

**FOOD & BEVERAGE
LAW: NEWS AND
ANALYSIS**



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**EXPANDED NUTRITION LABELING REQUIREMENTS
WILL EXTEND TO RESTAURANTS, RETAIL FOOD
ESTABLISHMENTS AND VENDING MACHINES**

President Barack Obama (D) signed the Patient Protection and Affordable Care Act into law on March 23, 2010. Pub. L. 111-148. Tucked into this sweeping health care reform measure is a provision that will require restaurants, retail food establishments and vending machines to provide certain nutrition information.

The new law expands the provisions of the Nutrition Labeling and Education Act of 1990, which requires nutrition labeling for packaged food products. When they take effect, the new requirements will apply to a broad range of establishments from restaurants, delis and bakeries, to grocery store soup and salad bars and possibly even soda fountains in gas stations and convenience stores, as well as concession stands at movie theatres and sports venues.

New Requirements Could Apply to Wide Range of Establishments

Section 4205 of the health care reform law amends the misbranded food provisions of the Federal Food, Drug, and Cosmetic Act to establish new nutrition labeling requirements for standard menu items offered for sale in a "restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items." 21 U.S.C. § 343(q)(5)(H)(i).

While the new statute does not define the terms "restaurant" or "similar retail food establishment," FDA guidance¹ has previously defined "restaurant" as including

establishments where foods are generally consumed immediately where purchased or while walking away (e.g., lunch wagons, cookie counters in a mall, and vending machines, including similar foods sold from convenience stores); and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices for immediate consumption.²

1 U.S. Food and Drug Administration, Guidance for Industry: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods, (Apr. 2008), available at <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocument/foodlabelingnutrition/ucm053455.htm>

2 *Id.* at Q.89.

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FDA will likely interpret the scope of what constitutes a restaurant or similar retail food establishment broadly to include not only restaurants and facilities such as bakeries and delicatessens, but also places such as movie theatre concessions and certain vendors at sports venues. In addition, the requirements will likely extend to self-service counters in convenience stores and gas stations along with soup and salad bars and other self-serve food stations.

Health Care Reform Bill Specifies Nutrient and Calorie Content Disclosures

Establishments subject to the new labeling requirements must disclose the following information in a clear and conspicuous manner:

- The number of calories contained in the standard menu item, as usually prepared and offered for sale. This information must be provided in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu listing the item for sale or on the menu board, including a drive-through menu board.
- A succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation. This information must be posted prominently on the menu or menu board, and designed to enable the public to understand, in the context of a total daily diet, the significance of the caloric information provided on the menu or menu board.

21 U.S.C. § 343(q)(5)(H)(ii).

In addition to providing the required information outlined above on menus and menu boards, restaurants and retail service establishments must also provide certain additional nutrition information, *e.g.*, fat content and information on other nutrients, to consumers on request. 21 U.S.C. § 343(q)(5)(H)(ii)(III). The additional information must be in writing and available on the premises of the restaurant or retail service establishment.

Some foods will be exempt from the labeling requirements such as items that are not listed on a menu or menu board, *e.g.*, condiments and daily specials or temporary menu items that appear on the menu for less than 60 days per calendar year.

FDA Rulemaking Necessary to Implement Law

Within one year of enactment, by March 21, 2011, the Food and Drug Administration (FDA) must issue proposed regulations to implement the new nutrition labeling requirements that address the following issues:

- standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors as determined by the Secretary;
- format and manner of the nutrient content disclosure requirements.

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21 U.S.C. § 343(q)(5)(H)(x).

FDA must also establish by regulation standards for determining and disclosing the nutrient content for standard menu items available in different flavors, varieties or combinations, but that are listed as a single menu item, *e.g.*, soft drinks, ice cream, pizza, doughnuts, or children's combination meals. 21 U.S.C. § 343(q)(5)(H)(v).

Nutrition Labeling Also Applies to Vending Machines

Vending machines operated by a person who is engaged in the business of owning or operating 20 or more vending machines are also subject to the new nutrition labeling requirements. Calorie content information must be provided by the vending machine operator when an article of food sold from a vending machine does not permit the prospective purchaser to examine the product's Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase. In such instances, the vending machine operator must provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the product. 21 U.S.C. § 343(q)(5)(H)(viii).

Express Preemption of State and Local Law Included in Nutrition Labeling Requirements

It is important to note that the new labeling requirements will preempt state and local laws that require nutrient disclosures of the type required by new section 403(q)(5)(H). Pub. L. 111-148, section 4205(d). As a result, when they become effective, the new labeling requirements will create a new national standard that will supersede existing state and local requirements, such as those in California and New York City.

Affected Companies Should Begin Preparing for Compliance

FDA is required to issue proposed regulations sometime before March 21, 2011, to implement the new labeling requirements. Following issuance of the proposed rule, FDA will allow for a comment period to facilitate feedback on the proposal's provisions. Most likely, the comment period will last 60-90 days, although it could be extended. Following the comment period, FDA will review the comments and issue a final rule to implement the new labeling requirements. The final rule should allow the industry several months, if not longer, to bring their operations into compliance with the new labeling requirements. This entire process will likely take 18 months or longer.

Although it will be some time before the new labeling requirements are finalized, companies that know they will be subject to the new requirements, as well as those that suspect they may be subject to the requirements, should begin to consider how they will comply with the final rule once it is issued. Part of this preparation may include talking with suppliers to determine how to obtain the information necessary to provide the required caloric and other nutrient disclosures.

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Companies should also be ready to review FDA's proposed rule when it is issued in the coming months to assess whether it will apply to their operations. Some companies may wish to provide comments on the proposed rule for consideration by FDA when developing the final rule to implement the new labeling requirements.

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SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.

