

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]

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Preliminary Small Entity Analysis

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Executive Summary

In response to requests from the vending and the packaged foods industries to reduce the regulatory burden and increase flexibility, the Food and Drug Administration (FDA) is proposing to revise the existing type size requirements when calories are displayed on the front of the package of foods sold in glass front vending machines. This Preliminary Regulatory Impact Analysis (RIA) qualitatively discusses the economic impacts of this proposed rule, including potential costs, cost savings, and benefits. Because this rule only proposes minor revisions to front of package calorie labeling type size requirements, 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 to outweigh the costs and, thus, the net effect to be positive, but lack the data to quantify this effect.

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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 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 proposed rule has been designated as a significant regulatory action as defined by Executive Order 12866. This proposed rule is expected to be an Executive Order 13771 deregulatory action. Additional details can be found in the proposed rule’s preliminary economic analysis.

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 to the suppliers of vending machine foods. While suppliers are not obliged to engage in front of package (FOP) calorie labeling, this proposed rule, if finalized, would allow for greater flexibility for the use of FOP calorie labeling in glass front vending machines than the existing regulations, potentially reducing the burden on covered vending machine operators of providing additional calorie labeling. Thus, 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 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 \$150 million, using the most current (2017) 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.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. We invite comments on this Preliminary Regulatory Impact Analysis.

B. Summary of Costs and Cost Saving Benefits

The Food and Drug Administration proposes to revise the type size labeling requirements for providing FOP calorie declarations for packaged food sold from certain vending machines. This action is being taken in response to requests from the vending and packaged foods industries to reduce the regulatory burden and increase flexibility. The proposed rule would revise the type size requirements for FOP calorie labeling on packaged foods displayed for sale in glass front vending machines.

There are currently several voluntary FOP labeling programs where calorie information is presented. If finalized, this proposal may provide an increased incentive for packaged food manufacturers to add new or amend current FOP calorie labeling to foods in order to comply with the updated standard. If so, glass front vending machine operators carrying exclusively those products will not have to provide signs with calorie information for the food, providing an opportunity to reduce operator costs. To the extent this occurs, some costs may shift from the vending machine operator to the manufacturer. Packaged food manufacturing firms may choose to incur additional costs associated with amending the FOP label in order to retain revenue streams

from current customers, including vending machine operators. If total revenue is greater than total cost, this proposed rule will provide cost savings for packaged food manufacturing firms. We expect the potential cost savings to both vending machine operators and packaged food manufacturers to outweigh the costs to packaged food manufacturers and, thus, the net effect to be positive, but lack the data to quantify this effect. We welcome data that would help us to better estimate these impacts.

C. 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 a final rule that requires vending machine operators who own or operate 20 or more vending machines to provide calorie declarations for food sold from vending machines (Ref. 1). 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 visible nutrition information must be clear and conspicuous and be able to be read easily on the article of food while in the vending machine in a type size of at least 50 percent of the size of the largest printed matter on the label.

After the final rule appeared in the Federal Register, several industry representatives contacted FDA to state that the type size requirement for FOP labeling presented significant technical challenges to the packaged foods industry. Consequently, this proposed rule would revise the type size requirement, anchoring type size to the net quantity of contents declaration, such that the minimum type size is 150% the size of the net quantity of contents declaration. Industry representatives have expressed support for FOP “type size of at least 150% of net quality of

contents” (Ref. 2; 3; 4; 5; 6). This proposed rule would change only the type size requirement when calories are displayed on the front of the package of foods sold in glass front vending machines. All other requirements for FOP calorie labeling on vended foods would remain unchanged.

D. Baseline Conditions

The final regulatory impact analysis (FRIA) for the vending machine labeling final rule serves as a baseline for this analysis (Ref. 7). On August 1, 2016, the compliance date for certain food products sold from a glass front vending machine that allow prospective purchasers to view front of pack calorie labeling on packaged foods offered for sale was extended from December 1, 2016 to July 26, 2018 (Ref. 8). In this proposed rule, FDA proposes that affected covered vending machine operators must comply with the final rule by January 1, 2020 to provide sufficient time for the packaged food industry to revise their labels, as appropriate, consistent with any new requirements. In addition, pending completion of this rulemaking, FDA intends to exercise enforcement discretion with respect to the July 26, 2018 compliance date for products sold in glass front vending machines that provide FOP calorie disclosure and the product complies with all aspects of the final vending machine labeling rule except that the disclosure is not 50 percent of the size of the largest print on the label. It is unlikely that the current rulemaking will be completed by then. 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.

E. Cost Saving Benefits of This Proposed Rule

The proposed 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. 9; 10; 11). 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. 9). If the proposed rule provides packaged food manufacturers with an incentive to add new or amend current FOP calorie labeling to vended food products, operators of glass front machines may benefit from the proposed 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 proposed 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 proposed rule as well. If vending machine operators prefer to use packaged foods with FOP labels meeting the proposed 150% standard, packaged food manufacturers may choose to update or expand the use of FOP calorie declarations that meet the 150% standard on foods that are likely to be sold in vending machines, thus increasing or maintaining revenues. Lastly, to the extent that this proposed rule increases the availability or clarity of calorie declarations, consumers may have increased potential benefits of the calorie label. Food purchased from all vending machines only makes up 0.3 percent of average total calorie intake. Therefore, any benefit accrued to an individual consumer would necessarily be mathematically very small.

F. Costs of This Proposed Rule

There are currently several voluntary FOP labeling programs where calorie information is presented on packaged foods likely to be sold in vending machines (Ref. 12). One of these voluntary labels, the American Beverage Association's Clear on Calories program, requires a type size 150 percent larger than the size of the net content declaration for beverage containers 20 ounces or less (Ref. 13). Thus, beverage manufacturers participating in this voluntary FOP labeling program would already align with the amendments of this proposed rule.

FDA has received letters from representatives of the packaged food, beverage, and vending machine industries supporting the use of a 150 percent standard for the FOP type size requirement (Refs. 2; 3; 4; 5; 6). Given this, we expect that many packaged food products sold in glass front vending machines that currently bear FOP calorie labeling would meet the proposed 150 percent requirement. However, we specifically invite comment and data on the percentage of food products commonly sold in glass front vending machines bearing voluntary FOP calorie labeling, and for those products that currently bear voluntary FOP calorie labeling, the type size of the FOP calorie labeling used on the products.

Packaged food manufacturers choosing to update other voluntary FOP labeling to align with this proposed rule or add new FOP calorie labeling may incur administration 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 to 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 proposed rule to such businesses. Because any change would be voluntary, we do not expect manufacturers to change labeling unless they anticipate revenues

would neutralize any costs. However, some packaged food manufacturers may risk exclusion from the vending machine marketplace unless they update packaging to meet the proposed 150 percent standard.

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

G. Analysis of Regulatory Alternatives

In addition to the proposed revision to the existing type size requirements, the proposed rule discusses two alternative approaches. This section provides a qualitative discussion of the costs and benefits of each approach. We invite comment on the possible economic impact of each regulatory alternative on packaged food manufacturers, vending machine operators, and consumers.

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

The first alternative 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 proposed approach, this alternative would 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 and making it less likely that operators would need to post signs with calorie information. Under this alternative approach it would also be less likely that food product manufacturers would update existing packaging if they already meet or exceed the 100 percent standard.

We lack the data to provide a quantitative analysis, but expect this approach, compared to the proposed approach, would decrease the burden to vending machine operators of providing calorie information for products in a glass front machine, while expanding the number of products available for consumers to choose from. We welcome information from public commenters to help us better estimate the impacts of this alternative approach.

Alternative Approach B: Not specifying any size

The second alternative approach would be to not specify any size for the visible nutrition information. This option would give the packaged food industry considerable flexibility in deciding how large – or how small – voluntary FOP calorie labeling could be, and may reduce the need for packaging changes for some manufacturers. Compared to the proposed rule, we would anticipate reduced costs to vending machine operators because, under this alternative, any product with a FOP calorie label – regardless of the size or location of that label – would meet the regulatory standard, resulting in a wider variety of products that would be available for stocking without the need for additional signage. At the same time, 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 welcome comment on ways to preserve the utility of FOP labeling under this alternative while also minimizing costs.

H. Distributional Effects

As described above, the proposed 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.

I. International Effects

The proposed rule should not create any adverse international effects.

J. Uncertainty and Sensitivity Analysis

We present uncertainty analyses within sections E and F describing the cost saving benefits and costs of this proposed rule. We also include qualitative discussions of two alternative regulatory approaches. We are not certain how many vended products will be affected by the proposed rule because we do not know precisely how many vended food products currently have FOP labeling or if that FOP labeling would meet the proposed standard nor do we know how vending machine operators will elect to provide additional calorie information to the consumers. We welcome data that would help us reduce this uncertainty. The costs and/or benefits to consumers of the proposed provisions are also uncertain and remain unquantified.

II. Preliminary 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. The vending machine final rule does not impose burdens to the suppliers of vending machine foods. While suppliers are not obliged to engage in FOP calorie labeling, this proposed rule, if finalized, would allow for greater flexibility for the use of FOP calorie labeling in glass front vending machines than the existing regulations, potentially reducing the burden on covered vending machine operators of providing additional calorie labeling. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

This proposed rule does not require suppliers 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 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 (Ref. 14). 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 proposed standard, nor do we know the proportion that would be compelled, but not required, to add or change existing labeling to meet the proposed standard. We welcome data that may refine this estimate.

This proposed rule provides increased flexibility for vending machine operators. For the purposes of the Regulatory Flexibility Act analysis, the relevant economic sector is NAICS 4542, vending machine operators (Ref. 14). SBA defines a small vending machine operator as one who 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 proposed 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 proposed rule. Therefore, we estimate that between 26 and 100 percent, 980-3,770 vending machine operators, would be given increased flexibility due to this proposed rule.

B. Alternatives to Minimize the Burden on Small Entities

The proposed rule discusses two alternative approaches. This section describes how these approaches may minimize burden on small entities. By expanding the number of products considered to have visible FOP calorie labeling, both alternative approaches would give vending machine operators a wider selection of products to choose from when stocking their machines and making it less likely that operators would need to post signs with calorie information. We lack the data to quantify the reduced burden of each alternative, but estimate that not specifying any size would reduce the burden of the vending machine final rule the most.

This proposed rule does not require FOP calorie labeling for foods in glass-front vending machines. To the extent that the proposed rule creates a burden to food manufacturers to make changes in order to retain current customers or attract new ones, the two alternatives described above are less burdensome than the proposed rule. Under Alternative Approach A, it would also be less likely that food product manufacturers would update existing packaging if they already meet or exceed the 100 percent standard. Alternative Approach B would minimize the burden even more, because any product with a FOP calorie label – regardless of the size or location of that label – would meet the regulatory standard.

III. References

- 1) 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>.
- 2) Letter from Karin F. R. Moore, Senior Vice President and General Counsel, Grocery Manufacturers Association, and cosigned by the American Beverage Association, National Automated Merchandising Association, National Confectioners Association, and SNAC International, to Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition, dated June 28, 2016.

- 3) Letter from Karin F. R. Moore, Senior Vice President and General Counsel, Grocery Manufacturers Association, and cosigned by the American Beverage Association, National Automated Merchandising Association, National Confectioners Association, and SNAC International, to Scott Gottlieb, M.D., Commissioner of Food and Drugs, U.S. Food and Drug Administration, dated July 19, 2017.
- 4) Letter from Jason Eberstein, Director, State & Federal Government Affairs, National Automatic Merchandising Association, to Scott Gottlieb, M.D., Commissioner of Food and Drugs, U.S. Food and Drug Administration, dated November 21, 2017.
- 5) Letter from Brad G. Figel, Vice President, North America Public Affairs, Mars, Inc., to Mick Mulvaney, Director, Office of Management and Budget, dated January 30, 2018.
- 6) Letter from Elizabeth Avery, President and CEO, SNAC International, to Dockets Management Staff, Food and Drug Administration, dated February 12, 2018.
- 7) 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>.
- 8) 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>.
- 9) Vending Times. 2012 Census of the Industry. Vending Times 2012; 52(12)
- 10) Automatic Merchandiser. 2012 State of the Vending Industry Report.
- 11) National Automatic Merchandising Association. Comments of: The National Automatic Merchandising Association. Docket No. FDA-2010-N-0298. 2010.
- 12) Letter from Karin F. R. Moore, Vice President and General Counsel, Grocery Manufacturers Association, and cosigned by the American Beverage Association, National Automated Merchandising Association, National Confectioners Association, and SNAC International, to Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition, dated March 31, 2016.
- 13) American Beverage Association. “Clear on Calories: The Calorie Label Initiative and Style Guide” November 30, 2017. Available from: <http://members.ameribev.org/files/toolkits/final-aba-clear-on-calories--calorie-label-initiat.pdf>
- 14) United States Census Bureau, U.S. Department of Commerce, Statistics of U.S. Businesses, June 10, 2018. Available from: www.census.gov/programs-surveys/susb.html