

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Food Labeling; Nutrition Labeling of Standard Menu
Items in Restaurants and Similar Retail Food
Establishments; Extension of Compliance Date and
Request for Comments

Docket No. FDA-2011-F-0172

Interim Final Regulatory Impact Analysis
Interim Final Regulatory Flexibility Analysis
Interim Final Small Entity Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

The Food and Drug Administration (FDA) is extending the compliance date to May 7, 2018, for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and similar retail food establishments. The principal benefit of this interim final rule will be the reduction in costs to covered establishments (*i.e.*, cost savings) associated with extending the compliance date by one year. The principal cost of this interim final rule will be the reduction in benefits to consumers associated with extending the compliance date a year. Extending the compliance date of the “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments” final rule by one year reduces the annualized net benefits (discounted at 3 percent) approximately 1 percent, from \$506 million to \$501 million. While average annualized net benefits decrease by \$5 million, they are still positive.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the interim final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with new regulations shall “be offset by the elimination of existing costs associated with at least two prior regulations.” We have developed an Economic Analysis of Impacts that assesses the impacts of the interim final rule, including cost savings to industry and foregone benefits to consumers. We estimate at least one type of impact in at least one year to be greater than \$100 million. Thus, this interim final rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule reduces the burden on covered establishments by further extending the compliance date for the Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments final rule (79 FR 71156, December 1, 2014 (menu labeling final rule); 80 FR 39675, July 10, 2015 (extending the compliance date to December 1, 2016); 81 FR 96364, December 30, 2016 (clarifying extension of the compliance date to May 5, 2017)), we certify the interim 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 an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This interim final rule would not result in an expenditure by industry in any year that meets or exceeds this amount.

We invite comment on both this Regulatory Impact Analysis and the Regulatory Impact Analysis for the December 2014 menu labeling final rule (Ref. 1).

B. Summary of Costs and Benefits

This rule extends the compliance date of the menu labeling final rule by one year: from May 5, 2017, to May 7, 2018. The effectiveness of the menu labeling final rule does not change. However, because the compliance date is being extended by a year, the discounted value of both

total costs and total benefits decreases, reducing the total net benefits of the menu labeling final rule by 1 percent.

The principal benefit of this interim final rule will be the *reduction in costs to covered establishments* associated with extending the compliance date of the menu labeling final rule to May 7, 2018. Covered establishments¹ will have an additional year to comply with the menu labeling final rule. Thus, while all initial start-up costs and recurring costs remain the same as estimated in the final regulatory impact analysis for the menu labeling final rule (Ref. 1), the 20-year stream of total costs, discounted at 3 percent, decreases from \$1.18 billion to \$1.11 billion.

The principal cost of this interim final rule will be the *reduction in benefits to consumers* associated with extending the compliance date of the menu labeling final rule by one year. Consumers purchasing standard menu items at covered establishments will not incur potential health benefits attributed to menu labeling for an additional year. Thus, the 20-year stream of total benefits to consumers, discounted at 3 percent, decreases by 1.6 percent from \$8.6 billion to \$8.5 billion.

The total annualized benefit of this interim final rule, using a 3-percent discount rate over 20 years, would be from \$2 to \$6 million; with a 7-percent discount rate, the annualized benefit would be \$3 to \$8 million. The total annualized cost of this interim final rule, using a 3-percent discount rate over 20 years, would be from \$5 to \$15 million; with a 7-percent discount rate, the annualized cost would be \$6 to \$19 million. Estimated benefits and costs over 20 years are summarized in Table 1. Average annualized net benefits of this interim final rule are estimated to be negative \$5 million discounted at 3 percent and negative \$6 million discounted 7 percent.

Table 1: Summary of this interim final rule’s estimated benefits to industry and costs to consumers annualized over 20 years, in millions 2016\$²

		Low	Mean	High
Benefits (Cost Savings)	3%	\$2	\$4	\$6
	7%	\$3	\$6	\$8
Costs (Foregone Benefits)	3%	\$5	\$9	\$15
	7%	\$6	\$12	\$19

¹ The final rule (at 21 CFR 101.11(a)) defines “covered establishment” as a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, e.g., individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that is voluntarily registered to be covered under 21 CFR 101.11(d).

² These quantitative estimates reflect an assumed baseline in which the menu labeling regulation eventually goes fully into effect. If statutory or other changes that are separate from FDA rulemaking were to impact full implementation, the quantitative benefits estimates would be lower and the quantitative cost estimates higher than shown here.

II. Interim Final Regulatory Impact Analysis

A. Background and Need for Regulation

The Food and Drug Administration (FDA) is extending the compliance date for the menu labeling final rule. The menu labeling final rule appeared in the Federal Register of December 1, 2014, and provided covered establishments a 1-year compliance period from the date of publication of the menu labeling final rule (by December 1, 2015). In the Federal Register of July 10, 2015, the compliance date was extended to December 1, 2016, to allow covered establishments additional time to fully implement the final rule’s requirements. In the Federal Register of December 30, 2016, FDA stated that the compliance date for the final rule would be further extended to May 5, 2017. FDA is now extending the compliance date to May 7, 2018, in order to consider what opportunities there may be to reduce the cost and enhance the flexibility of these requirements beyond those reflected in the final rule, in keeping with the Administration’s policies of reducing regulatory burden.

B. Baseline Conditions

The final regulatory impact analysis (FRIA) for “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date”, published December 2016 serves as a baseline for this analysis (Ref. 2). If there are statutory changes up to and including repeal of the Affordable Care Act (ACA), then the baseline would change and the estimated costs and benefits would not be realized; the implication for the analysis of this interim final rule is that forgone benefits would be overestimated, due to their largely not being realized in the baseline, and cost savings would be underestimated because compliance costs would be avoided, rather than delayed. Extending the compliance date an additional one year, changes the timeline of the menu labeling final rule, but it does not change the effectiveness of the menu labeling final rule. The menu labeling final rule preempts inconsistent state and local regulations across the country, providing a potential advantage to covered establishments that would otherwise operate under multiple regulatory contexts. However, we are unable to quantify this potential advantage. The analysis herein estimates how extending the compliance period changes the total cost to covered establishments and the total benefits to consumers. While extending the compliance date decreases net benefits, they are still positive. The estimated baseline costs and benefits are summarized in Table 2.

Table 2: Summary of menu labeling final rule’s estimated benefits and costs with May 5 2017 compliance date, in millions

		Estimated Benefits	Estimated Costs	Net Benefits
Total over 20 Years	3%	\$8,632	\$1,177	\$7,456
	7%	\$5,875	\$911	\$4,964
<i>Annualized over 20 years</i>	3%	<i>\$580</i>	<i>\$74</i>	<i>\$506</i>
	7%	<i>\$555</i>	<i>\$79</i>	<i>\$476</i>

C. Benefits of This Interim Final Rule

Extending the compliance date of the menu labeling final rule benefits covered establishments because they can delay the cost of complying with the menu labeling final rule for an additional year. Given the imminence of the current compliance date (May 5, 2017), it is likely that many covered establishments have already incurred some or all of the initial costs needed to be in compliance. We do not have data to estimate how much covered establishments have already spent to become compliant or the proportion of establishments already in compliance. We assume that 50 percent of covered establishments are already in compliance and therefore 50 percent of initial, upfront costs have already been incurred.

Table 3 summarizes the costs for the menu labeling final rule with the published compliance date of May 5, 2017, and with the extension to May 7, 2018.³ If the compliance date for the menu labeling final rule is May 5, 2017, covered establishments will spend an average estimated \$208 million in 2016 and \$237 million in 2017 in order to be in compliance. Total average recurring costs are estimated at \$58 million per year. If the compliance date for the menu labeling final rule is May 7, 2018, we estimate initial costs to be \$104 million in 2016 and \$119 million in 2017, half of the baseline costs. In 2018, we expect that the remaining 50 percent of covered establishments will incur initial costs of \$223 million in order to be in compliance by May 7, 2018. If there are statutory changes up to and including repeal of the ACA, and affected entities anticipate these changes, they may be likely to delay taking compliance actions as long as possible, as reflected in Table 3’s shift of pre-2018 costs to 2018, rather than coordinating regulatory and non-regulatory menu changes to the extent feasible, as would typically be modeled in the FDA Labeling Cost Model (used as a key input in Ref. 1).

Table 3: Primary estimates, 20-year stream of costs, in millions

	With published compliance date of May 5, 2017	With an extension to May 7, 2018
2016	\$208.44	\$104.22
2017	\$237.38	\$118.69
2018	\$57.89	\$222.91
2019	\$57.89	\$57.89
2020	\$57.89	\$57.89
.	.	.
.	.	.
.	.	.
2035	\$57.89	\$57.89
Total	\$1,488	\$1,430
PV @3%	\$1,177	\$1,115
PV @7%	\$911	\$844
<i>Annualized @3%</i>	<i>\$74</i>	<i>\$70</i>

³ Initial and recurring costs are based on estimates from Table 8 in the final regulatory impact analysis for the menu labeling final rule (Ref. 1). They have been updated, in 2016 dollars, to reflect previous compliance date extensions.

<i>Annualized @7%</i>	\$79	\$73
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The benefit to industry of extending the compliance date of the menu labeling final rule is the difference in costs, as covered establishments can defer costs (that is, receive cost savings). Thus, annualized benefits at 3 percent are an estimated \$4 million: the reduction in total cost between the menu labeling final rule with the published compliance date and the menu labeling final rule with a May 7, 2018, compliance date (\$4 million=\$74 million - \$70 million). To the extent that more than 50 percent of covered establishments have already incurred start-up costs, these benefits are overestimated because firms have not delayed costs. At the limit, for illustration, if 100 percent of covered establishments have already incurred costs of compliance, the estimated cost savings of this interim final rule would be small, possibly zero, because we would expect most or all complying covered establishments to continue to obtain calorie information for newly introduced menu items and add it to menus in anticipation of the new compliance date.

Table 4 summarizes low, mean, and high annualized benefit estimates. This 90 percent confidence interval is calculated using the low and high estimates from the FRIA of the menu labeling final rule (Ref. 1).

Table 4: Estimated benefits to industry of this interim final rule, in millions

		Low	Mean	High
Total over 20 Years	3%	\$34	\$62	\$89
	7%	\$39	\$66	\$93
<i>Annualized over 20 years</i>	3%	\$2	\$4	\$6
	7%	\$3	\$6	\$8

The total annualized benefit of this interim final rule, using a 3-percent discount rate over 20 years, would be from \$2 to \$6 million; with a 7-percent discount rate, the annualized benefit would be \$3 to \$8 million.

D. Costs of This Interim Final Rule

Extending the compliance date of the menu labeling final rule creates a potential cost to consumers because they do not gain the potential benefits of the calorie and other nutrition information for standard menu items provided by the menu labeling final rule for an additional year. As discussed above, we estimate that 50 percent of covered establishments are already in compliance. Similarly, we estimate that consumers will begin experiencing 50 percent of the potential benefits of calorie labeling at covered establishments. We acknowledge this may be an oversimplification as different types of covered establishments may come into compliance at varying rates, altering the baseline benefits incurred pre-2020. For instance, covered restaurants may be more likely to already be in compliance with the menu labeling final rule than covered movie theaters. Since more calories are consumed on average at restaurants than at movie

theaters, in this scenario, the foregone benefits estimated below represent an overestimate. We lack the data to quantify this adjustment to the baseline.

Table 5 summarizes the benefits for the menu labeling final rule with the published compliance date of May 5, 2017, and with the extension to May 7, 2018.⁴ If the compliance date for the menu labeling final rule is May 5, 2017, on average, consumers will gain \$299 million in total benefits in 2017. Annual benefits increase each year as the total population increases. If the compliance date is extended to May 7, 2018, we assume consumers will forego half of total benefits in 2017. As all covered establishments become compliant with the menu labeling final rule by May 7, 2018, annual benefits are identical to the benefits under the current compliance date of May 5, 2017.

Table 5: Primary estimates, 20-year stream of benefits, in millions

	With published compliance date of May 5, 2017	With an extension to May 7, 2018
2016	\$ -	\$ -
2017	\$ 299.07	\$ 149.53
2018	\$ 603.42	\$ 603.42
2019	\$ 608.72	\$ 608.72
2020	\$ 614.02	\$ 614.02
2021	\$ 619.33	\$ 619.33
2022	\$ 624.65	\$ 624.65
2023	\$ 629.95	\$ 629.95
2024	\$ 635.25	\$ 635.25
2025	\$ 640.54	\$ 640.54
2026	\$ 645.81	\$ 645.81
2027	\$ 651.07	\$ 651.07
2028	\$ 656.31	\$ 656.31
2029	\$ 661.53	\$ 661.53
2030	\$ 666.73	\$ 666.73
2031	\$ 671.92	\$ 671.92
2032	\$ 677.10	\$ 677.10
2033	\$ 682.34	\$ 682.34
2034	\$ 687.62	\$ 687.62
2035	\$ 692.74	\$ 692.74
Total	\$11,968	\$11,819
PV @3%	\$8,632	\$8,491
PV @7%	\$5,875	\$5,744

⁴ Annual estimated benefits are based on information from Table 11 in the final regulatory impact analysis for the menu labeling final rule (Ref. 1). They have been updated, in 2016 dollars, to reflect previous compliance date extensions. In addition to the general request for comment appearing earlier in this regulatory impact analysis, we particularly invite comment on Ref. 1's use of willingness-to-pay results estimated with a data set that ends fairly soon after the expansion of nutrition labeling (see Ref. 3) as a measure of long-term annual benefits of such labeling.

<i>Annualized @3%</i>		\$580	\$571
<i>Annualized @7%</i>		\$555	\$542

The cost of extending the compliance date of the menu labeling final rule is the loss as consumers forego potential benefits of calorie labeling for an additional year. For instance, annualized costs to consumers (i.e., foregone benefits) at 3 percent are an estimated \$9 million: the reduction in total benefit between the menu labeling final rule with the published compliance date and the menu labeling final rule with an extended compliance date (\$9 million = \$580 million - \$571 million). These estimates are based on the assumptions of compliance at the time of this extension. Consequently, to the extent that more than 50 percent of consumers see calorie and other nutrition information provided by covered establishments choosing to comply with the menu labeling final rule prior to May 7, 2018, these costs would be overestimated because consumers would not forego as many benefits of calorie labeling. There are negligible additional industry compliance costs associated with this extension.

Table 6 summarizes low, mean, and high annualized benefit estimates. This 90 percent confidence interval is determined using the low and high estimates from the FRIA for the menu labeling final rule.

Table 6: Estimated cost to consumers of this interim final rule, in millions

		Low	Mean	High
Total over 20 Years	3%	\$67	\$141	\$221
	7%	\$62	\$131	\$204
<i>Annualized over 20 years</i>	3%	\$5	\$9	\$15
	7%	\$6	\$12	\$19

The total annualized cost of this interim final rule, using a 3-percent discount rate over 20 years, would be from \$5 to \$15 million; with a 7-percent discount rate, the annualized cost would be \$6 to \$19 million.

III. Interim Final Small Entity Analysis

FDA has examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that will lessen the economic effect of the rule on small entities. In this interim final rule, the cost burden lies solely on the consumers in the way of lost benefits. We certify that this interim final rule will not have a significant economic impact on a substantial number of small entities.

We estimate that at least two thirds of the establishments affected by the requirements of the interim final rule, or approximately 199,000 establishments, will be part of small businesses (Ref. 1). Because of the complicated market structure in the food industry, and because a

majority of affected establishments are part of small businesses, flexibility was built into the menu labeling final rule for all establishments rather than adopting special extensions or rules for small entities. In addition to the flexibility provided in the menu labeling final rule, delaying the compliance date of the menu labeling final rule by an additional year allows greater flexibility in cost-effective compliance. This analysis, together with other relevant sections of this document, serves as the Interim Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. References

- 1) FDA. “Final Regulatory Impact Analysis, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.” November 2014. Available from:
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM426165.pdf>
- 2) FDA. “Final Regulatory Impact Analysis, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, Extension of Compliance Date.” December 2016. Available from:
<https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm535077.htm>
- 3) Abaluck, J. “What Would We Eat if We Knew More: The Implications of a Large-Scale Change in Nutrition Labeling.” Working Paper 2011.