DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Adding Requirement to Submit Mail Tracking Number for Articles of Food Arriving by International Mail and Timeframe for Post-refusal and Post-hold Submissions

Docket No. FDA-2011-N-0179

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, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), 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 "significant" under Executive Order 12866 Section 3(f)(1) 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 final rule is not a significant regulatory action under 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 final rule is not an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866.

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or to meet other criteria specified in the Congressional Review Act/Small

Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the change to prior notice requirements will not significantly increase costs to small entities, we certify that the final 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 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 $187 million, using the most current (2024) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits, Costs, and Transfers

This rule would amend existing prior notice regulations to require the submission of the name of the mail service and tracking number for food articles imported using international mail. The rule would also require transmitters to resubmit prior notice within 10 calendar days from the date a notice of refusal or hold is issued or 10 calendar days from the date the response to a request for FDA review is issued, and to submit food facility registration within 30 calendar days from the date a notice of refusal or hold is

issued or 30 days from the date the response to a request for FDA is issued. The rule also makes other technical changes.

To estimate costs and benefits associated with the rule, we assume that the appropriate baseline is the state of the world with current prior notice regulations. We then compare the likely impacts of the rule against this baseline. The costs of the rule accrue to submitters or transmitters of prior notices for reading and understanding the rule and the additional time needed to gather and provide the tracking information. When annualized over a period of 10 years, we estimate these costs range from approximately $0.04 million to $0.44 million at a 3 percent rate of discount. At a 7 percent rate of discount, these costs range from approximately $0.04 million to $0.43 million. Our primary annualized estimates are approximately $0.24 million at both the 3 and 7 percent rates of discount.

We estimate benefits in the form of cost-savings which accrue to transmitters of prior notices and to FDA. These cost-savings range in annualized value from approximately $0.03 million to $0.14 million at the 3 and 7 percent rates of discount. The primary annualized value for both discount rates is $0.07 million. These estimates are summarized in Table 1. Other benefits, and resulting impacts on social welfare, are highly uncertain. These benefits may include improvements in public health from a decreased incidence in outbreaks of foodborne illness or bioterrorism events. However, because it is difficult to forecast the likelihood and magnitude of such events, we do not quantify their benefits.

Table 1. Summary of Benefits, Costs and Distributional Effects of Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$0.07	$0.03	$0.14	2023	7%	10 years	
		$0.07	$0.03	$0.14	2023	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Unquantified improvements to public health from better surveillance						
Costs	Annualized Monetized $millions/year	$0.24	$0.04	$0.43	2023	7%	10 years	
		$0.24	$0.04	$0.44	2023	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: None							
	Small Business: None							
	Wages:							
	Growth:							

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. We

estimate that this rule will generate $0.16 million in annualized net costs 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	$3.40	$0.40	$6.41
Present Value of Cost Savings	$1.05	$0.53	$2.10
Present Value of Net Costs	$2.35	($0.12)	$4.31
Annualized Costs	$0.24	$0.03	$0.45
Annualized Cost Savings	$0.07	$0.04	$0.15
Annualized Net Costs	$0.16	($0.01)	$0.30

Note: Values in parentheses denote net negative costs (i.e., net cost savings).

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

None of the public comments on the proposed rule addressed the economic analysis.

D. Summary of Changes

This analysis updates much of the underlying data in the preliminary regulatory impact analysis (PRIA). This includes adjusting dollar values to 2023 values and including recent wage data. In addition, we include a new supplemental section that presents estimates from the main analysis assuming a 2 percent rate of discount. Finally, there are changes to the estimates from the PRIA because we are delaying the requirement to provide the name of the mail service and tracking number until October 1, 2026.

II. Final Economic Analysis of Impacts

A. Background

Federal regulations require advance notice of food that is imported into the United States. These notifications come in the form of a prior notice (PN), which requires shippers and transmitters of food to submit information about the product that will be imported or offered for import into the United States. Prior notice allows FDA to determine which products should be inspected upon arrival in the country, with the goal of protecting the U.S. food supply from adulterated food items and products that pose public health risks.

Prior notice regulations have been updated since the original proposed and interim final rules in 2003. This includes an amendment in 2011 that requires additional information be included with each PN, specifically the names of countries where an article of food was denied entry. The changes in this rule are similar in scope, requiring each PN sent using international mail to include the name of the mail service and tracking numbers. This requirement would allow FDA to track food shipments more effectively, thereby improving our ability to prevent adulterated food from entering the country. The rule would also require transmitters to resubmit prior notice within 10 calendar days from the date a notice of refusal or hold is issued or 10 calendar days from the date the response to a request for FDA review under § 1.283(d) is issued and to submit food facility registration within 30 calendar days from the date a notice of refusal or hold is issued or 30 days from the date the response to a request for FDA review under § 1.285(j) is issued. The rule also makes other technical changes.

B. Need for Federal Regulatory Action

This rule is not associated with a market failure. Rather, the purpose of the tracking information requirement is to enhance the ability of FDA to meet its obligations under current federal regulations. The tracking information will help FDA identify and inspect food items imported using international mail, improving the agency's ability to coordinate with other federal agencies to limit public health risks from imported foods. These improvements will reduce costs and improve outcomes of government food safety efforts, ultimately improving social welfare by allowing the government to allocate its resources to other areas.

C. Purpose of the Rule

The rule is intended to facilitate FDA efforts to protect the food supply from external threats and adulterated products. Tracking information submitted within a PN may be used to better identify and inspect food items imported using international mail and coordinate with other federal agencies on food safety efforts. Requiring transmitters to respond to a refusal or hold within a 10-day or 30-day timeframe, as applicable, will allow FDA to avoid reviewing non-compliant responses over a lengthy period of time. This will free resources for the agency to address other issues related to the food supply.

D. Baseline Conditions

Table 2 shows recent information on prior notices for food articles shipped via international mail, as well as transmitters of prior notices. Based on internal FDA data,

there were approximately 7,500 transmitters of food articles sent using international mail in calendar year 2020. Of these, 2,500 transmitters, or 34 percent of the total, are domestic. We apply this percentage to the total number of prior notices sent during 2020 to estimate the number of prior notices submitted by a domestic transmitter. We estimate that there are nearly 239,000 domestic prior notices (34% x 700,994 = 238,990).

Table 3. Baseline Information on Prior Notices in Calendar Year 2020

Category	Total	Domestic	Domestic % of Total
Prior Notices via international mail*	700,994	238,990	34.09%
Transmitters and Shippers using international mail	7,459	2,543	34.09%
* We assume that the distribution between domestic and international transmitters is the same for PNs. We apply the estimated 34% of transmitters that are domestic to the total number of PNs, resulting in nearly 239,000 domestic PNs.			

E. Benefits of the Rule

We estimate benefits resulting from the provisions that transmitters have 10 calendar days to resubmit prior notice after notice of refusal or response to a request for FDA review is issued and 30 calendar days to submit registration after a notice of hold or response to a request for FDA review is issued. Other benefits, and resulting impacts on social welfare, are highly uncertain. These benefits may include improvements in public health from a decreased incidence in outbreaks of foodborne illness or bioterrorism

events. However, because it is difficult to forecast the likelihood and magnitude of such events, we do not quantify their benefits.

Benefits from the 10-day and 30-day timeframe provision come in the form of cost-savings. Cost-savings are the result of a reduction in non-compliant post-refusal PN or post-hold registration submissions. These submissions are costly because they require transmitters to prepare a new PN. In the case of a registration hold, transmitters must register a foreign facility that was previously unregistered. FDA then reviews these submissions. In the case of post-refusal PN, transmitters submit multiple non-compliant PN submissions over a lengthy period of time. The timeframe in this rule will eliminate many of these follow-on responses.[1]

We estimate cost-savings using internal data on refusals and holds from fiscal years 2020 and 2021. In each of these years, an average of roughly 1,940 import lines of food were initially held or refused entry for lacking PN, submitting inadequate PN, or failing to register a foreign food facility. An average of approximately 1,000 of these were later corrected, leaving about 940 uncorrected each year. We use this value of uncorrected PNs as the primary estimate of the number of non-compliant responses that are submitted to FDA on an annual basis in the baseline. We make further assumptions to develop lower and upper bound estimates of non-compliant responses. The lower-bound assumes each uncorrected PN represents 0.5 non-compliant responses. The upper-bound assumes each uncorrected PN represents 2 non-compliant responses. This range is necessary to account for the uncertainty in the number of non-compliant submissions

[1] Transmitters may also incur large demurrage charges if their goods fail to quickly leave a port of entry. We did not receive any comments on the magnitude of these charges. We do not estimate possible reductions of these charges in this analysis because we lack sufficient data to do so.

FDA typically receives in response to a refusal or hold. Finally, we estimate impacts accruing to domestic transmitters by multiplying these numbers by the 34 percent value discussed in Table 2.

To value the cost of both preparing and reviewing a non-compliant submission, we use estimates from the 2008 Prior Notice final rule. In the analysis for this rule, the agency estimated that each import entry costs $75 to prepare (73 FR 66294 at 66386, November 7, 2008). Adjusting this value to 2023 dollars, the cost to a transmitter is $106.14. The agency also estimates that the average import entry contains 3.6 lines, requiring 3.6 PNs. This implies that each PN costs roughly $29.48 to prepare on average ($106.14 / 3.6 = $29.48). We estimate FDA review costs based on the hourly wage equivalent to the grade 13 step 7 pay level. In 2023, this amount is $48.61 per hour (US Office of Personnel Management, 2023). To account for benefits and other indirect costs, we double this value to $97.22.

Finally, we multiply these values with estimates of the number of non-compliant responses discussed above. This results in the total cost-savings to both transmitters and FDA. For transmitters, the primary estimate of cost-savings is approximately $9,400. The low and high values are roughly $4,700 and $18,900. For FDA, the reduction in reviews results in a primary estimate of cost-savings of approximately $91,400. The low and high estimates are $45,700 and $182,800, respectively.

1. Summary of Benefits

The overall present value of cost-savings in the 10 years after rule publication ranges from approximately $0.30 million to $1.18 million at a 3 percent rate of discount,

with a primary estimate of $0.59 million. For the 7 percent rate of discount, the present value of cost-savings ranges from roughly $0.24 million to $0.95 million. The primary value is approximately $0.47 million. The primary annualized values of these cost-savings are approximately $0.07 million at both the 3 and 7 percent rates of discount. The annualized cost estimates range in value from approximately $0.03 million to $0.14 million for both 3 and 7 percent rates of discount. These values are summarized in Table 3.

Table 4. Summary of Cost-Savings

	Discount Rate	Low	Primary	High
Present Value of Cost-Savings	3%	$0.30	$0.59	$1.18
	7%	$0.24	$0.47	$0.95
Annualized Value of Cost-Savings	3%	$0.03	$0.07	$0.14
	7%	$0.03	$0.07	$0.14

Note: Dollar values in millions of 2023 dollars

F. Costs of the Rule

1. Costs to industry to read and understand the rule

Manufacturers incur a one-time cost to read and understand the rule. As recommended by HHS guidance, we assume a reading speed of between 200 and 250 words per minute (Office of the Assistant Secretary for Planning and Evaluation, 2016). For simplicity, we take the midpoint of this range, 225 words per minute, as our primary estimate of reading time. The rule consists of roughly 7,500 words. This implies that just over 33 minutes, or 0.56 hours, are needed to read the rule (7,500 words / 225 words per

minute = 33 minutes). Estimates of reading time based on a reading speed of 200 and 250 words per minute range from roughly 38 to 30 minutes, respectively.

We use these estimates to calculate the monetary costs associated with reading and understanding the rule. To do so, we use information on hourly wages. We assume that 1 lawyer reads and interprets the rule for each firm or entity. The mean hourly wage for lawyers in NAICS codes 44 and 45 (Retail Trade) is $104.43 (US Bureau of Labor Statistics, 2024). We double the wage to account for the value of benefits and other indirect costs. This fully-loaded hourly wage is $208.86. For each firm, the cost to read and understand the rule is nearly $117 ($208.86 per hour x 0.56 hours = $117). Across all 2,543 domestic PN transmitters in the data, the total cost is roughly $297,400 ($117 per firm x 2,543 transmitters = $297,400). The low and high reading speed cost estimates are approximately $265,600 and $332,000. We assume that firms incur this cost immediately after publication of the rule.

2. Costs to industry from requirement to provide tracking information

Transmitters of prior notices using international mail may incur additional costs because of the rule. These costs are the result of the requirement to obtain and provide tracking information within the prior notice for food articles submitted by international mail. We assume that an international mail tracking number is available in most countries with little or no additional cost, and we did not receive comments that indicate otherwise. We measure the impact of this extra information requirement by estimating the value of the marginal increase in time for transmitters who submit PNs. To do so, we assume hourly wages for transmitters are similar to shipping and receiving clerks under NAICS

codes 445 (Food and Beverage Stores) and mail clerks under 492110 (Courier and Express Delivery Services).[2] We take the average hourly wage for clerks from both industries. These wages are $17.01 under NAICS code 492100 and $19.91 under NAICS code 445000 (US Bureau of Labor Statistics, 2024). The average hourly wage is $18.46. The fully-loaded value of this wage is $36.92.

Our estimates of the marginal increase in time for transmitters come from the analysis for the 2011 interim final rule (IFR) that updated prior notice requirements (76 FR 25542, May 5, 2011). The regulatory impact analysis for the 2011 IFR includes estimates of the marginal increase in time for providing additional information with the prior notice. The additional information provision requirement is similar in scope to this rule.[3] The estimates in the 2011 analysis range from 7 to 108 seconds per PN. We take 7 seconds as the lower bound for this analysis. Our upper bound is 4 minutes, or 240 seconds. The average of these two estimates is 124 seconds.

To determine the overall cost of the requirement to provide tracking information, we first estimate the cost for each PN. This value, when calculated using the primary time estimate of 124 seconds, is roughly $1.27 (124 seconds x $36.92 per hour = $1.27). The aggregate cost for all international mail PNs in a year is approximately $302,700 ($1.27 per PN x 238,990 annual PNs = $302,700). The lower and upper bound annual estimates are approximately $17,200 and $588,200, respectively.

[2] We note that "express consignment operators or carriers or other private delivery services" are specifically excluded from the definition of international mail in 21 CFR 1.276(b)(8) and would not be required to provide a tracking number under this rule. However, we are relying on this NAICS code to provide an estimated wage for mail clerks.

[3] The 2011 IFR requires PNs to report the name of any country that refused entry for the article of food.

3. Summary of costs

Table 3 summarizes the costs associated with the rule in the 10-year period after publication of the rule. The one-time costs to read and understand the rule are incurred immediately after the rule is published. The ongoing costs to provide tracking information in the prior notice begin once the provision requiring the submission of the name of the mail service and tracking number becomes effective, approximately 2 years after rule publication in the *Federal Register*.[4] The full annual value of these on-going costs does not fully accrue until the end of the third year after publication.

The overall present value of these costs ranges from approximately $0.37 million to $3.79 million at a 3 percent rate of discount, with a primary estimate of $2.07 million. For the 7 percent rate of discount, the present value of costs in the 10 years after rule publication range from $0.35 million to $3.10 million. The primary value is approximately $1.72 million. The primary annualized values of these costs are approximately $0.24 million at both the 3 and 7 percent rates of discount. The annualized cost estimates range in value from $0.04 million to $0.44 million at a 3 percent rate of discount, and $0.04 million to $0.43 million at a 7 percent rate of discount.

Table 5. Summary of Costs

	Discount Rate	Low	Primary	High
Present Value of Costs	3%	$0.37	$2.07	$3.79
	7%	$0.35	$1.72	$3.10
Annualized Value of Costs	3%	$0.04	$0.24	$0.44
	7%	$0.04	$0.24	$0.43

Note: Dollar values in millions of 2023 dollars

[4] Specifically, the final rule stipulates that provision of the rule will be in effect beginning October 1, 2026.

G. International Effects

The rule will have impacts on foreign entities. These foreign entities are transmitters that use international mail to export foreign food articles to the United States. In our data, roughly 66 percent of PN transmitters are foreign. The aggregate economic impacts on foreign transmitters are higher than for domestic transmitters, which we estimated in section F of this analysis. Using the same methods, the annualized on-going cost estimates for foreign transmitters in the 10 years after rule publication range from $0.02 million to $0.78 million at a 3 percent rate of discount.

However, we do not present formal estimates of international impacts in this section. This is because the on-going and one-time costs are based on an estimate of the value of time in the United States. These values are unlikely to be applicable to other countries.

H. Analysis of Regulatory Alternatives to the Rule

1. Increase the compliance period to 3 years after publication in the *Federal Register*

The effective date of the rule is 30 days from publication in the *Federal Register*, however, the provision requiring the submission of the name of the mail service and tracking number for international mail does not begin until October 1, 2026. Therefore, all of the rule's requirements are in effect after a period of approximately 2 years from publication of the rule in the *Federal Register*. One alternative to the rule is a longer compliance period of 3 years. As a result, the full annual value of on-going costs does not accrue to industry until the end of third year after rule publication. In the main analysis,

we assume the full value of these costs occur at the end of the second year. We further assume that this alternative does not affect the timing of one-time costs related to reading and understanding the rule. These costs are still incurred immediately after rule publication.

Table 5 summarizes the overall costs associated with the alternative. This includes one-time costs related to reading and understanding the rule. In the 10 years following rule publication, the primary present values of overall costs now range from approximately $0.35 million to $3.25 million at a 3 percent rate of discount, with a primary estimate of $1.80 million. For the 7 percent rate of discount, the present value of costs ranges from $0.33 million to $2.62 million, with a primary estimate of $1.47 million. The primary annualized values of these costs are approximately $0.21 million and $0.17 million at 3 and 7 percent rates of discount, respectively. Overall, these cost estimates are slightly smaller than comparable estimates from the main analysis.

Table 6. Costs of Rule if Compliance Period Is Extended to 3 Years

	Discount Rate	Low	Primary	High
Present Value of Costs	3%	$0.35	$1.80	$3.25
	7%	$0.33	$1.47	$2.62
Annualized Value of Costs	3%	$0.04	$0.21	$0.38
	7%	$0.01	$0.17	$0.33

Note: Dollar values in millions of 2023 dollars.

Cost-savings will also be affected by this alternative. Now, transmitters may not deviate from baseline activities until the beginning of the third year after rule publication.

This implies that transmitters and FDA do not accrue the full value of cost-savings until the end of the third year after rule publication. We summarize the estimates of cost-savings under this alternative in Table 6. As with costs, these estimates are smaller than comparable estimates in the main analysis. In the 10 years following rule publication, the primary present values of cost-savings now range from approximately $0.25 million to $1.00 million at a 3 percent rate of discount, with a primary estimate of $0.50 million. For the 7 percent rate of discount, the present value of cost-savings ranges from $0.20 million to $0.78 million, with a primary estimate of $0.39 million. The primary annualized values of cost-savings are approximately $0.06 million for both the 3 and 7 percent rates of discount.

Table 7. Cost-Savings of Rule if Compliance Period Is Extended to 3 Years

	Discount Rate	Low	Primary	High
Present Value of Cost-Savings	3%	$0.25	$0.50	$1.00
	7%	$0.20	$0.39	$0.78
Annualized Value of Cost-Savings	3%	$0.03	$0.06	$0.12
	7%	$0.03	$0.06	$0.11

Note: Dollar values in millions of 2023 dollars.

2. Enhanced information provision requirements

Under this regulatory alternative, FDA imposes a second requirement in addition to the tracking information. This requirement is to provide additional information to FDA in the prior notice. For this alternative, we assume that FDA requires submitters or transmitters of PNs to list all previous PNs submitted in the last 12-month period using

international mail. This regulatory alternative would increase on-going costs to transmitters and industry due to the increase in time needed to prepare a PN.

We assume that the additional time required to satisfy this provision is the same as providing tracking information from the main analysis. That is, with this regulatory alternative, the increase in time needed to complete a PN is twice the amount described in the main analysis. The resulting cost estimates are larger than in the main analysis. We summarize these estimates in Table 7. In the 10 years following rule publication, the primary present values of overall costs now range from approximately $0.47 million to $7.24 million at a 3 percent rate of discount, with a primary estimate of $3.85 million. For the 7 percent rate of discount, the present value of costs ranges from $0.43 million to $5.87 million, with a primary estimate of $3.14 million. The primary annualized values of these costs are approximately $0.45 million at a 3 percent rate of discount and $0.41 million at a 7 percent rate of discount. The annualized cost estimates range in value from $0.05 million to $0.85 million at a 3 percent rate of discount, and $0.02 million to $0.79 million at a 7 percent rate of discount.

Table 8. Costs of the Rule with Additional Information Provision

	Discount Rate	Low	Primary	High
Present Value of Costs	3%	$0.47	$3.85	$7.24
	7%	$0.43	$3.14	$5.87
Annualized Value of Costs	3%	$0.05	$0.45	$0.85
	7%	$0.02	$0.41	$0.79

Note: Dollar values in millions of 2023 dollars.

Cost-savings will be affected by the enhanced information provision alternative. Because of the alternative, transmitters are required to submit more costly PNs. This will increase the size of cost-savings derived from the reduction in PN submissions due to the 10-day response requirement in the rule. Similarly, because FDA must review lengthier post-refusal and post-hold responses, the cost-savings from avoiding review are increased. We summarize the estimates of cost-savings under this alternative in Table 8. In the 10 years following rule publication, the primary present values of cost-savings now range from approximately $0.59 million to $2.37 million at a 3 percent rate of discount, with a primary estimate of $1.18 million. For the 7 percent rate of discount, the present value of cost-savings ranges from $0.47 million to $1.90 million, with a primary estimate of $0.95 million. The primary annualized values of cost-savings are approximately $0.14 million at both the 3 and 7 percent rates of discount.

Table 9. Cost-Savings of the Rule with Additional Information Provision

	Discount Rate	Low	Primary	High
Present Value of Cost-Savings	3%	$0.59	$1.18	$2.37
	7%	$0.47	$0.95	$1.90
Annualized Value of Cost-Savings	3%	$0.07	$0.14	$0.28
	7%	$0.07	$0.14	$0.27

Note: Dollar values in millions of 2023 dollars.

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs

imposed by the rule on industry are small relative to firm revenue, we certify that the final rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document and the Preamble of the final rule, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

We find that most firms likely to be affected by this rule are classified as small. We examine firms belonging to 2 different industries. The first industry, food and beverage stores, is classified under the North American Industry Classification System (NAICS) code 445. There are various subcodes under this classification.[5] The Small Business Administration (SBA) definition for a small firm varies across these subcodes (US Small Business Administration, 2023). The largest of these thresholds is $40 million and the smallest is $9 million. We compare this threshold with firm data from the Economic Census (US Census Bureau, 2022). As shown in Table 10, over 95 percent of firms under NAICS 445, nearly 110,000 firms, are below the $9 million threshold. Just over 99 percent, more than 114,000 firms, are below the $40 million threshold.

The second industry, couriers and express delivery services, is classified under NAICS code 492110. For this code, SBA defines firms with 1,500 or fewer employees as small (US Small Business Administration, 2023). Based on data from the Economic Census, over 4,100 firms in this industry are considered small. This represents nearly 100 percent of all firms under this code. Only 13 firms have more than 1,500 employees.

[5] For instance, code 445110 covers supermarkets and 445220 covers fish and seafood markets.

Table 10. Distribution of Firms under NAICS Codes 445 and 492110

SBA Threshold Status	Number of Firms in NAICS Category	Percent of Total Establishments	Revenue (Millions of 2023 Dollars)
Panel A: Food and Beverage Stores (NAICS 445000)			
Below $9 million threshold*	109,863	95.38%	$141,268.43
Below $40 million threshold	114,339	99.27%	$206,387.47
Above $40 million threshold	844	0.73%	$680,963.54
Panel B: Couriers and Express Delivery Services (NAICS 492110)			
Below 5 employees	2,148	51.45%	$1,059.90
Below 1,500 employee threshold	4,162	99.69%	$8,632.83
Above 1,500 employee threshold	13	0.31%	$16,246.47
*Census data aggregates all firms with revenues between $7.5-$9.9 million. This overlaps with the SBA threshold. Consequently, we include only firms with less than $7.5 million in annual revenue in the below threshold status category.			

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

We certify that the final rule will not have a significant impact on a substantial number of small entities. Table 11 shows information on firm revenue. Based on data from the 2017 Economic Census, the average revenue per firm under the $40 million threshold for NAICS code 445 is roughly $1.81 million, in 2023 dollars (US Census Bureau, 2022). Under the $9 million threshold, this value is $1.29 million. For NAICS code 492110 the average revenue per firm under the small business threshold is $2.07 million. The smallest firm size category, firms with fewer than 5 employees, has an average revenue of $0.49 million. These average revenue numbers are considerably

larger than the per-entity costs from the main analysis. Average costs per transmitter never exceed 0.05 percent of average revenue.

Table 11. Comparison of Final Rule Costs and Firm Revenues

SBA Threshold Status	Average revenue per firm (in millions of 2023 dollars)	Low: Average cost per facility (in 2023 dollars)	Low: Cost as percent of average revenue	Primary: Average cost per facility (in 2023 dollars)	Primary: Cost as percent of average revenue	High: Average cost per facility (in 2023 dollars)	High: Cost as percent of average revenue
Panel A: Food and Beverage Stores (NAICS 445000)							
Below $9 million threshold*	$1.29	$16	0.00%	$95	0.01%	$173	0.01%
Below $40 million threshold	$1.81	$16	0.00%	$95	0.01%	$173	0.01%
Above $40 million threshold	$806.83	$16	0.00%	$95	0.00%	$173	0.00%
Panel B: Couriers and Express Delivery Services (NAICS 492110)							
Below 5 employees	$0.49	$16	0.00%	$95	0.02%	$173	0.04%
Below 1,500 employee threshold	$2.07	$16	0.00%	$95	0.00%	$173	0.01%
Above 1,500 employee threshold	$1,249.73	$16	0.00%	$95	0.00%	$173	0.00%
*Census data aggregates all firms with revenues between $7.5-$9.9 million. This overlaps with the SBA threshold. Consequently, we include only firms with less than $7.5 million in annual revenue in the below threshold status category.							

IV. References

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