

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Requirement for Submission of Mail Tracking Number or Tracking Code for Food Articles Arriving by International Mail

Docket No. FDA-2011-N-0179

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

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, 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, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are “significant” under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they “have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); 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, territorial, or tribal governments or communities.” OIRA has determined that this proposed rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed change to prior notice requirements would not significantly increase costs to small

entities, 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 one year.” The current threshold after adjustment for inflation is \$177 million, using the most current (2022) 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. Summary of Costs and Benefits

This proposed rule would amend existing prior notice regulations to require the submission of tracking information for food articles imported using international mail. To estimate costs and benefits associated with the proposed 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 proposed rule against this baseline. The costs of the proposed rule, if finalized, 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 \$0.50 million at a 3 percent rate of discount. At a 7 percent rate of discount, these costs range from approximately \$0.04 million to \$0.52 million. Our primary annualized estimates are approximately \$0.27 million and \$0.28 million at 3 and 7 percent rates of discount, respectively.

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 \$0.04 million to \$0.18 million for both 3 and 7 percent rates of discount. The primary annualized value is \$0.09 million for both rates of discount. 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 Proposed Rule

| Category | | Primary Estimate | Low Estimate | High Estimate | Units | | | Notes |
|-----------|--|---|--------------|---------------|--------------|---------------|----------------|-------|
| | | | | | Year Dollars | Discount Rate | Period Covered | |
| Benefits | Annualized Monetized \$millions/year | \$0.09 | \$0.04 | \$0.18 | 2021 | 7% | 10 years | |
| | | \$0.09 | \$0.04 | \$0.18 | 2021 | 3% | 10 years | |
| | Annualized Quantified | | | | | 7% | | |
| | | | | | | 3% | | |
| | Qualitative | Unquantified improvements to public health from better surveillance | | | | | | |
| Costs | Annualized Monetized \$millions/year | \$0.28 | \$0.04 | \$0.52 | 2021 | 7% | 10 years | |
| | | \$0.27 | \$0.04 | \$0.50 | 2021 | 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: | | | | | | | |

II. Preliminary 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 proposed 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 or food facility registration within 10 calendar days from the date a notice of refusal or hold is issued and would make other technical changes.

B. Need for Federal Regulatory Action

This proposed rule is not associated with a market failure. Rather, the purpose of 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 Proposed Rule

The proposed 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 timeframe 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 ($34\% \times 700,994 = 238,990$).

Table 2. 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 Proposed Rule

We only estimate benefits resulting from the provision that transmitters have 10 days to respond to a refusal or hold. 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 timeframe provision come in the form of cost-savings. Cost-savings are the result of a reduction in non-compliant post-refusal or post-hold PN 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. Often, transmitters submit multiple non-compliant submissions over a lengthy period of time. The proposed 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 FDA typically receives in response to a refusal or hold. Finally, we estimate impacts

¹ Transmitters may also incur large demurrage charges if their goods fail to quickly leave a port of entry. We do not estimate possible reductions of these charges in this analysis because we lack sufficient data to do so. We request comment on the magnitude of charges that may be affected by this rule.

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 66386). Adjusting this value to 2021 dollars, the cost to a transmitter is \$94.39. The agency also estimates that the average import entry contains 3.6 lines, requiring 3.6 PNs. This implies that each PN costs roughly \$26.22 to prepare on average ($\$94.39 / 3.6 = \26.22). We estimate FDA review costs based on the hourly wage equivalent to the grade 13 step 7 pay level. In 2022, this amount is \$46.70 per hour (US Office of Personnel Management, 2022). To account for benefits and overhead, we double this value to \$93.40.

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 \$8,400. The low and high values are roughly \$4,200 and \$16,800. For FDA, the reduction in reviews results in a primary estimate of cost-savings of approximately \$87,800. The low and high estimates are \$43,900 and \$175,600, respectively.

1. Summary of Benefits

The overall present value of cost-savings in the 10 years after rule publication ranges from approximately \$0.37 million to \$1.5 million at a 3 percent rate of discount, with a primary estimate of \$0.75 million. For the 7 percent rate of discount, the present value of cost-savings ranges from roughly \$0.31 million to \$1.25 million. The primary

value is approximately \$0.63 million. The primary annualized values of these cost-savings are approximately \$0.09 million at both the 3 and 7 percent rates of discount. The annualized cost estimates range in value from approximately \$0.04 million to \$0.18 million for both rates of discount. These values are summarized in Table 3.

Table 3. Summary of Cost-Savings

| | Discount Rate | Low | Primary | High |
|----------------------------------|---------------|--------|---------|--------|
| Present Value of Cost-Savings | 3% | \$0.37 | \$0.75 | \$1.50 |
| | 7% | \$0.31 | \$0.63 | \$1.25 |
| Annualized Value of Cost-Savings | 3% | \$0.04 | \$0.09 | \$0.18 |
| | 7% | \$0.04 | \$0.09 | \$0.18 |

Note: Dollar values in millions of 2021 dollars

F. Costs of the Proposed Rule

1. Costs to industry to read and understand the rule

Manufacturers incur a one-time cost to read and understand the proposed 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 proposed rule consists of roughly 7,500 words. This implies that just over 33 minutes, or 0.56 hours, are needed to read the proposed 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 \$87.6 (US Bureau of Labor Statistics, 2022). We double the wage to account for the value of benefits and overhead. This fully-loaded hourly wage is \$175.20. For each firm, the cost to read and understand the rule is just over \$98 ($\$175.20 \text{ per hour} \times 0.56 \text{ hours} = \98). Across all 2,543 domestic PN transmitters in the data, the total cost is roughly \$247,500 ($\$98 \text{ per firm} \times 2,543 \text{ transmitters} = \$247,500$). The low and high reading speed cost estimates are approximately \$222,800 and \$278,500. We assume that firms incur this cost immediately after publication of the final 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 proposed rule, if finalized. 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. We invite comments regarding the extra cost of obtaining a tracking number for international mail shipments. 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 \$15.33 under NAICS code 492100 and \$17.07 under NAICS code 445000 (US Bureau of Labor Statistics, 2022). The average hourly wage is \$16.20. The fully-loaded value of this wage is \$32.40.

Our estimates of the marginal increase in time for transmitters come from the analysis for the 2011 interim final rule that updated prior notice requirements (76 FR 25542). The regulatory impact analysis for the 2011 rule 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 the proposed 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 \$1.12 (124 seconds x \$32.4 per hour = \$1.12). The aggregate cost for all international mail PNs in a year is approximately \$265,600 (\$1.12 per PN x 238,990 annual PNs = \$265,600). The lower and upper bound annual estimates are approximately \$15,100 and \$516,200, 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 proposed 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 proposed 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 on-going costs to provide tracking information in the prior notice begin once the rule becomes effective, 90 days after publication in the Federal Register. The full annual value of these on-going costs does not fully accrue until the end of the year.

The overall present value of these costs ranges from approximately \$0.34 million to \$4.30 million at a 3 percent rate of discount, with a primary estimate of \$2.32 million. For the 7 percent rate of discount, the present value of costs in the 10 years after rule publication range from \$0.32 million to \$3.64 million. The primary value is approximately \$1.98 million. The primary annualized values of these costs are approximately \$0.27 million at a 3 percent rate of discount and \$0.28 million at a 7 percent rate of discount. The annualized cost estimates range in value from \$0.04 million to \$0.50 million at a 3 percent rate of discount, and \$0.04 million to \$0.52 million at a 7 percent rate of discount.

Table 4. Summary of Costs

| | Discount Rate | Low | Primary | High |
|---------------------------|---------------|--------|---------|--------|
| Present Value of Costs | 3% | \$0.34 | \$2.32 | \$4.30 |
| | 7% | \$0.32 | \$1.98 | \$3.64 |
| Annualized Value of Costs | 3% | \$0.04 | \$0.27 | \$0.50 |
| | 7% | \$0.04 | \$0.28 | \$0.52 |

Note: Dollar values in millions of 2021 dollars

G. Distributional Effects

We do not anticipate that the proposed rule would result in differential effects across varying income, ethnic, geographic, gender, or age groups. Because the rule may have beneficial impacts on food safety and public health, it may provide benefits to groups with limited access to food security and access. It may also confer benefits to groups that consume a relatively large quantity of imported foods.

H. International Effects

The proposed rule, if finalized, 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 \$0.03 million to \$0.91 million at a 3 percent rate of discount. This is approximately double the value for domestic transmitters, who experience annualized costs from the increased information provision of \$0.01 million to \$0.47 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.

J. Analysis of Regulatory Alternatives to the Proposed Rule

1. Increase the compliance period to 1 year

Currently, the proposed rule becomes effective after a period of 90 days from publication of the rule in the *Federal Register*. One alternative to the rule is a longer compliance period of 1 year. As a result, the full annual value of on-going costs does not accrue to industry until the end of second year after rule publication. In the main analysis, we assume the full value of these costs occur at the end of the first 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 \$0.33 million to \$3.80 million at a 3 percent rate of discount, with a primary estimate of \$2.06 million. For the 7 percent rate of discount, the present value of costs ranges from \$0.31 million to \$3.16 million, with a primary estimate of \$1.73 million. The primary annualized values of these costs are approximately \$0.24 million at both the 3 and 7 percent rates of discount. Overall, these cost estimates are slightly smaller than comparable estimates from the main analysis.

Table 5. Costs of Proposed Rule if Compliance Period is Extended to 1 Year

| | Discount Rate | Low | Primary | High |
|------------------------|---------------|--------|---------|--------|
| Present Value of Costs | 3% | \$0.33 | \$2.06 | \$3.80 |
| | 7% | \$0.31 | \$1.73 | \$3.16 |

| | | | | |
|---------------------------|----|--------|--------|--------|
| Annualized Value of Costs | 3% | \$0.04 | \$0.24 | \$0.44 |
| | 7% | \$0.04 | \$0.24 | \$0.45 |

Note: Dollar values in millions of 2021 dollars.

Cost-savings will also be affected by this alternative. Now, transmitters may not deviate from baseline activities until the beginning of the second year after rule publication. This implies that transmitters and FDA do not accrue the full value of cost-savings until the end of the second 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 \$0.33 million to \$1.31 million at a 3 percent rate of discount, with a primary estimate of \$0.66 million. For the 7 percent rate of discount, the present value of cost-savings ranges from \$0.27 million to \$1.07 million, with a primary estimate of \$0.54 million. The primary annualized values of cost-savings are approximately \$0.08 million for both the 3 and 7 percent rates of discount.

Table 6. Cost-Savings of Proposed Rule if Compliance Period is Extended to 1 Year

| | Discount Rate | Low | Primary | High |
|----------------------------------|---------------|--------|---------|--------|
| Present Value of Cost-Savings | 3% | \$0.33 | \$0.66 | \$1.31 |
| | 7% | \$0.27 | \$0.54 | \$1.07 |
| Annualized Value of Cost-Savings | 3% | \$0.04 | \$0.08 | \$0.15 |
| | 7% | \$0.04 | \$0.08 | \$0.15 |

Note: Dollar values in millions of 2021 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 \$0.46 million to \$8.32 million at a 3 percent rate of discount, with a primary estimate of \$4.38 million. For the 7 percent rate of discount, the present value of costs ranges from \$0.42 million to \$7.01 million, with a primary estimate of \$3.71 million. The primary annualized values of these costs are approximately \$0.51 million at a 3 percent rate of discount and \$0.53 million at a 7 percent rate of discount. The annualized cost estimates range in value from \$0.05 million to \$0.97 million at a 3 percent rate of discount, and \$0.06 million to \$0.99 million at a 7 percent rate of discount.

Table 7. Costs of the Proposed Rule with Additional Information Provision

| | Discount Rate | Low | Primary | High |
|--|---------------|--------|---------|--------|
| | 3% | \$0.46 | \$4.38 | \$8.32 |

| | | | | |
|---------------------------|----|--------|--------|--------|
| Present Value of Costs | 7% | \$0.42 | \$3.71 | \$7.01 |
| Annualized Value of Costs | 3% | \$0.05 | \$0.51 | \$0.97 |
| | 7% | \$0.06 | \$0.53 | \$0.99 |

Note: Dollar values in millions of 2021 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 proposed 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 \$0.75 million to \$3.00 million at a 3 percent rate of discount, with a primary estimate of \$1.50 million. For the 7 percent rate of discount, the present value of cost-savings ranges from \$0.63 million to \$2.51 million, with a primary estimate of \$1.25 million. The primary annualized values of cost-savings are approximately \$0.18 million for both the 3 and 7 percent rates of discount.

Table 8. Cost-Savings of the Proposed Rule with Additional Information Provision

| | Discount Rate | Low | Primary | High |
|----------------------------------|---------------|--------|---------|--------|
| Present Value of Cost-Savings | 3% | \$0.75 | \$1.50 | \$3.00 |
| | 7% | \$0.63 | \$1.25 | \$2.51 |
| Annualized Value of Cost-Savings | 3% | \$0.09 | \$0.18 | \$0.35 |
| | 7% | \$0.09 | \$0.18 | \$0.36 |

Note: Dollar values in millions of 2021 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 proposed rule on industry are small relative to firm revenue, we propose to certify that the proposed 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, serves as the Initial 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.⁴ The Small Business Administration (SBA) definition for a small firm varies across these subcodes (US Small Business Administration, 2019). The largest of these thresholds is \$35 million and the smallest is \$8 million. We compare this threshold with firm data from the Economic Census (US Census Bureau, 2022). As shown in Table 9, over 95 percent of firms under NAICS 445, nearly 110,000 firms, are below the \$8 million threshold. Just over 99 percent, more than 114,000 firms, are below the \$35 million threshold.

⁴For instance, code 445110 covers supermarkets and 445220 covers fish and seafood markets.

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, 2019). 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.

Table 9. 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 2021 Dollars) |
|---|-----------------------------------|---------------------------------|------------------------------------|
| Panel A: Food and Beverage Stores (NAICS 445000) | | | |
| Below \$8 million threshold* | 109,863 | 95.38% | \$113,869.91 |
| Below \$35 million threshold | 114,228 | 99.17% | \$166,359.34 |
| Above \$35 million threshold | 955 | 0.83% | \$548,893.04 |
| Panel B: Couriers and Express Delivery Services (NAICS 492110) | | | |
| Below 5 employees | 2,148 | 51.45% | \$854.34 |
| Below 1,500 employee threshold | 4,162 | 99.69% | \$6,958.52 |
| Above 1,500 employee threshold | 13 | 0.31% | \$13,095.52 |
| *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 propose to certify that the proposed rule will not have a significant impact on a substantial number of small entities. Table 10 shows information on firm revenue.

Based on data from the 2017 Economic Census, the average revenue per firm under the \$35 million threshold for NAICS code 445 is roughly \$1.46 million, in 2021 dollars (US Census Bureau, 2022). Under the \$8 million threshold, this value is \$1.04 million. For

NAICS code 492110 the average revenue per firm under the small business threshold is \$1.67 million. The smallest firm size category, firms with fewer than 5 employees, has an average revenue of \$0.40 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 10. Comparison of Proposed Rule Costs and Firm Revenues

| SBA Threshold Status | Average revenue per firm (in millions of dollars) | Low: Average cost per facility (in dollars) | Low: Cost as percent of average revenue | Primary: Average cost per facility (in dollars) | Primary: Cost as percent of average revenue | High: Average cost per facility (in dollars) | High: Cost as percent of average revenue |
|---|---|---|---|---|---|--|--|
| Panel A: Food and Beverage Stores (NAICS 445000) | | | | | | | |
| Below \$8 million threshold* | \$1.04 | \$15 | 0.00% | \$106 | 0.01% | \$198 | 0.02% |
| Below \$35 million threshold | \$1.46 | \$15 | 0.00% | \$106 | 0.01% | \$198 | 0.01% |
| Above \$35 million threshold | \$574.76 | \$15 | 0.00% | \$106 | 0.00% | \$198 | 0.00% |
| Panel B: Couriers and Express Delivery Services (NAICS 492110) | | | | | | | |
| Below 5 employees | \$0.40 | \$15 | 0.00% | \$106 | 0.03% | \$198 | 0.05% |
| Below 1,500 employee threshold | \$1.67 | \$15 | 0.00% | \$106 | 0.01% | \$198 | 0.01% |
| Above 1,500 employee threshold | \$1,007.35 | \$15 | 0.00% | \$106 | 0.00% | \$198 | 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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