DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Requirements for Additional Traceability Records for Certain Foods

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

Final Regulatory Impact Analysis
Final 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 final rule under Executive Order 12866, Executive Order 13563, 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). The Office of Information and Regulatory Affairs has designated this final rule as 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 final 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 issuing "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 $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule would result in an expenditure in at least one year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This final rule will 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 recipients of the contaminated product. This rule will only apply to foods FDA has designated for inclusion on the Food Traceability List[1] and foods that contain listed foods as ingredients that remain in the same form (e.g., fresh) in which they appear on the list. By allowing faster identification of contaminated foods and increasing rates of successful tracing completions, the rule results in public health benefits if foodborne illnesses directly related to those outbreaks are averted. This might 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 covered foods.

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

While the primary benefits from the rule are the value of the reduction of foodborne illnesses and deaths, we also examine non-health related benefits. Non-health related benefits of this rule will be from avoiding costs associated with conducting overly broad recalls and market withdrawals that affect products that otherwise would not need to be withdrawn or recalled.

[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.

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. Benefits from avoiding overly broad recalls may be realized only when recalls are initiated in response to an FDA public health advisory.

It is possible, but not certain, that both of these categories of benefits could be experienced to the extent quantified in this regulatory impact analysis. On the other hand, it is also possible that a given instance of baseline contamination would lead to a very broad recall (that could be narrowed by the final rule) or to illnesses (that could be avoided due to the final rule) but not both.

Additional benefits of the rule 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; reduction of food waste; 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 (Ref. [1, 2]).

This rule will impose compliance costs on covered entities by increasing the number of records that are required for covered food products. Entities that manufacture, process, pack, or

[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 recalls of insured products which may have long term consequence to retailers from increases in their insurance rates due to imprecise recalls.

hold covered foods will incur costs to establish and maintain a traceability plan and traceability records. Some firms may also incur initial and recurring capital investment and training costs for systems that will enable them to keep, maintain, and make available to other supply chain entities (and to us upon our request) their traceability records. Moreover, firms will incur one-time costs of reading and understanding the rule.[3]

Table 1a and Table 1b summarize the costs and benefits of the final rule. At a seven percent discount rate, 20-year annualized costs range from about $63 million to $2.3 billion, with a primary estimate of $570 million per year. At a three percent discount rate, annualized costs range from about $53 million to $2.3 billion, with a primary estimate of $551 million per year. The present value of costs with seven percent discounting over 20 years (not shown in Table 1a) ranges from about $0.7 billion to $24.6 billion, with a primary estimate of about $6 billion. The present value of costs with three percent discounting over 20 years (not shown in Table 1a) ranges from about $0.8 billion to $33.7 billion, with a primary estimate of $8.2 billion.

In section II.E.1 we estimate public health benefits using several case studies of outbreak tracebacks for four pathogens associated with illnesses caused by covered foods.[4] We calculate these benefits based on an estimated 83 percent reduction of traceback time resulting from the requirements of this rule. At a seven percent discount rate over twenty years, the annualized monetized health benefits of the rule range from $59 million to $2.2 billion with a primary

[3] The information flows brought about by the rule may also prompt new protective actions — for example, in farming, manufacturing, or cooking processes — that could also have costs. We have not quantified these potential costs, but they would likely correlate with the realization of health and longevity benefits of this rule.

[4] This approach has 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. However, adjustments made for undiagnosed and unattributed illnesses may have the opposite tendency of overstating both FTL-associated illnesses and benefits. 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.1 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.

estimate of $780 million (Table 1a).[5] At a three percent discount rate over twenty years, the annualized monetized health benefits range from $61 million to $2.3 billion with a primary estimate of $810 million. The present value of health benefits with seven percent discounting over 20 years (not shown in Table 1a) ranges from about $0.6 billion to $23.7 billion, with a primary estimate of $8.3 billion. The present value of health benefits with three percent discounting over 20 years (not shown in Table 1a) ranges from about $0.9 billion to $34.5 billion, with a primary estimate of $12.0 billion.

In section II.E.2 we estimate (non-health) benefits from avoiding overly broad recalls and market withdrawals. At a seven percent discount rate over twenty years, these annualized monetized benefits range from $233 million to $1.8 billion with a primary estimate of $575 million (Table 1a). At a three percent discount rate over twenty years, these annualized monetized benefits range from $242 million to $1.8 billion with a primary estimate of $596 million. The present value of benefits from avoiding overly broad recalls with seven percent discounting over 20 years (not shown in Table 1a) ranges from about $2.5 billion to $18.8 billion, with a primary estimate of $6.1 billion. The present value of these benefits with three percent discounting over 20 years (not shown in Table 1a) ranges from about $3.6 billion to $27.3 billion, with a primary estimate of $8.9 billion.

Table 1a. Summary of Benefits, Costs and Distributional Effects of Final Rule ($Millions)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized Millions$/year	$780	$59	$2,238	2020	7%	20 years	Monetized health benefits from an estimated
		$810	$61	$2,322	2020	3%	20 years	

[5] We examined multiple case studies of tracing success rates for outbreaks. As explained in detail in section II.E.1.iii, Table 7, and Appendix C, our estimated percentage range of illnesses prevented vary widely.

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
								83% improvement in traceback time for four pathogens. Additional (non-health) benefits of avoiding overly broad recalls range from $233 million to $1.8 billion, with a primary estimate of $575 million (at 7% discount rate) and from $242 million to $1.8 billion, with a primary estimate of $596 million (at 3% discount rate).
	Annualized Quantified							
	Qualitative	Additional potential benefits include increased food supply system efficiencies; more expedient initiation and completion of recalls; avoidance of costs due to unnecessary preventive actions; reduction of food waste; and other efficiencies from a standardized approach to traceability.						
Costs	Annualized Monetized Millions$/year	$570	$63	$2,323	2020	7%	20 years	A portion of foreign costs could be passed on to domestic consumers. We estimate that up to $50.5 million in annualized costs (7%, 20 years) to foreign facilities could be passed on to
		$551	$53	$2,267	2020	3%	20 years	

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
								domestic consumers.
	Annualized Quantified							
	Qualitative							Costs of farming-, manufacturing- or cooking-related actions that, as a result of new information flows, address risks of foodborne illness.
Transfers	Federal Annualized Monetized Millions$/year							
	From/To	From:			To:			
	Other Annualized Monetized Millions$/year							
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No significant effect. Small Business: Potential impact on small entities that are currently not keeping traceability records described by the rule. Wages: N/A Growth: N/A							

Table 1b explores the possibility that baseline costs—of recalls and possibly also FTL-associated foodborne illnesses—are already internalized by market actors. If so, then rule-induced costs would form an upper bound on rule-induced benefits. Especially in the case of recall costs, the same entities experiencing baseline costs (or entities with whom they have business contracts) would incur the costs of the rule. As shown in column (b) in Table 1b, if these costs are fully internalized in the baseline and if the narrowed-recall benefits estimates in RIA section II.E.2 are plausible, they would form a lower bound on the cost of the final rule; alternatively, if the rule-induced cost estimates in sections II.F and II.H are plausible, they would form an upper bound on the narrowed-recall category of benefits.

Table 1b. Summary of Rule-Induced Benefits and Costs, as a Function of Baseline Cost Internalization *

<table>
<tr><td></td><td>(a)
Neither adverse health effects nor recall-associated costs fully internalized in market transactions for FTL foods</td><td>(b)
Recall-associated costs, but not adverse health effects, fully internalized in market transactions for FTL foods</td></tr>
<tr><td>RIA Section II.E.1</td><td rowspan="3">Health Benefits: $780M
(range: $59M to $2.2B)

and/or

Recall-Associated Benefits: $575M
(range: $233M to $1.8B)</td><td>Health Benefits: $780M
(range: $59M to $2.2B)</td></tr>
<tr><td>RIA Section II.E.2</td><td rowspan="2">Recall-Associated Benefits: $575M
(range: $233M to $1.8B)

Direct Compliance Costs > $575M
(range: $233M to $1.8B)

Protective Action Costs (potential): not quantified

and/or

Recall-Associated Benefits < Costs

Direct Compliance Costs (if foreign passed through to U.S. supply chain & consumers): $620M
(range: $67M to $2.6B)

Direct Compliance Costs (if foreign not passed through to U.S. supply chain & consumers): $570M
(range: $63M to $2.3B)

Protective Action Costs (potential): not quantified</td></tr>
<tr><td>RIA Sections
II.F and II.H</td><td>Protective Action Costs (potential): not quantified

Direct Compliance Costs (if foreign passed through to U.S. supply chain & consumers): $620M
(range: $67M to $2.6B)

Direct Compliance Costs (if foreign not passed through to U.S. supply chain & consumers): $570M
(range: $63M to $2.3B)</td></tr>
</table>

* 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 2020 dollars and annualized over 20 years. Abbreviations: M=million, B=billion.

C. Terminology

In Table 2, we describe the key terms we use in this document. We note that these definitions only apply to this document.

Table 2. 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 final rule (2004)
CDC	The Centers for Disease Control and Prevention
CORE	FDA's Coordinated Outbreak Response and Evaluation Network
CTE	Critical tracking event
Establishment, facility	We use these terms interchangeably. Each firm may operate one or more establishments.
FD&C Act	Federal Food, Drug, and Cosmetic Act
FSMA	FDA Food Safety Modernization Act of 2011
FTL	Food Traceability List
FTL foods, FTL products, covered foods	Foods listed on the FTL and foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list.
FTE	Full-time-equivalent employee
KDE	Key data element
NAICS	North American Industry Classification System
O&M	Operation and Maintenance
Persons, entities	We use these terms interchangeably to refer to businesses covered by the rule
PRIA	Preliminary Regulatory Impact Analysis of the proposed rule
RIA, FRIA	Regulatory Impact Analysis of the final rule
Small businesses, small entities	In this RIA except in section II.E.2, but not elsewhere in the docket for this rule, we use these terms to refer to small businesses as defined by the Small Business Administration[6]
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

[6] https://www.sba.gov/document/support-table-size-standards

D. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

On September 23, 2020, we published the proposed rule "Requirements for Additional Traceability Records for Certain Foods" (85 FR 59984). Accompanying the proposed rule was a preliminary regulatory impact analysis document on which we requested public comments (Ref. [3]). We received many comments, including a large number of comments on the estimation of costs. We organize these comments and our responses by topic in the paragraphs below. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

Comment 1 (Underestimation of Costs)

Many comments stated that costs are substantially underestimated. Some comments elaborated on specific types of costs, including the time to learn the rule, capital investments, training, and recordkeeping. Others noted that correcting this underestimation would cause the costs of the rule to outweigh its benefits.

Response: After reviewing these comments, FDA determined a need to obtain additional data for cost estimates and to revise requirements of the rule to reduce their burden. FDA contracted with Eastern Research Group (ERG) to research additional literature and elicit information from a panel of industry experts to further inform the costs of the rule to various covered entities based on their baseline traceability practices (Ref. [4]). Experts based their input on the rule as proposed (with additional brief definitions of some new CTEs in their draft-final state at the time of the elicitation). In addition, we updated our estimates for the number of covered entities. Revised cost estimates consistent with revisions to the rule are explained in detail in section II.F of this analysis. We discuss changes to cost estimation from the Preliminary

Regulatory Impact Analysis (PRIA) in appendix E of this analysis. Revised coverage estimates are explained in detail in section II.D.2 and appendix D.

Comment 2 (Costs of Reading the Rule)

Many comments stated that the time to read and understand the rule is substantially underestimated. Due to the rule's complexity and detailed requirements, comments stated that reading and understanding the rule would require more than one employee per covered entity and significantly more time than assumed in the preliminary economic analysis. Relatedly, several commenters stated that they had already incurred labor costs to read and understand the proposed rule (in addition to the time they will need to spend when the final rule publishes).

Response: In estimating the time to read and understand the rule, we have used methods consistent with previous FDA analyses of the economic impacts of rulemakings. In this final analysis, we have accounted for multiple employees reading the rule at larger companies. Our estimate is an average over all firms, and now includes an assumption that in small firms one employee will read the rule and in large firms three employees will read the rule.

Note also that we consider reading costs alone in the section II.F.2 "Reading and Understanding the Rule" to be separate from the costs to identify FTL products and plan for compliance, which we estimate below in section II.F.5.a "Traceability Plan."

Comment 3 (Capital Investment Costs)

Many comments stated that the capital investment costs required to comply with the rule are substantially underestimated. Several comments proposed higher estimates of capital investment costs particularly for small businesses, for example $45,000. Comments also

challenged the PRIA's estimates of capital investment costs on the basis that FDA did not consult with small businesses in forming those estimates.

Response: After reviewing received comments, FDA sought additional information on existing industry practices to improve our capital investment cost estimates. FDA contracted with ERG to research additional literature and elicit information from a panel of industry experts to further inform our estimates of capital investment costs faced by covered entities of various sizes based on their baseline traceability practices (Ref. [4]). The estimates of capital investment costs in this final Regulatory Impact Analysis (RIA) consider both one-time investments and recurring operating and maintenance costs to affected businesses across several broad industry categories. Revised capital investment cost estimates are explained in detail in section II.F.3 of this analysis.

Comment 4 (Need for Costly New Systems)

Several comments stated that the rule would require businesses to adopt new practices and systems to identify and track traceability lot codes upon receipt and shipment of FTL foods. Comments suggested that such systems could include processes to maintain consistency of records, methods, and storage, procedures for internal verification of records, and a measurable and consistent recall process. Comments suggested changes might involve new technology, operations, and management. Moreover, some commenters stated that businesses would be forced to implement these new systems for all foods, not just foods on the FTL, because it would not be practical to maintain two separate recordkeeping systems.

Response: Due to commenters' concerns that the proposed rule would impose costly drastic changes to existing practices and systems, FDA revised the requirements in this final rule,

including removing requirements for certain data elements not typically captured or communicated between supply chain entities to better align with existing best business practices. Such changes concerned requirements that did little to enhance traceability (especially in the context of other requirements) but would be burdensome to industry. For example, FDA removed requirements to record the time of receipt and the name of the transporter of received food, and, for imports, the entry number. FDA also removed the requirement to generate, send, and record unique location and product "identifiers." These are not always part of existing practices and FDA did not consider them to contribute enough to public health to warrant requiring their introduction, collection, and sharing. Additionally, FDA removed the requirement to generate traceability lot codes when growing foods and simplified the transmission of traceability lot code source information when sending and receiving.

To gain more insight into industry's possible adoption of new practices and systems in response to the rule, FDA contracted with ERG to elicit input from an external panel of industry experts. We have incorporated their input in section II.F.5.a "Traceability Plan," in which we estimate the costs of planning new procedures to comply with the final rule. Experts expressed mixed expectations on whether and to what extent businesses would conform recordkeeping of non-FTL foods to the requirements for FTL foods (Ref. [4]). We expect that it will be possible for businesses to implement changes on an as-needed basis for compliance purposes, though some might voluntarily opt to enhance traceability more broadly. In section II.F.5 on "Costs of Recordkeeping," we therefore estimate recordkeeping costs based on entities' volume handled of traceability lots specifically of foods on the FTL.

Comment 5 (Electronic Records)

Though the rule does not require use of electronic records, some comments stated that it creates a de facto requirement of electronic recordkeeping due to the number of attributes needed for each record, the need to send records downstream, and the 24-hour response time for providing a sortable spreadsheet to FDA when requested. Comments stated that electronic recordkeeping would entail significant financial cost to small businesses who currently keep paper records, including costs for data storage and management, as well as costs to acquire equipment necessary for generating records. A comment stated that the 24-hour response time for providing FDA with a sortable spreadsheet would necessitate maintaining electronic records in the course of business, and that, in switching from paper-based recordkeeping to electronic recordkeeping, the commenter's business incurred $10,000 in upfront costs and $2,500 in annual costs. Relatedly, comments stated that Amish-owned businesses do not use electrical devices, and consequently may face particular difficulty complying with the requirement to produce a sortable spreadsheet within 24 hours.

Response: The final rule does not require electronic recordkeeping. Firstly, the final rule simplifies the attributes needed for each record to align them more closely with data elements already captured and communicated in standard business practices. Although FDA encourages the use of electronic recordkeeping for traceability, persons subject to the rule may keep their records in paper or electronic form. In response to comments on the proposed rule, the final rule also expands the exemption from producing an electronic sortable spreadsheet to farms with less than $250,000 in annual sales and all other businesses with less than $1 million in annual sales. Finally, we note that the final rule, like the proposed rule, states that FDA will withdraw a request for an electronic sortable spreadsheet to accommodate a religious belief (see §

1.1455(c)(3)(iv)), and includes provisions under which persons may request a waiver of subpart S requirements (see §§ 1.1405-1.1450 of the rule) or an exemption from (or modification of) the requirements (see §§ 1.1360-1.1400).

Comment 6 (Training)

Many comments said that the training required to comply with the rule is substantially underestimated. Comments asserted that training was likely to apply to all employees, rather than a limited number of employees as assumed in the preliminary economic analysis, and that it would be extensive and ongoing, instead of one-time. Some comments stated that training is likely to vary depending on job role. One comment suggested that annual training on the requirements of the proposed rule would take five hours of each employee's time but did not cite any associated references or data to support this estimate. One comment, summarizing feedback from retailers, estimated training costs would range from $15,000 to nearly $3 million, but did not cite any associated references or data.

Response: In the PRIA, we assumed that training would be a one-time cost to train only a limited number of current employees on the new requirements and traceability practices. We also assumed that, for training new employees, some outdated training content will be replaced with training related to this rule. We note that commenters did not provide additional data in support of alternative estimates. However, after reviewing public comments on our estimates of training costs, FDA determined a need for and sought additional data and information to improve our estimates. FDA contracted with consultants to survey a panel of external industry experts to further inform training costs to various covered entities based on their size and baseline industry practices (Ref. [4]). In this final analysis, we estimated the number of trainees for entities of

different sizes across different industry sectors based on input by the expert panel. Revised training cost estimates are explained in detail in section II. F.4. of this analysis.

Comment 7 (General Recordkeeping)

Many comments said that the time to establish and maintain general records and/or other records to comply with the rule is substantially underestimated.

Response: FDA contracted with ERG to research additional literature and survey a panel of external experts to better inform the costs of the rule to various covered entities based on their baseline traceability practices (Ref. [4]). In estimating recordkeeping time for general records in this final RIA, we used the results of this expert elicitation to update our estimates of the burden per traceability lot for each critical tracking event (CTE) for affected businesses across several broad industry categories. Revised cost estimates of recordkeeping are explained in detail in section II. F.5. of this analysis.

Comment 8 (Recordkeeping per Lot)

Several commenters expressed that the PRIA underestimated the costs of recordkeeping per lot. Comments stated that the time spent breaking a pallet or shipment down into lots for data entry would increase the time needed to process each lot. One commenter also stated that capturing and sending information should be treated as distinct activities. Some commenters estimated that recordkeeping costs would be at least $1 per case.

Response: After reviewing public comments, FDA revised the requirements of this final rule to better reflect current industry practices. We have updated our estimates of recordkeeping burden per traceability lot, accounting both for changes between the proposed and final rules and

input from industry experts external to FDA. Additionally, unlike the PRIA, this RIA treats capturing and sending information as distinct activities. We used the results of the expert elicitation regarding the time needed to capture and send the relevant data for each CTE (Ref. [4]). Revised cost estimates of recordkeeping are explained in detail in section II.F.5. of this analysis.

Comment 9 (Number of Lots)

Comments stated that we underestimated the number of covered lots per entity. In particular, commenters stated that warehouses and distribution centers receive more than the primary estimate of 1,000 lots of FTL foods.

Response: We thank the commenters for raising this concern. We agree and for this Final Regulatory Impact Analysis (FRIA) we contracted with ERG to survey a panel of external industry experts to further inform the number of traceability lots handled by various covered entities based on their size and role in the supply chain (Ref. [4]). Estimates of recordkeeping costs, now accounting for revised numbers of FTL lots, are explained in detail in section II.F.5. of this analysis.

Comment 10 (Product Identifier)

A comment stated that obtaining a product identifier, one of the proposed KDEs, imposes minimal costs on both small and large entities. The comment notes that a single global trade item number has a one-time cost of $30.

Response: We appreciate public input on the cost of product identifiers. The final rule, unlike the proposed rule, no longer includes the product identifier as a KDE.

Comment 11 (Effect on Food Prices, Availability, and Product Diversity)

Many commenters stated that the rule would increase prices of FTL foods because producers will pass their compliance costs on to consumers. Some commenters suggested that the increase in price could reduce food availability. Relatedly, commenters expressed concern that the rule would discourage product diversification in pursuit of lower costs. Among these comments, some stated that the rule would impose higher costs on growers with diverse products relative to growers with one or few products, irrespective of farm size. Also, commenters suggested that costs to food hubs (which collect products from multiple farms and sell them to consumers) in their capacity as first receivers were not adequately considered and would be high due to their product diversity. Some of these comments claimed that the rule would thus reduce or eliminate consumer access to locally grown produce, namely by rendering local food hubs unprofitable, and that this might lower community resilience to events like COVID that interrupt longer supply chains. Comments also suggested that third party logistics providers, importers, and distributors may opt not to handle foods on the FTL, thereby preventing small specialty food makers from reaching retail markets.

Response: We agree that producers might pass some of their compliance costs on to consumers through higher prices. The RIA attempts to represent the total costs of compliance consistent with the rule to industry and society as a whole. Section II.F of the RIA estimates compliance costs to various covered domestic entities depending on their size and role in the supply chain and section II.H discusses costs to foreign entities. However, we do not determine the exact incidence of those costs, which might be passed on to other entities in the supply chain. We do not think that the rule will cause food and ingredient prices to rise substantially, although

depending on entities' market power some costs of the rule might be passed all the way to consumers and retail buyers.

We agree it is possible that some producers may cease to offer some products. We expect that this would occur when the additional traceability requirements cause that product to become unprofitable — that is to say that the baseline costs of producing that product, together with the incremental cost of traceability, exceed consumer willingness to pay for the product. We do not predict individual product discontinuation, which would require detailed knowledge of markets for an unknown number of products.

We note that the final rule shifts traceability lot code assignment from growing to initial packing. Furthermore, the final rule states that instead of maintaining records of the growing area coordinates for each traceability lot of food grown (as proposed), growers will only need to maintain a farm map with field names, which are assigned once only and do not update based on what is grown. Additionally, the final rule replaces the requirements of the first receiver critical tracking event (CTE) with requirements for an initial packing CTE, and therefore food hubs will not be first receivers. We updated our estimates of these burdens in this RIA accordingly.

Comment 12 (Costs to State and Local Jurisdictions)

Several comments suggested the rule would increase burdens on state and local jurisdictions, particularly with respect to monitoring and enforcement.

Response: While we anticipate having states continue to do inspections under contract with FDA (especially for farms), we also expect that monitoring and enforcement of the new traceability requirements would occur during FDA inspections and following tracebacks of foodborne illness outbreaks by FDA's Coordinated Outbreak Response and Evaluation (CORE)

investigators. As such, CORE would discover non-compliance and follow up as needed. We do not yet know whether or to what extent states will be expected to engage in education and outreach.

Comment 13 (Identifying FTL Foods)

Commenters stated that the preliminary analysis did not sufficiently account for the cost of time spent identifying which of foods that are subject to the rule. In particular, a comment states that the rule would require foodservice distributors to determine the ingredients in each product they receive on a shipment-by-shipment basis. The comment notes that distributors do not currently collect such information, which may also change frequently when suppliers change or substitute ingredients.

Response: We thank the commenters for raising this issue and agree that the analysis should include the cost to identify FTL foods. In section II.F of this final RIA, we estimate the cost to covered businesses to identify products containing FTL foods. To update our estimates, we used information elicited from a panel of external industry experts (Ref. [4]). We note also that the rule requires producers who ship FTL foods, to a distributor or other supply chain entity, to provide traceability information to the recipient, which might help in identifying FTL foods.

Comment 14 (Additional Employees)

Some comments said that the rule represents substantial changes from current practice and would cause businesses to hire additional full-time employees, create new job positions in sectors where workers are not equipped for administrative duties, or assemble teams dedicated

solely to recordkeeping requirements. Among these comments, some stated that small businesses in particular would need to hire additional staff to perform traceability-related duties.

Response: We thank the commenters for their input. We do not believe in general that the final rule, as revised from the proposed rule, will necessitate hiring additional employees dedicated to compliance. To further inform our estimates of impacts of the rule on various covered entities, including small businesses, based on their baseline traceability practices, FDA contracted with consultants to research additional literature and survey a panel of external industry experts (Ref. [4]). This final RIA uses the elicited information on baseline prevalence of traceability recordkeeping among businesses by size and the steps that businesses of different sizes will take to establish traceability procedures compliant with the rule's requirements, including expected amounts of employee labor required. We explain cost estimates in further detail in section II.F of this RIA.

Comment 15 (Benefits and Electronic Systems)

Comments also suggested that not requiring all firms to submit electronic records may undermine benefits.

Response: We thank the commenters for their concerns but disagree that estimated benefits depend on electronic recordkeeping. Although we encourage the use of electronic records and communications for traceability, effective traceability under the final rule does not require electronic recordkeeping or any specific technologies for records maintenance or supply chain communications.

Comment 16 (Benefits and Epidemiology)

A comment asserted that benefits are overstated because FDA did not consider epidemiological complexities associated with the outbreak.

Response: We thank the commenter for their concerns but disagree with their assessment of our benefits estimates. Our estimates, which considered the outbreak epidemiological curve and incorporated feedback from FDA epidemiologists, use assumptions that account for complexities associated with disease outbreaks and investigations.

Comment 17 (Benefits Will be Marginal as Compared to Costs of the Rule)

A comment claimed that the added costs of this rule will offer only marginal public health benefits since foodservice distributors already have a demonstrated record of being able to quickly and effectively conduct recalls and tracing activities. Another comment noted that given the complexity of the proposed rule, the benefits of the proposed rule would be very limited for the baking industry which already has a track record of conducting timely trace-back and trace-forward activities using their current recordkeeping systems.

Response: We note that FDA's efforts to ensure food safety are largely incremental. The new requirements complement Subpart J that put in place 'one-up, one-back' tracing requirements. This rule will enable FDA and the food industry to more quickly and efficiently trace covered foods to the sources of an outbreak. In updating our estimates, we took into consideration existing industry practices and baseline compliance, as discussed in section II.D and throughout this analysis.

Comment 18 (Benefits Estimates are Flawed)

One comment claimed that the benefits estimates were flawed. The commentor suggested that FDA's assessment of the benefits assumed that the rule would quickly reduce the impact of illness outbreaks and prevent overly broad recalls, when in most foodborne illness outbreaks, FDA has prevented overly broad recalls without this rule.

Response: We thank the commenter for their concerns but disagree with their assessment of our benefits estimates. The analysis is informed by historical data and incorporates FDA's extensive experience of conducting outbreak investigations and issuing recalls. We discuss updated benefits of this rule both qualitatively and quantitatively in section II.E, including public health benefits, benefits from avoiding overly broad recalls, and efficiency savings to FDA.

Comment 19 (Feedback Supporting Benefits Estimates)

Some comments affirmed the benefits estimates in the PRIA and stated that the health benefits resulting from the rule would outweigh the costs of implementing and enforcing the rule.

Response: We thank the commenters for their feedback on our benefits estimates. We estimate that implementation of this rule will have significant public health benefits and help streamline more targeted removal of implicated covered foods from the market during foodborne illness outbreaks.

Comment 20 (Traceback Time)

Several comments challenged our estimate of an 84 percent reduction in traceback time, which informed the estimated benefits in the PRIA. Commenters suggested that we overestimated this improvement in traceback time and thereby overestimated benefits.

Response: We thank the commenters for their concerns but believe our estimate of the expected reduction in FDA's traceback time is realistic and not overstated. We previously based our 84 percent estimate on traceback data from FDA CORE. We have since consulted with field experts and received additional traceback data from FDA CORE. Using the additional data, we have updated the estimated traceback time reduction to 83 percent. Although the estimate has not changed significantly, we nevertheless revised our benefits estimates to reflect the slightly lower percent improvement.

Comment 21 (Cost Savings)

One comment provided a case study and supporting data demonstrating the effectiveness of their food traceability solutions, which resulted in cost savings from reduced labor hours to identify contaminated foods.

Response: We thank the commenter for providing this detailed example and agree that in the long run this rule might lead to private cost savings to some businesses. We acknowledge that not all entities will likely experience private cost savings.

Comment 22 (Baseline and COVID-19)

Some comments suggested that practices implemented in response to COVID-19 would require changing the baseline estimates of the rule. Relatedly, comments stated that this rule will

lower resilience to COVID-19 by inhibiting growth and innovation between farmers and food hubs. In particular, commenters expressed concern that the rule will reduce product variety and availability already impacted by the pandemic. Comments also suggested that, in light of the low risk of foodborne illnesses posed by small farms and retailers, this rule would unduly burden a large number of businesses already adversely affected by the COVID-19 pandemic.

Response: We agree with the comment that our baseline estimates may not accurately reflect a baseline during or immediately following the COVID-19 pandemic. However, as we anticipate that pandemic restrictions and the circumstances they created will be temporary, and since the rule will not take effect until more than three years after publication, the period before COVID-19 informs the baseline for this analysis.

We expect the greater proportion of uncertainty in our analysis to concern knowledge of typical traceability practices that were in place before COVID-19. In order to reduce some uncertainty around our estimates, FDA contracted with ERG to research additional literature and interview a panel of industry experts to further inform the costs of the rule to various covered entities based on their ordinary baseline traceability practices (Ref. [4]). In addition, FDA has revised the rule to provide additional exemptions to many small entities. We explain our revised baseline in detail in section II.D of this analysis.

Comment 23 (PTI and Current Traceability Practices)

Several comments addressed the rule's implications for existing baseline practices. Comments stated that new traceability requirements should recognize, support, and align with voluntary (already existing) efforts, which have also shown to be effective. One comment stated that more than 50% of respondents of the 2020 Leafy Greens Marketing Agreement (LGMA)

survey indicated that they are utilizing the Produce Traceability Initiative (PTI) for labeling and traceback. A commenter stated that results of a 2020 LGMA survey showed that produce growers are capable of quickly tracking product in 2 hours or less, regardless of whether they had a paper-based or electronic system. Some comments mentioned that while technologies exist to meet new traceability requirements, these technologies are inoperable because the data is not standardized, normalized, and harmonized (suggesting that many have already made capital investment in technology). Other baseline related comments provided background information describing current traceability practices pertinent to issues related to interoperability, recordkeeping, capital investment and industry specific practices such as seafood producers, farmers, and growers.

Response: To the extent that PTI practices overlap with FDA traceability requirements, any incremental costs incurred by those who have implemented a similar traceability program would be less than if they had no traceability program at all. We adjust our baseline (and therefore costs) estimates to reflect the costs to the estimated proportion of entities that have instituted similar traceability requirements to those in this rule. Our updated estimates are addressed in sections II.D and II.F of this document.

Comment 24 (Coverage Underestimated)

Comments claimed that the numbers of farms and small retailers affected by the rule are underestimated.

Response: We thank the commenters for raising this concern. After reviewing comments, FDA determined a need for additional data to improve coverage estimates. FDA revised the numbers of covered entities affected by the rule by using newer data from the 2017 SUSB and

2017 North American Product Classification System (NAPCS) data from the U.S. Census, and the 2017 USDA National Agricultural Statistics Service (NASS) data. We explain revised coverage estimates in detail in section I.E, section II.D.3, and appendix D of this analysis.

Comment 25 (Spillover on Non-FTL Foods)

Some comments stated that the rule will likely affect all foods and that FDA thus underestimated the effect of the rule on covered entities. One comment said that although the PRIA's assessment mirrors the scope of the proposed rule, in practice the new recordkeeping requirements will likely affect entities handling all foods. Covered entities will be required to revise their recordkeeping systems to comply with the rule, and it would be more time- and energy-intensive to maintain two sets of recordkeeping systems (one for covered foods and one for non-covered foods), than to apply the recordkeeping system necessary for compliance with the rule to all foods. The commenter argued that since covered entities will expand their recordkeeping systems to all foods they handle, they will in turn require their suppliers to adopt similar practices, whether those suppliers handle covered foods or not.

Response: We thank the commenters for raising these concerns but do not believe that these issues impact our estimated costs to covered entities or that we have underestimated the number of entities affected by the rule. Concerning firms who handle both covered and non-covered foods, we do not believe the decision on their part to keep KDEs for non-covered foods would affect our estimates. In the first place, our accounting of new equipment, software, services, training, and procedures—which we grant might necessarily displace existing such systems rather than operate in parallel with them—considers these to be fixed costs with respect to the number of foods handled. Second, we estimate the variable costs of recordkeeping as

labor, and we do not believe in general that requiring an employee to perform an action for certain foods creates a need to perform that action for all other foods. For a firm to decide to perform new traceability steps for all foods, doing so must cost less than distinguishing between FTL and non-FTL foods and subsequently performing new traceability steps for just FTL foods. Because the FTL is limited and additions take two years to become effective, and because in practice FTL foods will also come shipped with traceability KDEs such as the Traceability Lot Code, we do not find it plausible that this will hold generally as a consequence of the rule. We would thus not attribute to the rule the additional labor cost of performing traceability recordkeeping on all other foods.

Concerning the possibility that firms who do not handle covered foods might nonetheless adopt certain traceability practices of business partners who do, we would not generally attribute such behavior to the rule. When certain practices prove optimal on business grounds, or when large firms—including those not subject to the rule—exert influence over supplier practices via market power, practices might converge over time for reasons other than regulatory compliance. Moreover, as documented in the product tracing pilots, firms with widely varying traceability practices already conduct business with each other while serving the traceability demands of downstream customers and industry initiatives (Ref. [5]). Since the rule does not prescribe specific technologies for records maintenance, and since KDEs mostly consist of information already commonly communicated between business partners, we expect supply chains to continue to accommodate widely varying traceability practices.

Comment 26 (Effects on Global Supply of Seafood)

One comment said that because seafood is globally sourced, the rule will have a major impact on U.S. trading partners. The commenter stated that the seafood "originator" or even the "first receiver" often does not know the destination of the finished products and that the regulation will therefore impose a recordkeeping burden on companies with respect to seafood products that will never enter the United States.

Response: We disagree with the commentor that seafood "originator" or even the "first receiver" often do not know the destination of the finished products. This rule applies equally to both foreign and domestic firms which are expected to work with their supply chain partners to determine whether their products will be sold in the United States as they already must be doing to comply with several other FDA existing regulations. The rule provides exemptions for those directly selling their products to consumers or products covered by the requirement of the National Shellfish Sanitation Program (NSSP).

Comment 27 (Mung Bean Sprouts)

One comment asks for a more comprehensive economic analysis on the impacts of the proposed rule on the sprout supply chain, including the sprout seed supply chain. The commenter said that requiring sprout growers to trace mung bean seeds back to individual farms would effectively prohibit the importation and sale of almost all internationally sourced mung bean seeds and thereby virtually eliminate the mung bean seed/sprout market in the U.S.

Response: We thank the commenter for raising this concern. We have revised this requirement so that the final rule only requires initial packers of sprouts to maintain records related to the grower of sprout seeds when that information is available. As the final rule does

not require sprout growers to trace seeds back to individual farms when such information is unavailable, we do not expect it to create a significant obstacle to the importation and sale of internationally sourced sprout seeds. Because the rule includes sprouts as covered food (but does not include "seed for sprouting"), sprout growers are required to comply with the subpart S requirements.

In addition, according to Observatory of Economic Complexity (OEC) data, in 2019 mung bean sprouts constituted about $1.1 billion worth of world trade. Myanmar, China, Uzbekistan, and Indonesia accounted for 73 percent of all mung bean exports with India, Vietnam, China, Japan, Indonesia, and Pakistan accounting for the largest share of mung bean imports totaling 66 percent. The U.S. accounts for roughly 3.5 percent of world mung bean imports and only 0.7 percent of mung bean exports. Given the small trade volume of mung bean imports in the U.S., it is highly unlikely that this rule will substantially impact the global market or the U.S. mung bean industry. We believe that given the relatively low volume of mung bean trade, it is unlikely for internationally sourced mung bean seeds producers to be negatively affected because only sprout growers that supply the U.S. market will be affected by the rule.

Comment 28 (Disproportionate Effects on Consumers and Small Businesses)

Comments variously stated that the costs and benefits of this rule will not be distributed evenly. Some commenters stated that the general public bears the brunt of the health impacts caused by poor traceability, with poor and minority communities paying an especially heavy toll. Comments also noted that a constriction in the U.S. mung bean seed/sprout market would disproportionately impact the Asian American community in the U.S., for whom mung beans/sprouts are a staple of the daily diet. Another comment mentioned that the undue burden of

this rule on industry manufacturers and distributors might raise consumer prices, making certain food items, including many fresh fruits and vegetables, less affordable. This comment suggested that such price increases could harm low-income consumers with a limited food budget.

Response: To further inform our understanding of the distributional impacts of the final rule, FDA analyzed a nationwide cross-section of diet data to understand FTL consumption rates of various demographic groups. While we find some differences in FTL foods consumption, we have no data on substitution patterns for non-FTL foods, and thus on the effect the final rule will have on the overall diet quality of consumers. Similarly, FDA contracted with ERG to understand the anticipated effect of the final rule on costs and, therefore, on consumer prices (Ref. [4]). Industry subject matter experts said they expect consumer prices to increase as a result of the final rule. However, FDA found no evidence on the magnitude of the cost pass-through, the incidence of cost pass-through on non-FTL items, substitution patterns of different segments of consumers, or price elasticity estimates for FTL items for different demographics. Without this information, we cannot assess the distributional effects of the final rule on various consumers. We nonetheless acknowledge that the costs and benefits of the rule may accrue unequally to various consumer segments. We addressed distributional impacts of this rule in Section II.G.

Comment 29 (Gasoline Sales)

A comment stated that FDA's estimated number of covered small retailers should account for gasoline sales. The commenter stated that, by inflating the sales of gas station convenience stores without adding significantly to profits, gasoline sales cause these stores to exceed the sales threshold for retail exemption.

Response: The proposed rule did not contain a sales-based exemption for retail food establishments. The final rule specifies that the exemption threshold for retail food establishments, $250,000 (during the previous 3-year period on a rolling basis, adjusted for inflation using 2020 as the baseline year), and similarly the threshold for exemption from the sortable spreadsheet, $1 million, are based on the value of food sold or provided to consumers. We have updated our estimate of the number of covered gasoline stations with convenience stores based on approximating the share of food sales. We present our updated analysis of impacts on small businesses in section III.

Comment 30 (Small Business Exit)

Several comments stated that restaurants and small farms in general do not generate sufficient profit margins to absorb the costs of compliance with the proposed rule and remain in business.

Response: We appreciate public input on the viability of small food businesses. We note that the final rule extends full exemptions from all requirements to retailers, including restaurants, with under $250,000 in annual food sales. We have updated our estimates to reflect these exemptions, including the revised exemptions for restaurants. In addition, the final rule includes an exemption for retailers, including restaurants, with less than $1 million in annual food sales, from providing the information requested by FDA in the form of an electronic sortable spreadsheet.

We note also that the final rule shifts traceability lot code assignment from growing to initial packing. The final rule specifies that farms are required to assign the field names on the farm map only once and do not need to update them based on what is grown. Additionally, the

final rule provides an exemption from producing an electronic sortable spreadsheet to farms with less than $250,000 in annual sales. We present revised estimates of impacts on small businesses in section III.B of this RIA. Section III.B breaks down one-time and annualized costs, in dollar values and as a percentage of revenue, across broad industry categories.

Comment 31 (Input from Small Businesses)

Several comments claimed that the PRIA inadequately addresses small business impacts and, in particular, that FDA did not estimate costs specifically for small entities in its economic impact analysis. Among these, commenters stated that FDA underestimated small retailers' compliance costs under the proposed rule, including costs for traceability systems and training. Commenters suggested that FDA should inform its estimates with data or stakeholder input specifically representing small businesses, including by consulting with organizations that comprise or represent small businesses regarding compliance costs.

Response: After reviewing public comments, FDA determined a need for additional data to improve cost estimates, including costs to small businesses. FDA contracted with ERG to research additional literature and interview a panel of food industry experts to further inform the costs of the rule to various covered small entities based on their baseline traceability practices (Ref. [4]). Section III of this final RIA now incorporates the expert elicitation results specifically addressing costs to small businesses.

Comment 32 (Proposed Option 1 - Very small, Retail)

One comment stated that if retail food regulatory jurisdictions will need to include this rule as part of their inspection process the inclusion of very small retail operations will have an additional financial impact on the regulatory jurisdiction.

Response: We don't anticipate additional financial impact on food regulatory jurisdictions from including very small retail operations to their inspection process because very small retail operations are exempt from the requirements of this rule.[7] We are also still considering the best approach for structuring and conducting inspections for compliance with the subpart S recordkeeping requirements, including the roles that FDA and State investigators should play. While FDA anticipates conducting periodic, routine inspections of traceability records outside of an outbreak traceback investigation, we will work with state and local partners to consider mechanisms for how to conduct routine records checks of retail food establishments and restaurants. We will consider obtaining additional funding for our regulatory partners through various mechanisms, such as grant programs. In addition, we intend to publish guidance for industry and provide training to regulatory partners who will be conducting inspections of records under this rule ahead of the compliance dates.

Comment 33 (Number of Foods by FTL Commodity)

One comment stated that we have underestimated the number of covered foods within each designation in light of having covered commodities as foods on the FTL.

[7] 1.1305(i) of the final rule provides that subpart S does not apply to RFEs and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

Response: Both in the preliminary and final regulatory impact analyses, we base our estimates of regulatory impacts on the number of entities that manufacture, process, pack or hold FTL foods and not on the number of foods by FTL commodity. As discussed in the Preliminary Regulatory Impact Analysis for the proposed rule (Ref. [3]), in estimating the impact of the proposed rule, we accessed data from multiple sources, including the U.S. Economic Census - 2012 Statistics of U.S. Businesses (SUSB), FDA's Food Facility Registration Module, and the USDA National Agricultural Statistics Service (NASS) 2017 Census of Agriculture. We have since updated our estimates in the final rule RIA using additional data sources, including the 2017 SUSB and the 2017 North American Product Classification System (NAPCS) from the U.S. Census to better inform the number of covered entities that manufacture, process, pack or hold various FTL foods. We discuss our revised coverage estimates in greater detail in sections I.E.2, II.D.2, and appendix D of this analysis.

Comment 34 (General)

Some comments stated that the measures needed for compliance with the proposed rule would vary widely as some entities rely almost exclusively on paper records. Others requested that FDA adopt a more universal method of data storage and dissemination.

Response: We agree with the comment that measures needed for compliance with this rule will vary widely among different types and sizes of entities. This final rule does not prescribe any specific technology for maintaining records, nor does it preclude anyone from using paper records if that is their business practice. This final rule sets forth minimum standards for data elements used in records, but otherwise provides flexibility to accommodate a variety of existing practices and business needs. Although FDA strongly encourages the use of electronic

recordkeeping for traceability, persons subject to the rule may keep their records in paper or electronic form. Firms may also contract with others to establish and maintain records required under subpart S on their behalf as long as the firm can provide the information to FDA in accordance with the rule. To protect certain confidential business information, the rule allows firms to provide their customers with a reference to the information instead of directly identifying the traceability lot code source of an FTL food they handle. For this final analysis, FDA contracted with ERG to research additional literature and interview a panel of food industry experts to further inform the costs of the rule to various covered entities based on their size, broad industry category, and baseline traceability practices (Ref. [4]).

E. Summary of Changes

Compared to the preliminary economic analysis (Ref. [3]), the final regulatory impact analysis reflects revisions to the rule and to our analytical methodology. It includes updates and revisions to our discussion of baseline conditions, estimated health and non-health benefits, costs to domestic entities, estimates of international impacts, distributional effects, and impacts to small entities in the Regulatory Flexibility Analysis (RFA) section III of this analysis as summarized below.

1. General Changes to the Rule

- We have adjusted for inflation using the GDP deflator and report all benefits and costs in 2020-year dollar values.
- FDA extended the effective date of compliance from 2 years to 3 years from the publication of this final rule. Section II.J. of this RIA quantifies the impact of this change in the Analysis of Regulatory Alternatives to the Rule ("Reduce compliance date to two years").

- Given expected long-term impacts of this rule, we have extended the time horizon for estimating annualized costs and benefits from 10 years to 20 years.
- To inform our analysis, FDA contracted with ERG to research additional literature and elicit information from two sets of panels of industry experts (Ref. [4]). The first set of experts further informed the benefits of avoiding overly broad recalls (hereinafter referred to as the recall elicitation). The second set of experts further informed the costs of the rule as proposed, with additional brief definitions of some new CTEs in their draft-final state at the time of the elicitation (hereinafter referred to as the traceability costs elicitation).
- The final rule replaces the threshold for full exemption for retail food establishments (RFEs) from 10 full-time equivalent employees (Option 1 in the proposed rule) to monetary threshold of no more than $250,000 in average annual monetary value of food sold or provided during the previous 3-year period (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment. Appendix D discusses differences in coverage estimates between the proposed and the final rule. In addition, section II.J of this RIA quantifies the impacts of an alternative scope and an alternative exemption policy in the Analysis of Regulatory Alternatives to the Rule ("Cover all firms in the same broader industry (NAICS) category as covered firms" and "Broader exemption for retail food establishments and restaurants").
- The final rule expands the exemption from producing an electronic sortable spreadsheet to:
    a. Farms whose average annual sum of the monetary value of their sales of raw agricultural commodities and the market value of raw agricultural commodities they manufacture, process, pack, or hold without sale (*e.g.*, held for a fee) during the previous 3-year period

is no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

b. Retail food establishments or restaurants[8] with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

c. Persons (other than a farm, retail food establishment, or restaurant) whose average annual sum of the monetary value of their sales of food and the market value of food they manufacture, process, pack, or hold without sale (*e.g.*, held for a fee) during the previous 3-year period is no more than $1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

2. Baseline Conditions: Coverage and Current Industry Practices

- We updated our estimates of covered entities using additional data sources, including the 2017 Statistics of U.S. Businesses (SUSB) and the 2017 North American Product Classification System (NAPCS) of the U.S. Census, and the 2017 USDA National Agricultural Statistics Service (NASS) data.
- We estimate the number of covered entities that produce, manufacture, process, pack, or hold foods on the FTL by counting the number of establishments by NAICS industry sector. In doing so, we derive a share of FTL establishments by approximating the share of the covered entities by each NAICS industry using the NAPCS data.

[8] While the PRIA included non-restaurant retailers and restaurants in the same category of retail food establishments, the FRIA reports separate estimates of the non-restaurant retailers and restaurants provided by an elicitation of industry experts (Ref. [4]). Both non-restaurant retailers and restaurants have the same requirements as each other under the final rule. Experts assumed the non-restaurant retailer includes mostly grocery stores, specialized grocery stores (fish markets, fruit markets, bakeries, etc.), supercenters, and club stores.

- Some NAICS industry codes that were included in the preliminary estimates are now excluded from our analysis due to clarifications to the FTL and revision to the FTL definition. For example, we now exclude from our analysis some entities in each NAICS industry if the form of the FTL food is no longer fresh and has been changed (e.g., frozen pizza with a spinach topping).
- To estimate the share of entities who currently have traceability programs in place and the degree to which their programs meet the requirements of this rule, ERG completed the traceability costs elicitation in December 2021 and January 2022 providing both qualitative and quantitative input on current traceability practices (Ref. [4]). We use the information provided by experts to better characterize current traceability practices and update our estimates on the proportion of firms that will incur costs from this rule and per entity costs as explained in Section II.D.
- We estimate the number of covered gasoline stations with convenience stores by approximating the share of food sales only.

3. Benefits

- We use additional data on disease outbreaks associated with covered foods to extend our outbreak data from January 2009 to December 2020 (see Appendix C).
- We revise estimated benefits from avoiding overly broad recalls by using new information from an industry expert elicitation study conducted by ERG (Ref. [4]) from December 2021 through January 2022. Experts provided information on labor and non-labor costs incurred by firms when responding to an overly broad recall.

4. Costs

- Our revised coverage estimates that we use for estimating compliance costs now explicitly exclude fully exempt entities as well as those not handling FTL foods.
- Cost estimates now reflect the revised requirements of the final rule, which redefine what activities are CTEs and exclude or redefine several proposed KDEs. These updates are further summarized in appendix E. Among these updates there is one, for example, that shifts traceability lot code assignment requirements from growers to initial packers. Under the final rule, entities that grow or raise FTL foods (other than eggs) will need to maintain a farm map(s) with field names, rather than having to assign traceability lot codes and link those codes to the geographic coordinates where each lot is grown. The farm map(s), which must show the area(s) in which food is grown or raised, do not need to be updated based on what is grown.
- We incorporate new inputs throughout our analysis from the literature review and multiple industry experts, elicited by ERG in December 2021 and January 2022, who described anticipated cost-incurring compliance activities and expenditures, estimated variables related to cost calculations, and further commented on factors likely to influence costs of the rule (Ref. [4]).
- We consider recurring capital costs for those cases where capital investments made towards compliance with the rule result in higher operation and maintenance expenses than covered entities would otherwise face (section II.F.3 “Costs of Capital Investment”).
- We consider recurring training costs for those cases where new training is more time consuming than what covered entities would otherwise have implemented as a refresher for continuing employees and because of turnover (section II.F.4 “Costs of Training”).

- We now separately estimate costs specific to small versus large entities in different categories of industries.
- We updated wage data (average wages for various occupations) using the Bureau of Labor Statistics' (BLS) 2020 Occupational Employment Statistics (OES).

5. International Effects

- We updated the number of registered foreign food facilities using internal FDA data. We revised it from 127,925 to 68,566 establishments due to double counting error discovered earlier in the PRIA estimates.
- We updated our estimates of costs to foreign facilities based on additional exemptions of firms granted by FDA (Section II. H).

6. Distributional Effects

- We updated our analysis of distributional impacts of the rule by considering additional data on FTL consumption rates across consumers, geographic concentration of covered retail food establishments, and the distribution of costs across affected entities.

7. Regulatory Flexibility Analysis

- In the Initial Regulatory Flexibility Analysis, we assumed that the compliance costs faced by small businesses would fall between the low end and middle of the range of costs estimated for all businesses overall. We now use input from external experts (Ref. [4]) to separately estimate costs specific to small versus large businesses in different categories of industries.
- Unlike in the Initial Regulatory Flexibility Analysis, our revised coverage estimates, which inform both the main cost analysis and Regulatory Flexibility Analysis, now explicitly exclude fully exempt entities as well as those not handling FTL foods.

- Finally, we updated small firm revenue data previously sourced from the 2012 Statistics of U.S. Businesses (SUSB) with data from the 2017 SUSB.

II. Final Economic Analysis of Impacts

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: 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. [6]). 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.

Inadequate traceability and the exclusion of farms from Subpart J requirements also triggered the need for broad recalls that inadvertently affected 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. [7]).

On January 4, 2011, 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.

On September 23, 2020, FDA published the preliminary regulatory impact analysis (PRIA) of the proposed rule "Requirements for Additional Traceability Records for Certain Foods" (85 FR 59984). The preliminary regulatory impact analysis included two proposed options for how this rule would apply to retail food establishments. The first option proposed a full exemption from the requirements of the rule for retail food establishments (RFEs) that

employ 10 or fewer full-time equivalent employees (FTEs). The second option proposed only partial exemption to RFEs that employ 10 or fewer FTEs, stating that they would be exempt from the requirement to provide FDA, under specified circumstances, with an electronic sortable spreadsheet containing certain traceability information but that they would be required to comply with all other aspects of the rule.

This FRIA analyzes the economic impact of the traceability requirements set forth in this final rule by making revisions and updating the 2020 PRIA, based on information from comments, changes to the rule, and new information not formerly considered in the PRIA.

B. Potential Need for Federal Regulatory Action

A traceability system or program is a method that allows for information about product attributes to flow among entities in a supply chain.[9] Industry reports offer some evidence that implementing intra-firm traceability is beneficial for the firm because it helps in improving supply chain efficiencies and minimizing the impact of food safety hazards (Ref. [8]). However, private incentives to implement traceability systems vary among different industries and industry sectors and depend on many factors. Aside from return-on-investment decisions by individual firms, reasons for adopting a traceability system or program may include reasons other than food safety. The motivations also depend largely on private decisions of the firm which may also depend on specific attributes of products, whether they are included in the FTL or not. However, depending on the level of sophistication, traceability can be costly and considering the differences in the characteristics of inter-firm or inter-industry traceability systems, benefits may

[9] For purposes of this analysis, we use the terms traceability system, program, or method interchangeably.

not be evenly distributed across firms in the supply chain, thus lowering incentives for some firms to adopt a socially optimal level of traceability.[10]

The effectiveness of a traceability 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 others with 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.

Several types of market failure may impact current traceability efforts. First, private incentives for investing in socially optimal level traceability may be low. When traceability is limited for a product, producers and other supply chain participants can remain anonymous and therefore not as accountable for the quality or safety of their product. Anonymity can also allow someone to freeride on the reputation of other competing producers with better traceability and maybe even safer food, thus creating a market failure. Since unsafe food can originate at different levels of the supply chain, the probability of a prolonged foodborne outbreak due to inefficient tracing is more likely with imperfect inter-firm participation (Ref. [9]).

Second, firms currently utilize various traceability methods at times with competing data standards, creating interoperability challenges and making costs of coordination prohibitively high, reducing the incentives to adopt uniform standards. Without broad adoption of

[10] 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).

interoperable traceability methods and standards, the system will not work as effectively to allow fast and efficient traceback when an outbreak occurs. When the value of adopting a good or service (such as a new technology or traceability system) depends on the number of users adopting the good or service, it is sometimes referred to as a network effect (Ref. [10]). In the same manner, the value of adopting traceability would depend on the number of users adopting traceability. Interoperability challenges caused by the absence of uniform standards are considered a network externality that affects the entire industry and reduces the value of adopting traceability among individual potential users, therefore reducing their incentives to adopt.

Third, 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 some firms to invest. According to a study by Mai et al. (Ref. [11]), costs and benefits of current traceability investments are not evenly shared among different entities in the supply chain. For example, while processors and producers in the seafood industry may incur a greater share of the costs of implementing traceability than retailers and distributors, retailers and distributors may capture a larger portion of the benefits in the form of market growth. This misalignment of benefits and costs might explain the lack of incentives for some entities in the supply chain to adopt traceability. As a result, the risk of foodborne illnesses that can sometimes be attributed to FTL foods is likely not fully priced into FTL products (Ref. [11]).

While the last decade has experienced growth of technology enabled traceability methods, 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 is 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 to 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 certain CTEs and KDEs, which would lower the cost for suppliers across and within industries among other benefits.

So far FDA has often 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 needs to effectively 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, harvesters, shippers, distributors, retailers, and restaurants lack incentives to standardize recordkeeping in the form of common key data elements. This rule would ensure that producers, distributors, retailers, and other covered entities know what information they need to keep and provide. Without uniform recordkeeping standards, competing traceability solution providers promote mutually exclusive, proprietary frameworks, whose incompatibility increases traceability costs. The current lack of system interoperability impedes collaboration in identifying sources and/or recipients of potentially contaminated covered food. While the effectiveness of each traceability system increases with the number of participants throughout the supply chain, the lack of standardization in recordkeeping and data sharing among incompatible systems causes duplication of efforts. In addition, high transaction and coordination costs of setting up a complete farm-to-retail national traceability system may even disincentivize some firms from investing in traceability systems, particularly those firms that are not vertically integrated. This final rule will standardize the key data elements and critical tracking events, significantly reduce the private coordination and transaction costs of setting up a complete tracing system and 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.[11] 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[12] 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 effective and rapid tracing.

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 gaps in tracing information through the supply chain can prevent the FDA and others from being able to trace or to effectively trace contaminated products to their source. Full supply chain traceability requires policy intervention as some firms do not have an immediate financial incentive to institute traceability systems (Ref. [12]). For example, the Institute of Food Technologists (IFT) noted in the Product Tracing Pilots report (Ref. [5], see page 217, subtitled "Lack of Standards Results in Fragmented Requirements") that traceability is likely to stay in a state of perpetual flux until FDA clearly

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

[12] 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.

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.

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. As discussed in section I.D and the preamble of the final rule we also received comments in response to this proposed rule in support of the need for the rule.

In sum, market prices convey most of the necessary information for the ordinary production and distribution of foods, including the foods on the FTL.[13] 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 quickly and efficiently find the source and cause of contamination, FDA must be able to trace covered food backward and forward through the entire supply chain. Although the nation's food manufacturers, processors, distributors, retail food establishments, and others may benefit from such a system, the private costs of creating it would be prohibitively expensive for any single firm or third-party organization. As discussed in the following section II.C, this rule addresses many of the known limitations of current

[13] 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.

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 final rule will also 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 have not received any comments that would refute the market failure claims above nor have we received any information in comments that may be used to quantify the scope of incomplete internalization of relevant baseline costs.[14]

C. Purpose of the 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 rule will 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 keep, along with information they must provide to the next entity in the supply chain. The core requirements are to establish and maintain a traceability plan and keep and provide records of KDEs associated with different CTEs in a covered food's supply chain, including the harvesting, cooling, receiving, initial packing, transforming, and shipping of the FTL food. Required traceability plans include: a description of the procedures used to keep required subpart S records; a description of the procedures used to identify foods on the FTL

[14] Industry internalizes costs when they incorporate society-wide costs as part of a pricing structure (to be specific, social costs that are born from their economic activities).

they manufacture, process, pack, or hold; a description of how they assign traceability lot codes to foods on the FTL; a statement identifying a point of contact for questions about the traceability plan and records; and, for persons who grow or raise an FTL food (other than eggs), a farm map showing the area in which the food is grown or raised. To protect certain confidential business information that some firms may be reluctant to share, the rule allows the flexibility for firms to provide a reference to information on the traceability lot code source instead of directly identifying this information for an FTL food.

The rule also provides consistent food tracing terminology, encourages a transition from paper-based recordkeeping to electronic records (although persons subject to the rule may keep their records in paper or electronic form) and promotes a broader understanding of the data elements needed for efficient traceability and product recalls. Further, this rule enables FDA and industry to faster and more effectively 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. This rule further helps 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

We consider the current state of the world, including current trends towards greater traceability capabilities, as a reasonable approximation of the baseline (the projected future without the rule) against which to measure the costs and benefits of the rule and the regulatory alternatives discussed in section II.J.[15] While we are not able to explicitly estimate trends in

[15] We acknowledge that health benefits of this rule are linked, at least in part, to other rules issued by FDA. Some of

industry investment in traceability capabilities,[16] which might result in some overestimation of costs as discussed in sections II.F.3 "Costs of Capital Investment" and II.I "Uncertainty and Sensitivity Analysis," many food businesses have been increasingly adopting traceability systems or practices, including technologies, for reasons other than regulatory mandate. Such reasons include operational efficiency, transparency, and customer demand. Existing supply chain practices of many affected businesses already partially satisfy this rule's requirements for traceability records of FTL foods. In estimating the baseline, we use the information provided by the traceability costs elicitation (Ref. [4]) in assuming that a portion of covered entities is already moving toward implementing traceability with or without the rule and that another portion of covered entities would not implement traceability without the rule.

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

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 and Response Act of*

these rules addressing foodborne illnesses have not taken effect or are not captured in the data used to characterize the baseline scenario of this analysis. In particular, FDA's Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water proposed rule (https://www.federalregister.gov/documents/2021/12/06/2021-26127/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-relating), if finalized, might prevent some of the illnesses that this RIA estimates will occur at baseline absent food traceability. We cannot confidently predict the impact of the Agricultural Water rule on the baseline for traceability, partly because the Agricultural Water rule has not been finalized at the time of this writing. We thus possibly overestimate benefits of the traceability rule in section II.E.1 of this document.

[16] We acknowledge that data available prior to finalization of this 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 haven't received comments on estimating the baseline trajectory, given the dynamic nature of the regulatory environment. However, to address uncertainty in our estimates we use the results from an expert elicitation in which ERG asked experts not to consider as impacts of the rule current and probable future traceability practices that would occur in any case (Ref. [4]).

2002 final rule issued in 2004*,* as estimated in the economic impact analysis for that rule and further modified by updated assumptions discussed below.[17]

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.[18] Benefits of the 2004 BT final rule were estimated as the number of averted illnesses due to improved recordkeeping practices. Nevertheless, in almost twenty 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 sections III.A and III.B of the preamble of the final rule, suggest that the benefits of the 2004 BT rule may have not been realized and were consequently overestimated. However, as described elsewhere in this document, advances in information technology in the last decade are such that private incentives have led some entities to implement food traceability beyond the 2004 requirements. This suggests that the annualized costs of the BT rule estimated in 2004 may not have fully accounted for baseline trends towards increased traceability and thus were also overestimated.

2. Coverage of the Rule

Covered entities (firms or establishments[19]) will incur costs from the final rule to the extent that compliance requires them to change their current practices. Covered entities are those

[17] Federal Register /Vol. 69, No. 236 / Thursday, December 9, 2004 / Rules and Regulations, page 71611.
[18] Federal Register / Vol. 69, No. 236 / Thursday, December 9, 2004 / Rules and Regulations, page 71640.
[19] Each firm may operate one or several establishments. Some costs are estimated on per-firm level and some are on per-establishment level.

that manufacture, process, pack, or hold foods that FDA has designated as requiring additional recordkeeping and placed on the FTL.[20] The traceability recordkeeping requirements will generally not apply to:

- Farms or the farm activities of farm mixed-type facilities with respect to the produce they grow that are not covered under the FSMA Produce Safety Rule, 21 CFR 112.4(a).
- Produce farms and producers of raw agricultural commodities other than produce or shell eggs (e.g., aquaculture operations) when the average annual sum of the monetary value of their sales of food and the market value they manufacture, process, pack, or hold without sale (e.g., held for a fee) during the previous 3-year period is no more than $25,000 (on a rolling basis), adjusted for inflation, using 2020 as the baseline year for calculating the adjustment.
- Shell egg producers with fewer than 3,000 laying hens at a particular farm, with respect to the shell eggs they produce at that farm.
- Covered foods produced on a farm (including food that is also packaged on the farm) that is sold or donated directly to a consumer by the owner, operator, or agent in charge of the farm.
- Covered foods produced and packaged on a farm if the packaging of the food remains in place until the food reaches the consumer and maintains the integrity of the product, prevents subsequent contamination or alteration of the product, and has labeling that includes the name, address, and business phone number of the farm.

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

- Covered produce that receives commercial processing to adequately reduce the presence of microorganisms of public health significance if the conditions set forth in 21 CFR 112.2(b) are met (regarding the commercial processing exemption to the FSMA Produce Safety rule).
- Shell eggs when all eggs produced at the particular farm receive a treatment (as defined in 21 CFR 118.3) in accordance with 21 CFR 118.1(a)(2).
- Foods on the FTL subject to a kill step, provided that records document the receipt of the food (as specified in § 1.1345) and application of the kill step.
- Covered foods that are changed such that the foods are no longer on the FTL, provided that records document the receipt (as specified in § 1.1345) of the food to be changed.
- Food that has previously been subjected to a kill step or that has previously been changed such that the food is no longer on the FTL.
- Food that will be subjected to a kill step or will be changed by an entity other than a retail food establishment, restaurant, or consumer such that the food will no longer be on the FTL, provided that there is a written agreement between the shipper of the food and the receiver as specified in § 1.1305.
- Produce that is listed as rarely consumed raw in 21 CFR 112.2(a)(1).
- Raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation Program (NSSP), subject to the requirements of part 123, subpart C, and 21 CFR 1240.60, or covered by a final equivalence determination by FDA.
- Persons who manufacture, process, pack, or hold covered foods during or after the time when the food is within the exclusive jurisdiction of the U.S. Department of

Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq*.), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq*.), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq*.).

- Commingled raw agricultural commodities and raw agricultural commodities that will become commingled, provided that there is written agreement between the shipper of the food and the receiver as specified in § 1.1305.[21]
- Retail food establishments and restaurants whose average annual monetary value of food sold or provided during the previous 3-year period is no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.
- Retail food establishments or restaurants with respect to covered foods that are produced on a farm, and both sold and shipped directly to the retail food establishments or restaurants by the owner, operator, or agent in charge of that farm.[22]
- Either entity when a retail food establishment or restaurant purchases a covered food from another retail food establishment or restaurant, when such purchases occur on an ad hoc basis outside of the buyer's usual purchasing practice (e.g., not pursuant to a contractual agreement to purchase food from the seller).[23]

[21] A written agreement must include the effective date, printed names and signatures of the persons entering into the agreement and the substance of the agreement, and the agreement must be maintained by both parties as long as it is in effect and must be renewed at least once every 3 years. If registered under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable foods, such person must maintain records identifying the immediate previous source of such raw agricultural commodity and the immediate subsequent recipient of such food. Such records must be maintained for 2 years.

[22] The only records retail food establishments or restaurants must maintain in such cases are the name and address of the source farm. They must maintain such records for 180 days.

[23] The buyer must keep a record (e.g., a sales receipt) containing the name of the product purchased, the date of purchase, and the name and address of the place of purchase.

- Farm to school or farm to institution programs, with respect to a food that is produced on a farm and sold or donated to the school or institution.[24]
- The owner, operator, or agent in charge of a fishing vessel with respect to foods obtained from the fishing vessel; and any entities that manufacture, process, pack, or hold the food until such time as it is sold by the owner, operator, or agent in charge of the fishing vessel.[25]
- Transporters of covered foods.
- Nonprofit food establishments.
- Persons who manufacture, process, pack, or hold covered foods for personal consumption.
- Persons who hold covered foods on behalf of specific individual consumers, provided that these persons are not parties to the transaction involving the food they hold and are not in the business of distributing food.
- Food for research or evaluation use, provided that such food is not intended for retail sale and is not sold or distributed to the public and is accompanied by the statement "Food for research or evaluation use."

To estimate the number of domestic covered entities, we use several data sources. These sources include the 2017 Statistics of U.S. Businesses (SUSB) from the U.S. Census Bureau, the 2017 North American Product Classification System (NAPCS) from the U.S. Census Bureau,

[24] The school food authority or relevant food procurement entity must maintain records 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 for retail food establishments purchasing foods on the FTL directly from farms.

[25] If registered under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food. The records must be maintained for 2 years.

and the summary reports of the 2017 Census of Agriculture and the 2018 Census of Aquaculture from the USDA NASS (Ref. [13] [14]).[26] Appendix D of this document discusses our estimates in detail. We use number of registered facilities from FDA's Food Facility Registration Module (FFRM) to estimate the number of foreign facilities affected by this rule and use those estimates only in the international effects section II.H.2.

The U.S. Census Bureau's SUSB publishes the number of firms, establishments, employment by firm size and industry on an annual basis, and annual payroll for most U.S. business establishments. The most recent data available are from 2017. Many SBA small business size standards covered in section III are based on the number of employees, so the 2017 SUSB employment size categories are additionally useful for identifying the number of small entities in each affected industry. The data are tabulated by geographic area, industry, and employment size of the enterprise. The industry classification is based on 2017 North American Industry Classification System (NAICS) codes.

We estimate that the final rule will cover approximately 323,872 domestic firms operating 484,124 establishments. These entities include 11,760 farms, 7,991 manufacturers, 12,007 wholesalers, 2,504 warehouses, 102,424 non-restaurant retailers and 187,185 restaurants. We estimate that the total number of domestic farms that produce foods on the FTL (including produce, eggs, and seafood) and will thus be affected by the final rule is 11,760.[27] This includes 7,089 produce farms, 95 sprout growers[28], 2,521 shell egg farms, and 2,055 aquaculture farms. These numbers include only domestic entities (firms or establishments) that manufacture,

[26] All datasets used in this analysis were the latest available to us as of January 2022.
[27] The first domestic entity that takes physical possession of an imported product will receive 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).
[28] 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. The number of sprout growers is included in the total number of farms in Table 3.

process, pack, or hold FTL foods destined for consumption or use in the United States. Table 3 contains a summary and breakdown of by NAICS codes.[29]

Table 3. Number of Affected Entities by Industry Sector

Type	Number of Firms	Number of Establishments	NAICS Codes
Farms /Aquaculture / Growers	11,760	11,796	111219, 111339, 111419, 112310, 112511, 112512, 114111, 114112
Manufacturers / Processors / Packers	7,991	8,650	311340, 311351, 311352, 311411, 311513, 311710, 311811-311813, 311821, 311911, 311941, 311991
Wholesalers / Distributors	12,007	15,101	424410, 424420, 424430, 424450, 424460, 424480, 424490
Warehouse and Storage	2,504	5,176	493110, 493120, 493130
Retail Food Establishments (Non-restaurants)	102,424	171,380	445110, 445120, 445220, 445230, 445291, 445292, 445299, 447110, 452311, 454110, 454210, 722310, 722320, 722330, 722410, 722514-722515
Restaurants	187,185	272,021	722511, 722513
Total	323,872	484,124	

As discussed in section II.H, we use FDA's FFRM biennial registration data for our estimates of foreign entities affected by this final rule. While the data do not include farms and retail establishments, we believe the number of foreign retail food establishments affected by this rule to be small. Thus, we estimate that in addition to entities summarized in table 3, the rule will cover approximately 61,741 firms and 68,784 foreign establishments. We do not have a detailed breakdown of foreign firms and establishments by industry, and instead assume the same proportional breakdown as in the main analysis.

[29] https://www.census.gov/naics/
In each NAICS code category, only entities that manufacture, process, pack, or hold foods on the FTL will be affected by this rule. Some NAICS codes that were included in the PRIA estimates are now excluded from our analysis due to updates to the text of the rule between the proposed and final (NAICS 311412, 311421-311423, 311520, 311824, and 311942).

3. 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.[30] Subpart J requires that non-transporters of food (persons 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 many of the entities covered by this rule, such as farms and restaurants.

Under existing Subpart J requirements (whose coverage, unlike in this rule, applies to all foods, not just those on the FTL), firms must know and record information regarding the immediate previous sources of foods 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; the date it was received or released; 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 for either records or identifiers (Ref. [5]).

Additionally, some firms already voluntarily conform to traceability standards and best practices developed by outside groups, for example, the consensus standards developed by GS1, an international non-profit organization that develops and maintains standards for barcodes[31].

[30] We use the results of the expert elicitation to estimate the portion of entities that would implement traceability without the rule. We have not received comments on whether compliance with the earlier regulations may increase as a result of this rule nor on how to quantify the impact.
[31] https://www.gs1.org/

Other examples of business communication standards include QR codes[32], 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. [15]). GS1 has developed standards and best practices for various entities in the food supply system. For example, GS1 standards for farmers 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. [16]). GS1 standards for subsequent supply chain entities enable enhanced forward and backward traceability between farms and retailers.

When describing traceability practices that were prevalent in the U.S. in the early years of the first decade of the 2000s, a 2004 report from the USDA Economic Research Service (ERS) found that private sector food firms had already developed substantial capacity to trace food products by the time the BT final rule was published (Ref. [17]). 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 those firms, Subpart J one-up-and-one-back traceability for a standard set of data elements required little change to their existing systems.

While some entities covered by this rule already maintain, to varying degrees, KDEs required by this rule and will likely incur little cost to comply, other covered entities might face more substantial changes to their existing recordkeeping systems. For example, some firms might need to establish a traceability plan and assign traceability lot codes to FTL food where these codes do not already exist. Additionally, growers of sprouts, whom we assume to perform

[32] A Quick Response code – so-called 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.

initial packing of the sprouts, might need to collect additional documentation from seed vendors. 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.

In section II.F "Costs of the Rule," we aim to estimate only the costs that businesses will incur specifically for compliance with the rule. We therefore estimate the extent to which current industry practices align with the requirements of the rule using information from the ERG expert elicitation study (Ref. [4]). ERG asked food industry experts for estimates of the proportion of industry, by business size, that would have required new traceability-related capital (e.g., equipment, software, etc.), training, and recordkeeping specifically for compliance with the proposed version of the rule, with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation. We apply these estimates based on the revised requirements of the final rule.

In consideration of existing baseline trends towards greater traceability for business purposes, ERG asked experts to consider costs specifically to comply with the proposed rule (with additional brief definitions of certain CTEs in their draft-final state at the time of the traceability costs elicitation) in excess of what they spend in the absence of the rule. Reasons for adopting a traceability system or program vary and may reflect concerns other than food safety. These decisions of the firm might also depend on private incentives relating to specific attributes of products, whether they are included in the FTL or not. Therefore, we consider firms affected by the rule to be a subset of firms who are covered by this rule. We present the estimated number of entities affected by each provision of the rule in Table 4 below.

We acknowledge the large variability in the characteristics of traceability systems within and across industries. Due to the large number of NAICS industries relevant to the rule, we

group these industries by similar business activities with respect to the CTEs we have deemed them likely to perform. ERG elicited incremental estimates of necessary traceability-related capital, training, and recordkeeping for small and large businesses in each of these broader groupings of NAICS industries while attempting to account for baseline. Though our resulting estimates of costs per entity represent averages spanning broad industry and size groups, we acknowledge that baseline traceability capabilities of individual covered entities, and hence the degree of changes needed for compliance, vary widely.

Table 4. Entities Incurring Costs Due to Provisions of the Rule

Provision	Entities incurring one-time costs	Entities incurring recurring costs	Firms or establishments
Reading and Understanding the Rule	323,872		Firms
Capital Investment[1]	17,615	15,854	Establishments
Training	34,737	26,053	Establishments
§ 1.1315 Traceability Plan	212,368		Firms
Seed lot records (Growers of sprouts)[2]		95	Establishments
§ 1.1325 Records of Harvesting		6,058	Establishments
§ 1.1325 Records of Cooling		3,511	Establishments
§ 1.1330 Records of Initial Packing		4,218	Establishments
§ 1.1335 Records of First Land-Based Receiving		367	Establishments
§ 1.1340 Records of Shipping		31,434	Establishments
§ 1.1345 Records of Receiving		470,580	Establishments
§ 1.1350 Records of Transformation		8,574	Establishments
§ 1.1455(c)(3)(ii) Electronic Sortable Spreadsheet Upon Request		75	Establishments

[1] With respect to Capital Investment and Training, we assume the entities facing recurring costs to be a subset of the entities facing one-time costs.
[2] Although seed lot records fall under § 1.1330 Records of Initial Packing, we assume the incidence of these costs will fall on growers of sprouts.

E. Benefits of the Rule

We expect the following benefits from this rule:

1) Public health benefits from averted foodborne illnesses and deaths caused by foods covered by the rule.
2) Benefits from avoiding overly broad recalls following FDA issued public health advisories.
3) Other benefits discussed qualitatively.

To account for public health benefits of this rule, we adopt the framework developed by the Institute of Food Technologists (IFT) in their 2012 commissioned report to FDA (Ref. [5]). We estimate and quantify two types of benefits. These include benefits from averted illnesses and benefits from preventing overly broad recalls following FDA issued public health advisories.[33] We discuss other benefits qualitatively.

This rule will improve FDA's ability to: (1) quickly and efficiently trace the movement of covered 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 through the supply chain from the point of sale or service to a common source is important for identifying contaminated foods or ingredients and removing such products from the marketplace to prevent additional illnesses. The ability to trace covered foods forward can help FDA ensure timely removal of all affected products from the marketplace. It can also help FDA understand how the distribution of a covered food product relates to illnesses or illness clusters,

[33] A public health advisory is issued for an outbreak investigation that has resulted in specific, actionable steps for consumers to take to protect themselves.

especially for outbreaks that are challenging to resolve, such as those involving multiple foods and foods with multiple ingredients.

The mechanisms through which health benefits are realized are through disease outbreaks averted or reduced-duration foodborne illness outbreaks from covered foods. Benefits from avoiding overly broad recalls may be realized only when recalls are initiated in response to an FDA public health advisory. Meanwhile, other benefits may be realized regardless of whether an outbreak had or had not occurred. [34]

In the absence of standardized records, the time needed to identify implicated foods by linking shipments through the supply chain and back to their sources can be unacceptably long, leading to a larger and more costly disease outbreak. Yet, 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. [18]). For example, the 2010 shell eggs *Salmonella* contamination illustrates this point as it shows how conducting a food recall can be 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. [19]). Because of the time it took to identify the food vehicle, this outbreak became the largest reported foodborne disease outbreak since the early 1970s, when outbreak surveillance was first established (Ref. [20] [21]). With better tracing tools and standardized records, the illnesses and costs associated with this outbreak could have been mitigated or avoided.[35]

[34] Costs of the rule will be incurred by all covered entities regardless of whether there is an outbreak investigation or recall underway, and regardless of whether they are implicated in the outbreak.
[35] More details about this outbreak can be found in Appendix F.

1. Public Health Benefits from Averted Illnesses

Public health benefits from this rule are possible only if the following two conditions hold: (1) a foodborne outbreak occurs and (2) the traceability records required by this rule help FDA to locate a commercially distributed violative product quickly and accurately to ensure it is removed from the market. Therefore, primary public health benefits from this rule arise when foodborne illnesses from covered foods are averted. To assess these benefits, we must first place a value on risk reduction and health-related costs for illnesses that may be averted. To quantify health benefits of this rule we estimate the following:

i. Baseline risks of foodborne illness attributable to foods covered by the rule

ii. Economic burden of foodborne illness associated with covered foods

iii. Value of foodborne illnesses reduced from improved traceability

The baseline risk of foodborne illness is a component in estimating the economic burden of foodborne illness. The value on reducing the risk of foodborne illness through this rule is expressed as a reduction of the economic burden of foodborne illness associated with covered foods.

i. Baseline Risk of Foodborne Illnesses Attributable to FTL Foods

As explained in more detail in Appendix B, we estimate that on average 153,807 cases of foodborne illnesses per year in the U.S. are caused by known pathogens associated with foods that are covered by this rule. Though we use data from multiple past years to obtain this average, we do not estimate trends in illnesses, hospitalizations, or deaths. Each year's numbers reflect changes in measurement, such as increased testing, improved technologies, and changes to outbreak surveillance, which would confound estimation of trends in the number and size of

outbreaks. We are also not able to account for likely drivers of coming increases in foodborne illness, such as new pathogens, new food vehicles, climate change, and density of served populations. Furthermore, increasing globalization of the food supply and production concentration continue to create new challenges for detection, investigation, control, and prevention of foodborne illnesses, making quantification of future foodborne illnesses even more challenging (Ref. [22]). As such, our constant-trend assumption reflects an analytic limitation rather than confidence in the constant-trend projection.

From FDA CORE foodborne illness outbreak data (Ref. [23]), we identified a total of four microbial pathogens responsible for most (98%) of illnesses attributable to foods covered by this rule. Of these pathogens, *E. coli* accounts for approximately 68 percent of the foodborne illnesses, *Salmonella* accounts for approximately 13 percent, *Cyclospora cayetanensis* accounts for approximately 16 percent and Listeria monocytogenes accounts for less than one percent. In terms of annual hospitalizations, the leading pathogen is *Salmonella*, which accounts for 57 percent, followed by *E. coli*, which accounts for 21 percent, Listeria which accounts for 14 percent and *Cyclospora* which accounts for 6 percent of total annual hospitalizations (see Table 5). Other pathogens within FDA data that cause foodborne illnesses from FTL foods include y*ersinia entorocolitica, hepatitis A, norovirus*, *campylobacter*, and *vibrio* spp. In addition to pathogens, naturally occurring chemical contaminants such as ciguatoxin and scombrotoxin can also cause foodborne illnesses from FTL foods.

The foods covered by this rule have a higher public health risk because of their associated frequency and severity of illness outbreaks as well as their frequency of consumption.

Table 5 summarizes the estimated number of illnesses, hospitalizations, and deaths attributable to covered foods. As described in Appendix B, to obtain these numbers, we reviewed

FDA's CORE outbreak data for FTL foods covering the period from January 2009 to December 2020. We used several multipliers from peer-reviewed literature to account for underreporting and underdiagnoses of foodborne illnesses (Ref. [24] [25]). We use the methodology outlined in the Scallan et al. follow-up article to account for unspecified and unknown agents[36] (Ref. [26]). Based on this article, the estimated number of annual illnesses in

Table 5 (153,807) before adjusting it for the number of illnesses from unspecified and unknown agents constitute only 20 percent of all illnesses. Therefore, the total number of illnesses from known toxins and pathogens is 153,807 and from unspecified and unknown agents is 615,226 (= 153,807 x (1-0.2)/0.2), which yields a total of 769,033 illnesses (= 153,807 + 615,226).[37]

Table 5. Estimated Baseline Illnesses, Hospitalizations, and Deaths Attributable to Foods Covered by the Final Rule[38]

Type of Pathogen	Annual Estimates	Hospitalization	Deaths	*Percent of total cases*
Campylobacter	63	0	0	0.04
Ciguatoxin	31	0	0.0	0.02
Cyclospora cayetanensis	25,332	20	0.0	16.47
E. coli (STEC) O157	55,074	66	1.7	35.81
E-coli (STEC) non-O157	50,156	10	0.0	32.61
Hepatitis A Virus	13	1	0.3	0.01
Listeria Monocytogenes	62	52	9.7	0.04
Norovirus	803	1	0.0	0.52
Salmonella typhoidal	200	3	0.0	0.13
Salmonella non-typhoidal	20,005	207	2.3	13.01
Scombrotoxin	107	0	0.0	0.07
Vibrio-parahaemolyticus	1,279	2	0.0	0.83

[36] 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.

[37] Figures are rounded to nearest whole number

[38] 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.

Vibrio-Cholerae	36	0	0.0	0.02
Yersinia enterocolitica	63	0	0	0.42
Estimated total from known pathogens[39]	**153,807**	**364**	**14**	**100**

ii. 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 5 by the updated burden of illness estimates. We update burden of illness estimates first published in 2015 (Ref. [27]) to 2020-dollar values[40] (Ref. [28]). 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) because 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. [29]). The total economic burden of illness 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.[41] We rely on

[39] 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). We assume their hospitalization and death rates were constant.

[40] The model updates included revised annual dollar estimates of foodborne illness costs from the 2015 estimates to 2020 values using BLS deflators. Additionally, new foodborne illness causing agents, which include *scombrotoxin* fish poisoning and ciguatera fish poisoning, were added into the model. For these multipliers, we cite Pennotti *et al.* (2013) [25] because they were not included in Scallan *et al.* (2011a) [24].

[41] Minor *et al.,* (2015) [27] present their estimates of cost per illness using illness data from Scallan *et al.,* (2011a) [24] which uses data from 2000 to 2008 from several sources. By contrast, the estimates in this RIA are based on FDA CORE data from 2009 to 2020. While the Scallan *et al.,* (2011a)*,* 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) [52] indicate

these estimates for our analysis and refer the reader to Minor, *et al.,* 2015 for more detailed discussion of these computations.

Table 6 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 each pathogen. We estimate the economic burden of foodborne illnesses associated with foods covered by this final rule as approximately $5.8 billion dollars per year (Table 6). More detailed calculations of the estimated range of the economic burden and cost per illness can be found in table B2 of Appendix B.

Table 6. Estimated Economic Burden of Foodborne Illnesses Associated with Foods Covered by this Final Rule (2020$)

Pathogen	Estimated Annual Illnesses	Monetized Burden per Illness	Total: Primary ($1,000)
Campylobacter	63	$4,748	$300
Ciguatoxin	31	$31,402	$985
Cyclospora cayetanensis	25,332	$4,451	$112,751
E. coli (STEC) O157	55,074	$13,757	$757,657
E-Coli (STEC) non-O157	50,156	$2,506	$125,691
Hepatitis A Virus	13	$58,440	$780
Listeria Monocytogenes	62	$1,987,005	$123,774
Norovirus	803	$487	$391
Salmonella typhoidal	200	$7,116	$1,420
Salmonella non-typhoidal	20,005	$7,248	$144,993
Scombrotoxin	107	$548	$59
Vibrio-Cholerae	36	$1,675	$61

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.

Yersinia enterocolitica	645	$6,255	$4,033
Campylobacter	63	$4,748	$300
Subtotal Illnesses from Known Pathogens	**153,807**		$1,276,266
Adjusting Subtotal for Unidentified/Unspecified Pathogens	**615,226**		$5,105,063
Total Illnesses	**769,033**		$6,381,329

iii. Value of foodborne illnesses reduced from improved traceability.

We estimate the value of foodborne illnesses reduced from improved traceability (i.e., 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 7 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 7 includes results from four of the eight case studies from the IFT report (excluding two involving foods not on the FTL). It also includes 17 case studies using epidemic curve data from CDC and investigation and intervention data from FDA as explained in Appendix C of this analysis. All cases used in this analysis cover outbreaks

associated with four pathogens: *Cyclospora, E. coli (STEC), Listeria monocytogenes* and *non-typhoidal Salmonella*.[42]

Appendix S of the IFT report describes in detail the analytical process and the applicability of the analysis[43] 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 traceability recordkeeping requirements from this rule. However, FDA outbreak investigation processes and outbreak data collection have changed since the IFT report. In 2011 the 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.[44] We therefore use "initiation" and "completion" dates provided by CORE in estimating the percentage of illnesses potentially prevented for post-2011 outbreaks. We extend the IFT analysis by including additional pathogens and using multiple case studies per pathogen to

[42] FTL associated outbreaks caused by these four pathogens represent about 98% of all FTL associated illnesses.
[43] 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).
[44] 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.

estimate the average percentage of preventable illnesses by pathogen. Minimum and maximum preventable illnesses in Table 7 represent variable potential impact of traceability among case studies involving the same pathogen.

Table 7. 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)
2018	Shell eggs	*Salmonella* Braenderup	45	11	24%	Appendix C
2018	Tahini	*Salmonella* Concord	8	2	25%	Appendix C
2019	Ground Tuna	*Salmonella* Newport	14	6	43%	Appendix C
2019	Tahini	*Salmonella* Concord	6	1	17%	Appendix C
2019	Cantaloupe	*Salmonella* Javiana	163	25	15%	Appendix C
Percentage range of cases prevented for *Salmonella*		**Average**	**618**	**122**	**24%**	
		Minimum	**6**	**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%**	

Year	Commodity	Pathogen	Total Illnesses per Epidemic Curve	Preventable illnesses	Percentage of Illnesses That Are Preventable	Source
2012	Clover sprouts	*E. coli* O26	29	10	34%	Appendix C
2010	Romaine Lettuce	*E. coli* O145	26	0	0%	Appendix C
2019	Ground Bison	*E. coli* O121:H19; O103:H2	33	4	12%	Appendix C
Percentage range of cases prevented for other *E. coli*		**Average**	**29**	**5**	**16%**	
		Minimum	**26**	**0**	**0%**	
		Maximum	**33**	**10**	**34%**	
2011	Cantaloupe	*Listeria monocytogenes*	139	69	50%	Appendix C
2019	Hard boiled eggs	*Listeria monocytogenes*	8	5	63%	Appendix C
Percentage range of cases prevented for *Listeria monocytogenes*		**Average**	**74**	**37**	**56%**	
		Minimum	**8**	**5**	**50%**	
		Maximum	**139**	**69**	**63%**	
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

After estimating the number of illnesses that may be prevented with better tracing, we then multiply the percentage range of preventable illnesses from Table 7 by the estimated number of annual illnesses for each pathogen in Table 8. 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. [24] [26]). 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.

We make one more adjustment to our estimates to account for certain establishments that are now fully exempt from this rule. As mentioned in Section 2.D.2 Coverage of the Rule, retail food establishments and restaurants with under $250,000 in annual sales and farms with less than $25,000 in annual sales are fully exempt from this rule. We adjust our benefits estimates to account for this exemption assuming that the reduction in illnesses averted, and therefore the reduction in benefits is commensurate in proportion with food revenues by these exempt entities. We use 2017 Statistics of U.S. Businesses (SUSB) data from the U.S. Census and estimate that about 2% of revenues would correspond to 2% reduction in cases averted. This means that by exempting these entities, health benefits from this rule are slightly less than benefits if the rule had no exemptions. To account for this reduction, the number of annual illnesses in Table 8 represent 98% (= 100% - 2%) of all annual illnesses.

Table 8. 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	24,838	3,337	928	5,747
E. coli (STEC) non-O157	49,179	7,740	0	16,958
E. coli (STEC) O157	54,001	5,782	1,714	9,054
Listeria monocytogenes	61	34	30	38
Salmonella (non-typhoidal)	19,615	4,805	370	10,746
Subtotal	147,694	21,598	3,042	42,543
Unspecified unknowns[36]	590,775	86,390	12,169	170,174
Total	**738,469**	**107,988**	**15,211**	**212,717**

In Table 9, we estimate the burden of foodborne illnesses attributed to FTL foods by multiplying the estimated total annual number of illnesses from Table 8 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 II.E.1.vi.

Hence, the columns in Table 9 rely on the primary, minimum, and maximum possible burden of illness for the selected pathogens from our burden-of-illness model. [45]

Table 9. Annual Benefits Based on 83% Improved Product Tracing Time

Pathogen	Annual Undiscounted Benefits from Tracing Time Reduction by 83% to 6 Days (Based on Weighted Burden per Illness) (1)(2)		
	Primary	Minimum	Maximum
Weighted burden per illness for four pathogens	$10,020	$5,377	$14,586
Total annual benefit from faster tracing	$896,548,792	$67,775,664	$2,570,829,560
Annualized Present Value Benefit (7%, 20 years)	$780,498,704	$59,002,721	$2,238,059,052
Annualized Present Value Benefit (3%, 20 years)	$809,640,406	$61,205,722	$2,321,622,098
Present Value Benefit (7%, 20 years)	$8,268,614,390	$625,075,667	$23,710,029,480
Present Value Benefit (3%, 20 years)	$12,045,404,783	$910,586,595	$34,539,874,403

(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).

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. [30]). The outbreak illustrates the difference in time to identify implicated farms 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

[45] For estimating discounted costs and benefits, with a 3-year effective compliance date, we assume the publication date of the rule is year 0 and that one half of first year costs will be incurred in year 1 (which is two years before the 3-year effective date) and that the other half of first year's costs will be incurred in year 2. Therefore, we assume half of benefits will begin to accrue on year 2 (one year after half the requirements were implemented in year 1) and full annual benefits will begin to accrue on year 3 (two years after requirements would have been implemented).

available from an ill consumer, farms 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, traceability lot code sources, 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. [30]).[46] 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.

The average number of days used for identifying a product source without lot codes is about 35 (ranging from about 0 to 84),[47] 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

[46] 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.

[47] We estimate the average number of days used for identifying a product source without lot codes by taking the average difference between FDA traceback completion date and FDA traceback initiation date of the 23 outbreaks identified in Table C.1 of Appendix C.

sources in five to seven days would range between 80% to 86%. We use the middle estimate of six days which is equivalent to an 83% improvement (Table 9).

We estimate that corresponding (undiscounted) public health benefits would range between $68 million and $2.6 billion per year with a primary estimate of $897 million per year (Table 9). The present value of health benefits with seven percent discounting over 20 years (Table 9) ranges from about $625 million to $23.7 billion, with a primary estimate of $8.3 billion. The present value of health benefits with three percent discounting over 20 years (Table 9) ranges from about $911 million to $34.5 billion, with a primary estimate of $12.0 billion. At a seven percent discount rate over twenty years, the annualized monetized health benefits of the rule range from $59 million to $2.2 billion with a primary estimate of $780 million. At a three percent discount rate over twenty years, the annualized monetized health benefits range from $61 million to $2.3 billion with a primary estimate of $810 million.

These benefits are slightly underestimated as the annual dollar value of the burden associated with outbreaks caused by these four pathogens represents about 99% 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.

2. Benefits from Avoiding Overly Broad Recalls Following FDA Issued Public Health Advisories

In addition to the public health benefits discussed above, implementation of more precise food recalls due to improved tracing may result in social benefits realized by avoiding overly broad recalls when contaminated FTL foods covered by the rule are identified. Overly broad recalls may occur when the source of an outbreak cannot be promptly identified or is originally

misidentified, so that the recall extends to product lots and products beyond the implicated product.

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 regulation may help us to more quickly and accurately locate a violative product that was commercially distributed, which could reduce the likelihood of conducting an overly broad recall. 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.[48] 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.[49]

Although recall of rightly implicated foods is necessary and costly, overly broad recalls that involve entire industries or loosely or unrelated products can be extremely expensive. According to a survey of companies conducted by the Grocery Manufacturers Association

[48] 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.

[49] 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.

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

In cases when the firm cannot be identified in a timely manner, FDA is more likely to issue an advisory, which has much greater potential spillover effects than a manufacturer-initiated recall. Rolling recalls can also occur, such as when a recall continues to grow because implicated ingredients are found in other products, as with the peanut butter recall in 2009.

To inform our analysis of the benefits of avoiding overly broad recalls, ERG completed a literature review and a recall elicitation of industry experts in December 2021 and January 2022 (Ref. [4]). One purpose of the literature review was to find data on the three overly broad recalls presented in Appendix F and identify other possible case studies to help structure the expert elicitation instrument for developing data on the spillover effects from an overly broad recall.[50] We present the case study data summarized by ERG in

[50] Case studies of overly broad recalls were used to help experts consider how more-targeted recalls might affect some of the identified case study costs.

Table **10** below.

Table 10. Findings of Recalls Case Studies

Recall	Data[51]	Source
2018 Romaine Recall	• Romaine growers who sell through spot sales lost $750,000 due to the advisory • Romaine growers who sell through contracts gained $690,000 due to the advisory • Processors and shippers lost $23.8 million in pulling harvested lettuce from the supply chain, and $43.1 million from lettuce under their control that could not be sold, totaling $60.9 million • Grocery retailers lost $21.2 million from pulling product and $8.4 million from price changes, totaling $29.7 million • Food service operators lost $4.2 million from an inability to sell but gained $2.8 million from reduced acquisition costs. Food service operators lost a total of $1.4 million • Total societal loss (including loss on the parts of consumers, damages to suppliers of labor and materials, employment reduction in related industries, etc.) was $320-$400 million	Kiesel et al. (2021) (Ref. [31])
2008 Tomato Recall	• Large, publicly owned distributors, retail outlets, and restaurant chains saw no drop in stock value during the advisory • National Restaurant Association claimed members lost $130 million • Florida tomato industry estimated loss of $660 million (including $50 million of tomatoes from Florida removed from the distribution system) • Over 33,000 farm workers hired daily to pick tomatoes in Florida lost work • One Texas distributor estimated $660,000 in their own company's losses • Georgia claimed losses of $11 million • California lost $400,000 in the destruction of good product; • $1.3 million in product sales following the announcement of the advisory; and	Meyerson (2009) (Ref. [32]) Kawamura (2008) (Ref. [33])

[51] All estimates have been adjusted to December 2021 dollars (BLS, 2022).

	• $26-$32 million in indirect losses due to low demand and poor prices over time • U.S. tomato farms may have lost $33 million • Total societal loss is estimated at $330 million	Palma et al. (2010) (Ref. [34]) Hussain and Dawson (2013) (Ref. [35])

In the literature review, ERG found that while much has been written qualitatively to address the benefits of traceability in food production and recall processes, little has been done to quantify those effects and that even less has been done to assess the spillover costs of broad recalls. Existing research, as presented in

Table **10**, confirms that broad recalls can cost society hundreds of millions of dollars, with economic harm felt along entire supply chains. The recall elicitation (designed to develop estimates of the reduction in spillover costs) provided quantitative information on the potential effects of traceability on food recalls due to FDA advisories and also insights on how firms react under different recall scenarios.

Experts made a noteworthy distinction between two scenarios in which an overly broad recall can occur:

- The first scenario is when a recalling firm or its downstream customers cannot definitively track the movement of outbreak causing recalled product and therefore recall additional products as a "buffer". In this situation, when the recalling firm is known, some of these costs through the supply chain may be partially or wholly reimbursed by the firm (depending on existing contracts).
- Under the second scenario firms recall products following FDA-issued public health advisories about products when no one can identify the specific firm, brand, or production dates of the product that is causing a foodborne illness outbreak. A public health advisory is issued for an outbreak investigation that has resulted in specific, actionable steps for consumers to take to protect themselves.

Under both scenarios the source of an outbreak cannot be promptly identified or is originally misidentified, so that the recall extends to product lots and products beyond the implicated product. The main difference is that under the first scenario some of these "spillover" costs are internalized by the recalling firm, and under the second scenario these "spillover" costs are borne by others in society (including processors, distributors, retailers, consumers, and producers other than the implicated producers). In summary much greater spillover impacts

occur when an FDA advisory is issued and an implicated firm is not identified. Under the second scenario, firms may not be able to recover their losses. Generally, the faster a recall is completed, the less it costs, and fewer firms will be affected.

Another insight by experts is that by requiring firms to implement traceability for FTL foods, this rule will reduce the scope of advisories and possibly even eliminate the need for some advisories. We therefore identify as a benefit of this rule the reduction in spillover costs incurred by manufacturers, producers, distributors and retailers from inadvertently being part of a broad scope or undifferentiated product recall following an FDA advisory. The benefits of avoiding overly broad recalls following an FDA advisory is the reduction in spillover costs.

We estimate the reduction in spillover costs as the difference between total costs incurred by firms affected by an FDA advisory and total costs to firms affected under a more targeted recall.

i. Costs per Firm

During the recall elicitation, ERG asked experts to consider the overly broad recalls that occur when an FDA advisory has been issued but no firm has been identified yet as the source of the problem. As presented below, they were asked to estimate the per firm costs incurred by type of entity or industry category (e.g., processor, distributor, retailer, etc.), to respond to an FDA advisory that implicates a food from FDA's food traceability list.

Keeping in mind that answers to questions about labor and non-labor costs often include some variability due to different factors (firm's response to FDA advisories, size of operations, type of product, variation in FDA advisories, etc.), ERG therefore asked for ranges of estimates

(low to high) and average that reflect that variability for each industry category. ERG also asked that they explain how they arrived at their answers (for example, to describe the scenario that they were thinking about in generating their answers, how they estimated the low, most likely, and high estimates, etc.)[52]. They were also asked to note any costs that were not specifically captured in the recall elicitation. All estimated per firm costs from the expert elicitation include labor and non-labor costs by industry category affected by an FDA advisory.

Assumptions

Industry categories used by experts included 1) producer/processor, 2) shipper distributor 3) non-restaurant retailers and 4) restaurants. For context, the term producer/processor also applied to manufacturers, farms, packers and growers. The responses under the category for shipper/distributor also applies to wholesalers and warehouses. For the term "non restaurant retailer" experts assume the term includes mostly grocery stores, specialized grocery stores (fish markets, fruit market, bakeries, etc.) supercenters and club stores.

In describing low and high costs estimates, experts treated the range for low and high-cost estimates as costs incurred by small and large firms respectively. Experts participating in the recall elicitation did not necessarily use SBA definitions when referring to certain entities as small. The assumptions from experts on the criteria of low, most likely, and high estimates varied among experts and also varied considerably by industry. For small firms across different industry categories, experts were generally thinking about single establishment firms or independent operators (not part of a chain). For large firms some experts considered firms with 50 or more establishments. Other experts provided specific size breakdowns by industry category. For producers/processors some considered their low to high estimates applied to one

[52] Although experts provided low, most likely and high estimates, they didn't include their rationale for the most likely estimate.

establishment firm to firms with two or more manufacturing facilities or with annual revenues in excess of $250 million. For restaurant and retail firms, some experts considered them small if they had at most two to three establishments with two or three employees per establishment. Other experts considered small regional store chains with two to three employees per establishment as small. For restaurants, some experts considered small firms could range from being a single establishment to a chain with 2 to 3 sites while others consider a small firm from being a single establishment to a chain with up to 150 locations. For non-restaurant firms experts considered the range of small to large firms from respectively having 50 or fewer locations to more than 1,000 locations.

For the most likely estimate some experts considered costs to be also small because the average number of locations included in a firm is skewed toward small firms. Others considered that under this cost category, the firms would be part of a regional chain.

We describe estimates for labor, non-labor and total costs per firm by industry category below.

Labor hours

From the recall expert elicitation by ERG experts provided estimated ranges and average labor hours expended per firm by type of labor category and type of firm when responding to an FDA advisory in which:

- No firm(s) has/have been identified as the source of the problem.
- The implicated product is on the FTL food list (e.g., romaine lettuce or peanut butter).

The type of labor hours is broken down by industry category: producers/processors, shippers/distributors, restaurants and non-restaurant retailers. Depending on the industry category, the type of labor hours may include costs to identify, remove, quarantine, store and

dispose product, and resupply customers. Labor hours are also broken down by labor type including executive management, mid-level management, legal, administrative, expert consultant, and production hours. Table 11 provides a general description of the types of costs and labor incurred by industry category.

Table 11. Type of Labor and Wages by Industry and Occupation Expended During an FDA Advisory

Industry category	Type of cost	Type of labor [2]
Producers/ processors	Incur costs to: - identify product to be removed - if large, contact each processing facility - public relations/monitor public response -meet and determine public response - contact distributors/retailers - hire legal experts and other expert consultants - quarantine and store or dispose of product - resupply customers - effectiveness checks	Executive management $110.14 Midlevel management: $59.93 Legal $80.39 Production labor hours: $17.32 Administrative labor hours $20.16 Expert consultant: $75.50 Other: $32.47 [1]
Shippers/ distributors	Incur costs to: - identify product to be removed - clean and sanitize if bulk product is affected - quarantine and store or dispose of product - resupply customers	Executive management $105.64 Midlevel management: $56.56 Legal $74.42 Production labor hours: $18.41 Administrative labor hours $22.90 Expert consultant: $75.50 Other: $32.62 [1]
Restaurants	Incur costs to: -identify product to be removed -if large, contact each restaurant - public relations/monitor public response -remove product from inventory -quarantine and store or dispose of product	Executive management $74.58 Midlevel management: $40.75 Legal $74.42 Production labor hours: $14.30 Administrative labor hours $15.44 Expert consultant: $75.50 Other: $23.50 [1]

Non-restaurant retailers	Incur costs to: - identify product to be removed - if large, contact each retailer - remove product from shelves and storage -restock product - quarantine and store or dispose of product - public relations/monitor public response	Executive management $85.99 Midlevel management: $40.75 Legal $74.42 Production labor hours: $16.60 Administrative labor hours $16.49 Expert consultant: $75.50 Other: $24.61(1)

(1) Assume "other" labor hours are a blend of administrative, production, and midlevel management labor hours
(2) Source for wages: *https://www.bls.gov/oes/current/oessrci.htm*

From the range of labor cost responses from all nine experts, presented through the columns in Table 12, firms in the producer/processor category lead in labor cost shares at every estimate level and restaurants appear to have the smallest share of labor costs. According to some experts, managerial and administrative costs are largely fixed across scale of operations, but production hours may vary the most according to the size of the operation. Spillover costs can include labor costs from meetings to determine response, costs to notify downstream entities and the public, costs to hire legal and food safety experts, identification and disposition of product, and resupplying customers.

Table 12. Labor Costs of Advisory Event per Firm ($1,000).(1)

Cost Range by Industry	Min	Median	Average	Max
Producer/ Processor				
Low estimate	$3	$11	$30	$90
Most likely estimate	$9	$37	$76	$242
High estimate	$15	$59	$1,486	$11,585
Shipper/ Distributor				
Low estimate	$1	$8	$9	$23
Most likely estimate	$1	$17	$45	$230
High estimate	$2	$25	$511	$2,230
Restaurant				
Low estimate	$0.1	$6	$9	$35

Most likely estimate	$0.1	$19	$36	$114
High estimate	$1	$29	$232	$1,259
Non-Restaurant Retailer				
Low estimate	$2	$7	$11	$30
Most likely estimate	$5	$22	$34	$82
High estimate	$8	$33	$558	$4,086
Total labor cost per firm per advisory [(1)]				
Low estimate	**$9**	**$34**	**$57**	**$166**
Most likely estimate	**$24**	**$94**	**$183**	**$474**
High estimate	**$38**	**$148**	**$2,700**	**$13,815**

[(1)] The total labor cost per firm per advisory is the range of the sum of individual expert estimates by industry category and is not additive.

Non-labor hours

Experts also provided estimates of non-labor costs expended per firm by type of non-labor costs and type of firm when responding to an FDA advisory in which:

- No firm(s) has/have been identified as the source of the problem.
- The implicated product is on the FTL food list (e.g., romaine lettuce or peanut butter).

Similar to labor costs, they are broken down by industry (Table 13).

Table 13. Type of Non-Labor Costs by Industry Type Expended During an FDA Advisory

Industry type	Type of cost
Producers/ processors	Incur costs: - for lost sales - product destruction - product restocking - product storage - public relations and advertising costs
Shippers/ distributors	Incur costs: - for lost sales - product destruction - product restocking - product storage

Restaurants	Incur costs: - for lost sales - product destruction - product restocking - product storage
Non-restaurant retailers	Incur costs: - for lost sales - product destruction - product restocking - public relations and advertising costs

The estimated range of non-labor costs varies even more widely than labor costs. The share of costs appears to be at the producer/processor level and disproportionately much larger than other industry categories. For example, reduced demand for products (due to the recall) may result in growers having to plow product under. One possible explanation is that many non-labor costs in the producer/processor category are estimated by a discrete unit such as a batch or field (Table 14).

Table 14. Non-Labor Costs of Advisory Event per Firm ($1,000)[(1)(2)]

Cost Range by Industry	Min	Median	Average	Max
Producer				
Low estimate	$0	$3,020	$8,885	$48,000
Most likely estimate	$2,400	$7,925	$21,965	$82,000
High estimate	$5,800	$66,600	$59,612	$127,000
Shipper Distributor				
Low estimate	$0	$75	$1,214	$10,000
Most likely estimate	$0	$200	$3,186	$16,000
High estimate	$0	$2,275	$7,041	$22,000
Restaurant				
Low estimate	$0	$29	$63	$276
Most likely estimate	$4	$117	$695	$2,500
High estimate	$15	$925	$2,825	$14,200
Non-Restaurant Retailer				
Low estimate	$0	$113	$343	$1,001
Most likely estimate	$45	$1,208	$2,139	$10,500
High estimate	$165	$2,975	$8,576	$33,000
Total non-labor cost per advisory				

Low estimate	**$0**	**$3,148**	**$10,461**	**$58,750**
Most likely estimate	**$3,175**	**$7,925**	**$27,669**	**$111,000**
High estimate	**$9,315**	**$66,600**	**$76,788**	**$186,000**

(1) The total non-labor cost per firm per advisory is the range of the sum of individual expert estimates by industry category and is not additive.

(2) Estimates include the addition of short- and long-term sales losses reported by all experts for consistency.

There are multiple reasons that could explain the wide variation among expert response, the main one being that outbreaks and therefore FDA advisories vary in characteristics. Costs can also vary widely depending on the size and magnitude of the recall but also by industry. For example, according to experts, large firms are more likely to react to an advisory as they have more resources to address publicity that may be related to the advisory. Small firms, on the other hand, are not as likely to be prepared and/or have similar resources that support them to take an action.

Total Costs per Firm

Costs incurred by firms is essentially driven by how they think they should respond to the FDA advisory. Total costs of an advisory event per firm are the sum of labor costs and non-labor costs) are summarized in Table 15.

Table 15. Total Cost of Advisory Event per Firm ($1,000)

Cost Range by Industry	Min	Median	Average	Max
Producer				
Low estimate	$7	$3,031	$8,915	$48,006
Most likely estimate	$2,471	$8,167	$22,041	$82,011
High estimate	$5,859	$72,658	$61,098	$127,015
Shipper Distributor				
Low estimate	$1	$98	$1,223	$10,006
Most likely estimate	$2	$300	$3,231	$16,011
High estimate	$7	$2,311	$7,552	$22,016
Restaurant				
Low estimate	$2	$36	$73	$311
Most likely estimate	$7	$163	$731	$2,518

High estimate	$20	$1,118	$3,057	$14,368
Non-Restaurant Retailer				
Low estimate	$3	$129	$354	$1,031
Most likely estimate	$52	$1,220	$2,172	$10,524
High estimate	$179	$3,068	$9,134	$33,034
Total cost per advisory				
Low estimate	**$17**	**$3,182**	**$10,518**	**$58,784**
Most likely estimate	**$3,649**	**$8,212**	**$27,852**	**$111,063**
High estimate	**$9,463**	**$80,028**	**$79,487**	**$186,091**

(1) The total cost per firm per advisory is the range of the sum of individual expert estimates by industry category and is not additive.

While non-labor costs vary widely by industry and size of firms, they also make over 99% on average of total costs across all industries and about half of non-labor costs are incurred by producers/processors in lost sales.

ii. Affected Firms

Experts did not have information to help estimate the reduction in scope (number of firms affected) of an overly broad recall, as they did not know the number of firms affected overall. The following steps we use in estimating the number of affected firms and then characterizing the firms in a way that is closest to the criteria laid out by experts for firms with a low, most likely, and high estimate require a series of calculations described below. Once we have laid out the series of calculations, our final step involves using Monte Carlo simulations. A Monte Carlo simulation requires assigning parameters to corresponding probability density functions to 1) characterize the variability inherent in the cost estimates, and 2) to characterize the inherent uncertainty in the estimated number of firms by their respective cost category. Parameter estimates and results of the simulation are presented in Appendix G.

To estimate the scope of a broad recall, we assume that the annual number of firms affected by an advisory is dependent on the probability that:

1) at least one firm in any given industry is affected by an outbreak and

2) a number of firms in any given state in the country will experience an outbreak.

To estimate these probabilities, we selected nine outbreaks of the 23 Outbreaks in Appendix C. We only use those with 100 or more illnesses and for which there was an FDA advisory (such as in the case studies used by experts) and present them in Table 16.[53]

Table 16. Outbreak Used for Estimating the Probability of a Large Outbreak.

Year	Commodity	Pathogen	Total Illnesses per Epidemic Curve
2008-2009	Peanut Butter and peanut butter products	*Salmonella Typhimirium*	636
2008	Peppers and tomatoes	*Salmonella St Paul*	1,442
2009	Sprouts	*Salmonella St Paul*	235
2010	Shell eggs	*Salmonella Enteritidis*	3,578
2011	Cantaloupe	*Listeria Monocytogenes*	139
2013	Salad mix	Cyclospora *cayetanensis*	631
2019	Cantaloupe	*Salmonella Javiana*	163
2019	Romaine Lettuce	E. *coli* O157: H7	167
2019	Fresh Basil	Cyclospora *cayetanensis*	241

Source: www.cdc.gov

We created two matrices: one outlines the number of states affected by each advisory while the other outlines the number of FTL related industries associated with each outbreak.

1) To estimate the probability that a producer/processor firm (associated with production or farming) is affected by an outbreak advisory we use the matrix of outbreaks affecting

[53] Links with information on each outbreak can be found in Appendix C.

industry categories by matching their corresponding NAICS code. We use the ratio of the sum of outbreaks per NAICS to estimate the probability range (min, average, max) of an outbreak by multiplying the ratio by the number of firms in each firm category. The probability that any producing firm is associated with an outbreak in a 12-year period ranges from 0 to 25 percent with an average of 3 percent. In a similar manner we estimate the probability that a farm is associated with an outbreak in a 12-year period ranges from 0 to 29 percent with an average of four percent (Table 17).[54]

Table 17. Probability of Outbreak by Industry Category (NAICS) Over 12-year Period

Year / Commodity	Pathogen	Number of Large Outbreaks by Pathogen	
		Farms	Producers
2008 / Peppers and tomatoes	*Salmonella St Paul*	2	2
2008-2009 / Peanut Butter and peanut butter products	*Salmonella Typhimirium*	0	3
2009 / Sprouts	*Salmonella St Paul*	2	0
2010 / Shell eggs	*Salmonella Enteritidis*	1	0
2011 / Cantaloupe	*Listeria Monocytogenes*	1	2
2013 / Salad mix	Cyclospora *cayetanensis*	1	2
2019 / Cantaloupe	*Salmonella Javiana*	1	2
2019 / Romaine Lettuce	E. *coli* O157: H7	1	1
2019 / Fresh Basil	Cyclospora *cayetanensis*	1	2
Ratio of selected outbreaks by industry category (sum of large outbreaks/ total number of large outbreaks)	Min	0%	0%
	Average	4.2%	2.9%
	Max	29%	25%

[54]Source: Statistics of U.S. Businesses SUSB is an annual series that provides national and subnational data on the distribution of economic data by enterprise size and industry. https://www.census.gov/programs-surveys/susb.html

NAICS	111219, 111339, 111419, 112310, 112511, 112512, 114111, 114112, 115114, 115115	311340, 311351, 311352, 311411, 311412, 311423, 311513, 311520, 311710, 311811-311813, 311821, 311824, 311911, 311941, 311942, 311991

2) To estimate the probability that firms in the distributor, wholesaler, retailer and restaurant categories are affected by an outbreak advisory, we use the matrix of the same selected outbreaks as in Table 17 by states (depicted best using a map, see Figure 1). We use the ratio of the sum of outbreaks per state to estimate the probability range (min, average, max) of an outbreak by multiplying the ratio by the number of firms in each state. The probability that any firm in the retail, restaurant, or distributor category in any given state is associated with an outbreak in a 12-year period ranges from 0.4 percent to 3.2 percent with an average of 2 percent (Figure 1).

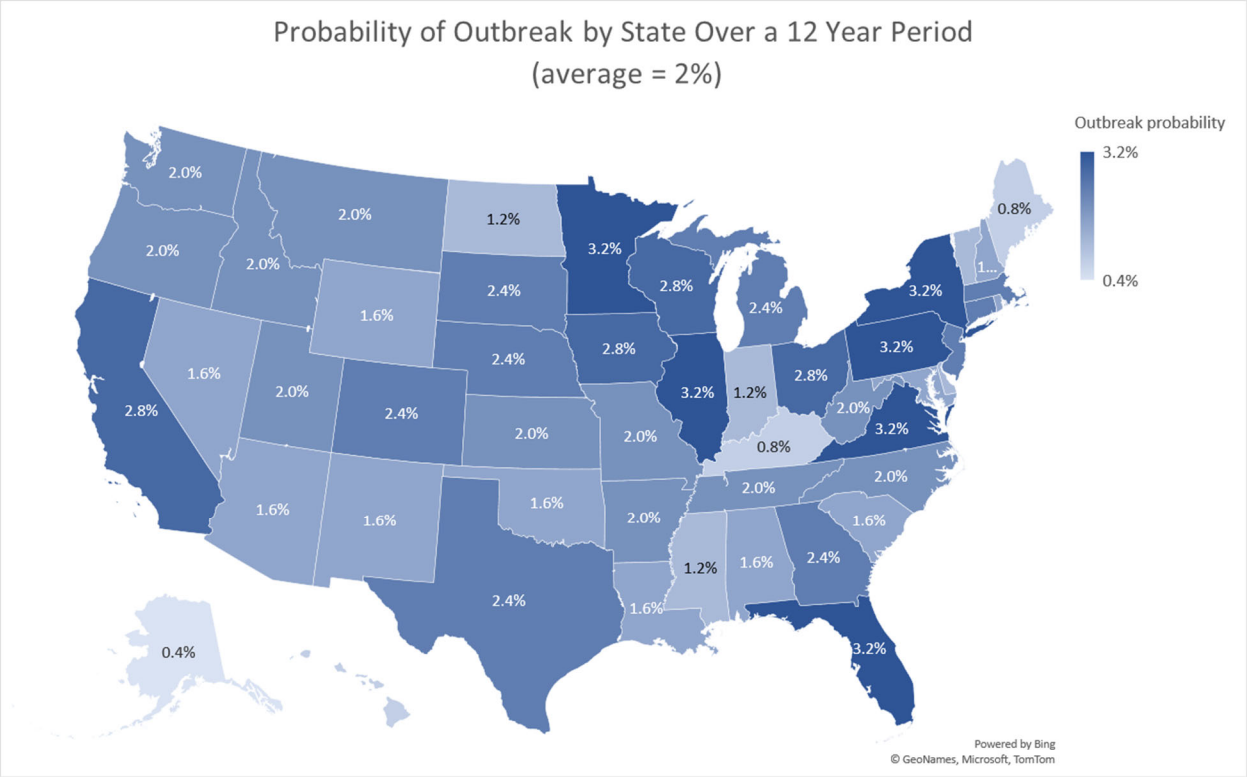

Figure 1. Probability of a Large Outbreak from Covered Foods by State Over a 12-Year Period.

The estimated annual range of firms affected by an FDA advisory is shown in Column D of Table 18 and is expressed as the product of columns A x B x C divided by 12 (for 12 years of outbreak data) where:

- A is the number of firms by NAICS category,
- B is the percentage of firms associated with covered products; and
- C is the probability of an outbreak by firm category.

To arrive at the estimated range on column D, we first use the estimated number of covered firms by their corresponding NAICS using SUSB data from the U.S. Census in Column A. Column B in Table 18 represents the share of firms associated with covered products by the

ratio of sum of covered NAPCS establishments over total NAICS establishments, derived from the Coverage section estimates on Appendix D and in section II.D.2 Coverage of the Rule.

The product of Columns A, B and C divided by 12 in Table 18 gives us Column D: The annual number of firms affected by advisory. The total annual number of firms is, in effect, the weighted sum of the number of firms affected by an advisory.[55] The estimated annual number of firms potentially affected by an advisory range from 141 to 1,278 with an average of 710.

Table 18. Annual Number of Firms Affected by Advisory (1).

Category of Firms	(A) NAICS Firms	(B) Percent FTL Firms	(C) Probability of Outbreak by Firm Category over period of 12 years			(D) = (A x B x C)/12 Annual number of Firms Affected by Advisory		
			min (all)	average (all)	max (all)	min (all)	average (all)	max (all)
Farms	50,756	67%	0.0%	0.6%	4.6%	1	16	130
Producers/ Manufacturers	18,907	55%	0.0%	0.5%	4.0%	1	3	33
Wholesaler/ Shipper/Distributors	32,160	43%	0.4%	2.0%	3.2%	5	23	37
Retailers	485,893	66%	0.4%	2.0%	3.2%	106	524	845
Restaurants	180,577	49%	0.4%	2.0%	3.2%	29	145	233
Weighted Sum	**768,293**	**61%**				**141**	**710**	**1,278**

(1) Sums and sums of products may not be exact due to rounding.

[55] Using ratio of outbreaks per NAICS for farms and producer/processor firm (0%,0.6% and 4.6%) divided by 12 and using ratio of outbreaks per state for firms in the categories for distributor/shipper, restaurants, and non-restaurant retail (0.4%,2% and 3.2%) divided by 12.

iii. Firms Affected by Low, Middle (Most Likely) and High Estimate.

The next step of this calculation involves finding the corresponding proportion of firms in Column D that would most likely be affected by either the low, most likely or high-cost estimate provided by the recall expert elicitation in Table 12, Table 14 and Table 15[56].

To match the four product categories in the cost estimates from the recall expert elicitation, and as discussed in the Averted costs per firm section, we assume farms and producers will fit in the same cost category.

Table 19. Proportion of Firms Associated with Low, Middle and High Estimate Categories

Category	(E) % Firms for low estimate	(F) % Firms for middle estimate	(G) % Firms for high estimate
Farm	45.43%	51.30%	3.26%
Producer/processor	45.43%	51.30%	3.26%
Shipper/ Distributor	49.41%	45.41%	5.18%
Restaurant	36.76%	62.77%	0.63%
Non-Restaurant Retailer	61.20%	38.17%	0.48%

Assigning the percentages in Table 19 to low, most likely, and high-cost ranges used in the recall elicitation, requires that we make the following assumptions:

1. The proportion of firms affected by the low estimate is equivalent to the number of firms from SUSB Census with five or less employees.
2. The proportion of firms affected by most likely estimate is equivalent to the number of firms from the SUSB with 6 to 499 employees.

[56] Some experts may have interpreted the middle estimate as the most likely, while others may have interpreted it to be the same as the median.

3. The proportion of firms affected by the high estimate is equivalent to the number of firms from the SUSB with 500+ employees.

We multiply the range in column D of Table 18 by Columns E, F and G in Table 19 to obtain the annual number of firms affected by advisory according to cost category characterized by the range of H, I and J in Table 20.

Table 20. Annual Number of Firms Affected by Advisory by Cost Category.

	H Firms affected by low estimate			I Firms affected by middle most likely estimate			J Firms affected by high estimate		
Category of Firms	min (small)	average (small)	max (small)	min (small)	average (small)	max (small)	min (large)	average (large)	max (large)
Producers/ Processor	2	8	73	2	9	83	2	2	4
Shipper/Distributors	2	11	18	2	10	17	0	1	2
Restaurants	39	193	311	66	329	530	1	3	4
Non restaurant retailers	18	88	143	11	55	89	0	1	1
Weighted Sum	61	300	544	82	403	719	3	7	12

iv. Estimated Benefits from Reduction in Overly Broad Recalls

Table 21 shows a central point estimate for the average (middle) number of affected firms from Table 20 Columns H, I & J by industry and cost category per firm from Table 15. The estimated annual benefit of $862 million in

Table 21 is illustrative as it does not account for variability and uncertainty.

Table 21.- Average Estimated Benefits by Industry ($1,000)

Industry Category	Average Cost per Firm	Firms (Average Estimate)	Product (Cost per Firm x Number of Firms)
Producer			
Low estimate	$8,915	8	$68,760
Most likely estimate	$22,041	9	$193,090
High estimate	$61,098	2	$122,197
Shipper Distributor			
Low estimate	$1,223	11	$13,732
Most likely estimate	$3,231	10	$33,320
High estimate	$7,552	1	$8,886
Restaurant			
Low estimate	$73	193	$13,969
Most likely estimate	$731	329	$240,326
High estimate	$3,057	3	$7,650
Non-Restaurant Retailer			
Low estimate	$354	88	$31,359
Most likely estimate	$2,172	55	$119,897
High estimate	$9,134	1	$8,323
Total			
Low estimate	$10,565	300	$127,820
Most likely estimate	$28,175	403	$586,633
High estimate	$80,842	7	$147,055
Sum		**710**	**$861,508**
Annual Benefit from avoiding overly broad recalls following FDA advisories			**$861,508**

The final step in this series of calculations involves using Monte Carlo simulations to estimate the range of possible benefit estimates using the value ranges discussed so far.[57] Parameter estimates and results of the simulation are presented in Appendix G.

[57] A Monte Carlo simulation is a probabilistic technique used to model the probability of different outcomes in a process that cannot easily be predicted.

Table 22 presents simulated results of primary, low, and high (undiscounted) cost estimates expected to be averted by improved traceability. We use the median as our primary (central estimate), bounded by the 5th percentile and the 95th percentile for the low and high estimates. The estimated annual benefit from avoiding overly broad recalls after an FDA advisory ranges from $270 million to $2 billion dollars with a primary estimate of $661 million.

Table 22.Total Averted Costs from Overly Broad Recalls Resulting from Improved Traceability (Undiscounted, $1,000)

	Primary Estimate	Low	High
Total Averted Cost, including	$660,509	$268,103	$2,032,980
- Cost from Labor	$18,521	$7,433	$50,094
- Cost from Non-labor	$638,059	$248,279	$2,005,029

The present value of benefits from avoiding overly broad recalls with seven percent discounting over 20 years (not shown in Table 22) ranges from about $2.5 billion to $18.8 billion, with a primary estimate of $6.1 billion. The present value of these benefits with three percent discounting over 20 years (not shown in Table 22) ranges from about $3.6 billion to $27.3 billion, with a primary estimate of $8.9 billion. At a seven percent discount rate over twenty years, these annualized monetized benefits from avoiding overly broad recalls range from $233 million to $1.77 billion with a primary estimate of $575 million. At a three percent discount rate over twenty years, these annualized monetized benefits range from $242 million to $1.84 billion with a primary estimate of $596 million.

The estimated benefit from improved traceability, especially in averted lost sales due to reduced consumer confidence, may not fully capture costs of unnecessary preventive actions by consumers. Such preventive measures by consumers may involve throwing away food, stopping

their consumption of the suspect food item resulting in reduced consumer welfare, or visiting physicians or emergency rooms to determine if they have been exposed to a pathogen.

3. Other Benefits

There are additional benefits that may arise from this rule. We briefly discuss these benefits qualitatively hereunder. These may include:

- Avoidance of costs due to unnecessary preventive actions by consumers.
- Reduction in food waste by both consumers and producers.
- More expedient initiation and completion of recalls of covered foods.
- Improvements in supply chain management and inventory control.
- Other supply system efficiencies due to a standardized approach to traceability, including greater transparency, an increase in trust among food supply system participants, and potential deterrence of fraud.

Broad recalls that take long to implement may have devastating consequences to both businesses and consumers, especially in situations when a recalling firm or its downstream customers cannot definitively track the movement of outbreak causing recalled product and therefore recall additional products as a "buffer". In this situation, when the recalling firm is known, some but not all of these costs through the supply chain may be partially or wholly reimbursed by the firm (depending on existing contracts). Market withdrawals and advisories result in additional costs to FDA and industry and may force consumers to take unnecessary costly preventive actions (Ref. [36]). For example, the disposal of unimplicated food increases the amount of food waste generated which may be associated with a negative externality. The social impact of higher food waste may lead to an increase in the price level of food in the long-term (Ref. [37]).

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 could help firms 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 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. When this is done timely, issuance of warning notices to the public to avoid certain contaminated foods may be unnecessary and the demand for those goods may be unaffected. The 2015 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 about 8 percent. Of the 493 million Blue Bell products recalled because of Listeria contamination, only 39 million (or about 8 percent) were recovered and successfully destroyed (Ref. [38]).

Finally, other benefits may include supply chain management improvements, increase in transparency and food system trust, and potential deterrence of fraud (Ref. [2, 1]). While this rule's primary focus is not to deter fraud, it might result is some potential ancillary benefits that may be realized through a reduction in fraudulent activity or an exit from the market by some

firms because of increased accountability due to more standardized and improved traceability. Since the rule requires improved recordkeeping that includes product name, lot codes, and who put the lot code on the product, such requirements would potentially limit food fraudsters and consequently result to spillover benefit effects for the entire food industry.

i. Costs Savings to FDA

In addition to outlined benefits above, this final rule will result in substantial cost savings to FDA due to outbreak investigation efficiencies that would be achieved. Currently, nearly 18 percent of FDA's budget is spent on the agency's foods program, including food safety surveillance, risk assessment, research, inspection, and food safety related education (Ref. [39]). The costs of conducting outbreak investigations can be substantial especially when mechanisms to trace contaminated foods are inefficient. The costs of outbreak investigation can be multifaceted to include epidemiological, laboratory confirmation, records collection activities, traceback investigation, coordinating the environmental related investigations as well as issuing recalls once the implicated food is established. Depending on the nature of the investigation and the time it takes to investigate, identify and recall an implicated food product, the costs can be substantial. FDA outbreak investigation experts believe that some of these costs can be reduced significantly resulting in substantial cost savings to FDA. Investigations will require less personnel hours to complete, resulting in significant savings to FDA. Some of these savings can be used to address other FDA public health priority needs.

F. Costs of the Rule

To better inform our analysis of the costs of this final rule, ERG completed a literature review and an elicitation of industry experts, the traceability costs elicitation, on current industry practices and traceability costs in December 2021 and January 2022 (Ref. [4]). In the elicitation,

experts provided both qualitative and quantitative input based on the proposed version of the rule, with additional brief definitions of some new CTEs in their draft-final state at the time of the elicitation. Input included describing anticipated cost-incurring compliance activities and expenditures, estimating variables related to cost calculations, and further commenting on factors likely to influence costs of the rule. We have incorporated their input, as well as input from the ERG literature review, while updating our analysis to reflect changes in requirements under the final versus the proposed rule.

Throughout this analysis, we refer to small firms as defined by the Small Business Administration.[58] Where we report estimates for small establishments, we refer to those establishments owned by small firms.

We consider baseline food traceability practices of all covered entities (firms or establishments) and estimate the incremental costs related to changes in these practices that these entities choose to implement to meet the requirements of the final rule. We estimate the following costs of the rule to industry:

- one-time labor costs of reading and understanding the rule;
- one-time labor costs of searching inventory for covered products and planning new traceability practices as necessary;
- one-time capital investment costs to establish and maintain a traceability plan and maintain and make available required records;
- recurring costs of operating and maintaining capital;
- one-time costs of training personnel to implement new recordkeeping systems;
- recurring costs of refresher training, and;

[58] https://www.sba.gov/document/support-table-size-standards

- recurring costs of maintaining and making available records required by this rule during critical tracking events.

In tables throughout this and other sections, figures might not sum to the displayed totals due to rounding.

1. Main Assumptions of the Cost Analysis

For discounting purposes, we assume the publication date of the rule is year zero and that costs will gradually begin to be incurred in year one (which is two years before the three-year compliance date).[59] We expect that one-time costs of the final rule will occur evenly over the first two years after the rule becomes effective. We expect that recurring costs will begin in the second year, though at only half the estimated amount, lagging by one year behind the half of one-time costs occurring in year one.

We estimate that the costs of this final rule will mainly 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 final rule requires different entities within the food supply system to maintain different sets of records and key data elements, we list estimated costs by provision. First, all covered entities must establish and maintain a traceability plan 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 (or raise), harvest (or cool), initially pack, first receive on land from fishing vessels, ship, receive, or transform foods on the

[59] The year of publication is year zero and the effective date is year three. For covered entities to comply with the requirements of this rule by the effective date (year three), we assume they will begin to incur compliance costs in year one.

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 depends on the number of entities affected and the additional burden of each requirement relative to baseline practices. In this final rule, FDA specifies the records and information a covered entity must maintain and provide 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 this rule's recordkeeping requirements using existing systems. Furthermore, we assume that firms will comply with new recordkeeping requirements by modifying existing shipping or purchase records such as Advance Shipping Notices, Bills of Lading, Invoices, or Purchase Orders.

Some entities already follow certain traceability-related 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. Additionally, food businesses have increasingly adopted traceability-related technologies and practices as part of their internal business decisions, regardless of the rule. The likelihood of an entity already adhering to certain recordkeeping practices or planning to adopt them depends on its size, industry, and position in the food supply system. We used input by food industry experts in estimating the expected baseline prevalence of the recordkeeping practices required by the rule (Ref. [4]).

Finally, as discussed in the baseline section of this document and in further detail below, certain entities covered by the final rule are exempt or partially exempt from new recordkeeping requirements. In all our cost estimates below, we exclude produce farms, shell egg producers, and certain other producers of raw agricultural commodities that would be fully exempt from the

final rule because of their very small size. Additionally, this final rule also exempts retail food establishments and restaurants with average annual food sales below $250,000, which we therefore exclude from our analysis.[60] 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 final rule.

We conduct our analysis by provision to parallel the structure of the rule. We cover a twenty-year horizon following the final rule's compliance date and assume one-time costs to occur evenly over years one and two. All wage rates come from the Bureau of Labor Statistics, Occupational Employment Statistics (OES), May 2020, National Industry-Specific Occupational Employment and Wage Estimates. We estimate hourly labor costs by doubling the OES reported mean wage to account for benefits and overhead.

2. Costs of Reading and Understanding the Rule

We estimate that all covered firms will read and understand the rule. Note that we consider reading costs in this section to be separate from the costs to identify FTL products and plan for compliance, which we estimate below in section II.F.5.a "Traceability Plan."

To estimate the number of firms that will need to read the rule, we use the 2017 SUSB from Census Bureau and the 2017 Census of Agriculture from the National Agricultural Statistics Service. We first identify the NAICS categories of firms that likely manufacture, process, pack or hold foods on the FTL. Because not all firms in each NAICS industry would be

[60] An average annual monetary value of food sold or provided during the previous 3-year period of no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

affected by this rule, we remove exempt firms and those not likely to handle foods on the FTL. We estimate that about 323,872 firms will incur a one-time cost to read and understand the rule.

Table 23 summarizes the estimated costs of reading and understanding the rule. The preamble and regulatory text of the rule contains approximately 219,000 words. Per HHS guidelines on reading speed (Ref. [29]), 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 16.2 hours (= (219,000 / 225) / 60) to read the rule, with a lower bound of 14.6 hours (= (219,000 / 250) / 60) and an upper bound of 18.3 hours (= (219,000 / 200) / 60).

We assume that one employee will read the rule at small firms and that three employees will read the rule at large firms. We expect that the type of employees reading the rule at small firms will be roughly equivalent to supervisors of food preparation (occupation code 35-1010 in NAICS 445), and that those at large firms will be compliance officers (occupation code 13-1041 in NAICS 311). The mean wage of a supervisor of food preparation is $20.12 per hour, which we double to $40.24 to account for benefits and overhead. The mean wage of a compliance officer is $32.71 per hour, which we double to $65.42 to account for benefits and overhead. We obtained this wage information from the 2020 BLS Occupational Employment and Wage Statistics. We therefore estimate that the one-time cost of reading and understanding the rule is approximately $507 per covered small firm (= 12.6 hours x 1 employee x $40.24) and $2,471 per covered large firm (= 12.59 hours x 3 employees x $65.42). We estimate the total cost of reading and understanding the rule (sum of costs to small and large firms in the table below) to range from about $203 million to $254 million, with a primary estimate of $226 million.

Table 23. One-time Costs of Reading and Understanding the Final Rule (2020$)

	Small firms	Large firms

	Primary	Low	High	Primary	Low	High
(a) Average reading speed (words/min)	225	250	200	225	250	200
(b) Words to read	219,000	219,000	219,000	219,000	219,000	219,000
(c) Hours = (b/a)/60	16.2	14.6	18.3	16.2	14.6	18.3
(d) Employees	1	1	1	3	3	3
(e) Hourly labor cost	$40.24	$40.24	$40.24	$65.42	$65.42	$65.42
(f) Per firm cost = c x d x e	$652.78	$587.50	$734.38	$3,183.77	$2,865.40	$3,581.75
(g) Number of firms	318,252	318,252	318,252	5,620	5,620	5,620
Total = f x g	**$207,749,096**	**$186,974,187**	**$233,717,733**	**$17,892,613**	**$16,103,352**	**$20,129,190**

3. Costs of Capital Investment

Capital investment refers to equipment and software and 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 final rule.

As discussed above, some entities will be able to comply without additional capital investments, while others will 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, which surveyed 22 entities, 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. 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.[61] More recently, ERG's literature review revealed that traceability accounts for 20 to 45

[61] 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/).

percent of the roughly $80 to $91 million that California Leafy Green Marketing Agreement (LGMA) members spend on meeting LGMA safety standards each year (Ref. [4]).

The following Table 24 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]). Participants reported that total costs for traceability systems they used at the time of survey to capture KDEs ranged from tens of thousands to millions of dollars. They reported that additional improvements in traceability would range from minimal cost to hundreds of thousands of dollars.

Table 24. 2012 Costs of Traceability-Related Investments, as Reported by Selected Entities

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
Base 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

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 back 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. For example, in ERG's literature review, traceability solution providers report several recurring subscription costs that vary by volume of product or number of users, such as hardware rental, software licenses, and user accounts (Ref. [4]).

There are several important considerations for interpreting the costs from the IFT report and applying them to the final rule (Ref. [5]). First, the report surveyed selected companies about costs to update system-wide traceability operations. In other words, companies may have also accounted for training and system integration costs, in addition to capital, in their estimates. The incremental costs of complying with the final rule may be significantly less than the cost of a total system upgrade, particularly because we believe that over a third of covered companies already perform some form of traceability recordkeeping (Ref. [4]).

Second, entities surveyed in the report are not fully representative of sectors and sizes affected by the final 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 traditionally 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 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. [40]). 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.[62] For example, web and mobile platforms are now able to streamline links between retailers and their wholesale suppliers.[63] 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 39 percent in December 2021.[64]

A literature review by ERG finds several other case studies on traceback efforts and traceability systems (Ref. [4]). Some cost categories such as traceability software and hardware such as scanners and printers are commonly mentioned in the literature. However, capital investments needed to comply with the rule will 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). To better understand incremental capital investment costs

[62] See, for example, IBM's Food Trust: https://www.ibm.com/blockchain/solutions/food-trust.
[63] See, for example, BlueCart: https://welcome.bluecart.com/.
[64] 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, February 1, 2022.

related to the rule for smaller entities, as opposed to complete system upgrades for large firms described above, ERG elicited one-time and recurring cost estimates from a panel of external industry experts based on the proposed version of the rule, with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation (Ref. [4]). In addition to cost estimates, experts identified and described, in general terms, the primary expected capital expenditures, such as scanners, label printers, and mobile computers, as well as the share of covered entities that would choose to invest in capital to comply with the rule as proposed.

Although the traceability costs elicitation asked for estimates of expected costs due specifically to compliance with the proposed traceability requirements, some experts suggested that their estimates included capital investments likely to occur for reasons other than regulatory compliance, such as obsolescence (Ref. [4]). Since experts did not separately quantify the extent to which regulatory compliance drives their estimates, we nonetheless attribute all estimated capital investment to the proposed traceability requirements when using the elicitation to inform our analysis of the final rule. This likely results in us overestimating the capital costs stemming specifically from the rule.

Capital requirements for traceability will likely be more complex for some businesses than others. For instance, only entities downstream from harvesting and cooling raw agricultural commodities will be responsible for assigning traceability lot codes. Hence, we do not generally expect covered produce farms, shell egg producers, and other producers of raw agricultural commodities who do not also initially pack to incur capital costs due to the final rule. First, under the final rule, these entities do not need to assign lot codes. We also note that with respect to the farm map record that is a part of the traceability plan requirement, FDA has previously received

farm maps with field names and coordinates during outbreak investigations. Given the widespread use of free mapping and direction websites and web applications with GPS coordinate plotting functionality, we expect most affected entities either already keep the required map (in paper or electronic format) or will be able to produce it in minutes without any specialized equipment. Additionally, shipments of food that occur prior to initial packing or for food obtained from a fishing vessel prior to first land-based receiving are not subject to the shipping or receiving requirements of the final rule. However, for industries in which we were unable to distinguish between initial packers and other growers or producers of raw agricultural commodities, we use expert estimates (Ref. [4]) of the proportion of establishments that will incur capital costs.

We also note that under the final rule's partial exemption of sales between retailers, the purchasing retailer needs only to keep information typically communicated via sales receipts and there are no traceability requirements on the selling retailer. Thus, restaurants and other retailers under the final rule are generally only receivers, but not shippers, of covered foods. Because the final rule does not require retailers to regularly use the received information for compliance purposes, and because compliant storage options include taking pictures of records or not digitizing at all, we do not expect retailers to purchase equipment or services towards compliance. While retailers need to keep the required records provided to them by suppliers, which we expect to take the form of receipts and purchase and delivery documents, they may keep these records as either paper or electronic originals or "true copies" including photocopies, pictures, scans, or other accurate reproductions of the original record. As such, we do not expect these entities to require additional capital for compliance purposes.

Table 25 summarizes our estimates of the incremental one-time compliance related costs of capital for affected establishments owned by small and large firms, based on reconciling experts' estimates and assumptions with differences between the final and proposed rule (with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation) (Ref. [4]). Experts in ERG's panel estimated overall one-time capital costs per small and large entity from different industry sectors and identified, but did not individually price, component elements of capital cost. We apply experts' input on the proportion of establishments that will incur capital costs to the industry categories that we expect to make capital investments faced with the revised requirements of the final rule. We estimate that about 34,737 establishments will incur these costs. Nearly all experts mentioned software, while a majority also mentioned label printers and scanners. Some experts also mentioned traceability consulting and training, which we do not consider as capital costs. To the extent that those experts did not exclude these items from their capital cost estimates, it is possible that we count such costs both in this section and in later sections. For example, experts estimated that the one-time, per-firm capital cost for a small manufacturing/processing facility is $21,875. We use the experts' estimates and assume other costs such as consulting or training are not included in the total.

We estimate the total one-time capital investment costs (sum of costs to small and large firms in the table below) of the final rule to range from about $278 million to $4,867 million, with a primary estimate of about $1,139 million.

Table 25. One-time Capital Investment Costs of the Final Rule (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Farms/ growers (produce)						

(a) One-time cost per establishment	$11,250	$5,000	$50,000	$300,000	$100,000	$1,000,000
(b) Percent of establishments needing capital	50%	50%	70%	50%	40%	50%
(c) Number of covered establishments	1,065	1,065	1,065	134	134	134
Subtotal = a*b*c	$5,988,645	$2,661,620	$37,262,680	$20,052,800	$5,347,413	$66,842,665
Shell Eggs Producers						
(a) One-time cost per establishment	$13,000	$7,500	$50,000	$300,000	$100,000	$1,000,000
(b) Percent of establishments needing capital	60%	60%	60%	50%	50%	50%
(c) Number of covered establishments	2,500	2,500	2,500	21	21	21
Subtotal = a*b*c	$19,501,794	$11,251,035	$75,006,901	$3,165,493	$1,055,164	$10,551,644
Fishing/ aquaculture						
(a) One-time cost per establishment	$20,000	$6,250	$52,500	$200,000	$75,200	$1,100,000
(b) Percent of establishments needing capital	60%	60%	60%	50%	20%	80%
(c) Number of covered establishments	2,021	2,021	2,021	69	69	69
Subtotal = a*b*c	$24,252,698	$7,578,968	$63,663,332	$6,911,518	$1,039,492	$60,821,356
Manufacturing/ processing						
(a) One-time cost per establishment	$21,875	$10,000	$50,000	$226,000	$100,000	$1,000,000
(b) Percent of establishments needing capital	48%	15%	65%	50%	30%	50%
(c) Number of covered establishments	8,203	8,203	8,203	447	447	447

Subtotal = a*b*c	$85,237,913	$12,305,022	$266,608,810	$50,471,676	$13,399,560	$223,326,000
Wholesale/ Distributors/ Warehouse/ Storage						
(a) One-time cost per establishment	$42,500	$10,000	$65,000	$200,800	$100,000	$1,000,000
(b) Percent of establishments needing capital	50%	15%	70%	50%	33%	55%
(c) Number of covered establishments	14,053	14,053	14,053	6,224	6,224	6,224
Subtotal = a*b*c	$298,620,957	$21,079,126	$639,400,166	$624,914,609	$202,288,096	$3,423,337,001
Total	**$433,602,007**	**$54,875,772**	**$1,081,941,890**	**$705,516,095**	**$223,129,725**	**$3,784,878,666**

As noted above, not all entities will need to make the same types of investments, depending on their sector and size. We also do not expect that all covered entities will need to make capital investments due to the final rule. In particular, if the rule would have been finalized as proposed, covered retailers and restaurants would have faced significant potential burden when receiving covered foods. To address this, FDA removed requirements for data elements that would require record creation by the retailer, such as the time of receipt. We therefore expect retailers and restaurants to satisfy the requirements of the final rule by keeping receipts and purchase documents provided by suppliers, as many likely already do for reasons unrelated to regulatory compliance.

For some of the other supply chain entities, who must further use the traceability information they receive for compliance activities, capital investment might include software subscriptions and other systems with ongoing operation and maintenance (O&M) costs. Thus, we also estimate recurring capital costs, which we treat as a percent of one-time costs. Through ERG's traceability costs elicitation, external industry experts confirmed that not all firms incurring capital investment costs will face incremental operation and maintenance costs

associated with new capital (Ref. [4]). Namely, firms that replace existing capital might face operation and maintenance costs that are higher, lower, or the same as those for the capital being replaced.

Table 26 summarizes our estimates of recurring capital costs for those firms whose capital investments due to the final rule will result in an incremental increase in operation and maintenance costs. Experts estimated recurring capital costs per establishment as a percentage of one-time costs. Similarly, experts estimated the share of establishments whose capital investments result in higher operating and maintenance costs as a percentage of all those making capital investments. We thus obtain an estimate of about 15,854 establishments facing recurring capital costs as a result of the rule. We estimate the total recurring capital costs (sum of costs to small and large firms in the table below) of the rule to range from about $15 million to $980 million, with a primary estimate of about $185 million.

Table 26. Recurring Capital Investment Costs of the Final Rule (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Farms/ growers (produce)						
(a) Recurring cost per establishment	$2,250	$425	$10,000	$60,000	$8,500	$200,000
(b) Establishments with higher O&M	479	426	745	60	43	67
Subtotal = a*b	$1,077,956	$180,990	$7,452,536	$3,609,504	$363,624	$13,368,533
Shell Egg Producers						
(a) Recurring cost per establishment	$2,600	$300	$12,500	$60,000	$4,000	$225,000
(b) Establishments with higher O&M	1,350	1,200	1,500	9	8	11

Subtotal = a*b	$3,510,323	$360,033	$18,751,725	$569,789	$33,765	$2,374,120
Fishing/ aquaculture						
(a) Recurring cost per establishment	$4,000	$531	$13,125	$35,000	$4,512	$247,500
(b) Establishments with higher O&M	1,091	970	1,213	31	11	55
Subtotal = a*b	$4,365,486	$515,370	$15,915,833	$1,088,564	$49,896	$13,684,805
Manufacturing/ processing						
(a) Recurring cost per establishment	$4,102	$700	$15,000	$39,550	$7,000	$225,000
(b) Establishments with higher O&M	3,507	615	4,799	201	67	201
Subtotal = a*b	$14,383,898	$430,676	$71,984,379	$7,949,289	$468,985	$45,223,515
Wholesale/ Distribution/ Warehouse/ Storage						
(a) Recurring cost per establishment	$7,969	$700	$19,500	$35,140	$7,000	$175,000
(b) Establishments with higher O&M	6,324	1,686	9,837	2,801	1,618	3,423
Subtotal = a*b	$50,392,286	$1,180,431	$191,820,050	$98,424,051	$11,328,133	$599,083,975
Total	$73,729,949	$2,667,500	$305,924,523	$111,641,197	$12,244,403	$673,734,948

4. Costs of Training

Covered establishments will also incur costs to train employees to comply with the final rule. We expect operational changes on a day-to-day basis to be disseminated through routine meetings and trainings, such that establishments will not face additional costs of training all employees specifically due to the final rule. However, we assume that establishments will need

to conduct new education of key personnel in traceability practices, particularly relating to the use of new investments in capital, such as equipment, systems, and software. We estimate that about 34,737 establishments will incur these costs.

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.

For this final analysis, we base training costs on estimates that ERG elicited from external industry experts on the costs of traceability training related to the rule as proposed (with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation) (Ref. [4]). As mentioned in the Baseline section II.D, firms vary in the degree to which their baseline training already aligns with the rule's requirements. Experts estimated the training costs imposed by the rule on small versus large establishments accounting broadly for industry and position in the supply chain.

Traceability activities will likely be more complex for some businesses than others. While restaurants and other retailers need to keep the required records provided to them by suppliers, which we expect to take the form of receipts and purchase and delivery documents, the

rule allows keeping these records as either paper or electronic originals or "true copies" such as photocopies, pictures, scans, or other accurate reproductions of the original record. Because the final rule does not require retailers to regularly use the received information for compliance purposes, we do not expect retailers to purchase equipment or services towards compliance, nor do we expect them to develop extensive or highly formal plans for maintaining traceability records beyond determining physical or digital storage locations. Therefore, we do not expect the requirements of the rule to generate a new training burden for restaurants and other retailers.

Table 27 summarizes our estimates of the incremental one-time training costs for affected establishments owned by small and large firms, based on reconciling experts' estimates with differences between the final and proposed rule (with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation). Experts in ERG's panel estimated the cost of developing a training program, the number of trainees needed, and the hours for training (Ref. [4]). In addition to the cost of developing or purchasing training courses, training costs also include the labor cost of the employees in training. While training may involve many kinds of employees, we approximate the average wage of First-Line Supervisors of Production and Operating Workers (code 51-1011) in Food Manufacturing from the 2020 BLS Occupational Employment and Wage Statistics, which is $29.10, for manufacturing and distribution establishments. We double this wage to account for benefits and overhead, obtaining an hourly labor cost of $58.20. For establishments in initial packing of raw agricultural commodities, we use the average wage of Agricultural Workers (code 45-2000) in Agriculture, Forestry, Fishing and Hunting, which is $14.53. We double this wage to account for benefits and overhead, obtaining an hourly labor cost of $29.06. We estimate the total one-time

training costs (sum of costs to small and large firms in the table below) of the rule to range from about $13 million to $409 million, with a primary estimate of about $241 million.

Table 27. One-time Training Costs of the Final Rule (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Farms/ growers (produce)						
(a) Cost of training course	$3,000	$500	$10,000	$14,000	$3,024	$25,000
(b) Trainees per establishment	8.25	1.00	10.00	19.25	4.50	35.00
(c) Training hours	4.00	1.50	12.00	4.50	4.00	18.00
(d) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(e) Number of establishments w/ training costs	1,065	1,065	1,065	134	134	134
Subtotal = (a + (b*c*d))*e	$4,214,920	$289,366	$10,051,384	$2,208,124	$189,677	$2,894,809
Shell Eggs Producers						
(a) Cost of training course	$2,875	$500	$7,500	$13,250	$2,500	$24,596
(b) Trainees per establishment	8.25	1.00	10.00	19.25	4.00	35.00
(c) Training hours	4.00	1.00	8.00	4.25	2.00	16.00
(d) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(e) Number of establishments w/ training costs	2,500	2,500	2,500	21	21	21
Subtotal = (a + (b*c*d))*e	$9,585,832	$793,663	$14,738,556	$329,791	$28,832	$431,241
Fishing/ aquaculture						
(a) Cost of training course	$3,000	$950	$7,500	$12,292	$3,012	$21,572
(b) Trainees per establishment	6.50	1.00	10.00	11.00	4.00	35.00
(c) Training hours	4.00	1.00	8.00	4.25	2.00	16.00
(d) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06

(e) Number of establishments w/ training costs	2,021	2,021	2,021	69	69	69
Subtotal = (a + (b*c*d))*e	$7,590,205	$1,187,242	$11,913,895	$943,461	$44,849	$2,092,564
Manufacturing/processing						
(a) Cost of training course	$3,000	$750	$7,500	$10,750	$3,012	$17,500
(b) Trainees per establishment	8.50	1.50	10.00	19.25	5.50	35.00
(c) Training hours	4.25	1.00	8.00	5.25	2.00	16.00
(d) Hourly labor cost	$58.20	$58.20	$58.20	$58.20	$58.20	$58.20
(e) Number of establishments w/ training costs	8,203	8,203	8,203	447	447	447
Subtotal = (a + (b*c*d))*e	$41,857,378	$1,030,299	$64,817,934	$7,428,643	$489,379	$11,186,846
Wholesale/ Dist./ Warehouse/ Storage						
(a) Cost of training course	$3,000	$750	$7,500	$10,750	$3,012	$17,500
(b) Trainees per establishment	8.50	1.50	10.00	19.25	4.50	35.00
(c) Training hours	4.00	1.00	8.00	4.25	2.00	16.00
(d) Hourly labor cost	$58.20	$58.20	$58.20	$58.20	$58.20	$58.20
(e) Number of establishments w/ training costs	14,053	14,053	14,053	6,224	6,224	6,224
Subtotal = (a + (b*c*d))*e	$69,965,836	$1,764,955	$119,577,668	$96,547,362	$7,152,502	$171,481,797
Total	**$133,214,172**	**$5,065,526**	**$221,099,438**	**$107,457,381**	**$7,905,239**	**$188,087,258**

In addition to one-time costs to develop training, we consider establishments to incur recurring costs if refresher training necessary for compliance with the rule is more burdensome than what an establishment would have otherwise implemented. Table 28 summarizes our estimates of recurring training costs for those establishments who, due to the final rule, incur an incremental increase over what they would otherwise have spent on recurring training. We base the numbers of establishments with recurring training costs on estimates from ERG's expert

panel of the share of such establishments. In estimating the recurring costs of training, we use the same wages and numbers of trainees as in Table 27. Experts in ERG's panel provided separate estimates of the hours of recurring training. We assume that establishments would reuse the existing training course in later years and therefore count only the labor cost of the employees in training. We estimate total recurring training costs (sum of costs to small and large firms in the table below) of the rule to range from about $1 million to $202 million, with a primary estimate of about $40 million.

Table 28. Recurring Training Costs of the Final Rule (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Farms/ growers (produce)						
(a) Trainees per establishment	8.25	1.00	10.00	19.25	4.50	35.00
(b) Training hours	3.00	2.50	10.00	3.00	2.50	10.00
(c) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(d) Number of establishments w/ recurring training	798	586	798	100	74	100
Subtotal = a*b*c*d	$574,299	$42,541	$2,320,400	$168,265	$24,038	$1,019,785
Shell Eggs Producers						
(a) Trainees per establishment	8.25	1.00	10.00	19.25	4.00	35.00
(b) Training hours	2.00	2.00	8.00	2.00	2.00	8.00
(c) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(d) Number of establishments w/ recurring training	1,875	250	1,875	16	2	16
Subtotal = a*b*c*d	$899,126	$14,531	$4,359,401	$17,708	$491	$128,785
Fishing/ aquaculture						
(a) Trainees per establishment	6.50	1.00	10.00	11.00	4.00	35.00

(b) Training hours	2.00	2.00	8.00	2.00	2.00	8.00
(c) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(d) Number of establishments w/ recurring training	1,516	202	1,516	52	7	52
Subtotal = a*b*c*d	$572,637	$11,746	$3,523,917	$33,140	$1,607	$421,782
Manufacturing/processing						
(a) Trainees per establishment	8.50	1.50	10.00	19.25	5.50	35.00
(b) Training hours	2.00	2.00	8.00	2.00	2.00	8.00
(c) Hourly labor cost	$58.20	$58.20	$58.20	$58.20	$58.20	$58.20
(d) Number of establishments w/ recurring training	6,153	820	6,153	335	45	335
Subtotal = a*b*c*d	$6,087,294	$143,230	$28,646,091	$750,610	$28,595	$5,458,981
Wholesale/ Dist./ Warehouse/ Storage						
(a) Trainees per establishment	8.50	1.50	10.00	19.25	4.50	35.00
(b) Training hours	3.00	2.50	10.00	3.00	2.50	10.00
(c) Hourly labor cost	$58.20	$58.20	$58.20	$58.20	$58.20	$58.20
(d) Number of establishments w/ recurring training	10,540	1,405	10,540	4,668	622	4,668
Subtotal = a*b*c*d	$15,641,766	$306,701	$61,340,258	$15,690,009	$407,533	$95,090,966
Total	**$23,775,122**	**$518,750**	**$100,190,067**	**$16,659,732**	**$462,263**	**$102,120,299**

5. Costs of Recordkeeping

The final rule will require certain persons to keep records related to the CTEs identified in the rule, such as initial packing, shipping, receiving, and transforming of covered foods. We estimate the new costs of each recordkeeping requirement, considering 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 rule, including frequency of recordkeeping and the average time spent keeping records for covered foods by record type, we consulted estimates that ERG elicited from external food industry experts (Ref. [4]). Experts expressed a high degree of uncertainty regarding the time burden per record across activities. In general, experts provided estimates of manual entry times in minutes while conveying in supplemental comments that scanning using an electronic system would take seconds. As experts also estimated the proportion of industry that currently keeps records mostly manually, we scaled estimated times they provided by the proportion of industry with electronic recordkeeping capabilities in order to account for baseline practices in estimating the incremental burden of the rule. Our estimates of time burden per record therefore represent averages between manual and electronic recordkeeping weighted by the baseline prevalence of these practices. Finally, we reconciled estimates of the recordkeeping burden under the proposed version of the rule (with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation) to the revised requirements in the final rule. As in previous sections, all wage rates come from the Bureau of Labor Statistics, Occupational Employment Statistics (OES) from May 2020.

As most experts included scanning and label printing equipment and systems when asked to describe anticipated capital investments (Ref. [4]), we account for expected adoption of these capabilities among the proportion of establishments estimated by experts to invest in capital towards compliance with the rule. In particular, we expect that entities making capital

investments will be motivated by interoperability to prioritize streamlining shipping and receiving recordkeeping, since these are the CTEs performed by the most entities across the supply chain. In our estimates of the time burden per record for shipping and receiving, we therefore additionally consider the proportion of entities making capital investments to be capable of keeping and sending records via scanning and the use of barcodes (or related technology, e.g., RFID).

Some entities perform multiple CTEs and will 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). Each CTE involves a different set of KDEs, some of which they share in common; however, entities that perform multiple CTEs will need to maintain all KDEs that pertain to the CTEs they perform. For example, an entity that receives a covered food and then transforms and ships it will need to record the quantity of food received, transformed, and shipped. 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) are required for multiple CTEs; however, no two CTEs contain exactly the same KDE requirements.

a. Traceability Plan (§ 1.1315)

The final rule will require entities that manufacture, process, pack, or hold covered foods to establish and maintain a traceability plan containing:

- a description of procedures for maintaining required records,
- a description of procedures for identifying foods on the FTL,
- a description of traceability lot code assignment, if applicable,
- a statement identifying a point of contact for questions about traceability records, and

- for entities that grow or raise FTL foods (except shell eggs), a map showing the areas in which FTL food is grown or raised.

Entities affected by this provision will therefore incur one-time costs at the firm level to create a traceability plan. While the final rule requires firms to update their traceability plans "as needed," possible future updates to the FTL, which might require some firms to identify additional products, will only take effect two years after publication in the Federal Register. We expect that this delay will allow firms to make necessary updates within the scope of routine updates to standard operating procedures in the normal course of business. We thus expect that entities affected by this provision will incur one-time costs at the firm level to create a traceability plan.

Some firms already follow practices that satisfy some or most of the requirements in this provision. Experts in ERG's panel estimated the average proportion of small and large establishments across business types (e.g., distributors, retail, etc.) that already keep traceability records as part of a traceability system (Ref. [4]). For these entities with existing traceability systems and practices, we expect that the three-year compliance period prior to the effective date of the rule will allow necessary changes to take place within the scope of routine updates to standard operating procedures in the normal course of business. We estimate that about 212,368 firms will incur incremental costs of the rule due to this provision.

Additionally, planning for traceability will likely be more complex for some businesses than others. For instance, only certain entities will be responsible for assigning traceability lot codes. Additionally, we do not generally expect growers and other producers of raw agricultural commodities to incur substantive costs in identifying covered foods, since their products would not contain multiple ingredients and thus identifying covered foods would be straightforward.

Growers who do not pack also will not need to assign lot codes. Given that FDA has previously received farm maps with field names and coordinates during outbreak investigations, and given the widespread use of free, mapping and direction websites and web applications with GPS coordinate plotting functionality, we expect most affected entities either already keep the required map or will be able to produce it in minutes. We intend our estimate in Table 29 of the time for growers to produce a traceability plan to represent an average. Individual growers who initially pack might spend more time, while those who do not initially pack will likely spend less.

We also note that under the final rule's partial exemption of ad hoc sales between retailers, the purchasing retailer needs only to keep information typically communicated on ordinary sales receipts and there are no additional traceability requirements on the selling retailer. Thus, restaurants and other retailers under the final rule are generally only receivers, but not shippers, of covered foods. We expect these entities will identify covered foods based on the required records provided to them by suppliers. Alternatively, retailers might opt to keep all receipts and delivery documents for two years or might already do so for tax purposes. Because the final rule does not require retailers to regularly use the received information for compliance purposes, and because compliant storage options include taking pictures or not digitizing at all, we do not expect restaurants and other retailers to develop extensive or highly formal plans for maintaining traceability records beyond determining physical or digital storage locations.

Table 29 summarizes our estimates of the one-time costs of creating a traceability plan, including identifying covered foods. Experts in ERG's panel provided descriptive comment on the types and numbers of employees who might work on procedures for traceability (Ref. [4]). We interpreted their comments in estimating the numbers of employees below. After reviewing descriptions of tasks involved, we assumed the numbers of hours per employee below. While

different types of employees might work on traceability plans, we use the wage of a Business Operations Specialist (occupation code 13-1000) in the 2020 BLS Occupational Employment and Wage Statistics, taking the average from different industries for different types of firms. For growers and other producers of raw agricultural commodities, we use the average wage from Agriculture, Forestry, Fishing, and Hunting, $29.51. For manufacturers and distributors, we use the average wage from Food Manufacturing, $32.19. For retailers we use the average wage from Food & Beverage Stores, $23.48. For restaurants, we use the average for Food Service and Drinking Places, $23.48. We double all wages to account for benefits and overhead. We estimate the total cost (sum of costs to small and large firms in the table below) of this provision of the rule to range from about $15 million to $345 million, with a primary estimate of about $79 million.

Table 29. One-Time Traceability Plan Costs of the Final Rule (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Farms/ growers (produce)						
(a) Number of employees needed	3	1	10	10	2	30
(b) Hours	10	10	10	10	10	10
(c) Hourly labor cost	$59.02	$59.02	$59.02	$59.02	$59.02	$59.02
(d) Cost per firm = a*b*c	$1,771	$590	$5,902	$5,902	$1,180	$17,706
(e) Number of firms needing new traceability plan	3,303	1,651	4,624	202	0	231
Subtotal = d*e	$5,848,266	$974,711	$27,291,909	$1,194,034	$0	$4,093,832
Shell Egg Producers						
(a) Number of employees needed	3	1	10	10	2	30
(b) Hours	10	10	10	10	10	10
(c) Hourly labor cost	$59.02	$59.02	$59.02	$59.02	$59.02	$59.02
(d) Cost per firm = a*b*c	$1,771	$590	$5,902	$5,902	$1,180	$17,706

(e) Number of firms needing new traceability plan	1,250	1,000	2,000	9	0	15
Subtotal = d*e	$2,213,454	$590,254	$11,805,086	$56,048	$0-	$261,558
Fishing/ aquaculture						
(a) Number of employees needed	3	1	10	10	2	30
(b) Hours	10	10	10	10	10	10
(c) Hourly labor cost	$59.02	$59.02	$59.02	$59.02	$59.02	$59.02
(d) Cost per firm = a*b*c	$1,771	$590	$5,902	$5,902	$1,180	$17,706
(e) Number of firms needing new traceability plan	998	599	1,297	24	7	35
Subtotal = d*e	$1,766,538	$353,308	$7,654,997	$139,606	$8,725	$628,228
Manufacturing/ processing						
(a) Number of employees needed	3	1	10	10	2	30
(b) Hours	20	20	20	20	20	20
(c) Hourly labor cost	$64.38	$64.38	$64.38	$64.38	$64.38	$64.38
(d) Cost per firm = a*b*c	$3,863	$1,288	$12,876	$12,876	$2,575	$38,628
(e) Number of firms needing new traceability plan	3,924	2,354	4,708	36	0	43
Subtotal = d*e	$15,156,579	$3,031,316	$60,626,316	$462,714	$0	$1,665,771
Wholesale/ Distribution/ Warehouse/ Storage						
(a) Number of employees needed	3	1	10	10	2	30
(b) Hours	20	20	20	20	20	20
(c) Hourly labor cost	$64.38	$64.38	$64.38	$64.38	$64.38	$64.38
(d) Cost per firm = a*b*c	$3,863	$1,288	$12,876	$12,876	$2,575	$38,628
(e) Number of firms needing new traceability plan	8,002	5,334	10,669	529	235	823
Subtotal = d*e	$30,908,472	$6,868,549	$137,370,985	$6,811,905	$605,503	$31,788,889
Non-restaurant retail						

(a) Number of employees needed	3	1	10	10	2	30
(b) Hours	0.5	0.5	0.5	0.5	0.5	0.5
(c) Hourly labor cost	$46.96	$46.96	$46.96	$46.96	$46.96	$46.96
(d) Cost per firm = a*b*c	$70	$23	$235	$235	$47	$704
(e) Number of firms needing new traceability plan	58,168	30,349	91,046	631	252	883
Subtotal = d*e	$4,097,368	$712,586	$21,377,571	$148,115	$11,849	$622,083
Restaurants						
(a) Number of employees needed	3	1	10	10	2	30
(b) Hours	0.5	0.5	0.5	0.5	0.5	0.5
(c) Hourly labor cost	$46.96	$46.96	$46.96	$46.96	$46.96	$46.96
(d) Cost per firm = a*b*c	$70	$23	$235	$235	$47	$704
(e) Number of firms needing new traceability plan	133,983	83,162	166,324	1,309	476	1,666
Subtotal = d*e	$9,437,789	$1,952,646	$39,052,921	$307,438	$22,359	$1,173,855
Total	**$69,428,465**	**$14,483,370**	**$305,179,786**	**$9,119,861**	**$648,436**	**$40,234,217**

b. Seed Lot Records for Sprouts

Under the final rule initial packers of sprouts will need to maintain records regarding the seeds they use for sprouting, and we expect that sprout growers will incur costs to establish and maintain these records. This required information includes:

- the location description of the grower of seeds for sprouting and the date of seed harvesting, if either is available,
- the location description of the seed conditioner or processor and the associated seed lot code,
- the date of conditioning or processing,

- the location description of the seed packinghouse, including any repackers (if applicable),
- the associated seed lot code assigned by the seed packinghouse (if applicable),
- the date of packing (and repacking, if applicable),
- the location description of the seed supplier,
- any seed lot code assigned by the seed supplier, including the master lot and sub-lot codes,
- any new seed lot code assigned by the sprouter,
- a description of the seeds, including the seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment,
- the date of receipt of the seeds by the sprouter, and
- the reference document type and reference document number.

We estimate that sprout growers not already performing certain recordkeeping activities would incur new recurring recordkeeping costs for the records outlined above. Some sprout growers might already keep some of the required records as described in the 2017 FDA draft guidance for the sprout operations industry (Ref. [41]) or as recommended by good agricultural practices. 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 that we believe will incur recurring costs due to this provision. We assume the same proportion of these growers are small as the proportion among other produce growers.

Table 30 summarizes our estimates of the annual recordkeeping costs of the final rule on growers of sprouts. We estimate the annual number of FTL lots based on input elicited by ERG from the expert panel (Ref. [4]), assuming that growers of sprouts grow as many lots as the

number of lots that other produce growers handle. We estimate the recordkeeping times below using experts' input, adjusting for our expected degree of electronic recordkeeping and differences between the requirements of the final and proposed rule (with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation).[65] Because we are unable to separate entities who do not initially pack from those who do, we assume, for the purpose of estimating initial packing costs in section II.F.5.d, that all sprout growers initially pack. However, for the purpose of estimating costs to sprout growers, we assume that sprout growers will incur costs to provide seed lot records to initial packers. To the extent that sprout growers initially pack their own sprouts, estimating costs to provide seed lot records to initial packers results in an overestimate of costs. To estimate hourly labor cost, we use the average wage of Agricultural Workers (code 45-2000) in Agriculture, Forestry, Fishing and Hunting, which is $14.53. We double this to account for benefits and overhead, obtaining an hourly labor cost of $29.06. We estimate the total cost (sum of costs to small and large firms in the table below) of this provision to growers of sprouts to range from about $4,000 to about $836,000, with a primary estimate of about $97,000.

Table 30. Annual Recordkeeping Costs of Growing Sprouts (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Sprout growers						
(a) Number of seed lots per establishment	832	364	2,600	1,456	1,456	9,100
(b) Hours per lot to capture record	0.02	0.002	0.07	0.02	0.0007	0.03

[65] As explained in the beginning of section II.F.5, we scaled experts' estimates of manual entry times by the proportion of industry they estimated to have electronic recordkeeping capabilities in order to account for baseline practices in estimating the incremental burden of the rule. Our estimates of time burden per record therefore represent averages between manual and electronic recordkeeping weighted by the baseline prevalence of these practices. For our primary estimates, we thus estimate that about 60 percent of small and large businesses will keep records manually at about two minutes per record, while the remainder will scan records at about 2.5 seconds per record.

(c) Hours per lot to provide record	0.02	0.002	0.04	0.02	0.0005	0.03
(d) Labor cost of hourly employee	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(e) Number of covered establishments	87	87	87	8	8	8
Total = a*(b+c)*d*e	**$85,700**	**$3,686**	**$734,879**	**$11,549**	**$380**	**$101,100**

c. Records of Harvesting or Cooling a Food on the Food Traceability List (§ 1.1325)

The final rule will require entities that harvest or cool raw agricultural commodities on the FTL other than those obtained from a fishing vessel to maintain traceability records and to make these records available to the initial packer of the foods they harvest or cool.

Specifically, entities that harvest FTL foods will need to keep records describing the food, including the commodity and (if applicable) variety of the food, the quantity harvested and the unit of measure of the food, the harvest location (including the name of the field or aquaculture container in which food was grown or raised), the location of the immediate subsequent recipient (other than a transporter), harvest date, and the reference document type and reference document number. Harvesters must provide this information (except the reference document type and number) to the initial packer of the food, along with their own business name and phone number. Entities that cool FTL foods before initial packing will need to maintain records describing the food, including the location of the immediate subsequent recipient (other than a transporter), the commodity and (if applicable) variety of the food, the quantity cooled and unit of measure of the food, the cooling location, the cooling date, the harvest location, and the reference document type and reference document number. Coolers must provide this information (except the reference document type and number) to the initial packer of the food.

Some harvesters and coolers might already follow practices meeting the requirements in this provision. Experts in ERG's panel estimated the average proportion of small and large harvesters and coolers already keeping records (Ref. [4]). In these cases, we expect that existing recordkeeping practices already include date and location of harvest or cooling, and the food, quantity, and subsequent recipient. We expect that amending existing location information to include the name of the field or aquaculture container in which food was grown or raised will occur via a letter or number designation (e.g., Tank A, B, etc.) and not appreciably increase current recordkeeping time. However, entities who do not currently keep records for these activities will incur a new recurring recordkeeping burden.

We estimate the total number of harvesters and coolers affected by identifying NAICS categories likely to harvest or cool foods on the FTL and removing exempt and non-covered entities. We assume that all growers and other producers of raw agricultural commodities (other than those obtained from a fishing vessel) harvest food, but that only those growers who cool also perform initial packing. We estimate that about 6,058 establishments that harvest and about 3,511 that cool FTL foods will incur recurring costs due to this provision of the rule.

Table 31 summarizes our estimates of the annual costs to harvesting and cooling establishments belonging to small and large firms. Under the final rule, traceability lot codes are not assigned prior to initial packing. Hence, we expect harvesters and coolers to be able to satisfy the requirements of the final rule via relatively few instances of recordkeeping compared with transformers (e.g., once per commodity per field per harvest date per immediate subsequent recipient). While affected entities may keep and provide records with varying frequency, we assume that they will keep one record and provide one record with each truckload delivered to a subsequent recipient. We estimated numbers of truckloads after reviewing comments by experts

in ERG's panel. We estimate the recordkeeping times below using experts' input, adjusting for the elicited degree of electronic recordkeeping and differences between the requirements of the final and proposed rule (with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation).[66] To estimate labor cost, we use the average wage of an Agricultural Worker (occupation code 45-2000) in Agriculture, Forestry, Fishing, and Hunting from the 2020 BLS Occupational Employment and Wage Statistics, which is $14.53. We double the wage to $29.06 to account for benefits and overhead. We estimate the total recurring costs (sum of costs to small and large firms in the table below) of recordkeeping related to harvesting and cooling to range from about $0.2 million to about $36.2 million, with a primary estimate of about $4.9 million.

Table 31. Annual Recordkeeping Costs of Harvesting and Cooling (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Harvesters						
(a) Truckloads per establishment	549	366	732	1,098	915	1,281
(b) Hours to capture per truckload	0.01	0.001	0.04	0.01	0.001	0.03
(c) Hours to provide per truckload	0.02	0.001	0.13	0.02	0.001	0.11
(d) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(e) Establishments not already capturing	4,782	1,435	7,173	128	32	192
(f) Establishments not already providing	5,738	5,738	6,934	320	256	352

[66] As explained in the beginning of section II.F.5, we scaled experts' estimates of manual entry times by the proportion of industry they estimated to have electronic recordkeeping capabilities in order to account for baseline practices in estimating the incremental burden of the rule. Our estimates of time burden per record therefore represent averages between manual and electronic recordkeeping weighted by the baseline prevalence of these practices. For our primary estimates, we thus estimate that about 60 percent of small and large businesses will keep records manually at about two minutes per record, while the remainder will scan records at about 2.5 seconds per record.

Subtotal = a*b*d*e + a*c*d*f	$2,862,912	$113,571	$25,255,544	$251,716	$5,760	$1,747,598
Coolers						
(a) Truckloads per establishment	549	366	732	1,098	915	1,281
(b) Hours to capture per truckload	0.02	0.00	0.05	0.02	0.00	0.02
(c) Hours to provide per truckload	0.02	0.00	0.07	0.02	0.00	0.11
(d) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(e) Establishments not already capturing	2,171	1,737	2,605	49	15	73
(f) Establishments not already providing	3,365	3,365	4,124	146	146	207
Subtotal = a*b*d*e + a*c*d*f	$1,646,470	$93,199	$8,280,650	$115,356	$3,170	$932,450
Total	**$4,509,381**	**$206,770**	**$33,536,194**	**$367,072**	**$8,929**	**$2,680,048**

d. Records of Initial Packing of Raw Agricultural Commodities on the FTL (§ 1.1330)

The final rule will require entities that initially pack raw agricultural commodities on the FTL other than those obtained from a fishing vessel to maintain traceability records. Initial packing records must include:

- the commodity and (if applicable) variety of the food received, and the product description of the packed food,
- the date the food was received,
- the traceability lot code assigned by the packer,
- the quantity and the unit of measure of the food received, and of the packed food,
- the packing location,
- the packing date,

- the harvest location (including the name of the field or aquaculture container in which food was grown or raised),
- harvest dates,
- business name and phone number for the harvester,
- cooling location and dates (if applicable), and
- the reference document type and reference document number.

To the extent that initial packers do not already maintain these records, these entities will face a recurring recordkeeping cost at the establishment level to comply with the final rule. We assume that some of these requirements together or in part will impose a new recordkeeping burden on all covered establishments that initially pack and estimate the average burdens for establishments owned by small and large firms. We estimate that about 4,218 total initial packing establishments will incur recurring costs due to this provision.

For initial packing of sprouts, records must also include the data elements described above in section II.F.5.b "Records of Growing a Food on the Food Traceability List." We expect the incidence of these costs will fall on growers of sprouts and therefore estimate them in section II.F.5.b. In this section, we estimate costs to initial packers of sprouts similarly to the costs that we expect other initial packers to face.

Not all growers and producers of raw agricultural commodities are initial packers. For growers of produce other than sprouts, we estimate the number of initial packing establishments using the USDA NASS 2017 Census of Agriculture. However, for sprout growers, shell egg producers, and aquaculture operations, we are unable to separate entities who do not initially pack from those who do and therefore assume that all are initial packers.

Table 32 summarizes our estimates of the annual recordkeeping costs of the final rule to initial packing establishments owned by small and large firms. We estimate the annual number of FTL lots initially packed based on input elicited by ERG from the expert panel (Ref. [4]). We estimate the recordkeeping times below using experts' input, adjusting for the elicited degree of electronic recordkeeping and differences between the requirements of the final and proposed rule (with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation).[65] To estimate labor cost, we use the average wage of an Agricultural Worker (occupation code 45-2000) in Agriculture, Forestry, Fishing, and Hunting from the 2020 BLS Occupational Employment and Wage Statistics, which is $14.53. We double the wage to $29.06 to account for benefits and overhead. We estimate the total recurring recordkeeping costs (sum of costs to small and large firms in the table below) related to initial packing to range from about $0.1 million to $22.8 million, with a primary estimate of about $2.2 million.

Table 32. Annual Recordkeeping Costs of Initial Packing (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Initial Packers						
(a) FTL lots per year	832	364	2,600	1,456	1,456	9,100
(b) Hours to capture per lot	0.02	0.002	0.07	0.02	0.001	0.03
(c) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(d) Number of covered establishments	4,022	4,022	4,022	195	195	195
Total = a*b*c*d	$2,028,025	$91,961	$21,359,019	$183,872	$5,766	$1,454,898

e. Records of First Land-Based Receiving of Seafood on the FTL (§ 1.1335)

The final rule will require entities performing the first land-based receiving of FTL food that was obtained from a fishing vessel to maintain traceability records. First land-based receivers of these foods will need to link certain information covered below to the traceability lot. First land-based receiver records must include:

- the traceability lot code they assign,
- a description of the food,
- the quantity and unit of measure of the food,
- the first land-based receiver location description (i.e., the traceability lot code source) and (if applicable) the traceability lot code source reference,
- the date the food was landed,
- the harvest date range,
- the harvest locations, and
- the reference document type and reference document number.

We estimate the total number of first land-based receivers affected based on NAICS 311710 Seafood Product Preparation and Packaging. After removing exempt and non-covered entities, we estimate that the final rule will impose recurring costs on about 319 small establishments and 48 large establishments that perform first land-based receiving of FTL foods obtained from a fishing vessel.

Table 33 summarizes our estimates of the annual recordkeeping costs of the final rule to first land-based receiving establishments owned by small and large firms. We estimate the annual number of FTL lots processed based on input elicited by ERG from the expert panel (Ref. [4]). We estimate the recordkeeping times below using experts' input, adjusting for the elicited

degree of electronic recordkeeping and differences between the requirements of the final and proposed rule (with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation).[67] To estimate labor cost, we use the average wage of an Agricultural Worker (occupation code 45-2000) in Agriculture, Forestry, Fishing, and Hunting from the 2020 BLS Occupational Employment and Wage Statistics, which is $14.53. We double the wage to $29.06 to account for benefits and overhead. We estimate the total recurring costs (sum of costs to small and large firms in the table below) of recordkeeping related to first land-based receiving of FTL food to range from about $0.004 million to $1.5 million, with a primary estimate of about $0.3 million.

Table 33. Annual Recordkeeping Costs of First Land-Based Receiving of FTL Food (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
First Land-Based Receivers of FTL food Obtained from a Fishing Vessel						
(a) FTL lots per establishment	871	187	1,560	5,460	365	13,000
(b) Hours to capture per lot	0.02	0.002	0.07	0.02	0.001	0.03
(c) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(d) Number of covered establishments	319	319	319	48	48	48
Total = a*b*c*d	$163,900	$3,751	$1,041,129	$136,768	$354	$456,091

[67] As explained in the beginning of section II.F.5, we scaled experts' estimates of manual entry times by the proportion of industry they estimated to have electronic recordkeeping capabilities in order to account for baseline practices in estimating the incremental burden of the rule. Our estimates of time burden per record therefore represent averages between manual and electronic recordkeeping weighted by the baseline prevalence of these practices. For our primary estimates, we thus estimate that about 60 percent of small and large businesses will keep records manually at about two minutes per record, while the remainder will scan records at about 2.5 seconds per record.

f. Records to Be Kept and Provided When Shipping Foods on the Food Traceability List (§ 1.1340)

The final rule will require entities who ship foods on the FTL to maintain and provide traceability records. Entities shipping FTL foods must maintain and link the following information to the traceability lot and provide it to the immediate subsequent recipient:

- the traceability lot code for the food,
- the quantity shipped and unit of measure,
- a description of the food,
- the location from which they ship the food,
- the location of the immediate subsequent recipient,
- the ship date,
- the location description of the traceability lot code source (TLCS) or source reference, and
- the reference document type and reference document number

Shippers must additionally provide the above information to the immediate subsequent recipient (other than a transporter), except for the reference document type and reference document number. We note that the traceability lot code source reference can be an internet link or other means of digitally accessing the required information. Additionally, shipping recordkeeping requirements do not apply to shipments of food prior to initial packing.

We estimate the total number of shippers affected by identifying NAICS categories likely to ship foods on the Food Traceability List and removing exempt and non-covered entities. We expect most categories of supply chain entities that handle FTL foods to incur recordkeeping costs associated with shipping. However, as previously mentioned, the final rule's partial

exemption of ad hoc sales between retailers places no traceability requirements on the selling retailer, while the purchasing retailer can satisfy minimal requirements by keeping the sales receipt. Thus, restaurants and other retailers under the final rule are generally only receivers, but not shippers, of FTL foods. We thus estimate that the final rule will impose recurring costs on approximately 24,909 small and 6,524 large establishments that ship FTL foods.

We expect that entities making capital investments will be motivated by interoperability to prioritize streamlining shipping and receiving recordkeeping, since these are the CTEs performed by the most entities across the supply chain. In our estimates of the time burden per record for shipping, we therefore consider the proportion of entities making capital investments, in addition to those currently already performing electronic recordkeeping, to be capable of keeping and sending records via scanning and barcodes (or related technology, e.g., RFID).

Table 34 summarizes our estimates of the annual recordkeeping costs of the final rule to establishments, owned by small and large firms, that ship foods on the FTL. We estimate the annual number of lots shipped based on input elicited from the expert panel (Ref. [4]). We estimate the recordkeeping times below using experts' input, adjusting for our expected degree of electronic recordkeeping and differences between the requirements of the final and proposed rule (with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation).[68] To estimate the hourly labor cost to growers and other producers of raw agricultural commodities, we use the average wage of an Agricultural Worker

[68] As explained in the beginning of section II.F.5, we scaled experts' estimates of manual entry times for each activity by the proportion of industry they estimated to have electronic recordkeeping capabilities in order to account for baseline practices in estimating the incremental burden of the rule. Our estimates of time burden per record therefore represent averages between manual and electronic recordkeeping weighted by the baseline prevalence of these practices. In our estimates of the time burden per record for shipping and receiving, our weighting of this average additionally considers the proportion of entities making capital investments to be capable of keeping and sending records via scanning versus manual entry. For our primary estimates, we thus estimate that about seven percent of small and large businesses will keep records manually at about two minutes per record, while the remainder will scan records at about 2.5 seconds per record.

(occupation code 45-2000) in Agriculture, Forestry, Fishing, and Hunting from the 2020 BLS Occupational Employment and Wage Statistics, $14.53, which we double to $29.06 to account for benefits and overhead. To estimate the hourly labor cost to manufacturers and distributors, we use the average wage of a Food Processing Worker (occupation code 51-3000) in Food Manufacturing, $15.73, which we double to $31.46 to account for benefits and overhead. We estimate the total recurring costs (sum of costs to small and large firms in the table below) of recordkeeping related to shipping to range from about $0.5 million to $123.8 million, with a primary estimate of about $30.3 million.

Table 34. Annual Recordkeeping Costs of Shipping (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Produce Farms and Sprout Growers						
(a) FTL lots per year	832	364	2,600	1,456	1,456	9,100
(b) Hours to capture per lot	0.003	0.001	0.013	0.003	0.0003	0.004
(c) Hours to provide per lot	0.003	0.001	0.013	0.003	0.0005	0.007
(d) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(e) Number of covered establishments	1,065	1,065	1,065	134	134	134
Subtotal = a*(b+c)*d*e	$151,273	$15,978	$2,129,719	$35,475	$4,588	$388,203
Shell Eggs Producers						
(a) FTL lots per year	832	364	2,600	1,456	1,456	9,100
(b) Hours to capture per lot	0.003	0.001	0.013	0.003	0.0003	0.004
(c) Hours to provide per lot	0.003	0.001	0.013	0.003	0.0005	0.007
(d) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(e) Number of covered establishments	2,500	2,500	2,500	21	21	21

Subtotal = a*(b+c)*d*e	$355,251	$37,524	$5,001,454	$5,600	$724	$61,281
Fishing/ aquaculture						
(a) FTL lots per year	1,040	364	2,080	3,120	1,483	16,900
(b) Hours to capture per lot	0.003	0.001	0.013	0.003	0.0003	0.004
(c) Hours to provide per lot	0.003	0.001	0.013	0.003	0.0005	0.007
(d) Hourly labor cost	$29.06	$29.06	$29.06	$29.06	$29.06	$29.06
(e) Number of covered establishments	457	457	457	41	41	41
Subtotal = a*(b+c)*d*e	$81,221	$6,863	$731,833	$23,141	$1,422	$219,464
Manufacturing/ processing						
(a) FTL lots per year	871	187	1,560	5,460	365	13,000
(b) Hours to capture per lot	0.003	0.001	0.013	0.003	0.0003	0.004
(c) Hours to provide per lot	0.003	0.001	0.013	0.003	0.0005	0.007
(d) Hourly labor cost	$31.46	$31.46	$31.46	$31.46	$31.46	$31.46
(e) Number of covered establishments	8,145	8,145	8,145	429	429	429
Subtotal = a*(b+c)*d*e	$1,311,614	$67,987	$10,583,363	$462,482	$3,999	$1,927,961
Wholesale/ Distribution/ Warehouse/ Storage						
(a) FTL lots per year	4,875	202	4,940	14,040	1,500	24,700
(b) Hours to capture per lot	0.003	0.001	0.013	0.003	0.0003	0.004
(c) Hours to provide per lot	0.003	0.001	0.013	0.003	0.0005	0.007
(d) Hourly labor cost	$31.46	$31.46	$31.46	$31.46	$31.46	$31.46
(e) Number of covered establishments	12,742	12,742	12,742	5,900	5,900	5,900
Subtotal = a*(b+c)*d*e	$11,484,421	$114,890	$52,429,124	$16,343,099	$225,840	$50,340,431
Total	**$13,383,780**	**$243,243**	**$70,875,494**	**$16,869,797**	**$236,573**	**$52,937,340**

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

The final rule will require entities who receive foods on the FTL to maintain traceability records. Entities receiving FTL foods must maintain records containing:

- the traceability lot code of the foods,
- the quantity received and unit of measure,
- a description of the food,
- the location for the immediate previous source (other than a transporter),
- the location where the food was received,
- the date of receipt,
- the location of the TLCS, or a TLCS reference, and
- the reference document type and reference document number.

As noted previously, entities receiving FTL foods do not need to establish a record, but rather only need to maintain the record provided to them by the shipper (provided that record includes all the required KDEs). In our analysis, we have also accounted for the fact that receivers of FTL foods do not need to retrieve TLCS information made available via a TLCS reference (e.g., following a web address to retrieve TLCS information), but are allowed to store whatever record the shipper provides containing the TLCS reference. Additionally, receiving recordkeeping requirements do not apply to shipments of food prior to initial packing, or to receipt of a food by the first land-based receiver.

We estimate the total number of receivers affected by identifying NAICS categories likely to receive foods on the FTL and removing exempt and non-covered entities. Particularly, since shipments prior to initial packing or first land-based receiving do not require receiver recordkeeping, we do not expect harvesters, coolers, and initial packers—whether or not they are

also growers—or first land-based receivers to incur receiver costs under the final rule. We assume that all other entities who receive FTL foods will incur some recurring cost to keep receiver records. We estimate that about 470,580 establishments will incur recurring costs due to this provision.

However, we expect recordkeeping requirements to require more sophisticated tasks of some supply chain entities than others. On one hand, intermediate supply chain entities, such as manufacturers and distributors, will need to capture information upon receipt in a way that can link incoming and outgoing product. On the other hand, entities at the end of the supply chain, such as restaurants and other retailers, only need to maintain receiving records. We therefore anticipate that entities at the end of the supply chain are likely to store the records provided by their suppliers in whatever format they are provided (e.g., receipts, labels, electronic documents, etc.).

We expect that entities making capital investments will be motivated by interoperability to prioritize streamlining shipping and receiving recordkeeping, since these are the CTEs performed by the most entities across the supply chain. In our estimates of the time burden per record for receiving, we consider the proportion of entities making capital investments, in addition to those currently already performing electronic recordkeeping, to be capable of keeping records via scanning and the use of barcodes (or related technology, e.g., RFID).

Table 35 summarizes our estimates of the annual recordkeeping costs of the final rule to establishments, owned by small and large firms, that receive foods on the FTL. We estimate the annual number of lots received based on input elicited from the expert panel (Ref. [4]). We estimate the recordkeeping times using experts' input, adjusting for our expected degree of electronic recordkeeping and differences between the requirements of the final and proposed rule

(with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation).[69] To estimate the hourly labor cost to manufacturers and distributors, we use the average wage of a Food Processing Worker (occupation code 51-3000) in Food Manufacturing from the 2020 BLS Occupational Employment and Wage Statistics, $15.73, which we double to $31.46 to account for benefits and overhead. To estimate the hourly labor cost to restaurants and other retailers, we use the average wage of a Retail Sales Worker (occupation code 41-2000) in Food and Beverage Stores, $12.91, which we double to $25.82 to account for benefits and overhead. We estimate the total recurring recordkeeping costs (sum of costs to small and large firms in the table below) related to receiving FTL foods to range from about $5.6 million to $681.7 million, with a primary estimate of about $220.3 million.

Table 35. Annual Recordkeeping Costs of Receiving (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Manufacturing/ processing						
(a) FTL lots per year	871	187	1,560	4,680	365	13,000
(b) Hours per lot to keep	0.003	0.001	0.008	0.003	0.0003	0.004
(c) Hourly labor cost	$31.46	$31.46	$31.46	$31.46	$31.46	$31.46
(d) Number of covered establishments	8,111	8,111	8,111	426	426	426
Subtotal = a*b*c*d	$653,058	$35,870	$3,092,591	$190,075	$1,683	$639,639

[69] As explained in the beginning of section II.F.5, we scaled experts' estimates of manual entry times for each activity by the proportion of industry they estimated to have electronic recordkeeping capabilities in order to account for baseline practices in estimating the incremental burden of the rule. Our estimates of time burden per record therefore represent averages between manual and electronic recordkeeping weighted by the baseline prevalence of these practices. In our estimates of the time burden per record for shipping and receiving, our weighting of this average additionally considers the proportion of entities making capital investments to be capable of keeping and sending records via scanning versus manual entry. For our primary estimates, we thus estimate that about seven percent of small and large businesses will keep records manually at about two minutes per record, while the remainder will scan records at about 2.5 seconds per record.

Wholesale/ Distribution/ Warehouse/ Storage						
(a) FTL lots per year	4,615	202	4,940	17,420	1,500	32,500
(b) Hours per lot to keep	0.003	0.001	0.008	0.003	0.0003	0.004
(c) Hourly labor cost	$31.46	$31.46	$31.46	$31.46	$31.46	$31.46
(d) Number of covered establishments	12,742	12,742	12,742	5,900	5,900	5,900
Subtotal = a*b*c*d	$5,435,959	$60,872	$15,384,940	$9,787,952	$95,701	$22,122,771
Non-restaurant retail						
(a) FTL lots per year	4,550	520	7,800	28,600	2,080	28,600
(b) Hours per lot to keep	0.003	0.001	0.008	0.003	0.0003	0.004
(c) Hourly labor cost	$25.82	$25.82	$25.82	$25.82	$25.82	$25.82
(d) Number of covered establishments	115,451	115,451	115,451	55,929	55,929	55,929
Subtotal = a*b*c*d	$39,853,968	$1,165,260	$180,642,166	$125,032,354	$1,032,525	$151,472,888
Restaurants						
(a) FTL lots per year	1,560	520	5,200	3,120	2,080	15,600
(b) Hours per lot to keep	0.003	0.001	0.008	0.003	0.0003	0.004
(c) Hourly labor cost	$25.82	$25.82	$25.82	$25.82	$25.82	$25.82
(d) Number of covered establishments	215,359	215,359	215,359	56,662	56,662	56,662
Subtotal = a*b*c*d	$25,488,853	$2,173,643	$224,643,263	$13,818,543	$1,046,049	$83,703,718
Total	**$71,431,838**	**$3,435,645**	**$423,762,960**	**$148,828,924**	**$2,175,958**	**$257,939,016**

h. Records of Transformation of Foods on the Food Traceability List (§ 1.1350)

The final rule will require entities who transform food on the FTL to maintain traceability records. For covered food used in transformation (if applicable), entities must keep records that contain:

- the traceability lot code of the food transformed,
- a description of food transformed to which the traceability lot code applies, and
- the quantity and unit of measure of food from each TLC transformed.

For covered food that was produced through transformation, entities must keep records that contain:

- the new traceability lot code of the food,
- the location description for where the food was transformed,
- the date transformation was completed,
- a description of the food post transformation,
- the quantity and unit of measure of food post transformation, and
- the reference document type and reference document number for the transformation event.

Transformation recordkeeping requirements do not apply to retail food establishments and other food service providers with respect to foods they do not ship (e.g., foods they sell or send directly to consumers). Transformation recordkeeping requirements also do not apply to transformation of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the FTL that was not initially packed prior to transformation. In that situation, initial packing records must be kept instead.

As in previous sections, we estimate the total number of affected entities transforming FTL foods by identifying NAICS categories likely to transform foods on the Food Traceability List and removing exempt and non-covered entities. We expect that all covered manufacturers will incur recurring costs at the establishment level to keep records of transformation under the final rule. We estimate that about 8,574 manufacturing or processing establishments will incur recurring costs due to this provision of the rule. We expect that entities affected by this provision will incur annual recordkeeping costs at the establishment level.

Table 36 summarizes our estimates of the annual recordkeeping costs of the final rule to establishments owned by small and large firms that transform foods on the FTL or that produce FTL foods through transformation. We estimate the annual number of lots transformed based on input elicited from the expert panel (Ref. [4]). We estimate the recordkeeping times using experts' input, adjusting for the elicited degree of electronic recordkeeping and differences between the requirements of the final and proposed rule (with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation).[70] To estimate the hourly labor cost, we use the average wage of a Food Processing Worker (occupation code 51-3000) in Food Manufacturing from the 2020 BLS Occupational Employment and Wage Statistics, $15.73, which we double to $31.46 to account for benefits and overhead. We estimate total recurring recordkeeping costs (sum of costs to small and large firms in the table below) of transformation to range from about $0.1 million to $43 million, with a primary estimate of about $6 million.

[70] As explained in the beginning of section II.F.5, we scaled experts' estimates of manual entry times by the proportion of industry they estimated to have electronic recordkeeping capabilities in order to account for baseline practices in estimating the incremental burden of the rule. Our estimates of time burden per record therefore represent averages between manual and electronic recordkeeping weighted by the baseline prevalence of these practices. For our primary estimates, we thus estimate that about 60 percent of small and large businesses will keep records manually at about two minutes per record, while the remainder will scan records at about 2.5 seconds per record.

Table 36. Annual Recordkeeping Costs of Transforming (2020$)

	Small			Large		
	Primary	Low	High	Primary	Low	High
Manufacturing/ processing						
FTL lots per year	871	187	1,560	5,460	365	13,000
Hours per lot to capture	0.02	0.002	0.08	0.02	0.001	0.07
Hourly labor cost	$31.46	$31.46	$31.46	$31.46	$31.46	$31.46
Number of covered establishments	8,145	8,145	8,145	429	429	429
Total	**$4,525,747**	**$87,453**	**$31,351,044**	**$1,442,656**	**$7,275**	**$12,092,811**

i. *Electronic Sortable Spreadsheet Upon Request*

When necessary to help FDA prevent or mitigate a foodborne illness outbreak, assist in the implementation of a recall, or to otherwise address a threat to the public health, some entities would be required to provide FDA with the information required under subpart S in the form of an electronic sortable spreadsheet. While some may already keep records in sortable electronic spreadsheets, others might need to put their records for the requested lots and dates in an electronic sortable spreadsheet format upon FDA request. The final rule exempts farms with average annual sales of no more than $250,000 and other supply chain entities with average annual sales of no more than $1 million dollars from having to provide information in the form of an electronic sortable spreadsheet. As this will be a low probability event for any given establishment, we treat our estimated number of annual requests by FDA as the number of affected establishments per year (thus assuming that no establishment receives more than one such request in the same year).

Table 37 summarizes our estimates of the annual cost of providing traceability information to FDA in the form of an electronic sortable spreadsheet upon request. We estimate

that FDA will make between 40 and 110 such requests annually (to entities not exempt from the spreadsheet requirement) based on internal counts of CORE assignments (information requests) between 2016 and 2021. We estimate that such requests will entail, on average, between eight and twenty-four total hours of formatting information into a spreadsheet. We expect that the type of employees formatting spreadsheets will be roughly equivalent to supervisors of food preparation (occupation code 35-1010 in NAICS 445), the mean wage of which is $20.12 per hour, which we double to $40.24 to account for benefits and overhead. We estimate the total annual cost of formatting responses to requests for traceability information as electronic sortable spreadsheets to range from about $0.01 million to $0.1 million, with a primary estimate of about $0.05 million.

Table 37. Annual Cost of Providing Electronic Sortable Spreadsheets Upon Request

	Primary	Low	High
(a) Average hours to generate spreadsheet	16	8	24
(b) Hourly labor cost	$40.24	$40.24	$40.24
(c) Expected annual requests to establishments not exempt from spreadsheet requirement	75	40	110
Total cost = a*b*c	$48,288.00	$12,876.80	$106,233.60

6. Non-Quantified Costs

The information flows brought about by the final 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 due to lack of data; however, 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.[71]

More generally, provisions of the final rule might generate costs that we cannot quantify, as explained below. FDA might incur costs 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 requirements on our own initiative (§1.1440), determine that a waiver should be modified or revoked (§1.1450), and respond to a failure to comply[72] with the provisions of the final rule (§1.1460).

For provisions concerning petitions, costs to FDA might 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 will receive, we cannot estimate the costs of these provisions.

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 (§

[71] As noted previously, the outcomes of earlier FSMA regulations should be taken into account in the characterization of this final rule's regulatory baseline.

[72] Enforcing the final rule on entities that are not in compliance may generate costs to the FDA. As explained in the preamble, the FDA does not have the authority to impose fines for violations of section 204 of FSMA or subpart S. We also note that the compliance strategy for the FDA is still in development, and that we plan to work with our State, Local, Tribal, and Territorial (SLTT) and other regulatory partners to implement efficient enforcement of the rule. Depending on the nature of the violation, it is generally FDA's practice to give individuals and firms an opportunity to take prompt and voluntary corrective action before we initiate an enforcement action. We may issue advisory action letters, which include Untitled and Warning Letters, to notify firms of violations and to prompt voluntary compliance. When voluntary compliance is not forthcoming, the Federal government may bring an action in Federal court. We believe noncompliance will be a relatively uncommon event and when it does occur, entities will generally take voluntary action to correct the noncompliance. Further, we expect coordination with SLTT partners to minimize costs to the FDA.

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, we cannot estimate the costs associated with these actions. However, these potential costs will likely not increase the net costs of this rule. First, since petitions are voluntary, firms will only submit petitions if the cost of submitting a petition is lower than the cost of compliance. Our cost estimates do not account for petitions, so in the case of a petition submission, the lower cost of submitting a petition would replace the higher cost of compliance. Second, petitions must either demonstrate that "application of the requirements requested to be modified or from which exemption is requested is not necessary to protect the public health" (in the case of a request for modified requirements or an exemption) or – in the case of a waiver – that "[t]he waiver will not significantly impair [FDA's] ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death." Thus, the existence of these mechanisms is not likely to interfere with FDA's ability to conduct traceback investigations. The cost of submitting petitions and waiver requests would therefore replace the higher cost of compliance without compromising benefits as estimated in this analysis.

Finally, we note that a request from FDA to produce an electronic 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 of this requirement other than stating a religious reason, we believe any such additional costs to be negligible.

7. Summary of Costs

Table 38 summarizes our estimates of the one-time and recurring costs of the final rule. We estimate that the total one-time costs of the final rule will be approximately $1,684 million, with a lower bound of $509 million and an upper bound of $5,875 million. We estimate that the total recurring costs of the final rule will be approximately $490 million per year, with a lower bound of $22 million and an upper bound of $2,092 million.

Table 38. Total Costs of the Final Rule (millions 2020$)

One-time Costs	Primary	Low	High
Reading and Understanding the Rule	$225.64	$203.08	$253.85
Capital Investment	$1,139.12	$278.01	$4,866.82
Training	$240.67	$12.97	$409.19
§ 1.1315 Traceability Plan	$78.55	$15.13	$345.41
Total One-time Costs	$1,683.98	$509.19	$5,875.27
Annually Recurring Costs			
Capital Operation and Maintenance	$185.37	$14.91	$979.66
Recurring Training	$40.43	$0.98	$202.31
Seed lot records (Growers of sprouts) [(1)]	$0.10	$0.004	$0.84
§ 1.1325 Records of Harvesting	$3.11	$0.12	$27.00
§ 1.1325 Records of Cooling	$1.76	$0.10	$9.21
§ 1.1330 Records of Initial Packing	$2.21	$0.10	$22.81
§ 1.1335 Records of First Land-Based Receiving	$0.30	$0.004	$1.50
§ 1.1340 Records of Shipping	$30.25	$0.48	$123.81
§ 1.1345 Records of Receiving	$220.26	$5.61	$681.70
§ 1.1350 Records of Transformation	$5.97	$0.09	$43.44
§ 1.1455(c)(3)(ii) Electronic Sortable Spreadsheet Upon Request	$0.05	$0.01	$0.11
Total Recurring Costs	**$489.82**	**$22.41**	**$2,092.40**

[(1)] Although seed lot records fall under §1.1330 Records of Initial Packing, we assume the incidence of these costs will fall on growers of sprouts.

We present a summary of the estimated twenty-year stream of costs of the final rule in Table 39. We expect that one-time costs of the final rule will occur evenly over the first two years after the rule becomes effective. We expect that recurring costs will begin in the second year, though at only half the estimated amount, lagging by one year behind the half of one-time costs occurring in year one. We estimate that in the first year after the final rule becomes

effective, total costs will be approximately $842 million dollars, with a lower bound of $255 million and an upper bound of $2,938 million. In the second year, total costs will be approximately $1,087 million dollars, with a lower bound of $266 million and an upper bound of $3,984 million. In subsequent years, the annual cost of the final rule will decrease to $490 million, with a lower bound of $22 million and an upper bound of approximately $2,092 million. We estimate that the total costs of the rule over 20 years will be approximately $10.7 billion, ranging from a lower bound of $0.9 billion and an upper bound of approximately $44.6 billion.

The present value of total estimated costs of the rule is approximately $6 billion at a seven percent discount rate and $8.2 billion at a three percent discount rate over 20 years. The twenty-year annualized value of costs is $570.12 million at a seven percent discount rate and $550.63 million at a three percent discount rate.

Table 39. Twenty-Year Timing of the Costs of the Final Rule (millions 2020$)

	Primary	Low	High
Year 1	$841.99	$254.59	$2,937.63
Year 2	$1,086.90	$265.80	$3,983.83
Years 3-20	$489.82	$22.41	$2,092.40
Total Costs of the Final Rule	$10,745.71	$923.84	$44,584.63
Present Value of Total Costs (3%)	$8,192.05	$788.29	$33,733.08
Present Value of Total Costs (7%)	$6,039.83	$667.02	$24,608.89
Annualized Value of Costs (3%)	**$550.63**	**$52.99**	**$2,267.39**
Annualized Value of Costs (7%)	**$570.12**	**$62.96**	**$2,322.90**

G. Distributional Effects

The final rule will generate benefits and costs that may accrue unequally to establishments depending on their industry sector and size and may also accrue unequally to various segments of society. In this section, we discuss differential effects for consumers and broad differences across industry sectors. We address differential effects for small entities by industry sector in Section III of this analysis.

As described in Section II.F, we expect that the costs of this final rule will mainly arise from recordkeeping requirements. Currently, entities have different baseline business practices and therefore may face different costs depending on their size, industry, and position in the food supply chain. Wholesalers/distributors and manufacturers are generally expected to bear the highest per-firm costs associated with additional recordkeeping requirements, while retailers and farms are expected to bear lower per-firm costs overall. As discussed throughout sections II.F and III, we therefore expect the costs of the rule to be more concentrated on those industries in the middle of the food supply chain.

The rule's effect on traceback time and avoidance of overly broad recalls of FTL foods will result in health benefits for consumers (estimated in section II.E), but existing inequities in healthcare access, quality of care, and local FTL food availability and variety may result in more benefits for some groups than others. As described in section II.E, we estimate the value of averted illnesses and deaths by estimating 1) the cost burden of an illness on a typical individual and 2) the number of averted illnesses through improved traceback time. The cost burden of an illness consists of the medical care costs and the monetized value of the loss in health status. There are significant differences in health status, healthcare access, and healthcare affordability across sociodemographic groups (Ref. [42]). Thus, the cost burden of an illness may be unequal across sociodemographic groups. The effect of an illness may also be unequal across groups as differences in accessing healthcare may result in different recovery times, additional illnesses, change in employment and income status, or other associated effects. Additionally, the risk of contracting an illness depends on exposure, which in turn depends on the volume of FTL foods consumed by an individual. Unfortunately, although we have information on average quality of life measures across racial, gender, and income groups (Ref. [43, 44]), we do not have

information on quality-of-life loss under different illnesses for various sociodemographic groups. We therefore cannot identify the difference in averted costs for different sociodemographic groups associated with better traceback time and assume these averted costs to be the same across these groups. We nevertheless acknowledge the rule could yield differential benefits from averted illnesses for some sociodemographic groups.

The concentration of retail food establishments (RFEs) and therefore availability of covered foods near consumers' homes may be correlated with sociodemographic characteristics. There is evidence that sociodemographic characteristics are correlated with the location of food deserts (Ref. [45]). We use 2020 data from Dun & Bradstreet[73] on RFE locations[74] and data from the USDA Economic Research Service on zip code-level rural/urban classifications[75] to understand the distribution of covered retail entities across the country. We find that rural areas have the highest number of covered RFEs per 1,000 people, but in general there are few significant differences of RFE concentrations across the country. The geographic distribution of covered RFEs suggests that most people have a similar amount of retail food availability. It should be noted, however, that access to transportation and purchasing behavior can also affect food availability. For example, consumers in rural areas may have to travel far to access food and therefore buy more foods in bulk to use for longer periods. Similarly, consumers in urban areas without easy access to transportation may exhibit similar bulk purchasing behavior. The rate of eating in restaurants may also differ across geographic areas. We do not, however, have information on access to transportation and associated purchasing behavior for consumers.

[73] Dun & Bradstreet, Dun & Bradstreet Global Business Database. 2020.
[74] Only covered retail food establishments are analyzed; establishments that do not handle FTL foods or are exempt based on annual sales are excluded from the analysis.
[75] https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx

Using 2017 – 2018 dietary survey data from the National Health and Nutritional Examination Survey (NHANES)[76], we observed food items consumed by individuals from across the country. We observed the diet of each respondent over two days and searched for any item they consumed that would be on the FTL. We found some significant differences in FTL food consumption across demographic characteristics. However, despite the observed differences, we cannot quantify differences in benefit accrual to various socio-demographic groups. First, diets may have changed since the data were gathered.[77] Second, the final rule may have spillover effects that affect foods not currently on the FTL. The difference in consumption rates across sociodemographic groups may not extend to other foods. Third, not all FTL foods carry the same risk of contamination, so the differences in consumption do not imply differences in the risk of disease contraction.

Covered entities may pass increased costs on to consumers, raising the price of FTL foods. We elicited input from a panel of experts, who agreed that some of the costs of the final rule will likely be passed on through the supply chain to consumers (Ref. [4]). If the difference in observed FTL consumption rates is due to price concerns, increased prices passed down the supply chain may exacerbate current FTL consumption rate differences across groups. We discuss cost pass-throughs to consumers in Section II.G and provide some evidence of increased prices for covered foods. However, we have no evidence of the magnitude of spillover cost pass-throughs to non-covered food items, the quality of diet of demographic groups, or the substitution patterns of demographic groups as a result of price changes to FTL foods. We

[76] The most recent dietary data from NHANES (also referred to as *What We Eat In America*) is from 2017 – 2018, and can be found at: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweia-documentation-and-data-sets/

[77] The most recent data was gathered prior to the COVID-19 pandemic and might not reflect the current diet pattern after the significant disruption of eating patterns.

recognize that current differences in consumption rates of FTL foods suggests some differential accrual of benefits to different demographic groups, but without more information, we cannot quantify the distribution of welfare impacts across demographic groups.

Using data[78] on the distribution of covered entities and consumption of certain food items linked to demographic data, we observe some differences across demographic characteristics. However, potential correlations between demographic characteristics and other outcomes (healthcare access, employment opportunities, access to transportation, etc.) suggest the observed differences could be potentially misleading. For example, the difference in FTL food consumption rates could be because of budgetary constraints, dietary preferences, dietary restrictions, local food availability, or several other reasons. Each of the potential causes of the observed differences in FTL consumption rates may also be correlated with demographic characteristics. Thus, a dedicated causal study is needed to fully understand what is causing the differences. Because of the novelty of the FTL, there are naturally no causal studies available. We therefore have limited knowledge on what is causing differences in FTL consumption rates, so we also cannot determine how the final rule will affect the difference in FTL consumption rates, and subsequently health outcomes for consumers.

In sum, we expect costs of the rule to be concentrated in industries in the middle of the food supply chain (manufacturers, distributors, etc.), and while we recognize the potential for benefits to accrue to some consumer segments more than others, we lack the information necessary to quantitively estimate the distribution of benefits across sociodemographic characteristics.

[78] We specifically use Dun & Bradstreet (2020), USDA ERS rural/urban classification (2019), and NHANES (2017-2019) data.

H. International Effects

This section estimates costs for foreign entities (firms or establishments) who manufacture, process, pack, or hold covered foods that are exported to the U.S. market. We estimate foreign impacts using data from FDA's FFRM to estimate compliance costs to foreign entities.

In estimating the compliance costs to foreign entities, we use the average cost of the rule per domestic entity with adjustments described below. These costs by activity type include one-time costs of reading and understanding the rule, capital investment, training, and developing traceability plan, and recurring costs of operation and capital maintenance, training, and recordkeeping as described in detail in section II.F of this analysis. The per entity cost is then multiplied by the total number of foreign entities affected by each provision to get the total compliance costs to foreign entities.

To estimate compliance costs to foreign entities, we use costs for domestic entities and introduce adjustments to account for the number of foreign entities, foreign employee wages, internet access, and English language proficiency as detailed below. We use 2019 FDA's FFRM data which contains 212,404 foreign and domestic facilities. FDA FFRM does not include data on RFEs because they are not covered by the food facility registration regulation.[79] While it is possible that there might be a small number of foreign entities that offer covered food for sale 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. From FDA's FFRM data, there is a total of 212,404 foreign and domestic registered facilities of which about 75 percent (or 159,482)

[79] https://www.regulations.gov/document/FDA-2002-N-0323-0163

are facilities that manufacture, process, pack, or hold covered foods. Of the 159,482 facilities, a total of 68,566 (43 percent) are foreign facilities.

We assume that the same proportion of registered foreign establishments[80] to firms is affected by the rule (i.e., manufacture, process, pack, or hold FTL foods) as the proportion of domestic establishments to firms. We use the ratio of 1.19 of covered domestic non-retail and non-restaurant establishments to firms (40,754 establishments / 34,389 firms = 1.19) to estimate that the number of foreign firms affected by the rule is 57,618 firms (68,566 foreign establishments / 1.19 = 57,618). These estimates enable us to calculate costs of the rule to foreign entities. We make the same assumptions in estimating compliance costs by foreign entities as for domestic entities. Similarly to estimates in Section II.F, some costs such as costs of reading and understanding the rule and establishing traceability plan, will occur at the firm level, while all other costs such as those related to capital investments, training and recordkeeping are assumed to occur at the facility level. Since the FFRM data does not contain information on farms including firm sizes or annual receipts, we assume that the share of small foreign entities is the same as for domestic entities.

We make two important adjustments to our estimates of compliance costs for foreign establishments. First, since foreign wages are generally lower than domestic wages, we make adjustment to account for this variation. To estimate wages for foreign employees and supervisors, we take the weighted average of general wages for the top twenty foreign countries by value of their covered foods exported to the United States and adjust this weighted average wage to 2020 U.S. dollar (Ref. [46]). For example, this yields an average foreign general employee wage of $3.45 per hour, mid-level supervisor wage of $7.81 per hour, and supervisor

[80] We use ‘establishments’ and ‘facilities’ interchangeably.

wage of $10.77 per hour, etc. We double the wage rates to account for employees benefits and overhead. This yields $6.91 per hour (= $3.45 x 2) for general employees, $15.63 per hour (= 7.81 x 2) for mid-level supervisor employees, etc.

The second adjustment we make is related to the time it takes for employees of foreign entities to read and understand the rule to account for varying levels of both English proficiency and internet accessibility. In learning about the requirements of this rule, we assume that entities from countries with both high English proficiency and high internet access will spend a comparable amount of time as domestic entities. However, entities from countries with lower 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 or internet access.

To account for language proficiency differences, we use information from the 2020 "Education First English Proficiency Index" (EF EPI) report (Ref. [47]). This report ranks countries by the average level of English language skills amongst adults using data collected via English tests available over the internet. To account for country differences in internet accessibility, we use 2022 internet user percentage estimates by country (Ref. [48]). We estimate that on average, foreign establishments will spend 1.41 hours for every hour a domestic establishment spends on reading the rule.

The weights are based on English language proficiency and internet access for foreign facilities currently registered with FDA representing 114 countries who export FDA regulated food to the U.S. The average of both weighted sums of 1.65 hours to account for differences in

English proficiency and of 1.17 hours to account for differences in internet usage give us a single estimate of 1.41 (=(1.65 hours +1.17 hours)/2) for foreign establishments as equivalent to one hour for domestic establishments.

As explained in Appendix H, we take the average between proficiency and internet weighted hours because internet access is positively correlated with English proficiency and also because high English proficiency alone is not enough to account for the amount of time that an entity would require to learn about the rule. Even entities from countries with high English proficiency would rely on using the internet insofar as to only download the rule to save it or e-mail it to a device, whereas an entity in a country with low internet access would need to spend more time finding internet access in order to download the rule from the internet.

Section II.F of this analysis calculates that the burden for domestic employees of reading this rule is 16.22 hours. Assuming one foreign mid-level supervisor would be responsible for reading and understanding the rule for small firm and three for large firms, we estimate the burden of reading and understanding this rule per supervisor is 26.11 hours (= 16.22 hours x 1.41).

Table 40. Total Costs to Foreign Entities (Millions 2020$)

One-time Costs	**Primary**	**Low**	**High**
Reading and Understanding the Rule	$15.15	$13.63	$17.04
Capital Investment	$161.33	$19.71	$876.75
Training	$25.51	$1.67	$37.16
§ 1.1315 Traceability Plan	$3.74	$0.72	$16.46
Total One-time Costs	$205.74	$35.74	$947.41
Annually Recurring Costs			
Capital Operation and Maintenance	$26.25	$0.89	$191.23
Recurring Training	$1.54	$0.05	$10.26

Seed lot records (Growers of sprouts)[1]	$0.00	$0.00	$0.03
§ 1.1325 Records of Harvesting	$0.12	$0.00	$1.02
§ 1.1325 Records of Cooling	$0.07	$0.00	$0.35
§ 1.1330 Records of Initial Packing	$0.08	$0.00	$0.87
§ 1.1335 Records of First Land-Based Receiving	$0.01	$0.00	$0.06
§ 1.1340 Records of Shipping	$1.15	$0.02	$4.69
§ 1.1345 Records of Receiving	$8.35	$0.21	$25.84
§ 1.1350 Records of Transformation	$0.23	$0.00	$1.65
§ 1.1455(c)(3)(ii) Electronic Sortable Spreadsheet Upon Request	$0.01	$0.00	$0.02
Total Recurring Costs	$37.80	$1.18	$236.01

[1] Although seed lot records fall under § 1.1330 Records of Initial Packing, we assume the incidence of these costs will fall on growers of sprouts.

As summarized in Table 40, we estimate that one-time costs to foreign entities range from approximately $35.74 million to $947.41 million, with a primary estimate of $205.74 million. Just like for domestic entities, we expect that these one-time costs of the final rule to foreign entities will occur evenly over the first two years after the rule becomes effective. Recurring costs to foreign entities range from approximately $1.18 million to $236.01 million, with a primary estimate of $37.80. million. Again, just like for domestic entities, we expect that recurring costs to foreign entities will begin in the second year, though at only half the estimated amount, lagging by one year behind the half of one-time costs occurring in year one.

At a seven percent discount rate, our primary estimate of the present value of costs to foreign entities over twenty years is approximately $534.64 million, ranging from $43.22 million to $3.03 billion. At a three percent discount rate, our primary estimate of the present value of costs to foreign entities over twenty years is approximately $704.74 million, ranging from $50.1 million to $4.08 billion. The primary estimate of the annualized costs at a seven percent discount rate to foreign entities is approximately $50.47 million, ranging from $4.08 million to $286.31

million. At a three percent discount rate, the primary estimate of the annualized costs to foreign entities is approximately $47.37 million, ranging from $3.37 million to $274.06 million.

The costs presented in Table 40 are costs to foreign entities only. To the extent that these costs are passed on to U.S. entities, U.S. consumers and firms that purchase covered foods from foreign entities may experience higher costs. We assume that the requirements of this rule will affect domestic entities in the same manner regardless of whether their suppliers are domestic or foreign. We lack information to determine the portion of foreign producers' compliance costs that may be passed on to U.S. consumers.

Overall gains or losses from this rule would likely be caused by price increase or reductions for covered varieties of foods in foreign markets. Gains to foreign consumers may likely result from an increase in supply of domestic and imported varieties of covered foods from other foreign markets.

I. Uncertainty and Sensitivity Analysis

The prospective nature of this analysis means that all our estimates have a varying degree of uncertainty. This is the reason we present ranges to our estimates throughout this document.

1. Coverage

We derive the number of covered farms using raw USDA NASS data. Due to lack of information on the percentage of farms producing FTL foods, we assume that all farms in corresponding covered NAICS categories, excluding farms exempt because of their low annual sales or direct sales to consumers, are covered entities. To that extent, we may overestimate the number of covered farms.

For egg farms and aquaculture farms, we derive the number of covered farms from the summary reports of the 2017 Census of Agriculture and the 2018 Census of Aquaculture (Ref. [13], [14]). We may overestimate the number of covered egg farms as we assume all of the egg farms with greater than 3,000 layers are packers. Similarly, we assume all of the aquaculture farms with annual sales greater than $100,000 are packers, which means that we may overestimate the number of covered egg farms and aquaculture farms.

To the extent that the U.S. Census data only cover primary NAICS codes, we potentially exclude non-primary NAICS and may underestimate the number of total covered firms and establishments. Due to lack of data counts specific to only entities that handle covered foods, we modify the U.S. Census data to approximate the number of covered entities in each NAICS category. In estimating the number of entities that handle covered foods, we only include the numbers that were available from the NAPCS data. Hence, we may underestimate the number of entities that we believe manufacture, process, pack, or hold foods currently covered on the FTL and foods that contain them as ingredients.

2. Costs

In estimating costs, we are mainly uncertain of baseline trends in traceability investment. As explained in section II.F.3 "Costs of Capital Investment," as demand for traceability increases and technology advances, we expect that lower-cost traceability solutions will become available on the market. While ERG's traceability costs elicitation provided some information on current industry practices, we are generally unsure to what extent the rule itself drives estimated future expansion of traceability. Although ERG's expert elicitation asked for estimates of expected capital costs due specifically to compliance with the proposed traceability requirements, some experts suggested that their estimates included capital investments likely to occur for reasons

other than regulatory compliance, such as obsolescence. Furthermore, longstanding widespread awareness of FSMA complicates extricating baseline traceability investment using past trends. Past trends likely reflect, at least in part, business' expectations of coming traceability regulation and might change once said regulation materializes. Since experts did not separately quantify the extent to which regulatory compliance drives their estimates, we nonetheless attributed all estimated capital investment to the proposed traceability requirements when using the elicitation to inform our analysis of the final rule.

Additionally, some entities that we count as distributors might also manufacture and thereby perform the transformation CTE. We do not know the number of such entities nor the extent to which they already factor into our manufacturing category, since, as previously stated, Census data counts entities under only their primary activities. Some entities that we count as distributors might also transform FTL foods via repacking (e.g., mixing peppers of different colors). We do not know how often this would specifically be done by distributors with respect to foods on the FTL.

Finally, throughout the cost section, we present ranges of estimates for a number of variables to account for uncertainty stemming from yearly variability as well as imprecise knowledge. We base these ranges mostly on ranges provided by experts in ERG's panel, who were asked for low, most likely, and high values. For example, low and high counts of FTL lots handled per entity with respect to various CTEs, as well as counts of employees involved in cost-incurring tasks, reflect variability that we expect in yearly averages. Low and high estimates of the proportion of industry engaged in various traceability practices, or expected to invest in capital, account for imprecision in experts' knowledge of these variables.

3. Benefits from Avoiding Overly Broad Recalls

In estimating benefits from avoiding overly broad recalls, our main source of uncertainty was the number of firms typically impacted by an FDA advisory. While ERG's recall expert elicitation provided us with information about per-firm costs of dealing with an overly broad recall, even the experts were uncertain about the scope of such an event, should one occur (Ref. [4]). To characterize our uncertainty about the scope and variability in experts' cost information, we laid out a series of calculations to run a Monte Carlo simulation. Estimated benefits from the reduction in overly broad recalls required that we assign parameters to corresponding probability density functions to characterize the variability inherent in the costs estimates. We also assigned parameter estimates and probability density functions to characterize the inherent uncertainty in the estimates for the number of firms according to their respective cost category. Probability density functions and their parameter estimates along with results of the sensitivity analysis in the simulation showed that our estimates were mostly sensitive to the number of firms affected, which was also our most uncertain estimate (see section II. E and Appendix G).

J. Analysis of Regulatory Alternatives to the Rule

We considered four different regulatory alternatives as described below.

- Alternative a: No new regulatory action.
- Alternative b: Broader exemption for retail food establishments and restaurants.
- Alternative c: Reduce compliance date to two years.
- Alternative d: Extend compliance date to four years.

Table 41 below shows a detailed summary of the costs and benefits associated with each regulatory alternative (annualized using a seven percent discount rate over 20 years), the change in the estimated costs and benefits relative to the final rule, the net health benefits of each alternative, and the number of covered establishments under each alternative.

Table 41. Summary of Costs and Benefits of Regulatory Alternatives (millions $).

	No. Covered establishments	Annualized Total Costs (7%)	Annualized Benefits (7%)	Net Benefit (7%)
Final Rule	**484,124**	**$570**	**$780**	**$210**
Alt A: No action	0	$0	$0	$0
Change from FR	-484,124	($570)	($780)	($210)
Alt B. Fully exempt RFEs below $1M	306,680	$508	$761	$253
Change from FR	-177,444	($62)	($19)	$43
Alt C: Reduce compliance date to two years	484,124	$595	$857	$262
Change from FR	0	$25	$77	$51
Alt D: Extend compliance date to four years	484,124	$546	$709	$163
Change from FR	0	($24)	($71)	($48)

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 BT Act 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. Broader exemption for retail food establishments and restaurants

Under this alternative, retail food establishments and restaurants with an annual monetary value of food sold or provided during the previous 3-year period below $1 million (on a rolling basis) would be fully exempt from the rule. Using SUSB data we approximate that these entities are responsible for less than 5 percent of sales of covered foods.

As a result of exempting these entities, the Alternative b will exempt an additional 177,444 establishments throughout the entire supply chain of covered foods. The full exemption of these entities will thus decrease the number of covered establishments from 484,124 to 306,680 (Table 41). The annualized costs of the rule will decrease from $570 million to $508 million, which is $62 million less than the estimated costs of the rule. While this will provide relief to many smaller entities in the food supply chain, we estimate that health benefits associated with Alternative b will decrease by $19 million, from $780 million to $761 million. The benefits will decrease because in case of an outbreak of covered food, FDA and industry may have less information available to them if these newly exempt entities will not be able to provide the same traceability records in the same timely manner as covered entities. It is possible that we underestimate the change in health benefits for this regulatory alternative because we base it only the share of sales of covered foods and assume that the share of illnesses is proportional to the share of sales.

Alternative c. Reduce compliance date to two years

This alternative reduces the compliance date of the rule to two years following the effective date of the final regulation. Under this alternative, we assume that one-time costs of the rule will occur in the first year and the recurring costs will begin in the second year without lag.

The number of covered establishments under this alternative will be the same as under the rule (Table 41). The estimated annualized costs of this Alternative c will be $595 million, which is $25 million higher than the estimated costs of the rule. The estimated annualized health benefits will be $857 million, which is $77 million higher than the estimated benefits of the final rule. The shorter compliance period will result in the higher annualized benefits because they would begin year two, which is one year earlier than under the final rule. However, a shorter compliance period means that covered entities including small entities would have less time to prepare for implementation of the rule, especially if the supply chain is affected by the COVID-19 pandemic. And it might not be feasible for small establishments to come into compliance. Hence, our estimated benefits of this alternative could be overstated if some establishment including small establishments would not receive capital equipment in time, have the sufficient time to adequately train employees to use it, and have their traceability system in place before the compliance date.

Alternative d. Extend compliance date to four years

This alternative extends the compliance date of the rule to four years following the effective date of the final regulation. We assume that one-time costs of the rule under this alternative will occur evenly over the first three years after the rule becomes effective. And we assume that recurring costs will begin in the second year, though at only one-third of the estimated amount, lagging by one year behind the third of one-time costs occurring in year one. The number of covered establishments under this alternative will be the same as under the rule (Table 41). Compared to the final rule, delaying the compliance date would reduce the burden on the covered entities by shifting costs into the future as they would have additional time to comply

with the rule. The estimated annualized costs of this alternative will be $546 million, which is $24 million less than the estimated costs of the rule. However, the estimated health benefits will also decrease from $780 million to $709 million, which is $71 million less than the estimated benefits of the final rule because delaying the compliance date of one year would result in illnesses and death that could have been avoided.

III. Final 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 covered entities might have annualized costs (over 20 years at a seven percent discount rate) that exceed one percent of their annual revenue, we find that the final 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 Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.[81]

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 NAICS codes. SBA defines each NAICS code's small business threshhold either in terms of sales revenue or number of employees. Using the 2019 SBA size standards[82] in conjunction with the SUSB counts of

[81] For descriptions of the steps that FDA has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including extending the compliance period from three to four years for all firms, please see Sections I.D comment 30, I.E, II.D.2, and Appendix D.
[82] Small Business Association. Table of Size Standards. Aug 19, 2019. Available from: https://www.sba.gov/document/support--table-size-standards

firms in each NAICS code by revenue and employment size,[83] we estimate the numbers of covered small firms by industry sector.[84] Overall, we estimate that about 98 percent of firms covered by this rule are small businesses by SBA standards. Table 42 shows estimated counts of covered small firms by NAICS code.

Table 42. Small Entities Affected by the Final Rule

2017 NAICS Code	NAICS Industry Description	Firm type	Number of Covered Small Firms	Annual Revenue in Millions$	Revenue per Firm in Millions$	SBA Size Standard (Millions$ or Number of employees)
111219	Other Vegetable (except Potato) and Melon Farming[85]	Farms/Growers	3889	$791	$0.20	$1
111219	Sprouts (under "Other Vegetable (except Potato) and Melon Farming")[86]	Farms/Growers	87	$47	$0.54	$1
111339	Other Noncitrus Fruit Farming[85]	Farms/Growers	2249	$583	$0.26	$1
111419	Other Food Crops Grown Under Cover[85]	Farms/Growers	380	$76	$0.20	$1

[83] We use the 2017 SUSB, the last release that contained revenue data, and inflate revenues to 2020-dollar values using the GDP deflator.
Census Bureau. 2017 SUSB Annual Datasets by Establishment Industry. Updated 2021. Available from: https://www.census.gov/data/datasets/2017/econ/susb/2017-susb.html

[84] This rule exempts a number of firms based on size, which hence do not factor into this analysis. For discussion of exemption thresholds and related calculations, please see Sections I.E.7, II.D.2, and Appendix D.

[85] We base the small entity count and revenue estimate for this industry on the USDA National Agricultural Statistics Service data. The SBA defines produce farms small if their total revenues are lee than $1 million.

[86] We base the revenue estimate for sprout growers on Table 25 of the regulatory impact analysis for the prior Produce Rule (Ref. [53]). We take the average of the "Average Sales Volumes" in the third and fourth columns weighted by number of sprouting operations in each column. For our estimate of the number of covered small sprout growers under this final rule, 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. We then assume that the same proportion of sprout growers are small as among other growers of produce.

112310	Chicken Egg Production[87]	Farms (Eggs)	2500	$7,720	$3.09	$16.5
112511	Finfish Farming and Fish Hatcheries[88]	Aquaculture	310	$83	$0.27	$1
112512	Shellfish Farming[89]	Aquaculture	147	$35	$0.24	$1
114111	Finfish Fishing	Fishing	767	$555	$0.72	$22
114112	Shellfish Fishing	Fishing	771	$382	$0.50	$6
311340	Nonchocolate Confectionery Manufacturing	Manufacturing/ Processing	290	$4,155	$14.30	1,000
311351	Chocolate and Confectionery Manufacturing from Cacao Beans	Manufacturing/ Processing	109	$1,880	$17.20	1,250
311352	Confectionery Manufacturing from Purchased Chocolate	Manufacturing/ Processing	498	$3,824	$7.67	1,000
311411	Frozen Fruit, Juice and Vegetable Manufacturing	Manufacturing/ Processing	46	$2,956	$64.52	1,000

[87] 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. We use Table 75 from the summary report of the 2017 USDA Census of Agricultural to estimate the number of shell egg farms. Out of total shell egg farms, we first remove shell egg farms with less than 3,000 layers who are exempt. Out of the shell egg farms with more than 3,000 layers, we then estimate that the 99 percent of the farms are considered small by SBA standards.

[88] 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.

[89] 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). We assume 75% of mollusks are exempt as the raw bivalve molluscan shellfish under the NSSP are not covered by the rule, so we include 25% of mollusks. Finally, we multiply the average revenue by the total number of small farms to obtain the total revenue for all small farms.

311513	Cheese Manufacturing	Manufacturing/ Processing	238	$18,091	$75.89	1,250
311710	Seafood Product Preparation and Packaging	Manufacturing/ Processing	293	$6,953	$23.76	750
311811	Retail Bakeries	Manufacturing/ Processing	4392	$2,866	$0.65	500
311812	Commercial Bakeries	Manufacturing/ Processing	1143	$9,258	$8.10	1,000
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing	Manufacturing/ Processing	57	$1,343	$23.52	750
311821	Cookie and Cracker Manufacturing	Manufacturing/ Processing	114	$2,377	$20.83	1,250
311911	Roasted Nuts and Peanut Butter Manufacturing	Manufacturing/ Processing	87	$4,533	$52.19	750
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing	Manufacturing/ Processing	123	$2,995	$24.33	750
311991	Perishable Prepared Food Manufacturing	Manufacturing/ Processing	455	$3,279	$7.20	500
424410	General Line Grocery Merchant Wholesalers	Wholesalers/ Distributors	1273	$15,063	$11.83	250
424420	Packaged Frozen Food Merchant Wholesalers	Wholesalers/ Distributors	1260	$19,761	$15.69	200

424430	Dairy Product (except Dried or Canned) Merchant Wholesalers	Wholesalers/ Distributors	627	$7,183	$11.46	200
424450	Confectionery Merchant Wholesalers	Wholesalers/ Distributors	690	$3,558	$5.16	200
424460	Fish and Seafood Merchant Wholesalers	Wholesalers/ Distributors	1239	$9,085	$7.33	100
424480	Fresh Fruit and Vegetable Merchant Wholesalers	Wholesalers/ Distributors	2783	$30,826	$11.08	100
424490	Other Grocery and Related Products Merchant Wholesalers	Wholesalers/ Distributors	3645	$21,360	$5.86	250
445110	Supermarkets and Other Grocery (except Convenience) Stores	Retail Food Establishments	21597	$63,463	$2.94	$35
445120	Convenience Stores	Retail Food Establishments	13161	$15,051	$1.14	$32
445220	Fish and Seafood Markets	Retail Food Establishments	976	$1,206	$1.24	$8
445292	Confectionery and Nut Stores	Retail Food Establishments	679	$503	$0.74	$8
445230	Fruit and Vegetable Markets	Retail Food Establishments	938	$1,200	$1.28	$8
445299	All Other Specialty Food Stores	Retail Food Establishments	1913	$1,636	$0.85	$8

447110	Gasoline Stations with Convenience Stores	Retail Food Establishments	18182	$52,743	$2.90	$32
452311	Warehouse Clubs and Supercenters	Retail Food Establishments	2	$0.1	$0.08	$32
454210	Vending Machine Operators	Retail Food Establishments	1003	$1,310	$1.31	$12
493110	General Warehousing and Storage	Warehouses and Storage	1520	$3,230	$2.12	$30
493120	Refrigerated Warehousing and Storage	Warehouses and Storage	194	$648	$3.35	$30
493130	Farm Product Warehousing and Storage	Warehouses and Storage	104	$194	$1.86	$30
722310	Food Service Contractors	Retail Food Establishments	1513	$3,330	$2.20	$41.5
722320	Caterers	Retail Food Establishments	4776	$5,222	$1.09	$8
722330	Mobile Food Services	Retail Food Establishments	1360	$683	$0.50	$8
722410	Drinking Places (Alcoholic Beverages)	Retail Food Establishments	14082	$11,041	$0.78	$8
722511	Full-Service Restaurants	Retail Food Establishments	110150	$129,223	$1.17	$8
722513	Limited-Service Restaurants	Retail Food Establishments	74655	$85,238	$1.14	$12
722514	Cafeterias, Grill Buffets, and Buffets	Retail Food Establishments	2350	$3,046	$1.30	$30

722515	Snack and Nonalcoholic Beverage Bars	Retail Food Establishments	18630	$13,345	$0.72	$8

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

ERG's panel of industry experts, via the traceability costs elicitation, informs our estimates of small firm compliance costs reported in this section as well as those throughout this analysis (Ref. [4]). Whereas section II.F presented costs attributable to provisions of the final rule, this section breaks down costs small firms across different broad industry categories are facing. 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 will incur one-time costs to read and understand the rule. Depending on business activities and baseline practices, some but not all covered small entities will also incur one-time and recurring capital investment and training costs and a one-time cost to plan for compliance with the rule, in addition to various recurring annual recordkeeping costs.

Note therefore that the following primary, low, and high per-entity estimates throughout this section represent industry averages. Depending on business activities and baseline practices, individual entities will likely incur costs outside our range of estimates of industry averages for small businesses. For example, in forming our low and high estimates, we use low and high expert estimates of the proportion of small entities in various industries that will purchase equipment or software to comply with this rule.

Table 43 presents our estimates of the one-time cost per covered small entity. Among small firms, we expect one-time per firm compliance costs of about $2,975 for growers of

produce other than sprouts, $11,122 for growers of sprouts, $13,172 for shell egg farms, $17,496 for fishing and aquaculture producers, $18,780 for manufacturers, $30,609 for wholesalers, distributors, and warehouses, $693 for non-restaurant retailers, and $704 for restaurants.

Table 43. One-Time per Firm Compliance Costs of the Final Rule

	Primary	Low	High
Farms/Growers (Produce, non-sprouts)	$2,975	$1,151	$11,528
Farms/Growers (Sprouts)	$11,122	$3,507	$49,307
Farms (Shell Eggs)	$13,172	$5,641	$41,351
Fishing/Aquaculture	$17,496	$5,158	$42,446
Manufacturing/Processing	$18,780	$2,673	$50,694
Wholesalers/Distributors/Warehouses and Storage	$30,609	$2,816	$67,947
Retail - Not Restaurants	$693	$595	$946
Retail - Full and Limited-Service Restaurants	$704	$598	$946

As previously mentioned in section II.F "Costs of the Rule," growers of produce are the only category of growers among which we were able to estimate counts of establishments that do not initially pack. In all other categories of growers, we assumed that all establishments initially pack and therefore face the possibility of capital investment costs, which we estimate in II.F.3 "Costs of Capital Investment."

Using the same breakdown, Table 44 shows estimated cost per covered small entities, anualized over 20 years at a seven percent discount rate. Among small firms, we expect annualized compliance costs of about $849 for growers of produce other than sprouts, $4,295 for growers of sprouts, $3,801 for shell eggs farms, $3,941 for fishing and aquaculture producers, $4,625 for manufacturers, $8,027 for wholesalers, distributors, and warehouses, $402 for non-restaurant retailers, and $180 for restaurants.

Table 44. Annualized per Firm Compliance Costs of the Final Rule (Over 20 Years, Seven Percent Discount Rate)

	Primary	Low	High
Farms/Growers (Produce, non-sprouts)	$849	$144	$5,700
Farms/Growers (Sprouts)	$4,295	$581	$29,950

Farms (Shell Eggs)	$3,801	$674	$22,007
Fishing/Aquaculture	$3,941	$684	$14,197
Manufacturing/Processing	$4,625	$314	$20,668
Wholesalers/Distributors/Warehouses and Storage	$8,027	$349	$26,751
Retail - Not Restaurants	$402	$61	$1,636
Retail - Full and Limited-Service Restaurants	$180	$61	$729

We use the SUSB[90] data 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 45 shows our estimate of the one-time compliance costs as a percentage of revenue for small firms, broken down by broad industry categories. Among small firms, we expect one-time costs, as a percentage of annual revenue, of about 1.34% for growers of produce other than sprouts, 2.05% for growers of sprouts, 0.43% for shell egg farms, 3.31% for fishing and aquaculture producers, 0.23% for manufacturers, 0.37% for wholesalers, distributors, and warehouses, 0.04% for non-restaurant retailers, and 0.06% for restaurants.

Table 45. One-time per Firm Compliance Costs as a Percentage of Small Firm Annual Revenue

	Primary	Low	High
Farms/Growers (Produce, non-sprouts)	1.34%	0.52%	5.18%
Farms/Growers (Sprouts)	2.05%	0.65%	9.08%
Farms (Shell Eggs)	0.43%	0.18%	1.34%
Fishing/Aquaculture	3.31%	0.98%	8.03%
Manufacturing/Processing	0.23%	0.03%	0.62%
Wholesalers/Distributors/Warehouses and Storage	0.37%	0.03%	0.82%
Retail - Not Restaurants	0.04%	0.03%	0.06%
Retail - Full and Limited-Service Restaurants	0.06%	0.05%	0.08%

Using the same categorical breakdown, Table 46 shows the annualized values of our estimates of compliance costs over 20 years at a seven percent discount rate, again as a

[90] For small farms and producers of raw agricultural commodities, we estimate revenues based on the FSMA Produce Rule economic impacts analysis (Ref. [53]), the USDA National Agricultural Statistics Service, and the USDA Census of Aquaculture. We describe these estimates in the footnotes of Table 42.

percentage of the revenues of covered small firms. Over 20 years at a seven percent discount rate, we expect annualized costs, as a percentage of annual revenue, of about 0.38% for growers of produce other than sprouts, 0.79% for growers of sprouts, 0.12% for shell egg farms, 0.75% for fishing and aquaculture producers, 0.06% for manufacturers, 0.10% for wholesalers, distributors, and warehouses, 0.02% for non-restaurant retailers, and 0.02% for restaurants.

Table 46. Annualized per Firm Compliance Costs as a Percentage of Annual Revenue (20 Years, Seven Percent Discount Rate)

	Primary	Low	High
Farms/Growers (Produce, non-sprouts)	0.38%	0.06%	2.56%
Farms/Growers (Sprouts)	0.79%	0.11%	5.52%
Farms (Eggs)	0.12%	0.02%	0.71%
Fishing/Aquaculture	0.75%	0.13%	2.69%
Manufacturing/Processing	0.06%	0.00%	0.25%
Wholesalers/Distributors/Warehouses and Storage	0.10%	0.00%	0.32%
Retail - Not Restaurants	0.02%	0.00%	0.10%
Retail - Full and Limited-Service Restaurants	0.02%	0.01%	0.06%

In Table 47, we estimate that, on average, the total costs of the final rule per covered small firm over 20 years will be about $13,911. At a seven percent discount rate, our estimate of the present value of the average total costs of the final rule per covered small firm is about $8,010. Discounted at three percent, our estimate of the present value of the average total costs of the final rule per covered small firm is about $10,714. Over 20 years, the estimated annualized value of average costs of the final rule per small firm is about $756 when discounting at seven percent and $720 whan discounting at three percent.

Table 47. Costs of the Final Rule per Small Firm (Over 20 Years)

	Primary	Low	High
Total Costs of the Final Rule	$13,911	$1,244	$56,211
Present Value of Total Costs (7%)	$8,010	$953	$33,889
Present Value of Total Costs (3%)	$10,714	$1,093	$47,284
Annualized Value of Costs (7%)	$756	$90	$3,199
Annualized Value of Costs (3%)	$720	$73	$3,178

C. Alternatives to Minimize the Burden on Small Entities

As the vast majority (roughly 98 percent) of covered firms qualify as small entities, the analysis of regulatory alternatives for covered firms in Section II.J above effectively describes the effects of the alternatives on small entities. In particular, Alternative B in Section II.J would extend full exemption to retail food establishments and restaurants with an annual monetary value of food sold or provided during the previous 3-year period below $1 million (on a rolling basis), up from $250,000 in the rule as written. Alternative D would extend the compliance period for all firms from three to four years. Due to traceability relying on linkages throughout the supply chain, delaying the compliance date even for just small entities would delay the implementation of the final 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 final rule, it would also reduce the present value of the health benefits.

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V. Appendices

A. Food Traceability List (FTL)

As of this writing, the Food Traceability List includes the following foods (Table A.1). After publication of the final rule, the list can be updated using the procedure set forth in § 1.1465.

Table A.1. Food Traceability List

Foods	Description
Cheeses, other than hard cheeses, specifically:	
• Cheese (made from pasteurized milk), fresh soft or soft unripened	Includes soft unripened/fresh soft cheeses. Examples include, but are not limited to, cottage, chevre, cream cheese, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
• Cheese (made from pasteurized milk), soft ripened or semi-soft	Includes soft ripened/semi-soft cheeses. Examples include, but are not limited to, brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
• Cheese (made from unpasteurized milk), other than hard cheese[91]	Includes all cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
Shell eggs	Shell egg means the egg of the domesticated chicken.
Nut butters	Includes all types of tree nut and peanut butters. Examples include, but are not limited to, almond, cashew, chestnut, coconut, hazelnut, peanut, pistachio, and walnut butters. Does not include soy or seed butters.

[91] "Hard cheese" includes hard cheeses as defined in 21 CFR 133.150, colby cheese as defined in 21 CFR 133.118 and caciocavallo siciliano as defined in 21 CFR 133.111. Examples of hard cheese include, but are not limited to, cheddar, romano, and parmesan.

Cucumbers (fresh)	Includes all varieties of fresh cucumbers.
Herbs (fresh)	Includes all types of fresh herbs. Examples include, but are not limited to, parsley, cilantro, and basil. Herbs listed in 21 CFR 112.2(a)(1), such as dill, are exempt from the requirements of the rule under 21 CFR 1.1305(e).
Leafy greens (fresh)	Includes all types of fresh leafy greens. Examples include, but are not limited to, arugula, baby leaf, butter lettuce, chard, chicory, endive, escarole, green leaf, iceberg lettuce, kale, red leaf, pak choi, Romaine, sorrel, spinach, and watercress. Does not include whole head cabbages such as green cabbage, red cabbage or savoy cabbage. Does not include banana leaf, grape leaf and leaves that are grown on trees. Leafy greens listed in § 112.2(a)(1), such as collards, are exempt from the requirements of the rule under § 1.1305(e).
Leafy greens (fresh-cut)	Includes all types of fresh-cut leafy greens, including single and mixed greens.
Melons (fresh)	Includes all types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, muskmelon, and watermelon.
Peppers (fresh)	Includes all varieties of fresh peppers.
Sprouts (fresh)	Includes all varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts. Examples include, but are not limited to, alfalfa sprouts, allium sprouts, bean sprouts, broccoli sprouts, clover sprouts, radish sprouts, alfalfa & radish sprouts, and other fresh sprouted grains, nuts, and seeds.
Tomatoes (fresh)	Includes all varieties of fresh tomatoes.
Tropical tree fruits (fresh)	Includes all types of fresh tropical tree fruit. Examples include, but are not limited to, mango, papaya, mamey, guava, lychee, jackfruit, and starfruit. Does not include non-tree fruits such as bananas, pineapple, dates, soursop, jujube, passionfruit, Loquat, pomegranate, sapodilla, and figs. Does not include tree nuts such as coconut. Does not include pit fruit such as avocado. Does not include citrus, such as orange, clementine, tangerine, mandarins, lemon, lime, citron, grapefruit, kumquat, and pomelo.

Fruits (fresh-cut)	Includes all types of fresh-cut fruits. Fruits listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Vegetables other than leafy greens (fresh-cut)	Includes all types of fresh-cut vegetables other than leafy greens. Vegetables listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Finfish (fresh and frozen), specifically:	
• Finfish, histamine-producing species	Includes all histamine-producing species of finfish. Examples include, but are not limited to, tuna, mahi mahi, mackerel, amberjack, jack, swordfish, and yellowtail.
• Finfish, species potentially contaminated with ciguatoxin	Includes all finfish species potentially contaminated with ciguatoxin. Examples include, but are not limited to, grouper, barracuda, and snapper.
• Finfish, species not associated with histamine or ciguatoxin	Includes all species of finfish not associated with histamine or ciguatoxin. Examples include, but are not limited to, cod, haddock, Alaska pollock, salmon, tilapia, and trout.[92] Siluriformes fish, such as catfish, are not included.[93]
Smoked finfish (refrigerated and frozen)	Includes all types of smoked finfish, including cold smoked finfish and hot smoked finfish.[94]
Crustaceans (fresh and frozen)	Includes all crustacean species. Examples include, but are not limited to, shrimp, crab, lobster, and crayfish.
Molluscan shellfish, bivalves (fresh and frozen)[95]	Includes all species of bivalve mollusks. Examples include, but are not limited to, oysters, clams, and mussels. Does not include scallop adductor muscle. Raw bivalve molluscan shellfish that are (1) covered by the requirements

[92] For a more comprehensive list see Chapter 3 of the Fish and Fishery Products Hazards and Controls Guidance at https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls.

[93] Data for catfish were excluded from the Risk-Ranking Model because Siluriformes fish (such as catfish) are primarily regulated by the U.S. Department of Agriculture.

[94] "Smoked finfish" refers to a finfish product that meets the definition of a smoked or smoke-flavored fishery product in 21 CFR 123.3(s).

[95] Per 21 CFR 123.3(h) *molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

	of the National Shellfish Sanitation Program; (2) subject to the requirements of 21 CFR part 123, subpart C, and 21 CFR 1240.60; or (3) covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish are exempt from the requirements of the rule under § 1.1305(f).
Ready-to-eat deli salads (refrigerated)	Includes all types of refrigerated ready-to-eat deli salads. Examples include, but are not limited to, egg salad, potato salad, pasta salad, and seafood salad. 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 (Ref. [23]). We report the summary of these data, covering the 12-year period from January 2009 through December 2020, in columns 1-4 of Table B.1 in this appendix. We do not use CDC outbreak data for our estimates because CDC data include illnesses resulting from improper food handling, as well as illnesses associated with foods not regulated by FDA. We note that CORE data include more illnesses than those attributable to covered food products. These include adverse reactions and fungus-related illnesses. We therefore use only a subset of CORE data on foodborne illness outbreaks associated with covered foods.[1] Based on these data, of 31 known foodborne illness-causing pathogens, 14 are commonly associated with foods currently designated by FDA on the FTL. We list these pathogens in Table B.1.

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 below. 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 (Ref. [24]). Column 5 contains Scallan *et al.'s* underdiagnosis multipliers specifically for hospitalizations and deaths, taken from the authors' Technical Appendix 3 (Ref. [24]). 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 illnesses, hospitalizations, and deaths from covered foods over the 12-year period.

Scallan *et al.* (2011a) does not provide underreporting multipliers for three pathogens (*Ciguatoxins*, *Listeria*, *Norovirus* and *Salmonella*), and two contaminants (Ciguatoxin or Scombrotoxin), and for Norovirus, *Ciguatoxins*, and *Scombrotoxins* the authors do not provide underdiagnosis multipliers. Furthermore, at least two foodborne illness-causing agents (*Ciguatoxins and Scombrotoxin*) do 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. [25]).

Following Scallan *et al.'s* (2011a) treatment of other pathogens/contaminants, we assume 100 percent reporting for pathogens/contaminants without underreporting multipliers and 100 percent diagnosis for those without underdiagnosis multipliers (Ref. [24]).[2] To estimate the number of annual illnesses, hospitalizations, and deaths caused by each pathogen/contaminant, we divide columns 8, 9, and 10 of Table B.1 by 12 years. Columns 11, 12, and 13 provide the resulting annual estimates. We estimate that these pathogens/contaminants cause 153,807 illnesses 364, hospitalizations, and 14 deaths annually via consumption of covered foods.

According to Scallan *et al.* (2011b) and CDC[3], 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/contaminants (Ref. [26]). We multiply the number of hospitalizations and deaths by 2.13 (= 1/ (1 - 0.53)) and 2.28 (= 1/ (1 - 0.58)) respectively to account for unspecified agents. Not considering the burden caused by unspecified and unknown pathogens/contaminants could result in underestimation of covered foods caused illnesses. Following Scallan *et al*. (2011b), the estimated number of annual illnesses in

Table **5** (153,807) before adjusting it for the number of illnesses from unspecified and unknown agents constitute only 20 percent of all illnesses [26].

In our estimates we assume the same ratios for unidentified to identified illnesses due to covered foods. The assumption is consistent with FDA's past regulatory impact analyses, including the RIA for the 2015 final rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. We made this assumption 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/contaminants, attributable to FTL products and ingredients would be lower than the percentage of illnesses from unidentified pathogens/contaminants attributable to same products.

The last row of Table B.1 present estimates of total illnesses, hospitalizations, and deaths from covered foods after scaling for unspecified and/or unknown agents. We estimate that the total number of illnesses from known toxins and pathogens is 153,807 and from unspecified and unknown agents is 615,226 (= 153,807 x (1-0.2)/0.2), which yields a total of 769,033 illnesses (= 153,807 + 615,226).[96] We used these estimates in our Final Regulatory Impact Analysis. We also scale up the number of hospitalizations and deaths to account for unspecified agents and estimate that in total 775 hospitalizations (= 364 / (1 - 0.53)) and 33 deaths (= 14 / (1 - 0.58)) are caused by covered foods annually. Table B2. Shows the estimated range of the burden of foodborne illnesses and cost per illness associated with covered foods.

[96] Figures are rounded to the nearest dollar.

Table B.1. Illnesses, Hospitalizations, and Deaths Attributable to Illness-Causing Pathogens Associated with Covered 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 (2009-2020)			Estimated Annual Total (2009-2020)		
		(2) *Illnesses*	(3) *Hospitalizations*	(4) *Deaths*				(8) *Total Illnesses*	(9) *Hospitalization*	(10) *Deaths*	(11) *Total Illnesses*	(12) *Hospitalization*	(13) *Deaths*
Campylobacter	1	25	0	0	1	1	30.3	758	0	0	63	0	0
Ciguatoxin	8	38	4	0	1	1	9.91	377	4	0	31	0	0
Cyclospora	14	3658	122	0	2	1	83.1	303,980	244	0	25,332	20	0
E. coli (STEC) O157	27	993	396	10	2	25.5	26.1	660,891	792	20	55,074	66	2
E-Coli (STEC) non-O157	9	221	62	0	2	25.5	106.8	601,871	124	0	50,156	10	0
Hepatitis A Virus	1	16	8	2	2	1.1	9.1	160	16	4	13	1	0
Listeria	19	325	310	58	2	1	2.3	748	620	116	62	52	10
Norovirus	8	329	5	0	1.5	1	29.3	9,640	8	0	803	1	0
Salmonella typhoidal	81	180	20	0	1	1	13.3	2,394	40	0	200	3	0
Salmonella non-typhoidal	5	8193	1240	14	2	1	29.3	240,055	2480	28	20,005	207	2
Scombrotoxin	21	105	3	0	1	1	12.21	1,282	3	0	107	0	0
Vibrio-para	8	98	14	0	2	1.1	142.4	15,351	28	0	1,279	2	0
Vibrio-Cholerae	1	12	0	0	2	1.1	33.1	437	0	0	36	0	0
Yersinia enterocolitica	2	63	7	0	2	1	122.8	7,736	14	0	645	1	0
Total from specified pathogens	**205**	**14,256**	**2,192**	**84**				**1,845,679**	**4,374**	**168**	**153,807**	**364**	**14**
Total including unspecified/unidentified pathogens								**9,228,394**	**9,261**	**400**	**769,033**	**775**	**33**

Table B2. Estimated Range of the Baseline Economic Burden of Foodborne Illnesses Associated with Covered Foods (2020$)

	Estimated Annual Cases	Cost of Illness: Primary	Cost of Illness: Low	Cost of Illness: High	Total: Primary	Total: Low	Total: High
Campylobacter	63	$4,748	$2,487	$6,971	$299,718	$156,992	$440,044
Ciguatoxin	31	$31,402	$15,333	$47,208	$985,447	$481,175	$1,481,466
Cyclospora cayentanensis	25,332	$4,451	$2,092	$6,771	$112,751,174	$52,993,812	$171,520,602
E. coli (STEC) O157	55,074	$13,757	$8,122	$19,299	$757,656,629	$447,313,160	$1,062,878,192
E-Coli (STEC) non-O157	50,156	$2,506	$1,305	$3,687	$125,690,811	$65,453,515	$184,924,988
Hepatitis A Virus	13	$58,440	$28,640	$87,752	$779,979	$382,249	$1,171,197
Listeria Monocytogenes	62	$1,987,005	$991,975	$2,965,723	$123,773,853	$61,791,776	$184,739,829
Norovirus	803	$487	$281	$690	$391,211	$225,730	$554,283
Salmonella typhoidal	200	$7,116	$5,380	$8,824	$1,419,642	$1,073,310	$1,760,388
Salmonella non-typhoidal	20,005	$7,248	$3,800	$10,639	$144,993,160	$76,017,385	$212,828,673
Scombrotoxin	107	$548	$485	$611	$58,547	$51,816	$65,278
Vibrio-parahaemolyticus	1,279	$2,636	$1,300	$3,951	$3,372,041	$1,662,995	$5,054,225
Vibrio-Cholerae	36	$1,675	$971	$2,367	$60,987	$35,354	$86,182
Yersinia enterocolitica	645	$6,255	$3,000	$9,457	$4,032,599	$1,934,100	$6,096,928
(i) Subtotal/Weighted Average (rounded): Known Pathogens	**153,807**				$1,276,265,797	$709,573,368	$1,833,602,274
Average Cost per Illness		$8,298	$4,613	$11,921			
(ii) Unidentified/ Unspecified Pathogens	**615,226**				$5,105,063,190	$2,838,293,471	$7,334,409,096
(iii) Total cases (i) & (ii) (rounded)	**769,033**	$8,298	$4,613	$11,921	**$6,381,328,987**	**$3,547,866,839**	**$9,168,011,370**

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

The dataset (Table C.1) represents 23 foodborne outbreaks from 2008 – 2019 coordinated by FDA's Emergency Coordination Response Team (ECRT) (2008 – 2010) and FDA's Coordinated Outbreak Response and Evaluation (CORE) Network (2011 – 2019), yielding 23 Public Health Benefit Case Studies[97]. Each outbreak included in this analysis:

- involved a major pathogen/contaminant (*Salmonella*, Escherichia coli (STEC), *Listeria monocytogenes*, *Cyclospora cayetanensis, Vibrio parahemolyticus and Scombrotoxin*);
- 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.

[97] Outbreaks numbered 1-15 in Table C.1 were used in the PRIA appendix C. We update this analysis with 6 additional outbreaks numbered 17 through 23 (2018-2019) from FDA's Coordinated Outbreak Response and Evaluation (CORE) Network.

- 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 covered foods. 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 food product being implicated as the cause of an outbreak during that timeframe.

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

No.	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
1	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
2	2008	*Salmonella*	Saintpaul	Hot Peppers	5/28/2008	6/1/2008	7/17/2008	8/5/2008	8/28/2008	https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5734a1.htm
3	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
4	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/enteritidis/se_timeline_092010.pdf
5	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
6	2011	*Listeria*	*monocytogenes*	Cantaloupe	9/7/2011	9/11/2011	11/23/2011	12/16/2011	8/27/2012	https://www.cdc.gov/listeria/pdf/listeriosis-timeline102711.pdf
7	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
8	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
9	2013	*Cyclospora*	*cayetanensis*	Leafy Greens (1)	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
10				Cilantro (1)		8/13/2013	11/7/2013			
11	2016	*E. coli*	O157:NM	Alfalfa Sprouts	2/18/2016	2/19/2016	3/22/2016	4/5/2016	3/5/2016	https://www.cdc.gov/ecoli/2016/o157-02-16/index.html
12	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
13	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
14	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
15	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

No.	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
16	2018	*Salmonella*	Braenderup	Shell Eggs	3/19/2018	3/22/2018	4/3/2018	6/13/2018	7/26/2019	https://www.cdc.gov/salmonella/Braenderup-04-18/index.html
17	2018	*Vibrio*	*parahaemolyticus*	Crab Meat	7/2/2018	7/10/2018	8/3/2018	10/24/2018	9/27/2018	https://www.cdc.gov/vibrio/investigations/vibriop-07-18/index.html
18	2018	*Salmonella*	Concord	Tahini	11/9/2018	11/14/2018	11/23/2018	2/21/2019	2/27/2019	https://www.cdc.gov/salmonella/concord-11-18/index.html
19	2019	*Salmonella*	Newport	Ground Tuna	2/26/2019	2/26/2019	4/9/2019	5/16/2019	5/22/2019	https://www.cdc.gov/salmonella/newport-04-19/epi.html
20	2019	*Salmonella*	Concord	Tahini	4/22/2019	4/25/2019	5/1/2019	6/27/2019	6/26/2019	https://www.cdc.gov/salmonella/concord-05-19/index.html
21	2019	*E. coli*	O121:H19; O103:H2	Ground Bison	7/1/2019	7/2/2019	8/19/2019	9/11/2019	9/13/2019	https://www.cdc.gov/ecoli/2019/bison-07-19/index.html
22	2019	*Scombrotoxin*		Tuna	10/1/2019	10/4/2019	11/14/2019	1/15/2020	1/24/2020 [(2)]	https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-scombrotoxin-fish-poisoning-yellowfinahi-tuna-november-2019
23	2019	*Listeria*	*monocytogenes*	Hard Boiled Eggs	12/10/2019	12/10/2019	1/9/2020	2/20/2020	3/4/2020	https://www.cdc.gov/listeria/outbreaks/eggs-12-19/index.html

[(1)] Outbreaks number 9 and 10 represent two concurrent outbreak investigations attributed to the same pathogen/contaminant but different commodities.

[(2)] Outbreak number 22 only shows FDA posting - no CDC post for this outbreak.

D. Estimation of the Number of Covered Entities

To obtain the number of covered entities by the traceability rule, we use several sources. These include the 2017 SUSB and the 2017 North American Product Classification System (NAPCS) data from the U.S. Census, data and summary reports from the 2017 Census of Agriculture, and the 2018 Census of Aquaculture from the 2017 USDA National Agricultural Statistics Service (NASS) (Ref. [13] [14]). All datasets used in this analysis were the latest available to us as of January 2022.

Produce Farms

For the number of produce farms and sales of covered foods, we use the raw 2017 USDA NASS data. We first derive total number of produce farms by NAICS code (111219, 111339, and 111419). We also derive the number of produce farms that are fully exempt by their annual sales with less than $25,000, and by selling directly to consumers. We then derive the number of farms eligible for both exemption criteria. We first subtract the estimates of the fully exempt farms (if their sales are below $25,000 or they sell their covered foods directly to consumers) from the total number of produce farms. We separate out farms that are packers from the total number of produce farms as they are not exempt by the rule[98] and still exclude packers who are eligible for the sales exemption (annual sales less than $25,000) or sell covered food directly to consumers. To estimate the number of produce farms covered by the rule, we then multiply the remaining number of farms in NAICS codes 111219, 111339, and 111419 by the FTL share to

[98] To account for farms with packing operations, we use an indicator variable of on-farm packing facilities from the 2017 USDA NASS data.

account only for farms producing FTL foods. Due to lack of information on how many farms produce covered foods, we assume that all covered produce farms produce foods on the FTL.[99]

For sprout growers, 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 that we believe to be covered by this rule.

Shell Egg Farms Estimates

We derive the number of shell egg farms and sales of shell eggs sold directly to consumers, and number of layers less than 3,000 from 2017 USDA NASS summary report.[100] Out of 232,500 shell egg farms, most of the farms (227,340 shell egg farms) have less than 3,000 layers that approximately 98 percent of the total shell egg farms will be exempt by the final rule. According to the 2017 NASS summary report, 8,107 shell egg farms sell directly to consumers, which is about 3 percent of the total shell egg farms. We assume that the remainder shell egg farms with 3,000 layers or more do not sell directly to consumers as most of the covered farms are large farms. We therefore estimate that 3,782 shell egg farms (2 percent of the total shell egg farms) are covered by the rule. Because we do not have additional information on the number of packers out of the remainder shell egg farms (2 percent), we assume that all of these farms are packers. As mentioned in the section II. I, we may overestimate the number of shell egg farms covered by the rule as we assume direct to consumer sales among the farms with more than 3,000 layers are zero percent. Similar with the produce farms, we multiply the number of covered shell egg farms by the FTL share to account for shell egg farms producing covered

[99] Because we are unsure to the exact the number of produce farms who manufacture, process, pack, or hold covered foods, we use probable estimates using triangular distribution parameter estimates assuming 0,1,1, resulting in an expected value of 0.67.

[100] We use Table 75 from the summary report of the 2017 USDA NASS to get the estimates (Ref. [13]). https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/usv1.pdf

foods. Due to lack of information on how many farms produce covered foods, we assume that all of the covered shell egg farms produce covered foods.[101]

Aquaculture Farms Estimates

We derive total number of finfish and shellfish farms from the summary report of the 2018 Census of Aquaculture.[102] We consider finfish and shellfish for covered aquaculture categories. As bivalve molluscan shellfish under the NSSP are not covered in the traceability rule (75 percent of mollusks), we assume 25 percent of mollusks will be covered by the final rule. According to the summary report of the 2018 Census of Aquaculture, 2 percent of finfish and 5 percent of shellfish by point of first sales are direct sales to consumers. We are unable to separate the aquaculture farms sell directly to consumers from those fully exempt by sales (less than $25,000) from the summary report of the 2018 Census of Aquaculture. Given that 2 percent of finfish and 5 percent of shellfish farms total sales fall under less than $100,000 category of farms, we only include finfish and shellfish farms with annual sales greater than $100,000 to calculate the total number of covered aquaculture farms (percentage of total sales of finfish and shellfish less than $100,000 are 2.5 percent and 7 percent, respectively).

We are uncertain of how many aquaculture farms are packers, so we assume that all of covered aquaculture farms are packers. Similar with the produce and shell egg farms, we multiply the number of covered aquaculture farms by the FTL share to account for aquaculture

[101] Because we are unsure to the exact the number of shell egg farms who manufacture, process, pack, or hold covered foods, we use probable estimates using triangular distribution parameter estimates assuming 0,1,1, resulting in an expected value of 0.67.

[102] We use Table 9 for value of sales by sales category and Table 21 for direct sales to consumers from the summary report of the 2018 Census of Aquaculture (Ref. [14]): https://www.nass.usda.gov/Publications/AgCensus/2017/Online_Resources/Aquaculture/Aqua.pdf

farms producing foods on the FTL. Additionally, we assume 100 percent of the covered aquaculture farms produce covered foods.[103]

Manufacturers, Wholesalers, Warehouses, and Retailers

For manufacturers, wholesalers, warehouses, and retailers, we use the 2017 Census data to estimate the total number of firms and establishments by North American Industry Classification System (NAICS) industry category.[104] We first calculate the number of retail food establishments and restaurants that are fully exempt by their average annual food sales below $250,000. Then we subtract the number of the exempt entities from the total number of entities by each NAICS industry category. We use the 2017 Census data to approximate the number of entities who manufacture, process, pack, or hold covered foods of each NAICS industry category then divide them by the total entities by NAICS category to get a FTL share of each industry.[105] Then we multiply the FTL share by the number of the entities after removing the fully exempt entities (both FTL and non-FTL food products) to estimate the final number of covered entities with foods on the FTL. To estimate the total number of covered establishments, we use triangular distribution of the FTL share.[106] We then multiply the ratio of total number of firms to total number of establishments to estimate the total number of firms covered by the rule.

[103] Because we are unsure to the exact the number of aquaculture farms who manufacture, process, pack, or hold covered foods, we use probable estimates using triangular distribution parameter estimates assuming 0,1,1, resulting in an expected value of 0.67.

[104] As the Census data only cover primary NAICS, we may underestimate the total number of covered entities by not counting non-primary NAICS.

[105] The share is based on the ratio of FTL NAPCS establishments sum over total NAICS establishments. The share of the FTL food products ranges from 0 (non-FTL foods) to 1 (100 percent of FTL foods). When the share of the FTL foods related to NAPCS code is larger than total per NAICS, we truncated to 1. The shares of the FTL using 2017 Census data may be underestimated because we only include the numbers that were available from the 2017 Census data.

[106] Because we are unsure of the exact number of establishments who manufacture, process, pack, or hold covered foods, we use probable estimates using triangular distribution to estimate the FTL shares. We assume a minimum of 0, a maximum of 1, and a mode equal to the FTL share of each NAICS industry category (0; non-FTL foods to 1; 100 percent of FTL foods), resulting in expected values between 0 and 0.67.

Difference Between Proposed and Final RIA Estimates

The overall estimates of the number of covered entities in this RIA are lower than our previous Option 2 estimates (98,272 fewer firms and 82,325 fewer establishments, see Table D.1). For example, compared to our previous Option 2 estimates, the estimated numbers of covered produce farms, egg farms, and aquaculture farms in this RIA are lower by 11,152 fewer firms and 11,151 fewer establishments. Coverage estimates in this RIA are higher than our previous Option 1 estimates (135,581 more firms and 152,270 more establishments, see Table D.1).

The first reason for this difference is that for the final analysis, we use different data sources than those used in our preliminary analysis. We use 2017 USDA NASS data in this RIA while we previously used 2012 USDA NASS data. For egg and aquaculture farms, we derive estimates from the 2017 USDA NASS summary report and use the 2017 USDA NASS data for the produce farms in this RIA. We also use 2017 SUSB data from the Census instead of the 2012 SUSB data.

Other reasons for this difference are explained by changes to the proposed requirements. While the proposed rule exemptions for retail food establishments and restaurants were based on the threshold of 10 FTEs, the final rule exempts retail food establishments and restaurants with annual sales below $250,000. The final rule also adds several exemptions, such as the exemption for molluscan shellfish. Furthermore, the final rule specifies that a multi-ingredient food is covered only if the FTL ingredient it contains is in the same form in which it appears on the FTL (e.g., frozen pizza with a spinach topping is not covered because only fresh spinach is on the FTL, not frozen spinach). Consequently, some businesses under certain NAICS codes that were

previously included in PRIA estimates are now excluded in our final analysis (NAICS 311412, 311421-311423, 311520, 311824, 311942, 445292, and 454110).

Additionally, we calculate the share of the covered entities handling foods on the FTL by counting the number of entities that we believe manufacture, process, pack, or hold covered foods by each NAICS industry category. In this analysis, we added the number of these entities by NAICS category then divide the sum by the total number of establishments by NAICS category to get the ratio of FTL establishments. Hence, the FTL shares in this analysis are lower than the preliminary analysis. Table D.1 below contains a summary of the changes in the estimates of the preliminary and final analyses by industry.

Table D.1. Number of Affected Entities of the Proposed and Final Rule by Industry Sector

Type	Preliminary RIA (Option 1)		Preliminary RIA (Option 2)		Final RIA	
	Number of Firms	Number of Establishments	Number of Firms	Number of Establishments	Number of Firms	Number of Establishments
Farms /Aquaculture / Growers	22,912	22,947	22,912	22,947	11,760	11,796
Manufacturers / Processors / Packers	10,623	11,557	10,623	11,557	7,991	8,650
Wholesalers / Distributors	18,686	24,224	18,686	24,224	12,007	15,101
Warehouse and Storage	3,519	6,880	3,519	6,880	2,504	5,176
Retail Food Establishments and Restaurants	132,551	266,246	366,404	500,841	289,609	443,401
Total	**188,291**	**331,854**	**422,144**	**566,449**	**323,872**	**484,124**

E. Changes to Cost Estimation from the Preliminary Analysis

To inform our analysis of the costs of this final rule, ERG completed an elicitation of industry experts in December 2021 and January 2022 (Ref. [4]). Experts provided both

qualitative and quantitative input based on the proposed version of the rule, with additional brief definitions of some new CTEs in their draft-final state at the time of the traceability costs elicitation. Input included describing anticipated cost-incurring compliance activities and expenditures, estimating variables related to cost calculations, and further commenting on factors likely to influence costs of the rule.

Among changes to one-time costs, our estimates of costs to read and understand the rule, in section II.F.2 "Costs of Reading and Understanding the Rule," now account for three employees reading the rule at large firms, versus only one employee regardless of firm size in the preliminary analysis. We consider reading costs in this section to be separate from the costs to identify FTL products and plan for compliance, which we estimate in section II.F.5.a "Traceability Plan." Additionally, we note that the final rule and preamble are about four times as long in total number of words as the proposed versions, nearly quadrupling reading time per affected employee.

Unlike in the preliminary analysis, in which we only considered one-time capital costs, we now also consider recurring capital costs for those cases where capital investments made towards compliance with the rule result in higher operation and maintenance expenses than covered entities would otherwise face (section II.F.3 "Costs of Capital Investment"). Whereas we previously based estimates per entity on equipment price information extrapolated from literature, we now base cost per entity on expert estimates elicited by ERG (Ref. [4]). We now also explicitly account for the proportion of establishments requiring additional capital using estimates provided by the expert panel.

Unlike in the preliminary analysis, in which we considered only one-time training costs, we now also consider recurring training costs for those cases where new training is more time

consuming than what covered entities would otherwise have implemented as a refresher for continuing employees and because of turnover (section II.F.4 "Costs of Training"). Whereas we previously proxied for the cost of a training program based on pricing offered for a single online training course, we now use expert estimates elicited by ERG. For estimating employee labor costs, we now use estimates by the expert panel to inform numbers of employees and training hours in place of our previous assumptions. We now also explicitly account for the proportion of establishments requiring additional training using estimates by the expert panel.

The final rule replaces the proposed requirement for traceability program records with the requirement for a traceability plan. We previously estimated a recurring cost of this provision in addition to a one-time cost because the proposed program records required operational information that we expected to require frequent updates. In particular, these requirements included the traceability product identifiers and product descriptions of each FTL food shipped by an establishment. Since the traceability plan instead requires more general descriptions of procedures, which we do not expect will change often at a typical establishment, we consider the traceability plan to impose a one-time cost (section II.F.5.a "Traceability Plan") and the routine as needed updates to take de minimis time. While the final rule requires firms to update their traceability plans "as needed," possible future updates to the FTL, which might require some firms to identify additional products, will only take effect two years after publication in the Federal Register. We expect that this delay will allow firms to make necessary updates within the scope of routine updates to standard operating procedures in the normal course of business. Additionally, we now incorporate estimates by the expert panel on the number of employees who will work on planning for traceability and the baseline proportion of covered entities engaging in traceability practices.

The final rule also makes several changes to CTEs that affect our estimates of recurring recordkeeping costs (section II.F.5 "Costs of Recordkeeping"). The final rule introduces harvesting, cooling, initial packing, and first land-based receiving as CTEs, while removing growing and first receipt CTEs and redefining transformation to include events previously referred to as creation. As a result, we now estimate recordkeeping costs for each of these new CTEs. Whereas in the preliminary analysis we assumed counts of traceability lots handled per entity with regard to each CTE, we now base these counts on estimates, by the expert panel, of the number of FTL lots handled by establishments in different categories of industries (Ref. [4]).

Additionally, the final rule changes each CTE's corresponding set of KDEs, which we describe in the subsections under II.F.5 "Costs of Recordkeeping." While in this analysis we newly base estimates of recordkeeping time on input from multiple experts, we reconcile expert input with changes between the final and proposed KDEs, as well as baseline electronic recordkeeping and improved efficiency from expected capital investments (described in section II.F.3 "Costs of Capital Investment").

Notably, as covered entities under the final rule do not assign traceability lot codes prior to initial packing of raw agricultural commodities or first land-based receiving of food obtained from a fishing vessel, we no longer estimate costs on a lot-level basis prior to these steps. We now also exclude entities upstream of these new CTEs in the supply chain from our counts of entities affected by shipping and receiving requirements, which do not apply prior to initial packing and first land-based receiving. However, we account for information that the final rule requires the newly defined harvesters and coolers to provide.

F. Case Studies Considered by Experts in Estimating Reduced Costs from Avoiding Overly Broad Recalls Following an FDA Issued Public Health Advisory.

We present case studies of overly broad recalls used to help experts in their estimates considering how more-targeted recalls might affect some of the identified case study costs. The following case studies include 2008 tomato recall and the more recent 2018 and 2019 leafy green recalls.

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.[107] 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 shelves and customers began ordering their customary dishes at restaurants without tomatoes.[108] 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

[107] Press Release, FDA, FDA Warns Consumers Nationwide Not to Eat Certain Types of Raw Red Tomatoes (June 7, 2008) [hereinafter FDA Recall June 7].
[108] *Salmonella scare hold the tomato,* Chicago Tribune (Illinois), June 10, 2008. https://www.chicagotribune.com/news/ct-xpm-2008-06-10-0806090798-story.html

tracebacks and provided timely information that there was no common source of tomatoes (Ref. [49]). Ultimately the source of the outbreak was later attributed to jalapeño and serrano peppers produced in Mexico (Ref. [50]). The investigation showed that jalapeño peppers were a major source of contamination and that serrano peppers also were a source.[109] 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.[110]

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

[109] 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

[110] 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.

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.[111] 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.[112] 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.

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

[111] https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-romaine-november-2018
[112] 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

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 requested 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. [30]).

d) Outbreak Investigation of Salmonella: Shell eggs (May 2010- November 2010). The 2010 shell eggs Salmonella contamination illustrates how conducting a food recall can be 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. [19]). Because of the length of time it took to identify the food vehicle, this outbreak was the largest reported foodborne disease outbreak since the early 1970s when outbreak surveillance was established (Ref. [20] [21]). The outbreak resulted in many illnesses and proved to be costly to businesses, something which could have otherwise been mitigated or avoided with better tracing tools and standardized records.

At the start of the outbreak investigation, 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.

Whenever epidemiological investigations fail to clearly implicate possible ingredients or foods that are causing an outbreak, 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. [51]). 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. Such a process is labor-intensive and time consuming.

In absence of standardized records, linking shipments through the supply chain and back to their sources, the time taken to identify implicated foods can be unacceptably long leading to larger and more costly disease outbreak. In the shell egg-related salmonella outbreak, some district offices had to return some clusters to the firm for additional clarification on linking incoming to outgoing product shipments, which prolonged and complicated 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 because of this outbreak. The number of illnesses could have been meaningfully reduced if a better tracing system had been in place.

G. Detailed Calculations Used for Estimating Benefits from Avoiding Overly Broad Recalls Following an FDA Issued Public Health Advisory

The final step in the series of calculations used in estimating the benefits from reduction in overly broad recalls, involves assigning parameters to corresponding probability density functions to characterize the variability inherent in the costs estimates and also for the inherent uncertainty in the estimates for the number of firms characterized by their respective cost category. Column L for firms in Table G.1 shows the minimum, central and maximum estimate for the range of affected firms from Table 20. We characterize variables in Column L as a lognormal distribution with parameters mean and standard deviation. For Column K, or Cost per firm we characterize variability from expert cost estimates using a Beta Subjective distribution which uses parameters, minimum, median, average, and maximum values as shown in Table G1.[113] Column M shows all the intermediate calculations allowing us to estimate a weighted sum of $862 million as a central estimate of total averted annual costs of overly broad recalls.

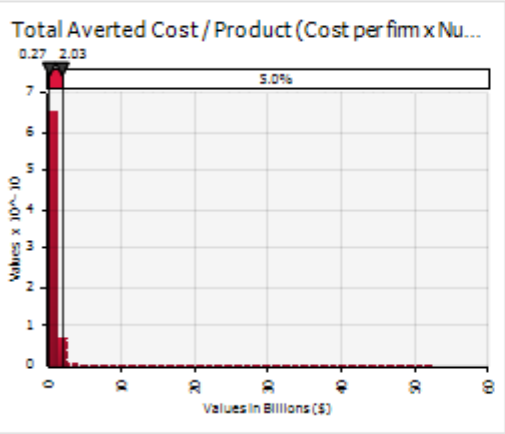
Table G1.- Estimate for Averting Costs due to Overly Broad Recalls (by Industry)

	Cost per firm ($1,000) (K)	Distribution	Firms (L)				Distribution	Product (Cost per firm x Number of firms) ($1,000) (M)	Calculation
			min	avg	max	Standard deviation			
Producer									
Low estimate	$8,915	riskbeta subj	2	8	73	39	lognormal	$68,760	(a1) low
Most likely estimate	$22,041	riskbeta subj	2	10	83	45	lognormal	$193,090	(b1) middle
High estimate	$61,098	lognormal	2	2	4	1	lognormal	$122,197	(c1) high

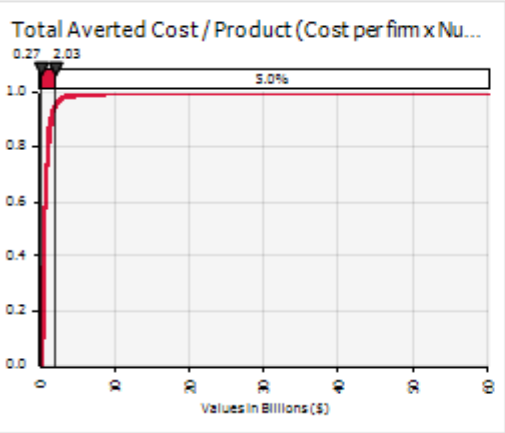
[113] For producer high estimate the median is larger than the mean, and for this reason we characterize it as a lognormal distribution.

Shipper or Distributor									
Low estimate	$1,223	riskbeta subj	2	11	18	8	lognormal	$13,732	(a2) low
Most likely estimate	$3,231	riskbeta subj	2	10	17	8	lognormal	$33,320	(b2) middle
High estimate	$7,552	riskbeta subj	-	1	2	1	lognormal	$8,886	(c2) high
Restaurant									
Low estimate	$73	riskbeta subj	39	193	311	136	lognormal	$13,969	(a3) low
Most likely estimate	$731	riskbeta subj	66	329	53	156	lognormal	$240,326	(b3) middle
High estimate	$3,057	riskbeta subj	1	3	4	2	lognormal	$7,650	(c3) high
Non-Restaurant Retailer									
Low estimate	$354	riskbeta subj	18	88	143	63	lognormal	$31,359	(a4) low
Most likely estimate	$2,172	riskbeta subj	11	55	89	39	lognormal	$119,897	(b4) middle
High estimate	$9,134	riskbeta subj	-	1	1	1	lognormal	$8,323	(c4) high
Cost of Advisory / Event -Sum, using									
- Number of firms incurring low estimate			61	301	545			$127,820	A = sum (a) low
- Number of firms incurring most likely estimate			81	404	242			$586,633	B = sum (b) middle
- Number of firms incurring high estimate			3	7	11			$147,055	C = sum (c) high
Central Cost Value (Sum)			**145**	**711**	**798**			**$861,508**	**Total =A + B+ C**
Annual Benefit from avoiding overly broad recalls following FDA advisories (Central Value)								**$861,508**	

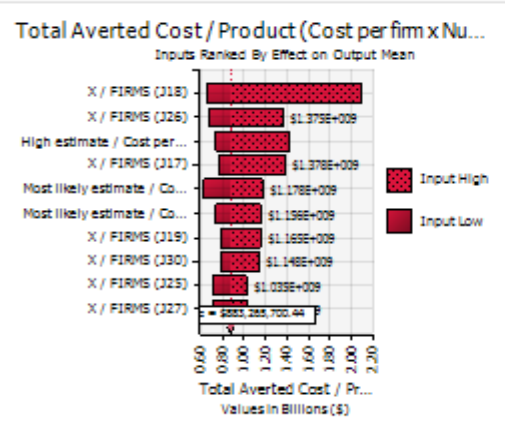
Table G2. Simulation and Sensitivity Analysis Results for Averted Costs of an Overly Broad Recall.



Simulation Summary Information	
Workbook Name	Benefits from Broad recalls or advisories - I
Number of Simulations	1
Number of Iterations	10000
Number of Inputs	209
Number of Outputs	27
Sampling Type	Latin Hypercube
Simulation Start Time	2/13/2022 11:48
Simulation Stop Time	2/13/2022 12:06
Simulation Duration	00:17:15
Random # Generator	Mersenne Twister
Random Seed	673304825
Total Errors	14640
Collect Distribution Samples	All
Convergence Testing	Disabled
Smart Sensitivity Analysis	Enabled



Summary Statistics for Total Averted Cost / Product (Cost per firm x Number			
Statistics		**Percentile**	
Minimum	$77,237,776.67	**1.0%**	$185,186,199.80
Maximum	$52,396,774,232.02	**2.5%**	$223,340,399.39
Mean	$883,265,700.44	**5.0%**	$268,102,920.29
Std Dev	$1,176,981,080.36	**10.0%**	$322,344,609.06
Variance	1.38528E+18	**20.0%**	$406,130,136.89
Skewness	17.58843227	**25.0%**	$447,949,839.84
Kurtosis	557.9720898	**50.0%**	$660,508,926.31
Median	$660,508,926.31	**75.0%**	$991,678,046.30
Mode	$475,754,707.02	**80.0%**	$1,111,032,350.40
Left X	$268,102,920.29	**90.0%**	$1,533,360,415.01
Left P	5%	**95.0%**	$2,032,980,497.41
Right X	$2,032,980,497.41	**97.5%**	$2,745,013,248.48
Right P	95%	**99.0%**	$4,359,750,729.50
#Errors	976		



Change in Output Statistic for Total Averted Cost / Product (Cost per firm x N			
Rank	**Name**	**Lower**	**Upper**
1	X / FIRMS (J18)	$661,901,616.03	$2,094,436,010.12
2	X / FIRMS (J26)	$689,011,563.76	$1,375,011,638.79
3	High estimate / Cost per	$751,686,260.89	$1,428,052,267.59
4	X / FIRMS (J17)	$780,818,927.20	$1,377,863,851.07
5	Most likely estimate / C	$627,461,626.82	$1,177,881,290.60
6	Most likely estimate / C	$755,415,682.77	$1,156,254,348.90
7	X / FIRMS (J19)	$785,250,290.22	$1,165,456,153.46
8	X / FIRMS (J30)	$791,938,620.64	$1,147,564,079.13
9	X / FIRMS (J25)	$724,610,013.68	$1,035,233,230.30
10	X / FIRMS (J27)	$723,805,663.48	$1,033,495,047.88

H. Accounting for English Proficiency and Internet Access

For estimating costs associated with learning about the requirements of this rule, we adjust time estimates for foreign establishments to account for potential differences in time due to differences in English language proficiency and internet accessibility for foreign facilities representing 114 countries with valid registrations who offer FDA regulated food for sale in the U.S. from FDA's Food Facility Registration Module. We create a combined multiplier for each country to simultaneously account for the two adjustment factors. We estimate this combined multiplier for all foreign establishments as 1.41 hours. This estimate is the average of an estimated English proficiency multiplier of 1.65 hours and an estimated internet usage multiplier of 1.17 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 2020.[114] This report ranks countries by the average level of English language skills amongst adults using data collected via English tests available over the internet.

To account for country differences in internet accessibility, we use 2022 internet user percentage estimates by country.[115] Table H.1 shows establishment counts from countries scaled according to the country's English proficiency index (EPI). We estimate that for every hour used by an establishment with high to very high EPI score, that establishments in countries with low and very low EPI score would require two to three hours respectively. Similarly, we estimate that for each hour used by an establishment with high to very high EPI score, that establishments in countries with a moderate EPI score would require one and a half hours. We estimate 1.65

[114] 2020 EF English Proficiency Index – Comparing English skills between countries – EF EPI. Ef.com. Retrieved on 2021-9-1. http://www.ef.edu/epi/.

[115] Internet Usage and world populations Statistics Estimates. www.internetworldstats.com. Copyright © 2018, Miniwatts Marketing Group. All rights reserved worldwide. Last accessed on Jun 11, 2022.

proficiency weighted hours as the sum of the product of the establishment percentage (A) and the hourly equivalent (B) within each proficiency index range.

Table H.1.— Number of Foreign Establishments from FDA's FFRM in Countries According to their English Proficiency

English Proficiency Index (Range)	Number of Establishments	Percent Establishments (A)	Hourly Multiplier (B)	Proficiency Weighted Hours (A X B)
Very High (63.2 - 100)	18,579	16%	1.00	0.16
High (58.14 - 63.1)	6,890	6%	1.00	0.06
Moderate (52.82 - 58.13)	43,254	37%	1.50	0.55
Low (48.78 - 52.81)	42,497	36%	2.00	0.72
Very Low (0 - 48.77)	6,294	5%	3.00	0.16
Sum	117,514	100%		**1.65**

Table H.2 shows the estimated number of establishments from countries scaled according to their country's internet access. We estimate that for every hour used by an establishment with high to very high internet access, establishments with moderate, low, and very low internet usage would require 1.5, two and three hours respectively. We estimate that for every hour used by an establishment with high to very high internet usage, that establishment in countries with low and very low internet usage would require two to three hours respectively. Similarly, we estimate that for every single hour used by an establishment with high to very high internet usage, that establishments in countries with moderate internet accessibility would require one and a half hours. We estimate 1.17 internet weighted hours as the sum of the product of the establishment percentage (A) and the hourly equivalent (B) within each accessibility index range.

Table H.2.— Number of Foreign Establishments from FDA's FFRM in Countries According to Percent Internet Access

Internet Use (Scale)	Number of Establishments	Percent Establishments (A)	Hourly Multiplier (B)	Internet Weighted Hours (A X B)
Very High (90%-100%)	67,715	58%	1.00	0.58
High (71% - 89%)	21,196	18%	1.00	0.18
Moderate (59% - 70%)	24,154	21%	1.50	0.31
Low (57% - 58%)	1,200	1%	2.00	0.02
Very Low (0 - 56%)	3,249	3%	3.00	0.08
Sum	117,514	100%		**1.17**

The average of both weighted sums of 1.65 hours to account for differences in English proficiency and of 1.17 hours to account for differences in internet usage give us a single multiplier estimate of 1.41 (= (1.65 hours +1.17 hours)/2) for foreign establishments. We take the average between proficiency and internet multipliers because internet access is positively correlated with English proficiency and also because high English proficiency alone is not enough to account for the amount of time that an entity would require to learn about the rule.[116] Even entities from countries with high English proficiency would rely on using the internet insofar as to only

[116] Source: https://www.visualcapitalist.com/the-most-used-languages-on-the-internet/#:~:text=English%20is%20by%20far%20the,with%20over%201.13%20billion%20speakers viewed on September-3-2021. Based on the top 10 million websites by traffic rankings from Alexa.com Source W3Techs, Ethnologue and the United Nations via Hootsuite.

download the rule and print it or e-mail it to a device, whereas an entity in a country with low internet access would need to spend more time finding internet access in order to download the rule from the internet.

The following three examples may help to better illustrate the relationship between proficiency and internet adjusted hours.

1) For an entity in an English speaking country with high internet access we assign an hourly multiplier of 1 for proficiency (Table H.1, column B) and 1 for internet access (Table H.2, column B). The amount of time needed by an entity from a highly proficient English speaking country with high internet access would be the same as a domestic entity, therefore we estimate that one hour is the average of 1 hour for proficiency and 1 hour for internet access ((1 hour from proficiency + 1 hour from internet)/2 = 1 domestic hour).
2) For entities in a country with moderate English proficiency assigned with a multiplier of 1.5 (Table H.1, column B) but assigned with the number 1 for high internet hours (Table H.2 column B) we estimate the average of 1.25 hours would be needed for every domestic hour spent learning and reading the rule ((1.5 hours +1 hour)/2) = 1.25).
3) Entities from countries with very low English proficiency, (assigned a multiplier of 3) and with low internet (assigned a multiplier of 2.5) would require 2.5 more hours for every domestic hour used in learning and reading the rule ((3 hours + 2 hours/2) = 2.5).