

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Labeling; Calorie Labeling of Articles
of Food Sold from Certain Vending Machines;
Front of Package Type Size

Docket No. FDA-2011-F-0171

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

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Contents

I. Introduction and Summary 3

 A. Introduction 3

 B. Executive Summary 4

 C. Comments on the Preliminary RIA and Our Responses 4

 D. Summary of Changes 5

II. Final Regulatory Impact Analysis..... 6

 A. Background and Need for Regulation..... 6

 B. Purpose of the Rule 7

 C. Baseline Conditions..... 7

 D. Cost Savings of the Final Rule..... 8

 E. Foregone Benefits of the Rule..... 9

 F. Distributional Effects 10

 G. International Effects 10

 H. Uncertainty and Sensitivity Analysis 10

 I. Analysis of Regulatory Alternatives to the Rule 10

 Alternate Approach A: At least 100 percent of the size of the net quantity of
contents declaration 11

 Alternate Approach B: Not specifying any size 11

III. Final Small Entity Analysis 12

 A. Description and Number of Affected Small Entities 12

 B. Description of the Potential Impacts of the Rule on Small Entities..... 13

 C. Alternatives to Minimize the Burden on Small Entities 13

IV. References 15

I. Introduction and Summary

A. Introduction

We have examined the impacts of the 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 significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This rule is not a significant regulatory action as defined by Executive Order 12866. This rule is an Executive Order 13771 deregulatory action.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. The vending machine final rule does not impose burdens on the suppliers of vending machine foods. While suppliers are not obliged to engage in front of package (FOP) calorie labeling, this rule will allow for greater flexibility for the use of FOP calorie labeling in glass-front vending machines than our previous requirements, potentially reducing the burden on covered vending machine operators of providing additional calorie labeling. Thus, we certify that the 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 \$154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Executive Summary

In response to requests from the vending and the packaged foods industries to reduce regulatory burden and increase flexibility, the Food and Drug Administration (FDA) is revising the existing type size requirements when front of package (FOP) labeling is used to meet the calorie declaration requirements for articles of food sold from glass-front vending machines. This final regulatory impact analysis (RIA) qualitatively discusses the economic impacts of this final rule, including potential costs, cost savings, and benefits.

Because this final rule only requires minor revisions to FOP calorie labeling type size requirements when FOP labeling is used to meet the calorie declaration requirements for articles of food sold from glass-front vending machines, we estimate there are no costs to vending machine operators and potential cost savings to vending machine operators and packaged food manufacturers. We expect the cost savings of this revision to outweigh the costs, with no significant effect on consumer behavior or health.

C. Comments on the Preliminary RIA and Our Responses

In 2018, FDA published the proposed rule “Food Labeling; Calorie Labeling of Articles of Food Sold from Certain Vending Machines; Front of Package Type Size” (Ref. 1). We prepared a comprehensive preliminary regulatory impact analysis for the 2018 proposed rule. In the following paragraphs, we describe and respond to comments we received on our analysis of the impacts of the proposed rule.

Comment: Because potentially smaller FOP type size may not make food calorie counts as obvious to consumers, several comments asked us to consider the economic impact of obesity and opposed the proposed type size requirements in favor of maintaining the requirements set in the 2014 “Food Labeling: Calorie Labeling of Articles of Food in Vending Machines” final rule (“2014 final rule”). The 2014 final rule required that the calorie labeling type size be at least 50 percent of the size of the largest printed matter on the label.

Response: As discussed in the preliminary RIA and in the ‘Foregone Benefits’ section below, we do not believe that this change will, on net, have any significant adverse effect on consumer information or behavior. Therefore, we do not believe that it will increase costs related to obesity. The comments did not provide us with additional new information that would allow us to begin estimating the economic impact of obesity.

Comment: One comment stated that the proposed revisions to the existing type size requirements will save vending machine operators between \$50 - \$300 per vending machine with the greatest savings coming from small businesses.

Response: We do not dispute this estimate. However, the comment did not provide information that would allow us to estimate what percentage of these cost savings would be attributable to this final rule.

D. Summary of Changes

The proposed rule preceding this final rule set the compliance date for January 1, 2020. FDA has finalized a compliance date of July 1, 2021 for type size FOP labeling requirements (21 CFR 101.8(b)(2)) for articles of food sold from glass-front vending machines. There are no other substantive changes between this final RIA and the preliminary RIA.

II. Final Regulatory Impact Analysis

A. Background and Need for Regulation

Section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires certain vending machine operators to provide calorie declarations for certain articles of food sold from vending machines. To implement this requirement, FDA published the 2014 final rule, which became effective on December 1, 2016, requiring vending machine operators who own or operate 20 or more vending machines to provide calorie declarations for food sold from vending machines (Ref. 2). Vending machine operators not subject to the requirements of section 403(q)(5)(H) can voluntarily become subject to the requirements by registering with FDA. Vending machine operators do not have to provide calories if the prospective purchaser can view nutrition information on the front of the package, including, at a minimum, the total number of calories for the article of food as vended. The 2014 final rule requires that the visible nutrition information must be clear and conspicuous and if FOP calorie labeling is used to meet that requirement, the calorie labeling print be at least 50 percent of the size of the largest printed matter on the label.

After the 2014 final rule appeared in the *Federal Register*, some trade associations and food manufacturers stated that the FOP type size requirement presented significant technical challenges to the packaged food industry. Consequently, FDA issued a proposed rule to revise the type size labeling requirements for FOP calorie declarations for packaged food sold from glass-front vending machines such that the minimum type size would be at least 150 percent (one and one-half times) the size of the net quantity of contents declaration, instead of being based on the largest printed matter on the label (Ref. 1).

FDA proposed a compliance date of January 1, 2020, and announced our intent to exercise enforcement discretion pending completion of the rulemaking for products sold in glass-front vending machines that (1) provided FOP calorie disclosures, and (2) complied with all aspects of the 2014 final rule except the type size requirement.

B. Purpose of the Rule

FDA is revising the type size labeling requirements when FOP labeling is used to meet the calorie declaration requirements for articles of food sold from glass-front vending machines. The previous regulation required that the FOP calorie declaration type size for articles of food sold from glass-front vending machines be at least 50 percent of the size of the largest printed matter on the label. We are amending our regulations to require instead that the FOP calorie declaration type size be at least 150 percent (one and one-half times) the minimum required size of the net quantity of contents (i.e., net weight) declaration on the package of the vended food. This change will reduce regulatory burdens on, and increase flexibility for, industry, while ensuring that calorie information is visible to consumers to help them make informed dietary decisions.

Affected covered vending machine operators must comply with this final rule by July 1, 2021 to provide sufficient time for the packaged food industry to revise their labels, as appropriate, consistent with any new requirements. We note that this date applies to products sold in glass-front vending machines that (1) provide FOP calorie disclosures, and (2) comply with all aspects of the 2014 final rule except the type size requirement.

C. Baseline Conditions

On August 1, 2016, the compliance date for calorie declaration requirements for certain foods sold from glass-front vending machines was extended from December 1, 2016 to July 26, 2018 (Ref. 3). The final regulatory impact analysis for this compliance date extension serves as a baseline for this analysis (Ref. 4). The analysis herein qualitatively estimates how revising the type size requirement, described above, changes the total costs and cost saving benefits to certain covered vending-machine operators, packaged food manufacturers, and consumers.

D. Cost Savings of the Final Rule

The revisions to the vending machine final rule may impact three primary parties: vending machine operators, packaged food manufacturers, and current or future consumers of vended foods. Vending machine operators together operate an estimated 4.7 to 7.0 million food vending machines in at least 1.5 million locations (Refs. 5; 6; 7). An industry census estimates that “multiproduct glass front venders” represent 26 percent of all machines, or 1.2 to 1.8 million vending machines (Ref. 5).

If the rule leads to packaged food manufacturers adding new or amending current FOP calorie labeling that complies with the final rule’s type size requirements to vended food products, operators of glass front machines may benefit from the rule by choosing not to declare additional calorie information for the foods, thus decreasing the cost of signage. However, it is possible that vending machine operators find managing calorie declarations on a package-by-package basis (i.e. ensuring the calorie label on each individual package will be clear and conspicuous or otherwise unobstructed from view at the point of purchase) may be less cost effective than managing all items together in a single sign. In this case, the rule would have little to no effect on vending machine operators. We lack the data to provide a quantitative analysis, but expect any potential cost saving benefits to vending machine operators to be nominal.

Packaged food manufacturers may indirectly benefit from this rule as well. If vending machine operators prefer to stock machines with packaged foods with FOP labels meeting the 150 percent standard, packaged food manufacturers may choose to update or expand the use of FOP calorie declarations that meet the 150 percent standard on foods that are likely to be sold in vending machines, thus increasing or maintaining revenues.

Lastly, to the extent that this rule increases the availability or clarity of calorie declarations, consumers may have increased potential benefits of the FOP calorie label. Food purchased from all vending machines only makes up 0.3 percent of average total calorie intake. Therefore, any benefit accrued to a typical individual consumer would necessarily be mathematically very small.

During the public comment period, FDA received comments from industry representatives expressing support for the requirement that the type size of FOP calorie declarations be at least 150 percent (one and one-half times) the minimum required size of the net quantity of contents declaration (see comment and response 3 in the final rule). Members of industry indicated that they would be able to comply with a rule that requires FOP type size for calorie labeling to be 150 percent of the minimum required type size of the net quantity of contents declaration, and many expressed support for using the 150 percent standard for purposes of the FOP type size requirement in their comments. The 150 percent type size requirement aligns with some existing voluntary food labeling programs and has already been implemented by many food manufacturers.

Packaged food manufacturers choosing to update other voluntary FOP labeling to align with this rule or add new FOP calorie labeling may incur administrative and relabeling costs. However, the vending machine final rule does not require FOP calorie labeling for vended food products and thus does not impose burdens on the suppliers of vending machine foods. Manufacturing firms may choose to incur additional costs associated with amending or adding a FOP label in order to retain revenue streams from current customers, including vending machine operators. If total revenues remain greater or equal to total costs, this implies zero net costs or potentially net cost savings from this rule to such businesses. Because any change would be voluntary, we do not expect manufacturers to change labeling unless they anticipate revenues would be equal to or greater than any costs. However, some packaged food manufacturers may risk exclusion from the vending machine marketplace unless they update packaging to meet the 150 percent standard.

We do not expect this rule to increase costs to vending machine operators or consumers.

E. Foregone Benefits of the Rule

We do not expect any significant foregone benefits from this deregulatory action. Relative to the baseline, this rule in many instances reduces the type size of the FOP calorie declarations used to satisfy calorie disclosure requirements for foods sold from vending machines. It is possible that a smaller FOP calorie label might be harder for consumers to read,

resulting in less informed dietary choices. However, the alternative to this rule is not necessarily a larger FOP label. If the label size requirement is too onerous, manufacturers might simply not use FOP labels, instead relying on separate vending signage. To the extent that this rule increases the use of FOP labels, consumers may find it easier to make informed dietary choices.

F. Distributional Effects

As described above, this final rule may provide an increased incentive for packaged food manufacturers to add new or amend current FOP calorie labeling foods in a way that makes calorie information available to consumers in a direct and accessible manner. To the extent this occurs, some costs may shift from the vending machine operator to the manufacturer. We have no reason to believe that such a wealth transfer generates any distributional or equity concerns.

G. International Effects

The rule should not create any adverse international effects.

H. Uncertainty and Sensitivity Analysis

We present qualitative uncertainty analyses within sections D and E describing the effects of this rule. We are not certain how many vended products will be affected by the rule because we do not know precisely how many vended food products currently have FOP labeling or if that FOP labeling would meet the standard, nor do we know how vending machine operators will elect to provide additional calorie information to the consumers.

I. Analysis of Regulatory Alternatives to the Rule

Solely for the purpose of this economic analysis, we have identified two regulatory alternatives to the rule. This section provides a qualitative discussion of the costs and benefits of each approach.

Alternate Approach A: At least 100 percent of the size of the net quantity of contents declaration

The first alternate approach would be to require the visible nutrition information to be in a type size that is at least 100 percent of the size of the net quantity of contents declaration; i.e., the visible nutrition information would, at a minimum, be the same size as the net quantity of contents declaration. Compared to the approach finalized in this rule, this alternative could expand the number of products considered to have visible FOP calorie labeling, thus giving vending machine operators a wider selection of products to choose from when stocking their machines. However, it is not clear whether this approach would reduce the vending machine operator's burden of posting signs with calorie information. Compared to the approach finalized in this rule, the smaller type size could limit the visibility of calorie information through a glass front machine. This approach could lead vending machine operators to spend extra time ensuring the smaller calorie disclosure is not covered up by the vending machine coils holding the packaged food items. We requested, but did not receive, information from the public to help us better estimate the impacts of this alternative approach. Hence, we lack data to provide a quantitative analysis.

Alternate Approach B: Not specifying any size

The second alternative approach would be to not specify any size for the visible nutrition information. This option could be difficult for industry to implement, difficult for FDA to enforce, and confusing for consumers. Section 403(q)(5)(H)(viii) of the FD&C Act requires calorie disclosures that are visible, clear, and conspicuous. By not specifying a specific type size requirement, this approach could make it more difficult for vending machine operators to determine whether each FOP calorie disclosure is visible, clear, and conspicuous. In addition, compared to the approach finalized in this rule, this alternative may have the unintended consequence of making it more difficult for consumers to identify and consider the calorie information available at the point of sale. We requested, but did not receive, information from the public on ways to preserve the utility of FOP labeling under this alternative while also minimizing costs. Hence, we lack data to provide a quantitative analysis.

III. Final 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 effect of this rule is to reduce the burden on covered vending machine operators of providing additional calorie labeling, we certify that the 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 Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

This rule does not require manufacturers of vending machine foods to include FOP calorie labeling. It is possible that some manufacturers would feel they need to provide FOP calorie declarations to retain current vending machine operators as consumers. We do not have an estimate of the number of manufacturers providing foods for vending machines with glass fronts, to which this rule is limited. For the purposes of the Regulatory Flexibility Act analysis, we use the Small Business Association's (SBA's) definition of a small business as it applies to the relevant economic sectors, in this case, North American Industry Classification System (NAICS) 3113, Sugar and Confectionery Product Manufacturing, and 3118, Bakeries and Tortilla Manufacturing.¹ SBA generally defines a small food manufacturer as one that has 500 or fewer employees. Using Dun and Bradstreet data, we estimate that roughly 99 percent of food manufacturers, or about 12,800 food manufacturers, have 500 or fewer employees. We do not know how many manufacturers currently use FOP labeling that would meet the standard, nor do we know the proportion that would voluntarily add or change existing labeling to meet the standard.

This final rule provides increased flexibility for vending machine operators. For the purposes of the Regulatory Flexibility Act analysis, the relevant economic sector is NAICS

¹ See United States Census Bureau, U.S. Department of Commerce, Statistics of U.S. Businesses. Available from: www.census.gov/programs-surveys/susb.html

4542, vending machine operators. SBA defines a small vending machine operator as one that has less than \$10 million in annual receipts. Per this definition, we estimate that 97 percent of covered vending machine operators are small businesses totaling 3,770 operators. This rule only impacts glass-front machines, which represent 26 percent of all machines. Operators may have both glass-front machines and other machines not impacted by this rule. Therefore, we estimate that between 26 and 100 percent (980 to 3,770) of vending machine operators will have increased flexibility due to this rule.

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

This deregulatory action reduces the impacts on small vending machine operators.

C. Alternatives to Minimize the Burden on Small Entities

We discuss two alternate approaches above. This section describes how these approaches may minimize burden on small entities within the affected sectors: vending machine operators and food manufacturers. This final rule does not require FOP calorie labeling for foods in glass-front vending machines. However, to the extent that this rule creates a burden to small food manufacturers that would make changes voluntarily in order to retain current customers or attract new ones, the two alternatives described above are less burdensome than this final rule. First, under Alternate Approach A, it would be less likely that small food product manufacturers would update existing packaging if they already meet or exceed the 100 percent standard. Second, Alternate Approach B would minimize the burden on small food manufacturers even more, because any product with a FOP calorie could meet the regulatory standard as long as it was visible, clear, and conspicuous.

By expanding the number of products considered to have visible FOP calorie labeling, both alternate approaches could give small vending machine operators a wider selection of products to choose from that already satisfy calorie disclosure requirements when stocking their machines and could make it less likely that operators would need to post signs with calorie information. However, it is unclear if either alternative would provide calorie disclosures that are visible, clear, and conspicuous. The 150 percent type size requirement finalized in this rule

provides sufficient flexibility to industry while helping to ensure that prospective purchasers have visible calorie information.

IV. References

- 1) FDA. “Food Labeling: Calorie Labeling of Articles of Food Sold From Certain Vending Machines; Front of Package Type Size” (Proposed Rule). 83 FR 32221, July 12, 2018. Available from: <https://www.federalregister.gov/documents/2018/07/12/2018-14906/food-labeling-calorie-labeling-of-articles-of-food-sold-from-certain-vending-machines-front-of>
- 2) FDA. “Food Labeling: Calorie Labeling of Articles of Food in Vending Machines” (Final Rule). 79 FR 71259, December 1, 2014. Available from: <https://federalregister.gov/a/2014-27834>
- 3) FDA. “Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date” (Final Rule). 81 FR 50303, August 1, 2016. Available from: <https://www.federalregister.gov/documents/2016/08/01/2016-18140/food-labeling-calorie-labeling-of-articles-of-food-in-vending-machines-extension-of-compliance-date>
- 4) FDA. “Final Regulatory Impact Analysis, Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Extension of Compliance Date.” August 1, 2016. Available from: <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm516342.htm>
- 5) Vending Times. 2012 Census of the Industry. Vending Times 2012; 52(12). Available here: <https://www.regulations.gov/document?D=FDA-2011-F-0171-0200>
- 6) Automatic Merchandiser. 2012 State of the Vending Industry Report. Docket No FDA-2011-F-0171-0198; Available from: <https://www.regulations.gov/document?D=FDA-2011-F-0171-0198>
- 7) National Automatic Merchandising Association. Comments of: The National Automatic Merchandising Association. Docket No. FDA-2010-N-0298. 2010. Available from: <https://www.regulations.gov/document?D=FDA-2011-F-0171-0199>

