



Food & Beverage

ISSUE ALLIANCE

October 21, 2016

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Thomas Vilsack
Secretary
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

The Honorable Shaun Donovan
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Maria Contreras-Sweet
Administrator
Small Business Administration
409 Third Street, SW
Washington, DC 20416

Dear Secretary Burwell, Secretary Vilsack, Director Donovan, and Administrator Contreras-Sweet:

On behalf of the Food and Beverage Issue Alliance (FBIA), the undersigned trade associations respectfully request a harmonized compliance date for two federal mandatory label revisions--the Food and Drug Administration's (FDA's) rule revising the Nutrition Facts Label (NFL) and the U.S. Department of Agriculture's (USDA's) disclosure standard for bioengineered foods (GE rule) – that is mindful of the numerous additional regulatory changes affecting food labels and signs. These two mandatory label revisions will require new labels for hundreds of thousands of food products. The food industry is fully committed to making all the mandated changes, but we are requesting an implementation process that does not require multiple label changes and is cognizant of the time, complexity, and cost involved in making such changes.

As of today, our members, except for small businesses, have less than two years to comply with the FDA's July 26, 2018 compliance date for the mandatory revisions to the NFL and yet they still do not have the guidance documents that are essential to making these mandatory label changes, particularly the mandatory changes to the novel declarations of added sugars and dietary fiber. Additionally, Congress (in P.L. 114-216) has mandated the USDA to issue the final GE disclosure rule by July 29, 2018, three days after FDA's NFL compliance date. This means that only days after all food labels are required to be in compliance with FDA's NFL labels, industry must again begin to re-design labels and related materials and re-label their products.

To give context to the magnitude of what these mandates require, approximately 400,000 new products¹ have been introduced since the NLEA changes were made over 20 years ago (notably, the two-year¹ compliance timeframe 20 years ago was not sufficient for some sectors). Without question, the food and beverage world is immeasurably more complicated and globalized than it was 20 years ago. To change essentially every single food label in the U.S. requires adequate time, careful planning, significant resources, testing and analyzing products, entering ingredient information into databases, new label and packaging designs, new printing plates, and queuing up in line with the printing company. The process requires coordination between software vendors, ingredient suppliers, graphic designers, printing companies, and others on a scale of magnitude that has never been contemplated or done before. The costs incurred may range anywhere from \$250 - \$6,000 per SKU, with industry-wide cost upwards in the billions of dollars (costs that will ultimately trickle down to consumers). While the impact is industry-wide, small business will be particularly affected. Repeating this scenario back-to-back twice--once for the NFL and a second time for GE disclosures--will be unduly burdensome and enormously wasteful across every impacted sector and is in direct contravention to principles espoused in Executive Orders 12866 and 13563 (directing agencies to reduce redundancy and costs and to simplify and coordinate regulations).

Our members do not yet have all the information they need to make the mandatory NFL label changes. Presuming FDA can issue final guidance by the end of 2016 on added sugars and dietary fiber (including approving the dietary fiber citizen petitions because all approved fibers must be declared on the NFL), the entire food industry, except for small businesses, will have less than 18 months to change all food labels by July 2018, and just days later will be required to begin the process again, redesigning labels and relabeling products to comply with USDA's GE disclosure requirements.

A harmonized compliance date that aims to introduce consumers to a single label format should try to incorporate, where possible, the numerous other regulatory changes affecting food labels: the pending revisions to nutrient content claims and health claims; the voluntary sodium reduction targets; the vending machine labeling rule and relevant sections of the menu labeling rule²; and all the technical labeling revisions (e.g., rounding rules, formatting, and serving sizes). We note that 20 years ago with the NLEA changes, FDA completed its related rulemaking simultaneously, including the rulemaking on nutrient content claims and health claims, and provided a harmonized compliance date.

As of December 1, 2016, manufacturers will not be able to delay the NFL implementation process any longer and meet FDA's 2018 compliance deadline. Consequently, companies may start this complex, lengthy, and costly process (see explanation above) without sufficient information from FDA on how to properly label their products and may, therefore, inadvertently use labels that do not meet

¹ 58 Fed. Reg. 2930 (January 6, 1993)

(<http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/UCM385669.pdf>, accessed 10/5/16.

² We request that any harmonized compliance date apply to the compliance date for the one provision of the vending machine labeling rule regarding the prominence of the calorie disclosure on the front of pack of foods sold in glass-fronted vending machines (21 C.F.R. § 101.8(b)(2)) and the relevant sections of the menu labeling rule(21 C.F.R. § 101.11). FDA extended the compliance date for this provision until July 26, 2018 (the current compliance date for the NFL final rule) and if FDA provides a harmonized compliance date, we ask FDA to include these revisions as well so that companies need only to make one set of label changes.

FDA's expectations. To that end, we respectfully request that you notify us with your response to our request by December 1, 2016.

Beyond the efficiencies and consumer cost-savings explained above, there are significant additional benefits in allowing a single label change that can be achieved by issuing a harmonized compliance date. For example, consumers will be introduced to a single label format instead of potentially being exposed over several years to different versions of the same label at the same time. Introducing a single label format will greatly enhance the effectiveness of the label as a tool to assist consumers in making healthful dietary choices. Moreover, consumer education efforts--which are essential to the effectiveness of the label--will be much more efficient and effective using a single label format. Conversely, exposing consumers piece-meal to potentially numerous label changes over several years and to products using multiple versions of the label at the same time may significantly undermine consumer education efforts and the effectiveness of the label in guiding consumer choices.

Congress has mandated that the USDA issue its final GE disclosure rules by July 29, 2018. These requirements, similar to the mandatory NFL revisions, will likely apply to the vast majority of U.S. food labels. Given the magnitude of the number of products involved, it is reasonable to foresee the need for a compliance timeframe sufficient to make all the required changes. The GAO has urged that there be greater collaboration between FDA and the USDA on food-related matters. In that spirit, we respectfully request that you give serious consideration to coordinating a harmonized compliance date for the mandatory NFL revisions and GE disclosures that also takes into consideration the numerous other label revisions described above. This should provide FDA and USDA sufficient time to issue critical final guidance documents, allow industry to coordinate a single label revision, and facilitate effective consumer education initiatives, without undue burdens and excessive waste.

We appreciate your consideration of these issues and look forward to your response by December 1, 2016.

Sincerely,

American Bakers Association
American Frozen Food Institute
American Beverage Association
American Spice Trade Association
Calorie Control Council
Corn Refiners Association
Flavor and Extract Manufacturers Association
Food Marketing Institute
Grocery Manufacturers Association
Independent Bakers Association
Infant Nutrition Council of America
Institute of Shortening and Edible Oils
International Bottled Water Association
International Dairy Foods Association
International Food Additives Council
International Foodservice Distributors Association
Juice Products Association
National Association of Margarine Manufacturers

National Automatic Merchandising Association
National Confectioners Association
National Grocers Association
National Institute of Oilseed Products
National Pasta Association
National Restaurant Association
North American Millers' Association
Peanut and Tree Nut Processors Association
Produce Marketing Association
SNAC International
The Association for Dressings and Sauces
The Sugar Association
Vinegar Institute

cc: Robert M. Califf, M.D., Commissioner of Food and Drugs