DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Fish and Shellfish; Amendments to the Canned Tuna Standard of Identity and Standard of Fill of Container

Docket No. FDA-2016-P-0147

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), 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 rule would not significantly increase costs to manufacturers, 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

The proposed rule, if finalized, would amend existing requirements for the canned tuna standard of identity and standard of fill of container. These include changes to methods for determining the fill of a container, expanding the list of optional flavorings and spices, and reducing the maximum amount of vegetable broth that can be used as an ingredient. The proposed rule is in partial response to a 2015 citizen petition submitted by Bumble Bee Foods, LLC, StarKist Co., and Tri Union Seafoods, LLC (dba Chicken of the Sea).

To estimate costs and benefits associated with the proposed rule, we assume that the appropriate baseline is the state of the world with the current standard of identity and standard of fill of container for canned tuna. We then compare the likely impacts of the proposed rule against this baseline. The quantifiable benefits of the proposed rule accrue to canned tuna manufacturers. These firms benefit from switching to a less costly method for determining the fill of a container. We estimate ongoing annual cost savings ranging

from approximately $4.0 million to $15.9 million at a 3 percent discount rate, and approximately $3.9 million to $15.8 million at a 7 percent discount rate. Our primary annualized estimates are approximately $7.9 million at both the 3 percent and 7 percent discount rates. The primary estimate of the present value of total cost savings in the 10 years following any final rule that may be issued based on the proposed rule is $67.6 million at a 3 percent rate of discount and $55.4 million at a 7 percent rate of discount. Manufacturers and consumers may benefit from other provisions of the proposed rule, if finalized, but these impacts are harder to quantify. We summarize quantified benefits in Table below.

The costs of the proposed rule, if finalized, are associated with costs to industry for reading and understanding the rule, training employees on new requirements, and the purchase of new equipment. These are one-time costs that industry incurs immediately after any final rule that may be issued based on the proposed rule passes its compliance date. When annualized over a period of 10 years, we estimate these costs range from approximately $3,800 to $6,000 at a 3 percent discount rate, and approximately $4,500 to $7,100 at a 7 percent discount rate. Our primary annualized estimates are approximately $4,900 at a 3 percent discount rate and $5,800 at a 7 percent discount rate. The primary estimate of the present value of total costs in the 10 years following any final rule that may be issued based on the proposed rule is $41,600 at a 3 percent discount rate and $40,600 at a 7 percent discount rate.

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	$7.9	$3.9	$15.8	2022	7%	10 years	
		$7.9	$4.0	$15.9	2022	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $millions/year	$0.01	$0.00	$0.01	2022	7%	10 years	
		$0.00	$0.00	$0.01	2022	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: None							
	Growth: None							

II. Preliminary Economic Analysis of Impacts

A. Background

Federal law requires that manufacturers conform to the established standards for canned tuna to be marketed in the United States. The requirements of the canned tuna food standard relate to either the identity of the tuna or the fill of the container. For identity, the standard requires that the tuna be of a certain species, forms of pack (i.e., tuna in the form of solid muscle, chunks, or flakes), color, packed with optional media of specified types (e.g., vegetable oil or water), and may include specified flavorings and seasonings. The standard of fill of the container describes minimum weights for specific

package sizes and tuna forms. It also indicates that manufacturers must determine the weight using a pressed cake method.

In 2015, Bumble Bee Foods, LLC, StarKist Co., and Tri Union Seafoods, LLC (dba Chicken of the Sea) submitted a citizen petition to FDA requesting changes to the canned tuna standards. The proposed rule, if finalized, would revise the canned tuna standard of identity and standard of fill of container in 21 CFR 161.190 in partial response to the petition. The proposed changes would include replacing the pressed cake method with the drained weight method, the addition of "safe and suitable" flavorings and spices in accordance with 21 CFR 101.22, reducing the maximum level of vegetable broth allowed as an ingredient, along with other clarifying changes to the canned tuna regulation.

B. Need for Federal Regulatory Action

Food standards are intended to promote honesty and fair dealing in the interest of consumers by protecting consumer expectations about food and protecting against adulteration. Food standards are established rules related to the composition and production of certain food products so that consumers know that a food really is what it purports to be, reducing search times and costs for the consumer. However, food standards may also discourage innovation and the introduction of new products, lead to inconsistencies with international food standards, and may put certain companies and industries at a competitive disadvantage.

The proposed rule does not directly address a market failure. It does not, for instance, resolve informational failures for consumers who cannot easily observe

characteristics of a product, nor any externalities related to the production or consumption of canned tuna. The proposed rule does, however, include provisions meant to improve the well-being of society. Additional flavoring and spice options may lead to the launch of new, innovative products that meet consumer preferences and may increase tuna consumption. The drained weight method for determining container fill better aligns with international food standards, potentially encouraging trade and imports of new canned tuna products. Therefore, the proposed rule, if finalized, may lead to additional market entry and competition in the canned tuna market. This could improve consumer choice and welfare.

C. Purpose of the Proposed Rule

The proposed rule is intended to improve consumer choice by expanding the flavoring and spice options available for canned tuna. It may also facilitate trade by better aligning the canned tuna standard of identity and standard of fill of container with international food standards.

D. Baseline Conditions

Table 2 shows recent information on canned tuna processing facilities, domestic sales volume, and the number of domestically sold universal product codes (UPCs) associated with canned tuna. Based on internal FDA data, there are currently 123 processing facilities that produce canned tuna for sale in the United States.[1] We combine

[1] Of these facilities, 92 are foreign and 31 are domestic.

these data with retail sales scanner data from Information Resources, Incorporated (IRI). The scanner data from IRI shows that these facilities account for roughly 1,231 UPCs with positive sales, accounting for over $2.1 billion in total revenue.

As described below, the primary impacts of the proposed rule result from changes to the testing method for the standard of fill. Several manufacturers already use the drained weight method and are exempt from pressed cake testing.[2] This effectively reduces the number of facilities and products affected by the proposed rule. After accounting for the exemptions, there are approximately 102 facilities that currently use pressed cake testing. This corresponds to 907 UPCs and approximately $431.7 million in revenue.

Table 2: Baseline Information on Canned Tuna Processing Facilities and Sales

Baseline Scenario	Processing facilities	UPCs sold domestically*	Domestic sales*
Baseline without correction for current exemptions	123	1,231	$2,124.0
Baseline with correction for current exemptions	102	907	$431.7

Note: Dollar values in millions of 2022 dollars.[3]
*FDA custom research definitions based on IRI data, corresponding to the 52 weeks ending on May 16, 2021, dollar sales, total multi-outlet and convenience sales.

[2] To date, FDA has approved eight firms for temporary marketing permits (TMPs) to market products that deviate from the canned tuna standard of fill of container. Some firms may sell private label that we cannot uniquely identify in the data. Therefore, the true baseline is likely smaller than what is presented in this analysis. All else equal, this implies that we overestimate the impact of the proposed rule on industry.
[3] We use the Consumer Price Index (CPI) to adjust all monetary values in this analysis to 2022 dollar values (US Bureau of Labor Statistics, 2023).

E. Benefits of the Proposed Rule

1. Cost savings to industry from use of the drained weight method

We estimate cost savings associated with the proposed rule. These cost savings come from reductions in testing costs to determine the fill of tuna containers. We make several assumptions to estimate the value of cost savings. The first, based on feedback from FDA's Center for Food Safety and Applied Nutrition (CFSAN), is that the pressed cake method takes 5 minutes to perform per can of tuna. The drained weight method is assumed to take 2 minutes to perform per can of tuna. We assume that canned tuna processing facilities operate, on average, 5 days a week and 16 hours a day. Finally, we assume that each processing facility tests each UPC across a range of intervals. These range from a high frequency interval of 8 hours between testing for each UPC to a low frequency of 32 hours. The primary testing interval is 16 hours.[4] We request comment on these assumptions and other assumptions described below.

To estimate cost savings, we use these assumptions to estimate the difference between testing costs in the baseline and after implementation of any final rule that may be issued based on the proposed rule. Baseline testing costs are calculated by multiplying the per can testing cost (wage of 1 employee performing test x time needed to conduct test per can) by the minimum number of cans needed for each test (24 cans, as required in the standard of fill of container). We assume that the employee earns the mean wage for a food processing worker in the seafood industry. In 2021, this value was $16.23 per hour

[4] Inter-agency feedback from the National Oceanic and Atmospheric Administration suggests that testing intervals may be as high as 2 hours per UPC. However, this information corresponds to high volume processors. These processors may already be using the drained weight method, due to exemptions from FDA (see the section on baseline conditions, above). We assume that lower volume facilities process less tuna and test at a lower frequency.

(US Bureau of Labor Statistics, 2022). After inflating this value to 2022 dollars, the hourly wage is $17.53. To account for benefits and overhead, we double this value to $35.06 per hour. Thus, the cost to perform a test per UPC is just over $70 (24 cans x 5 minutes x $35.06 per hour). Multiplying this value by the total number of UPCs subject to any final rule that may be issued based on the proposed rule, 907 UPCs, we estimate that the cost to test all UPCs once is roughly $63,600.

Next, we use our assumptions regarding testing frequency to determine annual baseline testing costs for the canned tuna industry. Facilities are assumed to operate roughly 260 days a year (52 weeks x 5 days per week) and 16 hours daily. This results in 4,160 operating hours each year for each facility. Each UPC is assumed to test on an interval of either 8, 16, or 32 hours. Consequently, UPCs from each facility are tested 520, 260, or 130 times each year.[5] Because we lack sufficient data on UPCs and their associated processing facilities, we make the simplifying assumption that each UPC is made at a single facility. Finally, we multiply the number of tests by $63,600 to determine baseline testing costs. This results in a range of cost estimates. These vary from approximately $8.3 million to $33.1 million, with a primary value of $16.5 million.

Testing costs after implementation of any final rule that may be issued based on the proposed rule are estimated in a similar manner. The only difference is that we assume that it takes 2 minutes to test each container. Using this assumption, we estimate a range of cost estimates for the drained weight method. These vary from approximately $3.3 million to $13.2 million, with a primary value of $6.6 million. For these estimates,

[5] For instance, 4160/8 = 520 tests per UPC per facility each year.

we assume that the number of UPCs remains constant after any final rule that may be issued based on the proposed rule passes its compliance date.

The cost savings associated with the proposed rule is the difference between these values and the baseline testing costs calculated above. In each year after any final rule that may be issued based on the proposed rule is implemented, cost savings range from approximately $5.0 million to $19.8 million. The primary cost saving estimate is $9.9 million.

2. Benefits left unquantified

There are benefits associated with the proposed rule that we do not quantify or monetize. These benefits are difficult to predict and any impacts on social welfare are highly uncertain. Switching to drained weight testing would improve harmonization with foreign food standards, possibly improving trade and consumer choice. The use of new flavoring and spice options may increase innovation and lead to products that more closely align with consumer preferences. However, we lack sufficient data to estimate these impacts.

3. Summary of benefits

Table 3 summarizes the cost savings associated with the proposed rule. Over the 10-year period following publication of any final rule that may be issued based on the proposed rule, the primary present value of these savings is approximately $67.6 million at a 3 percent rate of discount and $55.4 million at a 7 percent rate of discount. Present values range from $33.8 million to $135.2 million at a 3 percent discount rate, and $27.7

million to $110.7 million at a 7 percent discount rate. The annualized values of the primary estimates are approximately $7.9 million at both the 3 and 7 percent rates of discount. Annualized values range from $4.0 million to $15.9 million at a 3 percent rate of discount, and $3.9 million to $15.8 million at a 7 percent rate of discount. Because of the uncertainty of some of the assumptions we use to generate these estimates, we request comment for more detailed information or data.

Table 3: Summary of benefits in 10-year period following rule publication

	Discount Rate	Low	Primary	High
Present Value of Benefits	3%	$33.8	$67.6	$135.2
	7%	$27.7	$55.4	$110.7
Annualized Value of Benefits	3%	$4.0	$7.9	$15.9
	7%	$3.9	$7.9	$15.8

Note: Dollar values in millions of 2022 dollars.

F. Costs of the Proposed Rule

1. Costs to industry to read and understand the Proposed Rule

Manufacturers incur a one-time cost to read and understand the proposed rule. As recommended by guidance from the Department of Health and Human Services, 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, including the preamble and codified, consists of approximately 10,000 words. This implies that over 44 minutes, or 0.68 hours, are needed to read and understand the proposed rule (10,000 words / 225 words per minute = 44.44 minutes).

Estimates of reading time based on a reading speed of 200 and 250 words per minute range from roughly 50 to 40 minutes, respectively.

We use these estimates to calculate the monetary costs associated with reading and understanding the proposed rule. To do so, we use information on hourly wages. We assume that 1 lawyer reads and interprets the proposed rule for their firm. The mean hourly wage for lawyers in the food manufacturing industry, as reported by the US Bureau of Labor Statistics (2021) and inflated to 2022 dollar values, is $100.50. We double this wage to account for the value of benefits and overhead. This fully-loaded hourly wage is $200.11. For each firm, the cost to read and understand the proposed rule is just over $148 ($200.11 per hour x 44.44 minutes = $148.23). Across all 102 tuna processing facilities in the baseline, the total cost is roughly $15,100 ($148.23 per firm x 102 firms = $15,119.23). The low and high reading speed estimates are approximately $13,600 and $17,000. We assume that firms incur this cost immediately after publication of the proposed rule, if finalized.

2. Costs to industry from one-time equipment purchases and staff training

The canned tuna industry would incur additional one-time costs because of the proposed rule. These include costs associated with equipment purchases and staff training. To perform drained weight testing, facilities have to purchase industrial sieves. These sieves range in price, (RTI International, 2015) but a cursory internet search shows prices ranging from approximately $160 to $271.[6] We take the average of these values as

[6] Lower and upper bound sieves can be found at these links: https://www.thomassci.com/Laboratory-Supplies/Sieves/_/US-STANDARD-SIEVES-6-INCH?q=* and https://www.fishersci.com/shop/products/fisherbrand-u-s-standard-stainless-steel-test-sieves-12-in-dia-3-1-4-in-d/p-2386805#?keyword=.

the primary price estimate. This value is just over $215. To determine total equipment costs, we multiply these prices by the number of tuna processing facilities. The primary estimate of equipment costs is approximately $23,700 in 2022 dollars, with low and high values of $17,600 and $29,800, respectively.

Next, we estimate industry training costs. Based on feedback from CFSAN, staff training on the drained weight method should take between 0.5 and 1.5 hours. The primary training time is the average of these values, or 1 hour. Further, we assume that only 1 employee at each processing facility receives training. Using the same fully-loaded wage estimate for food processing workers in the seafood industry from above, $35.06, the primary training cost is approximately $3,600 (1 hour of training x $35.06 per hour x 102 facilities = $3,575.88). The low and high estimates of training costs are approximately $1,800 to $5,400, respectively.

3. Costs left unquantified

We do not quantify all potential costs associated with the proposed rule. These include possible reformulation and relabeling costs for new and existing products. We leave these costs unquantified because of the substantial uncertainty predicting the frequency of future reformulations and new product introductions. In addition, it is unclear the extent to which firms would incorporate new flavoring and spice options in their products.

4. Summary of costs

Table 4 summarizes the equipment, training, and reading and understanding costs associated with the proposed rule. These one-time costs are incurred immediately after any final rule based on this proposed rule passes its compliance date. We propose that this compliance date occur 1 year after publication of the final rule. The present value of these costs ranges from approximately $32,400 to $51,100 at a 3 percent rate of discount. At a 7 percent rate of discount, total present values range from $31,700 to $49,900. Primary estimates of total present value are $41,600 at the 3 percent discount rate and $40,600 at the 7 percent discount rate. The primary annualized values of these costs in the 10 years following any final rule that may be issued based on the proposed rule are approximately $4,900 at a 3 percent rate of discount and $5,800 at a 7 percent rate of discount. The annualized cost estimates range in value from $3,800 to $6,000 at a 3 percent rate of discount, and $4,500 to $7,100 at a 7 percent rate of discount. Because of the uncertainty of some of the assumptions we use to generate these estimates, we request comment for more detailed information or data.

Table 4: Summary of costs in 10-year period following rule publication

	Discount Rate	Low	Primary	High
Present Value of Costs	3%	$32,447	$41,609	$51,148
	7%	$31,743	$40,618	$49,872
Annualized Value of Costs	3%	$3,804	$4,878	$5,996
	7%	$4,519	$5,783	$7,101

Note: Dollar values are presented in units of 2022 dollars, not millions of dollars. For cost estimates in millions of dollars, see Table 1.

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. It is possible, however, that any final rule that may be issued based on this proposed rule would lead to the introduction of new products that more closely align with consumer preferences. This may improve tuna consumption among subpopulations eating little to no seafood in the baseline.

H. International Effects

The proposed rule, if finalized, would impose costs on foreign entities. These include the costs discussed above, such as reading and understanding costs, training, and equipment purchases. These cost estimates are small in magnitude. Because the value of these impacts is so small, we do not anticipate that foreign entities would change their behavior due to these costs alone.

However, foreign entities may respond to the proposed rule by expanding the number of products they export to the United States. These firms would primarily be responding to the switch to drained weight testing. This testing method brings the canned tuna food standard more in line with international food standards. In particular, foreign tuna processing facilities that were not previously exporting may find it sufficiently less costly to begin selling their products in the United States.

I. Uncertainty and Sensitivity Analysis

1. Benefits and costs if all industry already performs drained weight testing

In this section, we assume that industry already performs drained weight testing in addition to the pressed cake requirements under the standard of fill of container. In this case, the only major impact of the proposed rule is cost savings that accrue to those still performing pressed cake testing in the baseline. All firms still incur reading and understanding costs, but they do not sustain costs related to training and equipment purchases.

Total benefits and costs under this scenario are summarized in Table 5. Panel A of Table 5 is identical to Table 3. That is, cost savings under this scenario are identical to the main analysis. Costs, shown in panel B, are the reading and understanding values described in section F. Relative to the main analysis, the ratio of benefits to costs is larger if industry already performs drained weight testing for canned tuna.

Table 5: Benefits and costs if all industry already performs drained weight testing

	Discount Rate	Low	Primary	High
Panel A: Benefits				
Present Value of Benefits	3%	$33.8	$67.6	$135.2
	7%	$27.7	$55.4	$110.7
Annualized Value of Benefits	3%	$4.0	$7.9	$15.9
	7%	$3.9	$7.9	$15.8
Panel B: Costs				
Present Value of Costs	3%	$0.01	$0.02	$0.02
	7%	$0.01	$0.02	$0.02
Annualized Value of Costs	3%	$0.00	$0.00	$0.00
	7%	$0.00	$0.00	$0.00

Note: Dollar values are in millions of 2022 dollars.

2. Impacts if industry only performs pressed cake testing in the baseline

Next, we assume that canned tuna processors only perform pressed cake testing in the baseline. This ignores TMPs from FDA to certain tuna companies allowing them to perform drained weight testing. In other words, this section implicitly assumes a different baseline where all firms must follow the canned tuna food standard. Under this scenario, the baseline corresponds to the information in the middle row of Table 2. This increases the number of facilities and UPCs subject to any final rule that may be issued based on the proposed rule. The number of facilities increases from 102 to 123, and the total UPC count increases from 907 to 1,231.

Benefits and costs under this scenario are shown in Table 6. Benefits, or cost savings, are larger under this scenario. This is because a greater number of facilities, and their associated UPCs, are no longer subject to pressed cake testing. In the 10 years following any final rule that may be issued based on the proposed rule, the primary present values of cost savings are now $91.8 million at a 3 percent rate of discount and $75.1 million at a 7 percent rate of discount. Similar values in the main analysis, shown in Table 3, are smaller. Primary annualized values under the pressed-cake only baseline are $10.8 million at a 3 percent rate of discount and $10.7 million at a 7 percent rate of discount. These are also larger than in the main analysis.

Costs are also larger than in the main analysis. The primary present value of these costs is approximately $49,200 at a 3 percent rate of discount and $47,000 at a 7 percent rate of discount. In the 10 years after any final rule that may be issued based on the proposed rule, primary annualized values under the pressed-cake only baseline are $5,800 at a 3 percent discount rate and $6,700 at a 7 percent discount rate.

Table 6: Benefits and costs if industry only performs pressed cake testing in the baseline

	Discount Rate	Low	Primary	High
Panel A: Benefits				
Present Value of Benefits	3%	$45.9	$91.8	$183.5
	7%	$37.6	$75.1	$150.3
Annualized Value of Benefits	3%	$5.4	$10.8	$21.5
	7%	$5.3	$10.7	$21.4
Panel B: Costs				
Present Value of Costs	3%	$0.04	$0.05	$0.06
	7%	$0.04	$0.05	$0.06
Annualized Value of Costs	3%	$0.00	$0.01	$0.01
	7%	$0.01	$0.01	$0.01

Note: Dollar values are in millions of 2022 dollars.

J. Analysis of Regulatory Alternatives to the Proposed Rule

1. Increase the compliance period to 2 years

The proposed rule, if finalized, includes a compliance date 1 year from publication of the final rule in the *Federal Register*. An alternative to the proposed rule is a longer compliance period of 2 years. As a result, the full annual value of cost-savings does not accrue to industry until the end of the third year after publication of any final rule that may be issued based on the proposed rule. Except for costs related to reading and understanding the rule, one-time costs incurred by industry are now realized at the end of the second year. In the main analysis cost-savings are assumed to occur at the end of the second year and costs at the end of the first year.

Table 7 shows benefits and costs under this regulatory alternative. In the 10 years following any final rule that may be issued based on the proposed rule, the primary present values of cost savings are now $58.3 million at a 3 percent rate of discount and

$46.7 million at a 7 percent rate of discount. Similar values in the main analysis, shown in Table 3, are larger. Primary annualized values under this alternative are $6.8 million and $6.6 million at 3 and 7 percent rates of discount, respectively. These are smaller than in the main analysis.

One-time costs are also smaller than in the main analysis. The primary present values of these costs under the alternative are approximately $40,800 at a 3 percent discount rate and $39,000 at a 7 percent discount rate. In the 10 years after any final rule that may be issued based on the proposed rule, primary annualized values under this alternative are $4,800 at a 3 percent discount rate and $5,500 at a 7 percent discount rate.

Table 7: Benefits and costs of increasing the compliance period to 2 years

	Discount Rate	Low	Primary	High
Panel A: Benefits				
Present Value of Benefits	3%	$29.1	$58.3	$116.5
	7%	$23.3	$46.7	$93.4
Annualized Value of Benefits	3%	$3.4	$6.8	$13.7
	7%	$3.3	$6.6	$13.3
Panel B: Costs				
Present Value of Costs	3%	$0.03	$0.04	$0.05
	7%	$0.03	$0.04	$0.05
Annualized Value of Costs	3%	$0.00	$0.00	$0.01
	7%	$0.00	$0.01	$0.01

Note: Dollar values are in millions of 2022 dollars

2. Require the net contents declaration on label to include net and drained weight values

We considered an additional regulatory alternative. This alternative requires that manufacturers include both the net and drained weight under the net contents declaration on the product label. This alternative does not affect the benefits estimated in the main analysis. Rather, it increases costs for industry. To estimate these costs, we used the FDA

Labeling Cost Model developed by RTI International (RTI International, 2015) . This model uses data provided by FDA to estimate the cost of a label change for specific types of products, minor to extensive label changes, and different compliance periods. The estimates we present in this section correspond to a minor label change for canned seafood.[7]

One-time labeling costs for this alternative are shown in Table 8. These costs are incurred immediately after any final rule that may be issued based on the proposed rule passes its compliance date. Estimates from the model range from approximately $23,400 to $151,700 per UPC, with a primary estimate of $58,000 per UPC. Aggregating across all UPCs, the total cost for the canned tuna industry to relabel their products ranges from approximately $21.3 million to $137.6 million. The primary estimate is $52.7 million.

The primary annualized values of these costs in the 10 years following any final rule that may be issued based on the proposed rule are approximately $6.0 million at a 3 percent rate of discount and $7.0 million at a 7 percent rate of discount. The annualized cost estimates range in value from $2.4 million to $15.7 million at a 3 percent rate of discount, and $2.8 million to $18.3 million at a 7 percent rate of discount.

These values, when added to the other one-time costs discussed above, raise total costs of any final rule that may be issued based on the proposed rule under this alternative to a level similar to total benefits. When relabeling costs are high and a discount rate of 7 percent is used, total costs exceed benefits. For the other estimates benefits are always larger, but the ratio of benefits to costs is significantly reduced relative to the main analysis.

[7] A minor label change has a specific definition in this model. This change is defined as a one-color change that does not require a redesign of the label itself.

Table 8: One-time labeling costs if net and drained weights required on label

	Discount Rate	Low	Primary	High
Present Value of Labeling Costs	3%	$20.6	$51.1	$133.6
	7%	$19.9	$49.2	$128.6
Annualized Value of Labeling Costs	3%	$2.4	$6.0	$15.7
	7%	$2.8	$7.0	$18.3

Note: Dollar values are in millions of 2022 dollars

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires us 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 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 and the Preamble of the proposed rule, 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 in the canned tuna industry are likely classified as small. Canned tuna firms belong to a broader set of manufacturing entities classified under the seafood product preparation and packaging industry. The North American Industry Classification System (NAICS) code for this industry is 311710. For this code, the Small Business Administration (SBA) defines firms with 750 or fewer employees as small (US

Small Business Administration, 2019). We compare this threshold with firm data from the Economic Census (US Census Bureau, 2020). Based on these data, shown in Table 9, there were 456 firms under NAICS code 311710 in 2017. All but 17 of these establishments had fewer than 750 employees. This implies that 439 firms in 2017 were small under the SBA standard. We assume that canned tuna processing facilities are similarly distributed in size as the rest of the seafood preparation and packaging industry.

Table 9: Distribution of firms under NAICS code 311710 by number of employees

Number of Employees	Number of Firms in NAICS 311710	Percent of Total Establishments	Revenue
Less than 5	153	34%	$184.6
5 to 9	59	13%	$152.8
10 to 99	165	36%	$2,335.2
100 to 499	56	12%	$5,272.9
500 to 749	6	1%	$1,556.3
Greater than 749	14	3%	$5,751.6
Total	456	100%	$16,035.9

Note: Dollar values are in millions of 2022 dollars.

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

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 NAICS code 311710 is over $35.2 million, in 2022 dollars (US Census Bureau, 2020). Combining the one-time costs associated with the proposed rule, the overall average cost per canned tuna processor ranges from $324 to $511, with a primary estimate of $416 per processor. As a percentage of average revenue per firm, these costs do not exceed 1 percent.

Revenue data specific to smaller firms does not change this conclusion. The smallest firm category, entities with less than 5 employees, show that one-time costs of the proposed rule do not exceed 0.04 percent of average revenue for these firms. None of the remaining employee size categories show cost as a percent of average firm revenue exceeding this amount.

Table 10: Comparison of proposed rule costs and firm revenues

Number of Employees	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
Less than 5	$1.2	$324	0.03%	$416	0.03%	$511	0.04%
5 to 9	$2.6	$324	0.01%	$416	0.02%	$511	0.02%
10 to 99	$14.2	$324	0.00%	$416	0.00%	$511	0.00%
100 to 499	$94.2	$324	0.00%	$416	0.00%	$511	0.00%
500 to 749	$259.4	$324	0.00%	$416	0.00%	$511	0.00%
Greater than 749	$410.8	$324	0.00%	$416	0.00%	$511	0.00%
Total	$35.2	$324	0.00%	$416	0.00%	$511	0.00%

IV. References

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