

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Requirements for Additional Traceability Records for Certain Foods: Compliance Date Extension

Docket No. FDA-2014-N-0053

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

Economics Staff
Office of Economics and Analysis
Office of Policy, Legislation, and International Affairs
Office of the Commissioner

Executive Summary

This proposed rule would, if finalized, extend the compliance date of the final rule titled “Requirements for Additional Traceability Records for Certain Foods” (the Food Traceability Rule) by 2.5 years, until July 20, 2028. The benefits of this proposed rule comprise the foregone benefits associated with extending the compliance date of the Food Traceability Rule by 2.5 years. The costs of this proposed rule comprise the cost savings associated with extending the compliance date of the Food Traceability Rule by 2.5 years. We estimate that the annualized benefits over 20 years would range from -\$260 million to -\$7 million, with a primary estimate of -\$91 million, using a 3 percent discount rate and from -\$322 million to -\$8 million, with a primary estimate of -\$112 million, using a 7 percent discount rate. The annualized costs would range from -\$227 million to -\$3 million, with a primary estimate of -\$54 million, using a 3 percent discount rate and from -\$308 million to -\$5 million, with a primary estimate of -\$73 million, using a 7 percent discount rate.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, 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 benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are economically significant under Executive Order 12866 if they have an annual effect on the economy of \$100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is an economically significant regulatory action under section 3(f)(1) of Executive Order 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant regulatory actions “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.” This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 deregulatory action.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule will reduce the burden on covered food entities by extending the compliance date of the final rule titled “Requirements for Additional Traceability Records for Certain Foods” (the Food Traceability Rule), we propose to certify that the proposed rule will not 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 estimates of anticipated impacts, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The current threshold after adjustment for inflation is \$187 million, using the most current (2024) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

FDA published the Food Traceability Rule on November 21, 2022. The Food Traceability Rule established additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods FDA has designated for inclusion on the Food Traceability List (FTL). The Food Traceability Rule adopts provisions requiring these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods, such as initially packing, shipping, receiving, and transforming these foods.

The Food Traceability Rule had an effective date of January 20, 2023, which was 60 days after the date of publication of the final rule in the *Federal Register*. It has a compliance date of 3

years after the effective date (January 20, 2026). Since the Food Traceability Rule issued, regulated entities from across the supply chain have voiced strong concerns with the 3-year implementation timeframe, stating that they need more time to prepare for compliance. At FDA's request, the Reagan-Udall Foundation for the Food and Drug Administration (the Foundation) held a series of roundtables and a public meeting to hear from stakeholders about challenges with implementation and to help facilitate cross-sector dialogue on potential solutions [Refs. 1 – 3]. The Foundation also accepted public feedback in writing. After carefully considering the public comments, feedback, and other information gathered since issuing the rule, FDA has tentatively concluded that additional time is needed for covered entities to prepare, including working with their supply chain partners, to help ensure successful implementation. The traceability requirements depend on a continuous chain of information being passed between supply chain entities, so if any entity fails to provide required data, the entire chain breaks and accurate traceability information will not reach retail locations where FDA outbreak investigations typically begin. If a significant number of supply chain entities struggle to comply by the January 20, 2026, deadline, this could substantially reduce the rule's overall effectiveness. FDA has tentatively concluded that a partial or phased compliance approach is not feasible because any break in the information chain would compromise outbreak investigations, and the complex, interconnected nature of supply chains makes it more operationally feasible to extend the compliance date for all entities rather than implementing different schedules. Therefore, FDA is proposing to extend the compliance date of the Food Traceability Rule by an additional 2.5 years, until July 20, 2028.

The benefits of this proposed rule comprise the foregone benefits associated with extending the compliance date of the Food Traceability Rule by 2.5 years, a description of which can be found in Section E of this document. We estimate that the present value of the benefits of the proposed rule over 20 years ranges from -\$3,866 million to -\$102 million, with a primary estimate of -\$1,348 million, using a 3 percent discount rate and from -\$3,408 million to -\$90 million, with a primary estimate of -\$1,188 million, using a 7 percent discount rate. The annualized benefits of the proposed rule range from -\$260 million per year to -\$7 million per year, with a primary estimate of -\$91 million per year, using a 3 percent discount rate and from -\$322 million per year to -\$8 million per year, with a primary estimate of -\$112 million per year, using a 7 percent discount rate.

The costs of this proposed rule comprise the cost savings associated with extending the compliance date of the Food Traceability Rule by 2.5 years, a description of which can be found in Section F of this document. The present value of the costs of the proposed rule over 20 years ranges from -\$3,381 million to -\$46 million, with a primary estimate of -\$797 million, using a 3 percent discount rate and from -\$3,258 million to -\$56 million, with a primary estimate of -\$775 million, using a 7 percent discount rate. Annualized, the costs of the proposed rule range from -\$227 million per year to -\$3 million per year, with a primary estimate of -\$54 million per year, using a 3 percent discount rate and from -\$308 million per year to -\$5 million per year, with a primary estimate of -\$73 million per year, using a 7 percent discount rate.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Proposed Rule (millions of 2024 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/year	-\$112	-\$322	-\$8	2024	7%	2024 - 2043	Foregone benefits associated with extending the compliance date of the Food Traceability Rule by 2.5 years.
		-\$91	-\$260	-\$7	2024	3%	2024 - 2043	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized \$millions/year	-\$73	-\$308	-\$5	2024	7%	2024 - 2043	The costs of this proposed rule comprise the cost savings associated with extending the compliance date of the Food Traceability Rule by 2.5 years. A portion of foreign cost savings could be passed on to domestic consumers. We estimate that between 0% and 100% of \$ 5 million in annualized costs savings (7%, 20 years) to foreign
		-\$54	-\$227	-\$3	2024	3%	2024 - 2043	

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes	
					Year Dollars	Discount Rate	Period Covered		
								facilities could be passed on to domestic consumers. This estimate is not included in total costs savings reported in this table.	
	Annualized Quantified					7%			
						3%			
		Qualitative	Farming-, manufacturing- or cooking-related actions form a necessary link between direct compliance activities and changing risks of foodborne illness; thus, negative benefits estimates imply cost savings in this unquantified category.						
Transfers	Federal Annualized Monetized \$millions/year					7%			
						3%			
		From:							To:
	Other Annualized Monetized \$millions/year					7%			
						3%			
		From:							To:
Effects	State, Local or Tribal Government: None Small Business: We estimate that small, covered food entities will experience a collective cost savings of between \$16 million and \$22 million annually. Wages: None. Growth: None								

Note: Benefits encompass positive and negative benefits. Costs encompass costs and cost savings.

In line with Executive Order 14192, in Table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 deregulatory action. We estimate that this proposed rule would generate \$54 million in annualized net cost savings at a 7 percent discount rate, discounted relative to year 2024 over a perpetual time horizon.

Table 2. Executive Order 14192 Summary Table (millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate)

	Primary Estimate	Low Estimate	High Estimate
Present Value of Costs	\$0	\$0	\$0
Present Value of Cost Savings	\$771	\$3,239	\$56
Present Value of Net Costs	-\$771	-\$3,239	-\$56
Annualized Costs	\$0	\$0	\$0
Annualized Cost Savings	\$54	\$227	\$4
Annualized Net Costs	-\$54	-\$227	-\$4

II. Preliminary Economic Analysis of Impacts

A. Background

FDA published the Food Traceability Rule on November 21, 2022. The final rule establishes additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL) based on risk. The final rule requires these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods (FTL foods), such as initial packing, shipping, receiving, and transforming these foods. The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death. The requirements will reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving the ability to quickly and efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated foods from the marketplace, and develop mitigation strategies to prevent future contamination. The final rule had an effective date of January 20, 2023 (60 days after publication of the final rule), and a compliance date of January 20, 2026 (three years after the effective date).

The Food Traceability Rule establishes first of its kind national standards for supply chain traceability from farm to restaurant/retail, for certain foods based on risk. The rule requires covered entities to maintain and share specific data elements for FTL foods throughout supply chains (and with FDA upon request). Entities along a supply chain must therefore coordinate to share relevant data elements with subsequent entities in the chain, in a compatible and timely manner.

B. Need for Federal Regulatory Action

Since issuing the Food Traceability Rule in November 2022, FDA has conducted extensive stakeholder outreach and education on the rule, in addition to providing technical assistance, tools, and other resources to assist industry with implementation. As the regulated industry has worked to comply with the rule's requirements, entities from across the supply chain have voiced strong concerns with the initial 3-year implementation timeframe, stating that they need more time to come into compliance. The final rule requires industry to comply with several new regulatory requirements. From discussions with industry, we have heard that more time is needed to comply with many of these requirements. More specifically, industry needs more time related to data management and accuracy challenges, as well as to create and implement interoperable systems that will store and share data with parties across the supply chain. After carefully considering the feedback the Agency has received, FDA is proposing to extend the compliance date of the Food Traceability Rule by 2.5 years, until July 20, 2028.

C. Purpose of the Proposed Rule

The purpose of the proposed rule is to extend the compliance date of the Food Traceability Rule by 2.5 years, until July 20, 2028, to provide industry more time to prepare for compliance, including working with their supply chain partners to help ensure successful implementation.

D. Baseline Conditions

The Regulatory Impact Analysis of the Food Traceability Rule serves as the baseline for this analysis [Ref. 4]. Throughout our analysis, we assume complete compliance by covered entities with the Food Traceability Rule. We request comment on this assumption, specifically any data that may inform this assumption.¹ Also, since the one-time costs associated with reading and understanding the Food Traceability Rule have likely already been incurred by covered food entities, we exclude such costs from our current analysis. Finally, we note uncertainty about the percentage of foreign producers' compliance costs that may be passed on to United States consumers. We request comment on any data or information that may inform a more precise percentage estimate than the 0-percent to 100-percent range currently used. Table 3 summarizes the benefits and costs of the Food Traceability Rule less such costs and in 2024 dollars instead of 2020 dollars.

The estimated present value of benefits over 20 years ranges from \$1,088 million to \$41,287 million with a primary estimate of \$14,398 million, using a 3 percent discount rate and from \$747 million to \$28,341 million, with a primary estimate of \$9,884 million, using a 7 percent discount rate. The estimated present value of costs over 20 years ranges from \$710 million to \$40,032 million, with a primary estimate of \$9,534 million, using a 3 percent discount rate, and from \$578 million to \$29,141 million, with a primary estimate of \$6,976 million, using a 7 percent discount rate.

Annualized benefits over 20 years range from \$73 million per year to \$2,775 million per year, with a primary estimate of \$968 million per year, using a 3 percent discount rate and from \$71 million per year to \$2,676 million per year, with a primary estimate of \$933 million per year, using a 7 percent discount rate. Annualized costs over 20 years range from \$48 million per year to \$2,690 million per year, with a primary estimate of \$641 million per year, using a 3 percent discount rate and from \$55 million per year to \$2,752 million per year, with a primary estimate of \$659 million per year, using a 7 percent discount rate. Prior to discounting, for a 3-year compliance period, these estimates assume industry will achieve full compliance by year 3. One-time costs begin in year 1 and are distributed evenly across all three years of the compliance period. Recurring costs begin in year 2 and increase in equal increments through year 3, when they reach their full annual amount. Annual benefits follow the same timeline as recurring costs, beginning to accrue in year 2 and reaching their full value by year 3. Present value and annualized benefits and costs are illustrated in Table 3.

¹ The reaction to the 2022 final rule from supply chain entities, discussed elsewhere in this analysis and in the regulatory preamble, indicates the likelihood of incomplete compliance in the baseline. Such incompleteness would decrease forgone benefits below what is yielded by unadjusted estimates and could also change the form and amount of costs.

Table 3 - Summary of the Costs and Benefits of the Food Traceability Rule (in millions of 2024 USD)

	Discount Rate	Benefits (Low)	Benefits (Primary)	Benefits (High)	Costs (Low)	Costs (Primary)	Costs (High)
Present Value	7%	\$747	\$9,884	\$28,341	\$578	\$6,976	\$29,141
	3%	\$1,088	\$14,398	\$41,287	\$710	\$9,534	\$40,032
Annualized Value	7%	\$71	\$933	\$2,676	\$55	\$659	\$2,752
	3%	\$73	\$968	\$2,775	\$48	\$641	\$2,690

Notes: Compliance period is 3 years, discounted over a 20 year time horizon. Key non-quantified costs are associated with farming-, manufacturing- or cooking-related actions that, due to new information flows, would address risks of foodborne illness.

E. Benefits of the Proposed Rule

The benefits of this proposed rule comprise the foregone benefits associated with extending the compliance date of the Food Traceability Rule by 2.5 years. The health-related benefits of the Food Traceability Rule come from its records requirements, which reduce the time that a contaminated covered food product is distributed in the market which, in turn, leads to a reduction in foodborne illnesses and deaths. A longer compliance period would delay such reductions and so would reduce the benefits of the Food Traceability Rule. Non-health related benefits of the Food Traceability Rule come from avoiding costs associated with conducting overly broad recalls and market withdrawals of products involved in a foodborne illness outbreak because the Food Traceability Rule allows FDA and industry to more rapidly and effectively trace food products that cause illnesses. A longer compliance period would delay this avoidance of costs and so would reduce the benefits of the Food Traceability Rule.

To estimate the benefits of this proposed rule, we first estimate the benefits of the Food Traceability Rule using a 5.5 year compliance period and using the same approach and methods used in the Regulatory Impact Analysis of the Food Traceability Rule [Ref. 4]. Prior to discounting, for a compliance period of 5.5 years, we assume annual benefits will begin to accrue in year 2 in even time increments reaching full annual benefits by year 5.5. Discounted benefits are illustrated in Table 4.

Table 4 – Summary of the Benefits of the Food Traceability Rule for a 5.5 Year Compliance Period (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	\$657	\$8,695	\$24,934
	3%	\$987	\$13,050	\$37,420
Annualized Value	7%	\$62	\$821	\$2,354
	3%	\$66	\$877	\$2,515

Notes: Compliance period is 5.5 years, discounted over a 20-year time horizon.

We then estimate the benefits of this proposed rule as the difference between the benefits of the Food Traceability Rule (which has a 3-year compliance period), presented in Table 3, and the

benefits of the Food Traceability Rule for a 5.5-year compliance period, presented in Table 4. The benefits of this proposed rule are illustrated in Table 5.

Table 5 – Summary of the Benefits of the Proposed Rule (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	-\$3,408	-\$1,188	-\$90
	3%	-\$3,866	-\$1,348	-\$102
Annualized Value	7%	-\$322	-\$112	-\$8
	3%	-\$260	-\$91	-\$7

Notes: The benefits of the proposed rule are calculated as the difference between the benefits of the Food Traceability Rule (which has a 3-year compliance period) and the benefits of the Food Traceability Rule for a 5.5-year compliance period.

F. Costs of the Proposed Rule

The costs of this proposed rule comprise the cost savings associated with extending the compliance date of the Food Traceability Rule by 2.5 years. These cost savings can be attributed to the delay in the realization by businesses of the capital investment, training, and recordkeeping costs associated with the Food Traceability Rule.

To estimate the costs of this proposed rule, we first estimate the costs of the Food Traceability Rule using a 5.5-year compliance period and using the same approach and methods used in the Regulatory Impact Analysis of the Food Traceability Rule [Ref. 4]. Prior to discounting, for a 5.5-year compliance period, these estimates assume industry will achieve full compliance by year 5.5. One-time costs begin in year 1 and are distributed evenly across all 5.5 years of the compliance period. Recurring costs, begin in year 2 and increase in equal increments through year 5.5, when they reach their full annual amount. Discounted costs are illustrated in Table 6.

Table 6 - Summary of the Costs of the Food Traceability Rule for a 5.5-Year Compliance Period (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	\$522	\$6,201	\$25,884
	3%	\$664	\$8,737	\$36,651
Annualized Value	7%	\$49	\$586	\$2,444
	3%	\$45	\$587	\$2,463

Notes: Compliance period is 5.5 years, discounted over a 20-year time horizon. Key non-quantified costs are associated with farming-, manufacturing- or cooking-related actions.

We then estimate the costs of this proposed rule as the difference between the costs of the Food Traceability Rule (which has a 3-year compliance period), presented in Table 3, and the costs of the Food Traceability Rule for a 5.5-year compliance period, presented in Table 6. The costs of this proposed rule are illustrated in Table 7.

Table 7 - Summary of the Costs of the Proposed Rule (in millions of 2024 USD)

	Discount	Low	Primary	High
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	Rate			
Present Value	7%	-\$3,258	-\$775	-\$56
	3%	-\$3,381	-\$797	-\$46
Annualized Value	7%	-\$308	-\$73	-\$5
	3%	-\$227	-\$54	-\$3

Notes: The costs of the proposed rule are calculated as the difference between the costs of the Food Traceability Rule (which has a 3-year compliance period) and the costs of the Food Traceability Rule for a 5.5-year compliance period. Key non-quantified cost savings are associated with farming-, manufacturing- or cooking-related actions.

We request comments and information that may inform the quantified costs and cost savings attributed to this proposed rule.

G. Transfers Caused by the Proposed Rule

We do not anticipate any transfers caused by the proposed rule.

H. Analysis of Regulatory Alternatives to the Proposed Rule

We present two regulatory options – (i) extending the compliance date of the Food Traceability Rule by 2 years and (ii) extending the compliance date of the Food Traceability Rule by 3 years. Each is considered in turn.

i. Extending the Compliance Date of the Food Traceability Rule by 2 Years

One regulatory option is to extend the compliance date of the Food Traceability Rule by 2 years, to January 20, 2028.

To estimate the benefits of the proposed rule under this regulatory option, we first estimate the benefits of the Food Traceability Rule using a 5-year compliance period and using the same approach and methods used in the Regulatory Impact Analysis of the Food Traceability Rule [Ref. 4]. For a compliance period of 5 years, we assume annual benefits will begin to accrue year 2 in even time increments reaching full annual benefits by year 5. These benefits are illustrated in Table 8.

Table 8 - Summary of the Benefits of the Food Traceability Rule for a 5-Year Compliance Period (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	\$681	\$9,008	\$25,830
	3%	\$1,014	\$13,417	\$38,474
Annualized Value	7%	\$64	\$851	\$2,439
	3%	\$68	\$902	\$2,586

Notes: Compliance period is 5 years, discounted over a 20-year time horizon.

We then estimate the benefits of the proposed rule under this regulatory option as the difference between the benefits of the Food Traceability Rule (which has a 3-year compliance period),

presented in Table 3 and the benefits of the Food Traceability Rule for a 5-year compliance period, presented in Table 8. The benefits of the proposed rule under this regulatory option are illustrated in Table 9.

Table 9- Summary of the Benefits of the Proposed Rule Under a 2-Year Compliance Date Extension (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	-\$2,511	-\$876	-\$66
	3%	-\$2,813	-\$981	-\$74
Annualized Value	7%	-\$237	-\$83	-\$6
	3%	-\$189	-\$66	-\$5

Notes: The benefits of the proposed rule are calculated as the difference between the benefits of the Food Traceability Rule (which has a 3-year compliance period) and the benefits of the Food Traceability Rule for a 5-year compliance period.

To estimate the costs of the proposed rule under this regulatory option, we first estimate the costs of the Food Traceability Rule using a 5-year compliance period and using the same approach and methods used in the Regulatory Impact Analysis of the Food Traceability Rule [Ref. 4]. Prior to discounting, for a compliance period of 5 years, we assume industry will achieve full compliance by year 5. One-time costs begin in year 1 and are distributed evenly across all five years of the compliance period reaching the full one-time cost amount in year 5. Our calculations assume annual costs will begin to accrue in year 2 in even time increments reaching full annual costs by year 5. Discounted costs are illustrated in Table 10.

Table 10- Summary of the Costs of the Food Traceability Rule for a 5-Year Compliance Period (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	\$535	\$6,398	\$26,713
	3%	\$675	\$8,950	\$37,558
Annualized Value	7%	\$51	\$604	\$2,522
	3%	\$45	\$602	\$2,524

Notes: Compliance period is 5 years, discounted over a 20-year time horizon. Key non-quantified costs are associated with farming-, manufacturing- or cooking-related actions.

We then estimate the costs of the proposed rule under this regulatory option as the difference between the costs of the Food Traceability Rule (which has a 3-year compliance period), presented in Table 3, and the costs of the Food Traceability Rule for a 5-year compliance period, presented in Table 10. The costs of the proposed rule under this regulatory option are illustrated in Table 11.

Table 11 - Summary of the Costs of the Proposed Rule Under a 2-Year Compliance Date Extension (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	-\$2,428	-\$578	-\$43

	3%	-\$2,474	-\$584	-\$35
Annualized Value	7%	-\$229	-\$55	-\$4
	3%	-\$166	-\$39	-\$2

Notes: The costs of the proposed rule are calculated as the difference between the costs of the Food Traceability Rule (which has a 3-year compliance period) and the costs of the Food Traceability Rule for a 5-year compliance period. Key non-quantified cost savings are associated with farming-, manufacturing- or cooking-related actions.

ii. Extending the Compliance Date of the Food Traceability Rule by 3 Years

Another regulatory option is to extend the compliance date of the Food Traceability Rule by 3 years, to January 20, 2029.

To estimate the benefits of the proposed rule under this regulatory option, we first estimate the benefits of the Food Traceability Rule using a 6-year compliance period and using the same approach and methods used in the Regulatory Impact Analysis of the Food Traceability Rule [Ref. 4]. Prior to discounting, for a compliance period of 6 years, we assume annual benefits will begin to accrue in year 2 in even time increments reaching full annual benefits by year 6. These benefits are illustrated in Table 12.

Table 12- Summary of the Benefits of the Food Traceability Rule for a 6-Year Compliance Period (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	\$650	\$8,598	\$24,655
	3%	\$978	\$12,941	\$37,108
Annualized Value	7%	\$61	\$812	\$2,328
	3%	\$66	\$870	\$2,494

Notes: Compliance period is 6 years, discounted over a 20-year time horizon.

We then estimate the benefits of the proposed rule under this regulatory option as the difference between the benefits of the Food Traceability Rule (which has a 3-year compliance period), presented in Table 3 and the benefits of the Food Traceability Rule for a 6-year compliance period, presented in Table 12. The benefits of the proposed rule under this regulatory option are illustrated in Table 13.

Table 13 - Summary of the Benefits of the Proposed Rule Under a 3-Year Compliance Date Extension (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	-\$3,686	-\$1,286	-\$97
	3%	-\$4,179	-\$1,457	-\$110
Annualized Value	7%	-\$348	-\$121	-\$9
	3%	-\$281	-\$98	-\$7

Notes: The benefits of the proposed rule are calculated as the difference between the benefits of the Food Traceability Rule (which has a 3-year compliance period) and the benefits of the Food Traceability Rule for a 6-year compliance period.

To estimate the costs of the proposed rule under this regulatory option, we first estimate the costs of the Food Traceability Rule using a 6-year compliance period and using the same approach and methods used in the Regulatory Impact Analysis of the Food Traceability Rule [Ref. 4]. Prior to discounting, for a compliance period of 6 years, we assume industry will achieve full compliance by year 6. One-time costs begin in year 1 and are distributed evenly across all six years of the compliance period reaching the full one-time cost amount in year 6. Our calculations assume annual costs will begin to accrue in year 2 in even time increments reaching full annual costs by year 6. Discounted costs are illustrated in Table 14.

Table 14 - Summary of the Costs of the Food Traceability Rule for a 6-Year Compliance Period (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	\$515	\$6,127	\$25,577
	3%	\$659	\$8,667	\$36,357
Annualized Value	7%	\$49	\$579	\$2,415
	3%	\$44	\$582	\$2,443

Notes: Compliance period is 6 years, discounted over a 20-year time horizon. Key non-quantified costs are associated with farming-, manufacturing- or cooking-related actions.

We then estimate the costs of the proposed rule under this regulatory option as the difference between the costs of the Food Traceability Rule (which has a 3-year compliance period), presented in Table 3, and the costs of the Food Traceability Rule for a 6-year compliance period, presented in Table 14. The costs of the proposed rule under this regulatory option are illustrated in Table 15.

Table 15- Summary of the Costs of the Proposed Rule Under a 3-Year Compliance Date Extension (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	-\$3,564	-\$849	-\$63
	3%	-\$3,675	-\$867	-\$51
Annualized Value	7%	-\$337	-\$80	-\$6
	3%	-\$247	-\$58	-\$3

Notes: The costs of the proposed rule are calculated as the difference between the costs of the Food Traceability Rule (which has a 3-year compliance period) and the costs of the Food Traceability Rule for a 6-year compliance period. Key non-quantified cost savings are associated with farming-, manufacturing- or cooking-related actions.

I. Distributional Effects

We estimate that there are no distributional effects associated with this proposed rule relative to the baseline.

J. International Effects

The costs to foreign establishments of this proposed rule comprise the cost savings associated with extending the compliance date of the Food Traceability Rule by 2.5 years. These cost savings can be attributed to the delay in the realization by businesses of the capital investment, training, and recordkeeping costs associated with the Food Traceability Rule.

The Regulatory Impact Analysis of the Food Traceability Rule estimated compliance costs for foreign food entities by using domestic entity costs as a baseline and applying specific adjustments to account for international differences.² As discussed in Section D. Baseline Conditions, we exclude one-time costs associated with reading and understanding the Food Traceability Rule because these costs likely have already been incurred by covered foreign food entities. In Table 16 below, we summarize the costs to foreign entities of the Food Traceability Rule less such costs and in 2024 dollars instead of 2020 dollars.

Table 16- Summary of Costs to Foreign Establishments of the Food Traceability Rule (in millions of 2024 dollars)

	Discount Rate	Low	Primary	High
Present Value	7%	\$51.49	\$620.24	\$3,611.21
	3%	\$59.67	\$821.83	\$4,854.61
Annualized Value	7%	\$4.86	\$58.55	\$340.87
	3%	\$4.01	\$55.24	\$326.31

Notes: Compliance period is 3 years, discounted over a 20-year time horizon. Key non-quantified costs are associated with farming-, manufacturing- or cooking-related actions that, due to new information flows, would address risks of foodborne illness.

To estimate the costs to foreign entities of this proposed rule, we next, estimate the costs of the Food Traceability Rule using a 5.5-year compliance period affecting foreign entities only, and using the same approach used in the cost section (Section F) of this analysis. These costs are illustrated in Table 17.

Table 17- Summary of Costs to Foreign Establishments of the Food Traceability Rule for a 5.5-Year Compliance Period (in millions of 2024 USD)

	Discount Rate	Low	Primary	High
Present Value	7%	\$50.23	\$571.95	\$3,307.62
	3%	\$60.49	\$779.03	\$4,569.76
Annualized Value	7%	\$4.74	\$53.99	\$312.22
	3%	\$4.07	\$52.36	\$307.16

Notes: Compliance period is 5.5 years, discounted over a 20-year time horizon.

² The analysis applied two key adjustments: foreign wage rates calculated from a weighted average of top exporting countries (resulting in significantly lower hourly costs), and a 1.41 multiplier for regulatory reading time to account for varying English proficiency and internet accessibility. Using FDA's Food Facility Registration Module data, the methodology identifies approximately 68,566 foreign establishments representing 57,618 firms, then multiplies the adjusted per-entity costs by the total number of affected foreign entities to calculate total compliance costs. [Ref.4]

We then estimate the costs to foreign establishments of this proposed rule as the difference between the costs of the Food Traceability Rule (which has a 3-year compliance period), presented in Table 16, and the costs of the Food Traceability Rule for a 5.5-year compliance period, presented in Table 17. The costs to foreign entities of this proposed rule are illustrated in Table 18.

Table 18 - Summary of Costs to Foreign Establishments of the Proposed Rule (in millions of 2024 USD)

	Discount Rate	Primary	Low	High
Present Value	7%	-\$48.29	-\$303.59	-\$1.26
	3%	-\$42.80	-\$284.85	\$0.82
Annualized Value	7%	-\$4.56	-\$28.66	-\$0.12
	3%	-\$2.88	-\$19.15	\$0.06

Notes: The costs of the proposed rule to foreign entities are calculated as the difference between the costs to foreign entities of the Food Traceability Rule (which has a 3-year compliance period) and the costs to foreign entities of the Food Traceability Rule for a 5.5-year compliance period. Key non-quantified cost savings are associated with farming-, manufacturing- or cooking-related actions.

The costs savings presented in Table 18 are costs savings to foreign entities only. To the extent that these costs savings are passed on to U.S. entities, U.S. consumers and firms that purchase covered foods from foreign entities may experience changes in 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 cost savings that may be passed on to U.S. consumers and request comments on this topic.

K. Uncertainty and Sensitivity Analysis

Underlying the benefits and costs of this proposed rule are the benefits and costs of the Food Traceability Rule. An uncertainty and sensitivity analysis of the benefits and costs of the Food Traceability Rule can be found in the 2022 Regulatory Impact Analysis of the Food Traceability Rule [Ref. 4].

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Small, covered food entities comprise 98 percent of covered firms and so are disproportionately affected by the Food Traceability Rule. Because the proposed rule would reduce the burden on covered food entities by extending the compliance date for the Food Traceability Rule, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small, covered food entities. More specifically, we estimate that small, covered food entities will experience a collective cost savings of between \$16 and \$22 million annually, depending on the discount rate used.³ This

³ Revenue earned by small, covered firms is about 30 percent of revenue earned by all covered firms and our

analysis, as well as other sections in this document and the Preamble of the proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. References

1. Reagan-Udall Foundation for the FDA, “Industry Roundtable Series on the FSMA Final Rule of Requirements for Additional Traceability Records for Certain Foods Top-Line Learnings Summary”. September 2024. Available at: https://reaganudall.org/sites/default/files/2024-09/Food%20Traceability%20Top-Line%20Summary%20090424_0.pdf
2. Reagan-Udall Foundation for the FDA, “Virtual Public Meeting on FDA’s Final Rule on Requirements for Additional Traceability Records for Certain Foods”. October 7, 2024. Available at: <https://reaganudall.org/news-and-events/events/virtual-public-meeting-fdas-final-rule-requirements-additional-traceability> .
3. Reagan-Udall Foundation for the FDA, “FDA’s Final Rule on Requirements for Additional Traceability Records for Certain Foods (Written Comments)”. Available at: <https://reaganudall.org/sites/default/files/2024-11/FDA%27s%20Final%20Rule%20on%20Requirements%20for%20Additional%20Traceability%20Records%20for%20Certain%20Foods%20%28Written%20Comments%29.pdf>.
4. U.S. FDA, “Requirements for Additional Traceability Records for Certain Foods (Final Rule) Regulatory Impact Analysis,” Docket No. FDA-2014-N-0053, November 21, 2022 Available at: <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

primary estimate of the annual cost savings that will be generated by the proposed rule is \$54 million per year using a 3 percent discount rate and \$73 million per year using a 7 percent discount rate. Hence, we estimate that small, covered food entities will experience a collective cost savings of between $0.3 \times \$54 \text{ million} = \$16 \text{ million per year}$ and $0.3 \times \$73 \text{ million} = \$22 \text{ million per year}$.