

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2014-N-0053]

RIN 0910-A144

Requirements for Additional Traceability Records for Certain Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to establish additional traceability recordkeeping requirements for persons that manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List. The proposed rule would require these entities to establish and maintain records containing information on critical tracking events in the supply chain for these designated foods, such as growing, shipping, receiving, creating, and transforming the foods. The proposed requirements are intended to help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. We are issuing this proposed rule in accordance with the FDA Food Safety Modernization Act (FSMA).

DATES: Submit either electronic or written comments on the proposed rule by January 21, 2021. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by November 23, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 21, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.

Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-N-0053 for "Requirements for Additional Traceability Records for Certain Foods." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on the information collection under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The title of this proposed collection is "Requirements for Additional Traceability Records for Certain Foods."

FOR FURTHER INFORMATION CONTACT:

Regarding the proposed rule: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4614, Brian.Pendleton@fda.hhs.gov.

Regarding the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

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I. Executive Summary

A. Purpose and Coverage of the Proposed Rule

In accordance with section 204(d) of FSMA, this proposed rule would establish traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods that FDA has designated as foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health. The requirements are intended to help us rapidly and effectively identify recipients of these foods to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death as a result of such foods being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342) or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). The proposed requirements would reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving the ability to quickly and

efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated food from the marketplace, and develop mitigation strategies to prevent future contamination.

We are issuing the proposed rule because Congress directed us, in section 204(d)(1) of FSMA, to establish recordkeeping requirements for these foods that would be additional to the traceability recordkeeping requirements in section 414 of the FD&C Act (21 U.S.C. 350c) and FDA regulations in 21 CFR part 1, subpart J (subpart J). The existing requirements in subpart J are designed to enable FDA to identify the immediate previous sources and immediate subsequent recipients of foods to address credible threats of serious adverse health consequences or death to humans or animals. The proposed rule would adopt additional recordkeeping requirements beyond those in subpart J for foods we designate as high-risk foods (including foods that contain foods designated as high risk) in accordance with factors specified by Congress in section 204(d)(2)(A) of FSMA. We will list these designated foods on a "Food Traceability List," a draft of which is available for comments. We will publish a final version of the Food Traceability List on our website when we issue the final rule, and we will update the list as appropriate under the procedures set forth in section 204(d)(2)(B) of FSMA and the proposed rule.

B. Summary of the Major Provisions of the Proposed Rule

We are proposing recordkeeping requirements for foods on the Food Traceability List ("listed foods") designed to improve the traceability information available for these foods during foodborne illness outbreaks and to increase the speed and precision of traceforward investigations for recall events. The proposed requirements are informed by the challenges we have faced in obtaining critical tracing information and the advancements in traceability approaches that industry has already begun to implement.

The proposed rule would require persons who manufacture, process, pack, or hold foods on the Food Traceability List (including foods that contain foods on the list as ingredients) to keep certain records describing their traceability operations and the listed foods they handle to help FDA investigators understand their traceability procedures and records when reviewing them during a foodborne illness outbreak or a routine

inspection. These traceability program records include a description of the reference records (e.g., bills of lading, purchase orders) in which they keep required tracing information, a list of foods on the Food Traceability List they ship, a description of how they assign traceability lot codes, and other information needed to understand their traceability programs.

The core components of the proposed rule are the requirements to establish and maintain records containing key data elements (KDEs) associated with different critical tracking events (CTEs) in a listed food's supply chain, including the growing, receiving, transforming, creating, and shipping of listed foods. The recordkeeping requirements we propose emphasize the importance of documenting the applicable traceability lot codes and linking these codes to other KDEs at critical points in the supply chain of a food to aid product tracing during an investigation of a foodborne illness outbreak or during a recall.

The proposed rule includes several proposed full and partial exemptions from the additional recordkeeping requirements, including some specified by Congress and some we are proposing on our own initiative. Proposed full exemptions include those for small retail food establishments (under one option of a "co-proposal" regarding such establishments), small farms, farms selling food directly to consumers, certain food produced and packaged on a farm, food that receives certain types of processing, and transporters of food. Partial exemptions would apply to certain commingled raw agricultural commodities (not including fruits and vegetables subject to the produce safety regulations), fishing vessels, retail food establishments that receive a listed food directly from a farm, and farm to school and farm to institution programs.

The proposed rule also includes special requirements for foods on the Food Traceability List that are subjected to a kill step.

In accordance with section 204 of FSMA, we are proposing to establish procedures under which persons subject to the proposed rule (when finalized) could request modified requirements or an exemption from these recordkeeping regulations for a specific food or a type of entity on the grounds that application of the requirements to that food or type of entity is not necessary to protect public health. In addition, the proposed rule includes procedures for requesting a waiver of one or more of the requirements for an individual entity or a type of entity on the grounds that

having to meet the requirements would impose an economic hardship.

The proposed rule also includes procedures for future updating of the Food Traceability List in accordance with section 204(d)(2)(B) of FSMA.

C. Legal Authority

Section 204(d)(1) of FSMA directs FDA to publish a notice of proposed rulemaking to establish recordkeeping requirements, in addition to the requirements under section 414 of the FD&C Act and the subpart J regulations, for facilities that manufacture, process, pack, or hold foods that FDA designates as foods for which additional recordkeeping requirements are needed under section 204(d)(2) of FSMA. Section 204(d)(2)(A) of FSMA directs FDA to designate foods for which the additional recordkeeping requirements described in section 204(d)(1) of FSMA are appropriate and necessary to protect the public health.

D. Costs and Benefits

This proposed rule, if finalized, would impose compliance costs on affected entities to establish and maintain traceability records for foods on the Food Traceability List and costs to read and understand the rule. Some entities may also incur initial capital investment and training costs. We estimate that the present value of costs of the rule over 10 years, if Option 1 of the co-proposal for retail food establishments with 10 or fewer full-time equivalent employees (full exemption from the rule) were selected, would range from \$238 million to \$17 billion, with a primary estimate of \$2.9 billion in 2018 dollars at a seven percent discount rate, and from \$285 million to \$20.1 billion, with a primary estimate of \$3.4 billion at a three percent discount rate. At a seven percent discount rate, annualized costs of the rule under proposed Option 1 would range from approximately \$34 million to \$2.4 billion per year in 2018 dollars, with a primary estimate of \$411

million per year. At a three percent discount rate, annualized costs under proposed Option 1 would range from approximately \$33 million to \$2.4 billion per year, with a primary estimate of \$400 million per year.

We estimate that the present value of costs of the rule over 10 years, if Option 2 of the co-proposal for retail food establishments with 10 or fewer full-time equivalent employees (exemption from the requirement to make available to FDA, in certain circumstances, an electronic sortable spreadsheet containing requested traceability information) were selected, would range from \$301 million to \$22.5 billion, with a primary estimate of \$3.8 billion in 2018 dollars at a seven percent discount rate, and from \$356 million to \$26.1 billion, with a primary estimate of \$4.4 billion at a three percent discount rate. At a seven percent discount rate, annualized costs of the rule under proposed Option 2 would range from approximately \$43 million to \$3.2 million per year in 2018 dollars, with a primary estimate of \$535 million per year. At a three percent discount rate, annualized costs under proposed Option 2 would range from approximately \$42 million to \$3.1 billion per year, with a primary estimate of \$513 million per year.

The proposed rule, if finalized, would result in public health benefits if it averts foodborne illnesses related to outbreaks linked to foods on the Food Traceability List. It would also improve the likelihood of conducting more targeted recalls and reduce the cost of conducting recalls by avoiding overly broad recalls and market withdrawals. Additional benefits may include increased food supply system efficiencies, such as improvements in supply chain management and inventory control; more expedient initiation and completion of recalls; avoidance of costs due to unnecessary preventive actions by consumers; and other benefits due to a standardized approach to traceability, including an

increase in transparency and trust and potential deterrence of fraud.

We estimate public health benefits using several case studies of outbreak tracebacks for four pathogens associated with illnesses caused by foods on the Food Traceability List. These benefits have a tendency toward underestimation of the total public health benefits because these four pathogens do not represent the total burden of all illnesses associated with listed foods. However, adjustments made for undiagnosed and unattributed illnesses may have the opposite tendency of overstating both illnesses and benefits associated with listed foods. We calculate these monetized benefits from illnesses averted per year based on an estimated 84 percent reduction of traceback time resulting from the requirements of this rule.

Under Option 1 of the co-proposal, for an estimated 84 percent traceback improvement, the annualized monetized benefits range from \$33 million to \$1.4 billion with a primary estimate of \$567 million, discounted at seven percent over ten years. At a three percent discount rate over ten years, the annualized monetized benefits range from \$33 million to \$1.4 billion with a primary estimate of \$580 million. Under Option 2 of the co-proposal, for an estimated 84 percent traceback improvement, the annualized monetized benefits range from \$36 million to \$1.5 billion with a primary estimate of \$626 million, discounted at a seven percent over ten years, and from \$37 million to \$1.5 billion with a primary estimate of \$640 million, discounted at three percent over ten years. Using examples from three recalls, additional (non-health) benefits for both Options 1 and 2 of avoiding overly broad recalls could range from \$1.7 billion to \$5.6 billion per year at a seven percent discount rate and from \$1.7 billion to \$5.8 billion using a three percent discount rate. We lack complete information on other benefits described above and discuss them qualitatively.

TABLE 1—COSTS AND BENEFITS
[In 2018 dollars annualized over 10 years at 7 percent discount rate]

	Option 1	Option 2
Total Costs	\$411 million	\$535 million.
Total Benefits	\$567 million in public health benefits for an estimated scenario of 84 percent traceback time improvement. Additional potential benefits that we describe qualitatively include increased food supply system efficiencies; more expedient initiation and completion of recalls; avoidance of costs due to unnecessary preventive actions; and other efficiencies from a standardized approach to traceability. However, if retail food establishments with 10 or fewer full-time equivalent employees are exempt from subpart S requirements, the timeliness, precision, and accuracy of traceability efforts can be impacted, and qualitative benefits, such as the ability to narrow the number of lots in a recall and the ability for retail food establishments with 10 or fewer full-time equivalent employees to have the data necessary to quickly identify and remove contaminated products from shelves, will be lessened in comparison to Option 2.	\$626 million in public health benefits for an estimated scenario of 84 percent traceback time improvement. Additional potential benefits that we describe qualitatively include increased food supply system efficiencies; more expedient initiation and completion of recalls; avoidance of costs due to unnecessary preventive actions; and other efficiencies from a standardized approach to traceability.

II. Table of Abbreviations and Commonly Used Acronyms in This Document

Abbreviation or acronym	What it means
ASN	Advance shipping notice.
BOL	Bill of lading.
CDC	Centers for Disease Control and Prevention.
CSA	Community supported agriculture.
CTE	Critical tracking event.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FSIS	Food Safety and Inspection Service.
FSMA	FDA Food Safety Modernization Act.
FOIA	Freedom of Information Act.
GAP	Good agricultural practices.
GPS	Global positioning system.
KDE	Key data element.
LACF	Low-acid canned foods.
OMB	Office of Management and Budget.
RAC	Raw agricultural commodity.
USDA	U.S. Department of Agriculture.

III. Background

A. Introduction

On January 4, 2011, President Obama signed the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) into law. As a component of FSMA’s overhaul of U.S. food safety law to better ensure the safety and security of the nation’s food supply, section 204(d) of FSMA requires that FDA establish recordkeeping requirements for facilities that manufacture, process,

pack, or hold foods that the Agency designates as high-risk to facilitate the rapid and effective traceability of such foods. These recordkeeping requirements will be additional to the food traceability requirements under section 414 of the FD&C Act (added to the FD&C Act in title III, subtitle A, section 306, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188)) and the implementing regulations in subpart J of part 1 of title 21 of the Code of Federal Regulations (§§ 1.326 to 1.368) (the subpart J regulations). Congress directed FDA to adopt the subpart J recordkeeping requirements to allow the Agency to identify the immediate previous sources and immediate subsequent recipients of foods (commonly referred to as “one-up, one-back” recordkeeping) to address credible threats of serious adverse health consequences or death to humans or animals. In section 204(d)(1) of FSMA, Congress directed FDA to adopt additional recordkeeping requirements to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death to humans or animals resulting from foods being adulterated under section 402 of the FD&C Act or misbranded with respect to allergen labeling under section 403(w) of the FD&C Act.

The proposed additional recordkeeping requirements, when finalized, will help FDA follow the movement of listed food products and ingredients both backward and forward throughout the supply chain. Documenting the movement of foods through the supply chain is called product tracing or traceability. In the case of a foodborne illness outbreak or evidence of contaminated food, product

tracing helps government agencies identify the points in the food supply chain, including the source of the product, where contamination may have occurred and, working in partnership with industry, subsequently remove the food from the marketplace. It also helps those who sell food to notify those in the distribution chain that they may have received the product. Efficient traceability enables the government and the food industry to take action more quickly, thus preventing illnesses and reducing economic harm.

Traceability includes traceback and traceforward investigations. Traceback begins at the end of the supply chain at the point of purchase or point of service (e.g., grocery stores and restaurants) and follows the food product back through the points of distribution, processing, and production to determine the source of the product and its ingredients. Traceforward follows the movement of a food in the opposite direction, from the source (e.g., a farm or manufacturer) forward to the retail shelf, to determine the scope of a potential recall and the impact of the contaminated product on the public health.

Even before the enactment of FSMA, FDA had been considering ways to improve food product traceability and increase the speed and accuracy of our traceback and traceforward investigations. For example, in 2008 we held two public meetings to discuss mechanisms to enhance product tracing systems for fresh produce and to improve our ability to identify the source of contamination associated with fresh produce-related outbreaks of foodborne illnesses (see 73 FR 55115, September 24, 2008). In the spring of 2009, we engaged in a pilot project with the Institute of Food Technologists (IFT) to conduct a mock traceback scenario on tomatoes with representatives of the

industry, academia, States, and two technology companies (Ref. 1). In December 2009, we conducted a public meeting, in collaboration with the United States Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS), regarding product tracing systems for human food and animal food (see 74 FR 56843, November 3, 2009).

After FSMA was enacted, FDA sought public comment, scientific data, and information in February 2014 to inform our draft approach to identifying high-risk foods (see 79 FR 6596, February 4, 2014). Section 204(d)(2)(A) of FSMA requires FDA to designate high-risk foods for which the proposed additional recordkeeping requirements are appropriate and necessary to protect the public health. The high-risk food designation must be based on the following factors:

- The known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention (CDC);
- the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce the food;
- the point in the manufacturing process of the food where contamination is most likely to occur;
- the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
- the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
- the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

Section 204(d)(2)(B) of FSMA requires the Agency to publish the list of high-risk foods on our website when we issue the final rule establishing the additional recordkeeping requirements for high-risk foods.

B. Need for the Regulation

Each day that a foodborne illness outbreak remains unresolved, the health of consumers remains at risk. We recognize that to fully realize the public health benefits envisioned by FSMA, we need to improve our ability to rapidly identify and trace foods that may be causing illness. While industry has generally adopted the requirements for

one-up, one-back tracing required under the subpart J regulations, the complexity and level of implementation of tracing systems that exceed those requirements vary. From our traceback investigations and discussions with food industry companies and organizations, we recognize that many firms have developed traceability procedures for internal use to help ensure the safety of their products and the security of their supply chains. A smaller number of firms employ tracing systems that are more robust and allow linking of incoming and outgoing products throughout the supply chain, primarily through reference to applicable lot codes in records documenting the production, processing, and distribution of the foods. The proposed recordkeeping requirements, which go beyond subpart J, including by mandating such linking information, would reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks. The requirements would achieve this by improving the ability to (1) quickly and efficiently trace the movement of listed foods through the supply chain and (2) identify and remove contaminated food from the marketplace during an outbreak.

This proposed rule is intended to establish the framework of information needed to be maintained in traceability records to accurately and efficiently trace contaminated foods (both domestic and imported) across the U.S. food supply chain to protect the health of all consumers. The rule would establish a consistent approach for product tracing for the different types of products and firms subject to this regulation. The rule also specifies the data elements and information firms must establish and maintain, along with information they must send, in certain circumstances, to the next entity in the supply chain. The rule also would help establish a foundation for the use of consistent food tracing terminology, a transition from paper-based recordkeeping to electronic records, and a universal understanding of the critical information needed for a standardized and efficient system for traceability.

Tracing a food back in the supply chain from the point of sale or service to a common source is important for identifying contaminated foods or ingredients and removing those products from the marketplace to prevent additional illnesses. Tracing foods forward can help FDA understand how the distribution of a food product relates to illnesses or illness clusters, especially for outbreaks that are

challenging to resolve, such as those involving multiple foods and foods with multiple ingredients.

The Agency has sometimes been unable to determine links between illnesses and specific product distribution due to inconsistent, unstandardized recordkeeping, lack of a deliberate method to connect records, and the frequent lack of lot tracing regarding distribution to specific retail locations. The retail food establishment is the first point in the supply chain where an investigation is initiated to collect traceback data to identify the source of a product. The more accurate and detailed the data available on the product of interest at the retail food establishment, the more refined record collection can be throughout the remainder of the supply chain. In 2018, FDA investigated a cluster of illnesses caused by *Cyclospora cayetanensis* at small restaurants. We were unable to obtain enough information to identify specific farms/growers (from among several suppliers) as the source of the products suspected of contamination (e.g., basil, cilantro, vegetable trays) due to the restaurants' lack of records indicating lot numbers received and lack of linking to information throughout the supply chain. In the absence of more specific data at the retail food establishment, we had to conduct a broader record collection involving numerous suppliers to ensure that we had sufficient tracing information to accurately determine what lots likely would have been available for consumption or purchase at the establishments by the sickened persons. One benefit of the proposed requirements is that they would allow us to conduct comparative analyses on supply chains of multiple commodities to rule in or out specific ingredients in outbreaks in which ill persons have reported concerns about mixed-ingredient foods.

When a foodborne illness outbreak occurs, a firm with an effective traceability program can lessen the potential adverse economic impact of the event. This is possible when the firm can quickly and precisely provide specific traceability information on a suspected product to regulatory agencies. This information can enable the confirmation of common foods and ingredients associated with illnesses and also help determine which foods and ingredients can be potentially eliminated from further consideration as possible sources of contamination. As a result, regulatory agencies can narrow the scope of necessary recall actions, public health alerts, and countrywide import alerts. Furthermore, being able to

identify the source of a contaminated product quickly enables FDA to conduct more timely root-cause analysis, which could provide important information to help in understanding how contamination may have occurred and prevent future outbreaks.

Lack of traceability has led to delays in product recalls and notification to the public, allowing potentially contaminated foods to remain on the market longer. In 2017, the manufacturer of a soy nut butter product recalled the product after it was found to be the source of a multistate outbreak of Shiga toxin-producing *Escherichia coli* (*E. coli*) that sickened 32 people (81 percent of whom were younger than 18) in 12 states (Refs. 2 to 4). Weeks later, another company announced a recall of its products because they were made with soy nut butter supplied by the original company (Ref. 5). Inadequate traceability significantly impeded product actions for potentially contaminated product associated with this outbreak investigation.

Inadequate traceability can affect both traceback and traceforward investigations. In 2015, FDA, CDC, and multiple states investigated a multistate outbreak of *Salmonella* associated with imported cucumbers that ultimately sickened 907 people (Ref. 6). While the traceback was able to identify a single grower of the cucumbers resulting in product recalls, the CDC reported additional sporadic cases of *Salmonella* 6 months after the recall. Having more robust traceforward information could have helped ensure a more complete recall by identifying more locations that received the contaminated product and may have helped assess whether there were other contaminated products on the market subject to the same conditions that led to contamination of cucumbers.

During an outbreak of *Salmonella* Typhimurium in 2008, almost 4,000 peanut butter-containing products were recalled over a period of three and a half months. Cases of illness were first seen in patients residing in a long-term care facility and other institutional settings. Records at these locations identified a common brand of peanut butter, which led to a common manufacturer, and a recall of the brand was initiated. But illnesses continued to be reported across the United States, and further case interviews indicated that the illnesses could not be explained by consumption of the recalled brand of peanut butter. An extensive traceback and traceforward investigation led to expanded recalls over several months, during which many potentially contaminated peanut butter products

remained available in the marketplace. This outbreak illustrates the challenges posed by ingredient-based outbreaks and lack of standardized records documenting a product's distribution chain. Manual review of a variety of records was necessary to determine the subsequent commercial recipients of the peanut butter and the inclusion of the peanut butter as an ingredient in other food products. This time-consuming review resulted in a delay in the identification of the many products ultimately recalled in this outbreak (Ref. 7).

Poor traceability records also can lead to an inability to appropriately narrow the scope of a recall. In 2018, a leafy greens mix was linked to an outbreak of Shiga toxin-producing *E. coli*. FDA identified numerous farms that could potentially have produced leafy greens linked to the outbreak. Traceback data gathered during the investigation led to issuance of a public advisory to not consume chopped romaine lettuce from the identified growing region. However, lack of traceability records hindered our ability to identify specific lots and growers of contaminated product. After the initial advisory was issued, we identified an additional cluster of illnesses in people who consumed whole-head romaine lettuce from the same region. As a result, we expanded the initial public advisory to include all romaine lettuce from the identified growing region. Because we were unable to identify a point of origin for the food that made people ill, we were unable to narrow the scope of the advisory but instead had to expand it (Ref. 8).

Lack of specific lot-level tracing data can impact FDA's ability to perform root-cause analyses to determine the point of contamination once the source(s) is identified, which can lead to recurring outbreaks. For example, in 2013, 2014, and 2015, the CDC and state public health officials identified annually recurring outbreaks of *Cyclospora cayetanensis* infections in the United States associated with fresh cilantro from the state of Puebla, Mexico. Although not confirmed by epidemiological means, FDA reviewed a cluster of cyclosporiasis illnesses from 2012 in which the state of Texas had previously identified cilantro as one of multiple possible suspect vehicles. FDA determined that cilantro from Puebla was supplied to the point of service implicated in that outbreak and was one potential source of the outbreak. After the outbreak investigation in 2015, FDA implemented an import alert for shipments of fresh cilantro from Puebla during April through August to align with the seasonality of previous

cyclosporiasis outbreaks (Ref. 9). There were numerous traceback challenges during all three of the investigations due to commingling of product, recordkeeping issues, and inconsistencies in documented firm names that hindered our ability to identify the suppliers of the contaminated cilantro. Poor traceability delayed us from taking product actions to ensure contaminated product was removed from the market and conducting environmental assessments that could have identified routes of contamination to reduce future illnesses.

Poor traceability can affect not only outbreaks caused by infectious pathogens but also illnesses associated with fish poisonings. For example, in 2019, FDA investigated a cluster of 50 illnesses that were attributed to Scombrototoxin fish poisoning. In cases of fish toxin poisonings, the illness onset can occur within minutes of consuming fish products, making it even more vital to have specific tracing data available at the point of sale. Because cases reported a variety of frozen tuna products due to inconsistent product descriptions, FDA's traceback investigation traced all cuts of tuna supplied by two firms rather than narrowing the focus to one specific cut of tuna (Ref. 10). The traceback investigation was unable to confirm that the most recent shipments to the points of sale contained the actual product used to prepare meals reported by the cases, due to the extended 2-year shelf life of the frozen product and lack of recordkeeping for this product. Additionally, the traceback investigation could not identify/implicate lot codes at the point of sale because at least two distributors reboxed product into different packaging, and there was potential commingling of product at least one point of sale. Given the extended shelf life and lack of lot codes available at the point of sale, the traceback investigation could not determine relevant lot codes for the implicated products. Due to these traceability limitations, the Agency was only able to place one of the importers of the contaminated tuna products on an import alert, and multiple recalls were required to ensure that importers removed all contaminated products.

Inconsistent product descriptions and commingling of product can also affect traceability efforts. In June 2017, FDA investigated an outbreak of multiple serotypes of *Salmonella* that caused 220 cases of illnesses associated with contaminated papayas (Ref. 11). Tracing the contaminated papayas was delayed by inconsistent descriptions of the papayas, making it difficult to link the

product with the records. Ultimately, the traceback investigation was not able to implicate the shipments of the contaminated papayas due to product commingling, resulting in an inability to differentiate suppliers of the papayas.

As these examples show, while some elements of internal product tracing information are kept by many food producers, manufacturers, distributors, and retailers, the types of information recorded and maintained, the format in which information is kept, the length of time information is retained, and the amount of information shared between trading partners varies among firms. These challenges are further compounded when looking at the traceability of a product moving through multiple entities in a supply chain. Standardization of data elements is needed to help ensure successful traceability throughout the supply chain.

Recognizing the need for improvement in food traceability, when Congress enacted FSMA in 2011 it included provisions, in section 204, intended to enhance tracking and tracing of food. As noted, section 204(d) of FSMA directed FDA to establish additional recordkeeping requirements for certain foods. Under section 204(a) of FSMA, Congress directed us to establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated or misbranded. At FDA's request, the IFT conducted two product tracing pilots (involving mock tracebacks and traceforwards) of foods that had been implicated in foodborne illness outbreaks between 2005 and 2010, assessed the costs and benefits of efficient and effective methods for tracking the foods, and evaluated the feasibility of such methodologies being adopted by different sectors of the food industry. In its 2012 final report to FDA on the pilot studies, the IFT found that pilot participants appeared to have many tools and procedures needed to capture and communicate key traceability information at critical points of product transfer and transformation. However, the IFT identified several problems with current tracing systems, including inconsistencies in terminology and the production of information in formats that cannot be electronically manipulated (Ref. 12).

C. FDA's Current Regulatory Framework

The subpart J traceability recordkeeping requirements stemming from the 2002 Bioterrorism Act require firms to know and record the immediate previous sources of their food products and ingredients and the immediate subsequent recipients of the products they make and/or distribute. The regulations, which we adopted in a final rule issued in 2004 (see 69 FR 71562, December 9, 2004), specify information that "non-transporters" of food (persons who own food or who hold, manufacture, process, pack, import, receive, or distribute food for purposes other than transportation) must maintain regarding their receipt and release of food, with more limited requirements for transporters of food. In accordance with section 414(b) of the FD&C Act, the subpart J regulations exempt farms and restaurants from the requirements. Also exempt are retail food establishments that employ ten or fewer full-time equivalent employees.

Since implementation of the subpart J regulations more than 10 years ago, FDA has learned that these one-up, one-back recordkeeping requirements do not capture all the data elements necessary to effectively and rapidly link shipments of food through each point in the supply chain. In many outbreak investigations, we typically request additional information not explicitly required to be maintained under subpart J to help us conduct traceback and traceforward investigations. This additional information often is available because many firms maintain it for business (other than tracing) purposes. However, piecing together information from several types of documents to extract useful tracing data at each point in the supply chain is laborious and time-consuming, significantly slowing the tracing process and potentially putting more consumers at risk.

Among the most significant gaps in the subpart J recordkeeping requirements are the following:

- Lack of coverage of all sectors involved in food production, distribution, and sale (*e.g.*, exemptions for farms and restaurants).
- Lack of uniform data collection (*e.g.*, regarding the source of food ingredients used in each lot of finished product; the requirement to record a lot code or other identifier only "to the extent this information exists" (see §§ 1.337(a)(4) and 1.345(a)(4)); and
- Inability to link incoming with outgoing product within a firm and from one point in the supply chain to the next (Ref. 13).

When FDA faces challenges during a traceback investigation, it is often due to one or more of the above-listed gaps in the subpart J requirements. The exemptions for point-of-service firms (foodservice and retail) affect almost every investigation because consumer data often is used to initiate a traceback event. During the investigation of an outbreak of *E. coli* O26 in 2015 at a restaurant, the available consumer data could not identify a single ingredient for tracing because customers who became ill had consumed a variety of dishes with multiple common ingredients. This problem was magnified by the lack of information linking the distribution center to the point of sale.

In the last few years, numerous outbreaks associated with leafy greens have resulted in expansive recalls due to, among other reasons, a lack of uniform data collection across the supply chain. While our traceback activities identified farms that could have supplied affected product during the timeframe of interest for those outbreaks, a lack of data about the source of individual lots restricted our ability to identify which farms actually supplied the contaminated product.

These limitations in the existing tracing recordkeeping requirements have been evident in FDA investigations of foodborne illness outbreaks since the adoption of the subpart J requirements. By including section 204 in FSMA, Congress recognized the need for improvement of food tracking and tracing generally and traceability recordkeeping requirements in particular. In not excluding farms and restaurants from the scope of the additional requirements for high-risk foods, Congress also recognized the importance of ensuring traceability to both ends of the supply chain. The requirements of this proposed rule, when finalized, will help ensure that the food industry maintains the traceability information we have determined is needed to enable us to respond quickly and effectively to foodborne illness outbreaks and recall events.

D. History of the Rulemaking

On February 4, 2014, FDA issued a notice in the **Federal Register** (79 FR 6596) announcing the opening of a docket (FDA-2014-N-0053) to obtain comments and scientific data and information to help us implement section 204(d)(2) of FSMA, which requires us to designate high-risk foods (2014 Notice). The 2014 Notice summarized our tentative draft approach for the review and evaluation of data to designate high-risk foods. We

included as a reference to the notice a draft approach document in which we described the process and methodology we were considering using to designate high-risk foods. We invited interested parties to submit comments, scientific data, and information that would help us refine the draft approach to identifying these foods. In addition to requesting comment and information related to the draft approach to high-risk food designation, we sought information on the following:

- Scientific data and methods that can be used to assess the public health impact of acute or chronic exposures to pathogens and chemical contaminants in food; and
- For representative foods in each food category or commodity group, a list of pathogens and chemical contaminants likely to be found in the food, the percentage prevalence of contaminants in the food, the levels of contaminants in the food, the point in the manufacturing process where contaminants are likely to be introduced, and the typical steps and control measures taken in the manufacturing process to reduce the possibility of contamination of the food with the pathogen or chemical contaminant (79 FR 6596 at 6597).

1. Risk-Ranking Model and Food Traceability List

FDA received many comments in response to the 2014 Notice. Taking into consideration the comments and other

information submitted, we developed a draft risk-ranking model and collected data to populate the model for chemical and microbiological hazards associated with specific foods, with technical assistance from external expert panels. We conducted an extensive internal review of the draft model and data with Agency subject-matter experts. Two separate peer-review panels of independent external experts reviewed the draft model and the data used to generate risk scores with the model. Taking into consideration comments from these peer reviews (Refs. 14 and 15), we revised the model and updated the data.

As discussed more fully in FDA’s “Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S.C. 2223)” (Ref. 16), which is available in the public docket for this rulemaking and on our website, the risk-ranking model uses a semiquantitative, multicriteria decision analysis risk-ranking approach. The approach is consistent with the factors set forth in section 204(d)(2) of FSMA and is operationalized with data relevant to those factors, enabling the Agency to rank, on the basis of public health risk criteria, commodity-hazard pairs and, ultimately, foods we regulate.

Although section 204(d) of FSMA does not exclude food for animals, we have not included animal foods in our risk-ranking model. The current risk-ranking model was designed to account

only for humans and cannot accommodate applicability to other animal species. A principal reason for this is that one of the criteria used in the risk model is illness data. While human illnesses related to food are tracked by the CDC, there is no Federal agency with the authority or capability to track foodborne illness outbreaks in animals. Although FDA and state animal food regulatory programs have begun efforts to collect data on animal food-related illnesses, there are no requirements for reporting such illnesses, which has led to significant gaps in the data.

Although animal foods are not included in FDA’s risk-ranking model, we may revisit the issue of animal foods when we conduct any future reassessments of the model. We welcome comments on whether and how we should consider incorporating animal foods or animal food-related illness into this or a separate model.

Using the results of the risk-ranking model, we tentatively identified foods for which additional traceability records will be required in accordance with section 204 of FSMA (see “Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing” (Ref. 17). Based on that analysis, and in accordance with section 204(d)(2) of FSMA, following is the tentative list of foods for which additional traceability records would be required under the proposed rule (the Food Traceability List) (Ref. 18):

TABLE 2—TENTATIVE FOOD TRACEABILITY LIST

Food traceability list	Description
Cheeses, other than hard cheeses.	Includes all soft ripened or semi-soft cheeses, and fresh soft cheeses that are made with pasteurized or unpasteurized milk.
Shell eggs	Shell egg means the egg of the domesticated chicken.
Nut butter	Includes all types of tree nut and peanut butters; does not include soy or seed butters.
Cucumbers	Includes all varieties of cucumbers.
Herbs (fresh)	Includes all types of herbs, such as parsley, cilantro, basil.
Leafy greens, including fresh-cut leafy greens.	Includes all types of leafy greens, such as lettuce, (e.g., iceberg, leaf and Romaine lettuces), kale, chicory, watercress, chard, arugula, spinach, pak choi, sorrel, collards, and endive.
Melons	Includes all types of melons, such as cantaloupe, honeydew, and watermelon.
Peppers	Includes all varieties of peppers.
Sprouts	Includes all varieties of sprouts.
Tomatoes	Includes all varieties of tomatoes.
Tropical tree fruits	Includes all types of tropical tree fruit, such as mango, papaya, mamey, guava, lychee, jackfruit, and starfruit.
Fruits and Vegetables (fresh-cut).	Includes all types of fresh-cut fruits and vegetables.
Finfish, including smoked finfish.	Includes all finfish species, such as cod, haddock, Alaska pollack, tuna, mahi mahi, mackerel, grouper, barracuda, and salmon; except does not include siluriformes fish, such as catfish.
Crustaceans	Includes all crustacean species, such as shrimp, crab, lobster, and crayfish.
Mollusks, bivalves	Includes all species of bivalve mollusks, such as oysters, clams, and mussels; does not include scallop adductor muscle.
Ready-to-eat deli salads	Includes all types of ready-to-eat deli salads, such as egg salad, potato salad, pasta salad, and seafood salad; does not include meat salads.

We note that, as discussed in section V.A, the proposed traceability

recordkeeping requirements would apply not only to foods specifically

appearing on the Food Traceability List

but also to foods that contain foods on the list as ingredients.

A proposed Food Traceability List, including descriptions of the foods on the list (referred to in this document as “listed foods”), is available in the public docket for this rulemaking and on FDA’s website. In accordance with section 204(d)(2)(B) of FSMA, when we issue the final rule, we will publish a finalized Food Traceability List on our website. That list might differ from the list we are publishing with this proposed rule. We also note that, as discussed in section V.K, we anticipate periodically conducting a review to determine whether it is appropriate to revise the Food Traceability List in accordance with the procedures set forth in the proposed rule.

2. Proposed Recordkeeping Requirements for Foods on the Food Traceability List

To help us develop appropriate traceability recordkeeping requirements under section 204(d) of FSMA, we have met with stakeholders and reviewed the current state of food traceability standards, systems, and technologies. We considered a broad range of domestic and international tracing standards and approaches, including those of the IFT, the business global standards organization GS1, the Produce Traceability Initiative, the International Standards Organization, the Global Food Safety Initiative, and others. We researched standards and systems for traceability in effect in several regions and countries, including the European Union, Canada, Australia, Japan, and China. We also discussed traceability approaches and concerns with food industry and consumer groups (Ref. 19). In addition, we have taken into account our experiences and challenges in conducting investigations in response to outbreaks of foodborne illness and recall events.

From our traceback investigations and discussions with food industry companies and organizations, we recognize that most firms have developed and use some traceability procedures. For those firms that have traceability processes, it appears that an increasingly common approach to traceability involves the identification of CTEs for which KDEs are recorded and maintained. One of the IFT’s recommendations in its 2012 final report was that FDA require firms to identify and maintain records of CTEs and KDEs as determined by the Agency (Ref. 12). While not all firms at all points in the supply chain employ KDE/CTE-specific tracing tools and procedures, those that do are

recognizing the benefits both to their businesses and to public health of adopting such an approach to product tracing recordkeeping (Ref. 20). However, the KDEs/CTEs the food industry uses are not consistently implemented across supply chains. Further, many firms have not adopted updated traceability approaches and are awaiting further agreement on standard KDEs and CTEs to be used throughout the food industry.

As discussed in more detail in section V.E, the proposed rule adopts an approach to recordkeeping for foods on the Food Traceability List focused on maintaining and sharing specific KDEs for certain CTEs in a food’s supply chain, which aligns with consensus standards for traceability currently used by industry. The information required to be kept would vary depending on the type of supply chain activity, such as the growing, receiving, transforming, creating, and shipping of listed foods. We believe that the proposed rule will align the tracing information for foods on the Food Traceability List with our need to quickly and effectively respond to foodborne illness outbreaks and other contamination events associated with these foods.

E. Improving Traceability for All Foods

Ideally, a robust traceability system would provide for traceability of all foods, not just foods on the Food Traceability List. Regardless of the type of food that is the subject of a foodborne illness outbreak investigation, sufficient traceability information is needed to identify the source of an outbreak, expedite the removal of contaminated food from the marketplace, and prevent additional consumer exposures. Although section 204 of FSMA limits recordkeeping requirements to foods on the Food Traceability List, the types of records required to be maintained under the proposed rule could be used by entities in the supply chains of all foods to improve traceability.

The tracing information required to be kept under the proposed rule is consistent with information FDA typically requests during an outbreak investigation, regardless of the food commodity. Firms that maintain records containing this information can help FDA more quickly trace the movement of products through the supply chain, identify the source of contamination, and reduce harm to consumers posed by tainted food. By facilitating faster and more accurate identification of contaminated foods, the availability of such records can help narrow the scope of an outbreak investigation and limit the adverse impact of an outbreak on

affected sectors of the food industry. In addition, maintaining records in accordance with the proposed requirements would help ensure that a firm is well-prepared if a food the firm produces or distributes is added to the Food Traceability List as a result of a future reassessment of the list.

Of particular importance to an effective food traceability system under the proposed rule is the use of lot codes in documenting CTEs. Tracebacks are most efficient when point-of-service entities can provide investigators with as much information as possible about the origination of the food. If a point-of-service entity can provide lot codes and other relevant information for suspect foods, including the originating farm or firm, FDA investigators can more quickly identify the potential common source of an outbreak and take regulatory action. Tracing the lot information associated with suspect products can narrow the scope of an investigation, provide FDA with information to quickly go directly to the person that created the lot, and limit further illnesses by enabling more rapid removal of contaminated food from the marketplace. Lot code information can also allow investigators to more quickly determine which products are outside the scope of the investigation, reducing the likelihood of unnecessary category-wide recalls.

Although the proposed rule does not require the use of electronic records and electronic communications for traceability (except to aid FDA’s review of records during investigations of foodborne illness outbreaks), we encourage all segments of the food industry to incorporate electronic recordkeeping and communication procedures into their traceability programs. Keeping records of KDEs in electronic, rather than paper, form and sharing tracing information electronically with others in the supply chain can greatly facilitate the analysis of information during investigations into foodborne illness outbreaks and speed the completion of traceback and traceforward operations. Sharing of standard KDEs electronically allows all entities in the supply chain access to reliable information on the traceability of a product.

Further, while this proposed rule would not require retail establishments to maintain KDEs for consumer purchases, we support efforts by retailers to identify and provide anonymized consumer purchase data for outbreak investigations. Presently, we rely on date ranges to identify potentially contaminated products purchased by consumers. Access to

traceability lot codes and product identifiers at the consumer level would further enhance our ability to focus on specific products purchased and narrow the scope of implicated shipments.

To realize the full benefits of end-to-end traceability, although the proposed rule applies only to foods on the Food Traceability List, we encourage all firms involved in food production, distribution, and sale to consumers to adopt the recordkeeping practices set forth in the proposed rule for all the foods they manufacture, process, pack, and hold. Consistent with FDA's "New Era of Smarter Food Safety" initiative (Ref. 21), we will pursue ways to help all supply chain entities adopt practices and technologies that will promote rapid and effective tracking and tracing of foods to prevent or mitigate foodborne illness outbreaks. The New Era of Smarter Food Safety is FDA's FSMA-based, technology-enabled, strategic initiative for modernizing food safety. Comments provided during and after the October 29, 2019, public meeting on the New Era initiative indicated a strong desire for FDA to specify required CTEs and KDEs to enable interoperability of tracing procedures among all stakeholders. The proposed rule defines the minimum CTEs and KDEs necessary for achieving the goal of improving food safety and will provide the food industry with the framework and language for communicating tracing information throughout the supply chain.

IV. Legal Authority

Under section 204(d) of FSMA, in order to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act, FDA is required to issue regulations to establish recordkeeping requirements, in addition to the requirements under section 414 of the FD&C Act and the subpart J regulations (or any successor regulations), for facilities that manufacture, process, pack, or hold foods that FDA designates under section 204(d)(2) of FSMA as high-risk foods.

We are proposing these regulations under the following authorities:

- Section 204 of FSMA, the specific provisions of which are discussed in the remainder of this section;
- section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which provides FDA with the authority to promulgate

regulations for the efficient enforcement of the FD&C Act; and

- sections 311, 361, and 368 of the Public Health Service Act (PHS Act) (42 U.S.C. 243, 264, and 271), which relate to communicable disease, including by providing FDA with authority to make and enforce such regulations as in FDA's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession (see section 361(a) of the PHS Act).

A. Designation of High-Risk Foods

Section 204(d)(2) of FSMA directs FDA to designate high-risk foods for which the additional recordkeeping requirements promulgated under the authority of FSMA section 204(d)(1) are appropriate and necessary to protect the public health. Each such designation is to be based on the factors enumerated in section 204(d)(2)(A), which are listed in section III.A of this document.

To assist with the fulfillment of this requirement, we developed a semi-quantitative risk-ranking model that utilizes multiple data sources to score commodity-hazard pairs according to a set of criteria that address the factors set out in section 204(d)(2)(A) of FSMA. This model is explained in greater detail in Reference 16 of this document. Foods were included on the list of foods FDA has tentatively designated as high-risk (the "Food Traceability List") based on the strength of the criteria scores that the model produced (Ref. 16).

FSMA section 204(d)(2)(B) provides that the list of foods designated under section 204(d)(2)(A) (*i.e.*, the Food Traceability List) shall be published on FDA's website at the time of publication of the final rule that creates the recordkeeping requirements described in section 204(d)(1). Proposed § 1.1300 would provide for such publication. FSMA section 204(d)(2)(B) further states that FDA may update the list to designate new foods or to remove foods that are no longer deemed necessary for inclusion, provided that each such update to the list is consistent with the requirements of FSMA section 204(d) and provided that notice of the update is published in the **Federal Register**. The procedures for updating the list that are set forth in proposed § 1.1465 would address this requirement.

B. Additional Recordkeeping Requirements

Section 204(d)(1)(A)–(M) of FSMA provides both general and specific guidelines that FDA must follow in

creating the additional recordkeeping requirements that are mandated by section 204(d)(1). These include the following:

- The requirement that these proposed regulations not require the creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business (section 204(d)(1)(E)), which is addressed in proposed § 1.1455(e);
- the requirement that persons subject to these regulations be allowed to maintain the required records at a central or reasonably accessible location provided that such records can be made available to FDA not later than 24 hours after we request them (section 204(d)(1)(H)), which is addressed in proposed § 1.1455(b)(2);
- the requirement to include a process by which FDA may issue a waiver of the recordkeeping requirements if we determine that such requirements would result in an economic hardship for an individual facility or a type of facility (section 204(d)(1)(I)), which is addressed in proposed §§ 1.1405 through 1.1450; and
- the requirement to include a process by which FDA may remove a high-risk food designation developed under section 204(d)(2) for a food or type of food (section 204(d)(1)(M)), which is addressed in proposed § 1.1465.

Furthermore, section 204(d)(5) of FSMA provides that FDA may require that a facility retain records for not more than 2 years, taking into consideration the risk of spoilage, loss of value, or loss of palatability of the applicable food when determining the appropriate timeframes; this is addressed in proposed § 1.1455(c).

Section 204(d)(6) of FSMA places a number of limitations on the requirements that FDA can impose, including limitations relating to the following:

- Farm to school or farm to institution programs (section 204(d)(6)(A)), which are addressed in proposed § 1.1305(i);
- identity-preserved labels with respect to farm sales of food that is produced and packaged on a farm (section 204(d)(6)(B)), which are addressed in proposed § 1.1305(c);
- fishing vessels (section 204(d)(6)(C)), which are addressed in proposed § 1.1305(j);
- commingled raw agricultural commodities (RACs) (section 204(d)(6)(D)), which are addressed in proposed § 1.1305(e); and
- the sale of a food directly from the farm that produced it to a grocery store

or consumer (sections 204(d)(6)(G)–(I)), which are addressed in proposed § 1.1305(h) and (b), respectively.

In addition, section 204(d)(6)(E) of FSMA states the conditions under which FDA may modify the additional recordkeeping requirements or exempt a food or type of facility from those requirements. This process is addressed in proposed §§ 1.1360 through 1.1400. Section 204(d)(6)(F) of FSMA sets forth limited requirements for a person or food who receives such a modification or exemption, as well as limited requirements for any person or food to which a limitation or exemption applies under the provisions relating to fishing vessels and commingled RACs. These limited requirements are included in the proposed provisions that would implement FSMA sections 204(d)(6)(C) through (E).

In addition to the limitations prescribed by Congress, we have identified certain persons or foods that we have tentatively concluded should not be covered by the rule. These include the following:

- Certain small originators of food, as described in proposed § 1.1305(a);
- foods that receive certain types of processing, as described in proposed § 1.1305(d);
- produce that is rarely consumed raw, as described in proposed § 1.1305(e);
- transporters of food, as described in proposed § 1.1305(k);
- nonprofit food establishments, as described in proposed § 1.1305(l);
- persons who manufacture, process, pack, or hold food for personal consumption, as described in proposed § 1.1305(m); and
- certain persons who hold food on behalf of individual consumers, as described in proposed § 1.1305(n).

In addition, we are proposing (in § 1.1305(h)) to extend section 204(d)(6)(G) of FSMA's partial exemption for grocery stores (with respect to food they purchase directly from a farm) to all retail food establishments.

To effectuate and efficiently enforce section 204 of FSMA, we are proposing several requirements for entities that are covered by the proposed rule. In accordance with FSMA section 204(d)(1), proposed § 1.1300 provides that, except as specified otherwise, these requirements would apply to persons who manufacture, process, pack, or hold foods on the Food Traceability List. The proposed requirements are as follows:

- Proposed requirements to establish and maintain certain traceability program records (proposed § 1.1315);

proposed requirements related to the establishment of traceability lot codes (proposed § 1.1320); proposed requirements for those who grow, receive, transform, create, or ship foods on the Food Traceability List (proposed §§ 1.1325 through 1.1350); proposed special requirements related to the application of a kill step (proposed § 1.1355); and proposed requirements relating to records maintenance and availability (proposed § 1.1455). These proposed requirements would address Congress's directive to create additional recordkeeping requirements for foods of the Food Traceability List.

- proposed requirements for when a traceability lot code must be established and when it cannot be established (proposed §§ 1.1320 and 1.1330(c)), which would help ensure that this key data element serves its intended function with respect to traceability, as discussed in sections V.D.1 to V.D.2.

- proposed requirements for those who ship a food on the Food Traceability List to send records containing certain information to the immediate subsequent recipient (other than a transporter) of the food (proposed § 1.1350(b)), which would help ensure that the recipient of the food has the information they would be required to maintain under the proposed rule.

- proposed requirements related to record availability (proposed § 1.1455(b)), which would help ensure that FDA has access to the required records in the event of an outbreak or other threat to the public health, and which would also assist FDA in ensuring compliance with these regulations and in identifying any violations.

The definitions we are proposing in proposed § 1.1310 would provide a common terminology, which would help all parties as they implement the proposed recordkeeping requirements. The consequences of a failure to comply with the recordkeeping requirements established under section 204 of FSMA were set forth by Congress in section 204(j)(1) and (2), which amended sections 301(e) and 801(a) of the FD&C Act (21 U.S.C. 331(e) and 381(a)), respectively. These consequences are reiterated in proposed § 1.1460.

V. Description of the Proposed Rule

We are proposing to establish additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods we have designated as requiring additional traceability records under section 204(d) of FSMA. Because we propose to establish these new requirements in a new subpart S to part

1 of the FDA regulations, we refer to the proposed requirements as “the subpart S regulations.”

A. Scope/Applicability (Proposed § 1.1300)

Proposed § 1.1300 answers the question, “Who is subject to this subpart?” Proposed § 1.1300 would provide that, except as specified otherwise in subpart S, the proposed regulations would apply to persons who manufacture, process, pack, or hold foods that appear on the list of foods for which additional traceability records are required in accordance with section 204(d)(2) of FSMA (the “Food Traceability List”). Proposed § 1.1300 also states that we will publish the Food Traceability List on our website in accordance with section 204(d)(2)(B) of FSMA.

Although section 204(d)(1) of FSMA refers to “facilities” that manufacture, process, pack, or hold food, we propose that the rule would apply to “persons” that manufacture, process, pack, or hold food to avoid possible confusion with other uses of the term “facilities” in other FDA food regulations. For example, regulations such as those on preventive controls for human food (21 CFR part 117), preventive controls for animal food (21 CFR part 507), and foreign supplier verification programs (21 CFR part 1, subpart L) define “facility” in part as a domestic or foreign entity that is required to register with FDA under section 415 of the FD&C Act (21 U.S.C. 350d). It is clear that Congress intended that these proposed recordkeeping requirements would apply to some persons that are not required to register with FDA, such as grocery stores (see section 204(d)(6)(G) of FSMA), which do not have to register with FDA under section 415 of the FD&C Act due to the exemption for retail food establishments in § 1.226(c). Consequently, we propose that these regulations apply to “persons” who manufacture, process, pack, or hold food, rather than “facilities,” to avoid possible confusion with other uses of the term “facility.” The term “person,” as defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) and proposed § 1.1310, includes an individual, partnership, corporation, and association.

In accordance with section 204(d)(1) of FSMA, the proposed recordkeeping requirements would apply to persons that “manufacture, process, pack, or hold” foods on the Food Traceability List. We note that this differs from the scope of section 414(b) of the FD&C Act and the subpart J requirements, which apply to persons (excluding farms and

restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. Unlike section 414 of the FD&C Act, section 204 of FSMA does not explicitly apply to persons who transport, distribute, receive, or import food. However, with respect to importation, section 204(j)(2) of FSMA (codified in section 801(a)(4) of the FD&C Act) authorizes FDA to refuse admission to foods for which the recordkeeping requirements under section 204 of FSMA have not been complied with. As discussed more fully in section V.C., we believe that many, but not all, persons who transport, distribute, receive, or import food also “hold” food, as we propose to define holding.

We propose that the additional recordkeeping requirements in subpart S would apply not only to persons who manufacture, process, pack, or hold foods specified on the Food Traceability List, but also to persons who manufacture, process, pack, or hold foods that contain foods on that list as ingredients. We identified foods on the Food Traceability List based on the factors that Congress provided in section 204(d)(2) of FSMA. The potential risk associated with these foods are not diminished when the foods are used as ingredients in other food products (absent application of a kill step). However, it would be unwieldy and impractical for the Food Traceability List to specify every food product of this sort, *i.e.*, food products whose risk derives from their having a listed food as an ingredient. Nonetheless, foods that contain foods on the Food Traceability List as ingredients would be considered part of the list, as stated in the definition of the list in proposed § 1.1310. If the proposed recordkeeping requirements did not apply to foods containing an ingredient that is on the Food Traceability List, it would be much more difficult for the Agency to quickly identify and remove common lots of such an ingredient when investigating a foodborne illness outbreak believed to be linked to the ingredient. A multi-ingredient food that contains a food on the Food Traceability List as an ingredient (*e.g.*, a pre-made sandwich containing leafy greens) may be a signal triggering an outbreak investigation that ultimately leads to identification of the contaminated ingredient. For these reasons, the proposed recordkeeping requirements would apply not only to specifically listed foods but also to foods that contain listed foods as ingredients. In proposed § 1.1310, we propose to define “Food Traceability List” to include both

the foods specifically listed and foods that contain foods on the list as ingredients. We use the term in this way for the remainder of this preamble.

B. Exemptions (Proposed § 1.1305)

Proposed § 1.1305 answers the question, “What foods and persons are exempt from this subpart?” We propose to create exemptions from the traceability recordkeeping requirements in proposed subpart S for certain types of food and certain types of persons who manufacture, process, pack, or hold foods on the Food Traceability List. Some of the proposed exemptions are specified in section 204 of FSMA, while others reflect our thinking that applying the proposed requirements to certain persons or foods is not appropriate at this time for the reasons discussed later in this document.

1. Exemption for Certain Types of Small Originators (Proposed § 1.1305(a))

On our own initiative, we propose to exempt from the proposed traceability recordkeeping requirements certain types of small or very small farms and other originators of food (*i.e.*, persons who grow, raise, or catch food or who harvest a non-produce commodity). These firms include very small produce farms, small producers of shell eggs, and other small originators of food. Given the relatively low volume of food produced by these entities, and the fact that subsequent parties in the supply chain will be required to maintain records regarding the food produced by these entities, covering these small originators would produce little measurable public health benefit.

a. Farms That Have No More Than \$25,000 in Annual Sales of Produce

Proposed § 1.1305(a)(1) would provide that subpart S would not apply to farms or the farm activities of farm mixed-type facilities with respect to the produce (as defined in 21 CFR 112.3 (§ 112.3) in the produce safety regulations) (21 CFR part 112) they grow, when the farm is not a covered farm under the produce safety regulations in accordance with § 112.4(a). The farms addressed in § 112.4(a) have no more than \$25,000 in annual sales of produce.

b. Certain Producers of Shell Eggs

Proposed § 1.1305(a)(2) would provide that subpart S would not apply to shell egg producers with fewer than 3,000 laying hens at a particular farm, with respect to the shell eggs produced at that farm. This designation of small shell egg producers as those with fewer than 3,000 laying hens is consistent

with the regulations on shell egg production, storage, and transportation (see 21 CFR 118.1(a) (§ 118.1(a))) and other FDA food safety regulations (*e.g.*, foreign supplier verification program regulations (see 21 CFR 1.512(a)(2)(iii))).

c. Certain Other Originators of Food

Proposed § 1.1305(a)(3) would provide that subpart S would not apply to originators of food with an average annual monetary value of food sold during the previous 3-year period of no more than \$25,000 (on a rolling basis), adjusted for inflation using 2019 as the baseline year for calculating the adjustment. This exemption would apply to, for example, small aquaculture farms and small farms that grow non-produce foods that may be on the Food Traceability List in the future.

2. Exemption for Farms Regarding Food Sold Directly to Consumers (Proposed § 1.1305(b))

Consistent with section 204(d)(6)(H) and (I) of FSMA, we propose to exempt farms from the proposed traceability recordkeeping requirements with respect to food produced on the farm (including food that is also packaged on the farm) when the owner, operator, or agent in charge of the farm sells the food directly to a consumer (proposed § 1.1305(b)). This means that if the owner, operator, or agent in charge of a farm sells food that is produced (or both produced and packaged) on the farm directly to a consumer, the farm would not be subject to the proposed subpart S requirements with respect to that food (*e.g.*, recordkeeping requirements applicable to food growers). These direct-to-consumer sales by farms would include applicable sales at farmers’ markets, roadside stands, over the internet, and through community-supported agriculture programs.

3. Inapplicability to Certain Food Produced and Packaged on a Farm (Proposed § 1.1305(c))

In addition to the farm-related exemptions in proposed § 1.1305(a) and (b), proposed § 1.1305(c) would provide, consistent with section 204(d)(6)(B) of FSMA, that the proposed traceability recordkeeping requirements would not apply to food produced and packaged on a farm, provided that:

- The packaging of the food remains in place until the food reaches the consumer, and such packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product (proposed § 1.1305(c)(1)); and
- the labeling of the food that reaches the consumer includes the name,

complete address (street address, town, State, country, and zip or other postal code for a domestic farm and comparable information for a foreign farm), and business phone number of the farm on which the food was produced and packaged (proposed § 1.1305(c)(2)).

In accordance with section 204(d)(6)(B) of FSMA, upon request we would waive the requirement for the farm to include a business phone number, as appropriate, to accommodate a religious belief of the individual in charge of the farm (proposed § 1.1305(c)(2)).

Examples of foods that might be exempt under proposed § 1.1305(c), provided the specified packaging and labeling requirements were met, include the following:

- Iceberg whole head lettuce that is harvested and packaged for the consumer in the field with individual non-vented cellophane wrapping that maintains the integrity of the lettuce and prevents subsequent contamination or alteration; and
- English cucumbers individually wrapped for the consumer by a farm in sealed plastic that maintains the integrity of the cucumbers and prevents subsequent contamination or alteration.

However, 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 from the subpart S requirements because such packaging does not necessarily maintain the product's integrity and prevent subsequent contamination and alteration.

We note that, consistent with section 204(d)(6)(B) of FSMA, the exemption in proposed § 1.1305(c) would only apply if, among other things, the labeling of the food that reaches the consumer includes the farm's complete address, including the street address, town, State, country, and zip or other postal code for a domestic farm and comparable information for a foreign farm. However, we recognize that not all farms have a street address. In the event that a farm without a street address wanted to rely on this proposed exemption for certain food produced and packaged on that farm, the farm could substitute its geographical coordinates for a traditional street address in the labeling of the food that reaches the consumer.

While the statute requires this exemption, we encourage retail food establishments to keep records on foods covered under the exemption as a best practice because packaging is often

discarded by consumers, resulting in loss of information identifying the farm. We recommend that retail food establishments maintain records on the receipt of the produce including the date of receipt and the name, complete address (street address, town, State, country, and zip or other postal code), and business phone number of the farm on which the food was produced and packaged.

4. Inapplicability to Foods That Receive Certain Types of Processing (Proposed § 1.1305(d))

On our own initiative, we propose to exempt from the proposed traceability recordkeeping requirements produce and shell eggs that receive certain types of processing. Under proposed § 1.1305(d)(1), subpart S would not apply to produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions set forth in § 112.2(b) in the produce safety regulations are met for the produce. We believe that because of the lesser risk to public health posed by this produce (as reflected in its being exempt from almost all of the requirements of the produce safety regulations), it is not necessary to apply the additional recordkeeping requirements to this food. This proposed exemption would apply to all persons who manufacture, process, pack, or hold such produce, not just the farms that grow it. This means that no persons handling produce that receives the commercial processing exemption in accordance with § 112.2(b) would be required to keep subpart S records for the produce.

Similarly, subpart S would not apply to shell eggs when all the eggs produced at a particular farm receive a treatment (as defined in 21 CFR 118.3 (§ 118.3)) in accordance with § 118.1(a)(2). Section 118.3 of the shell egg regulations (21 CFR part 118) defines "treatment" as a technology or process that achieves at least a 5-log destruction of *Salmonella* Enteritidis for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act. Under § 118.1(a)(2), if all shell eggs produced at a particular farm receive a treatment, the producer must comply only with the refrigeration requirements in § 118.4(e) for production of eggs on that farm and with the registration requirements in § 118.11. We believe that the lesser risk to public health posed by shell eggs that have received this treatment in accordance with § 118.1(a)(2) makes it unnecessary to apply the subpart S requirements to these eggs.

5. Exemption for Produce That Is Rarely Consumed Raw (Proposed § 1.1305(e))

On our own initiative, we propose to exempt from the proposed traceability recordkeeping requirements produce that is listed as "rarely consumed raw" in § 112.2(a)(1) in the produce safety regulations. We believe that because of the lesser risk to public health posed by this produce (as reflected in its being exempt from the produce safety regulations), it is not necessary to apply the additional recordkeeping requirements to these foods.

6. Partial Exemption of Commingled Raw Agricultural Commodities (Proposed § 1.1305(f))

Proposed § 1.1305(f)(1) would provide that, except as specified in proposed § 1.1305(f)(2), subpart S would not apply to commingled RACs, in accordance with section 204(d)(6)(D) of FSMA. Consistent with section 204(d)(6)(D) of FSMA, we propose to define "commingled raw agricultural commodity" for the purposes of this exemption as any commodity that is combined or mixed after harvesting but before processing, except that the term "commingled raw agricultural commodity" would not include types of fruits and vegetables that are RACs to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in part 112 apply (proposed § 1.305(e)(1)). As a result, the proposed exemption would *not* apply to produce subject to the produce safety regulations.

For the purpose of the definition of "commingled raw agricultural commodity," a commodity would be regarded as "combined or mixed . . . before processing" only when the combination or mixing involves food from different farms (proposed § 1.1305(f)(1)). We believe this clarification is appropriate because most of the traceability challenges associated with commingling of food from different farms are less present (or entirely absent) when food from different parts of a single farm is commingled.

In keeping with section 204(d)(6)(D)(ii)(III) of FSMA, the term "processing" as used in the definition of commingled RAC would mean operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization (proposed § 1.1305(f)(1)).

An example of a RAC that would be exempt from the proposed traceability recordkeeping requirements when they are commingled is shell eggs. For the

purposes of this rule, we would consider commingled shell eggs to be eggs from separate farms under different company management that are physically mixed before packing. Packed eggs that are from a single farm or from separate farms under the same management would not be considered commingled shell eggs. Shell eggs are the only commingled RAC (as defined in proposed § 1.1305(f)(1)) on the current proposed Food Traceability List. Although the limited exemption for commingled RACs in § 1.1305(f) applies to commingled shell eggs, we nevertheless encourage shell egg producers to keep records on the commingling of eggs as a transformation event to help ensure that we are able to determine the source of contaminated eggs in a foodborne illness outbreak or recall event.

Notwithstanding this proposed exemption from the subpart S requirements for commingled RACs, and in accordance with section 204(d)(6)(D) and (F) of FSMA, proposed § 1.1305(f)(2) would specify that, with respect to a commingled RAC that receives the exemption in proposed § 1.1305(f)(1), if a person manufactures, processes, packs, or holds a commingled RAC and is required to register with FDA under section 415 of the FD&C Act in accordance with 21 CFR part 1, subpart H (subpart H), such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with the subpart J traceability requirements in §§ 1.337 and 1.345 (which apply to the receipt and release of foods by nontransporters of food). Thus, although certain commingled RACs (as defined in proposed § 1.1305(f)(1)) generally would be exempt from the proposed rule, persons who manufacture, process, pack, or hold these RACs who are required to register with FDA as a food facility would have to comply with the existing food traceability recordkeeping requirements in §§ 1.337 and 1.345. While we recognize that many firms are already required to comply with §§ 1.337 and 1.345 because they are subject to the subpart J recordkeeping requirements, this provision creates an independent obligation to comply with these provisions with respect to foods on the Food Traceability List, including for firms that are not subject to subpart J.

Proposed § 1.1305(f)(2) would further specify that such records identifying immediate previous sources and immediate subsequent recipients of these commingled RACs would have to be maintained for 2 years, consistent

with the retention requirement for other records maintained in accordance with subpart S. We discuss the proposed retention requirements for subpart S records in more detail in section V.H.3.

7. Exemption or Partial Exemption for Small Retail Food Establishments (Proposed § 1.1305(g))

On our own initiative, we are co-proposing either a full exemption or a partial exemption from the proposed subpart S requirements for retail food establishments that employ 10 or fewer full-time equivalent employees. Such retail food establishments are exempt from the subpart J requirements under § 1.327(f), except that they are subject to §§ 1.361 and 1.363, which relate to record availability. Although we are considering adopting a full exemption from the proposed subpart S recordkeeping requirements for small retail food establishments, we also are considering whether a more limited exemption for these firms would be appropriate. Therefore, in proposed § 1.1305(g), we are co-proposing two options for full or partial exemption for small retail food establishments, as discussed in the following paragraphs.

a. Option 1: Full Exemption for Small Retail Food Establishments

Option 1 of the co-proposal would specify that subpart S does not apply to retail food establishments that employ 10 or fewer full-time equivalent employees. Option 1 would further state that the number of full-time equivalent employees is based on the number of such employees at each retail food establishment and not the entire business, which may own numerous retail stores. Because these smaller retail food establishments might handle a lesser volume of food than larger establishments, it is possible that requiring the smaller establishments to comply with subpart S would impose costs that would outweigh the benefits of such compliance. In addition, because many of the foods sold at small retail food establishments are nationally distributed and are also sold at larger retail food establishments, we may be able to obtain relevant information about the source of a foodborne illness outbreak from a larger establishment that sold the same food using the same distributor.

On the other hand, because these smaller firms might also be more likely to have less robust traceability records and procedures, fully exempting these firms from the proposed recordkeeping requirements would make it more difficult for FDA to obtain needed tracing information from these firms

when investigating a foodborne illness outbreak. There would likely be significant delays in obtaining pertinent tracing data due to the variability of information maintained by these small establishments. The need to rely on the supplier of these small establishments for the tracing data that would be required under this rule would likely result in at least a 24- to 48-hour delay in the traceback. In addition, small retail food establishments can make a particularly important contribution to tracebacks by serving to narrow the scope of products implicated during an investigation. Key data elements, such as lot codes, are not required at the consumer level, requiring traceback investigations to implicate all lot codes available for purchase on a given purchase date identified by the consumer. Retail food establishments, especially larger ones, often receive the same product from multiple distributors, which makes it difficult to narrow the suppliers of interest in an investigation. On the other hand, small establishments often receive product from limited sources, which can make them particularly valuable during an outbreak in narrowing the suppliers of interest and focusing the traceback investigation. The inability to narrow the suppliers of interest and focus the information relevant to the potential source of contamination not only prolongs a traceback effort but might also result in conducting a broader recall than would otherwise be necessary had the firms maintained records required under subpart S (Ref. 22).

b. Option 2: Partial Exemption for Small Retail Food Establishments

Option 2 for proposed § 1.1305(g) would specify that the requirement in proposed § 1.1455(b)(3) to make available to FDA under specified circumstances an electronic sortable spreadsheet containing the information required to be maintained under this subpart (for the foods and date ranges specified in FDA's request) does not apply to retail food establishments that employ 10 or fewer full-time equivalent employees. (The above-stated text regarding determination of the number of full-time equivalent employees also would be included.) As discussed in section V.I.2, we propose to require that, when necessary to help FDA 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, persons subject to the subpart S requirements must make available, within 24 hours of request by an authorized FDA representative, an

electronic sortable spreadsheet containing the information in the records they are required to maintain under subpart S, for the foods and date ranges specified in the request. We believe that having access to a firm's required traceability information in such electronic form would help us more quickly identify the source of potentially contaminated food on the Food Traceability List and remove the food from the marketplace.

Nevertheless, we recognize that smaller firms might be less likely to have the resources to readily produce their traceability information in such a format. Exempting small retail food establishments from this requirement could reduce their burden of complying with the subpart S requirements, while still providing us with access to relevant and specific tracing information when investigating foodborne illness outbreaks involving listed foods received by such establishments.

We request comment on whether we should adopt Option 1 of the co-proposal for § 1.1305(g), which would fully exempt small retail food establishments from subpart S, or Option 2, which would exempt these firms from the requirement to provide to FDA, under certain circumstances, an electronic sortable spreadsheet containing required traceability information. Of course, you may also comment on whether any full or partial exemption for small retail food establishments from the proposed traceability recordkeeping requirements is appropriate. We also request comment on whether having 10 or fewer full-time equivalent employees is an appropriate size limit for a "small" retail food establishment under these proposed options and, if not, what an appropriate limit would be.

8. Partial Exemption for Retail Food Establishments (Proposed § 1.1305(h))

In addition to the proposed full or partial exemption for small retail food establishments in proposed § 1.1305(g), in accordance with section 204(d)(6)(G) of FSMA, we propose to adopt a partial exemption from the subpart S requirements for all retail food establishments when they receive foods on the Food Traceability List directly from a farm. Proposed § 1.1305(h)(1) would provide that subpart S would not apply to a retail food establishment with respect to foods on the Food Traceability List that are produced on a farm (including foods produced and packaged on the farm) and sold directly to the retail food establishment by the owner, operator, or agent in charge of that farm, except as specified in

proposed § 1.1305(h)(2). Under proposed § 1.1305(h)(2), when a retail food establishment purchases a food on the Food Traceability List directly from the owner, operator, or agent in charge of a farm, the retail food establishment would be required to establish and maintain a record documenting the name and address of the farm that was the source of the food. Consistent with section 204(d)(6)(G) of FSMA, retail food establishments would be required to maintain these farm identification records for 180 days.

Although section 204(d)(6)(G) of FSMA specifies that this limited tracing requirement to document the farm that was the source of the food applies to grocery stores, we propose to broaden the application of this partial exemption to include all retail food establishments purchasing food directly from farms. We believe it is appropriate to apply this partial exemption to all retail food establishments because we think there is no meaningful or easy way to distinguish grocery stores from other retail food establishments such as convenience stores and vending machine locations.

9. Partial Exemption for Farm to School and Farm to Institution Programs (Proposed § 1.1305(i))

Having consulted with the USDA in accordance with section 204(d)(6)(A) of FSMA, we believe it is appropriate to establish, in proposed § 1.1305(i), a partial exemption from the subpart S requirements for farm to school and farm to institution programs operated under the auspices of the USDA, State agencies, or local jurisdictions to avoid placing undue burdens on these programs. Farm to school programs include, but are not limited to, programs in which farms sell food such as fruits, vegetables, eggs, beans, and meat to: (1) Schools under competitive procurement; (2) competitively procured food distributors; and (3) Child Nutrition Programs, including the USDA DoD Fresh Fruit and Vegetable Program, that provide USDA-purchased domestic agricultural products (USDA Foods). Proposed § 1.1305(i)(1) would provide that, except as specified in § 1.1305(i)(2), the subpart S requirements would not apply to an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966, or any other entity conducting a farm to school or farm to institution program, with respect to a food on the Food Traceability List that is produced on a farm (including food produced and packaged on the farm) and sold directly

to the school or institution. Under proposed § 1.1305(i)(2), when a school or institution conducting farm to school or farm to institution activities purchases a food on the Food Traceability List directly from a farm, the school food authority or relevant food procurement entity must establish and maintain a record documenting the name and address of the farm that was the source of the food. Proposed § 1.1305(i)(2) specifies that the school food authority or relevant food procurement entity must maintain the records identifying the farm for 180 days, the same retention period that we propose for records maintained under the partial exemption for retail food establishments in proposed § 1.1305(g).

10. Partial Exemption for Fishing Vessels (Proposed § 1.1305(j))

In accordance with section 204(d)(6)(C) of FSMA, we propose to adopt a partial exemption from the proposed traceability recordkeeping requirements for fishing vessels. Proposed § 1.1305(j)(1) would provide that, except as specified in proposed § 1.1305(j)(2), with respect to a food produced through the use of a fishing vessel, subpart S would not apply to the owner, operator, or agent in charge of the fishing vessel. In accordance with section 204(d)(6)(C) of FSMA, "fishing vessel" would be defined (in proposed § 1.1310) as that term is defined in section 3(18) of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(18)), *i.e.*, as any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for: (1) Fishing or (2) aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing. 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.

Under this exemption, the owner, operator, or agent in charge of a fishing vessel also would not have to keep tracing records on the sale and shipment of food produced through the use of the vessel, except as provided in proposed § 1.1305(j)(2) (discussed in the following paragraph). Section 204(d)(6)(C) of FSMA somewhat ambiguously states that the section 204(d) requirements applicable to fishing vessels would be limited to certain requirements for vessels that are required to register with FDA (set forth in proposed

§ 1.1305(j)(2)) “until such time as the food is sold by the owner, operator, or agent in charge of such fishing vessel.” Although the phrase “until such time” could be interpreted as meaning that the owner, operator, or agent in charge of the fishing vessel could be subject to requirements relating to the sale of the relevant food, we believe it is appropriate to exempt the owner, operator, or agent in charge of the fishing vessel from all requirements relating to the relevant food (except as specified in proposed § 1.1305(j)(2)).

In accordance with section 204(d)(6)(C) and (F) of FSMA, proposed § 1.1305(j)(2) would specify that if the owner, operator, or agent in charge of the fishing vessel who receives the exemption in proposed § 1.1305(j)(1) is required to register with FDA under section 415 of the FD&C Act with respect to the manufacturing, processing, packing, or holding of the applicable food, in accordance with subpart H, that person would be required to maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. This means that fishing vessels that must register with FDA because they process fish on the vessel would be required to comply with the existing subpart J traceability recordkeeping requirements in §§ 1.337 and 1.345, even though many such fishing vessels are currently exempt from those requirements under § 1.327(c). Affected fishing vessels would be required to maintain such records for 2 years (proposed § 1.1305(j)(2)), the retention period for subpart S records specified in proposed § 1.1460(c) (see section V.H.3).

11. Exemption for Transporters (Proposed § 1.1305(k))

On our own initiative, we propose to exempt transporters of food from the proposed traceability recordkeeping requirements (proposed § 1.1305(k)). We propose to define a “transporter” as a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air (proposed § 1.1310). We believe that transporters should be exempt from the proposed rule because we find that in most of our investigations of potential foodborne illness outbreaks, it is not necessary to inspect records maintained by food transporters because we generally are able to obtain the tracing information we need from other persons in the food’s supply chain. If necessary, we could review records maintained by transporters of the food in the usual

course of business or, when applicable, in accordance with the subpart J regulations.

12. Exemption for Nonprofit Food Establishments (Proposed § 1.1305(l))

Proposed § 1.1305(l) would provide that subpart S would not apply to nonprofit food establishments, consistent with their exclusion from the subpart J regulations (see § 1.327(l)). We propose to define a nonprofit food establishment as in subpart J (§ 1.328), *i.e.*, as a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States (proposed § 1.1310). The term would include central food banks, soup kitchens, and nonprofit food delivery services. In addition, 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 (26 U.S.C. 501(c)(3)).

13. Exemption for Persons Who Manufacture, Process, Pack, or Hold Food for Personal Consumption (Proposed § 1.1305(m))

Proposed § 1.1305(m) would provide that subpart S would not apply to persons who manufacture, process, pack, or hold food for personal consumption. Such persons are excluded from the subpart J requirements under § 1.327(m). As discussed in the preamble to the final rule adopting the subpart J requirements (69 FR 71562 at 71579), whether a food is for personal consumption depends on many factors, but we would consider food prepared in a private home and transported for other than business purposes (*e.g.*, to a “pot luck” dinner with friends) to qualify for this exemption.

14. Exemption for Persons Who Hold Food for Individual Consumers (Proposed § 1.1305(n))

Proposed § 1.1305(n) would provide that subpart S would not apply to persons who hold food on behalf of specific individual consumers, provided that such persons: (1) Are not parties to the transaction involving the food they hold and (2) are not in the business of distributing food. This would mirror the exemption for such persons from the subpart J requirements (see § 1.327(n)). This exemption would cover persons such as a hotel concierge, reception desk staff in an apartment building, and staff at an office complex who receive and store a food on the Food Traceability List on behalf of the consumer but are not parties to the

purchase of the food they hold and are not in the business of distributing food (see 69 FR 71562 at 71570 to 71571).

C. Definitions (Proposed § 1.1310)

Proposed § 1.1310 sets forth the meaning of several terms we propose to use in the regulations on additional traceability recordkeeping. Some of the definitions are self-explanatory or are being used for consistency with the existing traceability recordkeeping requirements in subpart J and/or other food safety regulations. In the following paragraphs we discuss definitions of terms used in the proposed rule.

1. Category

We propose to define “category” as a code or term used to classify a food product in accordance with a recognized industry or regulatory classification scheme, or a classification scheme a person develops for their own use. Examples of industry or regulatory classification schemes include the GS1 Global Product Classification standard, the United Nations Standard Products and Services Code, the Food and Agriculture Organization of the United Nations 3-Alpha Seafood Species Code, and the European Union Common Procurement Vocabulary. Rather than use a recognized product classification scheme, a firm might choose to develop its own classification scheme to meet its unique product, customer, or other business needs.

2. Cooling

We propose to define “cooling” as active temperature reduction of a food using hydrocooling, icing, forced air cooling, vacuum cooling, or a similar process, either before or after packing. We discuss proposed recordkeeping requirements related to the cooling of listed foods beginning in section V.E.2.

3. Creating

We propose to define “creating” as making or producing a food on the Food Traceability List (*e.g.*, through manufacturing or processing) using only ingredient(s) that are not on the Food Traceability List. The definition further states that creating does not include originating or transforming a food. We discuss proposed recordkeeping requirements related to the creation of listed foods in sections V.D and V.E.4.

4. Critical Tracking Event

We propose to define “critical tracking event” as an event in the supply chain of a food involving the growing, receiving (including receipt by a first receiver), transforming, creating, or shipping of the food. We discuss

proposed recordkeeping requirements for particular critical tracking events in section V.E.

5. Farm

The proposed rule would define “farm” as it is defined in § 1.328 of the subpart J traceability regulations (and other FDA food safety regulations). The definition further states that, for producers of shell eggs, “farm” means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program (matching the definition of farm under § 118.3 in the shell egg production regulations).

6. First Receiver

We propose to define “first receiver” as the first person (other than a farm) who purchases and takes physical possession of a food on the Food Traceability List that has been grown, raised, caught, or (in the case of a non-produce commodity) harvested. A first receiver of a food might be a manufacturer/processor, distributor, or other non-farm entity who receives a food that has been originated. As discussed in section V.E.2, we believe it is appropriate to require first receivers of listed foods to maintain records containing information about the production of the foods (including information on the harvesting, cooling, and packing of the foods, if applicable) and, for first receivers of seafood, information related to the harvest date range and locations for the trip during which the seafood was caught.

However, an entity that receives a listed food after it has been created (*e.g.*, the first purchaser of a nut butter product) would not be a first receiver under the proposed rule. It would not be appropriate to require the first purchaser of a created food to establish and maintain the first receiver KDEs because those KDEs focus on on-farm practices and other originating events, while created foods have already undergone some form of manufacturing or processing.

7. Fishing Vessel

We propose to define “fishing vessel” as any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for: (a) Fishing; or (b) aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing. In accordance with section 204(d)(6)(C) of FSMA, this matches the definition of “fishing vessel” in section

3(18) of the Magnuson-Stevens Fishery Conservation and Management Act.

8. Food Traceability List

We propose to define the “Food Traceability List” as the list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d)(2) of FSMA. The definition further states that the term “Food Traceability List” includes both the foods specifically listed and foods that contain specifically listed foods as ingredients.

9. Growing Area Coordinates

We propose to define “growing area coordinates” as the geographical coordinates (under the global positioning system (GPS) or latitude/longitude) for the entry point of the physical location where the food was grown and harvested. We discuss the importance for traceability of requiring growers of food to maintain information on the growing area coordinates for the food in section V.E.1.

10. Harvesting

We propose to define “harvesting” as it is defined in the subpart J regulations and other FDA food safety regulations, with some minor differences. Thus, “harvesting” applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots, or stems). Examples of harvesting also include collecting eggs, taking of fish and other seafood in aquaculture operations, milking, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm. Although egg collection and taking of fish and other seafood in aquaculture operations are not included among the examples of harvesting in the definition in subpart J,

we want to make clear that we consider these activities to be harvesting. We propose not to include “cooling” as an example of harvesting activities under subpart S, even though it is included in the subpart J definition, because for traceability purposes we wish to distinguish cooling from harvesting.

11. Holding

We propose to define “holding” as storage of food, and to also include activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding would also include activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets) but would not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the FD&C Act. The proposed definition specifies that holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

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, for example, that 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. For example, some firms buy food produced in foreign countries, arrange for the importation of the food into the United States, and sell the food to other U.S. firms without ever taking physical possession of the food; such firms would not be subject to the rule. Similarly, 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.

We are aware that such importers and brokers often maintain tracing information on the food, while some firms that would be subject to the rule because they hold food (such as distributors) might not currently maintain tracing information. For example, a cold storage facility that receives imported produce might not keep tracing records on such produce because the importer of record, broker,

or other firm has the relevant information on the produce. As discussed in section V.D.1, we propose to allow persons subject to the proposed rule to designate an individual or firm who will establish and maintain tracing records on behalf of the person, although the person subject to the rule would remain responsible for meeting the subpart S requirements. This would enable firms who hold imported foods to enter into agreements with importers of record, brokers, and others to keep required tracing records for the foods on their behalf.

We also recognize that the headquarters for retail food establishments typically provide centralized information technology resources for their stores, distribution centers, and, in most cases, franchisee locations. For example, even though a firm’s headquarters location may not hold food, the firm may decide that headquarters will maintain the records for each of the firm’s retail food establishment locations. In addition, retail food establishments may designate

third parties to maintain their traceability records on their behalf (although the establishment would remain responsible for ensuring the subpart S requirements are met for the foods the firm holds).

12. Key Data Element

We proposed to define “key data element” as information associated with a CTE for which a record must be established and maintained in accordance with subpart S. We discuss proposed requirements for records containing KDEs associated with CTEs in section V.E.

13. Kill Step

We propose to define “kill step” as processing that significantly minimizes pathogens in a food. Examples of kill steps include cooking, pasteurization, heat treatment, high-pressure processing, and irradiation, as long as those processes are conducted in a manner that significantly minimizes pathogens in the food. We discuss proposed requirements for foods on the

Food Traceability List that are subjected to a kill step in section V.F.

14. Location Description

We propose to define “location description” as a complete physical address and other key contact information, specifically the business name, physical location name, primary phone number, physical location street address (or geographical coordinates), city, state, and zip code for domestic facilities and comparable information for foreign facilities, including country; except that for fishing vessels, “location description” would mean the name of the fishing vessel that caught the seafood, the country in which the fishing vessel’s license (if any) was issued, and a point of contact for the fishing vessel.

Location descriptions are typically stored in business systems used for purchasing, manufacturing, and selling goods and services. Table 3 provides an example of the data attributes in a location description for a food processor.

TABLE 3—EXAMPLE OF DATA ATTRIBUTES FOR LOCATION DESCRIPTION

KDE	Data attributes	Example
Location Description	Business name Physical location name primary phone number Physical location street address City State ZIP code	Fin-to-Tail Processing Co. Facility #345. 222.222.2222. 456 Blue Water Way. Sarasota. FL. 98765.

15. Location Identifier

We propose to define “location identifier” as a unique identification code that an entity assigns to the physical location name identified in the corresponding location description; except that for fishing vessels, “location identifier” would mean the vessel identification number or license number (both if available) for the fishing vessel. Location identifiers are typically stored with location descriptions in business systems used for purchasing,

manufacturing, and selling goods and services.

Along with location descriptions, firms could keep all the location identifiers for their suppliers, customers, and other supply chain partners in an electronic master file. Many firms maintain “master data” containing information on products, companies, and locations, as well as other key commercial information. Trading partners often share certain master data information with each other

to simplify business transactions. Persons subject to the proposed rule could meet their requirements to keep records on different location descriptions and identifiers (e.g., for firms from which they receive foods and firms to which they ship food) in electronic master data files. Table 4 illustrates how a firm might maintain relevant information identifying the locations of its supply chain partners using location identifier and location description KDEs.

TABLE 4—EXAMPLE OF LOCATION MASTER DATA LISTING

Location identifier	Location description						
	Business Name	Physical Location Name	Primary Phone	Street	City	State	Zip code
ALPHA-01	Alpha Eggs	Bldg. 3	999.999.9999	101 Birch	Springfield	MO	111111
GG-CA-01	Gary Greens	Field 21	888.888.8888	818 Elm	Salinas	CA	222222
GG-AZ-02	Gary Greens	Cooler #1	777.777.7777	789 Maple	Yuma	AZ	333333

16. Lot

We propose to define “lot” as the food produced during a period of time at a single physical location and identified by a specific code, noting that a lot may also be referred to as a “batch” or “production run.” While each firm determines the size or quantity of a lot, we recommend that lots consist of product produced under uniform conditions, be as small as possible, and generally not exceed 24 hours of production. Limiting the size of a lot allows for more precise traceability of a product and helps narrow the scope of potentially recalled product.

17. Manufacturing/Processing

We propose to define “manufacturing/processing” as it is defined in subpart J and other FDA food safety regulations, *i.e.*, making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. The definition further provides that examples of manufacturing/processing activities include the following: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. The definition also states that for farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

18. Mixed-Type Facility

We propose to define “mixed-type facility” as it is defined in subpart J, *i.e.*, an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. The proposed definition further states that an example of a mixed-type facility is a farm mixed-type facility, which is an establishment that is a farm but also conducts activities outside the farm definition that require the establishment to be registered.

19. Nonprofit Food Establishment

We propose to define “nonprofit food establishment” as it is defined in subpart J, *i.e.*, a charitable entity that

prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term would include central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment would be required to meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code.

20. Originating

We propose to define “originating” as an event in a food’s supply chain involving the growing, raising, or catching of a food (typically on a farm, a ranch, or at sea), or the harvesting of a non-produce commodity. Section V.E.2 discusses a proposed requirement that the first receiver of a listed food keep information on the originator of the food, such as a farm.

21. Originator

We propose to define “originator” as a person who grows, raises, or catches a food, or harvests a non-produce commodity.

22. Packing

We propose to define “packing” as it is defined in subpart J and other food safety regulations, *i.e.*, placing food into a container other than packaging the food. “Packing” also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but would not include activities that transform a raw agricultural commodity (as defined in section 201(r) of the FD&C Act) into a processed food as defined in section 201(gg) of the FD&C Act.

23. Person

We propose to define “person” as including an individual, partnership, corporation, and association. This matches the definition of “person” in section 201(e) of the FD&C Act.

24. Physical Location Name

We propose to define “physical location name” as the word(s) used to identify the specific physical site of a business entity where a particular CTE occurs. Examples could be “Packing Shed 2,” “Store #7228,” or “Warehouse A.” The definition further states that a physical location name might be the same as an entity’s business name if the entity has only one physical location. Tables 3 and 4 provide additional examples of physical location names.

25. Point of Contact

We propose to define “point of contact” as an individual having familiarity with an entity’s procedures for traceability, including their name, telephone number, and, if available, their email address and fax number. As discussed, beginning in section V.E.2, the proposed rule would require certain first receivers, receivers, and shippers of listed foods to maintain information on points of contact for certain entities in a food’s supply chain.

26. Produce

We propose to define “produce” to mean produce as defined in § 112.3 in the produce safety regulations.

27. Receiving

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. We discuss the traceability records we propose to require for receipt of foods on the Food Traceability List in section V.E.3.

28. Reference Record

We propose to define “reference record” as a record used to identify an event in the supply chain of a food, such as a shipping, receiving, growing, creating, or transformation event. The proposed definition states that types of reference records include, but are not limited to, bills of lading (BOL), purchase orders, advance shipping notices (ASNs), work orders, invoices, batch logs, production logs, and receipts. We discuss the use of reference records in product tracing beginning in section V.D.1.

29. Reference Record Number

We propose to define “reference record number” as the identification number assigned to a reference record, such as a purchase order number, bill of lading number, or work order number.

30. Retail Food Establishment

We propose to define “retail food establishment” as it is defined in the food facility registration regulations (§ 1.227), *i.e.*, as an establishment that sells food products directly to consumers as its primary function. The definition further specifies the following:

- The term “retail food establishment” includes facilities that manufacture, process, pack, or hold food if the establishment’s primary function is to sell from that establishment food, including food that

it manufactures, processes, packs, or holds, directly to consumers;

- a retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers;

- the term "consumers" in the definition does not include businesses; and

- retail food establishments include, but are not limited to, grocery stores, convenient stores, and vending machine locations.

The definition of "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function. The definition further specifies that the sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers in the following circumstances:

- At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

- through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

- at other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

The definition further states that the sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers in the same circumstances just specified with

respect to sale of food directly to consumers from an establishment located on a farm.

Although not specified in this definition of "retail food establishment," we regard restaurants, online food retailers, and meal kit delivery companies as other examples of such establishments.

31. Shipping

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. This would mean that, for example, shipping would not include arranging for transport of a food between different locations of a single farm. The definition further specifies that shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food.

As with the subpart J regulations, the proposed traceability recordkeeping requirements would not apply to the sale of food to consumers by retail food establishments, such as grocery stores, convenience stores, and restaurants. We have tentatively concluded that to require retail facilities to keep records of each individual recipient consumer would be too burdensome and not necessary to address credible threats of serious adverse health consequences or death to humans or animals. However, we acknowledge that some retail food establishments are able to use their consumer loyalty cards to provide consumer-level data (see 68 FR 25188 at 25192, May 9, 2003). We discuss the traceability records we propose to require for shipment of foods on the Food Traceability List in section V.E.5.

32. Traceability Lot

We propose to define "traceability lot" as a lot of food that has been originated, transformed, or created.

33. Traceability Lot Code

We propose to define "traceability lot code" to mean a descriptor, often alphanumeric, used to identify a traceability lot. As with location descriptions and location identifiers, traceability lot codes are typically stored

in business systems and printed in human readable and machine-readable format on food product packaging. We discuss the generation and use of traceability lot codes in product tracing in section V.D.1.

34. Traceability Lot Code Generator

We propose to define "traceability lot code generator" to mean the person who assigns a traceability lot code to a product.

35. Traceability Product Description

We propose to define "traceability product description" to mean a description of a food product typically used commercially for purchasing, stocking, or selling, and includes the category code or term, category name, and trade description. As with traceability lot codes, traceability product descriptions are typically stored in business systems and printed in human readable format on food product packaging.

The definition of "traceability product description" further states that for single-ingredient products, the trade description includes the brand name, commodity, variety, packaging size, and packaging style; for multiple-ingredient food products, the trade description includes the brand name, product name, packaging size, and packaging style.

The same term might be used for different components of the traceability product description of a food. For example, "cucumber" may be used as both the category and the commodity.

36. Traceability Product Identifier

We propose to define "traceability product identifier" as a unique identification code (such as an alphanumeric code) that an entity assigns to designate a specific type of food product. As with traceability lot codes and traceability product descriptions, traceability product identifiers are typically stored in business systems and printed in human and machine-readable format on food product packaging. We discuss the use of traceability product identifiers in section V.E.3.

Table 5 illustrates how information in traceability product identifiers and descriptions could be maintained.

TABLE 5—EXAMPLE OF DATA ATTRIBUTES FOR TRACEABILITY PRODUCT DESCRIPTIONS AND TRACEABILITY PRODUCT IDENTIFIERS

Traceability product identifier	Traceability product description data attributes							
	Category		Trade Description					
	Category code or term	Category name	Brand name	Commodity	Variety	Product name	Packaging size	Packaging style
614141007349	10006162 ¹	Cherry Tomatoes—Round ¹ .	Brand ABC	Tomatoes	Cherry	n/a	25 LB	Carton.
183859303020	10006260 ¹	Sprouts (Fresh) ¹ .	Brand ABC	n/a	n/a	Sprout Mix	4 oz	Clamshell.
20614141004366	BFT ²	Blue Fin Tuna ² .	Brand 123	Tuna	Atlantic Bluefin ..	n/a	10 KG	Bin.
498265800732	Soft Cheese ³ .	Soft Cheese ³ .	Brand XYZ	N/A	N/A	Queso Fresco	12 × 8 Ounce.	Vac Pack.
5 1462872318 2	Fresh Cut Produce ³ .	Fresh Cut Produce ³ .	Brand 999	N/A	N/A	Small Vegetable Tray w/dip.	6 oz	Tray.
7483945748383	10000161 ¹	Biscuits/ Cookies (Shelf Stable) ¹ .	Brand CDE	N/A	N/A	Peanut Butter Sandwich Cracker.	12 oz	Box.

¹ Example of a category that is assigned using the GS1 Global Product Classification Scheme.
² Example of a category that is assigned using the United Nations Food and Agriculture Organization’s Aquatic Sciences and Fisheries Information System (ASFIS) List of Species for Fishery Statistics Purposes, 3A code.
³ Example of a category that is self-assigned by a firm.

37. Transformation

We propose to define “transformation” as an event in a food’s supply chain that involves changing a food on the Food Traceability List, 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 initial packing of a single-ingredient food or creating a food. We understand that this definition of “transformation” might differ from the way the term is defined in other traceability systems and approaches; however, we believe this definition is appropriate for use with traceability records for foods on the Food Traceability List, as discussed in section V.E.4.

38. Transporter

We propose to define “transporter” as a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air. This definition of “transporter” is the same as in subpart J except that it omits language differentiating foreign from domestic transporters, which is not necessary under subpart S. As discussed in section V.B.9, we propose to exempt transporters from the subpart S requirements.

39. Vessel Identification Number

We propose to define “vessel identification number” to mean the number assigned to a fishing vessel by the International Maritime Organization, or by any entity or organization, for the purpose of uniquely identifying the vessel. We request comment on whether the proposed definition provides appropriate flexibility regarding the manner in which fishing vessels are uniquely identified.

D. Traceability Program Records (Proposed §§ 1.1315 Through 1.1320)

We propose to require persons who manufacture, process, pack, or hold foods on the Food Traceability List to create and maintain certain records related to their internal traceability program. As described further below, these “traceability program records” concern the use of reference records, maintaining a list of foods on the Food Traceability List that are shipped, the assignment of traceability lot codes to listed foods, and information on the classification schemes a firm uses for traceability.

We encourage firms to maintain required traceability information in electronic form. Because electronic recordkeeping itself has not yet been universally adopted, it is especially important that firms be able to provide information on how they conduct their required traceability operations to help us more quickly review and understand the information we need to conduct an investigation into a foodborne illness outbreak involving a listed food.

1. Traceability Program Records (Proposed § 1.1315)

Proposed § 1.1315 answers the question, “What traceability program records must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold?” Proposed § 1.1315(a) would require persons subject to subpart S to establish and maintain certain traceability program records. We note that, for these and all other records required under subpart S, persons subject to these requirements may enter into agreements with individuals or firms to create and keep the records required under this rule on their behalf. As discussed later in this document, this could include records documenting KDEs for CTEs such as growing, receiving, shipping, transforming, and creating listed foods. Firms could, for example, retain consultants or other outside entities to perform some or all of their subpart S responsibilities, or rely on their supply chain partners, such as their brokers or suppliers, to establish and maintain required records on their behalf. We believe that allowing firms to enter into such agreements will 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.

a. Description of Reference Records (Proposed § 1.1315(a)(1))

Proposed § 1.1315(a)(1) would require persons subject to subpart S to establish and maintain a description of the reference records in which they

maintain the information required under subpart S, an explanation of where on the records the required information appears, and, if applicable, a description of how reference records for different tracing events for a food (e.g., receipt, transformation, shipment) are linked. We encourage firms to maintain required traceability information in a single electronic system; however, we recognize there are firms that currently do not have product tracing systems that enable them to do this. We therefore propose to require firms to describe the particular types of reference records in which they keep the required tracing information to help expedite the firm's production of records and facilitate our review of those records during a foodborne illness outbreak investigation. In some recent foodborne illness outbreaks, some firms' inability to quickly identify and make available to us pertinent information on such matters as production, receipt, and shipment of a possibly contaminated food has significantly delayed completion of our investigation, resulting in greater harm to consumers. Furthermore, even when a firm produces the relevant records, additional delays can occur when it is difficult for us to find the relevant information on those records.

Proposed § 1.1315(a)(1) also would require documentation, if applicable, of how the reference records used for different tracing events for a food are linked. The ability to link incoming with outgoing products within a firm and from one point in the supply chain to the next is critical for traceability. Rarely are there identifiers that link a product as it moves from firm to firm through the supply chain, and often identifiers are lacking within a single firm. One firm may assign a lot code to a product shipment, and the firm receiving the product may assign a new lot code or other identifying code to the product that is not connected by records to the incoming product. Additionally, the incoming product may be processed and used as an ingredient in many different products without any documentation of the link between the ingredient and the finished products, thus compounding the challenge of linking incoming products within a firm to outgoing products.

Another challenge associated with linking of traceability records is that a food product may not always retain the same description as it moves through the supply chain. For example, an FDA traceback of iceberg lettuce during a cyclosporiasis outbreak in 2013 revealed that the lettuce was referred to as "iceberg lettuce" by some firms and as

"lettuce liner size 24" by others. In a 2012 outbreak of *Salmonella* Bareilly in tuna, the tuna was identified as "tuna ground meat AAA" by one supplier and "frozen yellow fin tuna CO treated" by the next firm in the supply chain. Use of different descriptions for the same product can make it very difficult or impossible to determine whether two records refer to the same products or shipments.

Having information on how a firm links its records of incoming and outgoing food products, including records of any transformation that may occur at the firm, can help verify movement of a received product through the firm regardless of any changes made to the product or its naming convention. For example, a distributor may use invoices and BOLs as reference records for their traceability information. Knowing which pieces of information are kept within each type of reference record and how those records can be used to show the movement of products within the firm would help FDA understand the products a firm received and what the firm did with them. For example, if a distributor's BOL records contain the necessary information on products received and its invoice records contain the information on products shipped, the distributor could indicate in its traceability program records that an invoice sent to the next point in the supply chain contains the BOL number for the distributor's receipt of the product. This information would help FDA understand the distributor's recordkeeping system and verify movement of incoming and outgoing products at the firm.

b. List of Foods on the Food Traceability List Shipped (Proposed § 1.1315(a)(2))

Proposed § 1.1315(a)(2) would require persons subject to subpart S to establish and maintain a list of foods on the Food Traceability List that they ship, including the traceability product identifier and traceability product description for each food. Depending on the volume of product that a firm handles, if they did not maintain the list required under proposed § 1.1315(a)(2), during an outbreak investigation we might not be able to quickly and easily determine all of the foods on the Food Traceability List that the firm manufactures, processes, packs, or holds, which could delay completion of product tracing or recall. In addition, reviewing a firm's list would help us more quickly analyze information for traceforward purposes during an outbreak, such as when a firm has received and used a recalled ingredient

in manufacturing other listed foods of which we were unaware. For example, in a 2008 outbreak involving peanut butter, numerous recalls spanning several months were conducted due to the use of the contaminated peanut butter in other products. Even though we were able to identify the firm that was the source of the peanut butter, having access to a comprehensive list of peanut butter products produced and shipped from the source may have avoided multiple expanded recalls by the same firm over several weeks. In addition, review of a complete list of peanut butter products may have led to efficient and quick traceforward activities to determine additional recipients of potentially contaminated products, which might have enabled faster identification of products produced with potentially contaminated peanut butter by other firms, leading to earlier notification to consumers to avoid such products. In addition, reviewing a firm's list of all foods on the Food Traceability List the firm manufactures, processes, packs, or holds also would help us evaluate the firm's compliance with the subpart S requirements, and we anticipate it will also help firms with their own internal compliance programs.

Although proposed § 1.1315(a)(2) would only require maintenance of a list of foods on the Food Traceability List that a firm ships, best practice would be for a firm to maintain a list of all foods it ships. Firms following that practice could satisfy the requirements of § 1.1315(a)(2) by denoting the foods that are on the Food Traceability List (e.g., with an asterisk).

We realize that a firm's list of foods on the Food Traceability List that they ship may not be accurate in real time if the firm is temporarily out of a commodity or only handles certain products seasonally. The list of foods would indicate which foods on the Food Traceability List a firm generally ships, even if there are gaps in those shipments.

c. Description of How Traceability Lot Codes Are Established and Assigned (Proposed § 1.1315(a)(3))

Proposed § 1.1315(a)(3) would require persons subject to subpart S to establish and maintain a description of how they establish and assign traceability lot codes to foods on the Food Traceability List that they originate, transform, or create, if applicable. Assignment of a lot code allows a food product to be uniquely identified and provides information needed to link shipments of a food between different entities in the supply chain. We believe that tracking

foods to the lot level provides adequate information for traceability operations. (Although some firms conduct product tracing to the case level, the proposed rule would not require that, in accordance with section 204(d)(1)(L)(iii) of FSMA.) During a tracing or recall event, FDA routinely requests lot code information from firms to effectively link movement of foods within a firm and shipments throughout the supply chain. The availability of lot codes along an entire supply chain can facilitate identifying the specific food involved in a contamination event and limiting the scope of a recall event. Lot codes can contain data such as the production line used, plant location, or harvest date. Because of the significance of lot codes in food tracing, understanding how a firm creates and assigns traceability lot codes would provide us with information about the relevance of a code to a particular outbreak investigation and insight on how the code can help us appropriately narrow or broaden the investigation.

d. Other Information Needed To Understand Data (Proposed § 1.1315(a)(4))

Proposed § 1.1315(a)(4) would require persons subject to subpart S to establish and maintain records containing any other information needed to understand the data provided within any required subpart S records, such as internal or external coding systems, glossaries, and abbreviations. We need this information to be able to adequately understand the terminology, methods, and systems a firm uses in its traceability operations. For example, many firms use classification schemes developed by industry (such as the GS1 Global Product Classification standard and the Food and Agriculture Organization of the United Nations Fisheries and Aquaculture and Information Branch List of Species for Fishery Statistics Purposes) or regulatory agency schemes (such as the United Nations Standard Products and Services Code and the European Union Common Procurement Vocabulary) to categorize foods for traceability purposes. Use of standardized product classification schemes, lookup tables, and abbreviations can streamline a firm's internal records and promote interoperability throughout the supply chain, which can speed outbreak investigations. When the records kept in accordance with subpart S make use of such classification schemes, abbreviations, or similar methods, it is important that firms be able to provide us with the information we need to understand those records.

e. Retention Requirement for Traceability Program Records (Proposed § 1.1315(b))

Although we are proposing that most subpart S records be retained for 2 years from the date of creation (see section V.I.3), proposed § 1.1315(b) would require firms to retain the records required under proposed § 1.1315(a) for 2 years after their use is discontinued (e.g., because the firm changes the records in which the required information is maintained, updates the list of foods on the Food Traceability List it ships, or changes its procedures for establishing and assigning traceability lot codes). We believe that a different retention period is appropriate because the records in § 1.1315(a) involve procedures and processes, rather than documentation of the production and handling of particular lots of food products. For example, proposed § 1.1315(b) would ensure that even if a firm uses the same procedures to establish and assign traceability lot codes for many years, a record of these procedures will remain available for FDA review for 2 years after the procedures are discontinued.

2. When Traceability Lot Codes Must Be Assigned (Proposed § 1.1320)

Proposed § 1.1320 answers the question, "When must I establish and assign traceability lot codes to foods on the Food Traceability List?" Proposed § 1.1320(a) would require a person subject to subpart S to establish and assign a traceability lot code when they originate, transform, or create a food on the Food Traceability List. Proposed § 1.1320(b) would specify that, except as otherwise specified in the subpart S regulations, a person may not establish a new traceability lot code when conducting other activities (e.g., shipping, receiving) in the supply chain for a food on the Food Traceability List.

Typically, persons who grow or otherwise originate food assign a lot code to the food; the same is true when a food is transformed (e.g., processed in some way) or "created" by combining several different ingredients. As previously discussed, lot codes provide important tracing information for a food product. Therefore, we propose to require the assignment of a traceability lot code when a firm originates, transforms, or creates a food on the Food Traceability List. However, some firms assign lot codes to foods they receive even though they do not transform the food or use the food to create a new food product. We believe that assignment of new lot codes to foods in such circumstances can create

confusion that can hinder traceback and traceforward efforts during investigation of foodborne illness outbreaks.

Therefore, the proposed rule generally would prohibit establishment of a traceability lot code (for the purpose of meeting the proposed subpart S requirements) for a listed food except when originating, transforming, or creating a listed food. However, under proposed § 1.1330(c) (discussed in section V.F.2), if a first receiver receives a listed food to which the originator has not assigned a traceability lot code, the first receiver would be required to establish (and maintain a record of) a traceability lot code for the food.

E. Records of Growing, Receiving, Transforming, Creating, and Shipping Food (Proposed §§ 1.1325 to 1.1350)

As discussed in section III.D.2, we are proposing to require persons who manufacture, process, pack, or hold foods on the Food Traceability List to establish and maintain records containing KDEs related to CTEs in the production and transfer of such foods. Under the proposed rule, the CTEs for which records must be kept are growing a listed food, receiving a listed food (including receipt by a first receiver of a listed food), transforming a listed food, creating a listed food, and shipping a listed food. In addition, the proposed rule includes KDE requirements concerning activities such as harvesting, cooling, and packing food that are included in the CTE requirements just noted. The proposed rule also includes requirements concerning KDEs that shippers of foods on the Food Traceability List must provide to their customers.

As discussed in more detail in the following paragraphs, the KDEs required to be kept would vary depending on the type of supply chain activity. In developing the recordkeeping requirements, we identified which KDEs would be necessary to effectively trace a product based on the CTEs a firm performs (e.g., receiving, transformation, shipping). Not all KDEs are relevant for each CTE; however, firms that perform multiple CTEs would be required to maintain all the KDEs that pertain to the CTEs they perform. For example, a firm that receives a food on the Food Traceability List and then transforms and ships it would be required to keep records of KDEs relevant to the receiving, transforming, and shipping events.

The proposed KDE/CTE recordkeeping requirements would require the person performing the relevant CTE to establish and maintain records containing and linking the

food's traceability lot code to the KDEs that must be kept. As discussed in sections III.B and IV.D.1, lot codes play a critical role in linking a food to events in the food's supply chain, allowing firms and regulators to identify and verify the movement of a food throughout its supply chain to facilitate traceback and traceforward operations. For this reason, it is critical that firms maintain records, such as purchase orders and BOLs, that indicate a food's traceability lot code and link it to other information about the food.

For the most part, the proposed requirements related to KDEs associated with CTEs in a food's supply chain reflect tracing practices in use by many, though not all, sectors and individual firms in the food industry. We believe that firms' compliance with the proposed requirements would substantially improve our ability to understand how and where potentially harmful foods have moved in the supply chain and facilitate removal of such foods from the market.

1. Records of Growing a Food on the Food Traceability List (Proposed § 1.1325)

Proposed § 1.1325 answers the question, "What records must I keep when I grow a food on the Food Traceability List?" We propose to require persons who grow foods on the Food Traceability List (e.g., certain fruits and vegetables) to establish and maintain records on certain matters related to the growing of the food because they are the persons most likely to have certain information that is critical for traceability of the foods. We note that, in addition to these requirements for records of the growing of listed foods, farms are also subject to the proposed recordkeeping requirements applicable to the shipment of listed foods, which are discussed later in this document. Furthermore, farms would be subject to the proposed recordkeeping requirements for the receipt and transformation of listed foods, when applicable, as discussed later in this document.

For each food on the Food Traceability List grown, proposed § 1.1325 would require the grower of the food to establish and maintain records containing and linking the traceability lot code of the food to the following information:

- The growing area coordinates (proposed § 1.1325(a)); and
- for growers of sprouts, the following information (if applicable):
 - The location identifier and location description of the grower of seeds for sprouting, the associated seed lot code

assigned by the seed grower, and the date of seed harvesting (proposed § 1.1325(b)(1));

- the location identifier and location description of the seed conditioner or processor, the associated seed lot code assigned by the seed conditioner or processor, and the date of conditioning or processing (proposed § 1.1325(b)(2));
- the location identifier and location description of the seed packinghouse (including any repackers, if applicable), the associated seed lot code assigned by the seed packinghouse, and the date of packing (and of repacking, if applicable) (proposed § 1.1325(b)(3));
- the location identifier and location description of the seed supplier (proposed § 1.1325(b)(4));
- a description of the seeds, including the seed type or taxonomic name, growing specifications, volume, type of packaging, and antimicrobial treatment (proposed § 1.1325(b)(5));
- the seed lot code assigned by the seed supplier, including the master lot and sub-lot codes, and any new seed lot code assigned by the sprouter (proposed § 1.1325(b)(6));
- the date of receipt of the seeds by the sprouter (proposed § 1.1325(b)(7)); and
- for each seed lot code received by the sprouter, the sprout traceability lot code(s) and the date(s) of production associated with that seed lot code (proposed § 1.1325(b)(8)).

a. Growing Area Coordinates (Proposed § 1.1325(a))

Proposed § 1.1325(a) would require persons who grow a listed food to keep a record linking each traceability lot of the food to the growing area coordinates for that lot. Many farms are in rural locations that lack street addresses; in addition, many farms have multiple fields in which the same commodity is grown. FDA often requests growing area coordinates for foods under investigation to more precisely identify the place where the food was grown and to determine proximity to other farms that have been identified in the investigation. To meet this requirement to record growing area coordinates, farms typically would maintain the GPS coordinates for the entrance of the specific field or ranch where the food was grown. This information allows us to pinpoint the source of the food more specifically than would be possible with the address information for the farm. For example, in a 2018 traceback investigation of leafy greens, firms provided GPS coordinates for the locations at which the greens were grown, enabling us to triangulate the farms and narrow the focus of the

investigation to a limited number of farms.

b. Information on Seeds for Sprouting (Proposed § 1.1325(b))

Because sprouts pose unique food safety concerns, as reflected in the special provisions for sprouts in the produce safety regulations (subpart M of part 112) (see, e.g., 78 FR 3504 at 3594 to 3595 (January 16, 2013); 80 FR 74354 at 74496 to 74497 (November 27, 2015)), proposed § 1.1325(b) would require growers of sprouts to keep records linking the traceability lot code for each lot of sprouts to certain information about the grower and supply chain of the seeds they use for sprouting. (By "seeds" we mean everything sprouted to produce sprouts for human consumption, including beans.) Seeds have been the underlying source of contamination in numerous sprout outbreaks (Refs. 23 and 24). Although FDA encourages sprout operations to use seed that was grown according to good agricultural practices (GAPs), this does not always occur. Most seeds produced in the United States are used as planting stock to produce forages for livestock or for field cultivation. Such seeds are generally not grown according to GAPs, and may be grown, conditioned/processed, harvested, and/or stored under conditions where contamination is likely to occur. These seeds are sometimes diverted to be used for sprouting, which can create a risk to the public health. Contaminated seed represents a particular food safety issue for sprouts because the conditions under which sprouts are produced (time, temperature, water activity, pH, and available nutrients) are also ideal for the growth of pathogens, if present.

During sprout-related outbreak investigations, FDA frequently has been unable to obtain information needed to determine the scope of potentially affected sprouts and take action against firms that sold adulterated seeds or processed, packed, or re-packed seeds in a way that might result in adulterated product. Requiring sprout growers to keep records identifying seed growers, processors, packers, repackers, and suppliers (proposed § 1.1325(b)(1) through (4)) would provide the Agency with information needed to avoid these hurdles as well as help us conduct outbreak follow-up activities that would aid in preventing future outbreaks. Similarly, requiring sprout growers to keep records on seed lot codes assigned by seed harvesters, conditioners, processors, and repackers, along with the dates of seed harvesting, conditioning, processing, and repacking (proposed § 1.1325(b)(1) through (3)),

would help us scope a sprout recall event and identify the seed lot used to grow the sprouts involved in a contamination event.

The description of the seeds the sprout grower used, as required under proposed § 1.1325(b)(5), includes the seed type or taxonomic name, growing specifications, volume, type of packaging, and antimicrobial treatment. Examples of growing specifications could include production in accordance with GAP standards and/or FDA's draft guidance for industry on "Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting" (Ref. 25), certification under USDA's Seeds for Sprouting Export Certification Program, information on seed purity or germination rate, and whether the seeds are organic or conventionally grown. Antimicrobial treatment refers to treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans using a scientifically valid method to reduce microorganisms of public health significance. If seeds are not grown to any growing specifications or antimicrobial treatments are not used, that information should be included as part of the description.

Sprout growers would also be required to keep records of the lot codes for the seeds used for sprouting (including the master lot and sub-lot codes assigned by the seed supplier and any new seed lot code assigned by the sprouter) (proposed § 1.1325(b)(6)), the date of receipt of seeds by the sprouter (proposed § 1.1325(b)(7)), and sprout traceability lot codes for the sprouts produced from each lot of seeds received by the sprouter (and the dates of production) (proposed § 1.1325(b)(8)). Having information to identify incoming seed lots, any changes to seed lot codes, and outgoing sprout lots would greatly improve our ability to trace sprout-related foodborne illness outbreaks to their source.

2. Records To Be Kept by First Receivers of Foods on the Food Traceability List (Proposed § 1.1330)

Proposed § 1.1330 answers the question, "What records must I keep when I am the first receiver of a food on the Food Traceability List?" As stated in section V.C.3, a first receiver of a food is the first person (other than a farm) who purchases and takes physical possession of a listed food. Examples of first receivers could include manufacturers, processors, buyers of seafood from fishing vessels, and distribution centers. Only listed foods that are originated (*i.e.*, grown, harvested (if a non-produce

commodity), raised, or caught) would have a first receiver. As stated in section V.C.3, when a food on the Food Traceability List is created exclusively from ingredients that are not on the Food Traceability List, the first person who purchases and takes physical possession of the food would not be a first receiver. In other words, when a listed food is created, rather than originated, there would not be a first receiver.

We are proposing to establish the term "first receiver" of a food on the Food Traceability List and to require that first receivers keep certain records of their receipt (in addition to the receiving records they are required to keep under proposed § 1.1335) because a first receiver is the person who is best positioned to maintain comprehensive information about the origination and subsequent handling of a food. This includes information identifying the persons who originated, harvested, cooled, and packed the food. The foods on the Food Traceability List include foods in several different commodity types with varying growing and production practices and associated business relationships. For some foods, 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. Furthermore, 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. Identifying the first receiver of a food as the first person who purchases and takes physical possession of the food ensures that comprehensive records relating to the origination and handling of the food are maintained by a single person who both owns and possesses the food.

Because unique tracing information is relevant for seafood products obtained from fishing vessels, we are proposing to adopt separate recordkeeping requirements for: (1) First receivers of foods on the Food Traceability List other than food produced through the use of a fishing vessel (proposed § 1.1330(a)) and (2) first receivers of listed seafood products obtained from fishing vessels (proposed § 1.1330(b)), as discussed in the following paragraphs.

a. First Receivers of Food (Other Than Food Produced Through the Use of a Fishing Vessel) (Proposed § 1.1330(a))

Proposed § 1.1330(a) would require each first receiver of a food on the Food Traceability List (except first receivers of food produced through the use of a

fishing vessel, as addressed in proposed § 1.1330(b)) to establish and maintain records, in addition to the records of receipt of foods required under proposed § 1.1335 (discussed in section V.F.3), containing and linking the traceability lot code of the food received to the following information:

- The location identifier and location description of the originator of the food (proposed § 1.1330(a)(1));
- the business name, point of contact, and phone number of the harvester of the food, and the date(s) and time(s) of harvesting (proposed § 1.1330(a)(2));
- the location identifier and location description of the place where the food was cooled, and the date and time of cooling (if applicable) (proposed § 1.1330(a)(3)); and
- the location identifier and location description of the place where the food was packed, and the date and time of packing (proposed § 1.1330(a)(4)).

Maintenance of these records by first receivers of a listed food will help prevent delays in determining who grew and physically handled a product by alleviating the initial need to visit each entity performing farm activities. In addition, requiring first receivers to keep this information could help identify precisely where originating and handling activities occurred. In some cases, a food might undergo several handling steps (*e.g.*, cooling, packing) at different locations before the first receiver takes physical possession of the food. Sometimes all these activities are conducted by the originator of the food (*e.g.*, the farm that grew it), but in some cases other firms harvest, cool, and/or pack the food with or without taking ownership of it. During outbreak investigations, FDA has experienced delays in determining who was responsible for handling the contaminated product identified in a traceback because the documents available to us did not accurately indicate who conducted different activities with the product. Given the wide variety of business models used in the farming community, we believe it will be most efficient to have the first non-farm entity that has purchased and taken physical possession of a listed food—*i.e.*, the first receiver—maintain the tracing information provided by the farm(s) that originated and handled the product.

With respect to the location description for the cooler of a food, when a food has been cooled by a portable cooler, the first receiver of the food could satisfy the requirement in proposed § 1.1330(a)(3) by keeping a record of the location description for the headquarters of the firm that performed

the cooling. In this case, the physical location name would be the words identifying the portable cooler (e.g., “Cooler No. 17”).

As noted above, not all of the proposed requirements would apply to every first receiver of a listed food. For example, not all foods undergo cooling before the first receiver takes possession of the food.

b. First Receivers of Food Produced Through Use of a Fishing Vessels (Proposed § 1.1330(b))

Proposed § 1.1330(b) would require each first receiver of a seafood product on the Food Traceability List that was produced through use of a fishing vessel to establish and maintain records, in addition to the records of receipt of foods required under proposed § 1.1335 (discussed in section V.F.3), containing and linking the traceability lot code of the seafood product received to the harvest date range and locations (National Marine Fisheries Service Ocean Geographic Code or geographical coordinates) for the trip during which the seafood was caught. Compliance with these requirements by first receivers of seafood from fishing vessels would facilitate traceback efforts by helping us more quickly identify physical locations and date ranges that might be linked to a foodborne illness outbreak involving a seafood product.

c. Establishment of Traceability Lot Codes (Proposed § 1.1330(c))

Proposed § 1.1330(c) would require a first receiver of a food on the Food Traceability List to which the originator of the food has not assigned a traceability lot code to establish a traceability lot code for the food and maintain a record of the traceability lot code linked to the information specified in proposed § 1.1330(a) or (b) (as applicable to the type of food received). Although originators of food would be required to establish and assign a traceability lot code to the food under proposed § 1.1320(a), not all originators would be subject to the rule. For example, certain small farms, small shell egg producers, and other small originators of food would be exempt from subpart S under proposed § 1.1305(a). Because we believe it is critical that a traceability lot code is assigned to a food as early in its supply chain as possible, we propose to require first receivers of listed foods to establish a traceability lot code for the food when the food’s originator has not done so. For example, by establishing a traceability lot code for seafood produced from a fishing vessel that lacked such a lot code, the first receiver

of the seafood would facilitate traceback and traceforward operations to remove contaminated seafood from the market.

3. Records for Receipt of Foods on the Food Traceability List (Proposed § 1.1335)

Proposed § 1.1335 answers the question, “What records must I keep when I receive a food on the Food Traceability List?” Consistent with the existing subpart J regulations and common industry practice, we propose to require persons who receive foods on the Food Traceability List to keep certain records documenting this critical tracking event for the foods. We propose that, for each food on the Food Traceability List that is received, the receiver must establish and maintain records containing and linking the traceability lot code for the food to the following information:

- The location identifier and location description for the immediate previous source (other than a transporter) of the food (proposed § 1.1335(a));
- the entry number assigned to the food (if the food was imported) (proposed § 1.1335(b));
- the location identifier and location description of where the food was received, and date and time the food was received (proposed § 1.1335(c));
- the quantity and unit of measure of the food (e.g., 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds) (proposed § 1.1335(d));
- the traceability product identifier and traceability product description for the food (proposed § 1.1335(e));
- the location identifier, location description, and point of contact for the traceability lot code generator (proposed § 1.1335(f));
- the reference record type(s) and reference record number(s) (e.g., “Invoice 750A,” “BOL 042520 XYX”) for the document(s) containing the information specified in proposed § 1.1335(a) through (f) (proposed § 1.1335(g)); and
- the name of the transporter who transported the food to the receiver (proposed § 1.1335(h)).

Information linking the lot code for a received food with the immediate previous source of the food, the entry number (for an imported food), the location and date the food was received, and the quantity and unit of measure of the food received (proposed § 1.1335(a) through (d)) is widely regarded in the food industry as essential for effective tracing of food. For imported foods, knowing the entry number assigned to a food by U.S. Customs and Border Protection (who assigns the first three alphanumeric digits of a food’s entry

number) and the food’s filer/broker (who assigns the remaining parts of the entry number) can help FDA identify the shipper of an imported food, such as the foreign farm that grew imported produce. We note that if an imported food is subsequently transformed (as discussed in section V.E.4 of this document), the resulting food is not regarded as being imported, and the receiver of the food produced through transformation would not be required to keep a record of the entry number for any imported food that is a component of such food.

Although subpart J only requires receivers of food who manufacture, process, or pack food to record the lot code for the food “to the extent this information exists” (§ 1.337(a)(4)), we believe that all persons who receive listed foods should keep a record of the food’s traceability lot code because lot codes provide important tracing information that can link received food not just to manufacturers/processors and packers but also to others in the supply chain who receive the food, including distributors and retail food establishments. In addition, although it is not required under § 1.337(a)(3) (the provision in subpart J that requires receivers of foods to keep a record of the date of receipt), we believe that the time of receipt (proposed § 1.1335(c)) also is needed to more precisely identify foods that might be implicated in a foodborne illness outbreak, given that many firms receive multiple shipments of different food products each day.

We propose to require receivers of listed foods to maintain the traceability product identifier and traceability product description for each listed food they receive (proposed § 1.1335(e)) because this would provide descriptive information about the food to which the traceability lot code was assigned. For example, the originator (grower) of a lot of papayas might describe them as Maradol papayas or assign to the lot an identification code that the grower uses for papayas of this type. The availability of such product information would help prevent confusion during traceback investigations in situations in which a subsequent firm in the supply chain uses a different product identifier for the food. In addition, having information on the location of the person who generated the traceability lot code (proposed § 1.1335(f)) would provide another way of confirming that a traceability lot code applies to a particular food, as well as help the Agency identify the previous point in the supply chain that transformed, created, or originated the food (and generated the lot code for the food).

Information on the reference record (specific type and number) associated with receipt of a listed food (proposed § 1.1335(g)) would provide important documentation of receipt. As stated in section V.C.23, a reference record is a record used to identify an event in a food's supply chain; reference records commonly used to document receipt of a food include BOLs, invoices, sale receipts, and ASNs. Although keeping a reference record for receipt of a food is not required under subpart J, many firms do retain reference records, and we typically request reference records in our traceback investigations. We believe maintaining reference records for receipt of foods provides an important "cross-check" of relevant traceability lot codes as a food moves between supply chain partners.

Consistent with the subpart J requirements, we propose to require persons who receive listed foods to keep a record of the name of the transporter who delivered the food (proposed § 1.1335(h)). However, we believe it is not necessary for the receiver to retain other information on the transporter (e.g., address, telephone number). We note that in many cases, the receiver will have this information as a result of subpart J requirements (see § 1.337(a)(6)).

As stated in section V.E.2, in addition to meeting the requirements for "first receivers" of listed foods stated in proposed § 1.1330, the first receiver of a listed food would be required to establish and maintain records of receipt for the food in accordance with proposed § 1.1335.

4. Records of Transformation of Foods on the Food Traceability List (Proposed § 1.1340)

Proposed § 1.1340 answers the question "What records must I keep when I transform a food on the Food Traceability List?" As previously stated, transformation of a food, such as by processing it or combining it with other foods to make a new food product, is another critical event in product tracing. Foods (and their packaging and labeling) can be changed in a variety of ways, such as by cutting, cooking, commingling, boiling, mixing, freezing, milling, repacking, and repackaging. Documentation of transformation is needed to ensure traceability between the food that is changed during transformation and the resulting new product.

Transformation of a food on the Food Traceability List involves taking a listed food and changing the food (or its packaging and/or labeling) such as by processing it, combining it with other

ingredients, commingling it, or repackaging it. For example, processing whole head lettuce (a listed food) for inclusion in a bagged salad mix would involve transformation of the lettuce. We propose to require firms that transform listed foods to keep certain records of the transformation. However, we propose that this requirement would not apply to retail food establishments with respect to the listed foods they sell directly to consumers, as discussed in the following paragraphs.

Except as specified in proposed § 1.1340(b), proposed § 1.1340(a) would require, for each new traceability lot of food produced through transformation of foods on the Food Traceability List, that the person who transforms the food establish and maintain records containing and linking the traceability lot code of the food transformed to certain information regarding: (1) The food on the Food Traceability List used in transformation and (2) the food produced through transformation. For the food(s) on the Food Traceability List used in transformation (proposed § 1.1340(a)(1)), the transformer of the food must establish and maintain records containing and linking the traceability lot code of the food to the following information:

- The traceability lot code(s) for the food (proposed § 1.1340(a)(1)(i));
- the traceability product identifier and traceability product description for the foods to which the traceability lot code applies (proposed § 1.1340(a)(1)(ii)); and
- the quantity of each traceability lot of the food (proposed § 1.1340(a)(1)(iii)).

For the food produced through transformation (proposed § 1.1340(a)(2)), the transformer of the food must establish and maintain records containing and linking the traceability lot code of the food to the following information:

- The location identifier and location description for where the food was transformed (e.g., by a manufacturing/processing step), and the date the transformation was completed (proposed § 1.1340(a)(2)(i));
- the new traceability product identifier and traceability product description for the food produced through transformation to which the new traceability lot code applies (proposed § 1.1340(a)(2)(ii)); and
- the quantity and unit of measure of the food produced through transformation for each new traceability code (e.g., 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds) (proposed § 1.1340(a)(2)(iii)).

In addition to this information on foods used in transformation and foods

produced through transformation, the transformer of a listed food would have to establish and maintain records containing and linking the new traceability lot code for the food produced through transformation to the reference record type(s) and reference record number(s) (e.g., "Production Log 123," "Batch Log 01202021") for the documents containing the information specified in proposed § 1.1340(a)(1) and (2) (proposed § 1.1340(a)(3)).

The traceability lot code, traceability product identifier and traceability product description, and the quantity of each traceability lot for the food that is to be transformed (proposed § 1.1340(a)(1)(i) through (iii)) all provide important data linking the food produced through transformation to products the transforming firm has received from its suppliers. With respect to the food that has undergone transformation, the transformer of the food would have to keep information on the location and date the transformation was completed, the new traceability product identifier and traceability product description, and the quantity and unit of measure of the food produced through transformation (proposed § 1.1340(a)(2)(i) through (iii)). Finally, the transformer of a listed food would keep the reference record type (such as a production log) and reference record number that links the food produced through transformation with the listed food that was received and transformed (proposed § 1.1340(a)(3)). These proposed recordkeeping requirements for the transformation of listed foods would help ensure that vital tracing information linking a food produced through transformation to the incoming food that was subjected to transformation is available for review in a traceback investigation.

Most firms can provide information about what lots of product were available for potential use during the transformation or manufacturing process. However, some firms currently lack the ability to connect the finished transformed product to its ingredients and the amount of each ingredient lot used during the transformation. Depending on the quantity of food in an ingredient lot, one lot could be used for multiple days of production and commingled with other lots of the same ingredient. An inability to precisely identify ingredient lots used in transformation could adversely affect a traceback or recall by limiting our ability to accurately identify the products within the scope of such action. We believe that compliance with the proposed recordkeeping requirements for transformation of foods

will substantially improve traceability for these foods.

As previously stated, we propose to exempt retail food establishments (under certain circumstances) from this proposed requirement to keep records of transformation of listed foods. Proposed § 1.1340(b) would provide that proposed § 1.1340(a) would not apply to retail food establishments with respect to foods they do not ship (*e.g.*, foods they sell or send directly to consumers). As previously stated, we do not believe it is reasonable to expect restaurants, grocery stores, and other retail food establishments to keep traceability records of their sales of food to consumers. We believe that a similar exemption from recordkeeping requirements should apply when retail food establishments transform food they then sell directly to consumers (or that they donate or dispose of, if it is not sold). We would still be able to trace the movement of listed foods to retail food establishments from farms, manufacturers, distributors, and others because retail food establishments will be required, under proposed § 1.1335, to keep records on listed foods they receive.

However, this proposed exemption for retail food establishments would not apply when an establishment transforms a listed food it then ships to a distributor or another retail food establishment instead of selling the food directly to consumers. Because a retail food establishment that transforms a food and ships it to another business (rather than to consumers) would be functioning as a manufacturer, it is necessary and appropriate for effective traceability that such a retail food establishment be required to keep tracing records of the transformation in accordance with proposed § 1.1340(a).

5. Records of Creation of Foods on the Food Traceability List (Proposed § 1.1345)

Proposed § 1.1345 answers the question, “What records must I keep when I create a food on the Food Traceability List?” Creating a food on the Food Traceability List is a critical tracking event. Creation of a food on the Food Traceability List involves making or producing a listed food (such as through manufacturing or processing) using only ingredients that are *not* on the Food Traceability List. For example, manufacturing peanut butter, which is on the Food Traceability List, would constitute creating a listed food because none of the ingredients of peanut butter are listed foods. Because listed foods are not used in the creation (as opposed to transformation) of a listed food, and we

therefore cannot expect that firms will necessarily have relevant records for any of the ingredients in a created food, it is appropriate to apply different recordkeeping requirements to transformation and creation events.

We propose to require firms that create listed foods to keep tracing records of the creation, with a partial exemption for retail food establishments as proposed for transformation of listed foods. Therefore, except as specified in proposed § 1.1345(b), proposed § 1.1345(a) would require a person who creates a food on the Food Traceability List to establish and maintain records containing and linking the traceability lot code of the food created to the following information:

- The location identifier and location description for where the food was created (*e.g.*, by a manufacturing/processing step), and the date creation was completed (proposed § 1.1345(a)(1));
- the traceability product identifier and traceability product description for the food (proposed § 1.1345(a)(2));
- the quantity and unit of measure of the food (*e.g.*, 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds) (proposed § 1.1345(a)(3)); and
- the reference record type(s) and reference record number(s) (*e.g.*, “Production Lot 123,” “Batch Log 01202021”) for the document(s) containing the information specified in proposed § 1.1345(a)(1) through (3) (proposed § 1.1345(a)(4)).

Because creation of a food on the Food Traceability List does 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.

For the reasons discussed in section V.F.4, proposed § 1.1345(b) would provide that the requirement to establish and maintain records on the creation of listed foods would not apply to retail food establishments with respect to foods they do not ship (*e.g.*,

foods they sell or send directly to consumers).

6. Records To Be Kept and Sent for Shipment of Foods on the Food Traceability List (Proposed § 1.1350)

Proposed § 1.1350 answers the question, “What records must I keep and send when I ship a food on the Food Traceability List?” Shipment or release of foods from one person in the supply chain to another is widely recognized as a critical tracking event. As with records of receipt of foods, maintaining tracing records of shipment of foods to others in the supply chain is common industry practice and required under the subpart J regulations. Therefore, we propose to require persons who ship foods on the Food Traceability List to keep certain records documenting these shipments. In addition, to help ensure that those who receive listed foods obtain the information they would be required to keep under the proposed rule, we propose to require persons who ship listed foods to provide their customers with certain information related to the foods they ship, as this information might not always be provided under current commercial practices.

a. Records of Shipment (Proposed § 1.1350(a)).

Proposed § 1.1350(a) would require persons who ship a food on the Food Traceability List to establish and maintain records containing and linking the traceability lot code for the food to the following information:

- The entry number(s) assigned to the food (if the food is imported) (proposed § 1.1350(a)(1));
- the quantity and unit of measure of the food (*e.g.*, 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds) (proposed § 1.1350(a)(2));
- the traceability product identifier and traceability product description for the food (proposed § 1.1350(a)(3));
- the location identifier, location description, and point of contact for the traceability lot code generator (proposed § 1.1350(a)(4));
- the location identifier and location description for the immediate subsequent recipient (other than a transporter) of the food (proposed § 1.1350(a)(5));
- the location identifier and location description for the location from which the food was shipped, and the date and time the food was shipped (proposed § 1.1350(a)(6));
- the reference record type(s) and reference record number(s) (*e.g.*, “BOL No. 123,” “ASN 10212025”) for the document(s) containing the information

specified in proposed § 1.1350(a)(1) through (6) (proposed § 1.1350(a)(7)); and

- the name of the transporter who transported the food from the shipper (proposed § 1.1350(a)(8)).

The records we propose to require shippers of listed foods to keep are similar to the records that receivers of food would have to keep, except that rather than information on an incoming food, its source, and the place and date it was received, the shipper would keep information on the food it sent out, the recipient of the food, and the date of shipment and location from which the food was shipped. As with the requirements for receivers of food, if an imported food is subsequently transformed, a shipper of the food produced through transformation would not be required to keep (or send forward) a record of the entry number for any imported food that is a component of such food.

As described in proposed § 1.1320, there are circumstances in which the shipper would be required to establish and assign the traceability lot code for the shipped food. In all other circumstances, the traceability lot code would be the code assigned by a previous entity in the food's supply chain, which could be the immediate previous source of the food or a person several steps previous in the supply chain.

b. Records To Be Sent to Recipients of the Food (Proposed § 1.1350(b))

In many cases, persons who would be required under the proposed rule to keep certain records containing key information on events such as receipt and transformation of food either receive or generate this information in the normal course of business, such as in shipping records (*e.g.*, bills of lading, purchase orders) and production records (*e.g.*, batch logs, work orders, repack logs). However, as previously stated, in some circumstances firms such as manufacturers, distributors, and retailers may not always have all the information on foods they receive that we believe is essential for ensuring traceability of the foods throughout the supply chain. For example, some reference records will state a firm's post office box number but not identify the location where the food was handled. During a recent outbreak, FDA was delayed in gathering records from a distributor because the records available to us from the retailer of the food listed a home address of the distributor rather than the address of the physical location of the firm. This lack of critical tracing information can result in significant

delays in completing a traceback investigation.

For this reason, proposed § 1.1350(b) would require persons who ship a food on the Food Traceability List to send records (in electronic or other written form) containing the following information to the immediate subsequent recipient (other than a transporter) of each traceability lot shipped:

- The information in proposed § 1.1350(a)(1) through (6) (*i.e.*, traceability lot code, quantity and unit measure of food shipped for each traceability lot code, traceability product identifier and traceability product description, information on the traceability lot code generator, location identifier and location description for the immediate subsequent recipient, and location identifier and location description for the place of shipment) (proposed § 1.1350(b)(1)); and
 - if the shipper is a farm, the following information (if applicable) for each traceability lot of the food:
 - A statement that the shipper is a farm (proposed § 1.1350(b)(2)(i));
 - the location identifier and location description of the originator of the food (if not the shipper) (proposed § 1.1350(b)(2)(ii));
 - the business name, point of contact, and phone number of the harvester of the food (if not the shipper), and the date(s) and time(s) of harvesting (proposed § 1.1350(b)(2)(iii));
 - the location identifier and location description of the place where the food was cooled (if not by the shipper), and the date and time of cooling (proposed § 1.1350(b)(2)(iv)); and
 - the location identifier and location description of the place where the food was packed (if not by the shipper), and the date and time of packing (proposed § 1.1350(b)(2)(v)).

Shippers of listed foods would have to send the information in proposed § 1.1350(b) to the recipients of the food in electronic or other written form. We would encourage firms to send the information electronically, such as in an email to their customer or an ASN, but shippers could 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 BOL.

We believe it is necessary to require shippers of listed foods to send their customers the information in proposed § 1.1350(a)(1) through (6) (*i.e.*, traceability lot code, quantity of food shipped and unit measure of food shipped for each traceability lot code, traceability product identifier and

product description, information on the traceability lot code generator, location identifier and location description for the immediate subsequent recipient, and location identifier and location description for the place of shipment) because, as previously noted, this information is not always provided by firms to their customers under current businesses practices. Because we need to be able to review this information when we visit such a customer during a tracing investigation involving a listed food, we propose to require that shippers provide this information to their customers.

We are proposing the additional information disclosure requirements for shippers who are farms because we propose to require that the first receiver of a food on the Food Traceability List (*i.e.*, the first person other than a farm who purchases and takes physical possession of the food) maintain this information, and we understand that not all farms routinely provide this information to firms that buy food from the farms. Therefore, we believe it is appropriate to require farms to provide information on the origination (if not by the farm), harvesting, cooling, and packing of the food (if applicable) when they ship the food.

In situations where food is sold from one farm to a second farm before being sold to a first receiver, this system would allow for all of the necessary information to reach the first receiver, even if some of the activities (*e.g.*, origination and harvesting) took place on the first farm, while others (*e.g.*, cooling and packing) took place on the second farm. In that situation, the first farm would be obligated under proposed § 1.1350(b)(1) to send information about their location to the second farm, and they would be obligated under proposed § 1.1350(b)(3)(iii) to send the second farm information about the date and time of harvesting. This would allow the second farm to fulfill its obligation under proposed § 1.1350(b)(2)(ii) and (iii) to send the first receiver information about the originator of the food and the date and time of harvesting. Moreover, the statement that the sender is a farm would allow the first receiver to recognize its status as a first receiver of a listed food, which might not otherwise be clear in this situation, where the second farm did not originate the food but nonetheless is a farm as defined in proposed § 1.1310.

F. Special Requirements for Foods Subjected to a Kill Step (Proposed § 1.1355)

We are proposing to adopt special recordkeeping requirements for foods on the Food Traceability List that are subjected to a kill step to more appropriately address traceability issues associated with these foods. Proposed § 1.1355 answers the question, “What recordkeeping requirements apply to foods on the Food Traceability List that are subjected to a kill step?” We recognize that applying a kill step to a food can reduce the food’s potential to harm public health by significantly minimizing the presence of pathogens in the food. Adequately applying a kill step to a food on the Food Traceability List could potentially reduce the risk posed by the food and reduce the likelihood that the food would be involved in an outbreak, thereby reducing the need for further tracing of that food. Therefore, proposed § 1.1355(a) would provide that if a person applies a kill step to a food on the Food Traceability List, the proposed subpart S recordkeeping requirements would not apply to that person’s subsequent shipping of the food, provided that the person maintained a record of application of the kill step. We anticipate that many manufacturers/processors would be able to use records required under existing regulations, such as those requiring documentation of monitoring of a preventive control (see § 117.190(a)(2)) or documentation of thermal processing of low-acid canned foods (LACF) (see 21 CFR 113.100 (§ 113.100)), to meet the requirement to document application of the kill step to the food. In addition, proposed § 1.1355(b) would specify that if a person receives a food on the Food Traceability List that has been subjected to a kill step, the proposed recordkeeping requirements would not apply to that person’s receipt or subsequent transformation and/or shipping of the food.

As an example of application of these proposed provisions, consider the production of canned sardines. A manufacturer of canned sardines would be required to maintain records of receipt of the sardines under proposed § 1.1335 (assuming sardines are on the Food Traceability List at the time, as they are now), and the manufacturer would have to maintain records of transformation of the sardines under proposed § 1.1340(a) because it processes the sardines (including by canning them). These records would include the new traceability lot code that the manufacturer would be required

to assign to the canned sardines under proposed § 1.1320(a) (see proposed § 1.1340(a)(6)). However, under proposed § 1.1355(a), the manufacturer would *not* be required to maintain tracing records of shipment of the canned sardines (as otherwise would be required under proposed § 1.1350) provided that the manufacturer maintained a record of its application of the kill step to the sardines. The requirement to maintain records documenting the kill step could be fulfilled using records that are already required under the regulations on LACF (part 113) and hazard analysis and critical control point operations for seafood (21 CFR part 123). Documentation of the kill step would have to be maintained for 2 years, in accordance with proposed § 1.1460(c). In addition, under proposed § 1.1355(b), because the kill step had been applied, the manufacturer’s customer and subsequent persons in the supply chain would not be required to maintain any records required under proposed subpart S regarding receipt, transformation, or shipment of the canned sardines. However, both the manufacturer and subsequent persons in the supply chain would still need to maintain any records that are required of them under the subpart J regulations.

G. Procedures for Modified Requirements and Exemptions (Proposed §§ 1.1360 to 1.1400)

The proposed rule includes provisions allowing the Agency to modify the recordkeeping requirements applicable to certain foods or types of entities, or to exempt foods or types of entities from the requirements, under certain circumstances. Section 204(d)(6)(E) of FSMA states that FDA may, by notice in the **Federal Register**, modify the recordkeeping requirements applicable to a food or type of facility under section 204(d), or exempt a food or type of facility from these requirements, if we determine that product tracing requirements for such food or type of facility are not necessary to protect the public health. However, section 204(d)(6)(E) and (F) of FSMA also provide that, in situations where such modification or exemption applies, if the person who manufactures, processes, packs, or holds the food is required to register with FDA under section 415 of the FD&C Act with respect to the manufacturing, processing, packing, or holding of the food, we shall require the person to maintain records that identify the immediate previous source of the food and the immediate subsequent recipient of the food.

The following paragraphs discuss our proposed procedures for adopting exemptions from, and modifications to, the proposed traceability recordkeeping requirements for particular foods or types of entities.

1. Circumstances Under Which FDA Will Modify Requirements or Grant Exemptions (Proposed § 1.1360)

Proposed § 1.1360 answers the question, “Under what circumstances will FDA modify the requirements in this subpart that apply to a food or type of entity or exempt a food or type of entity from the requirements of this subpart?” Proposed § 1.1360(a) would specify that, except as stated in proposed § 1.1360(b), FDA will modify the requirements of subpart S applicable to a food or type of entity, or exempt a food or type of entity from subpart S, when we determine that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health.

Under proposed § 1.1360(b), if a person to whom modified requirements or an exemption applies under § 1.1360(a) (including a person who manufactures, processes, packs, or holds a food to which modified requirements or an exemption applies under § 1.1360(a)) is required to register with FDA under section 415 of the FD&C Act (and in accordance with subpart H) with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Proposed § 1.1360(b) further states that such records would have to be maintained for 2 years, consistent with the record retention requirement we are proposing for subpart S records (see section V.H.3).

2. Means by Which FDA Will Consider Whether To Adopt Modified Requirements or Grant Exemptions (Proposed § 1.1365)

Proposed § 1.1365 answers the question, “How will FDA consider whether to adopt modified requirements or grant an exemption from the requirements of this subpart?” Proposed § 1.1365 would provide that we will consider modifying subpart S requirements applicable to a food or type of entity, or exempting a food or type of entity from these requirements, on our own initiative or in response to a citizen petition submitted under 21 CFR 10.30 (§ 10.30) by any interested party. FDA’s citizen petition regulations in § 10.30 provide standardized

procedures for requesting that FDA take (or refrain from taking) an administrative action. A citizen petition may be submitted by any person (including a person who is not a citizen of the United States). Among other things, the citizen petition regulations provide a format for such requests and a procedure under which a docket is created and interested persons may submit comments to the docket regarding the requested action.

3. Requirements for Citizen Petition Requesting Modified Requirements or an Exemption (Proposed § 1.1370)

Proposed § 1.1370 answers the question, “What must be included in a petition requesting modified requirements or an exemption from the requirements?” Proposed § 1.1370 would require that, in addition to meeting the requirements on the content and format of a citizen petition in § 10.30, a petition requesting modified requirements or an exemption from the subpart S requirements would have to:

- Specify the food or type of entity to which the modified requirements or exemption would apply (proposed § 1.1370(a));
- if the petition requests modified requirements, specify the proposed modifications to the subpart S requirements (proposed § 1.1370(b)); and
- present information demonstrating why application of the requirements requested to be modified or from which exemption is requested is not necessary to protect the public health (proposed § 1.1370(c)).

4. Public Availability of Information in a Citizen Petition (Proposed § 1.1375)

Proposed § 1.1375 answers the question, “What information submitted in a petition requesting modified requirements or an exemption, or information in comments on such a petition, is publicly available?” Proposed § 1.1375 would specify that FDA will presume that information submitted in a petition requesting modified requirements or an exemption, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under 21 CFR part 20 (part 20) (FDA’s regulations on public information) and would be made public as part of the docket associated with the petition.

5. Process for Citizen Petitions Requesting Modified Requirements or an Exemption (Proposed § 1.1380)

Proposed § 1.1380 answers the question, “What process applies to a

petition requesting modified requirements or an exemption?” Proposed § 1.1380 would establish a process for FDA’s handling of citizen petitions requesting modified requirements or an exemption from subpart S. Proposed § 1.1380(a) would provide that, in general, the procedures in § 10.30 would govern our response to such a petition, and an interested person could submit comments on such a petition in accordance with § 10.30(d). Proposed § 1.1380(b) would specify that, under § 10.30(h)(3), we would publish a notification in the **Federal Register** requesting information and views on a submitted petition, including information and views from persons who could be affected by the modified requirements or exemption if we granted the petition.

Proposed § 1.1380(c) would provide that, under § 10.30(e)(3), we would respond to a petitioner in writing. If we granted the petition either in whole or in part, we would publish a notification in the **Federal Register** setting forth any modified requirements or exemptions and the reasons for them (proposed § 1.1380(c)(1)). If we denied the petition (including a partial denial), our written response to the petitioner would explain the reasons for the denial (proposed § 1.1380(c)(2)).

Proposed § 1.1380(d) states that we will make readily accessible to the public, and periodically update, a list of petitions requesting modified requirements or exemptions, including the status of each petition (for example, pending, granted, or denied). We believe that maintaining such a list would help ensure that all persons who might be affected by or otherwise interested in these petitions have access to information about the status of the petitions.

6. Adopting Modified Requirements or Granting an Exemption on FDA’s Own Initiative (Proposed § 1.1385)

Proposed § 1.1385 answers the question, “What process will FDA follow when adopting modified requirements or granting an exemption on our own initiative?” Proposed § 1.1385 would establish the procedures we would follow if, on our own initiative, we proposed to adopt modified requirements or grant an exemption from the traceability recordkeeping requirements. Proposed § 1.1385(a) would provide that if we, on our own initiative, determine that adopting modified requirements or granting an exemption from the requirements for a food or type of entity is appropriate, we will publish a notification in the **Federal Register**

setting forth the proposed modified requirements or exemption and the reasons for the proposal. The notification will establish a public docket so that interested persons may submit written comments on the proposal. Proposed § 1.1385(b) would provide that, after considering any comments timely submitted, we will publish a notification in the **Federal Register** stating whether we are adopting modified requirements or granting an exemption, and the reasons for our decision.

7. When Modified Requirements and Exemptions Become Effective (Proposed § 1.1390)

Proposed § 1.1390 answers the question, “When will modified requirements that we adopt or an exemption that we grant become effective?” Proposed § 1.1390 would provide that any modified requirements that we adopt or exemption that we grant will become effective on the date that notice of the modified requirements or exemption is published in the **Federal Register**, unless otherwise stated in the notification.

8. Circumstances Under Which FDA Might Revise or Revoke Modified Requirements or an Exemption (Proposed § 1.1395)

Proposed § 1.1395 answers the question, “Under what circumstances may FDA revise or revoke modified requirements or an exemption?” Proposed § 1.1395 would provide that we may revise or revoke modified requirements or an exemption if we determine that such revision or revocation is necessary to protect the public health. For example, we might conclude that revocation of an exemption was appropriate following the emergence of a significant safety concern (e.g., repeated contamination events) associated with the food or type of entity for which the exemption had been granted.

9. Procedures for Revision or Revocation of Modified Requirements or an Exemption (Proposed § 1.1400)

Proposed § 1.1400 answers the question, “What procedures apply if FDA tentatively determines that modified requirements or an exemption should be revised or revoked?” Proposed § 1.1400(a) would provide that if we tentatively determine that we should revise or revoke modified requirements or an exemption, we will provide the following notifications:

- We will notify the person that originally requested the modified requirements or exemption (if we

adopted modified requirements or granted an exemption in response to a petition) in writing at the address identified in the petition (proposed § 1.1400(a)(1)); and

- we will publish in the **Federal Register** a notification of our tentative determination that the modified requirements or exemption should be revised or revoked and the reasons for our tentative decision. The notification will establish a public docket so that interested persons may submit written comments on our tentative determination (proposed § 1.1400(a)(2)).

Under proposed § 1.1400(b), after considering any comments timely submitted, we will publish in the **Federal Register** a notification of our decision whether to revise or revoke the modified requirements or exemption and the reasons for the decision. Proposed § 1.1400(b) further states that if we do revise or revoke the modified requirements or exemption, the effective date of the decision will be 1 year after the date of publication of the notification, unless otherwise stated in the notification.

H. Waivers (Proposed §§ 1.1405 to 1.1450)

In accordance with section 204(d)(1)(I) of FSMA, we propose to establish a process for the issuance of a waiver of the additional traceability recordkeeping requirements in subpart S if we determine that application of the requirements would result in an economic hardship for an individual entity or a type of entity. Under the proposed procedures, a person could request a waiver for an individual entity by submitting a written request to FDA, or a person could request a waiver for a type of entity by submitting a citizen petition to FDA. In addition, we could elect to issue a waiver for an individual entity or a type of entity on our own initiative.

1. Circumstances Under Which FDA Will Waive Requirements (Proposed § 1.1405)

Proposed § 1.1405 answers the question, “Under what circumstances will FDA waive one or more of the requirements of this subpart for an individual entity or a type of entity?” Proposed § 1.1405 would provide that we will waive one or more of the subpart S requirements when we determine that all of the following conditions are met:

- Application of the requirements would result in an economic hardship for an individual entity or a type of entity, due to the unique circumstances

of the individual entity or type of entity (proposed § 1.1405(a));

- the waiver will not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 1.1405(b)); and

- the waiver will not otherwise be contrary to the public interest (proposed § 1.1405(c)).

Proposed § 1.1405(a) incorporates the concept of “economic hardship” that Congress set forth in section 204(d)(1)(I) of FSMA, while clarifying that such hardship must stem from the unique circumstances of the individual entity or type of entity. Examples of “unique circumstances” might include, but are not limited to, issues related to unique business operations or geographical factors. We note that merely having relatively low revenue or relatively few employees would not ordinarily constitute an economic hardship sufficient to qualify for a waiver from the subpart S requirements. As previously discussed, the proposed rule includes exemptions from the subpart S requirements for certain small produce farms, small shell egg producers, and other small originators of food (see section V.B.1), and it would either fully exempt retail food establishments having ten or fewer full-time equivalent employees from the rule (under Option 1 of the co-proposal) or exempt such establishments from the proposed requirement to provide traceability information to FDA in an electronic spreadsheet upon request during situations such as outbreak investigations (under Option 2 of the co-proposal) (see section V.B.7). The waiver process in proposed § 1.1405 is not meant to substitute for the decisions discussed in sections V.B.1 and V.B.7 regarding these proposed exemptions.

Under proposed § 1.1405(b) we would grant a waiver only if doing so would not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. In section 204(d)(1) of FSMA, Congress specified rapidly and effectively identifying recipients of a food in such

circumstances as the purpose for developing these proposed regulations. Therefore, we propose to adopt, as a condition for granting a waiver, a determination that the waiver would not undermine this central purpose of subpart S. For example, we likely would not grant a waiver to a certain type of entity that processes, distributes, or sells a food on the Food Traceability List if granting the waiver could significantly impair our ability to conduct traceback operations in response to a foodborne illness outbreak involving that food.

Proposed § 1.1405(c) states, as a final condition for a waiver, that the waiver will not otherwise be contrary to the public interest. For example, we might conclude that a waiver for an individual entity would not be appropriate because it might provide an unfair economic advantage over similarly situated firms in a particular sector of the food industry.

We request comment on the proposed criteria for granting a waiver of the proposed recordkeeping requirements and, in particular, what should constitute an economic hardship warranting such a waiver.

2. Mechanisms by Which FDA Will Waive Requirements (Proposed § 1.1410)

Proposed § 1.1410 answers the question, “How will FDA consider whether to waive a requirement of this subpart?” Proposed § 1.1410 would provide that we will consider whether to waive a requirement of subpart S on our own initiative or in response to the following:

- A written request for a waiver for an individual entity (proposed § 1.1410(a)); or

- a citizen petition requesting a waiver for a type of entity submitted under § 10.30 by any person subject to the requirements of subpart S (proposed § 1.1410(b)).

For a waiver request regarding an individual entity, we think that a written request to the Agency is sufficient, and the citizen petition process is unnecessary. But for requests that concern a type of entity, we believe that the fact that the waiver could apply to multiple parties, including persons unaware that the waiver request had been submitted, makes it appropriate to require that the request be submitted in a citizen petition.

3. Requesting a Waiver for an Individual Entity (Proposed § 1.1415)

Proposed § 1.1415 answers the question, “How may I request a waiver for an individual entity?” Proposed § 1.1415 would provide that a person

may request a waiver of one or more requirements of subpart S for an individual entity by submitting a written request to FDA that includes the following:

- The name, address, and point of contact of the individual entity to which the waiver would apply (proposed § 1.1415(a));
- the requirements of subpart S to which the waiver would apply (proposed § 1.1415(b));
- information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the entity, including information about the unique circumstances faced by the entity that result in unusual economic hardship from the application of these requirements (proposed § 1.1415(c));
- information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 1.1415(d)); and
- information demonstrating why the waiver would not otherwise be contrary to the public interest (proposed § 1.1415(e)).

We anticipate that after we publish the final rule on additional traceability requirements, we will establish an electronic mailbox to receive requests for waivers for individual entities. We also expect that we will publish on our website information about how to submit materials to this electronic mailbox, as well as specifying a physical FDA address to which waiver requests could be mailed.

4. Process for Request for Waiver for Individual Entity (Proposed § 1.1420)

Proposed § 1.1420 answers the question, "What process applies to a request for a waiver for an individual entity?" Proposed § 1.1420(a) would provide that, after considering the information submitted in a request for a waiver for an individual entity, we will respond in writing to the person that submitted the waiver request stating whether we are granting the waiver (in whole or in part) and the reasons for the decision. Proposed § 1.1420(b) would specify that any waiver for an individual entity that we grant will become effective on the date we issue our response to the waiver request, unless otherwise stated in the response.

5. Citizen Petition for Waiver for Type of Entity (Proposed § 1.1425)

Proposed § 1.1425 answers the question, "What must be included in a petition requesting a waiver for a type of entity?" Proposed § 1.1425 would provide that, in addition to meeting the requirements on the content and format of a citizen petition in § 10.30, a petition requesting a waiver for a type of entity must:

- Specify the type of entity to which the waiver would apply and the requirements of subpart S to which the waiver would apply (proposed § 1.1425(a));
- present information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the type of entity, including information about the unique circumstances faced by the type of entity that result in unusual economic hardship from the application of these requirements (proposed § 1.1425(b));
- present information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 1.1425(c)); and
- present information demonstrating why the waiver would not otherwise be contrary to the public interest (proposed § 1.1425(d)).

6. Public Availability of Information in Citizen Petition Requesting a Waiver (Proposed § 1.1430)

Proposed § 1.1430 answers the question, "What information submitted in a petition requesting a waiver for a type of entity, or information in comments on such a petition, is publicly available?" Proposed § 1.1430 would specify that we will presume that information submitted in a petition requesting a waiver for a type of entity, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under part 20 and would be made public as part of the docket associated with the petition.

7. Process for Citizen Petition Requesting a Waiver (Proposed § 1.1435)

Proposed § 1.1435 answers the question, "What process applies to a petition requesting a waiver for a type

of entity?" Proposed § 1.1435(a) would specify that, in general, the procedures in § 10.30 govern FDA's response to a petition requesting a waiver, and that an interested person may submit comments on a petition requesting a waiver in accordance with § 10.30(d). Proposed § 1.1435(b) would provide that, under § 10.30(h)(3), we will publish a notification in the **Federal Register** requesting information and views on a submitted petition requesting a waiver for a type of entity, including information and views from persons who could be affected by the waiver if we granted the petition.

Under proposed § 1.1435(c), we would respond to a petitioner in writing under § 10.30(e)(3), as follows:

- If we grant a petition either in whole or in part, we will publish a notification in the **Federal Register** setting forth any requirements we have waived and the reasons for the waiver (proposed § 1.1435(c)(1)); and
- if we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial (proposed § 1.1435(c)(2)).

Proposed § 1.1435(d) would provide that we will make readily accessible to the public, and periodically update, a list of petitions requesting waivers for types of entities, including the status of each petition (for example, pending, granted, or denied). As with citizen petitions requesting modified requirements or an exemption from subpart S, we believe that maintaining a list of these waiver petitions would help ensure that all persons who might be affected by or are otherwise interested in these petitions can obtain information about them.

8. Process for Granting Waivers on FDA's Own Initiative (Proposed § 1.1440)

Proposed § 1.1440 answers the question, "What process will FDA follow when waiving a requirement of this subpart on our own initiative?" Proposed § 1.1440(a) would provide that if FDA, on its own initiative, determines that a waiver of one or more requirements for an individual entity or type of entity is appropriate, we will publish a notification in the **Federal Register** setting forth the proposed waiver and the reasons for such waiver. The notification will establish a public docket so that interested persons may submit written comments on the proposal. Proposed § 1.1440(b) would provide that after considering any comments timely submitted, we will publish a notification in the **Federal Register** stating whether we are granting the waiver (in whole or in part) and the

reasons for our decision. Under proposed § 1.1440(c), any waiver for a type of entity that we grant will become effective on the date that notice of the waiver is published in the **Federal Register**, unless otherwise stated in the notification.

9. Circumstances Under Which FDA May Modify or Revoke a Waiver (Proposed § 1.1445)

Proposed § 1.1445 answers the question, “Under what circumstances may FDA modify or revoke a waiver?” Proposed § 1.1445 would provide that we may modify or revoke a waiver if we determine that:

- Compliance with the waived requirements would no longer impose a unique economic hardship on the individual entity or type of entity to which the waiver applies (proposed § 1.1445(a));

- the waiver could significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act (proposed § 1.1445(b)); or

- the waiver is otherwise contrary to the public interest (proposed § 1.1445(c)).

One way in which we might become aware that the circumstances under which we had granted a waiver to a firm had changed might be through a routine inspection of the firm or an inspection in the course of an investigation into a foodborne illness outbreak. In addition, we would encourage firms to which we had granted a waiver to notify us if their economic/financial circumstances had changed such that compliance with subpart S would no longer result in an economic hardship for them.

10. Procedures for Modification or Revocation of a Waiver (Proposed § 1.1450)

Proposed § 1.1450 answers the question, “What procedures apply if FDA tentatively determines that a waiver should be modified or revoked?” As with respect to requests for waivers, we propose to establish different procedures for modifications and revocations of waivers for (1) individual entities and (2) types of entities.

Proposed § 1.1450(a)(1) would provide that if we tentatively determine that we should modify or revoke a waiver for an *individual entity*, we will notify the person that had received the waiver in

writing of our tentative determination that the waiver should be modified or revoked. The notice will provide the waiver recipient 60 days in which to submit information stating why the waiver should not be modified or revoked. Proposed § 1.1450(a)(2) would provide that upon consideration of any information submitted by the waiver recipient, we will respond in writing stating our decision whether to modify or revoke the waiver and the reasons for the decision. The provision further states that if we modify or revoke the waiver, the effective date of the decision will be 1 year after the date of our response to the waiver recipient, unless otherwise stated in the response.

Proposed § 1.1450(b)(1)(i) would provide that if we tentatively determine that we should modify or revoke a waiver for a *type of entity*, we will notify the person that originally requested the waiver (if we granted the waiver in response to a petition) in writing at the address identified in the petition. Proposed § 1.1450(b)(1)(ii) would specify that we will also publish a notification in the **Federal Register** of our tentative determination that the waiver should be modified or revoked and the reasons for our tentative decision. The proposed provision further states that the notification will establish a public docket so that interested persons may submit written comments on our tentative determination.

Proposed § 1.1450(b)(2) would provide that, after considering any comments timely submitted, we will publish a notification in the **Federal Register** of our decision whether to modify or revoke the waiver and the reasons for the decision. Proposed § 1.1450(b)(2) further states that if we modify or revoke the waiver, the effective date of the decision will be 1 year after the date of publication of the notification, unless otherwise stated in that notification.

I. Records Maintenance and Availability (Proposed § 1.1455)

Proposed § 1.1455 answers the question, “How must records required by this subpart be maintained?” We propose to adopt several requirements concerning the maintenance of records required by subpart S and FDA access to these records.

1. General Requirements (Proposed § 1.1455(a))

Proposed § 1.1455(a)(1) would require that records be kept as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions

of the original records). Proposed § 1.1455(a)(2) would require that all records be legible and stored to prevent deterioration or loss.

As discussed in section IV.D, we understand that many firms in the food industry, including farms, manufacturers, distributors, and retail food establishments, have begun maintaining and sharing product information in electronic records, which can have substantial benefits for tracing foods throughout the supply chain. The use of paper records, on the other hand, can delay traceback activities as FDA investigators must request the records, wait for the firm to gather them, and then sort through the records by hand. In addition, individual paper records may not contain all the necessary information, and investigators may need to request additional information to determine how the records can be linked together for tracing purposes. When paper records are handwritten, there can be additional delays if the handwriting is not legible. In contrast, when firms provide data electronically in a sortable format, investigators can trace food through the supply chain more quickly. As previously stated, we strongly encourage all entities in the food industry to adopt the use of electronic data systems for their traceability operations, including for maintenance of KDEs, reference records, and traceability program records. However, we are aware that not all firms have systems in place that would allow for the maintenance of these records in electronic form, and it might be burdensome for some firms if we required that all subpart S records be kept electronically. Therefore, proposed § 1.1455(a)(1) would not require the maintenance of records in electronic form, although we strongly encourage electronic recordkeeping.

2. Record Availability (Proposed § 1.1455(b))

Proposed § 1.1455(b) sets forth proposed requirements on making records available to FDA. Proposed § 1.1455(b)(1) would require that all records required to be kept under the proposed regulations be made available to an authorized FDA representative as soon as possible but not later than 24 hours after the request. Proposed § 1.1455(b)(2) would specify that offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review; electronic records would be considered to be onsite if they are accessible from an onsite location.

Proposed § 1.1455(b)(3) would require that, when necessary to help FDA

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, including but not limited to situations where FDA has a reasonable belief that an article of food (and any other article of food that FDA reasonably believes is likely to be affected in a similar manner) presents a threat of serious adverse health consequences or death to humans or animals as a result of the food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act, persons subject to the subpart S requirements must make available, within 24 hours of request by an authorized FDA representative, an electronic sortable spreadsheet containing the information in the records they are required to maintain under subpart S, for the foods and date ranges specified in the request. Proposed § 1.1455(b)(3) further states that we will withdraw a request for such a spreadsheet when necessary to accommodate a religious belief of a person asked to provide a spreadsheet. (As previously discussed in section V.B.7, under Option 2 of our co-proposal regarding proposed § 1.1305(g), we would exempt retail food establishments with 10 or fewer full-time equivalent employees from this requirement.)

We believe that this proposed requirement to provide an electronic sortable spreadsheet containing traceability information on foods that are the focus of an FDA investigation into a foodborne illness outbreak or other threat to public health would be one of the most effective ways to improve the speed and efficiency of our traceback efforts. The electronic spreadsheet would contain, in a searchable format, all of the information the person is required to maintain under the proposed regulations, such as applicable records of shipment, receipt, and transformation, for the foods (and relevant date ranges) that are the subject of FDA's records request.

As noted, we would only request the specified spreadsheet when we conclude that obtaining the information in this format is necessary to help us prevent or mitigate a foodborne illness outbreak, assist in implementation of a recall, or address a credible threat of serious adverse health consequences or death due to an adulterated or misbranded food. Reviewing an electronic sortable spreadsheet would allow us to more quickly aggregate tracing information to link points in the supply chain of a potentially contaminated food, leading to faster

removal of the food from the market. Although we realize that not all persons subject to the proposed rule currently maintain such a spreadsheet or other electronic records, we believe it is not unduly burdensome to require firms to have the capacity to create such a spreadsheet—limited to the specific scope of the foods and dates at issue—in the event of an outbreak or other threat to the public health. Furthermore, requiring firms to make their tracing information available to us in such a concise yet comprehensive and accessible form is needed to facilitate Agency review of tracing information and consequently help minimize the potential harm to public health resulting from foodborne illness outbreaks.

We request comment on the appropriateness and feasibility of the proposed requirement that information be made available to FDA in this form when needed to prevent or mitigate a foodborne illness outbreak, assist in implementation of a recall, or address credible threats of serious adverse health consequences or death due to an adulterated or misbranded food, and, if not appropriate and/or feasible, what alternate approaches might be appropriate to address the need for expedited access to critical traceability information in such circumstances.

Proposed § 1.1455(b)(4) would specify that, upon FDA request, persons subject to the proposed recordkeeping requirements must provide within a reasonable time an English translation of records maintained in a language other than English. A reasonable time for translation might vary, for example, from a few days to several days, depending on the volume of records requested to be translated and the extent to which persons with the necessary language fluency are available to perform the translation.

3. Record Retention (Proposed § 1.1455(c))

Proposed § 1.1455(c) would specify that persons subject to these recordkeeping requirements must maintain the records containing information required under subpart S for 2 years from the date they created the records, except as specified elsewhere in subpart S. We note that this proposed record retention period differs from the retention periods in subpart J (§ 1.360), which applies different record retention requirements depending on the length of time before a food experiences a significant risk of spoilage, loss of value, or loss of palatability. For example, under § 1.360(b) through (d), nontransporters

of food must retain records according to the following schedule:

- Foods having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date of receipt or release: Retain records for 6 months;
- foods for which a significant risk of spoilage, loss of value, or loss of palatability occurs 60 days to 6 months after the date of receipt or release: Retain records for 1 year; and
- foods for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date of receipt or release: Retain records for 2 years.

These criteria are similar to the definitions of perishable, semiperishable, and long shelf-life food used in regulations of the National Institute of Standards and Technology (NIST). We adopted this record retention schedule for subpart J records because we concluded that the food industry was familiar with the classification of foods into these three categories due to existing regulations and practices, and we believed that use of this classification would mitigate the concern, raised by some commenters, regarding inadequate infrastructure for long-term storage of records for shorter shelf-life foods (69 FR 71562 at 71602 to 71603).

However, we believe that this tiered record retention approach would not be appropriate for the proposed additional traceability recordkeeping requirements in subpart S. Instead, we believe that, except for certain limited exceptions previously discussed in this document, records for all foods on the Food Traceability List should be retained for 2 years. Even though a highly perishable food might pose a risk to consumers for only a few weeks, illnesses caused by a contaminated food can be linked retrospectively to past illnesses through whole genome sequencing and other evidence months or even years after the food was sold. Exposure and consumption information collected from illness cases can be compared to such information from past cases of illness with the same whole genome sequencing pattern. Having access to traceability records for the food for up to 2 years after the records were created could greatly aid our investigation into an illness outbreak involving the food. In addition, if we could review food production records up to 2 years old, it could help us determine whether a current foodborne illness outbreak was part of a long-standing contamination problem with a food or firm. For these reasons, we propose to require that traceability records for all foods on the

Food Traceability List be maintained for 2 years after the records were created.

4. Electronic Records (Proposed § 1.1455(d))

Proposed § 1.1455(d) would provide that records that are established or maintained to satisfy the requirements of subpart S and that meet the definition of electronic records in 21 CFR 11.3(b)(6) (§ 11.3(b)(6)) are exempt from the requirements of 21 CFR part 11 (part 11), which contains FDA regulations on electronic records and electronic signatures. Proposed § 1.1455(d) would further specify that records that satisfy the requirements of subpart S, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11, if not otherwise exempt (*e.g.*, under other regulations).

5. Use of Existing Records (Proposed § 1.1455(e))

Proposed § 1.1455(e) would provide that persons subject to these recordkeeping requirements would not have to duplicate existing records (*e.g.*, records kept in the ordinary course of business or that are maintained to comply with other Federal, State, Tribal, territorial, or local regulations) if the records contain all of the information required under the proposed rule. For example, firms would be able to rely on tracing records they keep in accordance with subpart J to meet some of the requirements that would apply to them under proposed subpart S. Proposed § 1.1455(e) further states that persons may supplement any such existing records as necessary to include all of the information required by subpart S. Proposed § 1.1455(e) is consistent with section 204(d)(1)(E) of FSMA, which in part directs that the proposed traceability recordkeeping requirements not require the creation and maintenance of duplicate records where the required information is contained in other company records kept in the normal course of business.

Proposed § 1.1455(e) would also provide that persons subject to the recordkeeping requirements would not have to keep all of the required information in one set of records. However, the provision would specify that if a person keeps the required information in more than one set of records, the person must indicate the different records in which the information is maintained in accordance with proposed § 1.1315(a), which would require persons subject to subpart S to maintain a document describing the reference records in which required information is kept.

J. Consequences of Failure To Comply (Proposed § 1.1460)

Proposed § 1.1460 answers the question, “What consequences could result from failing to comply with the requirements of this subpart?” Section 204(j)(1) of FSMA amends section 301(e) of the FD&C Act to make it a prohibited act to violate any recordkeeping requirement under section 204 (except when the violation is committed by a farm). Therefore, proposed § 1.1460(a) would specify that the violation of any recordkeeping requirement under section 204 of FSMA, including the violation of any requirement of subpart S, is prohibited under section 301(e) of the FD&C Act, except when such violation is committed by a farm.

Section 204(j)(2) of FSMA amended section 801(a) of the FD&C Act by adding paragraph (a)(4), which states that FDA shall refuse admission to an article of food if it appears from examination of samples of the food or otherwise that the recordkeeping requirements under section 204 of FSMA (other than the requirements under section 204(f), which concern FDA requests for information from farms under certain circumstances, and which are not addressed in this rulemaking) have not been complied with regarding such article. Therefore, proposed § 1.1460(b) would specify that an article of food is subject to refusal of admission under section 801(a)(4) of the FD&C Act if it appears that the recordkeeping requirements under section 204 of FSMA (other than the requirements under section 204(f)), including the requirements of subpart S, have not been complied with regarding such article.

K. Updating the Food Traceability List (Proposed § 1.1465)

Proposed § 1.1465 answers the question, “How will FDA update the Food Traceability List?” Section 204(d)(2)(B) of FSMA states that we may update the Food Traceability List to designate new high-risk foods and remove foods no longer deemed to be high-risk foods, provided that the update of the list is consistent with section 204(d)(2) and we publish notice of the update in the **Federal Register**. We will monitor the factors set forth in section 204(d)(2) (*e.g.*, known safety risks of foods (including history and severity of attributed foodborne illness outbreaks), points in manufacturing processes where contamination is likely to occur, likelihood of contamination) and consider new scientific data or other scientific information that is

relevant to these factors. We anticipate periodically performing a review of such information to conclude whether it is appropriate to revise the Food Traceability List. In addition, we also will consider whether new data or other information warrants a reassessment of the methodology used to develop the list.

Upon review of relevant information, we might conclude that it would be appropriate to revise the Food Traceability List by deleting a food from the list, adding a food to the list, or both. Proposed § 1.1465(a) would provide that when we tentatively conclude, in accordance with section 204(d)(2) of FSMA, that it is appropriate to revise the Food Traceability List, we will 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.

Proposed § 1.1465(b) would provide that after considering any information and views submitted on the proposed changes to the list, we will publish a notice in the **Federal Register** stating whether we are making any changes to the list and the reasons for the decision. Proposed § 1.1465(b) further states that if we revise the list, we will also publish the revised list on our website.

Proposed § 1.1465(c) would specify that when we update the Food Traceability List in accordance with § 1.1465, any deletions from the list will become effective immediately, but any additions to the list will become effective 1 year after the date of publication of the **Federal Register** notice announcing the revised list, unless otherwise stated in the notice. We believe it would be appropriate to allow time for persons who manufacture, process, pack, or hold a food that we add to the Food Traceability List to come into compliance with the additional traceability recordkeeping requirements for the food under subpart S.

VI. Proposed Effective and Compliance Dates

We propose that any final rule on additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods on the Food Traceability List would become effective 60 days after the date on which the rule is published in the **Federal Register**. However, as discussed below, we are proposing to provide additional time before persons subject to the regulations would be required to comply with them.

Section 204(i) of FSMA directs that the traceability recordkeeping

requirements adopted under section 204(d) will apply to small businesses (as defined under section 103 of FSMA) 1 year after the effective date of the final regulations, and to very small businesses (as defined under section 103 of FSMA) 2 years after the effective date of the final regulations. As defined under section 103 of FSMA, a “small business” is a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees (see 21 CFR 117.3); a “very small business” is a business (including any subsidiaries and affiliates), averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). Although Congress established these later compliance dates for smaller entities, we believe that we could more effectively and efficiently implement the new traceability recordkeeping regulations by having all persons subject to them come into compliance by the same date. In particular, because proposed § 1.1350(b) would require that certain records be sent to the immediate subsequent recipient of the food—a provision which would help the recipient comply with the proposed requirements by providing them with some of the information necessary to comply—we are concerned that staggered compliance dates would hinder the rule’s effectiveness. Therefore, we propose that the compliance date for all persons subject to these recordkeeping requirements would be 2 years after the effective date of the final regulations. We request comment on our proposed approach to compliance dates.

VII. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs

associated with at least two prior regulations.” This proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because some small firms may incur annualized costs that exceed one percent of their annual revenue, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$156 million, using the most current (2019) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

This proposed rule, if finalized, would allow FDA and industry to more rapidly and effectively trace food products that cause illnesses back through the food supply system to the source and forward to determine recipients of the contaminated product. This rule would only apply to foods we have designated for inclusion on the Food Traceability List. By allowing faster identification of contaminated foods and increasing rates of successful tracing completions, the proposed rule may result in public health benefits if foodborne illnesses directly related to those outbreaks are averted. This may also lead to more efficient use of FDA and industry resources needed for outbreak investigations by potentially resulting in more precise recalls and avoidance of overly broad market withdrawals and advisories for listed foods.

Benefits from this rule could be generated if the following two conditions hold: (1) A foodborne outbreak occurs and (2) the traceability records required by this proposed rule help FDA to quickly and accurately locate a commercially distributed violative product and ensure it is removed from the market. The primary public health benefits of this rule are the value from the reduction of the foodborne illnesses or deaths because records required by the proposed rule

are likely to reduce the time that a violative or contaminated food product is distributed in the market.

Other non-health related benefits of this rule, if realized, would be from avoiding costs associated with conducting overly broad recalls and market withdrawals that affect products that otherwise would not need to be withdrawn or recalled. Although recalls of rightly implicated foods come with necessary costs, overly broad recalls that involve loosely related or unrelated products can make overall recalls unnecessarily costly. The costs of a broad recall or market withdrawal include lost revenues from unimplicated products, plus expenses associated with notifying retailers and consumers, collection, shipping, disposal, inventory, and legal costs.¹ There are no benefits from removing unimplicated products from the market. It is possible, but not certain, that both of these categories of benefits separately or jointly could be experienced to the extent quantified in this regulatory impact analysis. On the other hand, it is also possible, but not certain, that a given instance of baseline contamination would lead to a very broad recall (that could be narrowed by the proposed rule) or to illnesses (that could be avoided due to the proposed rule), but not both.

Additional benefits may include increased food supply system efficiencies, such as improvements in supply chain management and inventory control; more expedient initiation and completion of recalls; avoidance of costs due to unnecessary preventive actions by consumers; and other food supply system efficiencies due to a standardized approach to traceability, including an increase in transparency and trust and potential deterrence of fraud.

This proposed rule, if finalized, would impose compliance costs on covered entities by increasing the number of records that are required for food products on the Food Traceability List. Entities that manufacture, process, pack, or hold listed foods would incur costs to establish and maintain

¹ For example, in an undifferentiated product recall, a single firm’s investment in traceability may be ineffective when competitors and partners have not instituted a traceability system. This is problematic because, for example, in the event of an undifferentiated leafy greens outbreak, issuing a broad recall could be unavoidable, at least until the implicated product is identified and removed from the market. In situations where the recalled products are insured, targeted recalls will help prevent unnecessary recall of insured products, which may have long-term consequence to retailers from increases in their insurance rates due to imprecise recalls.

traceability records. Some firms may also incur initial capital investment and training costs in systems that would enable them to establish, maintain, sort, and make available upon our request their traceability records. Moreover, firms would incur one-time costs of reading and understanding the rule. The information flows brought about by the proposed rule may prompt new protective actions—for example, in farming, manufacturing or cooking processes—that themselves would have costs. These potential costs have not been quantified but their occurrence is likely to be correlated with the realization of health and longevity benefits of this rule.

Tables 6a and 6b summarize the costs and the benefits of the proposed rule. Table 6a shows our estimates of the rule's cost if proposed Option 1 of the co-proposal regarding retail food establishments with 10 or fewer full-time equivalent employees (full exemption from the proposed rule) were selected. At a seven percent discount rate, ten-year annualized costs would range from approximately \$34 million to \$2.4 billion per year in 2018 dollars, with a primary estimate of \$411 million per year. At a three percent discount rate, annualized costs would range from approximately \$33 million to \$2.4 billion per year, with a primary estimate of \$400 million per year.

Table 6b shows our estimates of the rule's cost under proposed Option 2 of the co-proposal, which would exempt retail food establishments with 10 or fewer full-time equivalent employees from the requirement to provide FDA, under certain circumstances, with an electronic sortable spreadsheet containing requested tracing information. At a seven percent discount rate, annualized costs under Option 2 would range from approximately \$43 million to \$3.2 billion per year in 2018 dollars, with a primary estimate of \$535 million per year. At a three percent discount rate, annualized costs would range from approximately \$42 million to \$3.1 billion per year, with a primary estimate of \$513 million per year.

We estimate public health benefits using several case studies of outbreaks tracebacks for four pathogens associated with illnesses caused by foods on the Food Traceability List. These benefits

have a tendency toward underestimation of the total public health benefits because these four pathogens do not represent the total burden of all illnesses associated with listed foods.² However, adjustments made for undiagnosed and unattributed illnesses may have the opposite tendency of overstating both illnesses and benefits associated with listed foods. We calculate these monetized benefits from illnesses averted per year based on an estimated 84 percent reduction of traceback time resulting from the requirements of this rule. Under Option 1 of the co-proposal, for an estimated 84 percent traceback improvement, the annualized monetized benefits range from \$33 million to \$1.4 billion with a primary estimate of \$567 million, discounted at seven percent over ten years.³ At a three percent discount rate over ten years, the annualized monetized benefits range from \$33 million to \$1.4 billion with a primary estimate of \$580 million.

Under Option 2 of the co-proposal, for an estimated 84 percent traceback improvement, the annualized monetized benefits range from \$36 million to \$1.5 billion with a primary estimate of \$626 million, discounted at seven percent over ten years, and from \$37 million to \$1.6 billion with a primary estimate of \$640 million, discounted at three percent over ten years. Using examples from three recalls, we also estimate that additional (non-health) benefits of avoiding overly broad recalls could range from \$1.7 billion to \$5.6 billion per year at a seven percent discount rate and from \$1.7 billion to \$5.8 billion using a three percent discount rate. As noted earlier, it is possible that both of these categories of benefits could be experienced to the extent quantified in the regulatory impact analysis, either separately or jointly. Therefore, tables

² We cannot scale up to 100 percent because our estimates of the percentage of illnesses potentially avoided with improved traceability depend on data specific to each pathogen. We describe our methods in detail in section II.E.2 ("Public Health Benefits from Averted Illnesses") of the full Preliminary Regulatory Impact Analysis (PRIA) for the proposed rule (Ref. 26). In short, these four pathogens may account for roughly 95 percent of the total dollar value of the illnesses for which traceability might be an effective preventive measure.

³ See the PRIA for the proposed rule (Ref. 26) for an explanation of the estimated range of benefits of the proposed rule.

6a and 6b avoid a definitive statement that they should be summed.

Costs are lower in Option 1, relative to Option 2, because fewer retail food establishments would need to comply with the proposed rule. However, if retail food establishments with 10 or fewer full-time equivalent employees are exempt from the Subpart S requirements, the timeliness, precision, and accuracy of traceability efforts can be impacted and non-quantified benefits, such as enhancement of our ability to narrow the number of lots in a recall and the ability of retail food establishments with 10 or fewer full-time equivalent employees to have the data necessary to quickly identify and remove contaminated products from shelves, will be lessened in comparison to Option 2. Requiring recordkeeping by retail food establishments of all sizes allows for more consistent, organized, and specific information that covers the entire supply chain.

TABLE 6b—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE—Continued
[Option 2, in millions of dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Annualized Monetized \$millions/year	\$626 640	\$36 37	\$1,497 1,531	2018 2018	7 3	10 10	Monetized benefits from an estimated 84% reduction in traceback time for four pathogens. Additional benefits of avoiding overly broad recalls could range from \$1.7 billion to \$5.6 billion (7%, 10 years) and \$1.7 billion to \$5.8 billion (3%, 10 years).
Annualized Quantified	
Qualitative	Additional unquantified benefits include increased food supply system efficiencies; more expedient initiation and completion of recalls; avoidance of costs due to unnecessary preventive actions; and other efficiencies from a standardized approach to traceability.			
Costs:							
Annualized Monetized \$millions/year	535 513	43 42	3,210 3,063	2018 2018	7 3	10 10	A portion of foreign costs could be passed on to domestic consumers. We estimate that up to \$259 million in annualized costs (7%, 10 years) to foreign facilities could be passed on to domestic consumers.
Annualized Quantified	
Qualitative	
Transfers:							
Federal Annualized Monetized \$millions/year	
From/To	From:			To:			
Other Annualized Monetized \$millions/year	
From/To	From:			To:			
Effects:	State, Local or Tribal Government: No significant effect.						
	Small Business: Potential impact on small entities that are currently not keeping traceability records described by the proposed rule.						
	Wages: N/A.						
	Growth: N/A.						

In accordance with Executive Order 13771, in tables 7a and 7b we estimate present and annualized values of costs and cost savings of the proposed rule over an infinite time horizon. This proposed rule is expected to be a regulatory action under Executive Order 13771.

TABLE 7a—E.O. 13771 SUMMARY TABLE
[Option 1, in millions 2016 dollars, over an infinite time horizon]

Item	Primary estimate (7%)	Lower estimate (7%)	Upper estimate (7%)
Present Value of Costs	\$5,105	\$438	\$29,659
Present Value of Cost Savings
Present Value of Net Costs	5,105	438	29,659
Annualized Costs	357	31	2,076
Annualized Cost Savings
Annualized Net Costs	357	31	2,076

TABLE 7b—E.O. 13771 SUMMARY TABLE
 [Option 2, in millions 2016 dollars, over an infinite time horizon]

Item	Primary estimate (7%)	Lower estimate (7%)	Upper estimate (7%)
Present Value of Costs	\$6,288	\$532	\$36,867
Present Value of Cost Savings			
Present Value of Net Costs	6,288	532	36,867
Annualized Costs	440	37	2,581
Annualized Cost Savings			
Annualized Net Costs	440	37	2,581

We have also considered an alternative way of describing costs and benefits. Given uncertainties in the data underlying our costs and benefits estimates, tables 8a and 8b explore the possibility that baseline costs of recalls are more fully internalized by market actors.

Column (a) of tables 8a and 8b explores the possibility that market actors do not already account for the costs of foodborne illnesses associated

with listed foods (e.g., public health benefits of products with better traceability are not captured in product price) and/or the costs of overly broad recalls (e.g., firms do not invest enough in traceability because they do not expect other firms to also invest). Primary estimates (and relatively large portions of the uncertainty ranges) indicate that benefits of the rule would be greater than the rule's cost. Column (b) of tables 8a and 8b considers

scenarios where market actors already fully account for the costs of overly broad recalls. Then recall-associated benefits would not be greater than the cost of the rule. This means firms have already invested in traceability to the point where further investment would cost more than the benefit they would expect to receive. Then the total benefits of the rule, including health benefits, may or may not be greater than the rule's cost.

TABLE 8a—SUMMARY OF BENEFITS AND COSTS OF PROPOSED RULE (OPTION 1), AS A FUNCTION OF ASSUMPTIONS REGARDING BASELINE COST INTERNALIZATION *

	Neither adverse health effects nor recall-associated costs fully internalized in market transactions for listed foods (a)	Recall-associated costs, but not adverse health effects, fully internalized in market transactions for listed foods (b)
PRIA Section IV.B. PRIA Section II.E.3.	Health Benefits: \$567M (range: \$33M to \$1.4B) and/or Recall-Associated Benefits: \$1.7B to \$5.6B	Health Benefits: \$567M (range: \$33M to \$1.4B) Recall-Associated Benefits: \$1.7B to \$5.6B. Direct Compliance Costs >\$1.7B to \$5.6B. Protective Action Costs (potential): Not quantified. or Recall-Associated Benefits < Costs.
PRIA Sections IV.C and IV.D.	Direct Compliance Costs (if foreign passed through to U.S. supply chain & consumers): \$670M (range: \$52M to \$4B). Direct Compliance Costs (if foreign <i>not</i> passed through to U.S. supply chain & consumers): \$411M (range: \$34M to \$2.4B). Protective Action Costs (potential): not quantified	Direct Compliance Costs (if foreign passed through to U.S. supply chain & consumers): \$670M (range: \$52M to \$4B). Direct Compliance Costs (if foreign <i>not</i> passed through to U.S. supply chain & consumers): \$411M (range: \$34M to \$2.4B). Protective Action Costs (potential): not quantified.

* Primary estimates presented in this table are calculated with a 7 percent discount rate; primary estimates discounted at 3 percent differ only slightly. All estimates are expressed in 2018 dollars and annualized over 10 years. Abbreviations: M = million, B = billion.

TABLE 8b—SUMMARY OF BENEFITS AND COSTS OF PROPOSED RULE (OPTION 2), AS A FUNCTION OF ASSUMPTIONS REGARDING BASELINE COST INTERNALIZATION *

	Neither adverse health effects nor recall-associated costs fully internalized in market transactions for listed foods (a)	Recall-associated costs, but not adverse health effects, fully internalized in market transactions for listed foods (b)
PRIA Section II.E.2. PRIA Section II.E.3.	Health Benefits: \$626M (range: \$36M to \$1.5B) and/or Recall-Associated Benefits: \$1.7B to \$5.6B	Health Benefits: \$626M (range: \$36M to \$1.5B). Recall-Associated Benefits: \$1.7B to \$5.6B. Direct Compliance Costs >\$1.7B to \$5.6B Protective Action Costs (potential): Not quantified. or Recall-Associated Benefits < Costs.
RIA Sections II.F and II.H.	Direct Compliance Costs (if foreign passed through to U.S. supply chain & consumers): \$794M (range: \$61M to \$4.8B). Direct Compliance Costs (if foreign <i>not</i> passed through to U.S. supply chain & consumers): \$535M (range: \$43M to \$3.2B).	Direct Compliance Costs (if foreign passed through to U.S. supply chain & consumers): \$794M (range: \$61M to \$4.8B). Direct Compliance Costs (if foreign <i>not</i> passed through to U.S. supply chain & consumers): \$535M (range: \$43M to \$3.2B).

TABLE 8b—SUMMARY OF BENEFITS AND COSTS OF PROPOSED RULE (OPTION 2), AS A FUNCTION OF ASSUMPTIONS REGARDING BASELINE COST INTERNALIZATION *—Continued

	Neither adverse health effects nor recall-associated costs fully internalized in market transactions for listed foods	Recall-associated costs, but not adverse health effects, fully internalized in market transactions for listed foods
	(a)	(b)
	Protective Action Costs (potential): Not quantified	Protective Action Costs (potential): Not quantified.

* Primary estimates presented in this table are calculated with a 7 percent discount rate; primary estimates discounted at 3 percent differ only slightly. All estimates are expressed in 2018 dollars and annualized over 10 years. Abbreviations: M = million, B = billion.

The full PRIA (Ref. 26) is available in the docket for this proposed rule and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section with an estimate of the reporting, recordkeeping, and disclosure burden associated with the proposed rule. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed

collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Traceability Records for Certain Foods—OMB Control No. 0910–0560—Revision.

Description: If the proposed rule is finalized, provisions in 21 CFR part 1, subpart S, would implement section 204(d)(1) of FSMA, which requires FDA to establish traceability recordkeeping requirements, in addition to the requirements under section 414 of the FD&C Act and 21 CFR part 1, subpart J (the subpart J requirements) (currently approved under OMB control number 0910–0560), for facilities that manufacture, process, pack, or hold foods that the Agency has designated as high-risk foods (*i.e.*, placed on the “Food Traceability List”) in accordance

with section 204(d)(2) of FSMA. The proposed subpart S recordkeeping, reporting, and disclosure requirements are intended to strengthen public health protections by improving FDA’s ability to trace the movement of foods throughout the supply chain to identify the source of contaminated foods and aid in the removal of contaminated products from the market. Access to and utilization of such records would better enable FDA to respond to and contain threats to the public health introduced through foods on the Food Traceability List (“listed foods”). Existing regulations in subpart J set forth traceability recordkeeping requirements for firms that manufacture, process, pack, transport, distribute, receive, hold, or import food. We are proposing to establish additional recordkeeping requirements for foods on the Food Traceability List.

Description of Respondents: Except as specified otherwise, the requirements in the proposed rule apply to persons who manufacture, process, pack, or hold foods that appear on the list of foods for which additional traceability records are required in accordance with section 204(d)(2) of FSMA (the Food Traceability List).

We estimate the burden of the information collection as follows:

TABLE 9—ESTIMATED ONE-TIME RECORDKEEPING BURDEN

Proposed activity	Number of respondents	Number of records per respondent	Total annual records	Average burden per record (in hours)	Total hours
Reading and understanding the new record-keeping requirements.	422,145	1	422,145	3.3	1,393,079
§ 1.1315; traceability program records (one-time set-up).	130,063	1,000	130,063,000	0.03 (2 minutes)	3,901,890
Training personnel	96,644	3	289,932	2	579,864
Total	5,874,833

As reflected in table 9, we assume all potential respondents to the information collection will incur burden for reading and understanding the proposed regulations. Based on our experience with similar information collection, we

assume that reading and understanding the new requirements will require an average of 3.3 hours for each of the 422,145 respondents, for an estimated burden of 1,393,079 hours. In addition, some firms will incur a one-time burden

of establishing traceability program records under proposed § 1.1315. We estimate that 130,063 firms will need 0.03 hours to establish each of an average of 1,000 records, for an estimated one-time burden of 3,901,890

hours. Additionally, upon reviewing the regulations and implementing procedures to satisfy the information collection, we expect that some firms will incur burden associated with

training employees in procedures for properly documenting key data elements identified in the proposed regulations. We estimate that 96,644 firms will need to conduct an average of

2 hours of training with respect to an average of 3 records, for a total of 579,864 hours. Cumulatively, this results in a total of 5,874,833 one-time burden hours for respondents.

TABLE 10—ESTIMATED ANNUAL REPORTING BURDEN

Proposed reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
§ 1.1370; Requests for modified requirements and exemptions	5	1	5	10	50
§§ 1.1415 through 1.1425; Requests for waivers	15	1	15	10	150
§ 1.1465(a); Comments on proposed revisions to the Food Traceability List	1	1	1	1	1
Total			22		202

Proposed §§ 1.1300 and 1.1305 set forth the scope and applicability of the regulations, as well as identify certain foods and persons that would be exempt from the additional recordkeeping requirements. Proposed §§ 1.1360 through 1.1400 discuss how respondents to the information collection may request modified requirements and exemptions from the subpart S requirements for certain foods or types of entities. If the proposed rule is finalized, the regulations would explain the procedures and identify the content and format elements that should be included in such requests submitted to FDA, as well as the procedures FDA will follow when proposing modified requirements or exemptions on its own initiative. Specifically, the proposed regulations provide that respondents requesting modified requirements and exemptions must petition the Agency under our regulations in § 10.30. In accordance with the proposed regulations, FDA will publish a notification in the **Federal Register** requesting information and views on a submitted petition. Based on our

experience with similar information collection, we assume few requests for modified requirements or exemptions will be submitted to the Agency and therefore provide a base estimate of five submissions annually, as reflected in table 10, row 1. Assuming each submission requires an average of 10 hours to prepare, this results in a total of 50 hours. We invite comment on the estimated burden associated with requests for modified requirements or exemptions from the proposed requirements.

Proposed §§ 1.1410 through 1.1455 pertain to waivers from the subpart S requirements for individual entities and types of entities. If the rule is finalized, these regulations would specify that the procedures for submitting waiver requests for types of entities are governed by § 10.30 and would identify requisite content and format elements for such requests. The regulations would further specify that requests for waivers for individual entities are to be made via written requests (not governed by § 10.30). Based on our experience with similar information collection, we believe that slightly more waiver

requests (compared to requests for modified requirements or an exemption) will be submitted and we therefore provide a base estimate of 15 submissions annually, as reflected in table 10, row 2. Assuming each submission requires an average of 10 hours to prepare, this results in a total of 150 hours. We invite comment on the estimated burden associated with requests for waivers from the proposed requirements.

Finally, proposed § 1.1465 provides for FDA publication of proposed updates to the Food Traceability List in the **Federal Register**, which would include the opportunity for public comment on proposed changes. Because we believe that, on an annualized basis, the burden associated with submitting comments on a proposed change to the Food Traceability List would be negligible, we provide a minimal estimate of one response requiring 1 burden hour annually, as reflected in table 10, row 3. We invite comment on the estimated burden associated with requesting views on a proposed updated Food Traceability List.

TABLE 11—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Proposed 21 CFR recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
§ 1.1305; partial exemption under: (e)(2)—commingled RACs; (h)(2)—retail food establishments; (i)(2)—farms; (j)(2)—fishing vessels.	1	1	1	1	1
§ 1.1315; traceability program general records (recurring).	130,063	1,000	130,063,000	0.004 (15 seconds)	520,252
§ 1.1325; grower (non-sprout growers)	9,408	1,000	9,408,000	0.03 (2 minutes)	282,240
§ 1.1325; grower (sprout growers)	51	1,000	51,000	0.07 (4 minutes)	3,570
§ 1.1330; first receiver	12,700	1,000	12,700,000	0.03 (2 minutes)	381,000
§ 1.1335; receiver	265,610	1,000	265,610,000	0.004 (15 seconds)	1,062,440
§ 1.1340; transformer	5,244	1,000	5,244,000	0.03 (2 minutes)	157,320
§ 1.1345; creator	222	1,000	222,000	0.03 (2 minutes)	6,660

TABLE 11—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

Proposed 21 CFR recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
§ 1.1350; shipper (wholesalers/warehouses/distribution centers; includes disclosure requirement).	12,657	48,333	611,750,781	0.008 (30 seconds)	4,894,006
§ 1.1350; shipper (other shippers; includes disclosure requirement).	16,936	1,000	16,936,000	0.06 (3.5 minutes)	1,016,160
Total	8,323,649

Proposed § 1.1305 provides for certain exemptions and partial exemptions from the proposed subpart S requirements. For the proposed partial exemptions for farm to school programs and for retail food establishments with respect to food produced on a farm and sold directly to the retail food establishment, we conclude that any burden under the proposed rule would be negligible because most retail food establishments and farms already keep the records they would be required to keep under the partial exemptions (*i.e.*, the name and address of the farm that was the source of the food) as part of their standard business practices. For these reasons, we therefore provide a minimum estimate of one respondent requiring 1 hour to establish one record, resulting in an estimated burden of 1 hour. We invite comment on the estimated burden associated with these partial exemptions in proposed § 1.1305.

The requirements in §§ 1.1315 through 1.1350 would identify respondents who are subject to the respective recordkeeping provisions, including with respect to general traceability program records and records documenting the critical tracking events of growing, receiving (including by first receivers), transforming, creating, and shipping foods on the Food Traceability List. The requirements specify when certain records should be established

and the key data elements that must be documented.

In table 11, we provide recordkeeping burden estimates associated with these recordkeeping requirements. The number of respondents, number of records, and time per recordkeeping activity is consistent with figures included in our PRIA for the proposed rule (Ref. 26). Although we note that shippers of listed foods must also disclose required records in accordance with proposed § 1.1350(b), we have included this burden as part of our recordkeeping estimate for this provision. This is because we believe that this disclosure burden would be minimal since, with the exception of certain information that farms must disclose (addressed in table 12 below), respondents must establish and maintain such information under the proposed rule. We invite comment on the estimated burden associated with both recordkeeping and disclosure provisions in §§ 1.1315 and 1.1325 through 1.1350 of the proposed rule.

Proposed § 1.1355 would exempt listed foods to which a kill step has been applied from all subsequent requirements of the proposed rule, provided that a record of application of the kill step is maintained. Because firms that apply a kill step to a food are required to document this activity under other FDA regulations (*e.g.*, 21 CFR 113.100, 21 CFR 117.190(a)(2)), the proposed requirement to maintain a

record of application of a kill step to listed foods would not create an additional recordkeeping burden for such firms under the proposed rule.

Proposed § 1.1455 discusses the maintenance and accessibility of records. Under proposed § 1.1455(b)(3), when necessary to help FDA prevent or mitigate a foodborne illness outbreak, assist in the implementation of a recall, or otherwise address a threat to the public health, respondents may be asked to make available within 24 hours of request by an authorized FDA representative an electronic sortable spreadsheet containing the information they are required to maintain under subpart S, for the foods and date ranges specified in the request. We anticipate that most firms will never be the subject of such a request, because the proposed provision only applies to situations where there is a threat to the public health. Furthermore, we believe that such spreadsheets can be created using software that is readily available and that is commonly used for other general business purposes. In situations where the firm does not maintain records electronically, the information for the specific foods and date ranges could be input manually into such software. We therefore estimate any additional burden posed by proposed § 1.1455(b)(3) would be negligible. We invite comment on this estimated burden.

TABLE 12—ESTIMATED ANNUAL DISCLOSURE BURDEN

Proposed disclosure activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
§ 1.1350(b)(2); farms	9,459	1,000	9,459,000	0.004	37,836
Total

In addition to the disclosures that entities other than farms must make under proposed § 1.1350(b), farms would incur additional burden

attributable to requirements to disclose information (if applicable) about the origination, harvesting, cooling, and packing of the food the farm shipped. In

table 12 we estimate that 9,459 farms will need to make 1,000 such disclosures, resulting in a total disclosure burden of 37,836 hours. We

invite comment on this estimated disclosure burden for farms under proposed § 1.1350(b)(2).

To ensure that comments on information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain> (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. We will announce OMB approval of the information collection requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. We invite comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through

Friday; they are also available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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21. * FDA, "A New Era of Smarter Food Safety; Public Meeting; Request for Comments," Docket No. 2019–N–4187, September 18, 2019 (<https://www.federalregister.gov/documents/>

2019/09/18/2019-20229/a-new-era-of-smarter-food-safety-public-meeting-request-for-comments).

22. * FDA Memorandum, "Inclusion of Retail Establishments of All Sizes Under FSMA Section 204," August 13, 2020.
23. National Advisory Committee on Microbiological Criteria for Foods, "Microbiological Safety Evaluations and Recommendations on Sprouted Seeds," *International Journal of Food Microbiology* 52(3): 123–153 (1999).
24. * FDA Memorandum, "2012–2020 Sprout-Related Outbreak Data," July 20, 2020.
25. * FDA, "Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Guidance for Industry" (Draft Guidance), June 2019 (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-reducing-microbial-food-safety-hazards-production-seed-sprouting>).
26. * FDA, "Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis," Docket No. FDA–2014–N–0053, September 2020.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

- 1. The authority citation for part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393, and 2223; 42 U.S.C. 216, 241, 243, 262, 264, 271.

- 2. Add subpart S, consisting of §§ 1.1300 through 1.1465, to read as follows:

Subpart S—Additional Traceability Records for Certain Foods

Sec.

General Provisions

- 1.1300 Who is subject to this subpart?
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Traceability Program Records

- 1.1315 What traceability program records must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold?

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1.1380 What process applies to a petition requesting modified requirements or an exemption?
1.1385 What process will FDA follow when adopting modified requirements or granting an exemption on our own initiative?
1.1390 When will modified requirements that we adopt or an exemption that we grant become effective?
1.1395 Under what circumstances may FDA revise or revoke modified requirements or an exemption?
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Waivers

- 1.1405 Under what circumstances will FDA waive one or more of the requirements of this subpart for an individual entity or a type of entity?
1.1410 When will FDA consider whether to waive a requirement of this subpart?
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- 1.1420 What process applies to a request for a waiver for an individual entity?
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1.1430 What information submitted in a petition requesting a waiver for a type of entity, or information in comments on such a petition, is publicly available?
1.1435 What process applies to a petition requesting a waiver for a type of entity?
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1.1445 Under what circumstances may FDA modify or revoke a waiver?
1.1450 What procedures apply if FDA tentatively determines that a waiver should be modified or revoked?

Records Maintenance and Availability

- 1.1455 How must records required by this subpart be maintained?

Consequences of Failure To Comply

- 1.1460 What consequences could result from failing to comply with the requirements of this subpart?

Updating the Food Traceability List

- 1.1465 How will FDA update the Food Traceability List?

Subpart S—Additional Traceability Records for Certain Foods

General Provisions

§ 1.1300 Who is subject to this subpart?

Except as specified otherwise in this subpart, the requirements in this subpart apply to persons who manufacture, process, pack, or hold foods that appear on the list of foods for which additional traceability records are required in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act (Food Traceability List). FDA will publish the Food Traceability List on its website in accordance with section 204(d)(2)(B) of the FDA Food Safety Modernization Act.

§ 1.1305 What foods and persons are exempt from this subpart?

(a) *Exemptions for small originators—*
(1) *Certain produce farms.* This subpart does not apply to farms or the farm activities of farm mixed-type facilities with respect to the produce (as defined in § 112.3 of this chapter) they grow, when the farm is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter.

(2) *Certain shell egg producers.* This subpart does not apply to 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.

(3) *Certain other originators of food.* This subpart does not apply to

originators of food with an average annual monetary value of food sold during the previous 3-year period of no more than \$25,000 (on a rolling basis), adjusted for inflation using 2019 as the baseline year for calculating the adjustment.

(b) *Exemption for farms when food is sold directly to consumers.* This subpart does not apply to a farm with respect to food produced on the farm (including food that is also packaged on the farm) that is sold directly to a consumer by the owner, operator, or agent in charge of the farm.

(c) *Inapplicability to certain food produced and packaged on a farm.* This subpart does not apply to food produced and packaged on a farm, provided that:

(1) The packaging of the food remains in place until the food reaches the consumer, and such packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and

(2) The labeling of the food that reaches the consumer includes the name, complete address (street address, town, State, country, and zip or other postal code for a domestic farm and comparable information for a foreign farm), and business phone number of the farm on which the food was produced and packaged. Upon request, FDA will waive the requirement to include a business phone number, as appropriate, to accommodate a religious belief of the individual in charge of the farm.

(d) *Inapplicability to foods that receive certain types of processing.* This subpart does not apply to the following foods that receive certain processing:

(1) Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions set forth in § 112.2(b) of this chapter are met for the produce; and

(2) Shell eggs when all eggs produced at the particular farm receive a treatment (as defined in § 118.3 of this chapter) in accordance with § 118.1(a)(2) of this chapter.

(e) *Exemption for produce that is rarely consumed raw.* This subpart does not apply to produce that is listed as rarely consumed raw in § 112.2(a)(1) of this chapter.

(f) *Partial exemption of commingled raw agricultural commodities.* (1) Except as specified in paragraph (f)(2) of this section, this subpart does not apply to commingled raw agricultural commodities. For the purpose of this subpart, a “commingled raw agricultural commodity” means any commodity that is combined or mixed after harvesting but before processing, except that the

term “commingled raw agricultural commodity” does not include types of fruits and vegetables that are raw agricultural commodities to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in part 112 of this chapter apply. For purposes of this paragraph (f)(1), a commodity is “combined or mixed” only when the combination or mixing involves food from different farms. Also, for purposes of this paragraph (f)(1), the term “processing” means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

(2) With respect to a commingled raw agricultural commodity that receives the exemption set forth in paragraph (f)(1) of this section, if a person who manufactures, processes, packs, or holds such commingled raw agricultural commodity is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable raw agricultural commodity, in accordance with the requirements of subpart H of this part, such person must maintain records identifying the immediate previous source of such raw agricultural commodity and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.

Option 1 for Paragraph (g)

(g) *Exemption for small retail food establishments.* This subpart does not apply to retail food establishments that employ 10 or fewer full-time equivalent employees. The number of full-time equivalent employees is based on the number of such employees at each retail food establishment and not the entire business, which may own numerous retail stores.

Option 2 for Paragraph (g)

(g) *Partial exemption for small retail food establishments.* The requirement in § 1.1455(b)(3) to make available to FDA under specified circumstances an electronic sortable spreadsheet containing the information required to be maintained under this subpart (for the foods and date ranges specified in FDA’s request) does not apply to retail food establishments that employ 10 or fewer full-time equivalent employees. The number of full-time equivalent employees is based on the number of such employees at each retail food establishment and not the entire

business, which may own numerous retail stores.

(h) *Partial exemption for retail food establishments.* (1) Except as specified in paragraph (h)(2) of this section, the recordkeeping requirements of this subpart do not apply to a retail food establishment with respect to a food that is produced on a farm (including food produced and packaged on the farm) and sold directly to the retail food establishment by the owner, operator, or agent in charge of that farm.

(2) When a retail food establishment purchases a food on the Food Traceability List directly from a farm in accordance with paragraph (h)(1) of this section, the retail food establishment must establish and maintain a record documenting the name and address of the farm that was the source of the food. The retail food establishment must maintain such records for 180 days.

(i) *Partial exemption for farm to school and farm to institution programs.*

(1) Except as specified in paragraph (i)(2) of this section, this subpart does not apply to an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966, or any other entity conducting a farm to school or farm to institution program, with respect to a food that is produced on a farm (including food produced and packaged on the farm) and sold directly to the school or institution.

(2) When a school or institution conducting farm to school or farm to institution activities purchases a food directly from a farm in accordance with paragraph (i)(1) of this section, the school food authority or relevant food procurement entity must establish and maintain a record documenting the name and address of the farm that was the source of the food. The school food authority or relevant food procurement entity must maintain such records for 180 days.

(j) *Partial exemption for food produced through the use of fishing vessels.* (1) Except as specified in paragraph (j)(2) of this section, with respect to a food that is produced through the use of a fishing vessel, this subpart does not apply to the owner, operator, or agent in charge of the fishing vessel.

(2) With respect to the owner, operator, or agent in charge of the fishing vessel who receives the partial exemption set forth in paragraph (j)(1) of this section, if such person is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the

applicable food, in accordance with the requirements of subpart H of this part, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.

(k) *Exemption for transporters.* This subpart does not apply to transporters of food.

(l) *Exemption for nonprofit food establishments.* This subpart does not apply to nonprofit food establishments.

(m) *Exemption for persons who manufacture, process, pack, or hold food for personal consumption.* This subpart does not apply to persons who manufacture, process, pack, or hold food for personal consumption.

(n) *Exemption for certain persons who hold food on behalf of individual consumers.* This subpart does not apply to persons who hold food on behalf of specific individual consumers, provided that these persons:

- (1) Are not parties to the transaction involving the food they hold; and
- (2) Are not in the business of distributing food.

§ 1.1310 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart. In addition, the following definitions apply to words and phrases as they are used in this subpart:

Category means a code or term used to classify a food product in accordance with a recognized industry or regulatory classification scheme, or a classification scheme a person develops for their own use.

Cooling means active temperature reduction of a food using hydrocooling, icing, forced air cooling, vacuum cooling, or a similar process, either before or after packing.

Creating means making or producing a food on the Food Traceability List (e.g., through manufacturing or processing) using only ingredient(s) that are not on the Food Traceability List. Creating does not include originating or transforming a food.

Critical tracking event means an event in the supply chain of a food involving the growing, receiving (including receipt by a first receiver), transforming, creating, or shipping of the food.

Farm means farm as defined in § 1.328. For producers of shell eggs, “farm” means all poultry houses and grounds immediately surrounding the poultry houses covered under a single

biosecurity program, as set forth in § 118.3 of this chapter.

First receiver means the first person (other than a farm) who purchases and takes physical possession of a food on the Food Traceability List that has been grown, raised, caught, or (in the case of a non-produce commodity) harvested.

Fishing vessel means any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing.

Food Traceability List means the list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act. The term “Food Traceability List” includes both the foods specifically listed and foods that contain specifically listed foods as ingredients.

Growing area coordinates means 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.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots, or stems). Examples of harvesting also include collecting eggs, taking of fish and other seafood in aquaculture operations, milking, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes activities performed

incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets) but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Key data element means information associated with a critical tracking event for which a record must be established and maintained in accordance with this subpart.

Kill step means processing that significantly minimizes pathogens in a food.

Location description means a complete physical address and other key contact information, specifically the business name, physical location name, primary phone number, physical location street address (or geographical coordinates), city, state, and zip code for domestic facilities and comparable information for foreign facilities, including country; except that for fishing vessels, *location description* means the name of the fishing vessel that caught the seafood, the country in which the fishing vessel’s license (if any) was issued, and a point of contact for the fishing vessel.

Location identifier means a unique identification code that an entity assigns to the physical location name identified in the corresponding location description; except that for fishing vessels, *location identifier* means the vessel identification number or license number (both if available) for the fishing vessel.

Lot means the food produced during a period of time at a single physical location and identified by a specific code. A lot may also be referred to as a *batch* or *production run*.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw

agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, viscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes 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 (26 U.S.C. 501(c)(3)).

Originating means an event in a food’s supply chain involving the growing, raising, or catching of a food (typically on a farm, a ranch, or at sea), or the harvesting of a non-produce commodity.

Originator means a person who grows, raises, or catches a food, or harvests a non-produce commodity.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Person includes an individual, partnership, corporation, and association.

Physical location name means the word(s) used to identify the specific physical site of a business entity where a particular critical tracking event occurs. A physical location name might be the same as an entity’s business name if the entity has only one physical location.

Point of contact means an individual having familiarity with an entity’s procedures for traceability, including their name, telephone number, and, if available, their email address and fax number.

Produce means produce as defined in § 112.3 of this chapter.

Receiving means 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.

Reference record means a record used to identify an event in the supply chain of a food, such as a shipping, receiving, growing, creating, or transformation event. Types of reference records include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, batch logs, production logs, and receipts.

Reference record number means the identification number assigned to a reference record, such as a purchase order number, bill of lading number, or work order number.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term “retail food establishment” includes facilities that manufacture, process, pack, or hold food if the establishment’s primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment’s primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “consumers” does not include businesses. A “retail food establishment” includes grocery stores, convenience stores, and vending machine locations. A “retail food establishment” also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or

thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers’ market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer’s crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers’ markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(2) Sale of food directly to consumers by a farm-oriented business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers’ market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer’s crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers’ markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(3) For the purposes of this definition, “farm-operated business” means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

Shipping means 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. Shipping does not include the sale or shipment of a food directly to a

consumer or the donation of surplus food.

Traceability lot means a lot of food that has been originated, transformed, or created.

Traceability lot code means a descriptor, often alphanumeric, used to identify a traceability lot.

Traceability lot code generator means the person who assigns a traceability lot code to a product.

Traceability product description means a description of a food product typically used commercially for purchasing, stocking, or selling, and includes the category code or term, category name, and trade description. For single-ingredient products, the trade description includes the brand name, commodity, variety, packaging size, and packaging style. For multiple-ingredient food products, the trade description includes the brand name, product name, packaging size, and packaging style.

Traceability product identifier means a unique identification code (such as an alphanumeric code) that an entity assigns to designate a specific type of food product.

Transformation means an event in a food's supply chain that involves changing a food on the Food Traceability List, 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). Transformation does not include the initial packing of a single-ingredient food or creating a food.

Transporter means a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air.

Vessel identification number means the number assigned to a fishing vessel by the International Maritime Organization, or by any entity or organization, for the purpose of uniquely identifying the vessel.

You means a person subject to this subpart under § 1.1300.

Traceability Program Records

§ 1.1315 What traceability program records must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold?

(a) If you are subject to the requirements in this subpart, you must establish and maintain records containing the following information:

(1) A description of the reference records in which you maintain the information required under this subpart, an explanation of where on the records the required information appears, and, if

applicable, a description of how reference records for different tracing events for a food (e.g., receipt, transformation, shipment) are linked;

(2) A list of foods on the Food Traceability List that you ship, including the traceability product identifier and traceability product description for each food;

(3) A description of how you establish and assign traceability lot codes to foods on the Food Traceability List you originate, transform, or create, if applicable; and

(4) Any other information needed to understand the data provided within any records required by this subpart, such as internal or external coding systems, glossaries, and abbreviations.

(b) You must retain the records required under paragraph (a) of this section for 2 years after their use is discontinued (e.g., because you change the records in which you maintain required information, you update the list of foods on the Food Traceability List that you ship, or you change your procedures for establishing and assigning traceability lot codes).

§ 1.1320 When must I establish and assign traceability lot codes to foods on the Food Traceability List?

(a) You must establish and assign a traceability lot code when you originate, transform, or create a food on the Food Traceability List.

(b) Except as specified otherwise in this subpart, you may not establish a new traceability lot code when you conduct other activities (e.g., shipping, receiving) in the supply chain for a food on the Food Traceability List.

Records of Growing, Receiving, Transforming, Creating, and Shipping Food

§ 1.1325 What records must I keep when I grow a food on the Food Traceability List?

For each food on the Food Traceability List that you grow, you must establish and maintain records containing and linking the traceability lot code of the food to the following information:

(a) The growing area coordinates; and
(b) For growers of sprouts, the following information (if applicable):

(1) The location identifier and location description of the grower of seeds for sprouting, the associated seed lot code assigned by the seed grower, and the date of seed harvesting;

(2) The location identifier and location description of the seed conditioner or processor, the associated seed lot code assigned by the seed conditioner or processor, and the date of conditioning or processing;

(3) The location identifier and location description of the seed packinghouse (including any repackers, if applicable), the associated seed lot code assigned by the seed packinghouse, and the date of packing (and of repacking, if applicable);

(4) The location identifier and location description of the seed supplier;

(5) A description of the seeds, including the seed type or taxonomic name, growing specifications, volume, type of packaging, and antimicrobial treatment;

(6) The seed lot code assigned by the seed supplier, including the master lot and sub-lot codes, and any new seed lot code assigned by the sprouter;

(7) The date of receipt of the seeds by the sprouter; and

(8) For each lot code for seeds received by the sprouter, the sprout traceability lot code(s) and the date(s) of production associated with that seed lot code.

§ 1.1330 What records must I keep when I am the first receiver of a food on the Food Traceability List?

(a) Except as specified in paragraph (b) of this section, in addition to the records of receipt of foods required under § 1.1335, the first receiver of a food on the Food Traceability List must establish and maintain records containing and linking the traceability lot code of the food received to the following information:

(1) The location identifier and location description of the originator of the food;

(2) The business name, point of contact, and phone number of the harvester of the food, and the date(s) and time(s) of harvesting;

(3) The location identifier and location description of the place where the food was cooled, and the date and time of cooling (if applicable); and

(4) The location identifier and location description of the place where the food was packed, and the date and time of packing.

(b) If you are the first receiver of a seafood product on the Food Traceability List that was obtained from a fishing vessel, in addition to the records of receipt of foods required under § 1.1335, you must establish and maintain records containing and linking the traceability lot code of the seafood product received to the harvest date range and locations (National Marine Fisheries Service Ocean Geographic Code or geographical coordinates) for the trip during which the seafood was caught.

(c) If you are the first receiver of a food on the Food Traceability List to

which the originator of the food has not assigned a traceability lot code, you must establish a traceability lot code for the food and maintain a record of the traceability lot code linked to the information specified in paragraph (a) or (b) of this section (as applicable to the type of food received).

§ 1.1335 What records must I keep when I receive a food on the Food Traceability List?

For each food on the Food Traceability List you receive, you must establish and maintain records containing and linking the traceability lot code of the food to the following information:

- (a) The location identifier and location description for the immediate previous source (other than a transporter) of the food;
- (b) The entry number(s) assigned to the food (if the food is imported);
- (c) The location identifier and location description of where the food was received, and date and time you received the food;
- (d) The quantity and unit of measure of the food (*e.g.*, 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds);
- (e) The traceability product identifier and traceability product description for the food;
- (f) The location identifier, location description, and point of contact for the traceability lot code generator;
- (g) The reference record type(s) and reference record number(s) (*e.g.*, “Invoice 750A,” “BOL 042520 XYZ”) for the document(s) containing the information specified in paragraphs (a) through (f) of this section; and
- (h) The name of the transporter who transported the food to you.

§ 1.1340 What records must I keep when I transform a food on the Food Traceability List?

(a) Except as specified in paragraph (b) of this section, for each new traceability lot of food produced through transformation you must establish and maintain records containing and linking the new traceability lot code of the food produced through transformation to the following information:

- (1) For the food(s) on the Food Traceability List used in transformation, the following information:
 - (i) The traceability lot code(s) for the food;
 - (ii) The traceability product identifier and traceability product description for the food to which the traceability lot code applies; and
 - (iii) The quantity of each traceability lot of the food.

(2) For the food produced through transformation, the following information:

- (i) The location identifier and location description for where you transformed the food (*e.g.*, by a manufacturing/processing step), and the date transformation was completed;
 - (ii) The new traceability product identifier and traceability product description for the food to which the new traceability lot code applies; and
 - (iii) The quantity and unit of measure of the food for each new traceability lot code (*e.g.*, 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds).
- (3) The reference record type(s) and reference record number(s) (*e.g.*, “Production Log 123,” “Batch Log 01202021”) for the document(s) containing the information specified in paragraphs (a)(1) and (2) of this section.
- (b) Paragraph (a) of this section does not apply to retail food establishments with respect to foods they do not ship (*e.g.*, foods they sell or send directly to consumers).

§ 1.1345 What records must I keep when I create a food on the Food Traceability List?

- (a) Except as specified in paragraph (b) of this section, for each food on the Food Traceability List you create, you must establish and maintain records containing and linking the traceability lot code of the food created to the following information:
 - (1) The location identifier and location description for where you created the food (*e.g.*, by a manufacturing/processing step), and the date creation was completed;
 - (2) The traceability product identifier and traceability product description for the food;
 - (3) The quantity and unit of measure of the food (*e.g.*, 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds); and
 - (4) The reference record type(s) and reference record number(s) (*e.g.*, “Production Log 123,” “Batch Log 01202021”) for the document(s) containing the information specified in paragraphs (a)(1) through (3) of this section.
- (b) Paragraph (a) of this section does not apply to retail food establishments with respect to foods they do not ship (*e.g.*, foods they sell or send directly to consumers).

§ 1.1350 What records must I keep and send when I ship a food on the Food Traceability List?

- (a) For each food on the Food Traceability List you ship, you must establish and maintain records containing and linking the traceability

lot code of the food to the following information:

- (1) The entry number(s) assigned to the food (if the food is imported);
 - (2) The quantity and unit of measure of the food (*e.g.*, 6 cases, 25 returnable plastic containers, 100 tanks, 200 pounds);
 - (3) The traceability product identifier and traceability product description for the food;
 - (4) The location identifier, location description, and point of contact for the traceability lot code generator;
 - (5) The location identifier and location description for the immediate subsequent recipient (other than a transporter) of the food;
 - (6) The location identifier and location description for the location from which you shipped the food, and date and time you shipped the food;
 - (7) The reference record type(s) and reference record number(s) (*e.g.*, “BOL No. 123,” “ASN 10212025”) for the document(s) containing the information specified in paragraphs (a)(1) through (a)(6) of this section; and
 - (8) The name of the transporter who transported the food from you.
- (b) You must send records (in electronic or other written form) containing the following information to the immediate subsequent recipient (other than a transporter) of each traceability lot that you ship:
- (1) The information in paragraphs (a)(1) through (6) of this section; and
 - (2) If you are a farm, the following information (if applicable) for each traceability lot of the food:
 - (i) A statement that you are a farm;
 - (ii) The location identifier and location description of the originator of the food (if not you);
 - (iii) The business name, point of contact, and phone number of the harvester of the food (if not you), and the date(s) and time(s) of harvesting;
 - (iv) The location identifier and location description of the place where the food was cooled (if not by you), and the date and time of cooling; and
 - (v) The location identifier and location description of the place where the food was packed (if not by you), and the date and time of packing.

Special Requirements for Certain Persons and Foods

§ 1.1355 What recordkeeping requirements apply to foods on the Food Traceability List that are subjected to a kill step?

- (a) If you apply a kill step to a food on the Food Traceability List, the requirements of this subpart do not apply to your subsequent shipping of the food, provided that you maintain a

record of your application of the kill step.

(b) If you receive a food on the Food Traceability List that has been subjected to a kill step, the requirements of this subpart do not apply to your receipt or subsequent transformation and/or shipping of the food.

Procedures for Modified Requirements and Exemptions

§ 1.1360 Under what circumstances will FDA modify the requirements in this subpart that apply to a food or type of entity or exempt a food or type of entity from the requirements of this subpart?

(a) *General.* Except as specified in paragraph (b) of this section, FDA will modify the requirements of this subpart applicable to a food or type of entity, or exempt a food or type of entity from the requirements of this subpart, when we determine that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health.

(b) *Registered facilities.* If a person to whom modified requirements or an exemption applies under paragraph (a) of this section (including a person who manufactures, processes, packs, or holds a food to which modified requirements or an exemption applies under paragraph (a) of this section) is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (and in accordance with the requirements of subpart H of this part) with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.

§ 1.1365 When will FDA consider whether to adopt modified requirements or grant an exemption from the requirements of this subpart?

FDA will consider modifying the requirements of this subpart applicable to a food or type of entity, or exempting a food or type of entity from the requirements of this subpart, on our own initiative or in response to a citizen petition submitted under § 10.30 of this chapter by any interested party.

§ 1.1370 What must be included in a petition requesting modified requirements or an exemption from the requirements?

In addition to meeting the requirements on the content and format of a citizen petition in § 10.30 of this chapter, a petition requesting modified requirements or an exemption from the requirements of this subpart must:

(a) Specify the food or type of entity to which the modified requirements or exemption would apply;

(b) If the petition requests modified requirements, specify the proposed modifications to the requirements of this subpart; and

(c) Present information demonstrating why application of the requirements requested to be modified or from which exemption is requested is not necessary to protect the public health.

§ 1.1375 What information submitted in a petition requesting modified requirements or an exemption, or information in comments on such a petition, is publicly available?

FDA will presume that information submitted in a petition requesting modified requirements or an exemption, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with the petition.

§ 1.1380 What process applies to a petition requesting modified requirements or an exemption?

(a) In general, the procedures set forth in § 10.30 of this chapter govern FDA's response to a petition requesting modified requirements or an exemption. An interested person may submit comments on such a petition in accordance with § 10.30(d) of this chapter.

(b) Under § 10.30(h)(3) of this chapter, FDA will publish a notification in the **Federal Register** requesting information and views on a submitted petition, including information and views from persons who could be affected by the modified requirements or exemption if we granted the petition.

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing, as follows:

(1) If we grant the petition either in whole or in part, we will publish a notification in the **Federal Register** setting forth any modified requirements or exemptions and the reasons for them.

(2) If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of petitions requesting modified requirements or exemptions, including the status of each petition (for example, pending, granted, or denied).

§ 1.1385 What process will FDA follow when adopting modified requirements or granting an exemption on our own initiative?

(a) If FDA, on our own initiative, determines that adopting modified requirements or granting an exemption from the requirements for a food or type of entity is appropriate, we will publish a notification in the **Federal Register** setting forth the proposed modified requirements or exemption and the reasons for the proposal. The notification will establish a public docket so that interested persons may submit written comments on the proposal.

(b) After considering any comments timely submitted, we will publish a notification in the **Federal Register** stating whether we are adopting modified requirements or granting an exemption, and the reasons for our decision.

§ 1.1390 When will modified requirements that we adopt or an exemption that we grant become effective?

Any modified requirements that FDA adopts or exemption that we grant will become effective on the date that notice of the modified requirements or exemption is published in the **Federal Register**, unless otherwise stated in the notification.

§ 1.1395 Under what circumstances may FDA revise or revoke modified requirements or an exemption?

FDA may revise or revoke modified requirements or an exemption if we determine that such revision or revocation is necessary to protect the public health.

§ 1.1400 What procedures apply if FDA tentatively determines that modified requirements or an exemption should be revised or revoked?

(a) If FDA tentatively determines that we should revise or revoke modified requirements or an exemption, we will provide the following notifications:

(1) We will notify the person that originally requested the modified requirements or exemption (if we adopted modified requirements or granted an exemption in response to a petition) in writing at the address identified in the petition; and

(2) We will publish notification in the **Federal Register** of our tentative determination that the modified requirements or exemption should be revised or revoked and the reasons for our tentative decision. The notification will establish a public docket so that interested persons may submit written comments on our tentative determination.

(b) After considering any comments timely submitted, we will publish notification in the **Federal Register** of our decision whether to revise or revoke the modified requirements or exemption and the reasons for the decision. If we do revise or revoke the modified requirements or exemption, the effective date of the decision will be 1 year after the date of publication of the notification, unless otherwise stated in the notification.

Waivers

§ 1.1405 Under what circumstances will FDA waive one or more of the requirements of this subpart for an individual entity or a type of entity?

FDA will waive one or more of the requirements of this subpart when we determine that:

(a) Application of the requirements would result in an economic hardship for an individual entity or a type of entity, due to the unique circumstances of the individual entity or type of entity;

(b) The waiver will not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and

(c) The waiver will not otherwise be contrary to the public interest.

§ 1.1410 When will FDA consider whether to waive a requirement of this subpart?

FDA will consider whether to waive a requirement of this subpart on our own initiative or in response to the following:

(a) A written request for a waiver for an individual entity; or

(b) A citizen petition requesting a waiver for a type of entity submitted under § 10.30 of this chapter by any person subject to the requirements of this subpart.

§ 1.1415 How may I request a waiver for an individual entity?

You may request a waiver of one or more requirements of this subpart for an individual entity by submitting a written request to the Food and Drug Administration. The request for a waiver must include the following:

(a) The name, address, and point of contact of the individual entity to which the waiver would apply;

(b) The requirements of this subpart to which the waiver would apply;

(c) Information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the entity, including information about the unique circumstances faced by the entity that result in unusual economic hardship from the application of these requirements;

(d) Information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and

(e) Information demonstrating why the waiver would not otherwise be contrary to the public interest.

§ 1.1420 What process applies to a request for a waiver for an individual entity?

(a) After considering the information submitted in a request for a waiver for an individual entity, we will respond in writing to the person that submitted the waiver request stating whether we are granting the waiver (in whole or in part) and the reasons for the decision.

(b) Any waiver for an individual entity that FDA grants will become effective on the date we issue our response to the waiver request, unless otherwise stated in the response.

§ 1.1425 What must be included in a petition requesting a waiver for a type of entity?

In addition to meeting the requirements on the content and format of a citizen petition in § 10.30 of this chapter, a petition requesting a waiver for a type of entity must:

(a) Specify the type of entity to which the waiver would apply and the requirements of this subpart to which the waiver would apply;

(b) Present information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the type of entity, including information about the unique circumstances faced by the type of entity that result in unusual economic hardship from the application of these requirements;

(c) Present information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health

consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and

(d) Present information demonstrating why the waiver would not otherwise be contrary to the public interest.

§ 1.1430 What information submitted in a petition requesting a waiver for a type of entity, or information in comments on such a petition, is publicly available?

FDA will presume that information submitted in a petition requesting a waiver for a type of entity, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with the petition.

§ 1.1435 What process applies to a petition requesting a waiver for a type of entity?

(a) In general, the procedures set forth in § 10.30 of this chapter govern FDA's response to a petition requesting a waiver. An interested person may submit comments on such a petition in accordance with § 10.30(d) of this chapter.

(b) Under § 10.30(h)(3) of this chapter, FDA will publish a notification in the **Federal Register** requesting information and views on a submitted petition requesting a waiver for a type of entity, including information and views from persons who could be affected by the waiver if we granted the petition.

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing, as follows:

(1) If we grant the petition either in whole or in part, we will publish a notification in the **Federal Register** setting forth any requirements we have waived and the reasons for the waiver.

(2) If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of petitions requesting waivers for types of entities, including the status of each petition (for example, pending, granted, or denied).

§ 1.1440 What process will FDA follow when waiving a requirement of this subpart on our own initiative?

(a) If FDA, on our own initiative, determines that a waiver of one or more requirements for an individual entity or type of entity is appropriate, we will publish a notification in the **Federal Register** setting forth the proposed

waiver and the reasons for such waiver. The notification will establish a public docket so that interested persons may submit written comments on the proposal.

(b) After considering any comments timely submitted, we will publish a document in the **Federal Register** stating whether we are granting the waiver (in whole or in part) and the reasons for our decision.

(c) Any waiver for a type of entity that FDA grants will become effective on the date that notice of the waiver is published in the **Federal Register**, unless otherwise stated in the notification.

§ 1.1445 Under what circumstances may FDA modify or revoke a waiver?

FDA may modify or revoke a waiver if we determine that:

(a) Compliance with the waived requirements would no longer impose a unique economic hardship on the individual entity or type of entity to which the waiver applies;

(b) The waiver could significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; or

(c) The waiver is otherwise contrary to the public interest.

§ 1.1450 What procedures apply if FDA tentatively determines that a waiver should be modified or revoked?

(a) *Waiver for an individual entity.* (1) If FDA tentatively determines that we should modify or revoke a waiver for an individual entity, we will notify the person that had received the waiver in writing of our tentative determination that the waiver should be modified or revoked. The notice will provide the waiver recipient 60 days in which to submit information stating why the waiver should not be modified or revoked.

(2) Upon consideration of any information submitted by the waiver recipient, we will respond in writing stating our decision whether to modify or revoke the waiver and the reasons for the decision. If we modify or revoke the waiver, the effective date of the decision will be 1 year after the date of our response to the waiver recipient, unless otherwise stated in the response.

(b) *Waiver for a type of entity.* (1) If FDA tentatively determines that we

should modify or revoke a waiver for a type of entity, we will provide the following notifications:

(i) We will notify the person that originally requested the waiver (if we granted the waiver in response to a petition) in writing at the address identified in the petition.

(ii) We will publish notification in the **Federal Register** of our tentative determination that the waiver should be modified or revoked and the reasons for our tentative decision. The notification will establish a public docket so that interested persons may submit written comments on our tentative determination.

(2) After considering any comments timely submitted, we will publish notification in the **Federal Register** of our decision whether to modify or revoke the waiver and the reasons for the decision. If we do modify or revoke the waiver, the effective date of the decision will be 1 year after the date of publication of the notification, unless otherwise stated in the notification.

Records Maintenance and Availability

§ 1.1455 How must records required by this subpart be maintained?

(a) *General requirements for records.*

(1) You must keep records as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records).

(2) All records must be legible and stored to prevent deterioration or loss.

(b) *Record availability.* (1) You must make all records required under this subpart available to an authorized FDA representative as soon as possible but not later than 24 hours after the request.

(2) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(3) When necessary to help FDA 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, including but not limited to situations where FDA has a reasonable belief that an article of food (and any other article of food that FDA reasonably believes is likely to be affected in a similar manner) presents a threat of serious adverse health consequences or death to humans or animals as a result of the food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of

the Federal Food, Drug, and Cosmetic Act, you must make available, within 24 hours of request by an authorized FDA representative, an electronic sortable spreadsheet containing the information in the records you are required to maintain under this subpart, for the foods and date ranges specified in the request. FDA will withdraw a request for such a spreadsheet when necessary to accommodate a religious belief of a person asked to provide such a spreadsheet.

(4) Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(c) *Record retention.* Except as specified otherwise in this subpart, you must maintain records containing the information required by this subpart for 2 years from the date you created the records.

(d) *Electronic records.* Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11, if not otherwise exempt.

(e) *Use of existing records.* You do not need to duplicate existing records you have (e.g., records that you keep in the ordinary course of business or that you maintain to comply with other Federal, State, Tribal, territorial, or local regulations) if they contain the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart. In addition, you do not have to keep all of the information required by this subpart in one set of records. However, you must indicate the different records in which you keep this information in accordance with § 1.1315(a).

Consequences of Failure To Comply

§ 1.1460 What consequences could result from failing to comply with the requirements of this subpart?

(a) *Prohibited act.* The violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act, including the violation of any requirement of this subpart, is prohibited under section 301(e) of the Federal Food, Drug, and Cosmetic Act, except when such violation is committed by a farm.

(b) *Refusal of admission.* An article of food is subject to refusal of admission

under section 801(a)(4) of the Federal Food, Drug, and Cosmetic Act if it appears that the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection (f) of that section), including the requirements of this subpart, have not been complied with regarding such article.

Updating the Food Traceability List

§ 1.1465 How will FDA update the Food Traceability List?

(a) When FDA tentatively concludes, in accordance with section 204(d)(2) of

the FDA Food Safety Modernization Act, that it is appropriate to revise the Food Traceability List, we will 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.

(b) After considering any information and views submitted on the proposed changes to the Food Traceability List, FDA will publish a notice in the **Federal Register** stating whether we are making any changes to the list and the reasons for the decision. If FDA revises the list,

we will also publish the revised list on our website.

(c) When FDA updates the Food Traceability List in accordance with this section, any deletions from the list will become effective immediately. Any additions to the list will become effective 1 year after the date of publication of the **Federal Register** notice announcing the revised list, unless otherwise stated in the notice.

Dated: September 8, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

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