

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

Docket No. FDA-2011-F-0172

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

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Executive Summary

In response to public comments and requests, the Food and Drug Administration (FDA) is extending the compliance date to December 1, 2016 for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and similar retail food establishments. The estimated costs and benefits accrued in any given year that the menu labeling rule is in effect, relative to the first year of compliance, does not change, however, because the compliance date is being extended by one year, the discounted value of both total costs and total benefits decreases. The principal benefit of this final rule will be the reduction in costs associated with extending the compliance date by one year. The principal cost of this final rule will be the reduction in benefits associated with extending the compliance date by one 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 6 percent, from \$489 million to \$457 million. While average annualized net benefits decrease by \$32 million, they are still positive.

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I. Introduction and Summary

A. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, 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 Agencies 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). The Agency believes that this final rule is not a significant regulatory action under 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 only extends the compliance date for the Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments final rule (Ref. 1) (menu labeling final rule), this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, 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 \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that will meet or exceed this amount.

B. Summary of Costs and Benefits

This rule extends the compliance date of the menu labeling final rule by one year. The estimated costs and benefits accrued in any given year that the menu labeling final rule is in effect, relative to the first year of compliance, does not change. However, because the compliance date is being extended by one year, the discounted value of both total costs and total benefits decreases, reducing the total net benefits of the menu labeling final rule by 6 percent.

The principal benefit of this final rule will be the reduction in costs associated with extending the compliance date of the menu labeling final rule by one year. 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. 2), the 20-year stream of total costs, discounted at 3 percent, decreases by 5 percent from \$1.2 billion to \$1.1 billion.

The principal cost of this final rule will be the reduction in benefits 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

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).

attributed to menu labeling for an additional year. Thus, the 20-year stream of total benefits to consumers, discounted at 3 percent, decreases by 6 percent from \$8.7 billion to \$8.1 billion.

The total annualized benefit of this 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 \$4 to \$9 million. The total annualized cost of this final rule, using a 3-percent discount rate over 20 years, would be from \$17 to \$59 million; with a 7-percent discount rate, the annualized cost would be \$21 to \$74 million. Average annualized net benefits of this final rule are estimated to be negative \$32 million discounted at 3 percent and negative \$38 million discounted 7 percent. Estimated benefits and costs are summarized in Table 1.

Table 1: Summary of this final rule’s estimated benefits and costs annualized over 20 years, in millions 2014\$

		<i>Low</i>	<i>Mean</i>	<i>High</i>
Benefits	3%	\$2	\$4	\$6
	7%	\$4	\$7	\$9
Costs	3%	\$17	\$36	\$59
	7%	\$21	\$45	\$74

II. Final Regulatory Impact Analysis

A. Background and Need for Regulation

In response to public comments and requests, 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). FDA is extending the compliance date for the menu labeling final rule to December 1, 2016.

B. Baseline Conditions

The final regulatory impact analysis (FRIA) for the menu labeling final rule serves as a baseline for this analysis (Ref. 2). Extending the compliance date changes the timeline of the menu labeling final rule, but it does not change the effectiveness of the menu labeling final rule. 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. These differ slightly from the costs and benefits published in the FRIA for the menu labeling final rule because 1) they have been updated from 2012 to 2014 dollars and 2) discounting methods have been altered to provide consistency across possible compliance periods. This small accounting difference can lead to large differences, particularly in estimated benefits, due to the magnitude of the estimates.² The analysis has not changed from the FRIA for the menu labeling final rule.

² For example, in 2014\$, annualized benefits discounted at 3 percent as estimated in the menu labeling FRIA are \$620 million and annualized costs are an estimated \$79 million.

Table 2. Summary of menu labeling final rule’s estimated benefits and costs, in millions

		Estimated Benefits	Estimated Costs	Net Benefits
Total over 20 Years	3%	\$8,673	\$1,187	\$7,486
	7%	\$5,969	\$931	\$5,039
<i>Annualized over 20 years</i>	3%	\$566	\$77	\$489
	7%	\$526	\$82	\$444

C. Benefits of This 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. If the compliance date for the menu labeling final rule is December 1, 2015, covered establishments will spend an average estimated \$409 million in 2015 in order to be in compliance. Total average recurring costs are estimated at \$57 million per year. If the compliance date is extended to December 1, 2016, we assume covered establishments will have the same fixed costs, but will not incur them until 2016. Table 3 summarizes the costs for the menu labeling final rule with the published compliance date of December 1, 2015 and with the one-year extension (to December 1, 2016). The benefits for this final rule are the difference in costs as covered establishments can defer costs an additional one year.

Table 3. Average 20-year stream of costs, in millions

	With published compliance date	With 1-Year Extension
2015	\$408.94	\$0.00
2016	\$56.78	\$408.94
2017	\$56.78	\$56.78
2018	\$56.78	\$56.78
.	.	.
.	.	.
.	.	.
2034	\$56.78	\$56.78
Total	\$1,488	\$1,431
<i>NPV @3%</i>	<i>\$1,187</i>	<i>\$1,122</i>
<i>NPV @7%</i>	<i>\$931</i>	<i>\$856</i>
<i>Annualized @3%</i>	<i>\$77</i>	<i>\$73</i>
<i>Annualized @7%</i>	<i>\$82</i>	<i>\$75</i>

The benefit of extending the compliance date of the menu labeling final rule is the reduction in total cost between the menu labeling final rule with the published compliance date (Table 3, column 2) and the menu labeling final rule with a 1-year extended compliance date (Table 3, column 3), i.e. annualized benefits at 3 percent are an estimated \$4 million (\$4=\$77-\$73). 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.

Table 4. Estimated benefits of this final rule, in millions

		Low	Mean	High
Total over 20 Years	3%	\$37	\$65	\$93
	7%	\$45	\$75	\$104
<i>Annualized over 20 years</i>	3%	\$2	\$4	\$6
	7%	\$4	\$7	\$9

The total annualized benefit of this 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 \$4 to \$9 million.

D. Costs of This Final Rule

Extending the compliance date of the menu labeling final rule creates a cost to consumers because they do not incur 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. If the compliance date for the menu labeling final rule is December 1, 2015, on average, consumers will gain \$582 million in total benefits in the first year. Annual benefits increase each year as the total population increases. If the compliance date is extended to December 1, 2016, we assume consumers will forego one year of total benefits. It is possible that some covered establishments may provide calorie labeling prior to the required compliance date. To the extent that this occurs, these costs are overestimated as consumers would have positive benefits in the first two years. Table 5 summarizes the benefits for the menu labeling final rule with the published compliance date and with the one-year extension (to December 1, 2016). The costs for this final rule are the difference in benefits as consumers forego benefits an additional one year.

Table 5. Average 20-year stream of benefits, in millions

	With published compliance date	With 1-Year Extension
2015	\$0.00	\$0.00
2016	\$581.57	\$0.00
2017	\$586.74	\$586.74
2018	\$591.92	\$591.92
2019	\$597.12	\$597.12
2020	\$602.33	\$602.33
2021	\$607.54	\$607.54
2022	\$612.75	\$612.75
2023	\$617.95	\$617.95
2024	\$623.15	\$623.15
2025	\$628.34	\$628.34
2026	\$633.51	\$633.51
2027	\$638.67	\$638.67
2028	\$643.81	\$643.81
2029	\$648.93	\$648.93
2030	\$654.03	\$654.03

2031	\$659.12	\$659.12
2032	\$664.20	\$664.20
2033	\$669.34	\$669.34
2034	\$674.52	\$674.52
Total	\$11,936	\$11,354
<i>NPV @3%</i>	<i>\$8,673</i>	<i>\$8,124</i>
<i>NPV @7%</i>	<i>\$5,969</i>	<i>\$5,461</i>
<i>Annualized @3%</i>	<i>\$566</i>	<i>\$530</i>
<i>Annualized @7%</i>	<i>\$526</i>	<i>\$482</i>

The cost of extending the compliance date of the menu labeling final rule is the reduction in total benefit between the menu labeling final rule with the published compliance date (Table 5, column 2) and the menu labeling final rule with a 1-year extended compliance date (Table 5, column 3). 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 of this final rule, in millions

		<i>Low</i>	<i>Mean</i>	<i>High</i>
Total over 20 Years	3%	\$261	\$548	\$901
	7%	\$242	\$508	\$835
<i>Annualized over 20 years</i>	3%	<i>\$17</i>	<i>\$36</i>	<i>\$59</i>
	7%	<i>\$21</i>	<i>\$45</i>	<i>\$74</i>

The total annualized cost of this final rule, using a 3-percent discount rate over 20 years, would be from \$17 to \$59 million; with a 7-percent discount rate, the annualized cost would be \$21 to \$74 million.

E. Analysis of Regulatory Alternatives to This Final Rule

We present two alternative regulatory options: extending the compliance period two-years (from Dec 1, 2015 to Dec 1, 2017) and extending the compliance period six-months (to June 1, 2016). The option to extend the compliance period by two years decreases estimated net benefits by 98 percent. The estimation methods are identical to those described in sections C and D above. This option is summarized in Table 7.

Table 7. Estimated benefits and costs with optional 2-year extension, in millions

		Estimated Benefits	Estimated Costs	Net Benefits
Total over 20 Years	3%	\$128	\$1,085	-\$957
	7%	\$144	\$987	-\$843
<i>Annualized over 20 years</i>	3%	<i>\$8</i>	<i>\$71</i>	<i>-\$62</i>
	7%	<i>\$13</i>	<i>\$87</i>	<i>-\$74</i>

An alternative regulatory option is to extend the compliance period for 6 months (from Dec 1, 2015 to June 1, 2016) instead of the one year extension. This option is summarized in Table 8. To estimate the annual costs (benefits) for this option, we average the costs (benefits) of the menu labeling final rule and the costs (benefits) with a one-year extension.

Table 8. Estimated benefits and costs with optional 6-month extension, in millions

		Estimated Benefits	Estimated Costs	Net Benefits
Total over 20 Years	3%	\$33	\$274	-\$242
	7%	\$37	\$254	-\$217
<i>Annualized over 20 years</i>	3%	\$2	\$18	-\$16
	7%	\$3	\$22	-\$19

III. Final Small Entity Analysis

FDA has examined the economic implications of this 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 final rule, the cost burden lies solely on the consumers in the way of lost benefits. This 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 final rule, or approximately 199,000 establishments, will be part of small businesses (Ref. 2). Because of the complicated market structure in the food industry, and because a majority of affected establishments are part of small businesses, substantial 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 Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. References

- 1) FDA. “Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments” (Final Rule). 79 FR 71155, December 1, 2014 Available from: <https://www.federalregister.gov/articles/2014/12/01/2014-27833/food-labeling-nutrition-labeling-of-standard-menu-items-in-restaurants-and-similar-retail-food>
- 2) 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>