DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Requirements for Additional Traceability Records for Certain Foods

Docket No. FDA-2014-N-0053

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

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.

B. Summary of Costs and Benefits

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.[1] 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

1 The list of applicable foods may be updated by publication of a notice in the Federal Register following consideration of comments on proposed changes. See Appendix A for the list as of this writing.

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.[2] 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 traceability records. Some firms may also incur initial capital investment and

[2] 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.

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 1a and 1b summarize the costs and the benefits of the proposed rule. Table 1a shows RIA section IV's 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 1b shows estimates from RIA sections II.F and II.H of the rule's cost under proposed Option 2 of the co-proposal, which would exempt retail food establishments with 10 or fewer fill-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.

In RIA sections IV.B and II.E.2, 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 FTL-associated illnesses.[3] However, adjustments made for undiagnosed and unattributed illnesses may have the opposite tendency of overstating both FTL-associated illnesses and benefits. We calculate these monetized benefits from illnesses 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 time 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.[4] Using examples from three recalls, RIA section II.E.3 presents estimates that additional (non-

3 We cannot scale up to 100% 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. In short, these four pathogens may account for roughly 95% of the total dollar value of the illnesses for which traceability might be an effective preventive measure.

4 These estimates reflect a wide uncertainty range because they were calculated using information from a small (possibly under-representative) number of outbreaks.

health) benefits of avoiding overly broad recalls could range from $1.7 billion to $5.6 billion per year at seven percent discount rate and from $1.7 billion to $5.8 billion using 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 this regulatory impact analysis, either separately or jointly. Therefore, Table 1a and Table 1b avoid a definitive statement that they should be summed.

Costs are lower in Option 1, relative to Option 2, because fewer retail food establishments (RFEs) would need to comply with the proposed rule. However, if RFEs 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 non-quantified benefits, such as enhancement of our ability to narrow the number of lots in a recall and the ability of RFEs 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 (Ref. [1]). Requiring recordkeeping by RFEs of all sizes allows for more consistent, organized, and specific information that covers the entire supply chain.

Table 1a. Summary of Benefits, Costs and Distributional Effects of Proposed Rule (Option 1, in Millions of Dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$567	$33	$1,355	2018	7%	10 years	Monetized benefits from an estimated 84% improvement 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).
		$580	$33	$1,385	2018	3%	10 years	

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Annualized Quantified							
	Qualitative	Additional potential 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. 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 RFEs 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.[5]						
Costs	Annualized Monetized $millions/year	$411	$34	$2,425	2018	7%	10 years	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.
		$400	$33	$2,352	2018	3%	10 years	
	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 some small entities that are currently not keeping traceability records described by the proposed rule. Wages: N/A Growth: N/A							

5 (Ref. [1]).

Table 1b. Summary of Benefits, Costs and Distributional Effects of Proposed Rule (Option 2, in Millions of Dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$626	$36	$1,497	2018	7%	10 years	Monetized benefits from an estimated 84% improvement 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).
		$640	$37	$1,531	2018	3%	10 years	
	Annualized Quantified							
	Qualitative	Additional potential 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	$43	$3,210	2018	7%	10 years	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.
		$513	$42	$3,063	2018	3%	10 years	
	Annualized Quantified							
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year							
	From/ To	From:			To:			

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	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 2a and 2b 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 2a. EO 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 2b. EO 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 3a and 3b explore the possibility that baseline costs of recalls are more fully internalized by market actors.

Column (a) of Tables 3a and 3b 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 3a and 3b 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 they 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 3a. Summary of Benefits and Costs of Proposed Rule (Option 1), As a Function of Assumptions Regarding Baseline Cost Internalization*

	(a)	(b)
	Neither adverse health effects nor recall-associated costs fully internalized in market transactions for FTL foods	Recall-associated costs, but not adverse health effects, fully internalized in market transactions for FTL foods
RIA Section IV.B	Health Benefits: $567M (range: $33M to $1.4B) ***and/or***	Health Benefits: $567M (range: $33M to $1.4B)

RIA Section II.E.3	Recall-Associated Benefits: $1.7B to $5.6B	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 Direct Compliance Costs (if foreign passed through to U.S. supply chain & consumers): $670M (range: $52M to $4B) Direct Compliance Costs (if foreign ***not*** passed through to U.S. supply chain & consumers): $411M (range: $34M to $2.4B) Protective Action Costs (potential): not quantified
RIA 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 ***not*** 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 3b. Summary of Benefits and Costs of Proposed Rule (Option 2), As a Function of Assumptions Regarding Baseline Cost Internalization*

	(a)	(b)
	Neither adverse health effects nor recall-associated costs fully internalized in market transactions for FTL foods	Recall-associated costs, but not adverse health effects, fully internalized in market transactions for FTL foods
RIA Section II.E.2	Health Benefits: $626M (range: $36M to $1.5B) ***and/or***	Health Benefits: $626M (range: $36M to $1.5B)

RIA Section II.E.3	Recall-Associated Benefits: $1.7B to $5.6B	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 Direct Compliance Costs (if foreign passed through to U.S. supply chain & consumers): $794M (range: $61M to $4.8B) Direct Compliance Costs (if foreign ***not*** passed through to U.S. supply chain & consumers): $535M (range: $43M to $3.2B) Protective Action Costs (potential): not quantified
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 ***not*** passed through to U.S. supply chain & consumers): $535M (range: $43M to $3.2B) 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.

We request comment on our estimates of costs and benefits of this rule and on the extent to which costs may already be internalized by covered entities.

C. Terminology

In Table 4, we describe the key terms we use in this document. We note that these definitions only apply to this document.

Table 4. Key Terms in the Regulatory Impact Analysis

Term	Description
BT Act	Bioterrorism Act of 2002. We use Subpart J (of 21 CFR part 1) and BT Act interchangeably.

BT rule	Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 Act final rule (2004)
CDC	The Centers for Disease Control and Prevention
CTE	Critical tracking event
FD&C Act	Federal Food, Drug, and Cosmetic Act
FSMA	FDA Food Safety Modernization Act
FTL	Food Traceability List
FTL foods	Foods on the FTL
FTE	Full-time-equivalent employee
Lot, batch	Food produced during a time period at a single physical location and identified by a specific code. A lot is sometimes referred to as a batch.
KDE	Key data element
NAICS	North American Industry Classification System
Persons, entities	We use these terms interchangeably to refer to businesses covered by the proposed rule
UPC	Universal Product Code
USDA	The U.S. Department of Agriculture
We, our, us, FDA, the Agency	We use these terms to refer to the U.S. Food and Drug Administration.

II. Preliminary Economic Analysis of Impacts[6]

A. Background

Current recordkeeping requirements that stem from the Bioterrorism Act (BT Act) of 2002 require firms to know and record the immediate previous source of their food products and the immediate subsequent recipient (commonly referred to as one-up, one-back recordkeeping). Since these requirements took effect, FDA has encountered significant limitations in the available food tracing-related information upon which government agencies and industry rely for rapid and effective tracing of food products in the event of an outbreak investigation. These limitations arise from gaps in recordkeeping requirements, including: no requirement to collect

6 Sections II and III of this document discuss our analysis of policy Option 2. Please see section IV for our analysis of Option 1.

specific key data elements for the type and quantity of food and ingredient source, a requirement to maintain a record of the lot code or other unique identifier only if it exists, no requirement to link incoming and outgoing product within a firm and from one point in the food supply chain to the next, and address requirements that do not distinguish between corporate headquarters and the physical location where the food was produced.

Inadequate traceability information and the challenge of having many point-of-service firms (retail and foodservice) excluded from Subpart J requirements has hampered recalls of potentially contaminated foods. In 2015, for example, an outbreak of Shiga toxin-producing *Escherichia coli* (*E. coli*) O26 (STEC O26) resulted in 55 illnesses in 11 states, leading to 21 hospitalizations (Ref. [2]). Though an investigation conducted by the CDC, FDA, and the USDA's Food Safety and Inspection Service linked a specific restaurant chain to the outbreak as early as October of 2015, investigators could not identify a particular ingredient or food item as the likely source of contamination. The lack of information in the records maintained by the restaurant caused an inability for regulatory officials to use traceability to narrow the ingredients to further investigate which ingredients came from common sources. Additionally, available consumer data could not identify a particular ingredient for tracing.

Inadequate traceability can also necessitate broad recalls that inadvertently affect non-contaminated product. In 2015, for example, FDA identified 36 farms as potentially having produced leafy greens for a leafy greens mix linked to an *E. coli* outbreak. Without being able to identify specific lots and growers of contaminated product, it was not possible to narrow investigative efforts to the source of the outbreak which would have allowed the Agency to narrow the scope of the recall (Ref. [3]).

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353) was signed into law. Section 204(d)(1) of FSMA requires FDA to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that we designate as high-risk foods. These recordkeeping requirements will be additional to the traceability recordkeeping requirements in 21 CFR Part 1, Subpart J (the Subpart J requirements), which were promulgated in accordance with the BT Act of 2002. Section 204(d)(2) of FSMA requires the Agency to designate the foods for which these additional recordkeeping requirements are appropriate and necessary to protect the public health, and to publish the list of such foods (the FTL) on our web site when we finalize this proposed rule.

B. Market Failure Potentially Relevant to Federal Regulatory Action

Several types of market failure may impact current traceability efforts, creating a need for regulatory action. First, firms currently utilize various traceability methods, creating interoperability challenges, and costs of coordination can be prohibitively high. Second, the return on each firm's additional investment in traceability depends on the level and type of investment made by other firms, potentially causing a disincentive for firms to invest. As a result, the risk of FTL-associated foodborne illnesses is likely not fully priced into FTL products.

While current traceability systems may in part originate from requirements of the BT Act, economic incentives, such as improved supply-side management and safety and quality control, may have motivated some producers to develop traceability systems of varying sophistication and comprehensiveness. Food producers in the U.S. use a variety of systems to trace the movement of food in the supply system. Tracing systems vary by the type and amount of information they collect and record, the record medium (e.g., paper vs. electronic), and the extent of the supply chain covered (e.g., the immediate previous and next steps vs. the entire chain from

farm to retailer). In some instances, owners of large supply chains (e.g., major retailers, major restaurant operators, brokers of different size that represent farms, food processors with many ingredient suppliers, importers of seafood from many vessels) compete on supply chain efficiency and consumer transparency, which requires traceability as a component of that strategy. However, to maintain competitive advantage, most supply chain owners require their suppliers share traceability data through private portals. This leads to a proliferation of different portals and data standards, which reduces the potential for interoperability. A universal standard for traceability would enable suppliers to insist their customers (and portals) accept, at minimum, a standard list of CTEs and KDEs, which would lower the cost for suppliers among other benefits.

The effectiveness of a tracing system depends on the accuracy, quality, uniformity and extent of collected information. Firms generally have private incentives to avoid the deliberate or accidental contamination of food linked to their products or facilities. Nevertheless, those incentives may not be enough for all firms to provide the socially optimal amount of information about their entire production and distribution network. Because firms' revenues may not capture all of the benefits that accrue to the public from improved food traceability, firms may collect and supply less information than would be socially optimal for adequate protection of public health.[7]

FDA has experienced the significant limitations in the available tracing-related information on which government agencies and industry currently rely to conduct tracing operations. Industry often does not fully understand what data the FDA need to effectively

[7] The socially optimal level of traceability considers all private costs and benefits (those faced by firms) as well as public costs and benefits (those faced by everyone other than firms). In other words, the socially optimal level of traceability maximizes the aggregate welfare of society, which includes firms and non-firms (e.g., consumers).

investigate foodborne illness outbreaks. Further, while standard production and distribution records carry a lot of useful information, they do not necessarily capture the complete set of information, in any standard format, that FDA would need to efficiently investigate a contamination of unknown origin. The result is that many of the systems and approaches that firms currently use for voluntary traceability are not interoperable, which results in potentially avoidable costs for all entities in the food supply chain. This failure of interoperability also slows outbreak investigations, sickens more consumers, and reduces trust in the U.S. food supply.

Although some supply chain owners have rapidly adopted traceability technology, recordkeeping practices lack uniformity across supply chains. Different supply chain entities such as growers, shippers, distributors, retailers and restaurants lack incentives to standardize recordkeeping in the form of common key data elements. Without uniform recordkeeping standards, competing software developers promote mutually exclusive, proprietary frameworks, whose incompatibility increases traceability costs. The current lack of system interoperability impedes collaboration in identifying sources or recipients of potentially contaminated food. While the effectiveness of each traceability system increases with the number of participants throughout the supply chain, the lack of standardization in recordkeeping among systems causes duplication of efforts. In addition, high transaction costs and costs of coordination in setting up a complete farm to retail national tracing system may even disincentivize some firms from investing in traceability systems, particularly those firms that are not vertically integrated. This proposed rule would standardize the key data elements and critical tracking events, would significantly reduce the private coordination and transaction costs of setting up a complete tracking system, and would enable FDA and other entities involved in a tracing investigation to accelerate and enhance the acquisition of robust product tracing information.

Underscoring the need for standardized data elements, food trade associations, technology providers, consumer advocacy groups, standards bodies, multi-unit restaurant operators, retailers, distributors and food producers have asked FDA to describe the types of data we need, and the format in which we prefer to receive such data, during an outbreak investigation.[8] This information would enable companies and solution providers to develop systems and procedures to efficiently collect that data, so it can be shared with the FDA when needed. Ultimately this might lower traceability costs for most members of the food supply chain because it would encourage the development of interoperable traceability systems.

From public comments[9] received as part of FDA's New Era for Smarter Food Safety Public Meeting held on October 21, 2019, one large food industry trade association representing food companies from around the world commented that one of the most foundational and significant actions FDA could take is identifying the key data elements that should be communicated throughout the global supply chain. Similar comments echoed the need to establish a common set of key data elements and to have clarification from FDA on the key data elements needed to provide rapid identification.

In addition to standardized key data elements and critical tracking events, the effectiveness of a tracing system depends on the extent to which firms throughout the supply chain participate. Unfortunately, even a small number of breaks in tracing information through the supply chain can prevent the FDA and others from being able to trace contaminated products to their source. Full supply chain traceability requires policy intervention as some firms do not

8 https://www.regulations.gov/searchResults?rpp=25&po=0&s=FDA-2019-N-4187&fp=true&ns=true

9 This section references public comments from the New Era for Smarter Food Safety Public Meeting - Docket ID: FDA-2019-N-4187(https://www.regulations.gov/searchResults?rpp=25&po=0&s=FDA-2019-N-4187&fp=true&ns=true), including comments by the Grocery Manufacturers Association, the US Apple Association, National Fisheries Institute, United Fresh, Produce Manufacturers Association, among others.

have an immediate financial incentive to institute tracing systems (Ref. [4]). For example, the Institute of Food Technologists (IFT) noted in the Product Tracing Pilots report (see page 217, subtitled "Lack of Standards Results in Fragmented Requirements") (Ref. [5]) that traceability is likely to stay in a state of perpetual flux until FDA clearly defines the data requirements and establishes a framework for full supply chain traceability. IFT found that producers were reluctant to invest in tracing systems if their fellow producers were not similarly investing, since tracing is not an isolated exercise.

Further comments received as part of FDA's New Era for Smarter Food Safety Public Meeting indicated that there are inconsistencies among suppliers and buyers in terms of the level of capability for traceability and that food supply chain companies cannot control the recordkeeping by entities that repackage product further up the supply chain. One comment from a large trade association indicated that "off the record" conversations with their broad membership indicated consensus that the time of hoping for voluntary adoption of effective traceability systems has passed.

In sum, market prices convey most of the necessary information for the ordinary production and distribution of foods, including the foods on the FTL.[10] However, an actual or suspected contamination of unknown origin requires more complete and standardized information as well as the ability to rapidly access and consolidate that information. In order to protect consumers from further exposure and to find the source and cause of contamination, FDA must be able to trace food backward and forward through the supply chain. Although the nation's food processors, distributors, retail food establishments, importers, and others may benefit from

[10] Prices provide most information about goods and services without the need for buyers and sellers to know much about each other. However, prices do not always communicate the difference between contaminated versus not contaminated product in the market, which explains the potential need for government intervention.

such a system, the private costs of creating it would be prohibitively expensive for any single firm or third-party organization.

As discussed in section C, the proposed rule, if finalized, would address the limitations of current traceability systems by requiring a rigorous and consistent approach to food tracing across different industry sectors for more efficient traceability of foods on the FTL. The proposed rule, if finalized, would enable FDA, its regulatory partners, and industry to better identify and remove contaminated FTL foods from the marketplace in the case of an outbreak, as well as to develop mitigation strategies to prevent future contamination.

We request comment on evidence that may support or refute the market failure claims above, or that may be used to quantify the scope of incomplete internalization of relevant baseline costs.

C. Purpose of the Proposed Rule

The purpose of this rule is to ensure that contaminated FTL foods covered by this rule can be swiftly identified and removed from the market to prevent or mitigate a foodborne illness outbreak. In order to improve FDA's ability to follow the movement of FTL foods through the supply chain, the proposed rule, if finalized, would establish traceability recordkeeping requirements for persons who manufacture, process, pack, or hold FTL foods. Namely, the rule 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 core requirements are to establish and maintain records of key data elements (KDEs) associated with different critical tracking events (CTEs) in a listed food's supply chain, including the growing, receiving, transformation, creating, and shipping of the FTL food. Required information also includes a description of the reference records in which firms keep required

tracing information, a list of foods on the FTL they ship, a description of how they assign traceability lot codes, and other information needed to understand their traceability programs. The proposed rule, if finalized, would also provide consistent food tracing terminology, encourage a transition from paper-based recordkeeping to electronic records, and promote a broader understanding of the data elements needed for efficient traceability and product recall.

This proposed rule would enable FDA and industry to identify the source of an outbreak or other contamination event, expedite removal of contaminated food from the marketplace, and prevent additional consumer exposures, as well as develop mitigation strategies to prevent future contamination. If finalized, this proposed rule would further help the Agency deter and limit the effects of foodborne outbreaks from FTL foods and thereby improve the safety of the food supply in the United States.

D. Baseline Conditions

1. Bioterrorism Act of 2002 and the 2004 BT Final Rule Recordkeeping Requirements

We consider the current state of the world as a reasonable approximation of the baseline (the projected future without the proposed rule) against which to measure the costs and benefits of regulatory options.[11] Before the enactment of FSMA, FDA implemented recordkeeping requirements (Subpart J) related to product tracing under authority of the BT Act of 2002. Thus, the current estimated baseline includes the costs and benefits of the pre-FSMA *Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness*

[11] However, we note that data available prior to finalization of the rule may show substantial changes relative to the present — due, for example, to other FSMA regulations increasingly taking effect and to societal changes associated with the COVID-19 pandemic. We request comment on estimating the baseline trajectory, given the dynamic nature of the regulatory environment.

and Response Act of 2002 final rule issued in 2004, as estimated in the economic impact analysis for that rule and as further modified by updated assumptions discussed below.[12]

The number of entities covered by Subpart J (which was promulgated pursuant to the BT Act) was estimated to be 707,672 (including persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the U.S.). Records redesign costs were assumed to be incurred by approximately 101,153 large and small firms two years following issuance of the BT final rule and by 222,316 very small firms three years following issuance of the BT final rule. Several types of entities that participate in the food supply system, however, were not covered by Subpart J. We list and discuss these entities in the next subsection.

The 2004 economic impact analysis of the BT final rule estimated annual and first-year costs of requiring establishment and maintenance of records to trace the transportation of all food to both foreign and domestic entities, as well as costs for future entities entering the market each year.[13] Benefits of the 2004 BT final rule were estimated as the number of averted illnesses due to improved recordkeeping practices. Nevertheless, in more than ten years since implementation of these recordkeeping requirements, FDA has learned that there are critical gaps in the requirements that limit the ability of regulatory agencies to conduct prompt, effective product tracing, especially in response to foodborne illness outbreaks. These critical gaps, which are discussed in section III.C of the proposed rule, suggest that the benefits of the 2004 BT rule may have not been realized and were consequently overestimated. However, as described in the next section, advances in information technology in the last decade are such that private incentives have led some entities to implement some degree of food traceability beyond the 2004 requirements, suggesting that annualized costs may have been overestimated in 2004 as well.

12 Federal Register /Vol. 69, No. 236 / Thursday, December 9, 2004 / Rules and Regulations, page 71611.
13 Federal Register / Vol. 69, No. 236 / Thursday, December 9, 2004 / Rules and Regulations, page 71640.

2. Current Industry Practices

For purposes of this analysis, we assume that firms in the food supply system already adhere to the Subpart J traceability recordkeeping requirements stemming from the BT Act.[14] Subpart J requires 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) maintain records regarding their receipt and release of food. More limited requirements apply to transporters of food. In accordance with section 414(b) of the FD&C Act, Subpart J does not apply to:

- Farms;
- Restaurants;
- Fishing vessels are exempt from all of the requirements except for those relating to records availability;
- Persons who distribute food directly to consumers are exempt from maintaining recipient records;
- Retail food establishments that distribute food to persons who are not consumers are only required to maintain recipient records if the information is reasonably available;
- Retail food establishments with ten or fewer full-time -equivalent employees (FTEs) are exempt from all of the requirements except for those relating to records availability;
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is within the exclusive jurisdiction of USDA are

[14] We request comment on whether compliance with the earlier regulations may increase as a result of this rule and, if so, how to quantify the impact.

excluded from all of the requirements with respect to that food while it is under the exclusive jurisdiction of USDA;

- Foreign persons, except those that transport food in the U.S.;
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging, except that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to the requirements relating to records availability with respect to the outer packaging of the food that bears the label and does not contact the food;
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food are exempt from all of the requirements except for those relating to records availability;
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are exempt from all of the requirements except for those relating to records availability; except that persons who place food directly in contact with its finished container are subject to all of Subpart J with respect to the finished container that directly contacts that food;
- Non-profit food establishments are exempt from all of the requirements except for those relating to records availability;
- Food for personal consumption; and
- Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food.

Under these existing requirements, firms must know and record information regarding the immediate previous sources of the food and the immediate subsequent recipients of the products they make or distribute or both (commonly referred to as one-up and one-back recordkeeping). This entails recording the name, address, and telephone number of source and receiver firms and of transporters; a description of the type of food, and the date it was received or released; and the quantity of the food, and how it is packaged. Firms covered by Subpart J that manufacture, process, or pack food also must record a lot or code number or any other identifier when available, though there is no standardized format (Ref. [5]).

Additionally, firms may already voluntarily conform to traceability standards and best practices developed by outside groups, such as the consensus standards developed by GS1, an international non-profit organization that develops and maintains standards for barcodes[15]. Other examples of business communication standards include QR codes[16], data matrices, and radio frequency identification (RFID) codes. At present, the Foodservice GS1 U.S. Standards Initiative, which promotes traceability standards, has 130 food service companies among its membership (Ref. [6]). GS1 has standards and best practices for various entities in the food supply system. For example, GS1 standards for growers include encoding and communicating trace lot codes, location identification, and other harvest information in order to link individual cases of product to harvest sites (Ref. [7]). GS1 standards for subsequent supply chain entities enable enhanced traceability from grower to retailer and back.

A 2004 report from the USDA Economic Research Service (ERS) addressing the traceability baseline in the United States found that private sector food firms had already developed

15 https://www.gs1.org/

16 A QR code is a machine-readable code consisting of an array of black and white squares normally for storing smartphone readable URLS or other information.

substantial capacity to trace by the time the BT final rule was published in 2004 (Ref. [8]). According to the report, food producers, manufacturers, and retailers were typically keeping traceability records for a wide range of foods and food attributes including elements concerning food safety. Recordkeeping systems needed for the Subpart J traceability requirements resembled the systems that already existed for recording receipts and bills. For many of these firms, one-up, one-back traceability for a standard set of data elements would require little change to their existing systems.

Similarly, some affected entities already maintain, to varying degrees, key data elements required by the proposed rule and would likely incur little cost to comply. However, other entities may face more substantial changes to their existing recordkeeping systems. For example, some firms may need to generate and assign traceability lot codes to food on the FTL in instances where these codes do not already exist. For some growers, new steps may include recording the growing area coordinates of each lot and collecting additional documentation from seed vendors. Growers may also need to send additional tracing documentation when shipping FTL foods. First receivers of FTL foods may face new data-entry costs. Firms that transform covered products but do not currently link supplier lots (of ingredients) to manufactured lots (of output) would need to add this step to their recordkeeping process.

We lack information on the extent to which current industry practices align with the requirements of the proposed rule. Namely, we lack information for identifying the number of firms by industry sector that would need to substantially alter or replace their current systems in order to comply with the proposed rule. Hence, for firms and establishments that we believe manufacture, process, pack, or hold foods on the FTL, we acknowledge that the levels of

upgrades needed to conform with the requirements of the proposed rule may vary widely. We seek comment on these estimates.

3. Coverage of the Rule

Covered entities (firms or establishments) would incur costs from the proposed rule, if finalized, to the extent that compliance requires them to change their current practices. Covered entities are those that manufacture, process, pack, or hold foods that FDA has designated as requiring additional recordkeeping and placed on the FTL.[17] The proposed traceability recordkeeping requirements would generally not apply to:

- Farm sales of food produced and packaged on a farm – if packaging of food maintains integrity of product and labeling includes name, complete address, and business phone of farm;
- Farm sales directly to consumers;
- Fishing vessels;
- Transporters of food;
- Nonprofit food establishments;
- Food for personal consumption;
- Certain persons who hold food on behalf of individual consumers;
- Commingled raw agricultural commodities that are not "covered produce" in the FSMA Produce Safety Rule;
- Produce and shell eggs that receive certain types of processing;

17 The list of applicable foods can be updated by publishing a notice in the Federal Register, using the process described in proposed § 1.1465. See Appendix A for the list as of this writing.

- Produce that is listed as rarely consumed raw in the FSMA Produce Safety Rule, 21 CFR § 112.2(a)(1);
- Food that has been subjected to a kill step;
- Certain small originators, including produce farms that are not covered by the FSMA Produce Safety Rule under 21 CFR § 112.4(a) and shell egg producers with fewer than 3,000 lay hens at a particular farm;
- Retail food establishments with respect to food that they purchase directly from a farm, provided they document the name and address of the farm; and
- Farm-to-school and farm-to-institution programs with respect to food that is produced on a farm and sold to the farm-to-school or farm-to-institution program, provided that the school food authority or relevant food procurement entity documents the name and address of the farm.

To estimate the number of covered entities, we use several sources. These include the U.S. Economic Census, the 2016 Statistics of U.S. Businesses (SUSB), FDA's Food Facility Registration Module, and the 2017 Census of Agriculture. All datasets used in this analysis were the latest available to us as of January 2020.

The Census Bureau's SUSB publishes the number of firms, establishments, and employment by firm size and industry on an annual basis. The most recent data available is from 2016. Many firm size standards are based on the number of employees, so the 2016 SUSB employment size categories are additionally useful for identifying the number of small entities in each affected industry. SUSB annual data include the number of firms, number of establishments, employment, and annual payroll for most U.S. business establishments. The data

are tabulated by geographic area, industry, and employment size of the enterprise. The industry classification is based on 2012 North American Industry Classification System (NAICS) codes.

We assume that the FSMA 204 rule as currently proposed would cover approximately 422,144 firms operating 566,448 establishments, including 22,912 farms, 10,623 manufacturers, 18,686 wholesalers, 3,519 warehouses, and 366,404 retailers. This number includes only domestic entities (firms or establishments) that manufacture, process, pack, or hold FTL foods destined for consumption or use in the United States. Table 5 contains a summary and breakdown of this estimate by NAICS code.[18]

Table 5. Number of Affected Entities by Industry Sector

Type	Number of Firms	Number of Establishments	NAICS Codes
Farms /Aquaculture / Growers	22,912	22,947	111219, 111339, 111419, 112310, 112511, 112512, 114111, 114112
Manufacturers / Processors / Packers	10,623	11,557	311340, 311351, 311352, 311411, 311412, 311421-311423, 311513, 311520, 311710, 311811-311813, 311821, 311824, 311911, 311941, 311942, 311991
Wholesalers / Distributors	18,686	24,224	424410, 424420, 424430, 424450, 424460, 424480, 424490
Warehouse and Storage	3,519	6,880	493110, 493120, 493130
Retail Food Establishments (including restaurants)	366,404	500,841	445110, 445120, 445220, 445292, 445230, 445291, 445299, 447110, 452910, 454111, 454210, 722310, 722320, 722330, 722410, 722511, 722513-722515

18 https://www.census.gov/eos/www/naics/
In each NAICS code category, only entities that manufacture, process, pack, or hold foods on the FTL would be affected by this rule.

We estimate that the total number of domestic farms that produce foods on the FTL, including produce, eggs, and fish, and would thus be affected by the proposed rule is 22,912.[19] This includes 18,918 farms that grow covered foods, including fruits and vegetables such as leafy greens, cucumbers, tomatoes, peppers, fresh herbs, tropical tree fruits, melons, and sprouts. We derived the number of farms from the 2017 USDA Census of Agriculture, which includes farms with on-farm packing, greenhouses, and other originators of covered produce foods (Ref. [9]).

We estimate that there are approximately 95 covered sprouting operations (included in the total number of farms in Table 5). There is little information on the size and structure of the sprout producing sector. We ask for comment on the distribution of sprouting operations across firm size categories.

The proposed rule also applies to shell egg producers and growers. Shell egg producers with fewer than 3,000 laying hens at an individual farm, with respect to the shell eggs they produce, are exempt. This exemption is the same as that found in the Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation Final Rule, or the Egg Safety Final Rule (Ref. [10]). Farmers who sell their eggs directly to consumers are exempt from all provisions. Sales of eggs directly to consumers include sales of a farmer's own eggs to neighbors, at farmers markets, and at roadside stands.

The Egg Safety Final Rule includes recordkeeping requirements related to the prevention of *Salmonella* Enteritidis, but not to enhance traceability of shell eggs within distribution networks. To estimate the number of covered egg producers, we use the National Agricultural

[19] The first domestic entity that takes physical possession of an imported product would be responsible for obtaining the required information from foreign farms – these firms are affected entities and included within other sector categories (manufacturers/processors/packers/holders, wholesalers/distributors, or warehouse and storage).

Statistics Service (NASS) 2017 Census of Agriculture to determine the number of farm sites with layers on hand. NASS estimated that there are 232,500 farms with layers over 20 weeks old in their inventory (Ref. [9]). There are over 228,000 farms with fewer than 3,000 laying hens, representing over 99 percent of egg producers but less than one percent of total domestic egg production. We estimate that out of 3,064 egg farm sites, 1,532 sites would be covered by some or all parts of the rule.[20]

We use FDA's Food Facility Registration Module (FFRM) biennial registration data for our estimates of foreign entities affected by this proposed rule. As discussed in more detail in section II.H, we compare the number of registered foreign facilities in the FFRM to the primary estimated number of affected domestic establishments minus retail food establishments. We then use this ratio, approximately 1.95, as a scaling factor to extrapolate from the number of affected domestic entities in the main analysis. We believe the number of foreign retail food establishments affected by this rule to be negligible. Thus, we estimate that the rule would cover approximately 89,977 foreign firms and 118,954 establishments operated by those firms. We do not have a detailed breakdown of foreign establishments and firms by industry, and instead assume the same proportional breakdown as in the main analysis. The International Effects section of this document discusses this process in detail.

We welcome comments on these estimates and our baseline discussion.

20 The NASS Census of Agriculture uses farms with 3,200 birds as its cutoff point for categorization. FDA uses 3,000 birds as its cutoff point for small versus large farms, because this is the measure that is used in other egg and poultry regulations. To adjust the NASS data, FDA assumes that all flocks are uniformly distributed across the 400 to 3,200 bird category. Using this assumption, 7.1 percent (200 ÷ 2,800) of these farms fall in the over 3,000 bird category while the remaining 92.9 percent fall in the small farm category.

E. Benefits of the Proposed Rule

The proposed rule, if finalized, is expected to improve FDA's 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. In the event of a foodborne outbreak, the ability to trace 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. The ability to trace foods forward can help FDA ensure the removal of all affected products from the marketplace and 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. Therefore, if finalized, this rule is expected to result in the following benefits:

1) Public health benefits from averted foodborne illnesses caused by foods covered by the proposed rule;
2) Benefits from avoiding broad recalls;
3) Other benefits that we discuss below.

The health-related benefits which are the primary focus of this analysis can only be realized in the event of an averted or reduced-duration foodborne illness outbreak from foods on the FTL; benefits from avoiding overly broad recalls may be realized only in the event of a recall; and the other benefits may be realized regardless of an outbreak. However, the costs would be incurred by all entities regardless of whether there is an outbreak investigation or recall underway, and regardless of whether they are implicated in the outbreak.

The benefits accrued from improved product traceback are difficult to quantify. An IFT report on food tracing pilot projects specifically notes that it was easier to identify costs associated with system upgrades for firms to implement product tracing than quantify the benefits of product traceability (Ref. [5]). There is uncertainty in assigning specific benefits from this rule alone relative to other FSMA and BT rules, which have been implemented over recent years.[21] FDA has the information about outbreaks and recalls and expects that the proposed rule would lead to achieving the described benefits. However, we are uncertain about the exact share of outbreaks that would be averted specifically as a result of this rule in relation to other FSMA rules. Other recently implemented FSMA rules also aim to avert foodborne illness outbreaks from FTL foods. Given that the same outbreaks dataset has been used in the past for discussing benefits of other FSMA rules in those RIAs, we aim to avoid double counting benefits by predicting that FTL food outbreaks will be averted as a result of this proposed rule alone.

We estimate benefits in two ways. First, we use case studies of four pathogens to estimate monetized benefits of potential averted illnesses from faster traceback. Second, we rely on three recall case studies to estimate potential benefits from avoiding overly broad recalls. We welcome comments on our assumptions and our estimates of the benefits of the proposed rule. We are particularly requesting any information that would permit the Agency to more accurately quantify the likely benefits.

21 Since the 2011 enactment of FSMA, FDA has finalized seven major rules implementing FSMA. These rules are based on the premise that the safety of the food supply is a shared responsibility at many different points in the global food supply chain for both human and animal food. All FSMA rules combined are designed to make clear specific actions that must be taken at each of these points to prevent contamination: https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma

1. Potential Benefits from the Proposed Rule

i. Establishing a framework for better tracing

This proposed rule would establish a framework to more accurately and efficiently trace potentially contaminated FTL foods (both domestic and imported) across the U.S. food supply system to protect the health of 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. These linkages of tracing information not only enable FDA to determine the source of a contaminated food but also provide visibility into the critical affected points of the food supply system and distribution chains.

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 ensure the removal of all affected products from the marketplace and 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.

Improved food product traceback will enhance FDA's ability to complete traceback investigations more efficiently, leading to a faster identification and removal of implicated food products from the market. This should consequently reduce the number of illnesses resulting from consumption of implicated foods. A shorter traceback investigation would reduce the duration of an outbreak. A shorter outbreak duration would result in fewer illnesses resulting

from consumption of contaminated foods. In contrast, a delay in a traceback investigation due to unavailability of adequate traceability records or their poor quality could result in a longer duration of the outbreak resulting in a larger number of illnesses. Prolonged outbreak response and product traceback can have devastating public health and economic outcomes because they increase the total number of illnesses.

The proposed rule, if finalized, would speed up tracing of FTL related outbreak investigations, because increased and improved records would mean that investigators spend less time trying to find and analyze information about FTL foods that might have been missing or incomplete. The proposed rule has the potential to improve traceability as it focuses on quickly identifying the food that is the source of a foodborne illness outbreak and tracking its movement throughout the food supply system. By establishing recordkeeping requirements for key data elements, the rule is designed to increase the rate of successful tracing completions for covered foods (Ref. [11]).

Implementation of the rule, therefore, is expected to put in place the mechanisms that should enable us to more swiftly and more precisely trace the source of an outbreak through the food supply system for foods on the FTL. Improved documentation and recordkeeping practices should increase the rate and speed of successful tracing completions. Consequently, fewer foodborne illnesses from foods on the FTL may occur, reducing hospitalizations and deaths.

ii. Better identification of food vehicle

When there are outbreaks that involve foods that are multi-ingredient, it is hard to tease out what the likely vehicle is if there is not another group of illnesses with exposure to a single food item for comparison. With the ability to collect linked records more quickly, the investigative and traceback efforts will move faster and be less burdensome, so less time will be

needed to identify the implicated food or ingredient. Tracing the ingredients and comparing to see if there are common suppliers could help identify the implicated food vehicle and reduce public exposure.

The Agency has sometimes been unable to link illnesses to a specific food vehicle due to inconsistent, unstandardized recordkeeping and the frequent lack of lot tracing during distribution to specific retail locations. Traceback investigations begin at retail food establishments to collect data to identify details about products suspected of causing illness, including information on brands, varieties, and sources of products of interest. More accurate and detailed data on the products of interest at the retail food establishment (RFE) enables more refined record collection throughout the rest of the supply chain (Ref. [1]). In 2018, FDA investigated a cluster of illnesses caused by *Cyclospora cayetanensis* at small restaurants. We were unable to obtain enough information to narrow down the products suspected of contamination (e.g., basil, cilantro, vegetable trays) due to the restaurants' lack of records indicating lot numbers received and 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.

Information from all RFEs, whether large or small, is integral in investigating foodborne illness outbreaks, especially since RFEs are most often the first stop in the traceback process. The examples noted above and in the supporting memo (Ref. [1]) represent just a few of the outbreaks where availability of "Receiving KDEs" at RFEs would have improved the outcomes of traceback investigations and recall efficiency. Requiring recordkeeping by RFEs of all sizes

allows for more consistent, organized, and specific information that covers the entire supply chain and will improve the ability for FDA to investigate foodborne illness outbreaks. The data available to investigators if all RFEs are covered by this rule would improve the timeliness, precision, and accuracy of foodborne illness outbreak investigations and thus contribute to prevention of illness (Ref. [1]).

The improved ability to identify the exact source of contaminated FTL foods may reduce the time needed to complete tracing investigations when a foodborne illness outbreak occurs, therefore enabling earlier initiation of a recall. Greater tracing speed can result in faster and more precise recalls (if the FTL product is still on the market) and other preventive actions that may reduce the number of illnesses during an outbreak. With the records required by this proposed rule, the Agency would be able to investigate outbreaks more quickly and may not be forced to terminate an investigation because of poor or nonexistent records. If finalized, this rule may reduce both the clinical and other economic burden of foodborne illnesses caused by these FTL foods outbreaks.

ii. Reducing outbreak duration due to standardization of data elements

When a foodborne illness outbreak occurs, effective traceability programs can lessen the potential adverse impact of the event by reducing the outbreak duration. 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 help determine which foods and ingredients can be eliminated from further consideration as possible sources of contamination. Furthermore, being able to identify the source of a contaminated product quickly enables FDA to conduct timelier

root-cause analysis, which could provide important information to help in understanding how contamination may have occurred and prevent future outbreaks.

Standardization of data elements is needed to help ensure successful and faster traceability throughout the supply chain. 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.

The IFT report recommended that FDA establish a uniform set of recordkeeping requirements, representing an enhanced framework from current mandates and practices. The framework outlined in this report, although not a formally adopted technical standard, has become a common way of thinking about traceability and is commonly used as a basis for developing food traceability software and options for food supply entities. As an example of the influence of the approach, the framework has been referenced in the GS1 Global Traceability Standard 2.0 (2017)[22], FAO Blockchain Application in Seafood Supply Chains (2020)[23], FAO Seafood Traceability for Fisheries Compliance (2017)[24], and multiple other research reports, best practices guidelines, and textbooks. By establishing a more uniform set of recordkeeping requirements based on IFT's framework of key data elements and critical tracking events, FDA can enable tracing software providers, large food supply system entities, and food network stakeholders to advance system interoperability and standardization. Such a framework enhances

22 https://www.gs1.org/standards/traceability/traceability/2-0
23 http://www.fao.org/3/ca8751en/ca8751en.pdf
24 http://www.fao.org/3/a-i8183e.pdf

the ability of firms within the food system to transmit and exchange information about suspect ingredients and products involved in investigations and recalls.

In 2016, for example, FDA performed a traceback investigation of frozen strawberries associated with illnesses of hepatitis A. A lack of traceable lot code information on the products at the retail level and time understanding the supply chain hindered the traceback investigation. These two factors, among others, had a significant impact on the speed and efficiency of the traceback investigation. While a single supplier of strawberries was identified, many of the complications and delays encountered during the tracing process could have likely been avoided with the provisions of this rule. Under the proposed provisions of this rulemaking, federal and state officials would have had access to the traceability lot code generator information at the retail location. Since there was no manipulation of the product once packaged by the source manufacturer, access to the traceability lot code generator would have immediately identified the source and traceable lot codes within the first 24 hours of the initiation of the traceback at the point of service. In situations where supply chains have secondary customers (i.e., brokers), FDA must spend time determining where the product physically went. In the case of the hepatitis A traceback, differentiating these firms increased the time needed to complete the traceback, ultimately impacting product actions. Because the product was packaged ready for the end-user and incurred no additional manipulation through its distribution, it would have been unlikely that contamination occurred at the other points in the supply chain. Knowing this early in the traceback investigation would have reduced the time necessary to gather information about the distribution of the product.

Under the existing requirements of Subpart J, it is necessary for FDA to collect information from each point in the distribution chain to effectively trace a product. Initiation of

the first product recall took approximately one month from the start of the frozen strawberry traceback based on the need to collect information from every point in the supply chain and determine where the product physically went. In this case, availability of the traceability lot codes and traceability lot code generator location identifier at the point of sale would have allowed FDA to contact the manufacturer of the product or importer immediately while verifying records across the supply chain simultaneously. Had the recordkeeping requirements of this proposed rule been in place, a recall would have likely occurred within days of the traceback being initiated, resulting in a significant time and cost savings.

iii. Reducing the Scale of Outbreaks of Complex and Commingled Products Through Improved Product Traceability

The IFT traceability pilot report includes a detailed description of a supply chain scenario where traceability could enhance withdrawal of products from the market even when some ingredients of the final product could not be linked to the product (Ref. [5]). At the core of this scenario were two products marketed under the same brand. One was a frozen product (skillet meal produced by one manufacturer) and the other was a dry version in which the consumer would add meat (produced by another manufacturer). These two products were manufactured in two different locations, and the dry product was produced by a co-manufacturer. Additionally, each product contained “pouches” (separate sauce and peanut pouches in each product, and whole chilis for the dry product) that were manufactured by additional parties (one produced the sauce and another pouched the whole dried chilis, with the peanuts packaged by the peanut supplier).

In this scenario, it was up to the solution provider to use traceability software to determine the ingredients/lots likely to have been used at both manufacturers. This scenario

demonstrated that the most time-consuming element of the task was harmonizing the six different data sets into uniform CTEs/KDEs. Once the data was standardized and connected, the software could display the supply chains and their points of convergence nearly instantly.

This scenario tested the process used to acquire product tracing information, with the product-brand owner functioning as the main source of the information collected within 24-36 hours. The final product owner was able to provide information to trace back to the specific ingredients, some of which were traced back to overseas suppliers. Traceability of these products was completed within 35 hours and the analysis took less than three hours even though some of the individual ingredients could not initially be linked to the processed food product. Ultimately, the products that were earmarked for a recall were identified with a degree of precision that would not have been possible without the availability of traceability records and the standardized system that allowed this coordination and convergence. The IFT report concludes that, with such a high level of precision and timeliness, traceability can be used to help resolve outbreaks caused by illnesses from commingled or more complex products with multiple manufacturers, facilities, and providers/suppliers. Illnesses from such outbreaks often remain unattributed when reports are compiled due to the difficulty of identifying the specific food responsible. Thus, improved traceability can reduce the number of unattributed foodborne illnesses.

iv. Findings of the IFT Report

The 2012 IFT report emphasizes the importance of public health benefits as the primary outcome from enhanced product traceability. The report provides a description of benefits for several case studies. The report provides some initial estimates of potential benefits, along with a framework on how broader estimates of benefits could be calculated. To estimate public health benefits of food product traceback, the report suggests the following three key assumptions:

(i) Product tracing can reduce the time between identification of an implicated food causing an outbreak and the identification of the specific product and recall or removal from commerce. This reduction of disease incidence is assumed to be proportional to the time reduced through effective whole supply chain product tracing.

(ii) The establishment of seamless product tracing system across the food industry would result in a near 'instantaneous' identification of a food source and the initiation of product intervention to remove it from commerce and stop public exposure to contaminated product. Instantaneous traceback gives the theoretical maximum possible reduction in illnesses.

(iii) Each illness-causing pathogen has a specific incubation period. Any calculation on benefits of reduced illness due to earlier food vehicle identification and intervention must consider the specific pathogen incubation period regardless of when the exposure to contaminated food was stopped.

The IFT report used case studies based on eight outbreaks caused by two pathogens (*Salmonella* and *Listeria monocytogenes*). For lack of reliable data, the report argues that these case studies can serve as a good guide in identifying and analyzing public health benefits. With a richer dataset, the methodology can also be replicated and expanded to analyze foodborne illness outbreaks that could help to provide a more accurate picture of the benefits of improved product tracing. The scope of the benefits discussed in the IFT report is limited and difficult to generalize to broader sets of food products and foodborne illness outbreaks, as are some of their assumptions, such as their estimated cost of *Listeria* and *Salmonella* illness of $10,300 and $17,900 per case, respectively (Ref. [5]). Our analysis uses validated and more generalizable data sources, including FDA's foodborne illnesses outbreak data, which consists of 10 pathogens

commonly known to cause FTL-associated illnesses, as compared to only two pathogens discussed in the IFT report based on a case study from eight outbreaks.

v. Effects of Tracing on Public Health

For public health benefits to be realized, the Agency and industry must take timely preventive actions. Executing effective and timely recall of contaminated foods is important but difficult to achieve (Ref. [12]). As the 2010 shell eggs *Salmonella* contamination illustrates, food recall is a complex process. According to CDC, the shell eggs outbreak was first reported in May 2010 and the recall was issued in August 2010. However, the outbreak continued until October 2010 when all contaminated food vehicles were identified and recalled (Ref. [13]). Because of the length of time it took to identify the food vehicle, this outbreak was the largest reported since the early 1970s when outbreak surveillance was established (Ref. [14] [15]), resulting in many illnesses that could have been avoided with better tracing.

At the start of the investigation for this outbreak, there was a lack of clusters of illness with an epidemiologic association to shell eggs. The clusters required more epidemiologic evidence to be obtained on the consumption of eggs and egg-containing foods in order to have enough information to begin a traceback investigation. When epidemiological studies cannot distinguish which of several possible ingredients or foods is clearly implicated in outbreaks, federal and state authorities often elect to identify the most likely one or two ingredients or foods in two to three of the clusters in which the best epidemiological information and case histories are available, and trace those foods to see if there are common suppliers. These are frequently referred to as “epidemiological tracebacks” and are meant to help inform the epidemiological investigations (Ref. [16]). This outbreak required an epidemiological traceback to verify that the

food vehicle was in fact shell eggs, and further traceback of additional clusters to verify the common supplier.

Standardized records linking shipments through the supply chain and back to their sources would have reduced the time needed to review the necessary information. For some clusters, the district offices had to return to the firm for additional clarification on linking incoming to outgoing product shipments, which prolonged the traceback investigation. Also, many firms did not record this information at all, causing traceback to rely on analysis of shipment dates alone. This analysis slowed the process for identification of the food vehicle, common supplier, and affected lots. Ultimately thousands of people were sickened as a result of this outbreak. The number of illnesses could have been meaningfully reduced if a better tracing system had been in place.

In sum, the public health benefits of this rule, if finalized, would arise when foodborne illnesses from foods on the FTL are averted. To assess these benefits, we must therefore place a value on risk reduction and health-related costs for illnesses that may be averted. However, any quantified estimates of health benefits from shortening outbreaks would be uncertain as the following information would be necessary to better estimate the rule's public health safety benefits:

- The baseline risk of foodborne illness attributable to foods covered by the rule;
- Estimates of lost health as measured by morbidity and mortality attributable to foodborne illnesses from foods covered by the rule;
- Value of lost health due to FTL-associated foodborne illnesses;
- Changes from baseline recordkeeping practices to post-rule practices; and

- The anticipated effectiveness of the proposed rule in reducing associated foodborne illnesses.

Therefore, while we believe this proposed rule, if finalized, would produce benefits, the lack of complete information introduces high uncertainty in estimating such benefits. Our estimates of these benefits thus include wide ranges based on the numbers of illnesses attributed to outbreaks in recent history, ranged assumptions in the IFT report about how effectively traceability measures would have shortened epidemic curves from foodborne illnesses, and ranged assumptions about the monetary value of lost health due to foodborne illnesses. Section E.2 Public Health Benefits from Averted Illnesses discusses our use of the model from the IFT report in conjunction with historical epidemic curve data to project the effectiveness of the rule at reducing foodborne illnesses associated with FTL foods.

vi. Baseline Risk of Foodborne Illnesses Attributable to FTL Foods

As explained in more detail in Appendix B, we estimate that 119,706 cases of foodborne illnesses per year in the U.S. are caused by known pathogens associated with foods that are on the FTL. From FDA foodborne illness outbreak data (Ref. [17] [18]), we identified a total of 10 microbial pathogens responsible for the majority of foodborne illnesses attributable to foods covered by this proposed rule were identified from FDA foodborne illness outbreak data. Of these pathogens, *E. coli* accounts for approximately 60 percent of the foodborne illnesses, *Salmonella* accounts for approximately 20 percent, and *Cyclospora cayetanensis* accounts for approximately 17 percent. In terms of annual hospitalizations, the leading pathogen was *Salmonella*, which accounts for 58 percent, followed by *Listeria*, which accounts for 15 percent, and *E. coli*, which accounts for 13 percent of total annual hospitalizations. Other pathogens

within FDA data that cause foodborne illnesses for FTL foods include ciguatoxins, hepatitis A, norovirus, scombrotoxins, tetrodotoxins, and *Vibrio* spp.

The foods covered by this rule have a higher public health risk based on the frequency and severity of outbreaks associated with these foods as well as their frequency of consumption.

Table 6 summarizes the estimated number of illnesses, hospitalizations, and deaths attributable to foods covered by the proposed rule. As described in Appendix B, to obtain these numbers, we reviewed FDA's Coordinated Outbreak Response and Evaluation (CORE) outbreak data for FTL foods covering the period from 2009 to July 2019. We used multipliers from peer-reviewed literature to account for underreporting and misdiagnoses of foodborne illnesses (Ref. [19] [20]). The methodology outlined in the Scallan et al. follow-up article is used to account for unspecified and unknown agents[25] (Ref. [21]). Including the roughly 80 percent of illnesses caused by unknown and unspecified agents, we estimate a total of 598,531 foodborne illnesses associated with FTL foods (= 119,706 illnesses x 5) (figures rounded to nearest whole number). Our estimates cover a different time period (2009 – 2019) as compared to Scallan et al. 2011 estimates, which covered the years 2000 – 2008. The distribution of the burden of foodborne illnesses by different types of pathogens has changed over time, as evidenced by recent CDC publication which noted that in 2019 there was a 12-fold increase in *Cyclospora* infections compared to 2016-2018 (Ref. [22]). Additionally, recent disease outbreaks associated with leafy greens, fresh herbs, and fresh-cut vegetables – all on the proposed FTL – have been linked to Cyclospora as evidenced on CDC's food outbreak records[26]. Though we follow these standard

[25] As explained in Appendix B, according to Scallan et al., (2011b), apart from foodborne illnesses caused by major known pathogens, nearly 80% of additional episodes of foodborne illness are caused by unspecified agents, including known agents about which we lack sufficient data to estimate agent-specific illness. There are also illnesses caused by known agents that are not yet recognized as causing foodborne illness as well as substances known to be in food but of unproven pathogenicity, and unknown agents.
26 https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreak/outbreaks-list.html

assumptions provided in peer-reviewed literature, we recognize that sparsity of data results in uncertainties in our accounting of unspecified and unknown agents. We request comment on how to best adjust our estimates for unspecified and unknown agents, as well as for underreported and misdiagnosed agents.

Table 6. Estimated Number of Illnesses, Hospitalizations, and Deaths Attributable to Foods Covered by the Proposed Rule[27]

Type of Pathogen	Annual Estimates	Hospitalization	Deaths	*Percent total cases*
Ciguatoxin	36	0	0	0.03%
Cyclospora cayetanensis	20,672	14	0	17.27%
E. coli (All strains)	72,060	53	2	60.02%
Hepatitis A Virus	584	39	0	0.49%
Listeria	73	60	12	0.06%
Norovirus	918	1	0	0.77%
Salmonella (All strains)	23,793	238	3	19.88%
Scombrotoxin	65	0	0	0.05%
Tetrodotoxin	1	0	0	0.00%
Vibrio (All strains)	1,504	3	0	1.26%
Estimated total from known pathogens[28]	**119,706**	**408**	**17**	**100.00%**

vii. Economic Burden of Foodborne Illnesses Associated with FTL Foods

We estimate the total burden of foodborne illnesses attributed to FTL foods by multiplying the estimated annual number of illnesses per pathogen from Table **6** by the updated burden of illness estimates. We update burden of illness estimates first published in 2015 (Ref.

[27] This table is compiled using FDA's foodborne illnesses outbreak data that was also used in the risk-ranking model, which was the basis for designating the FTL.

[28] Our estimates of hospitalization and death counts include specific pathogen multipliers according to Scallan's methodology. Except for Norovirus, the Scallan methodology doubles both death and hospitalization numbers, which we accounted for in this table.

Chemicals or substances like ciguatoxins, scombrotoxins and tetrodotoxins were not available in the original Scallan (2011a) article but have since been established as causes of foodborne illnesses. We obtain underdiagnosis multipliers for ciguatoxins and scombrotoxins from Pennotti et al (2013) (Pennotti, Scallan, Backer, Thomas, & Angulo, 2013), and use the same multiplier for tetrodotoxins as for ciguatoxins. We assume their hospitalization and death rates were constant.

[23]) to 2018 dollar values[29] (Ref. [24]). This burden includes both direct costs and indirect costs, and accounts for variations in the level of severity of foodborne illnesses. The direct costs are associated with doctor visits and hospitalization. Indirect costs are from the loss in quality of life (of which loss in productivity is a subset) as a result of the symptoms and severity of the foodborne illness. The burden is monetized using the value of a statistical life (VSL) as provided in HHS guidelines (Ref. [25]). The total economic burden of illness in Minor, et al., 2015, is therefore estimated by computing and combining for each illness the average monetized acute health loss, the average monetized secondary health loss (from long-term health effects), the average monetized loss of life years, and the acute and secondary medical costs.[30] We rely on these estimates for our analysis and refer the reader to Minor, et al., 2015 for more detailed discussion of these computations. Table 7 shows the estimated burden of illnesses associated with outbreaks attributable to foods covered by this rule. We list the common microbial pathogens associated with covered foods and the estimated average annual number of illnesses associated with these pathogens. The number of illnesses per pathogen is then multiplied by its expected burden of illness to produce the economic burden of foodborne illnesses caused by

29. The model updates included revised annual dollar estimates of foodborne illness costs from the 2015 estimates to 2018 values using BLS deflators. Additionally, new foodborne illness causing agents, which include scombrotoxin fish poisoning and ciguatera fish poisoning, were also added into the model. These had been missing in the original model for lack of reliable data. These agents were also never covered in Scallan et al., 2011a which is largely credited for establishing the basis for most foodborne illness pathogen causing agents. For these multipliers, we cite Pennotti et al 2013.

[30] Minor et al. (2015) present their estimates of cost per illness as applying to the illness episodes that Scallan et al. (2011a) quantify using data from 2000 to 2008 from several sources. By contrast, the estimates in this RIA are based on FDA CORE data from 2009 to 2019. While the Scallen et al. primary estimate of 11,407 cases annually across all food sources is far lower than what is attributed here just to FTL products, Tack et al. (2020) indicate that compared with 2016-2018, the incidence of *Cyclospora* increased significantly (1,209%). This increase has been seen in previous years as well – CDC notes that the incidence of *Cyclospora* infections increased markedly in 2018, in part because of large outbreaks associated with produce (https://www.cdc.gov/mmwr/volumes/68/wr/mm6816a2.htm?s_cid=mm6816a2_w). The increase in *Cyclospora* infections might be partly due to increased detection (by more labs using new tests) but also partly due to increased exposure to this pathogen, particularly contaminated FTL products.

known pathogens. We then multiply by five to account for illnesses caused by unidentified/unspecified pathogens. If the rule prevented all illnesses estimated as caused by FTL foods (about 598,500 foodborne illness per year), it would result in annualized public health benefits of approximately $4.3 billion dollars per year at a seven percent discount rate. We do not know, however, the extent to which the proposed rule, if finalized, may be able to avert this estimated number of foodborne illnesses.

To obtain our adjusted estimate of the total annual burden of foodborne illnesses from outbreaks from foods covered by the proposed rule, we account for exemptions and scale down our estimates in Table **6**. This proposed rule has exemptions for several types of entities and circumstances and, therefore, not all estimated illnesses may be averted. For example, certain farms are exempt from some activities because of their size, retail sales volume, or distribution channel, but are likely responsible for a portion of estimated foodborne illnesses from FTL foods. For this reason, the next entity in the supply chain after the (exempted) farm will need to start the record chain by applying the traceability lot code. We lack data on the number of foodborne illnesses that may continue to result from exempting very small farms. However, if we account for these illnesses by adjusting our estimates upward by the share of very small farm sales as in the Regulatory Impact Analysis for the Standards for Growing, Harvesting, Packaging and Holding of Produce for Human Consumption rule[31] (Ref. [26]), the estimated number of FTL-related illnesses would still be around 514,700 cases per year (= 598,531 x (1 – 0.14)). The adjusted annualized burden reduction of all FTL-caused illnesses would still be about $3.74 billion per year (= $4.3 billion x (1 – 0.14)).

31 The economic analysis for this rule estimates that very small farms represent a small proportion (14%) of produce sales. Because exempting these farms may perpetuate foodborne illnesses, the analysis adjusts the economic burden of illnesses upward by 14%. We follow the same procedure as an example, noting the small risk of illnesses associated with products from very small farms due to their limited reach.

We recognize the importance of this analysis considering the impact of other FSMA regulations in reducing the amount of foodborne illnesses. However, we do not have a good mechanism to assess whether the other FSMA rules will achieve the health benefits estimated in the regulatory impact analyses for those rules, particularly since the compliance dates for many of the other FSMA rules have only passed recently, and for some of the provisions the compliance dates have not yet passed. While estimated costs and benefits of other FSMA rules may (or may not) have been incurred entirely, estimated costs of this rule reflect the costs added by this rule only. Expected health benefits are calculated based on the most recent data on number of illnesses associated with foods covered by this rule. We ask for comment on best ways to account for the benefits of other FSMA rules.

Table 7. Estimated Economic Burden of Foodborne Illnesses Associated with Foods Covered by this Proposed Rule (2018$)

Pathogen	**Estimated Annual Cases**	***Monetized Burden per Illness***	***Total: Primary***
Ciguatoxin	36	$16,208	$581,284
Cyclospora cayetanensis	20,672	$4,022	$83,152,546
E. coli (STEC) O157	41,454	$9,376	$388,662,679
E-Coli (STEC) non-O157	30,606	$2,266	$69,362,601
Hepatitis A Virus	584	$52,854	$30,887,800
Listeria Monocytogenes	73	$1,797,753	$131,527,034
Norovirus	918	$442	$406,061
Salmonella non-typhoidal	23,778	$6,563	$156,060,310
Salmonella typhoidal	15	$6,504	$98,867
Scombrotoxin	65	$504	$32,800
Tetrodotoxin	1	$14,947	$14,107
Vibrio-parahaemolyticus	1,462	$2,385	$3,486,163
Vibrio-Cholerae	42	$1,520	$63,246
(i) Subtotal/Weighted Average (rounded): Known Pathogens	119,706	$7,220	$864,335,498
(ii) Unidentified/Unspecified Pathogens	478,825	$7,220	$3,457,115,056
(iii) Total cases (i) & (ii) (rounded)	598,531	$7,220	$4,321,450,554
Time Period (Years)			10

Estimated Total Burden of Illnesses from FTL Foods	$43,216,774,918
Present Value (3% discount rate)	$36,864,785,600
Present Value (7% discount rate)	$30,353,654,258
Annualized Value (3%, 10 years)	$4,321,677,492
Annualized Value (7%, 10 years)	$4,321,677,492

2. Public Health Benefits from Averted Illnesses

We estimate public health benefits using the model provided in the IFT report (Ref. [5]). In describing public health benefits related to tracing, the IFT report presents an analysis based on eight outbreaks. Seven of the outbreaks were from *Salmonella* infections and one was from Listeria monocytogenes. Each outbreak provided information on 1) the pathogen associated with the outbreak; 2) the investigation description; 3) the potential improvement from the estimated date of the initiation of traceback to the estimated date of recall or other intervention; and 4) total illnesses and deaths for the duration of the outbreak.

Table 8 below shows the estimated percentage of illnesses prevented assuming 100% product tracing improvement (a hypothetical maximum of instantaneous traceability) during the investigation of these foodborne outbreaks. Table 8 includes results from five of the eight case studies from the IFT report (excluding two involving foods not on the FTL) plus ten additional case studies using epidemic curve data from CDC and investigation and intervention data from FDA as explained in Appendix C of this analysis. The additional cases cover outbreaks associated with four pathogens: Cyclospora, E. coli (STEC), Listeria monocytogenes and non-typhoidal Salmonella.[32]

[32] FTL associated outbreaks caused by these four pathogens represent over 90% of all FTL associated illnesses.

Appendix S of the IFT report describes in detail the analytical process and the applicability of the analysis[33] that we use to estimate the percentage of illnesses that are potentially preventable with the tracing requirements of this rule. We use the same process in estimating the percentage of illnesses potentially prevented assuming FDA had 100% tracing improvement (i.e., instantaneous product tracing) resulting from the tracing requirements from this rule. However, FDA outbreak investigation processes and outbreak data collection have changed since the IFT report. In 2011 the Coordinated Outbreak Response and Evaluation (CORE) Network was created with the purpose of providing a structured process for responding to an outbreak which includes an outbreak response phase that centers on traceback of product, removal of product from the marketplace, and investigation of how the outbreak may have occurred. Due to this established framework, the best consistent date range for post-2011 traceback investigations is the initiation and completion dates of CORE traceability activities, as described in Appendix C.[34] We therefore use "initiation" and "completion" dates provided by CORE in estimating the percentage of illnesses potentially prevented for post-2011 outbreaks. Minimum and maximum preventable illnesses in Table 8 represent variable potential impact of traceability among case studies involving the same pathogen.

[33] In Appendix S of the IFT report, the estimated number of reduced illnesses potentially prevented is calculated by using the epidemic curve data for each associated outbreak. Over the outbreak timeline, the IFT report estimates the number of days (and illnesses) between the initiation of the traceback and the initial or final intervention date (depending on the outbreak). The number of illnesses over the time period is divided by the total number of illnesses during the outbreak to obtain the ratio of illnesses potentially prevented assuming 100% tracing improvement (i.e. instantaneous tracing).

[34] Since each outbreak presents unique circumstances, such as availability of product on the market to recall and the potential for multiple sequential recalls during one outbreak, using the initial date of recall may not represent the best end date to represent the end of traceability activities. The CORE traceback initiation date represents a point in time when traceability activities began, and the CORE traceback completion date represents a point in time in which the traceback activities and interventions such as a recall have ended.

Table 8. Estimated Percentage of FTL Associated Illnesses Preventable with Product Tracing Improvement.

Year	Commodity	Pathogen	Total Illnesses per Epidemic Curve	Preventable illnesses	Percentage of Illnesses That Are Preventable	Source
2008	Hot Peppers	*Salmonella* Saintpaul	1,442	790	55%	IFT report, table 48 and Appendix C
2008	Cantaloupe	*Salmonella* Litchfield	53	1	2%	
2009	Alfalfa Sprouts	Salmonella Saintpaul	235	73	31%	
2010	Shell eggs	*Salmonella* Enteritidis	3,578	120	3%	
2008-2009	Peanut Butter and peanut butter products	*Salmonella* Typhimurium	636	188	30%	CDC (1)
2019	Cantaloupe	*Salmonella* Javiana	163	25	15%	Appendix C
Percentage range of cases prevented for Salmonella		***Average***	***1,018***	***200***	***23%***	
		Minimum	***53***	***1***	***2%***	
		Maximum	***3,578***	***790***	***55%***	
2012	Spinach	E.coli O157: H7	29	4	14%	Appendix C
2016	Alfalfa sprouts	E.coli O157: H7	11	1	9%	Appendix C
2018	Romaine Lettuce	E.coli O157: H7	63	2	3%	Appendix C
2019	Romaine Lettuce	E.coli O157: H7	167	28	17%	Appendix C
Percentage range of cases prevented for E.coli O157:H7		***Average***	***68***	***9***	***11%***	
		Minimum	***11***	***1***	***3%***	
		Maximum	***167***	***28***	***17%***	
2012	Clover sprouts	E.coli O26	29	10	34%	Appendix C
2010	Romaine Lettuce	E. Coli O145	26	0	0%	Appendix C
Percentage range of cases prevented for other E.coli		***Average***	***28***	***5***	***17%***	
		Minimum	***26***	***0***	***0%***	
		Maximum	***29***	***10***	***34%***	
2011	Cantaloupe	*Listeria monocytogenes*	139	69	50%	Appendix C
Percentage range of cases prevented for LM		***Average***	***139***	***69***	***50%***	
		Minimum	***139***	***0***	***0%***[35]	
		Maximum	***139***	***69***	***100%***	

35 We assume zero for a lower bound because we only have one *Listeria monocytogenes* outbreak in this analysis.

Year	Commodity	Pathogen	Total Illnesses per Epidemic Curve	Preventable illnesses	Percentage of Illnesses That Are Preventable	Source
2019	Basil	*Cyclospora cayetanensis*	241	9	4%	Appendix C
2013	Leafy Greens, Cilantro	*Cyclospora cayetanensis*	631	146	23%	Appendix C
Percentage range of cases prevented for Cyclospora		***Average***	***436***	***78***	***13%***	
		Minimum	***241***	***9***	***4%***	
		Maximum	***631***	***146***	***23%***	

(1) https://www.cdc.gov/salmonella/2009/peanut-butter-2008-2009.html

We extend the IFT analysis by including additional pathogens and using multiple case studies per pathogen – with the exception of Listeria monocytogenes – to estimate the average percentage of preventable illnesses by pathogen.

After estimating the number of illnesses that may be prevented with better tracing, we then multiply the percentage range of preventable illnesses from Table 8 by the estimated number of annual illnesses for each pathogen in Table 9. The numbers of annual illnesses below are from the baseline number of illnesses as described in Appendix B, adjusted for unspecified, underreported, and undiagnosed illnesses (Ref. [19] [21]). We believe that accounting for such cases is critical because not all illnesses caused by outbreaks are ultimately documented and attributed to those outbreaks. This approach is consistent with FDA's past regulatory impact analyses . Nevertheless, we recognize the scope for uncertainty in these estimates and request comment on appropriate scaling and adjustment for unattributed illnesses.

Table 9. Estimated Annual Cases of Foodborne Illness That Are Preventable with Product Tracing Improvement

Pathogen	Annual Illnesses	Estimated Annual Preventable Illnesses		
		Primary	Minimum	Maximum
Cyclospora cayetanensis	20,672	2,778	772	4,783
E. coli (STEC) non-O157	41,454	7,147	-	14,295

E. coli (STEC) O157	30,606	3,277	972	5,132
Listeria monocytogenes	73	37	-	73
Salmonella (non-typhoidal)	23,778	5,389	449	13,027
Subtotal	116,583	18,627	2,192	37,309
Unspecified unknowns[25]	466,332	74,509	8,769	149,236
Total	**582,915**	**93,136**	**10,961**	**186,545**

In Table 10, we estimate the burden of foodborne illnesses attributed to FTL foods by multiplying the estimated total annual number of illnesses from Table 9 by the weighted average burden per illness (based on the prevalence of preventable illnesses related to each pathogen). We use the same burden of illness estimates for the selected pathogens as in section E.1.iii. Hence, the columns in Table 10 rely on the primary, minimum, and maximum possible burden of illness for the selected pathogens from our burden-of-illness model.

Table 10.- Annual Benefit Based on 84% Improved Product Tracing Time.

Pathogen	Annual Undiscounted Benefit from Tracing Time Reduction by 84% to 6 Days (Based on Weighted Burden per Illness)[(1)(2)]		
	Primary	**Minimum**	**Maximum**
Weighted burden per illness for four pathogens	$9,257	$4,525	$11,048
Total annual benefit from faster tracing	$722,618,159	$41,570,269	$1,727,263,276

(1) The estimated range of values (primary, minimum and maximum) represent the variability in the valuation of illness per pathogen.
(2) Foodborne Illnesses caused by *Cyclospora Cayetanensis, E. coli* (STEC), *Listeria monocytogenes and* Salmonella (non-typhoidal).

For discounting purposes, we assume that benefits will begin to accrue in year two after the publication date of this rule.[36]

[36] The costs for discounting purposes assume the publication date of the rule is year 0 and that costs will be incurred in year 1 (which is one year before the 2-year effective date). Therefore, we assume benefits will begin to accrue on year 2 (one year after requirements were implemented in year 1).

We estimate the percent improved traceback time resulting from better tracing requirements using information provided by FDA's CORE that includes a case study from the 2019 E. coli Romaine lettuce outbreak (Ref. [27]). The outbreak illustrates the difference in time to identify implicated growers from points of sale (POS) where lot codes were available versus POS where lot codes were not available. For POS where lot codes were available because product packaging from a sample that tested positive and matched the outbreak strain was available from an ill consumer, growers were identified within 24 hours compared to 29 days for those where no lot code information was available (1 day over 29 days would represent a 96 percent improvement). Although every case is unique, this provides an example of how the availability of lot code information at the POS could significantly shorten the time in determining the source of the contaminated product.

Given FDA CORE's combined years of experience in conducting traceback investigations associated with foodborne outbreaks at a national level, it is FDA CORE's expert judgment that access to lot codes and other key data elements throughout the supply chain would likely enable FDA to identify common product sources in about five to seven days, for an average of six days (Ref. [27]).[37] Given that product packaging is often discarded by consumers and not available to outbreak investigators, the five to seven days estimate assumes that the product package would not be available. We use this information to estimate the resulting percent improvement (reduction) based on the median number of days to reach maximum improvement from our sample outbreaks.

[37] This time period does not account for the time needed for the epidemiologic information (i.e., food exposures) provided by public health officials to identify POS clusters and be provided to FDA for tracing. Additionally, this timeframe may vary depending on the complexity of a food's supply chain. For example, if a food is transformed multiple times before it reaches an RFE, more time may be needed to identify source information. However, we account for this in our analysis of outbreak examples as we used the CORE traceback initiation date which represents a clear point in time when traceability activities began.

The average number of days used for identifying a product source without lot codes is about 37 (ranging from about 0 to 86), whereas the average number of days needed to identify a product source from a product with lot codes is six days (ranging between five and seven days). We estimate that the percent improvement that would result from identifying common product sources in five to seven days would range between 81% to 87%. We use the middle estimate of six days which is equivalent to an 84% improvement (Table 10). We estimate that corresponding (undiscounted) public health benefits would range between $42 million and $1.7 billion per year with a primary estimate of $723 million per year. These benefits are slightly underestimated as the annual dollar value of the burden associated with outbreaks caused by these four pathogens represents about 96% of the total annual burden of all FTL associated illnesses. These benefits may also be overestimated due to uncertainty in adjustments accounting for under reported, undiagnosed and unspecified illnesses from all FTL-associated illnesses. We ask for comment on our estimation of health benefits and request comments that would inform improved estimation of these benefits.

3. Benefits from Avoiding Overly Broad Recalls Quantified for Selected FTL Foods

In addition to the public health benefits discussed above, implementation of more precise food recalls may result in social benefits realized by avoiding overly broad recalls when contaminated FTL foods covered by the rule are identified. Market withdrawals and recalls are expensive and commercial distribution of contaminated food can result in economic harm to consumers. In the event of a food recall or market withdrawal, the records required by the proposed regulation may help us to more quickly and accurately locate a violative product that was commercially distributed, which would make conducting a broad recall unnecessary. Costs of conducting a recall or market withdrawal include lost sales (lost retail value of product),

expenses associated with notifying retailers and consumers, collection and shipping costs, disposal costs, and legal costs, among others.[38] In addition to costs of conducting a recall, aggregate costs include spillover costs to shareholders, competitors, wholesalers, retailers and customers. While well-established, profit-maximizing food manufacturers and distributors and retailers may be able to consider in their decisions the costs associated with recalling a product beyond the value of recalled units to include expenses associated with notifying retailers and consumers, collection, shipping, disposal and legal costs; there are spillover or negative externalities associated with a recalled product that may be larger in the aggregate than the losses of the recalled product to the producer.[39]

Although recall of rightly implicated foods is necessary and costly, broad recalls that involve loosely related to unrelated products can make overall recalls extremely expensive. According to a survey of companies conducted by the Grocery Manufacturers Association (GMA), 77 percent of respondents that faced a recall in the past five years estimated the financial impact of the recall to their company to be up to $30 million, with 23 percent reporting even higher costs (Ref. [15]). The GMA study suggests that the average cost of recalls to their members is about $2 billion over a five-year period or an annual loss of about $400 million. These costs represent an estimated fraction of 0.3 percent of the GMA sample's annual revenues and result from business interruption, product disposal costs, customer reimbursement, transportation, investigation, external professional fees, sanitizing production facilities,

38 One of the steps of a recall process involves disposing or destroying the recalled food product. While it may be possible for some companies to recover costs by repurposing their recalled products into pet or animal feed or even fertilizer, this practice is more common with meat producers. In the wake of foodborne illness outbreak-related recalls, repurposing or diverting recalled foods to recover losses is not a conventional response within our review of case studies and pilot projects. To the extent any repurposing does occur, the overall costs from lost retail sales would be defrayed by the value of the repurposed products. We welcome comments on the frequency of such responses by food supply system participants.

39 Jarrel, Gregg; Peltzman, Sam; The Impact of Product Recalls on the Wealth of Sellers. Journal of Political Economy, Vol. 93, No. 3 (1985), pp 512-536.

warehouse costs, decreased sales of the brand name product identified, internal time, and other expenses. This proposed rule, if finalized, may help ensure recalls are conducted in a more precise manner and unnecessary costs to both industry and consumers are mitigated.

We hereby showcase three case studies from recent food recalls covered under the proposed rule. The goal is to estimate the impact of avoiding overly broad food product recalls *to society*, including the impacts on manufacturers, distributors and retailers of their products, other firms in the market, and consumers as well as non-users. Better tracing could substantially reduce the costs from widespread industry losses from an overly broad recall to smaller losses from a targeted recall, particularly when it comes to the costs of lost sales of undifferentiated recalled products like the 2008 tomato recall and the more recent 2018 and 2019 leafy green recalls. Hence, implementation of this proposed rule may help reduce or eliminate the 'spill-over' impact of recalling uninvolved brands, products or industry segments. This can also help ensure that the volume of sales of unrelated products is not affected.

a) Multistate Outbreak of Salmonella Saintpaul Infections Linked to Raw Produce

This 2008 outbreak caused almost 1,500 illnesses and was initially attributed to tomatoes, leading to a recall. The warning for the 2008 tomato recall covered all red Roma, red plum and red round tomatoes and any other products containing these raw, red tomatoes.[40] Consumers began to avoid not only the tomatoes included in the warning, but also all other varietals of tomatoes as well. Even though the FDA explicitly stated that some varieties were safe, many stores removed them from their

40 Press Release, FDA, FDA Warns Consumers Nationwide Not to Eat Certain Types of Raw Red Tomatoes (June 7, 2008) [hereinafter FDA Recall June 7].

shelves and customers began ordering their customary dishes at restaurants without tomatoes.[41] Of the sixteen traceback investigations initiated by FDA, four were discontinued due to lack of records and the remaining 12 tracebacks resulted in no common growing region, grower, or supplier. Challenges to the tracebacks included lack of standardized product documentation throughout the supply chain, difficulty in linking incoming to outgoing shipments, repacking of product, and comingling of tomatoes. Standardized traceability documentation and linking of shipments throughout the distribution chain would have decreased the time to complete the tracebacks and provided timely information that there was no common source of tomatoes (Ref. [28]). Ultimately the source of the outbreak was later attributed to jalapeño and serrano peppers produced in Mexico (Ref. [29]). The investigation showed that jalapeño peppers were a major source of contamination and that serrano peppers also were a source.[42] Although the recall of red tomatoes and tomato products was later lifted, the negative impact on red tomatoes and tomato products significantly affected their sales volumes at the time. In fact, costs to the Florida tomato industry alone were estimated to be more than $100 million. In Georgia, the costs to the tomato industry came close to $14 million.[43]

41 *Salmonella scare hold the tomato*, Chicago Tribune (Illinois), June 10, 2008. https://www.chicagotribune.com/news/ct-xpm-2008-06-10-0806090798-story.html
42 Multistate Outbreak of Salmonella Saintpaul Infections Linked to Raw Produce (FINAL UPDATE) Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) Posted August 28, 2008 https://www.cdc.gov/salmonella/2008/raw-produce-8-28-2008.html
43 Reginald L. Brown testifying before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health, 110th Cong. 2nd sess., July 31, 2008, http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.073108. Brown-Testimony.pdf; "FDA tomato alert costly to Georgia producers" Southeast Farm Press, September 4, 2008, http://southeastfarmpress.com/vegetables-tobacco/salmonella-warning-0905/index.html.

b) Outbreak Investigation of E. coli: Romaine (November 2018- February 2019)

On November 20, 2018, FDA issued a public advisory in response to a multi-state outbreak of *E. coli* O157:H7 linked to romaine lettuce and advised against eating any romaine lettuce on the market at that time. As a result, producers and distributors voluntarily withdrew the product from the market. FDA performed a traceback investigation to determine the source of the romaine lettuce; however, at the time of the public advisory, FDA did not have enough traceback information to identify the source of the contamination that would allow conducting a targeted recall. The most efficient way to ensure keeping contaminated romaine off the market was for industry to voluntarily withdraw product from the market, and to withhold distribution of romaine while FDA and state partners conducted a traceback investigation to determine whether a common supplier or source of contamination could be identified. By December 13, 2018, FDA was able to refine the traceback investigation implicating one farm in Santa Barbara which promptly recalled red leaf lettuce, green leaf lettuce and cauliflower harvested on November 27, 2018, through November 30, 2018.[44] On February 13, 2019, FDA completed its investigation. At the conclusion of the outbreak, a total of 62 cases (with 25 hospitalizations and no deaths) in 16 states and Washington DC were associated with this outbreak.[45] Better traceback data would have allowed FDA to identify the implicated farm in Santa Barbara more quickly, such that a broad market withdrawal of all romaine lettuce might not have been necessary.

44 https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-romaine-november-2018

45 People Infected with the outbreak strain of E. Coli O157:H7, by date of illness onset. https://www.cdc.gov/ecoli/2018/o157h7-11-18/epi.htmlhttps://www.cdc.gov/ecoli/2018/o157h7-11-18/epi.html

c) Outbreak Investigation of E. coli: Romaine (November 2019- January 15, 2020)

In November 2019, FDA, along with CDC, U.S. Department of Agriculture's Food Safety Inspection Service (FSIS) and state health authorities, investigated an outbreak of 167 illnesses of *E.coli* O157:H7 associated with salads containing romaine lettuce. The Maryland Department of Health identified a positive sample of romaine lettuce used in a chicken Caesar salad kit. The contaminated romaine lettuce was supplied by farms in Salinas, CA. As a result of this positive sample, all chicken Caesar salad kits containing the positive lot were recalled. Simultaneously, FDA was investigating two additional outbreaks of *E. coli* O157:H7 associated with romaine lettuce and a chopped salad kit containing romaine lettuce. Based on traceback data available initially, FDA requested that industry voluntarily withdraw romaine grown in Salinas from the market and is requesting that industry withhold distribution of Salinas romaine for the remainder of the growing season in Salinas. This was a broad market withdrawal, because a significant portion of the romaine lettuce consumed in the United States is grown in Salinas; however, due to a lack of more specific traceback information, this was the most efficient way to ensure that contaminated romaine was off the market (Ref. [27]).

We therefore define as a benefit the foregone recall costs incurred by manufacturers, producers, distributors and retailers from inadvertently being part of a broad scope or undifferentiated product recall. To provide some examples of the magnitude of such potential benefits, we estimate the foregone recall costs for three commodities: Romaine lettuce, fresh salad kits, and fresh tomatoes. We use supermarket scanner data to estimate average sales per product during a 4-week sales period and a 13-week sales period. We assume the estimated cost

of one product recall is based on the average foregone sales for said product during the recall period (Columns A and B in Table 11).[46] We choose the time periods assuming four weeks is the shortest length of a class I recall (our best-case scenario) and 13 weeks as the longest length for a class I recall (our worst-case scenario)[47]. We then use the same data to estimate the sum of product sales within the same product class for the same four- and 13-week periods (Columns C and D in Table 11). We estimate the difference in sales between a targeted recall versus a broad recall as the value of foregone product sales during one recall event (Columns E and F in Table 11). The low and high difference in retail sales in columns E and F represent the estimated low and high foregone sales of products that were not sold due to a recall.

Table 11. Difference in retail costs between one average product and sum of product category sales (2018 $)

Category	Average Product Sales		Total Category Sales		Retail Sales Difference	
	*(A) Low estimate **	*(B) High estimate ***	*(C) Low estimate **	*(D) High estimate ***	*(E) Low estimate **	*(F) High estimate ***
Pre-cut Fresh Salad Mix	$358,396.38	$1,176,222	$374,882,618	$1,230,328,243	$374,524,222	$1,229,152,021
Fresh Lettuce-Romaine	$538,640	$1,768,684	$73,254,986	$240,541,021	$72,716,346	$238,772,337
Fresh Tomatoes	$111,534	$403,500	$118,226,323	$427,710,361	$118,114,788	$427,306,860
Jalapeño & Serrano Peppers	$4,970	$19,180	$118,226,323	$427,710,361	$118,221,352	$427,691,181
Sum	$1,013,541	$3,367,586	$684,590,249	$2,326,289,985	$683,576,709	$2,322,922,399

**Low estimate based on 4-week sales ending 09-27-2014*
***High estimate based on 13-week sales ending 09-27-2014*

46 A.C. Nielsen *Scantrack* data for 52 weeks ending on 09-27-2014.
47 Luis A. Ribera, Marco A. Palma, Michel Paggi, Ronald Knutson, Joseph G. Masabni, and Juan Anciso, Economic Analysis of Food Safety Compliance Costs and Foodborne Illness Outbreaks in the United States, *Hort. Technology*, Vol 22. No. 2 (2012), pp 150 – 156.

To arrive at total costs of a broad recall (columns G and H in Table 12), we multiply the low and high values from columns E and F in Table 11, above, by 2.5 to account for the estimated number of produce outbreaks per year.[48] We do not account in this analysis for costs of a recall beyond the retail value of the recalled product and request comments on this estimate.[49, 50] Total costs of a broad recall in columns G and H include spillover costs of a broad recall, including the amount over what a narrower recall cost should have been (columns I and J in Table 12). The difference between conduct of broad recalls and conduct of targeted recalls is estimated in columns K and L in Table 12 as the difference between total costs of a broad recall (columns G and H) and costs of a narrower recall (columns I and J).

Table 12. Difference Between Broad and Narrow Recall Costs (millions 2018 $)

Category	Total costs of a broad recall		Total costs of narrower recall		Social benefit of a targeted recall	
	(G) Low estimate *	*(H) High estimate* **	*(I) Low estimate* *	*(J) High estimate* **	*(K) Low estimate* *	*(L) High estimate* **
Pre-cut Fresh Salad Mix	$1,049	$3,442	$1	$2	$1,048	$3,440
Fresh Lettuce-Romaine	$204	$669	$1	$3	$203	$666
Fresh Tomatoes	$331	$1,196	$0	$1	$331	$1,196
Serrano Peppers	$331	$1,198	$0	$0	$331	$1,198
Sum (undiscounted)	$1,914	$6,504	$1	$5	$1,913	$6,499

48 From FDA outbreak data we estimate an average of approximately 7.3 leafy green/fresh cut related outbreaks per year and three produce related outbreaks per year over an 11-year period (from 2010 to 2019). We also estimate an average of two outbreaks from tomato, romaine, and other leafy greens combined over the same 11-year period using publicly available data. We use the median calculation between two (using publicly available data) and three (from FDA data) to obtain 2.5 outbreaks per year.

49 Ashley Kern, Dari Duval, George Frisvold, Arizona Leafy Greens: Economic Contributions of the Industry Cluster, *2015 Economic Contribution Analysis*, Agricultural & Resource Economics-University of Arizona: College of Agriculture and Life Sciences, (2017).

50 In addition to the value of recalled units, costs associated with a recall would have included expenses associated with notifying retailers and consumers, collection, shipping, disposal and legal costs among others. On the other hand, some portion of total sales value is not lost in a recall situation; for example, part of a grocery item's price represents the opportunity cost of shelf space, and that shelf space can be re-allocated to non-recalled product.

Implementation of the proposed regulation would likely result in a reduction of the number of recalled or withdrawn products. These estimates only account for the annual difference in costs of avoiding broad recalls for three commodities for which we have reliable data and therefore represent the minimum range of potential benefits from this rule. Additional estimated benefits from reduced recall costs could be expected by including estimates for other recalled commodities. Other benefits from replacing broad recalls with more targeted recalls would include reduced costs and resources used by government in terms of conducting outbreak investigations and recalls for a broader set of products beyond those implicated in an outbreak or a recall. There are no benefits from removing unimplicated products from the market.

It is possible, but not certain, that both these narrowed-recall benefits and the health and longevity benefits discussed earlier separately or jointly could be experienced to the extent quantified in this regulatory impact analysis. It is also possible, on the other hand, 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. We request comment on these estimates.

4. Other Benefits

There are additional benefits that may arise if this proposed rule is finalized. These include:

- Avoidance of costs due to unnecessary preventive actions by consumers;
- More expedient initiation and completion of recalls;
- Improvements in supply chain management and inventory control;

- Other supply system efficiencies due to a standardized approach to traceability, including an increase in transparency and food system trust among food supply system participants and potential deterrence of fraud.

Broad and long recall windows and not promptly initiated recalls and market withdrawals and advisories result in additional costs to FDA and industry and may force consumers to take unnecessary preventive actions. Such costly preventive measures by consumers may involve throwing away food, stopping their consumption of the suspect food item, or visiting physicians or emergency rooms to determine if they have been exposed to a pathogen.

Without having prompt access to records that provide timely information, FDA, state, and local authorities might spend additional time and resources on tracing the source of an outbreak, initiating broad recalls, and communicating to industry and consumers. The traceability records required by this rule may help in initiating recalls earlier and shortening recall periods, which can significantly reduce the costs associated with management and support of recall activities. Shorter recall periods may also mitigate the loss of future product sales by shortening the length of negative publicity these products received because of longer recalls.

Another benefit that may be realized should this rule be finalized relates to improved rate of recovery for contaminated products. When recall orders are issued and include a precise list of products suspected to be contaminated, the rate of recovery of this product may be substantially improved under traceability rule. The ability to precisely identify the lot numbers, production dates and other related information may help those collecting the product achieve a higher recovery rate than would be otherwise achievable in situations where robust traceability is unavailable. The Blue Bell ice cream recall is a good example. Since it took so long to be able to identify the contaminated products and the recalls were issued in piecemeal, the rate of recovery

was only less than ten percent. Of the 492,611,698 Blue Bell products recalled because of Listeria contamination, only 39,099,448 (or about 8 percent) were recovered and successfully destroyed (Ref. [30]).

Finally, other benefits may include supply chain management improvements, increase in transparency and food system trust, and potential deterrence of fraud. The latter benefits may be realized through a reduction in fraudulent activity or an exit from the market by some because of increased accountability due to more standardized, improved traceability.

F. Costs of the Proposed Rule

We considered baseline food traceability practices of all covered entities (firms or establishments) and estimated the incremental costs related to changes in these practices required by the proposed rule, if finalized. We estimate the following costs of the proposed rule to industry:

- one-time labor costs of reading and understanding the rule;
- one-time capital investment costs of redesigning or upgrading systems to establish, maintain, and transmit records;
- one-time costs of training personnel to implement new recordkeeping systems and establish and maintain records; and
- recurring costs of establishing, maintaining, retaining, and transmitting additional records required by this proposed rule.

For discounting purposes, we assume the publication date of the rule is year zero and that costs will be incurred in year one (which is one year before the two-year compliance date)[51].

1. Main Assumptions of Cost Analysis

We estimate that the costs of this proposed rule, if finalized, would largely arise from recordkeeping requirements, which represent new and substantive responsibilities for covered entities. Using the current version of the FTL, we identify the entities and food supply system sectors affiliated with covered foods. Because each provision of the proposed rule would require different entities within the food supply system to establish and maintain different sets of records and key data elements, we list estimated costs by provision. First, all covered entities must establish and maintain the general traceability records as outlined in § 1.1315. The following provisions, described in more detail in the sub-sections below, apply differently to entities depending on whether they grow, receive, transform, create, and/or ship foods on the FTL. If an entity performs more than one of these activities, it must keep the records required by all relevant provisions.

The total cost of each statutory requirement thus depends on the number of entities affected and the additional burden of each requirement relative to baseline practices. In this proposed rule, FDA specifies the records and information a covered entity must keep but does not specify the form or system in which those records should be maintained. We expect that, to the extent possible, firms would satisfy new recordkeeping requirements using their existing systems or invest in upgraded systems or technology. Furthermore, we assume that firms would

51 The year of publication is year zero and the effective date is year two. For manufacturers to comply with the requirements of this rule by the effective date (year two), we assume they will begin to incur compliance costs in year one.

comply with new recordkeeping requirements by modifying existing shipping or purchase records such as Advance Shipping Notices, Bills of Lading, Invoices, or Purchase Orders.

Moreover, we recognize that some entities may already follow certain recordkeeping practices as part of their baseline business practices. These entities include those covered by the Subpart J provisions as well as those following certain industry conventions and best practices. The likelihood of an entity already adhering to certain recordkeeping practices depends on its size, industry, and position in the food supply system. Because we lack data to separate the entities already in full or partial compliance from those who must come into compliance, our analysis uses a range to account for this uncertainty.

Finally, as discussed in the baseline section and in further detail below, certain entities covered by the proposed rule may be exempt or partially exempt from new recordkeeping requirements. From all our cost estimates below, we exclude those farms and other small originators that would be fully exempt from the proposed rule because of their very small size. Some entities or types of products are partially exempt, which we describe in further detail below. Of these partially exempt entities, we exclude farm-to-school and farm-to-institution entities from our cost estimates because we do not expect these entities to change their current practices due to the proposed rule. We do not consider in our cost estimates how many entities covered by the proposed rule transact partially exempt foods (for example, those sold from farms directly to retail food establishments) because we lack such detailed data.

We conduct our analysis by provision to parallel the structure of the proposed rule. It covers a ten-year horizon following the proposed rule's compliance date, and we assume all one-time costs occur in year one. All wage rates come from the Bureau of Labor Statistics, Occupational Employment Statistics (OES), May 2018, National Industry-Specific Occupational

Employment and Wage Estimates. Hourly wage rates are estimated by doubling the OES reported mean wage to account for benefits and overhead, in accordance with Department of Health and Human Services guidelines (Ref. [25]).

2. Costs of Reading and Understanding the Rule

Covered entities would incur one-time costs at the firm level to read and understand the proposed rule. To estimate the number of firms affected by this provision, we use the 2016 SUSB data (Ref. [31]). We first identify the 2012 NAICS categories of firms that likely manufacture, process, pack or hold foods on the FTL (Table 13). Because not all firms in each NAICS category would be affected by this proposed rule, we remove non-covered firms namely exempt firms and those that we estimate do not likely manufacture, process, pack or hold foods on the FTL. We estimate that 422,144 firms would be affected by the proposed rule and would thus need to read and understand the rule, if finalized. Our lower and upper bounds range from 224,679 to 636,809 firms. We request comment on these estimates.

Table 13. NAICS Categories Likely to Manufacture, Process, Pack, or Hold Foods on the Food Traceability List

2012 NAICS	Category
111219	Other Vegetable (except Potato) and Melon Farming
111339	Other Noncitrus Fruit Farming
111419	Other Food Crops Grown Under Cover
112310	Chicken Egg Production
112511	Finfish Farming and Fish Hatcheries
112512	Shellfish Farming
114111	Finfish Fishing
114112	Shellfish Fishing
311340	Nonchocolate Confectionery Manufacturing
311351	Chocolate and Confectionery Manufacturing from Cacao Beans
311352	Confectionery Manufacturing from Purchased Chocolate
311411	Frozen Fruit, Juice and Vegetable Manufacturing
311412	Frozen Specialty Food Manufacturing
311421	Fruit and Vegetable Canning
311422	Specialty Canning

311423	Dried and Dehydrated Food Manufacturing
311513	Cheese Manufacturing
311520	Ice Cream and Frozen Dessert Manufacturing
311710	Seafood Product Preparation and Packaging
311811	Retail Bakeries
311812	Commercial Bakeries
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing
311821	Cookie and Cracker Manufacturing
311824	Dry Pasta, Dough, and Flour Mixes Manufacturing from Purchased Flour
311911	Roasted Nuts and Peanut Butter Manufacturing
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing
311942	Spice and Extract Manufacturing
311991	Perishable Prepared Food Manufacturing
424410	General Line Grocery Merchant Wholesalers
424420	Packaged Frozen Food Merchant Wholesalers
424430	Dairy Product (except Dried or Canned) Merchant Wholesalers
424450	Confectionery Merchant Wholesalers
424460	Fish and Seafood Merchant Wholesalers
424480	Fresh Fruit and Vegetable Merchant Wholesalers
424490	Other Grocery and Related Products Merchant Wholesalers
445110	Supermarkets and Other Grocery (except Convenience) Stores
445120	Convenience Stores
445220	Fish and Seafood Markets
445292	Confectionery and Nut Stores
445230	Fruit and Vegetable Markets
445291	Baked Goods Stores
445299	All Other Specialty Food Stores
447110	Gasoline Stations with Convenience Stores
452910	Warehouse Clubs and Supercenters
454111	Non-store Retailers: Electronic Shopping
454210	Vending Machine Operators
493110	General Warehousing and Storage
493120	Refrigerated Warehousing and Storage
493130	Farm Product Warehousing and Storage
722310	Food Service Contractors
722320	Caterers
722330	Mobile Food Services
722410	Drinking Places (Alcoholic Beverages)
722511	Full-Service Restaurants
722513	Limited-Service Restaurants
722514	Cafeterias, Grill Buffets, and Buffets
722515	Snack and Nonalcoholic Beverage Bars

The preamble and draft regulatory text of the proposed rule contains approximately 44,000 words. Per HHS guidelines on reading speed (Ref. [25]), we estimate that an adult reads 200 to 250 words per minute, with an average speed of 225 words per minute. We divide the number of words in the preamble and codified by reading speed, producing an estimate of 3.3 hours (= 44,000 / 225 / 60) to read the rule, with a lower bound of 2.9 hours (= 44,000 / 250 / 60) and an upper bound of 3.7 hours (= 44,000 / 200 / 60). We expect that one employee responsible for reading the rule would be a supervisor or manager and request comment on the number of employees who might read the rule per firm. The mean wage of a supervisor or manager is $18.75 per hour, doubled to $37.50 to account for benefits and overhead. We obtained this wage information from the 2018 BLS wage data for Office and Administrative Support Occupations.

We thus estimate that the one-time labor cost of reading the rule is approximately $122 per covered firm (= $37.50 x 3.3), with a lower bound of $110 (= $37.50 x 2.9) and an upper bound of $138 (= $37.50 x 3.67). For all firms covered by the provision, the total labor cost of reading the rule is $51.6 million (= 422,144 x $122), with a lower bound of $24.7 million (= 224,679 x $110) and an upper bound of $87.6 million (= 636,809 x $138). We request comments on these estimates. Table 14 summarizes the estimated costs of reading and understanding the proposed rule.

Table 14. One-time Costs of Reading and Understanding the Proposed Rule (2018$)

	Primary	Low	High
Number of affected firms	422,144	224,679	636,809
Average reading speed (words per minute)	225	250	200
Word count of proposed preamble and codified	44,000	44,000	44,000
Employee hourly wage rate	$37.50	$37.50	$37.50
Hours to read	3.3	2.9	3.7
Per firm cost	$122	$110	$138
Total one-time cost of reading and understanding the rule	$51,595,417	$24,714,642	$87,561,214

3. Costs of Capital Investment

We expect the number of firms that may incur costs from capital investment to equal to the number of firms required to read and understand the proposed rule. However, as discussed above, some entities may be able to comply without additional capital investments, while others would need to invest in traceability-related capital. Case studies of prior traceback efforts in 2012 and earlier show a wide range of existing tracing capabilities across sectors and firm size (Ref. [5]). For example, according to the 2012 IFT study of pilot projects for improving product tracing, selected large growers, distributors, and processors already had the capacity to scan KDEs, while only 30-50 percent of selected small distributors, small processors, and large retailers had this capability at that time. Among the 22 entities surveyed, those that reported standardized naming capabilities ranged from 0 to 100 percent, indicating that some companies had no standardized names, while others had partially or fully standardized nomenclature. In general, traceability technologies, adoption, and implementation have continued to expand since 2012, supported by efforts in multiple industries to integrate standards like those of GS1 into common practice.[52]

Capital investment may include food traceability software, scanners or barcode readers, barcode printers, and increased data storage (hard disk or cloud storage) to handle the increased recordkeeping requirements of the proposed rule. These investments would depend on a firm's size, role in the supply chain, products, and existing traceability systems, as well as whether the firm decides to adopt an electronic recordkeeping system as a result of this rule (although the rule does not require electronic maintenance of records).

52 See, for example, the Produce Traceability Initiative (https://www.producetraceability.org/), the International Dairy-Deli-Bakery Association (https://www.iddba.org/initiatives/industry-initiatives/food-traceability), and the National Fisheries Institute (https://www.aboutseafood.com/traceability-and-sustainability-in-the-supply-chain-4/).

The following table summarizes baseline costs of operating product traceability systems and the additional investments related to specific system improvements, as reported by the 2012 pilot project participants (Ref. [5]).[53] They reported that the total costs for systems currently in place to capture KDEs at baseline range from tens of thousands to millions of dollars. The costs of additional improvements in traceability would range from no cost to hundreds of thousands of dollars.

Table 15: Current and additional costs of traceability-related investments, as reported by selected entities (Ref. [5])

Type of firm	Large Grower	Large Processor	Small Processor	Large Distributor	Small Distributor	Large Retailer
Number of firms surveyed	3	4	3	4	4	4
Baseline cost to capture KDEs (manual or electronic)	$350,000-$4.5M	$500,000-$1.2M	$250,000-$800,000	$50,000-$1M	$40,000-$1.5M	Unknown
Additional costs by activity						
Incoming KDEs by electronic data messages	Unknown	Unknown	Unknown	Unknown	$0-$15,000	Unknown
Supply chain link	$0-$65,000	$0-$60,000/year	Unknown	Unknown	$0-$150,000	Unknown
Standardized naming	$0-$500,000	Unknown	Unknown	$0-$80,000	$5,000-$150,000	Unknown
Outgoing KDEs electronic to customers	$2,000-$5,000	Unknown	Unknown	$0	Unknown	N/A
Provide data summary	Unknown	$0-$2,000	$0	$0	$0-$10,000	N/A

[53] For further presentation of cost estimates that are higher than those discussed elsewhere in this document, please see column (b) of Tables 3a and 3b.

Incoming lot number information	N/A	$0-$60,000/year	$0	$0	$0-$150,000	Unknown

These estimates reported above provide some insight into the types of capital investment costs surveyed companies needed to improve traceability systems in 2012, such as conversions to standardized naming and provision of data to supply chain partners. Importantly, not all entities expected to make the same types of investments, and some entities, like large distributors, already had the capability to integrate additional traceability practices into existing systems. While we expect such variability to exist today, we ask for comments on capital investment costs that would be required as a result of this proposed rule.

There are several important considerations for interpreting the costs from this report and applying them to the proposed rule. First, the report surveyed selected companies about costs to update system-wide traceability operations. Companies may have also accounted for training and system integration costs, in addition to capital, in their estimates. Moreover, these estimates pertained to pilot projects using specific food products, tomatoes and processed foods. Because the proposed rule identifies a specific list of foods for enhanced tracing, we expect that companies are unlikely to overhaul their existing systems; in other words, the incremental costs of complying with the proposed rule may be significantly less than the cost of a total system upgrade, particularly because we believe many traceability systems are already in place.

Second, entities surveyed in the report are not fully representative of sectors and sizes affected by the proposed rule. Most entities reported that they invested in and improved their tracing systems in the five years prior to the 2012 report (Ref. [5]). The reported costs came from large companies, which likely rely on relatively sophisticated systems. For example, the large growers surveyed were in the top two percent of the industry in terms of revenue, and no costs

were provided for small and medium growers. The survey also excludes small retailers, which represent the majority of entities affected by the proposed rule. The study contacted fifteen small businesses from unreported sectors, most of which reported that their existing tracing capabilities sufficed and that additional investments would be costly. Others had already invested in tracing networks that rely on standardized nomenclature.

Third, competition among providers of traceability products and services is likely to produce lower costs over time (Ref. [32]). Indeed, since the time of the 2012 pilot project report, technology and vendors have evolved to provide new traceability solutions, software, and off-the-shelf packages that were not available to companies until recent years. Today companies have access to new tools like web-based systems and blockchain subscriptions.[54] For example, web and mobile platforms are now able to streamline links between retailers and their wholesale suppliers.[55] Equipment has also become more accessible and lower-cost. As an indication of this trend, compared to the reference year of 2007, the consumer price index for computers, peripherals, and smart home assistants decreased from 74 percent in December 2010 to 38 percent in January 2020.[56]

Due to these considerations, we assume that larger entities, such as distribution centers, are more likely to already have sophisticated systems that can adapt to accommodate foods affected by the proposed rule. These entities may face incremental costs related to this system integration as well as increases in printing needs and additional equipment. We assume that these costs for larger firms are likely to be a fraction of the ranges reported in the table above.

54 See, for example, IBM's Food Trust: https://www.ibm.com/blockchain/solutions/food-trust.
55 See, for example, BlueCart: https://welcome.bluecart.com/.
56 U.S. Bureau of Labor Statistics, Consumer Price Index for All Urban Consumers: Computers, Peripherals, and Smart Home Assistants in U.S. City Average [CUSR0000SEEE01], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/CUSR0000SEEE01, June 18, 2020.

To better understand potential incremental capital investment costs related to the proposed rule for small- and medium-sized firms, as opposed to complete system upgrades for large firms described above, we compiled information on selected products from the literature and vendors in the table below. We ask for comments and request information that could help us improve our estimates.

Table 16: Examples of incremental capital investment costs related to the proposed rule

Type of capital investment	Cost (Mejia et al., 2010)	Cost (2013-2020)
Non-RFID mobile and desktop printers	$400-$1,500*	$140-$1,500 [abc]
RFID mobile and desktop printers	$400-$1,500*	$1,500 - $5,100 [bc]
Industrial printers	N/A	$180-$7,100 [abd]
Labels	$0.005-$0.255/label	$0.004-$0.006/label [abe]
Handheld mobile computers	$800	$13-$7,000 [abc]
Barcode scanners	$400-700	$15-$2,000 [abc]
Software licenses and data hosting for small-medium company (bundled and web-based)	$1,500-$5,000	$1,500-$5,000 [bfc]
Barcode printing software	$90	$0-$30 [bg]

*Range does not distinguish between non-RFID and RFID.
[a] https://www.thermalprinteroutlet.com/; [b] https://www.barcodegiant.com/; [c] https://lowrysolutions.com/; [d] https://www.propacksolutions.com/; [e] GS1 (2013); [f] https://pricingnow.com/; [g] http://www.ptiprint.com/

This table is intended to provide estimates of primary capital expenditures; we lack the information that would allow us to compile an exhaustive list of itemized costs. As noted above, we believe not all entities would need to make the same types of investments, depending on their sector and size. For example, we expect that independent retailers and restaurants may be increasingly reliant on their suppliers to capture much of the information required by the proposed rule; we request comment on this assumption (U.S. Food and Drug Administration, 2020). Moreover, some entities may already have the resources they need to comply with the proposed rule while others will incur additional costs.

Nevertheless, the table shows that the range of costs has widened over time due to greater product variety, including more affordable options at the low end. For example, (Ref. [33]) report that barcode scanners once ranged from $400-$700; in 2020, scanners ranged from $15-$2,000, depending on the level of sophistication needed. Costs of other products, such as software licenses and data hosting, remained relatively constant over time though these products have likely improved in quality. Some companies may also have access to free or paid updates to existing software. We believe necessary investments are likely to vary depending on supply chain role. For example, we expect retailers would likely need mobile computers and scanners but not labeling equipment, while growers, transformers, and shippers would likely need labeling equipment as well.

To comply with the proposed rule, we assume that smaller operations involved may require relatively limited additional investments, such as a desktop shipping label printer and a scanner connected to a laptop with label software (Ref. [34]). Using the sources in Table 16 above, a small entity could purchase a standard printer, scanners, and labels for roughly $300, which could be coupled with free web-based barcode software. A standalone traceability bundle included label design software with license, label printing, barcode printer, and starting labels for approximately $1,000.[57]

Using the sources above, a medium-sized entity could purchase an industrial printer, mobile data capture computer, network label print server, and labels for approximately $7,000. For roughly $6,500, a firm could purchase a kit including a mobile computer, barcode printer, set of labels, software and licenses.[58] In 2020, licenses for web-based enterprise management

57 https://www.redlineforproduce.com/products/low-cost-label-compliance
58 https://b2b.lowrysolutions.com/shop/product/aidc-pos/pos-solution-bundles/wasp-barcode-technologies/633808391362/24529041/1

systems that capture, order, receive, transform, and ship ranged from $1,500 to $5,000. (Ref. [35]) reported that a small-medium grower could expect to make $3,000 in hardware investments and $2,000-$3,000 in software and licensing to upgrade traceability systems.

To account for this considerable uncertainty in investments by firm and sector, we assume a wide range of existing tracing capabilities and treat non-restaurants and restaurants differently. For non-restaurants, we assume that 50 percent of covered firms would incur capital investment costs, with a lower bound of 25 percent and an upper bound of 75 percent. For restaurants, we assume that most would rely on suppliers to provide the necessary records, such that only 5-15 percent of restaurants would need to make their own capital investment as a result of rule, if finalized. We therefore estimate that 96,644 firms would incur costs of capital investment, with a lower bound of 21,547 firms and an upper bound of 229,597 firms. We request comment on these estimates of existing tracing capabilities. We also request comment on our approach to estimate costs at the level of firm, rather than establishment.

Because the majority of entities affected by the proposed rule are small- and medium-sized firms, we assume that the overall range of additional investment needed skews toward these firms. Considering variation in needs across firms' sector, size, and existing capabilities and synthesizing recent industry reports and vendor estimates with input from subject matter experts (Ref. [34]), we assume that an affected covered firm would spend between $500 and $25,000 on all additional capital investments to comply with the proposed rule, with a primary estimate of $7,500. We recognize that there is scope for substantial variability in investment and request comment on these assumptions. Specifically, we request comment on capital investment costs by firm sector, size, and existing capabilities. We also note that, in subsequent sections, this

analysis accounts separately for labor costs and costs of establishing and maintaining records for each provision.

To obtain the one-time capital investment costs of the proposed rule, we multiply the capital investment cost per firm by the total number of affected firms. The one-time capital investment costs of the proposed rule are thus $724.8 million (= 96,644 x $7,500), with a range of $10.8 million (= 21,547 x $500) to $5.7 billion (= 229,597 x $25,000). Table 17 presents a summary of the estimated capital investment costs of the proposed rule.

Table 17. One-time Capital Investment Costs of the Proposed Rule (2018$)			
	Primary	Low	High
Number of affected firms	96,644	21,547	229,597
Per firm cost	$7,500	$500	$25,000
Total one-time capital investment costs	$724,832,681	$10,773,308	$5,739,919,519

4. Costs of Training in New Traceability Practices

All firms covered by the general records provision would incur one-time costs to train employees and managers in new food traceability practices. These costs may include hiring a food traceability subject matter expert to train staff in person or via web seminars and the costs of producing training materials. We assume that the number of firms affected by these training costs is equal to the number of firms affected by capital investment costs. We therefore estimate that 96,644 firms would incur these costs, with a lower bound of 21,547 firms and an upper bound of 229,597 firms.

The labor cost of training depends on its duration and number of participants. Previous case studies from 2012 contain little information on the labor cost of training employees on new traceability systems and practices (Ref. [5]). One major food service chain with 20,000 restaurants reported a training cost of $100 per restaurant, but did not specify what this training

involved. One software provider reported a training cost of $1,000 per day, stating that the number of days could vary based on the size of the operation and nature of changes to processes. Other entities did not include separable training costs when reporting costs of capital investment, suggesting that the labor cost of training may be unknown, included in capital investment (such as a software package that includes training), or that new traceability training may replace current training that becomes obsolete.

We therefore assume that some covered firms may need to conduct new education of key personnel in traceability practices. This training will prepare firms to adapt their systems and identify necessary capital investments. We expect operational changes on a day-to-day basis to be disseminated through ongoing meetings and trainings, such that firms will not face additional costs of training all employees. We request comment on this assumption.

We use an industry-standard online training[59] as a proxy for the cost of additional training and assume that between one and five key supervisors or managers responsible for guiding traceability practices per firm will undergo this training. We recognize that needs may vary across firms and request comment on this assumption. For a half-day training, the cost ranges from $450 for one employee to $2,125 for five employees, with a primary estimate of $1,350 for three employees. We also account for the cost of labor time spent in training. Using the 2018 BLS wage data for Office and Administrative Support Occupations, the time cost of labor is equal to the hourly wage of these employees is $37.50, doubled to account for benefits and overhead (= $18.75 x 2).

Accounting for the cost of training as well as the labor cost of trainees, we estimate that the one-time training costs per firm are approximately $1,800 (= $1,350 + (4 x 3 x $37.50)), with

[59] We use the GS1 Standards for Food Traceability Online Certificate Course.

a lower bound of $600 (= $450 + (4 x 1 x $37.50)) and an upper bound of $2,875 (= $2,125 + (4 x 5 x $37.50)). The total one-time training costs of the proposed rule for all firms are thus $174 million (= 96,644 x $1,800), with a lower bound of $13 million (= 21,547 x $400) and an upper bound of $660 million (= 229,597 x $2,875). We request comments on these estimates. Table 18 presents a summary of the estimated training costs of the proposed rule.

Table 18. One-time Costs of Training in New Traceability Practices (2018$)			
	Primary	Low	High
Number of affected firms	96,644	21,547	229,597
Hours to train	4	4	4
Cost of training	$1,350	$450	$2,125
Trainee (employee) hourly labor cost	$37.50	$37.50	$37.50
Number of trainees per firm	3	1	5
Per firm cost	$1,800	$600	$2,875
Total one-time training costs	$173,959,861	$12,928,972	$660,083,977

5. Recordkeeping Requirements

The proposed rule, if finalized, would require certain persons to establish and maintain records related to the growing, receiving, transforming, creating, and shipping of FTL foods. We estimate the new costs of each recordkeeping requirement, taking into account such persons' current recordkeeping practices. Relevant records contain KDEs associated with different CTEs in a food supply system. These required records and data elements, which vary across the types of entities in the food supply system, are described in detail below.

To estimate the recordkeeping costs of the proposed rule, the time to perform the various recordkeeping functions, the frequency of recordkeeping by record type, and the average time spent keeping records by record type, we use several sources, including industry standards such as the Global Data Synchronization Network, Institute of Food Technologists publications, along with FDA's Evaluation of Recordkeeping Costs for Food Manufacturers. As in previous

sections, all wage rates come from the Bureau of Labor Statistics, Occupational Employment Statistics (OES) from May 2018.

Some entities perform multiple CTEs and would be subject to more than one recordkeeping provision. Each provision outlines the KDEs necessary to effectively trace a product based on the CTE an entity performs (e.g., receiving, transformation, shipping). Not all KDEs are relevant for each CTE; however, entities that perform multiple CTEs would be required to maintain all KDEs that pertain to the CTEs they perform. For example, an entity that receives a food on the FTL and then transforms and ships it would need to keep records of KDEs relevant to receiving, transforming, and shipping.

We estimate recordkeeping burdens by CTE because each entity must comply with all requirements in its relevant CTE. Some KDEs (e.g., traceability lot code, traceability product identifier) are required by multiple CTEs; however, no two CTEs contain exactly the same KDE requirements. We lack information about which entities may be able to use the same KDE for multiple CTEs. Because we cannot account for these potential time savings, our total recordkeeping burdens by CTE may be overestimated.

a. Exempt Entities (§ 1.1305)

As discussed above, our analysis excludes those farms and other small originators that would be fully exempt from the proposed rule because of their very small size. Specifically, farms that are not covered under the produce safety rule in accordance with 21 CFR 112.4(a) are exempt from this proposed rule with respect to the produce they grow. Shell egg producers with fewer than 3,000 laying hens are exempt with respect to the shell eggs they produce. Other originators of food are exempt if the average annual monetary value of the food sold during the previous 3-year period was no more than $25,000 (on a rolling basis), adjusted for inflation using

2019 as the baseline year for calculating the adjustment. Furthermore, when all eggs produced at a particular farm receive a treatment[60] in accordance with 21 CFR 118.1(a)(2), the rule does not apply to those shell eggs.

There are other exemptions in the proposed rule that we do not specifically identify in our cost analysis because we lack the data. As a result, our costs may be overstated. We discuss these additional exemptions below and request comment on potentially affected entities.

For instance, farms are exempt with respect to FTL foods produced on the farm that are sold directly to a consumer by the owner, operator, or agent in charge of the farm. Also, the proposed rule does not apply to FTL foods that are produced and packaged on a farm if the packaging of the food remains in place until the food reaches the consumer, and the packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product and maintains labeling that includes the name, address, and phone number of the farm. Produce FTL foods that receive commercial processing to adequately reduce the presence of microorganisms of public health significance are exempt from the recordkeeping requirements if the conditions set forth in 21 CFR 112.2(b) are met (regarding the commercial processing exemption to the produce safety rule). Produce that is listed as rarely consumed raw in 21 CFR 112.2(a)(1) is also exempt. The proposed rule also has partial exemptions related to certain commingled raw agricultural commodities on the FTL and FTL food produced through the use of fishing vessels.

Retail food establishments are partially exempt with respect to FTL foods that are produced on a farm and sold directly to the retail food establishment by the owner, operator, or

[60] Treatment (or treated) means a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act

agent in charge of that farm. The only records retail food establishments must maintain in such cases are the name and address of the source farm.

Other entities not subject to this rule's recordkeeping requirements include transporters of FTL foods; non-profit food establishments; persons who manufacture, process, pack, or hold FTL foods for personal consumption; and persons who hold FTL foods on behalf of specific individual consumers, provided that these persons are not parties to the transaction involving the FTL food they hold or are not in the business of distributing food. These entities are not included in our counts of covered establishments.

Under proposed § 1.1305(g), farm-to-school and farm-to-institution programs would be partially exempt from the proposed recordkeeping requirements. When such programs purchase a food on the FTL from a farm, the applicable requirement would be for the school food authority or relevant food procurement entity to establish and maintain a record documenting the name and address of the farm that was the source of the food. We believe that this is the same location description data element that is typically stored in distribution and shipping recordkeeping systems. This record must be maintained for 180 days, which is the same retention period proposed for retail food establishments purchasing foods on the FTL directly from farms.

This partial exemption applies to farm-to-school and farm-to-institution entities that operate under various Federal, state, and local jurisdictions facilitating these food distribution programs. These programs include, but are not limited to, programs in which farms sell food (1) directly to schools under competitive procurement, (2) to competitively procured food distributors, (3) to vendors in the USDA Fresh Fruit and Vegetable Program operated by the Department of Defense's Defense Logistics Agency, and (4) to the USDA's Agricultural Marketing Service for use in the National School Lunch Program.

Intermediaries facilitate most of these sales between originators and the school or institution (Ref. [36]). We assume these intermediaries, in the form of school food authorities or relevant food procurement entities that obtain foods on the FTL directly from farms, already keep the name and address of the farm as part of their conventional recordkeeping systems and existing regulatory mandates, and so no new costs would be incurred by these firms. We include food service contractors and other private procurement food distributors among our counts of entities covered by this proposed rule.

There are some schools and institutions that purchase foods on the FTL directly from farms and not through any of these intermediaries or procurers. The 2015 USDA Farm to School Census indicates that approximately 22 percent of participating school food authorities purchased foods directly from farms or farmer cooperatives (Ref. [37]). School food authorities purchase for one or many schools. Of the 42,711 reported schools that had farm-to-school activities in 2013-2014, this 22 percent would represent about 9,396 schools. We assume these schools, in the form of their school food authorities, already keep the name and address of the farm as part of their conventional recordkeeping systems and existing regulatory mandates, and so no new costs would be incurred by these schools. We invite comment on these assumptions.

We do not have additional information that would allow us to estimate the precise number of participating non-school institutions (e.g., hospitals, colleges, prisons) not already counted in our coverage discussion of food service contractors, wholesalers, and distributors. We ask for comments regarding estimates of the number of such institutions.

b. Traceability Program Records (§ 1.1315)

The proposed rule, if finalized, would require entities that manufacture, process, pack, or hold foods on the FTL to maintain general records of traceability and make them available to

FDA upon request. Entities affected by this provision would therefore incur one-time and recurring annual costs at the establishment level associated with establishing and maintaining general traceability records. These records would include a description of the reference records in which an establishment maintains required information, an explanation of where the information appears in the records, and, if applicable, a description of how reference records for different critical tracking events are linked. Additional records would include a list of foods on the FTL the establishment ships, including the traceability product identifier and traceability product description for each food, and a description of how the establishment establishes and assigns traceability lot codes to affected foods.

Some establishments may already follow practices that meet some requirements in this provision. To account for this uncertainty, we assume that 50 percent of establishments would incur costs related to changing their current recordkeeping practices to fulfill the requirements of this provision, with a lower bound of 25 percent and an upper bound of 75 percent. As in the previous sections, we apply a different assumption to restaurants, assuming 5-15 percent would incur costs. We estimate the costs of this provision on a per establishment basis and conclude that 130,063 establishments would incur costs related to this provision, with range of 30,107 to 306,464 establishments. We request comment on these estimates.

We assume that establishments covered by this provision would face one-time costs to develop procedures for recordkeeping and to set up traceability program records, as well as recurring annual costs to keep records up to date as inputs are added, deleted, or changed. Establishing traceability program records would involve setting up master data in a standardized format, such as a report, spreadsheet template, or software. Although some of the costs associated with establishing traceability program records may not be affected by the volume of

business done by the establishment, we assume that the costs associated with establishing these records will increase with the number of different FTL products handled by the establishment and with the number of lots of FTL foods that the establishment handles annually.

Because we lack information on the number of unique FTL products handled by establishments, and because there is no clear relationship between number of products and number of lots, we model only number of lots in accounting for variation in recordkeeping burden. Namely, we scale the time to establish general records based on number of lots. Furthermore, as we do not know the particular numbers of lots typical to each industry sector, we use a range of numbers of lots in our model to reflect variability in both sector and establishment size. Based on discussion with FDA subject matter experts, we assume that the average establishment (by type and size) has approximately 1,000 lots of FTL foods that they originate, create, or transform annually, with a lower bound of 500 lots and an upper bound of 2,000 lots (Ref. [34]). We apply this assumption to subsequent provisions. We request comments on these lot-based assumptions and on other appropriate measures for calculating the burden of general records, such as the number of different products handled by an average firm.

To calculate the labor cost of establishing and maintaining general records, we use the hourly wage rate of $37.50 (= $18.75 x 2 to account for benefits and overhead) for one employee at each covered establishment. Based on discussion with FDA subject matter experts, we assume that the one-time burden to establish general records by setting up master data ranges from one to three minutes per lot. We assume the time burden to maintain these records with periodic updates is lower, from ten to 20 seconds per lot (Ref. [34]). We request comments on these assumptions.

We multiply the annual number of affected FTL lots, the associated time burden of establishing and maintaining a record in accordance with the provision, and the employee labor

cost to yield the one-time and recurring costs per establishment. We estimate that the one-time cost per affected establishment is $1,250 (= 1,000 x 0.03 x $37.50) and the recurring cost is $156 (= 1,000 x 0.004 x $37.50). The total one-time cost of this provision for all affected establishments is $162.6 million (= 130,063 x $1,250) and the annual recurring cost is roughly $20.3 million (=130,063 x $156). Table 19 presents a summary of the estimated recordkeeping costs of this provision with lower and upper bounds.

Table 19. One-time and Recurring Recordkeeping Costs of the General Records, 1.1315 Provision (2018$)

	Primary	Low	High
Number of affected establishments	130,063	30,107	306,464
Number of FTL lots per establishment	1,000	500	2,000
Time to of establish records (hours)	0.03	0.02	0.05
Time to of maintain records (hours)	0.004	0.003	0.006
Labor cost of hourly employee	$37.50	$37.50	$37.50
Per establishment one-time cost	$1,250	$313	$3,750
One-time cost of general records	$162,578,510	$9,408,569	$1,149,240,155
Per establishment recurring cost	$156	$52	$417
Recurring cost of general records	$20,322,314	$1,568,095	$127,693,351

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

The proposed rule, if finalized, would require entities who grow foods on the FTL to establish and maintain records containing and linking the traceability lot code of the food to growing area coordinates. Growers of sprouts would be required to maintain additional records; their requirements are discussed below. Affected growers would incur recurring costs associated with establishing and maintaining these records, to be made available to FDA upon request.

In addition to the traceability lot code and growing area coordinates for each lot that all growers must establish and maintain, sprout growers would need to request documentation on the incoming seeds from their suppliers and record this information into their work order

systems. For each received seed lot, this includes 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; 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; the location identifier and location description of the seed packinghouse (including a re-packer), the associated seed lot code assigned by the seed packinghouse, and the date of packing (and repacking, if applicable); the location identifier and location description of the seed supplier; a description of the seeds, including the seed type or taxonomic name, growing specifications, volume, type of packaging, and antimicrobial treatment; 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; the date of receipt of the seeds by the sprouter; and for each seed lot code, the sprout traceability lot code(s) and the date(s) of production associated with that seed lot code.

Some sprout growers may already be following some or all of these recordkeeping requirements as discussed in the 2017 FDA draft guidance for the sprout operations industry (Ref. [38]) or as recommended by good agricultural practices. We estimate that sprout growers not already performing certain recordkeeping activities would incur new recurring recordkeeping costs for the records outlined above. In this analysis, we use the inventory of sprout farms and operations used by the FDA's Office of Regulatory Affairs. Excluding very small sprout growers, this internal inventory counts 95 sprout growers. To account for uncertainty, we halve and double this number to approximate a range of 48 to 190 sprout growers covered by this provision and add these ranges to the total number of affected growers. We request comment on this estimate.

As in previous sections, we estimate the total number of growers affected by identifying NAICS categories likely to grow foods on the Food Traceability List (Table 20) and removing exempt and non-covered growers. We lack information on how many growers already keep such records as a part of their current business practices. To account for this uncertainty, we assume that 50 percent of these growers would need to change their practices, with a range of 25 to 75 percent. We therefore estimate that in total 9,459 growers, including sprout growers, would incur costs related to this provision, with a lower bound of 482 and an upper bound of 26,964. Because our primary, low, and high estimates of sprout growers represent 0.54%, 0.14%, and 1.62% of all growers, we estimate that 51 sprout growers, with a lower bound of 13 and an upper bound of 153, would have to change their current practices to comply with this provision. We request comment on these estimates.

Table 20. NAICS Categories of Entities that Likely to Grow Foods on the Food Traceability List

2012 NAICS	Category
111219	Other Vegetable (except Potato) and Melon Farming
111339	Other Non-citrus Fruit Farming
111419	Other Food Crops Grown Under Cover

Growers covered by this provision would incur annually recurring recordkeeping costs related to establishing and maintaining traceability records for specific lots of food, to be made available to FDA upon request. We estimate that each covered grower would establish and maintain records required by this provision for each lot of FTL food that it grows. Applying our earlier lot assumptions, we assume that each grower affected by this provision grows 1,000 lots of FTL foods annually, with a lower bound of 500 lots and an upper bound of 2,000 lots. We request comments on these assumptions.

To calculate the labor cost of establishing and maintaining these records, we use the hourly wage rate of $37.50 (= $18.75 x 2 to account for benefits and overhead) for one employee at each covered establishment. For non-sprout growers we estimate that the time burden of establishing and maintaining a record for this provision ranges from one to three minutes. For sprouting growers, we double this burden. We request comments on these estimates.

We multiply the number of affected FTL lots per grower, the associated time burden of maintaining a record in accordance with the provision, and the employee labor cost to yield the per establishment cost of maintaining records of growing FTL foods. For non-sprout growers we estimate that the recurring cost of establishing and maintaining records for this provision is $1,250 (= 1,000 x 0.03 x $37.50), with a lower bound of $313 (= 500 x 0.02 x $37.50) and an upper bound of $3,750 (= 2,000 x 0.05 x $37.50). For sprouting growers, we estimate that the recurring cost of establishing and maintaining records for this provision is $2,500 (= 1,000 x 0.07 x $37.50), with a lower bound of $625 (= 500 x 0.03 x $37.50) and an upper bound of $7,500 (= 2,000 x 0.10 x $37.50).

For both non-sprouting and sprouting growers, we multiply the per establishment cost of establishing and maintaining records for this provision by the number of establishments affected by this provision to estimate the total cost of establishing and maintaining records of growing FTL foods. We estimate that this annually recurring cost is approximately $11.9 million (= (9,408 x $1,250) + (51 x $2,500)), with a lower bound of $0.2 million (= (469 x $312.50) + (13 x $625)) and an upper bound of approximately $101.7 million (= (26,811 x $3,750) + (153 x $7,500)). Table 21 presents a summary of the estimated recordkeeping costs of this provision.

Table 21. Recurring Recordkeeping Costs of the Records of Growing FTL Food, 1.1325 Provision (2018$)

	Primary	Low	High
Non-Sprout Firms			

Number of affected firms	9,408	469	26,811
Annual number of FTL lots per firm	1,000	500	2,000
Time to establish and maintain records (hours)	0.03	0.02	0.05
Labor cost of hourly employee	$37.50	$37.50	$37.50
Per firm cost	$1,250	$313	$3,750
Sprout Firms			
Number of affected firms	51	13	153
Annual number of FTL lots per firm	1,000	500	2,000
Time to establish and maintain records for sprouting firms (hours)	0.07	0.03	0.10
Labor cost of hourly employee	$37.50	$37.50	$37.50
Per firm cost	$2,500	$625	$7,500
Total recurring cost	$11,887,851	$154,624	$101,688,031

d. Records to Be Kept by First Receivers of Foods on the FTL (§ 1.1330)

The proposed rule, if finalized, would require entities that are the first receivers of FTL foods to establish and maintain records on traceability. We estimate that entities affected by this provision would incur annual recurring costs at the establishment level of establishing and maintaining such records. These records would link the traceability lot code of the food received to the location identifier and location description of the originator, cooler, and packer, as well as contact information for the harvester; records would also include the date and time of harvesting, cooling, and packing. For FTL foods that were obtained from a fishing vessel, first receivers must establish and maintain records containing and linking the traceability lot code of the received seafood product to the name of the vessel, its unique identifier or license number (both if available), its licensing country (if any), a point of contact for the vessel, and the harvest date range and locations for the trip during which the seafood was caught. Finally, first receivers that receive an FTL food without a traceability lot code would need to establish and maintain a traceability lot code.

As in previous sections, we estimate the total number of first receivers affected by identifying NAICS categories likely to grow foods on the Food Traceability List (Table 22) and removing exempt and non-covered establishments.[61] We lack information on how many first receivers already keep such records as a part of their current business practices. To account for this uncertainty, we assume that 50 percent of these establishments would need to change their practices, with a range of 25 to 75 percent. We therefore approximate that about 12,700 establishments would incur costs related to this provision, with a lower bound of 3,491 establishments and an upper bound of 25,791 establishments. We request comment on these estimates.

Table 22. NAICS Categories Likely to Be First Receivers of Foods on the Food Traceability List

2012 NAICS	Category
311340	Nonchocolate Confectionery Manufacturing
311351	Chocolate and Confectionery Manufacturing from Cacao Beans
311352	Confectionery Manufacturing from Purchased Chocolate
311411	Frozen Fruit, Juice and Vegetable Manufacturing
311412	Frozen Specialty Food Manufacturing
311421	Fruit and Vegetable Canning
311422	Specialty Canning
311423	Dried and Dehydrated Food Manufacturing
311520	Ice Cream and Frozen Dessert Manufacturing
311710	Seafood Product Preparation and Packaging
311811	Retail Bakeries
311812	Commercial Bakeries
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing
311824	Dry Pasta, Dough, and Flour Mixes Manufacturing from Purchased Flour
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing
311942	Spice and Extract Manufacturing
311991	Perishable Prepared Food Manufacturing
424410	General Line Grocery Merchant Wholesalers
424420	Packaged Frozen Food Merchant Wholesalers
424460	Fish and Seafood Merchant Wholesalers

6161. This provision may affect a small amount of retail food establishments, but we cannot estimate this number due to data limitations. We ask for comment on the number of these entities.

424480	Fresh Fruit and Vegetable Merchant Wholesalers
424490	Other Grocery and Related Products Merchant Wholesalers
445220	Fish and Seafood Markets
445230	Fruit and Vegetable Markets
493110	General Warehousing and Storage
493120	Refrigerated Warehousing and Storage
493130	Farm Product Warehousing and Storage

First receivers covered by this provision would incur recurring annual costs of establishing and maintaining these records, to be made available to FDA upon request. We estimate that each affected establishment would do that for each affected lot of FTL food. We estimate that each first receiver receives approximately 1,000 lots of FTL foods annually, with a lower bound of 500 lots and an upper bound of 2,000 lots. We request comments on these estimates.

To calculate the labor cost of establishing and maintaining these records, we use the hourly wage rate of $37.50 (= $18.75 x 2 to account for benefits and overhead) for one employee at each covered establishment. We estimate that the time burden of establishing and maintaining a record for this provision is approximately two minutes per record, with a lower bound of approximately one minute and an upper bound of approximately three minutes. We request comments on these estimates.

We multiply the number of affected FTL lots per first receiver, the associated per record time burden, and the employee labor cost to yield the per establishment cost of establishing and maintaining records required by this provision. We estimate that this recurring per first receiver cost is $1,250 (= 1,000 x 0.03 x $37.50), with a lower bound of $313 (= 500 x 0.02 x $37.50) and an upper bound of $3,750 (= 2,000 x 0.05 x $37.50). We multiply the per first receiver cost by the number of affected establishments to estimate the total cost of establishing maintaining first receiver records. We estimate that this annually recurring cost is $15.9 million (= 12,700 x

$1,250), with a lower bound of approximately $1.1 million (= 3,491 x $313) and an upper bound of approximately $96.7 million (= 25,791 x $3,750). Table 23 presents a summary of the estimated recordkeeping costs of this provision.

Table 23. Recurring Recordkeeping Costs of First Receiver Records, Provision 1.1330 (2018$)

	Primary	Low	High
Number of affected establishments	12,700	3,491	25,791
Number of FTL lots per establishment	1,000	500	2,000
Time to establish and maintain records (hours)	0.03	0.02	0.05
Labor cost of hourly employee	$37.50	$37.50	$37.50
Per establishment cost	$1,250	$313	$3,750
Total recurring cost	$15,875,215	$1,091,053	$96,715,230

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

The proposed rule, if finalized, would require receivers of foods on the FTL to establish and maintain records containing and linking the traceability lot code of the food to the location identifier and location description of the immediate previous source of an FTL food; its entry number (if imported); location identifier and location description for where food was received, and the receiving date and time of receipt; quantity and unit of measure of the food received; traceability product identifier and description; location identifier and description and POC for the traceability lot code generator; reference record type and record number for the receipt of the food; and the name of the transporter.

As in previous sections, we estimate the total number of receivers affected by identifying NAICS categories likely to grow foods on the Food Traceability List (Table 24) and removing exempt and non-covered establishments. We lack information on how many receivers already keep such records as a part of their current business practices. To account for this uncertainty, we assume that 50 percent of these establishments would need to change their practices, with a range

of 25 to 75 percent. We estimate therefore that approximately 265,610 establishments would incur costs related to this provision, with a lower bound of approximately 75,481 and an upper bound of approximately 587,043. We request comment on these estimates.

Table 24. NAICS Categories Likely to Receive Foods on the Food Traceability List

2012 NAICS	Category
311340	Nonchocolate Confectionery Manufacturing
311351	Chocolate and Confectionery Manufacturing from Cacao Beans
311352	Confectionery Manufacturing from Purchased Chocolate
311411	Frozen Fruit, Juice and Vegetable Manufacturing
311412	Frozen Specialty Food Manufacturing
311421	Fruit and Vegetable Canning
311422	Specialty Canning
311423	Dried and Dehydrated Food Manufacturing
311513	Cheese Manufacturing
311520	Ice Cream and Frozen Dessert Manufacturing
311710	Seafood Product Preparation and Packaging
311811	Retail Bakeries
311812	Commercial Bakeries
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing
311821	Cookie and Cracker Manufacturing
311824	Dry Pasta, Dough, and Flour Mixes Manufacturing from Purchased Flour
311911	Roasted Nuts and Peanut Butter Manufacturing
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing
311942	Spice and Extract Manufacturing
311991	Perishable Prepared Food Manufacturing
424410	General Line Grocery Merchant Wholesalers
424420	Packaged Frozen Food Merchant Wholesalers
424430	Dairy Product (except Dried or Canned) Merchant Wholesalers
424450	Confectionery Merchant Wholesalers
424460	Fish and Seafood Merchant Wholesalers
424480	Fresh Fruit and Vegetable Merchant Wholesalers
424490	Other Grocery and Related Products Merchant Wholesalers
445110	Supermarkets and Other Grocery (except Convenience) Stores
445120	Convenience Stores
445220	Fish and Seafood Markets
445292	Confectionery and Nut Stores
445230	Fruit and Vegetable Markets
445291	Baked Goods Stores
445299	All Other Specialty Food Stores
447110	Gasoline Stations with Convenience Stores

452910	Warehouse Clubs and Supercenters
454111	Non-store Retailers: Electronic Shopping
454210	Vending Machine Operators
493110	General Warehousing and Storage
493120	Refrigerated Warehousing and Storage
493130	Farm Product Warehousing and Storage
722310	Food Service Contractors
722320	Caterers
722330	Mobile Food Services
722410	Drinking Places (Alcoholic Beverages)
722511	Full-Service Restaurants
722513	Limited-Service Restaurants
722514	Cafeterias, Grill Buffets, and Buffets
722515	Snack and Nonalcoholic Beverage Bars

Receivers of FTL foods covered by this provision would incur recurring annual recordkeeping costs of establishing and maintaining these records, to be made available to FDA upon request. Each covered receiver would establish and maintain records for each lot of received FTL foods. We assume that all shipments sent by shippers must be received by receivers, and we estimate that each receiver receives from roughly 2,000-8,000 shipments per year on average. We request comment on this assumption, which we arrive at by dividing the number of shipments sent by shippers by the total number of receivers. We note that entities responsible for shipping, such as distribution centers, wholesalers, and warehouses, may maintain receiving records for clients. We do not make an assumption about how these costs are shared.

To calculate the labor cost of establishing and maintaining these records, we use the hourly wage rate of $37.50 (= $18.75 x 2 to account for benefits and overhead) for one employee at each covered establishment. We estimate that the time burden of establishing and maintaining receiver records ranges from 15 to 20 seconds per shipment. We request comments on these estimates.

We multiply the number of affected FTL food lots per receiver, the associated time burden, and the employee labor cost to yield the per receiver cost of this provision. We estimate that the recurring per receiver cost of this provision is $370 (= 2,367 x 0.004 x $37.50), with a lower bound of $137 (= 1,312 x 0.003 x $37.50) and an upper bound of $869 (= 4,169 x 0.006 x $37.50). We multiply the per receiver cost by the number of establishments affected by this provision to estimate the total cost of establishing and maintaining receiver records. We estimate that this annually recurring cost is $98.2 million (= 265,610 x $370), with a lower bound of $10.3 million (= 75,481 x $137) and an upper bound of $510 million (= 587,043 x $869). Table 25 presents a summary of the estimated recordkeeping costs of this provision.

Table 25. Recurring Recordkeeping Costs of Receiver Records, Provision 1.1335 (2018$)

	Primary	Low	High
Number of affected establishments	265,610	75,481	587,043
Number of FTL shipments per establishment	2,367	1,312	4,169
Time to establish and maintain records (hours)	0.004	0.003	0.006
Labor cost of hourly employee	$37.50	$37.50	$37.50
Per establishment cost	$370	$137	$869
Total recurring cost	$98,230,051	$10,316,392	$509,907,986

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

The proposed rule, if finalized, would require entities who transform foods on the FTL to establish and maintain traceability records containing and linking the new traceability lot code of the food produced through transformation to the information described below. We estimate that entities affected by this provision would annually incur recurring costs at the establishment level of establishing and maintaining records, to be made available to FDA upon request. For the food(s) on the FTL used in transformation, these records would include the information on the traceability lot codes, the traceability product identifier and product description, and the quantity

of each traceability lot. For the food produced through transformation, these records would include information on the location identifier and description of where food was transformed (and the date transformation was completed), the new traceability product identifier and product description for the food to which the new traceability lot code applies, the quantity and unit of measure of food produced through transformation for each new traceability lot code, and the reference record type and record number for the documents containing the information on the foods used in, and produced through, transformation.

As in previous sections, we estimate the total number of transformers affected by identifying NAICS categories likely to transform foods on the Food Traceability List (Table 26) and removing exempt and non-covered establishments. We lack information on how many transformers already keep such records as a part of their current business practices. To account for this uncertainty, we assume that 50 percent of these establishments would need to change their practices, with a range of 25 to 75 percent. We therefore estimate that 5,244 establishments would incur costs related to this provision, with a lower bound of 1,219 and an upper bound of 11,022 establishments. We request comment on these estimates.

Table 26. NAICS Categories Likely to Transform Foods on the FTL

2012 NAICS	Category
311340	Nonchocolate Confectionery Manufacturing
311351	Chocolate and Confectionery Manufacturing from Cacao Beans
311352	Confectionery Manufacturing from Purchased Chocolate
311411	Frozen Fruit, Juice and Vegetable Manufacturing
311412	Frozen Specialty Food Manufacturing
311421	Fruit and Vegetable Canning
311422	Specialty Canning
311423	Dried and Dehydrated Food Manufacturing
311513	Cheese Manufacturing
311520	Ice Cream and Frozen Dessert Manufacturing
311710	Seafood Product Preparation and Packaging
311811	Retail Bakeries

311812	Commercial Bakeries
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing
311821	Cookie and Cracker Manufacturing
311824	Dry Pasta, Dough, and Flour Mixes Manufacturing from Purchased Flour
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing
311942	Spice and Extract Manufacturing
311991	Perishable Prepared Food Manufacturing

Each person affected by this provision would incur recurring annual recordkeeping costs for establishing and maintaining these records, to be made available to FDA upon request. We estimate that each affected establishment would do that for each new traceability lot of food produced through transformation of FTL food(s). Using our previous lot assumptions, we estimate that each such establishment transforms approximately 1,000 lots of FTL foods annually, with a lower bound of 500 lots and an upper bound of 2,000 lots. We request comments on these estimates.

To calculate the labor cost of establishing and maintaining these records, we use the hourly wage rate of $37.50 (= $18.75 x 2 to account for benefits and overhead) for one employee at each covered establishment. We estimate that the time burden of establishing and maintaining a record for this provision is approximately two minutes per record, with a lower bound of approximately one minute and an upper bound of approximately three minutes. We request comments on these estimates.

We multiply the number of affected FTL lots per covered establishment, the associated time burden, and the employee labor cost to yield the per establishment cost of establishing and maintaining records required by this provision. We estimate that this recurring annual per establishment cost is $1,250 (= 1,000 x 0.03 x $37.50), with a lower bound of $313 (= 500 x 0.02 x $37.50) and an upper bound of $3,750 (= 2,000 x 0.05 x $37.50). We multiply the per establishment cost by the number of affected covered establishments to estimate the total cost of

establishing and maintaining the required food transformation records. We estimate that this annually recurring cost is $6.6 million (= 5,244 x $1,250), with a lower bound of $0.4 million (= 1,219 x $313) and an upper bound of $41.3 million (= 11,022 x $3,750). Table 27 presents a summary of the estimated recordkeeping costs of this provision.

Table 27. Recurring Recordkeeping Costs of Food Transformation Records, Provision 1.1340 (2018$)

	Primary	Low	High
Number of affected establishments	5,244	1,219	11,022
Number of FTL lots per establishment	1,000	500	2,000
Time to establish and maintain records (hours)	0.03	0.02	0.05
Labor cost of hourly employee	$37.50	$37.50	$37.50
Per establishment cost	$1,250	$313	$3,750
Total recurring cost	**$6,554,420**	**$381,066**	**$41,330,739**

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

The proposed rule, if finalized, would require entities who create foods on the FTL to establish and maintain records containing and linking the traceability lot code of the food created to the location identifier and location description for where a food was created, the creation date, the traceability product identifier and product description, the quantity and unit of measure of the food created, and the reference record type and record number for the documents containing the previously-stated information. We estimate that entities affected by this provision would incur recurring annual costs at the establishment level of establishing and maintaining these records, to be made available to FDA upon request.

As in previous sections, we estimate the total number of creators affected by identifying NAICS categories likely to create foods on the Food Traceability List (Table 28) and removing exempt and non-covered establishments. We lack information on how many creators already keep such records as a part of their current business practices. To account for this uncertainty, we

assume that 50 percent of these establishments would need to change their practices, with a range of 25 to 75 percent. We estimate therefore that approximately 222 establishments would incur costs related to this provision, with a lower bound of approximately 45 establishments and an upper bound of approximately 552 establishments. We request comment on these estimates.

Table 28. NAICS Categories Likely to Create Foods on the Food Traceability List

2012 NAICS	Category
311513	Cheese Manufacturing
311911	Roasted Nuts and Peanut Butter Manufacturing
311991	Perishable Prepared Food Manufacturing

Each affected establishment would need to establish and maintain records for each lot of created FTL food. We approximate that each affected establishment creates 1,000 lots of FTL foods annually, with a lower bound of 500 lots and an upper bound of 2,000 lots. We request comments on these estimates.

To calculate the labor cost of establishing and maintaining these records, we use the hourly wage rate of $37.50 (= $18.75 x 2 to account for benefits and overhead) for one employee at each covered establishment. We estimate that the time burden of establishing and maintaining a record for this provision is approximately one to three minutes per lot. We request comments on these estimates.

We multiply the number of created FTL lots per affected establishment, the associated time burden, and the employee labor cost to yield the per establishment cost of maintaining records of creating FTL foods. We estimate that this recurring annual cost is $1,250 (= 1,000 x 0.03 x $37.50), with a lower bound of $313 (= 500 x 0.02 x $37.50) and an upper bound of $3,750 (= 2,000 x 0.05 x $37.50). We multiply the per establishment cost by the number of establishments affected by this provision to estimate the total cost of establishing and

maintaining records of creating FTL foods. We estimate that this annually recurring cost is $278,000 (= 222 x $1,250), with a lower bound of $14,000 (= 45 x $313) and an upper bound of $2.1 million (= 552 x $3,750). Table 29 presents a summary of the estimated recordkeeping costs of this provision.

Table 29. Recurring Recordkeeping Costs of Creating FTL Food, Provision 1.1345 (2018$)

	Primary	Low	High
Number of affected establishments	222	45	552
Number of FTL lots per establishment	1,000	500	2,000
Time to establish and maintain records (hours)	0.03	0.02	0.05
Labor cost of hourly employee	$37.50	$37.50	$37.50
Per establishment cost	$1,250	$313	$3,750
Total recurring cost	**$278,018**	**$14,050**	**$2,069,114**

h. Records to Be Kept and Sent for Shipment of Foods on the Food Traceability List (§ 1.1350)

The proposed rule, if finalized, would require entities who ship foods on the FTL to establish, maintain, and send (to the immediate subsequent recipient (other than a transporter) of the food) certain records related to the covered food, including information on the location identifier and location description for the immediate subsequent recipient of the food; its entry number (if imported); the location identifier and location description of the place from which the food was shipped, and date and time the food was shipped; the traceability lot code; the quantity and unit of measure of the food shipped; the traceability product identifier and product description for the food; and the location identifier, location description, and point of contact for the traceability lot code generator. Entities who ship FTL foods would also be required to establish and maintain (but not send forward) records of the reference record type and record number for the shipment of each traceability lot of the food; and the name of the transporter. When sending records, farms must also include a statement that they are a farm and additional

information on the location identifier and location description of the originator, cooler, and packer of the transported FTL food, as well as the name, point of contact, and phone number of the harvester, and the dates and times of harvesting, cooling, and packing. Entities affected by this provision would incur recurring annual costs associated at the establishment level of establishing, maintaining, and sending these records.

As in previous sections, we estimate the total number of shippers affected by identifying NAICS categories likely to ship foods on the Food Traceability List (Table 30) and removing exempt and non-covered establishments. We lack information on how many shippers already keep and send such records as a part of their current business practices. To account for this uncertainty, we assume that 50 percent of these establishments would need to change their practices, with a range of 25 to 75 percent. We therefore estimate that approximately 29,593 establishments would incur costs related to this provision, with a lower bound of approximately 5,908 establishments and an upper bound of approximately 68,641 establishments. We request comment on these estimates.

Table 30. NAICS Categories Likely to Ship Foods on the Food Traceability List

2012 NAICS	Category
111219	Other Vegetable (except Potato) and Melon Farming
111339	Other Non-citrus Fruit Farming
111419	Other Food Crops Grown Under Cover
112310	Chicken Egg Production
112511	Finfish Farming and Fish Hatcheries
112512	Shellfish Farming
114111	Finfish Fishing
114112	Shellfish Fishing
311340	Nonchocolate Confectionery Manufacturing
311351	Chocolate and Confectionery Manufacturing from Cacao Beans
311352	Confectionery Manufacturing from Purchased Chocolate
311411	Frozen Fruit, Juice and Vegetable Manufacturing
311412	Frozen Specialty Food Manufacturing
311421	Fruit and Vegetable Canning

311422	Specialty Canning
311423	Dried and Dehydrated Food Manufacturing
311513	Cheese Manufacturing
311520	Ice Cream and Frozen Dessert Manufacturing
311710	Seafood Product Preparation and Packaging
311811	Retail Bakeries
311812	Commercial Bakeries
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing
311821	Cookie and Cracker Manufacturing
311824	Dry Pasta, Dough, and Flour Mixes Manufacturing from Purchased Flour
311911	Roasted Nuts and Peanut Butter Manufacturing
311991	Perishable Prepared Food Manufacturing
424410	General Line Grocery Merchant Wholesalers
424420	Packaged Frozen Food Merchant Wholesalers
424430	Dairy Product (except Dried or Canned) Merchant Wholesalers
424460	Fish and Seafood Merchant Wholesalers
424480	Fresh Fruit and Vegetable Merchant Wholesalers
424490	Other Grocery and Related Products Merchant Wholesalers
493110	General Warehousing and Storage
493120	Refrigerated Warehousing and Storage
493130	Farm Product Warehousing and Storage

Each covered shipper would establish, maintain, and send records for each shipment lot of the FTL food. Compared to other shippers affected by this provision, we assume distribution centers, wholesalers, and warehouses collect information at a faster pace (from ten to 20 seconds per shipment to record and ten to 20 seconds per shipment to send). Based on discussions with FDA subject matter experts, we assume these establishments have a higher volume of transactions because they service a larger number of clients (Ref. [34]). We assume these establishments service between ten and 100 clients, with a primary estimate of 35. We multiply our previous lot assumptions (500 to 2,000, with a primary estimate of 1,000) by this distribution to calculate the total time spent to establish, maintain, and send shipping records. Separately, we assume that the remaining establishments in this category, such as growers and manufacturers, collect and record information at a slower speed (from one to three minutes per shipment to

record and one to three minutes per shipment to transmit). We request comments on these estimates.

To calculate the labor cost of establishing, maintaining, and sending these records, we use the hourly wage rate of $37.50 (= $18.75 x 2 to account for benefits and overhead) for one employee at each covered establishment. We multiply the shipping time burden and the employee labor cost to yield the per establishment cost of establishing, maintaining, and sending shipping-related records. For distribution centers, wholesalers, and warehouses, the primary per establishment cost is $15,104 per year (= 48,333 shipments x 0.008 hours x $37.50). For all other entities, this per establishment cost is $2,500 (= 1,000 shipments x 0.06 hours x $37.50).

We multiply the per establishment cost by the number of affected establishments to estimate the total recordkeeping cost related to shipping FTL foods. We estimate that this annually recurring cost is $191.2 million (= 12,657 x $15,000) for distribution centers, wholesalers, and warehouses and $42.3 million for all other entities (=16,936 x $2,500). Table 31 presents a summary of the estimated recordkeeping costs of this provision, including lower and upper bounds.

Table 31. Recurring Recordkeeping Costs of Shipping FTL Foods, Provision 1.1350 (2018$)

	Primary	Low	High
Distribution Centers, Wholesalers, and Warehouses			
Number of affected establishments	12,657	4,060	24,404
Number of affected shipments per establishment	48,333	24,167	96,667
Time to establish and maintain records (hours)	0.004	0.003	0.006
Time to send records (hours)	0.004	0.003	0.006
Recordkeeping employee hourly labor cost	$37.50	$37.50	$37.50
Per establishment cost of recordkeeping	$15,104	$5,035	$40,278
Total shipping cost (annual)	$191,167,560	$20,440,229	$982,952,378
All Other Entities			
Number of affected establishments	16,936	1,849	44,236

Number of affected shipments per establishment	1,000	500	2,000
Time to establish and maintain records (hours)	0.03	0.02	0.05
Time to send records (hours)	0.03	0.02	0.05
Recordkeeping employee hourly labor cost	$37.50	$37.50	$37.50
Per establishment cost of recordkeeping	$2,500	$625	$7,500
Total shipping cost (annual)	$42,340,338	$1,155,325	$331,772,336
Total shipping cost (annual) for all establishments	$233,507,899	$21,595,554	$1,314,724,714

6. Non-Quantified Costs

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 costs have not been quantified because we lack information on both the nature and likelihood of these behavior changes; we therefore request comment on these potential costs. Indeed, there is a likely correlation between these costs' occurrence and the realization of health and longevity benefits attributable to this rule. One of the challenges of such attribution, for both health and longevity benefits and this category of costs, is the lag in data availability as other FSMA regulations continue to take effect.[62]

Other provisions of the proposed rule, if finalized, may generate costs that we cannot estimate quantitatively. There may be costs incurred by FDA to review petitions requesting modified requirements or exemptions (§1.1380), adopt modified requirements or grant exemptions on our own initiative (§1.1385), decide that modified requirements or exemptions should be revised or revoked (§1.1400), receive and respond to waiver petitions (§1.1435), waive

[62] As noted in section II.D, above, the outcomes of earlier FSMA regulations should be taken into account in the characterization of this proposal's regulatory baseline.

requirements on our own initiative (§1.1440), and determine that a waiver should be modified or revoked (§1.1450).

For provisions concerning petitions, costs to FDA could include time spent reviewing and responding, as well as publishing notices of decisions in the *Federal Register*. For provisions that allow FDA to modify requirements and grant exemptions and waivers on our own initiative, costs could include time spent making these determinations and publishing notices of decisions in the *Federal Register*. Because we cannot estimate the number of petitions FDA would receive if this proposed rule is finalized, we cannot estimate the costs of these provisions.

Unquantified costs incurred by industry may include the time to create and file petitions for modifications, exemptions, and waivers. Preparing and submitting these documents would present a one-time cost per firm per food product. However, we believe that firms would pursue this course of action only if it is in their best financial interests and thus that these costs would not increase the total costs of this rule.

If finalized, other provisions of the proposed rule may generate one-time costs for industry to meet FDA requests. One such requirement would be for entities (at the establishment level) to generate certain records in the form of a sortable electronic spreadsheet upon request by FDA. FDA would make such a request 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. The number of times establishments would generate this electronic spreadsheet depends on the number of times FDA would request said record. Some establishments may already keep records in a sortable electronic spreadsheet format while other may not. Because electronic sortable spreadsheets are commonly used for other general business purposes, such as for taxes, we estimate that any additional costs from this requirement would be

negligible. Moreover, because these spreadsheets would be needed only in the event of an investigation, we assume such costs would be incurred infrequently and unpredictably. We seek comment on these assumptions.

Other one-time costs would result from time spent completing and submitting petitions for modified requirements or exemptions (§ 1.1370), petitions for waiver for a type of entity (§ 1.1425), or waiver requests for an individual entity (§ 1.1415). Because we cannot estimate the number of persons or entities that will submit petitions and request waivers if the proposed rule is finalized, we cannot estimate the costs associated with these actions. However, we believe that because petitions and waiver requests are voluntary, firms would only incur such costs if they expect that this choice is in their best financial interest.

Finally, we note that a request from FDA to produce a sortable spreadsheet (under the circumstances described above) will be withdrawn when necessary to accommodate a religious belief of a person asked to provide such a spreadsheet. Because this does not require any further action from persons or entities requesting a waiver other than stating a religious reason, we believe any such additional costs to be negligible.

7. Summary of Costs

Table 32 summarizes our estimates of the one-time and recurring costs of the proposed rule. We estimate that the total one-time costs of the proposed rule, if finalized, would be approximately $1,113 million, with a lower bound of $58 million and an upper bound of $7.6 billion. We estimate that the total recurring costs of the proposed rule, if finalized, would be approximately $387 million per year, with a lower bound of $35 million per year and an upper bound of $2.2 billion per year.

Table 32. Total Costs of the Proposed Rule (millions 2018$)			
One-time Costs	Primary	Low	High

Reading and Understanding the Rule	$52	$25	$88
Capital Investment	$725	$11	$5,740
Training	$174	$13	$660
§ 1.1315 General Recordkeeping	$163	$9	$1,149
Total One-time Costs	**$1,113**	**$58**	**$7,637**
Annually Recurring Costs			
§ 1.1315 General Recordkeeping	$20	$2	$128
§ 1.1325 Growing Recordkeeping	$12	$0.2	$102
§ 1.1330 First Receiver Recordkeeping	$16	$1	$97
§ 1.1335 Receiver Recordkeeping	$98	$10	$510
§ 1.1340 Transformation Recordkeeping	$7	$0.4	$41
§ 1.1345 Creation Recordkeeping	$0.3	$0.01	$2
§ 1.1350 Shipping Recordkeeping	$234	$22	$1,315
Total Recurring Costs	**$387**	**$35**	**$2,194**

We estimate that in the first year after the proposed rule becomes effective, total costs would be $1,500 million dollars, with a lower bound of $93 million and an upper bound of approximately $9.8 billion. In subsequent years, the annual cost of the proposed rule would decrease to $387 million, with a lower bound of $35 million and an upper bound of approximately $2.2 billion. We estimate that the total costs of the proposed rule over ten years would be approximately $5.0 billion, ranging from a lower bound of $409 million and an upper bound of approximately $29.6 billion.

A summary of the estimated ten-year stream of costs of the proposed rule is presented in Table 33. The present value of total estimated costs is approximately $3.8 billion at a seven percent discount rate and $4.4 billion with a three percent discount rate. The ten-year annualized value of costs is $535 million with a seven percent discount rate and $513 million with a three percent discount rate.

Table 33. Ten-Year Timing of the Costs of the Proposed Rule (millions 2018$)

Year	Primary	Low	High
1	$1,500	$93	$9,831
2	$387	$35	$2,194
3	$387	$35	$2,194
4	$387	$35	$2,194

5	$387	$35	$2,194
6	$387	$35	$2,194
7	$387	$35	$2,194
8	$387	$35	$2,194
9	$387	$35	$2,194
10	$387	$35	$2,194
Total Costs of the Proposed Rule	$4,980	$409	$29,578
Present Value of Total Costs (3%)	$4,379	$356	$26,131
Present Value of Total Costs (7%)	$3,756	$301	$22,548
Annualized Value of Costs (3%)	**$513**	**$42**	**$3,063**
Annualized Value of Costs (7%)	**$535**	**$43**	**$3,210**

G. Distributional Effects

If this proposed rule is finalized, we do not expect any significant distributional effects, although the rule would potentially affect a significant proportion of entities (firms or establishments) that manufacture, process, pack, or hold foods that appear on the FTL. The rule does not require any additional tasks to specific types of entities compared to other affected entities other than establishing, maintaining, and sending records that would enable traceability of the covered foods. We therefore do not expect any significant distributional effects as a result of enforcing this rule should it be finalized.

H. International Effects

This section estimates costs for foreign entities (firms or establishments) who manufacture, process, pack, or hold foods listed on the FTL and who offer such foods for export to the U.S. market. While it is possible that there might be a small number of foreign entities that sell food in the United States and meet the definition of “retail food establishment,” we assume that the number of such entities affected by this rule is negligible. We request comment on this assumption.

We estimate that total one-time costs to foreign entities range from approximately $10.3 million to $3,494 million, with a primary estimate of $461 million. One-time costs occur in year one. We estimate that recurring costs to foreign entities (in each year) range from approximately $17.1 million to $1,149 million dollars, with a primary estimate of $198 million dollars. At a seven percent discount rate, our primary estimate of the present value of costs to foreign entities over ten years is approximately $1,821 million, and our primary estimate of the annualized value of these costs is approximately $259 million, ranging from $18.4 million to $1.6 billion. These cost estimates are costs to foreign entities only. To the extent that these costs are passed on to U.S. entities, U.S. consumers and U.S. firms that purchase products from foreign entities may experience higher costs. However, requirements of this rule affect all domestic entities in the same manner regardless of whether their suppliers are domestic or foreign and their estimated costs are estimated in section F of this analysis. We face uncertainty concerning the portion of foreign producers' compliance costs that may be passed on to U.S. consumers. It is possible that U.S. producers may also pass on some of their compliance costs to consumers of U.S. exports in other countries. We expect that U.S. and foreign producers alike will attempt to pass their costs onto consumers in markets where demand is least elastic. Bekkers et al. (2013) estimate that the pass-through rate from world food prices to final consumption prices is about 12 percent in high income countries (Ref. [39]), but this research does not speak to the extent to which country-specific costs (such as those imposed as a result of a regulation) are passed through to consumers or supply chain entities in that country.

To estimate these costs of the proposed rule on foreign entities, we extrapolate from the main cost estimates by comparing the number of foreign facilities in FDA's Food Facility Registration Module (FFRM) to the primary estimated number of domestic establishments minus

retail food establishments. As stated above, we assume that the number of foreign retail food establishments affected by this rule is negligible. Hence, we exclude domestic retail food establishments and their costs from the extrapolation to foreign entities. With 212,404 foreign food facilities, the ratio of foreign establishments to domestic establishments is approximately 1.95. Since the numerator of this ratio is all foreign facilities in the FFRM, the denominator of this ratio is likewise all 109,000 domestic non-RFE establishments in the NAICS codes relevant to the rule, and not just the ones (65,607) that we have estimated to manufacture, process, pack, or hold FTL foods in section II.D.iii "Coverage of the Rule." We then use this ratio as a scaling factor to extrapolate from counts of entities in the main analysis, namely the counts of affected entities. This implicitly assumes that the same proportion of registered foreign firms are affected by the rule (i.e., manufacture, process, pack, or hold FTL foods) as the proportion of domestic firms.

Thus, we estimate the count of foreign establishments affected by the rule to be about 1.95 times the main count of establishments affected by the rule (or approximately 127,925 = 65,607 x 1.95), and likewise for the count of affected firms (approximately 108,686 = 55,740 x 1.95). We do not have a detailed breakdown of these foreign establishments and firms by industry, and instead assume the same proportional breakdown as in the main analysis. In other words, for each cost element described in sections II.F.ii – II.F.v, we simply exclude RFEs and then scale the remaining number of affected entities by 1.95. Hence, we estimate foreign costs by: 1) multiplying the domestic firm and establishment counts from the main analysis by 1.95 (after excluding RFEs) to obtain foreign counts, and 2) replacing domestic wage estimates with foreign wage estimates in labor cost calculations.

We generally expect foreign wages to be lower than domestic wages. To estimate wages for foreign employees and supervisors, we take weighted average wages across the top twenty foreign countries by value of food exports to the United States (weighted by value of food exports) (Ref. [40]).[63] This produces a foreign employee wage of $6.91 per hour and a foreign supervisor wage of $15.63 per hour, which we double to account for benefits and overhead.

Additionally, we adjust estimates of the time to read and understand the rule accounting for potentially lower English language proficiency and internet accessibility among some foreign facilities.[64] For example, in learning about the requirements of this proposed rule, we assume that entities from English speaking countries will spend a comparable amount of time as domestic entities. Entities from countries with low English proficiency but with high internet access may spend more time learning about the rule than domestic entities because they may need to have internet access to translate the rule. Entities from countries with both low English proficiency and low internet access may spend even more time learning about the rule (and incur higher costs) than entities from countries with high English proficiency and/or internet access. We estimate that foreign establishments on average would spend 1.61 hours for every hour that domestic establishments spend reading the rule. This estimate is the average of an estimated English proficiency weighted average of 1.67 hours and an estimated internet usage weighted average of 1.56 hours. To account for language proficiency differences, we use information from a report titled "Education First English Proficiency Index" (EF EPI) published in November of 2018.[65] This report ranks countries by the average level of English language skills amongst

63 Except for Vietnam and Ecuador, for which the OWW dataset lacked data.
64 FDA does not require that records be maintained in English. Instead, we require that an English translation be provided upon request.
65 EF English Proficiency Index – Comparing English skills between countries – EF EPI. Ef.com. Retrieved on 2018 -11-16. http://www.ef.edu/epi/

adults using data collected via English tests available over the internet. To account for country differences in internet accessibility, we use 2018 internet user percentage estimates by country.[66]

We request comment on these estimates.

I. Uncertainty and Sensitivity Analysis

There are several sources of uncertainty associated with both the costs and benefits of the proposed rule. Most of these sources of uncertainty arise from inadequate data or information related to implementation of the proposed rule, if finalized.

We have very limited information regarding the number of entities (firms or establishments) that would be affected by the proposed rule. As there is no specific single registry for entities that currently manufacture, process, pack, or hold foods on the FTL, it is difficult to establish the total number of such affected entities. Moreover, should the rule be finalized, the Food Traceability List could potentially change through addition and/or deletion of foods. We are therefore unable to predict the foods that will in the future be on the FTL, and the number of entities that might become covered or cease to be covered. Instead, we more broadly consider Census Bureau industry classifications that we expect to encompass FTL products and related entities. Our estimates rely on assumptions about the share of each industry that would be affected by the proposed rule, if finalized. These share assumptions are based mostly on receipts data from the 2012 Economic Census.

Additionally, our cost estimates reflect uncertainty about the degree to which entities already satisfy the requirements of the proposed rule. While in recent years the food industry has adopted new technologies, including those related to product traceability, we are unable to

66 Internet Usage and world populations Statistics Estimates. www.internetworldstats.com. Copyright © 2018, Miniwatts Marketing Group. All rights reserved worldwide viewed on November 27,2018.

exactly quantify the extent of this change. For example, because of the volume and diversity of existing State and local recordkeeping requirements, our cost estimates do not account for State or local regulations that require similar recordkeeping practices for small sectors of the food economy. Overall, we expect the exclusion of these other regulatory factors to have a very small effect on our cost computations.

However, apart from technological change that corresponds to regulatory requirements (e.g., in response to FSMA or to State or local regulations), entities have been gradually adopting technologies for business reasons, including but not limited to enhanced inventory management and supply system efficiencies. To account for this, our main cost estimates use three different assumptions regarding the percentage of estimated traceability costs that entities would incur due to the rule: twenty-five percent, fifty percent, and seventy-five percent. Note that we only consider an average percentage over all covered entities. Particularly given the number of industries likely to be affected, we lack data to estimate the percentage of remaining traceability investment needed by each industry. As there may be significant variation between industries in size, supply chain complexity, and current practice, there may accordingly be significant uncertainty that our estimates do not capture.

We also face significant uncertainty in relation to the expected benefits of the proposed rule. While we expect the rule to improve public health by reducing the size and impact of outbreaks, we are unable to determine the magnitude of this improvement. Our uncertainty regarding the benefits of the rule primarily stems from the complexity of predicting the health benefits of shorter foodborne disease outbreaks.

Concerning our baseline scenario, we are also uncertain about the current number of foodborne illnesses caused by foods covered by the FTL rule. Our baseline estimates are

primarily based on 2009-2019 FDA outbreak data. During this period, numerous initiatives have taken effect, including publication of several FSMA-related rules intended to help prevent foodborne illness outbreaks, including outbreaks from foods on the FTL. We lack data on the extent to which these rules might have changed our baseline.

To address some of the uncertainties outlined above, we show estimates using wide ranges for the share of covered firms within each industry. We also allow the share of traceability investment needed among covered firms to range from twenty-five percent to seventy-five percent. Finally, our monetized benefits reflect a wide uncertainty range because they were calculated using information from a small (possibly under-representative) number of outbreaks.

J. Analysis of Regulatory Alternatives to the Proposed Rule

We considered five different regulatory alternatives in addition to the proposed and co-proposed options. We compare these regulatory alternatives to proposed Option 2 only. We estimate costs of regulatory alternatives keeping in mind that FDA is also proposing that the compliance date for any final rule would be two years after the date the final rule is effective. We estimate cost of all regulatory alternatives as if they have the same effective and compliance dates as the proposed rule.

The five alternatives we consider are Alternative a): No new regulatory action as the baseline for determining the costs and benefits of other alternatives including the proposed rule; Alternative b): Expand the FTL rule to cover all foods instead of the proposed rule; Alternative c): Expand coverage for very small farms; Alternative d): Include foods transformed or created at the retail level; and Alternative e): Extend compliance date to three years. Table 34 shows a

detailed summary of the costs associated with each regulatory alternative and the change in the estimated costs relative to those associated with the proposed rule.

Alternative a: No Action

We treat the alternative of taking no new regulatory action as the baseline for determining the costs and benefits of other alternatives. In choosing an appropriate baseline, OMB Circular A-4 recommends considering a wide range of factors, including market evolution, changes in external factors affecting expected benefits and costs, changes in regulations promulgated by the agency and the degree of compliance by regulated entities with other regulations. In choosing a baseline, we assume costs and benefits of the BTA food tracing requirements are already accounted for (although benefits have been either overestimated or not fully realized). As such, if FDA pursued Alternative a, there would be no additional costs or benefits under this alternative.

Alternative b: Expand the proposed rule to include all foods at covered firms

This option evaluated a scenario where traceability would be a requirement for all foods and not just for FTL foods. Although this option is not legally viable under current law, ideally such a requirement for the industry may be a logical step to further improve public health. It has been argued that the risk of food contamination is based more on handling practices rather than on the type of commodities (Ref. [41]). Some food traceability experts have argued that a traceability platform that focuses on a select list of foods runs the risk of becoming outdated, especially when new outbreak vehicles emerge. Thus far, firms that have chosen to invest in

traceability programs have generally done so for their entire inventory, maximizing their investment, rather than focusing on a specific subset of products. While many firms will not necessarily require additional traceability investments, we recognize that building a food traceability platform with wide scope and depth will likely be more feasible for larger businesses than for small businesses who constitute nearly 90 percent of firms (Ref. [42]).

Costs of including foods that are not on the FTL would affect mostly small businesses. We estimate the annualized cost of Alternative b would be $656 million, which is about $121 million more than the estimated cost of the proposed rule (Table 34).

Any additional benefits from including other foods beyond the FTL would depend on the extent to which other foods not on the FTL are involved in outbreaks. We are unable to quantify any additional benefits from this option and request comments on the benefits of including other foods beyond those on the FTL.

Alternative c: Expand coverage for very small farms and other originators.

We evaluate a scenario where implementation of the proposed rule will include over 22,000 very small farms and other originators which in the current proposed rule would be exempt. Including these additional firms will increase the annualized cost of the rule to $549 million (using a seven percent discount rate) which is roughly about $14 million more than the estimated cost of the rule. While the extension of the rule to include certain small farms and originators increases costs to these small entities, including them could also increase the benefits of the rule by improving public health. The expected additional benefits of such coverage would depend on the proportion of FTL foods from these very small farms and originators entering the market and may or may not offset the additional social costs of such a broad rule. If we assume a

small market share of FTL foods are from very small farms and originators, any additional estimated benefits of this option would also be small. We request comments on this assumption.

Alternative d: Include foods transformed or created at the retail level

Under this alternative, the proposed traceability recordkeeping requirements would apply to the transformation or creation of food performed by retail food establishments such as grocery stores and convenience stores (but not restaurants, who transform food for individual diners). We considered the additional recordkeeping requirements for non-restaurant retail food establishments if they create a food on the FTL that they sell directly to a consumer or if they transform a food on the FTL to food they sell directly to a consumer. For example, if the retail food establishment prepared fresh salsa using tomatoes and fresh herbs, it would be required to keep records for the lot numbers and other traceability product identifiers for the tomatoes and herbs, as well as records for the fresh salsa, as outlined by the requirements of § 1.1340 and § 1.1345.

FDA has tentatively concluded that to require non-restaurant retail food establishments to keep records of these transformation and creation events would be too burdensome and not necessary in order to address credible foodborne illness outbreak threats. We also do not anticipate this alternative having an impact on reducing the impact of overly broad recalls or market withdrawals and therefore assume estimated benefits of this option to be same as the estimated benefit of the proposed rule (Table 34). We request comments on this assumption.

Alternative e: Extend compliance date to three years

This alternative extends the compliance date of the rule to three years following the effective date of the final regulation. Under this Option 1 we assume that the rule would publish

in year 0, costs would begin in year 2 instead of year 1, and benefits would begin in year 3 instead of year 2. Compared to Option 2, delaying the compliance date would reduce the burden on covered entities by shifting costs into the future. Health benefits would also be lower under this alternative because they would begin one year later than under Option 2.

Table 34. Summary of Costs by Regulatory Alternatives Compared to Option 2 (the Proposed Rule) ($ millions)

Regulatory Option - Domestic Facilities	Costs		
	One-Time Costs	Recurring Costs ($/year)	Annualized Total (7%)
Proposed Rule Option 2	$1,113	$387	$535
Regulatory Alternative a: No Action	0	0	0
Change from Proposed Rule	($1,113)	($387)	($535)
Regulatory Alternative b: Expand coverage beyond FTL foods	$1,514	$455	$656
Change from Proposed Rule	$401	$68	$121
Regulatory Alternative c: Expand coverage for very small farms and other originators	$1,167	$394	$549
Change from Proposed Rule	$54	$7	$14
Regulatory Alternative d: Include foods transformed or created at the retail level	$1,113	$452	$600
Change from Proposed Rule	$0	$65	$65
Regulatory Alternative e: Extend compliance date to three years	$1,113	$387	$474
Change from Proposed Rule	$0	$0	($61)

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because some small firms may have annualized costs (over ten years at a seven percent discount rate) 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. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

The entities in this small entity analysis are firms. The Small Business Administration (SBA) publishes size standards for industry categories of firms defined by North American Industry Classification System (NAICS) codes. SBA defines each NAICS code's small business threshhold either in terms of sales revenue or number of employees of a firm. Using the 2019 SBA size standards[67] in conjunction with the SUSB counts of firms in each NAICS code by revenue and employment size,[68] we estimate the numbers of covered small firms by industry. Overall, about 89.7 percent of firms coverd by this rule count as small businesses by SBA standards. Table 35 shows estimated counts of covered small firms by NAICS code.

67 Small Business Association. Table of Size Standards. Aug 19, 2019. Available from: https://www.sba.gov/document/support--table-size-standards

68 We use the 2012 SUSB, the last release that contained revenue data, and inflate revenues to 2018 dollar values using the GDP deflator.
Census Bureau. 2012 SUSB Annual Datasets by Establishment Industry. Updated 2015. Available from: https://census.gov/data/datasets/2012/econ/susb/2012-susb.html

Table 35. Entities affected by the proposed rule

2012 NAICS Code	NAICS Industry Description	Firm type	Number of Covered Small Firms	Annual Revenue ($millions)	Revenue per Firm ($millions)	SBA Size Standard ($millions or no. of employees)
111219	Other Vegetable (except Potato) and Melon Farming[69]	Farms/Aquaculture/Growers	6,604	$927	$0.14	$1
111339	Other Non-citrus Fruit Farming[69]	Farms/Aquaculture/Growers	271	$38	$0.14	$1
111419	Other Food Crops Grown Under Cover[69]	Farms/Aquaculture/Growers	220	$31	$0.14	$1
112310	Chicken Egg Production[70]	Farms/Aquaculture/Growers	1,375	$4,024	$2.93	$16.5
112511	Finfish Farming and Fish Hatcheries[71]	Farms/Aquaculture/Growers	292	$82	$0.28	$1
112512	Shellfish Farming[71]	Farms/Aquaculture/Growers	311	$77	$0.25	$1
114111	Finfish Fishing	Farms/Aquaculture/Growers	586	$610	$1.04	$22.00
114112	Shellfish Fishing	Farms/Aquaculture/Growers	447	$256	$0.57	$6.00

69 We base the small entity count and revenue estimate for this industry on Tables 47 and 48 of the regulatory impact analysis for the prior Produce Rule (Ref. [43]): https://www.fda.gov/media/94153/download

70 The SBA defines chicken and egg producers to be small if their total revenues are less than $16.5 million. A producer that receives $0.85 per dozen eggs (the midpoint of seasonally adjusted December 2018 and December 2019 market egg prices) and has layers that produce 265 eggs per year would have to have over 879,000 layers in production to earn revenues of over $16.5 million. Because only about 320 farms fall into the category of 100,000 or more layers, more than 99 percent of the farms with more than 3,000 layers are considered small by SBA standards and account for roughly 76 percent of all production. Multiplying this production amount (76 percent) by the value of all egg production in 2018 ($10,586,262,000) (Ref. [44]) gives $8,045,559,120 in total revenue for small farms. If 99 percent of egg farms (2,777 x 0.99 = 2,749) are considered small by SBA standards, then we estimate the average revenue per SBA small egg farm to be $2,926,722.

71 We use Table 9 from the 2018 USDA Census of Aquaculture to compute the weighted average revenue of small farms (less than $1 million in sales) by fish type (baitfish, food fish, crustaceans, and mollusks). We then combine categories by weighted average of types of small farms (Finfish includes food fish and Shellfish includes Crustaceans and Mollusks). Finally, we multiply the average revenue by the total number of small farms to obtain the total revenue for all small farms.

311340	Nonchocolate Confectionery Manufacturing	Manufacturing/Processing/Packing	245	$5,813	$23.73	1,000
311351	Chocolate and Confectionery Manufacturing from Cacao Beans	Manufacturing/Processing/Packing	72	$3,090	$42.91	1,250
311352	Confectionery Manufacturing from Purchased Chocolate	Manufacturing/Processing/Packing	670	$5,716	$8.53	1,000
311411	Frozen Fruit, Juice and Vegetable Manufacturing	Manufacturing/Processing/Packing	92	$7,943	$86.33	1,000
311412	Frozen Specialty Food Manufacturing	Manufacturing/Processing/Packing	151	$7,367	$48.79	1,250
311421	Fruit and Vegetable Canning	Manufacturing/Processing/Packing	476	$21,900	$46.01	1,000
311422	Specialty Canning	Manufacturing/Processing/Packing	64	$6,823	$106.61	1,250
311423	Dried and Dehydrated Food Manufacturing	Manufacturing/Processing/Packing	138	$5,935	$43.01	750
311513	Cheese Manufacturing	Manufacturing/Processing/Packing	156	$18,143	$116.30	1,250
311520	Ice Cream and Frozen Dessert Manufacturing	Manufacturing/Processing/Packing	230	$5,278	$22.95	1,000
311710	Seafood Product Preparation and Packaging	Manufacturing/Processing/Packing	248	$5,649	$22.78	750
311811	Retail Bakeries	Manufacturing/Processing/Packing	4,214	$2,222	$0.53	500
311812	Commercial Bakeries	Manufacturing/Processing/Packing	1,923	$26,323	$13.69	1,000
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing	Manufacturing/Processing/Packing	134	$3,983	$29.73	750

311821	Cookie and Cracker Manufacturing	Manufacturing/Processing/Packing	157	$6,567	$41.83	1250
311824	Dry Pasta, Dough, and Flour Mixes Manufacturing from Purchased Flour	Manufacturing/Processing/Packing	211	$7,221	$34.22	750
311911	Roasted Nuts and Peanut Butter Manufacturing	Manufacturing/Processing/Packing	106	$6,080	$57.36	750
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing	Manufacturing/Processing/Packing	164	$5,982	$36.48	750
311942	Spice and Extract Manufacturing	Manufacturing/Processing/Packing	141	$2,033	$14.42	500
311991	Perishable Prepared Food Manufacturing	Manufacturing/Processing/Packing	300	$2,116	$7.05	500
424410	General Line Grocery Merchant Wholesalers	Wholesalers/Distributors	1,561	$26,983	$17.29	250
424420	Packaged Frozen Food Merchant Wholesalers	Wholesalers/Distributors	1,539	$29,023	$18.86	200
424430	Dairy Product (except Dried or Canned) Merchant Wholesalers	Wholesalers/Distributors	824	$13,135	$15.94	200
424450	Confectionery Merchant Wholesalers	Wholesalers/Distributors	1,142	$8,547	$7.48	200
424460	Fish and Seafood Merchant Wholesalers	Wholesalers/Distributors	1,285	$8,758	$6.82	100
424480	Fresh Fruit and Vegetable Merchant Wholesalers	Wholesalers/Distributors	3,384	$34,480	$10.19	100

424490	Other Grocery and Related Products Merchant Wholesalers	Wholesalers/ Distributors	7,945	$62,160	$7.82	250
445110	Supermarkets and Other Grocery (except Convenience) Stores	Retail Food Establishments	21,691	$58,995	$2.72	$35.00
445120	Convenience Stores	Retail Food Establishments	12,769	$11,135	$0.87	$32.00
445220	Fish and Seafood Markets	Retail Food Establishments	1,003	$1,187	$1.18	$8.00
445292	Confectionery and Nut Stores	Retail Food Establishments	1,253	$742	$0.59	$8.00
445230	Fruit and Vegetable Markets	Retail Food Establishments	1,411	$1,805	$1.28	$8.00
445291	Baked Goods Stores	Retail Food Establishments	2,015	$957	$0.48	$8.00
445299	All Other Specialty Food Stores	Retail Food Establishments	2,587	$1,843	$0.71	$8.00
447110	Gasoline Stations with Convenience Stores	Retail Food Establishments	21,087	$74,323	$3.52	$32.00
452910	Warehouse Clubs and Supercenters	Retail Food Establishments	10	$4	$0.36	$32.00
454111	Non-store Retailers: Electronic Shopping	Retail Food Establishments	7,954	$16,124	$2.03	$41.50
454210	Vending Machine Operators	Retail Food Establishments	2,033	$1,894	$0.93	$12.00
493110	General Warehousing and Storage	Warehouses and Storage	2,523	$16,733	$6.63	$30.00
493120	Refrigerated Warehousing and Storage	Warehouses and Storage	360	$1,322	$3.67	$30.00

493130	Farm Product Warehousing and Storage	Warehouses and Storage	239	$808	$3.38	$30.00
722310	Food Service Contractors	Retail Food Establishments	1,482	$2,063	$1.39	$41.50
722320	Caterers	Retail Food Establishments	7,604	$6,083	$0.80	$8.00
722330	Mobile Food Services	Retail Food Establishments	2,369	$652	$0.28	$8.00
722410	Drinking Places (Alcoholic Beverages)	Retail Food Establishments	18,104	$9,211	$0.51	$8.00
722511	Full-Service Restaurants	Retail Food Establishments	116,204	$99,411	$0.86	$8.00
722513	Limited-Service Restaurants	Retail Food Establishments	83,421	$77,268	$0.93	$12.00
722514	Cafeterias, Grill Buffets, and Buffets	Retail Food Establishments	3,731	$3,010	$0.81	$30.00
722515	Snack and Nonalcoholic Beverage Bars	Retail Food Establishments	31,711	$15,109	$0.48	$8.00

B. Description of the Potential Impacts of the Rule on Small Entities

In the main cost section of this economic impact analysis, we present low, medium, and high cost estimates for each provision of the rule. We estimate that costs to small firms would fall primarily between our low and primary estimates. We do not attempt to characterize the variability within this range, and hence present the low and primary estimates without suggesting any particular distribution of the costs between them. We do not suggest, for example, that the average of the low and primary estimates is particularly representative of small firms. In this small entity analysis, we call these estimates our lower and upper bounds.

Table 36 breaks down our estimate of one-time cost per covered small entitity across broad categories of industries. Though aggregate totals are displayed for these broad categories, the underlying analysis in this section accounts for applicable provisions at the level of each NAICS code. We assume that all covered small entities would incur one-time costs to read and understand the rule. Some covered small entities would also incur a one-time capital investment cost and a one-time cost of training, as well as recurring annual recordkeeping costs. We expect one-time per firm compliance costs to range from about $300 to $5,500 for small farms and small manufacturers, $300 to $5,700 for small wholesalers, $300 to $6,100 for small warehouses, and $100 to $2,200 for small retailers.

Table 36. One-time per firm compliance costs of the proposed rule

	Lower Bound	Upper Bound
Farms /Aquaculture / Growers	$287	$5,543
Manufacturers / Processors / Packers	$290	$5,597
Wholesalers / Distributors	$297	$5,727
Warehouse and Storage	$321	$6,139
Retail Food Establishments	$113	$2,178

Using the same breakdown, Table 37 shows estimated cost per covered small entities, anualized over ten years at a seven percent discount rate. We expect annualized costs to range from about $400 to $5,300 for small farms, $500 to $6,300 for small manufacturers, $500 to $6,000 for small wholesalers, $500 to $5,600 for small warehouses, and $0 to $600 for small retailers.

Table 37. Annualized per firm compliance costs of the proposed rule (over ten years, seven percent discount rate)

	Lower Bound	Upper Bound
Farms /Aquaculture / Growers	$416	$5,286
Manufacturers / Processors / Packers	$520	$6,339
Wholesalers / Distributors	$522	$6,057
Warehouse and Storage	$472	$5,618
Retail Food Establishments	$45	$582

We use the SUSB[72] to estimate the magnitude of costs as a percent of the revenues of covered small firms. We consider costs per firm exceeding one percent of annual revenues to be a substantial impact. Table 38 shows our estimate of the one-time compliance costs as a percentage of revenue for small firms, broken down by broad industry categories. We expect one-time costs as a percentage of annual revenue to range from about 0.1% to 0.9% for small farms overall, 0% to 0.2% for small chicken egg farms, 0.1% to 2.4% for other small farms, 0% to 0% for small manufacturers, 0% to 0.1% for small wholesalers, 0% to 0.1% for small warehouses, and 0% to 0.2% for small retailers.

Table 38. One-time per firm compliance costs as a percentage of small firm annual revenue

	Costs as a percent of revenue (Lower Bound)	Costs as a percent of revenue (Upper Bound)
Farms /Aquaculture / Growers	0.05%	0.93%
Chicken egg production	0.01%	0.19%
Other farms	0.12%	2.40%
Manufacturers / Processors / Packers	0.00%	0.04%
Wholesalers / Distributors	0.00%	0.06%
Warehouse and Storage	0.01%	0.10%
Retail Food Establishments	0.01%	0.19%

Using the same categorical breakdown, Table 39 shows the annualized values of our estimates of compliance costs over ten years at a seven percent discount rate, again as a percentage of the revenues of covered small firms. Over ten years, at a seven percent discount rate, we expect annualized costs as a percentage of annual revenue to range from about 0.07% to 0.9% for small farms overall, 0% to 0.2% for small chicken egg farms, 0.2% to 2.3% for other

[72] For small farms, we estimate revenues based on the Produce Rule economic impacts analysis, the USDA National Agricultural Statistics Service, and the USDA Census of Agriculture. We describe these estimates in footnotes 69, 70, and 71.

small farms, 0% to 0% for small manufacturers, 0% to 0.1% for small wholesalers, 0% to 0.1% for small warehouses, and 0% to 0.1% for small retailers.

Table 39. Annualized per firm compliance costs as a percentage of annual revenue (ten years, seven percent discount rate)

	Costs as a percent of revenue (Lower Bound)	Costs as a percent of revenue (Upper Bound)
Farms /Aquaculture / Growers	0.07%	0.88%
Chicken egg production	0.01%	0.18%
Other farms	0.18%	2.28%
Manufacturers / Processors / Packers	0.00%	0.04%
Wholesalers / Distributors	0.01%	0.06%
Warehouse and Storage	0.01%	0.09%
Retail Food Establishments	0.00%	0.05%

In Table 40, we estimate that the total costs of the proposed rule per covered small firm over ten years ranges from approximately $900 to $10,700. At a seven percent discount rate, the present value of the total costs of the proposed rule per covered small firm ranges from approximately $700 to $8,100. Discounted at three percent, the present value of the total costs of the proposed rule per covered small firm ranges from approximately $800 to $9,400. Discounted at either seven or three percent over ten years, the estimated annualized value of costs of the proposed rule per small firm ranges from approximately $100 to $1,100. We request comment on our small entity analysis. In particular, we recognize that there may be variability in the cost burden for very small firms and request comment and data on how to best characterize very small firms by sector.

Table 40. Costs of the proposed rule per small firm (over ten years)

	Lower Bound	Upper Bound
Total Costs of the Proposed Rule	$883	$10,700
Present Value of Total Costs (7%)	$651	$8,108
Present Value of Total Costs (3%)	$769	$9,428
Annualized Value of Costs (7%)	$93	$1,154
Annualized Value of Costs (3%)	$90	$1,105

C. Alternatives to Minimize the Burden on Small Entities

As the vast majority (roughly ninety-three percent) of covered firms qualify as small entities, the analysis of regulatory alternatives for covered firms described in Section J above effectively describes the effects of the alternatives on small entities. Delaying the compliance date for small entities would delay the implementation of the proposed rule for the vast majority of FTL products. While the postponement of capital investments and labor expenses for compliance would reduce the present value of costs of the proposed rule, it would also reduce the present value of the health benefits.

IV. Co-proposed Option 1

A. Summary

For purposes of estimating the economic impact of co-proposed Option 1 (full exemption for small retail food establishments (RFEs)), we use the same assumptions used to estimate the economic impact of Option 2 (exemption for small RFEs from the requirement to provide FDA, under certain circumstances, with an electronic sortable spreadsheet of requested tracing information). The rule under Option 1 would fully exempt RFEs with ten or fewer full-time equivalent employees from the proposed rule; all provisions are otherwise the same. Option 2 would only exempt such RFEs from the requirement that, under certain circumstances, entities provide an electronic sortable spreadsheet to FDA upon request. Our economic analysis of impacts of Option 2 is described in sections II and III. In this section IV, we summarize estimates for co-proposed Option 1 and compare them to estimates for Option 2. Table 41 shows

the overall reduction in covered firms and establishments and reduction in annualized costs for both Options.

Table 41. Comparison of Impacts Between Option 1 and Option 2

Measure	Option 2	Option 1	Difference (Option 1 - Option 2)
Covered Retail Food Firms	366,404	132,551	(233,853)
Covered Retail Food Establishments	500,841	266,246	(234,595)
Costs (Annualized at 7%, 10 years), Millions 2018$	$535	$411	($124)
International Costs that May Be Passed Through to US Supply Chain and Consumers (Annualized at 7%, 10 years), Millions 2018$	Up to $259	Up to $259	($0)
Public Health Benefits (Annualized at 7%, 10 years), Millions 2018$	$626	$567	($59)
Benefits from Avoiding Overly Broad Recalls, (Annualized at 7%, 10 years), Millions 2018$	$1,658 - $5,634	$1,658 - $5,634	($0)
Cost per Illness, 2018$	$7,220	$7,220	($0)

Costs are lower in Option 1, relative to Option 2, because fewer RFEs would need to comply with the proposed rule. However, if RFEs 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 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. The importance of RFEs, including small RFEs, to the efficiency and expediency of traceback and recalls is detailed in a memorandum by staff of FDA's Center for Food Safety and Applied Nutrition, Inclusion of Retail Establishments of all Sizes Under FSMA Section 204 (Ref. [1]).

To the extent that, in some outbreaks where small RFEs provide the only or best cluster identification for traceback, our estimates relying on simply scaling by sales volume may underestimate the full impact of exempting small RFEs.

B. Benefits

We provide a detailed description of benefits of this rule in sections I.B and II.E of this analysis. In this section we describe the difference in the benefits between the two options.

As explained in section E.3, we estimate benefits for co-proposed option 1 in the same manner as estimated for the proposed option 2.

Using the SUSB data, we estimate that RFEs with ten or fewer full-time equivalent employees account for approximately 9.5 percent of total RFE revenues. Using percent of revenue as a proxy for the percent of product that these RFEs handle – and in turn the percent of foodborne illnesses related to these RFEs – we estimate the benefits under Option 1 by scaling down our benefit estimates under Option 2 by 9.5 percent. We therefore estimate that (undiscounted) public health benefits from Option 1 would range between $38 million and $1.6 billion per year with a primary estimate of $654 million per year. Additional benefits from avoiding overly broad recalls could be the same as under option 2, ranging between $1.7 billion and $5.6 billion.

C. Costs

Using the SUSB data, we estimate that 47 percent of all RFEs (approximately 420,000 RFEs) have ten or fewer full-time equivalent employees. We estimate that Option 1 would cover in total approximately 188,291 firms (between 98,099 and 282,969 firms) and 331,858

establishments (between 180,280 and 494,115 establishments). Option 2 would in total cover approximately 422,144 firms (between 224,679 and 636,809 firms) and 566,448 establishments (between 307,246 and 849,095 establishments).

Table 42 compares the costs of Option 1 and Option 2; Table 42 summarizes the one-time and recurring costs of Option 1. Because Option 1 affects fewer entities, it would result in lower total costs than Option 2. The largest reduction in costs in Option 1 is due to fewer restaurants incurring costs of capital investment, which accounts for about 77 percent of the total difference (Table 42). In total, Option 1 avoids $548 million in one-time costs ($1,113 million - $565 million = $548 million) and $51 million in recurring costs ($387 million - $336 million = $51). Many recurring costs result from provisions that do not apply to RFEs, and our estimates of these costs are thus the same under both options.

Table 42. Comparison of Costs between Option 1 and Option 2 by Provision (undiscounted, Millions 2018$)

One-time Costs	*Option 2*	*Option 1*	*Difference (Option 1 – Option 2)*
Reading and Understanding the Rule	$52	$23	($29)
Capital Investment	$725	$356	($369)
Training	$174	$85	($89)
§ 1.1315 General Recordkeeping	$163	$101	($62)
Total One-time Costs	**$1,113**	**$565**	**($548)**
Annually Recurring Costs			
§ 1.1315 General Recordkeeping	$20	$13	($8)
§ 1.1325 Growing Recordkeeping	$12	$12	$0
§ 1.1330 First Receiver Recordkeeping	$16	$15	($1)

§ 1.1335 Receiver Recordkeeping	$98	$56	$(42)
§ 1.1340 Transformation Recordkeeping	$7	$7	$0
§ 1.1345 Creation Recordkeeping	$0	$0	$0
§ 1.1350 Shipping Recordkeeping	$234	$234	$0
Total Recurring Costs	**$387**	**$336**	**($51)**
Total Costs	**$1,500**	**$901**	**($599)**

Table 43 below summarizes the low, primary and high undiscounted cost estimates of Option 1 by provision. One-time costs for Option 1 would range from $23 million to $3,582 million. Recurring (annual) costs under Option 1 would range from $30 million to $1,917 million.

Table 43. Total Costs of Option 1 (Millions 2018$)

One-time Costs	Primary	Low	High
Reading and Understanding the Rule	$23	$11	$39
Capital Investment	$356	$5	$2,759
Training	$85	$6	$317
§ 1.1315 General Recordkeeping	$101	$6	$700
Total One-time Costs	**$565**	**$28**	**$3,816**
Annually Recurring Costs			
§ 1.1315 General Recordkeeping	$13	$1	$78
§ 1.1325 Growing Recordkeeping	$12	$0.2	$102
§ 1.1330 First Receiver Recordkeeping	$15	$1	$93
§ 1.1335 Receiver Recordkeeping	$56	$6	$287
§ 1.1340 Transformation Recordkeeping	$7	$0.4	$41
§ 1.1345 Creation Recordkeeping	$0.3	$0.01	$2
§ 1.1350 Shipping Recordkeeping	$234	$22	$1,315
Total Recurring Costs	**$336**	**$30**	**$1,917**

Table 44 shows the timing of costs of Option 1 over ten years. The total costs of Option 1 are $1,055 million less than Option 2 ($4,980 million - $3,925 million = $1,055 million). Annualized at a seven percent discount rate, the costs of Option 1 are $124 million less than the

costs of Option 2 ($535 million - $411 million = $124 million). At a three percent discount rate, the costs of Option 1 are $113 million less ($513 million - $400 million = $113 million).

Table 44. Ten-Year Timing of the Costs of Option 1 (Millions 2018$)

Year	Primary	Low	High
1	$901	$58	$5,733
2	$336	$30	$1,917
3	$336	$30	$1,917
4	$336	$30	$1,917
5	$336	$30	$1,917
6	$336	$30	$1,917
7	$336	$30	$1,917
8	$336	$30	$1,917
9	$336	$30	$1,917
10	$336	$30	$1,917
Total Costs of Co-proposed Option 1	$3,925	$330	$22,990
Present Value of Total Costs (3%)	$3,415	$285	$20,061
Present Value of Total Costs (7%)	$2,888	$238	$17,033
Annualized Value of Costs (3%)	**$400**	**$33**	**$2,352**
Annualized Value of Costs (7%)	**$411**	**$34**	**$2,425**

D. International Effects

We expect international costs of the proposed rule under co-proposed Option 1 to be the same as under Option 2. While it is possible that there might be a small number of foreign entities that sell food in the United States and meet the definition of "retail food establishment," we assume that the number of such entities affected by this rule is negligible. We request comment on this assumption.

E. Regulatory Alternatives

In Section II.J we considered five different regulatory alternatives to Option 2; in this section IV.E we compare these regulatory alternatives to co-proposed Option 1. We estimate

costs of regulatory alternatives, noting that FDA is also proposing that the compliance date for any final rule would be two years after the date the final rule is effective. We estimate costs of all regulatory alternatives as if they have the same effective and compliance dates as Option 2.

The five alternative options we consider are Alternative a): No new regulatory action as the baseline for determining the costs and benefits of other alternatives; Alternative b): Expand the FTL rule to cover all foods in affected industries; Alternative c): Expand coverage to include very small farms; Alternative d): Include foods transformed or created at the retail level; and Alternative e): Extend compliance date to three years. Table 45 shows a detailed summary of the costs associated with each regulatory alternative, and the change in the estimated costs relative to those associated with the co-proposed Option 1.

Table 45. Summary of Costs by Regulatory Alternatives Compared to Option 1 (millions 2018$)

Regulatory Option Domestic Facilities	**Costs**		
	One-Time Costs	**Recurring Costs ($/year)**	**Annualized Total (7%)**
Co-proposed Option 1	$565	$336	$411
Regulatory Alternative a: No Action	$0	$0	$0
Change from Option 1	*($565)*	*($336)*	*($411)*
Regulatory Alternative b: Expand coverage beyond FTL foods	$1,514	$454	$656
Change from Option 1	*$949*	*$118*	*$245*
Regulatory Alternative c: Expand coverage for very small farms and other originators	$1,167	$394	$549
Change from Option 1	*$603*	*$58*	*$138*

Regulatory Alternative d: Include foods transformed or created at the retail level	$1,113	$452	$600
Change from Option 1	*$565*	*$336*	*$411*
Regulatory Alternative e: Extend compliance date to three years	$565	$336	$362
Change from Option 1	*$0*	*$0*	*($49)*

F. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In Option 2 we found that, because some small firms may have annualized costs (over ten years at a seven percent discount rate) that exceed one percent of their annual revenue, the proposed rule would have a significant economic impact on a substantial number of small entities. The following analysis of Option 1 described in this sub-section and the analysis of Option 2 in Section III as well as other sections in this document, serve as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

For this analysis we report the difference in the impact to retail food establishments between Option 2 and Option 1. Table 46 summarizes the annualized difference in costs between Option 2 and Option 1 per small retail food establishment. The lower bound annualized cost per small retail food establishment is greater under Option 1 ($57) compared to Option 2 ($45) because the average cost per retail food establishment is greater under Option 1.

Table 46. Annualized Costs of Option 1 per Small Retail Food Establishment Firm (Ten years, Seven Percent Discount Rate, Millions 2018$)

Retail Food Establishments	Lower Bound	Costs as a percent of revenue (Lower)	Upper Bound	Costs as a percent of revenue (Upper)

Option 1	$57	0.01%	$679	0.07%
Option 2	$45	0.004%	$582	0.05%
Difference	$12	0.006%	$97	0.02%

As the vast majority (roughly ninety-three percent) of covered firms qualify as small entities, the analysis of regulatory alternatives for covered firms described in Section II.J above effectively describes the effects of the alternatives on small entities. Delaying the compliance date for small entities would delay the implementation of the proposed rule for the vast majority of FTL products. While the postponement of capital investments and labor expenses for compliance would reduce the present value of costs of the proposed rule, it would also reduce the present value of the health benefits. Under Option 1, we provide more flexibility to small entities by exempting all retail food establishments with ten or fewer full-time equivalent employees.

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[57] Institute of Food Technologists, "Pilot Projects for Improving Product Tracing along the Food Supply System - Final Report," Institute of Food Technologists, Chicago, IL, 2012.

VI. Appendices

A. Food Traceability List (FTL)

The list of applicable foods might change prior to publication of the final rule. After publication of the final rule, the list can be updated using the procedure set forth in proposed § 1.1465, if that provision is finalized. As of this writing, the list includes the following foods (Table A.1).

Table A.1. 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, etc.
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, endive, etc.
Melons	Includes all types of melons, such as cantaloupe, honeydew, watermelon, etc.
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, starfruit, etc.
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, salmon, etc.; except does not include siluriformes fish, such as catfish
Crustaceans	Includes all crustacean species, such as shrimp, crab, lobster, crayfish, etc.
Mollusks, bivalves	Includes all species of bivalve mollusks, such as oysters, clams, mussels, etc.; 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, seafood salad, etc.; does not include meat salads

B. Methodology Used to Estimate the Number of Illnesses

To obtain the number of illnesses, hospitalizations, and deaths reported in Table 5, we rely on FDA Coordinated Outbreak Response and Evaluation (CORE) data. We report these CORE data, covering the 10.5-year period from 2009 through July 2019, in columns 1-4 of Table B.1 in this appendix. We do not use CDC outbreak data for our estimates because those data include illnesses resulting from improper food handling, as well as illnesses associated with foods not regulated by FDA. Note that CORE data include more illnesses than those attributable to FTL food products. These include adverse reactions and fungus-related illnesses. We therefore use only the subset of CORE data on foodborne illness outbreaks associated with FTL foods.[73] Based on these data, of 31 known foodborne illness-causing pathogens, 10 are commonly associated with foods currently designated by FDA on the FTL. We list these pathogens in Table B.1.

To account for underreporting as well as underdiagnosing of foodborne illnesses, we apply Scallan et al. (2011a) multipliers for each pathogen, presented in columns 5, 6, and 7 of Table B.1. Column 5 contains Scallan et al.'s underdiagnosis multipliers specifically for hospitalizations and deaths, taken from the authors' Technical Appendix 3. Columns 6 and 7 contain the multipliers for underreporting and underdiagnosis of illnesses, also taken from Table 3.5 of the authors' Technical Appendix 3. Columns 8, 9, and 10 show the resulting estimates of the total number of cases, hospitalizations, and deaths from FTL foods over the 10.5-year period from 2009 through July 2019. Scallan *et al.* (2011a) did not provide illnesses underreporting multipliers for six pathogens (*Ciguatoxins*, *Listeria*, *Norovirus*, *Salmonella*, *Scombrotoxins,* and

73 We focus only on 2009-2019 outbreaks from this data set. Additionally, we subtract outbreaks related to adverse reactions, fungus, and those attributed to non-FTL foods, leaving 191 out of 557 outbreaks that we used for our analysis.

Tetrodotoxins), and for three of these pathogens (*Ciguatoxins*, *Norovirus*, and *Scombrotoxins*) the authors did not provide underdiagnosis multipliers. Furthermore, at least three foodborne illness-causing agents (*Ciguatoxins, Scombrotoxin* and *Tetrodotoxins*) did not have hospitalization and death underdiagnosis multipliers, for which we assume a value of one. We obtain underdiagnosis multipliers for illnesses from *Ciguatoxins* and *Scombrotoxin* from Pennotti et al. (2013) (Ref. [20]), and use the same multiplier for *Tetrodotoxins* as for *Ciguatoxins*. Following Scallan et al.'s (2011) treatment of other pathogens, we assumed 100 percent reporting for pathogens without underreporting multipliers and 100 percent diagnosis for pathogens without underdiagnosis multipliers.[74] To estimate the number of annual illnesses, hospitalizations, and deaths caused by each pathogen, we divide columns 8, 9, and 10 of Table B.1 by 10.5 years. Columns 11, 12, and 13 provide the resulting annual estimates. We estimate that these pathogens cause 119,706 illnesses, 408 hospitalizations, and 17 deaths annually via consumption of FTL-products.

Following Scallan et al. (2011b), we multiply the CORE number of illnesses from FTL foods by a factor of five to account for the roughly 80 percent of cases caused by unspecified agents. According to Scallan et al. (2011b) and CDC[75], nearly 80 percent of foodborne illnesses, 53 percent of hospitalized foodborne illnesses, and 58 percent of deaths from foodborne illnesses result from unspecified or unknown pathogens. Following Scallan et al. (2011b), we multiply the CORE number of illnesses from FTL foods by a factor of five to account for the roughly 80 percent of cases caused by unspecified agents; we also multiply the number of hospitalization and deaths by 2.13 (= 1/(1 - 0.53)) and 2.28 (= 1/(1 - 0.58)) respectively to account for

74 For Norovirus, we assumed the same overall case count underdiagnosis multiplier as for non-typhoidal *Salmonella*, which is 29.3.

75 https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html

unspecified agents. Not considering the burden caused by unspecified and unknown pathogens will result in substantial underestimation of FTL caused illnesses. We assume the same ratios for unidentified to identified cases due to FTL foods. The assumption is consistent with FDA's past regulatory impact analyses, including Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption of 2015. This assumption was made because outbreak data on unidentified pathogens, specifically their associated food commodity, is extremely sparse. The approach presumes that the percentage of identified illnesses, across all pathogens, attributable to FTL products would be lower than the percentage of illnesses from unidentified pathogens attributable to same products. The last row of Table B.1 present estimates of total illnesses, hospitalizations, and deaths from listed foods after scaling for unspecified and/or unknown agents. We estimate that in total about 598,500 foodborne illnesses are associated with FTL foods (= 119,706 cases from specified pathogens and 478,700 cases are illnesses from unspecified/unidentified pathogens). We use these estimates in our Preliminary Regulatory Impact Analysis. We also scale up the number of hospitalizations and deaths to account for unspecified agents and estimate that in total 869 hospitalizations (= 408 / (1 - 0.53)) and 39 deaths (= 16.6 / (1 - 0.58)) are caused by FTL foods annually.

Due to the sparsity of outbreak data on unspecified agents, as well as on underreporting and underdiagnosis of foodborne illnesses, our estimates are subject to assumptions described above. We request comment on our approach to estimating the number of illnesses, hospitalizations, and deaths associated with FTL foods.

Appendix Table B.1: Illnesses, Hospitalizations, and Deaths Attributable to Illness-Causing Pathogens Associated with FTL Foods

	(1) Number of FTL Related Outbreaks	Raw Count of FTL Illnesses			(5) Hospitalization and Death Multipliers due to Underdiagnosis	(6) Scallan Underreporting Multiplier	(7) Scallan/ Pennotti Underdiagnosis Multiplier	Estimated Total (2009-2019)			Estimated Annual Total (2009-2019)		
		(2) *Cases*	(3) *Hospitalizations*	(4) *Deaths*				(8) *Total Cases*	(9) *Hospitalization*	(10) *Deaths*	(11) *Total Cases*	(12) *Hospitalization*	(13) *Deaths*
Ciguatoxin	8	38	4	0	1	1	9.91	377	4	-	36	0	0
Cyclospora	8	2,612	75	0	2	1	83.1	217,057	150	-	20,672	14	0
E. coli (STEC) O157	18	654	241	9	2	25.5	26.1	435,270	482	18	41,454	46	2
E-Coli (STEC) non-O157	7	118	38	0	2	25.5	106.8	321,361	76	-	30,606	7	0
Hepatitis A Virus	4	613	203	2	2	1.1	9.1	6,136	406	4	584	39	0
Listeria	20	334	314	62	2	1	2.3	768	628	124	73	60	12
Norovirus	8	329	5	0	1.5	1	29.3	9,640	8	-	918	1	0
Salmonella non-typhoidal	86	8,521	1,242	14	2	1	29.3	249,665	2,484	28	23,778	237	3
Salmonella typhoidal	1	12	9	0	2	1	13.3	160	18	-	15	2	0
Scombrotoxin	21	56	2	0	1	1	12.21	684	2	-	65	0	0
Tetrodotoxin	1	1	1	0	1	1	9.91	10	1	-	1	0	0
Vibrio-para	8	98	14	0	2	1.1	142.4	15,351	28	-	1,462	3	0
Vibrio-Cholerae	1	12	0	0	2	1.1	33.1	437	-	-	42	0	0
Total from specified pathogens	**191**	**13,398**	**2,148**	**87**				**1,256,915**	**4,287**	**174**	**119,706**	**408**	**17**
Total including unspecified/unidentified pathogens								**6,284,575**	**9,120**	**414**	**598,531**	**869**	**39**

C. Outbreak Case Studies Used in Estimation of Public Health Benefits

This dataset represents 15 foodborne outbreaks from 2007 – 2019 coordinated by FDA's Emergency Coordination Response Team (ECRT) (2007 – 2010) and FDA's Coordinated Outbreak Response and Evaluation (CORE) Network (2011 – 2019), yielding 15 Public Health Benefit Case Studies. Each outbreak included in this analysis:

- involved a major pathogen/contaminant (*Salmonella*, Escherichia coli (STEC), *Listeria monocytogenes*, or *Cyclospora cayetanensis*);
- involved FDA-regulated food(s) from the Food Traceability List (FTL) that was identified as the outbreak vehicle and/or contaminated product;
- involved a formal traceback investigation that was coordinated by FDA;
- resulted in voluntary or enforced product interventions;
- and resulted in public communications issued by FDA and/or CDC.

Definitions:

- Year – The reported year that an outbreak was evaluated/investigated by FDA.
- Pathogen/Contaminant – The identified pathogen or contaminant associated with an outbreak according to the case definition, as defined by CDC.
- Species/Serotype – The species/serotype(s) that corresponds to the reported pathogen as determined by CDC.
- Commodity – The item(s) identified by FDA as the outbreak vehicle and/or contaminated product.
- Response Start Date – The date that a given outbreak was transferred to a CORE Response Team.

- Traceback Initiation Date – The date that represents when FDA's traceback investigation began.
    - This date represents when the first traceback information request was issued for record collection.
- Traceback Completion Date – The date that represents when FDA's traceback investigation (including the review of collected records and documentation of findings) ended.
    - This date represents when the last record was received by FDA for the traceback investigation.
- Response End Date – The date that a given outbreak was closed by a CORE Response Team.
- Final CDC Publication Date – The date of publication for the final outbreak web posting or corresponding update issued by CDC.
- Final CDC Web Post Link – The link to the final outbreak web posting or corresponding update issued by CDC.
    - For these case studies, the epidemiologic data that was used for the analysis included the final case count, hospitalization, and death totals that were publicly reported for a given outbreak.

Limitations:

The outbreaks used for the Public Health Benefit Case Studies were selected to represent significant outbreaks involving some of the commodities identified on the FTL. It should be noted that these cases studies do not represent all foodborne outbreaks investigated or traceback

investigations conducted from 2008 to 2019, nor do they represent all occurrences of an FTL product being implicated as the cause of an outbreak during that timeframe. Also, several outbreaks that were used for these case studies were excluded from the risk ranking analysis as this effort was performed as of 6/25/2020.

Another limitation of this analysis is the use of publicly reported epidemiologic data (case count, hospitalizations, deaths). For some outbreaks, the publicly reported values may differ from the final values internally reported by FDA and/or CDC, including the data that was used for the risk ranking analysis. Specifically, for outbreaks associated with *Cyclospora cayetanensis*, lack of a validated molecular subtyping methodology made it difficult to differentiate historical outbreaks that may have been occurring concurrently but were associated with different products. This led to challenges regarding the attribution of epidemiologic data to those distinct outbreaks and/or commodities.

Additionally, the level of FDA documentation that was readily available for the outbreak investigations included in this analysis varied, especially for those outbreaks that occurred before CORE was established in 2011. The Traceback Initiation and Completion Dates are estimations that best represent when the traceback investigations started and ended based on data pulled from varying sources documenting each outbreak (e.g., email correspondence, outbreak summary documents, etc.). The values in the dataset represent the best data currently available for comparing the investigational elements of interest across these outbreaks.

Table C.1.: Outbreak Case Studies Used for Estimation of Public Health Benefits

Year	Pathogen/ Contaminant	Species/Serotype	Commodity	Response Start Date	FDA Traceback Initiation Date	FDA Traceback Completion Date	Response End Date	Final CDC Publication Date	Final CDC Web Post Link
2008	Salmonella	Litchfield	Cantaloupe	3/4/2008	3/5/2008	4/10/2008	4/15/2008	4/2/2008	https://www.cdc.gov/salmonella/2008/cantaloupes-4-2-2008.html
2008	Salmonella	Saintpaul	Hot Peppers	5/28/2008	6/1/2008	7/17/2008	8/5/2008	8/28/2008	https://www.cdc.gov/salmonella/2008/raw-produce-8-28-2008.html
2009	Salmonella	Saintpaul	Alfalfa Sprouts	2/26/2009	3/2/2009	4/30/2009	5/1/2009	5/8/2009	https://www.cdc.gov/salmonella/2009/raw-alfalfa-sprouts-5-8-2009.html
2010	Salmonella	Enteritidis	Shell Eggs	7/26/2010	8/4/2010	8/31/2010	9/3/2010	12/2/2010	https://www.cdc.gov/salmonella/2010/shell-eggs-12-2-10.html
2010	E. coli	O145	Romaine Lettuce	4/21/2010	4/27/2010	5/11/2010	5/11/2010	5/21/2010	https://www.cdc.gov/ecoli/2010/shredded-romaine-5-21-10.html
2011	Listeria	monocytogenes	Cantaloupe	9/7/2011	9/11/2011	11/23/2011	12/11/2011	8/27/2012	https://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html
2012	E. coli	O26	Clover Sprouts	2/3/2012	2/7/2012	2/17/2012	5/22/2012	4/3/2012	https://www.cdc.gov/ecoli/2012/O26-02-12/index.html
2012	E. coli	O157:H7	Spinach	11/1/2012	11/1/2012	11/29/2012	12/21/2012	12/20/2012	https://www.cdc.gov/ecoli/2012/o157h7-11-12/advice-consumers.html
2013	Cyclospora	cayetanensis	*Leafy Greens	7/11/2013	7/11/2013	9/26/2013	12/16/2013	12/2/2013	https://www.cdc.gov/parasites/cyclosporiasis/outbreaks/investigation-2013.html
			*Cilantro		8/13/2013	11/7/2013		3/25/2016	
2016	E. coli	O157:NM	Alfalfa Sprouts	2/18/2016	2/19/2016	3/22/2016	4/5/2016		https://www.cdc.gov/ecoli/2016/o157-02-16/index.html
2018	E. coli	O157:H7	Romaine Lettuce	11/9/2018	11/15/2018	12/17/2018	3/25/2019	1/9/2019	https://www.cdc.gov/ecoli/2018/o157h7-11-18/index.html
2019	Cyclospora	cayetanensis	Basil	7/11/2019	7/15/2019	7/30/2019	2/3/2020	9/30/2019	https://www.cdc.gov/parasites/cyclosporiasis/outbreaks/2019/weekly/index.html
2019	E. coli	O157:H7	Romaine Lettuce	11/12/2019	11/18/2019	12/13/2019	3/16/2020	1/15/2020	https://www.cdc.gov/ecoli/2019/o157h7-11-19/index.html
2019	Salmonella	Javiana	Cantaloupe	12/6/2019	12/6/2019	1/8/2020	3/18/2020	2/18/2020	https://www.cdc.gov/salmonella/javiana-12-19/index.html

**Represents two concurrent outbreak investigations attributed to the same pathogen/contaminant, but different commodities.*