities. As discussed in the preamble to the proposed rule, we believe that persons who do not physically possess food are not engaged in “holding” of food within the meaning of the proposed rule. This means that some persons who import food may not be subject to the rule because they do not “hold” the food. For example, a person who coordinates the import of a listed food but never takes physical possession of the food would not be subject to the rule, while a person who imports a listed food they physically possess would be subject to the rule unless an exemption applied. (See 85 FR 59984, 60000.)

In the Preliminary Regulatory Impact Analysis, does the number of affected entities include foreign facilities?

The number of affected foreign entities is reported separately in section II.H (“International Effects”) of the [Preliminary Regulatory Impact Analysis](#) (PRIA). It is not included in the total count of covered entities reported in Table 5 of the PRIA (section II.D.3). This is consistent with the guidance in OMB Circular A-4 (2003), which states that international effects should be reported separately from those occurring within the U.S.

Where do the capital investment cost estimates in the Preliminary Regulatory Impact Analysis come from? What assumptions went into those estimates?

As discussed in section II.F.3 of the PRIA, some entities may be able to comply with the rule without additional capital investments, while others would need to invest in traceability-related capital. The incremental costs of complying with the proposed rule may be significantly less than the cost of a total system upgrade, particularly because we believe many traceability systems are already in place. Considering variation in needs across firms’ sector, size, and existing capabilities, and synthesizing recent industry reports and vendor estimates with input from subject matter experts (Ref. 34 of the PRIA), we assumed that an affected covered firm would spend between \$500 and \$25,000 on all additional capital investments to comply with the proposed rule, with a primary estimate of \$7,500. Because the majority of entities affected by the proposed rule are small- and medium-sized firms, we assumed that the overall range of additional investment needed skews toward these firms. We

recognize that there is substantial variability in investment, and we requested comment on these assumptions.

In the Preliminary Regulatory Impact Analysis, is the number of retail food establishments the number of stores selling to consumers (the restaurants, grocery stores etc.), or is it the number of corporations/brands (e.g., a restaurant chain that may have 200 stores)?

In the PRIA, we report both the number of covered firms and the number of covered establishments. One firm can operate several establishments (facilities). Some costs are estimated per firm while other costs are per establishment. To estimate the number of covered entities, we use several sources. These include the [U.S. Economic Census](#), the 2016 Statistics of U.S. Businesses, FDA's Food Facility Registration Module, and the 2017 Census of Agriculture. (See section II.D.3 of the PRIA.)

FDA listed training as a one-time cost. Wouldn't training be a recurring cost as new employees are hired and current employees re-trained?

In the PRIA, we assumed that all firms covered by the general records provision would incur one-time costs to train employees and managers in new food traceability practices. These costs may include hiring a food traceability subject matter expert to train staff in person or via web seminars and the costs of producing training materials. We assumed that the number of firms affected by these training costs is equal to the number of firms affected by capital investment costs. We expect operational changes on a day-to-day basis to be disseminated through ongoing meetings and trainings, such that firms would not face additional costs of training all employees. We requested comment on this assumption. (See section II.F.4 of the PRIA.)