



November 21, 2011

*Submitted Electronically*

The Honorable Cass R. Sunstein  
Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
Eisenhower Executive Office Building  
1650 Pennsylvania Avenue, NW  
Washington, DC 20503

**RE: Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments and OMB Review Pursuant to Executive Order 12866 and 13563**

**Docket No. FDA-2011-F-0172**

Dear Administrator Sunstein:

The Food Marketing Institute (FMI) appreciates your consideration of these comments to assist you with reviewing pursuant to Executive Order 12866 and Executive Order 13563 the Food and Drug Administration's (FDA or the Agency) final rule implementing § 4205 of the Affordable Care Act<sup>1</sup> (ACA), which requires restaurants and "similar retail food establishments" that are part of a chain with 20 or more locations doing business under the same name to provide calorie and other nutrition information for standard menu items (the Final Rule). On April 6, 2011, FDA published a proposed rule to implement § 4205 (Proposed Rule). The Proposed Rule<sup>2</sup> as written will impose a burden on the supermarket industry of \$1 billion in the first year alone. Indeed, the Office of Management (OMB) in the FY 2011 Information Collection Budget of the United States ranks the Proposed Rule as one of the most burdensome, imposing nearly 15 million burden hours.<sup>3</sup> We believe the hourly burden will actually be substantially greater and the cost estimate of the paperwork burden at \$70 million is far too low.

Fortunately, § 4205 gives FDA the authority to substantially reduce these burdens and the Agency is considering doing so. The law left the term "similar retail food establishment" undefined,

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<sup>1</sup> Pub. L. No. 111-48.

<sup>2</sup> 76 Fed. Reg. 19192 (April 6, 2011).

<sup>3</sup> FY 2011 Information Collection Budget of the United States, Office of Management, p. 6 (September 2011).

granting the Agency discretion is determining the scope of the regulations. While the Proposed Rule as written defines this term very broadly—in a manner we believe is inconsistent with the law—the Agency is considering an alternative which would cut the burden of the rule by hundreds of millions of dollars and result in the creation or retention of tens of thousands of jobs.

As stated in the Proposed Rule, FDA is considering Option 2, which would narrow the scope of menu labeling regulations to only restaurants and retail establishments whose primary business is the selling of restaurant or restaurant-type food. Option 2 reflects the text of § 4205 and the intent of Congress.

We believe that E.O 12866 and E.O. 13563 demand that the agency adopt Option 2 in the Final Rule and we respectfully request that OMB not approve any Final Rule for publication unless it incorporates Option 2 in the regulation.

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI’s members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of \$680 billion represents three-quarters of all retail food store sales in the United States. FMI’s retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI’s associate members include the supplier partners of its retail and wholesale members.

FMI offered extensive legal arguments as to why the term “similar retail food establishment” must be narrowly construed in our comments submitted to the Agency on July 5, 2011. These arguments include the facts that:

- Congress used the term “food retailer” and “retail establishment” to refer to supermarkets in the statute modified by § 4205 but omitted those terms in § 4205 itself;
- The heading of the §4205 refers only to restaurants;
- The law that served as the model for §4205 did not regulate supermarkets;
- All the laws the primary sponsor referred to in his floor statement introducing the legislation on which § 4205 is based did not regulate supermarkets.

- Nowhere in the legislative history does it indicate that Congress intended or even contemplated that the law would regulate supermarkets.<sup>4</sup>

Our comments are attached as Exhibit A. The Proposed Rule defined the term “similar retail food establishment” in a very expansive manner which we believe is inconsistent with both the language of the statute and legislative intent. We strongly urge OMB to carefully analyze the definition of the term in the Proposed Rule.

## Regulatory Alternatives

FDA has proposed defining similar retail food establishments in the following manner:

*Restaurant or similar retail food establishment* means a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of the establishment. The sale of food is the retail establishment’s primary business activity if the establishment presents itself, or has presented itself publicly as a restaurant, or a total of more than 50 percent of that retail establishment’s gross floor area is used for the preparation, purchase, service, consumption or storage of food.<sup>5</sup>

This definition essentially covers every supermarket and grocery store as FDA has indicated in the Proposed Rule:

TABLE 1—ARE THE FOLLOWING ESTABLISHMENTS “RESTAURANTS OR SIMILAR RETAIL FOOD ESTABLISHMENTS” UNDER THE PROPOSED RULE?

Generally yes	Generally no
Table service dining establishments	Movie theaters
Quick service (fast food) establishments	Amusement parks
Cafeterias	General merchandise stores
Pastry and retail confectionary stores	Hotels
Coffee shops	Trains
Snack bars	Planes
Ice cream parlors	
Multi-purpose establishments that have presented themselves publicly as restaurants	
Establishments within larger establishments that are part of a chain with locations outside of the larger establishment’s chain (e.g., chain coffee shop in a bookstore; see discussion below)	
Grocery stores	
Convenience stores	

FDA is considering an alternative definition under Option 2, which would define “restaurant or similar retail food establishment” to mean a retail establishment where the sale of restaurant or restaurant-type food—as opposed to food in general—is the primary business activity of that establishment.

<sup>4</sup> FMI Comments on Proposed Rule Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (July 5, 2011) pp. 6-12.

<sup>5</sup> 76 Fed. Reg. 19233 (April 6, 2011).

Under this alternative, the agency would consider the sale of restaurant or restaurant-type food to be a retail establishment's primary business activity if either (1) the establishment presents itself or has presented itself publicly as a restaurant, or (2) a total of more than 50 percent of a retail establishment's gross floor area is used for the preparation, purchase, service, consumption or storage of restaurant or restaurant-type food or its ingredients.<sup>6</sup>

The alternative, Option 2, would generally exclude supermarkets and greatly reduce the overall burden of the Proposed Rule. We believe E.O. 12866, and 13563, demand that FDA adopt Option 2 to maximize the benefits of the Proposed Rule and minimize the burdens. **OMB should not permit any Final Rule to be published that does not adopt Option 2.**

## Executive Order 13563 and 12866

Earlier this year, President Obama issued Executive Order 13563 which states:

Our regulatory system . . . must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. . . As stated in (Executive Order 12866) . . . each agency must . . . propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs. . . (and) tailor its regulations to impose the least burden on society.<sup>7</sup>

It is hard to conceive of a more perfect circumstance than the one presented in the Proposed Rule of which the principles of E.O 13563 should be applied. E.O. 13563 requires FDA to adopt Option 2. There is simply no way that the benefits of extending the rule to supermarkets justify its costs. FDA has not demonstrated that the benefits of regulating supermarkets exceed the costs and it is apparent that the Agency cannot. Indeed the Agency has failed to quantify any benefits at all of the Proposed Rule. E.O. 13563 demands that FDA adopt Option 2.

### A. Least Burdensome Tools for Achieving Regulatory Ends

FDA has acknowledged that § 4205 does not obligate the Agency to regulate supermarkets. The Agency has tentatively decided to do so in the Proposed Rule, but is considering Option 2 that would generally exclude supermarkets from the scope of the law. Consistent with E.O 13563 and 12866, Option 2 is the least burdensome tool FDA has expressed in the Proposed Rule that would permit the Agency to achieve its regulatory ends. The Agency has estimated that the Proposed Rule would impose compliance costs of \$76.8 million, assuming a discount rate of 3 percent, or \$82.3 million, assuming a discount rate of 7 percent. The Agency's high estimate of compliance costs is \$120.5 million, assuming a discount rate of 3 percent and \$130.1 million, assuming a discount rate

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<sup>6</sup> Id. at 19198.

<sup>7</sup> Exec. Order No. 13563 (January 18, 2011).

of 7 percent. FMI believes the compliance costs will be far higher for the reasons outlined later in these comments. Option 2 reduces the compliance costs of the Proposed Rule by more than 12.5 percent while the proportional dollar sales of restaurant or restaurant-type food not covered by menu labeling drops by only 5 percent. For every dollar of restaurant or restaurant-type food not covered at supermarkets, FDA saves the economy \$2.50 in compliance costs according to the preliminary regulatory impact analysis conducted by the Agency (PRIA).<sup>8</sup> FMI can attest that this cost savings will be much greater. According to our estimate it will result in approximately \$20.00 in compliance costs saved for every dollar of restaurant food not covered. These dollars will be put back into the economy to create jobs and reduce costs to consumers.

FDA in the PRIA states that “the primary support for government intervention is an absence of sufficient nutritional information, produced by an inadequate incentive for restaurants to produce that information on their own . . .”<sup>9</sup> In the case of food retailers, there is indeed sufficient nutritional information provided to consumers. The fact of the matter is that more than 95 percent of the food items sold at the typical chain supermarket already carry nutrition labeling.<sup>10</sup> The cost incurred in capturing the remaining 5 percent vastly exceeds any benefit obtained.

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<sup>8</sup> Department of Health and Human Services, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments Notice of Proposed Rulemaking, Preliminary Regulatory Impact Analysis (March 2011).

<sup>9</sup> PRIA at p.4.

<sup>10</sup> The average store in the industry carries about 39,000 stock keeping units according to FMI’s latest survey, the Food Retailing Industry Speaks.. 10- 15 percent of those items are non-food items. Assuming an average of 12.5 percent on non-food items, the typical chain supermarket carries 34,125 food items. Of these 700-1500 will not be labeled with nutrition labeling which equates to 2-4 percent of food items. Certain retailers carry significantly higher SKUs and proportionately more food items are not labeled. Many of the items in bakeries and delis are already labeled. All par baked items, defrosted cakes and deli items in consumer packages, must be labeled.

## B. FDA Has Failed to Account for Quantitative Benefits

E.O. 13563 requires agencies to “take into account benefits and costs, both quantitative and qualitative.”<sup>11</sup> FDA has not bothered to quantify any benefits of the Proposed Rule in spite of E.O. 13563 and the fact that the Proposed Rule will cost the supermarket industry hundreds of millions of dollars. FDA has failed to comply with E.O. 13563.

TABLE 5a—ACCOUNTING STATEMENT: ANNUALIZED COST AND BREAK-EVEN BENEFIT POINT FOR THE PROPOSED REQUIREMENTS

	Primary estimate	Low estimate	High estimate	Year dollar	Discount rate	Period covered
<b>Benefits</b>						
Annualized Monetized (\$millions/year) .....	Not quantified					
Annualized Quantified:						
Qualitative: FDA estimates that at least 0.06 percent of the adult obese population would need to reduce caloric intake by at least 100 calories per week in order for benefits from the proposed requirements to reach a break even point on annualized costs (at either 3% or 7%).						
<b>Costs</b>						
Annualized Monetized (\$millions/year) .....	\$82.3 76.8	\$34.9 33.4	\$130.1 120.5	2009 2009	7% 3%	10 10

## C. No Evidence That Menu Labeling Produces Significant Benefits

The evidence that menu labeling has little or no benefit outweighs the evidence that shows it has any significant impact on public health. Indeed, of the studies FDA cites in its PRIA, most demonstrate that menu labeling has little to no effect on purchasing habits. Furthermore, none show any link to reduction in obesity rates, the purported benefit of menu labeling. The enormous cost of extending menu labeling to supermarkets vastly outweighs any marginal benefits that could come from it.

## D. Burden of Cumulative Regulations

E.O. 13563 reaffirms the principles governing regulatory review that were established in E.O. 12866, which requires each agency to “tailor its regulations to impose the least burden on society. . . taking into account . . . the costs of cumulative regulations.”<sup>12</sup> Supermarkets face a profoundly larger array of regulations than restaurants. Compliance staff at supermarket firms are already being stretched thin coping with these existing rules, and the burden imposed by the Proposed Rule is going to push them to the brink.

<sup>11</sup>Exec. Order No. 13563 (January 18, 2011).

<sup>12</sup> Exec. Order No. 13563 (January 18, 2011).

**Regulations that supermarkets must comply with that restaurants do not:**

<b>Regulatory Burdens Faced by Supermarkets and Restaurants</b>		
<b>Regulation</b>	<b>Compliance Required by Supermarkets</b>	<b>Compliance Required by Restaurants</b>
Country of Origin Labeling (7 C.F.R. pt. 60; 21 U.S.C §§ 301-399)	Yes	No
Identity Statement (21 C.F.R. § 101.3; 21 U.S.C. § 343(i)(1))	Yes	No
Net Quantity of Contents (21 C.F.R. § 101.105; 21 U.S.C. § 343(e)(2))	Yes	No
Ingredient Labeling (21 C.F.R. §§ 101.4; 21 U.S.C. § 343(i)(1))	Yes	No
Use By Dating	Yes	No
Nutrition Labeling (FDA) (21 C.F.R. § 101.9; 21 U.S.C. § 343(q))	Yes	Pending
Nutrition Labeling of Raw Meat and Poultry (9 C.F.R. §§ 317.300-345 and 381.400-445; 21 U.S.C. § 343(q))	Yes	No
Allergen Labeling (Pub. L. No. 108-282)	Yes	No
Presence of Artificial Colors, Chemical Preservatives and Artificial Flavors (21 C.F.R. 101.22; 21 U.S.C. § 343(i)(1))	Yes	No
Signature Line (21 C.F.R. § 101.5; 21 U.S.C. § 343(e)(1))	Varies by state	No
Safe Handling Instructions (21 C.F.R. § 101.17)	Yes	No
Bioterrorism Act Recordkeeping	Yes	No

(21 C.F.R. § 1.327; Pub.L. No.107-188)		
Recall Notification (Pub. L. 111–353)	Yes	No

The supermarket industry faces hundreds of millions of more regulatory burdens annually than the restaurant industry. E.O. 13563 and E.O 12866 require FDA to consider this and adopt Option 2.

The fact of the matter is that more than 95 percent of the food items sold at the typical chain supermarket already carry nutrition labeling.<sup>13</sup> The cost incurred in capturing the remaining 5 percent vastly exceeds any benefit obtained.

## Burden Estimate

FMI estimates that 150 chains<sup>14</sup> will be impacted with an average of 1,500 items covered by the Proposed Rule. FMI estimates that the cost of determining the nutrition information for each item will be \$1,000. The cost of getting the nutrition information initially will be at least \$225,000,000 for the industry. Menu boards and signs will be \$1,000,000 for each retailer leading to a cost of \$150,000,000. New scale/software investments will be \$1,500,000 per retailer or \$225,000,000. Training store level associates and developing training materials will cost \$150,000,000 across the industry. Recordkeeping is estimated to cost \$2,000,000 per chain annually for a total of \$300,000,000. The total burden on the industry will be more than \$1 billion for the first year alone. Ongoing costs will amount to the hundreds of millions of dollars.

### A. Number of Items Grossly Underestimated By FDA

“Because of the more limited offerings for restaurant or restaurant-type foods at grocery and convenience stores, FDA estimates that these establishments have on average approximately one half the number of menu items of an average restaurant, or 40 menu items.”<sup>15</sup> FDA has grossly underestimated the number of items covered. Here the estimate and the Proposed Rule simply don’t match. The Proposed Rule requires virtually every food item in a supermarket that is not

<sup>13</sup> The average store in the industry carries about 39,000 stock keeping units according to FMI’s latest survey, the Food Retailing Industry Speaks.. 10- 15 percent of those items are non-food items. Assuming an average of 12.5 percent on non-food items, the typical chain supermarket carries 34,125 food items. Of these 700-1500 will not be labeled with nutrition labeling which equates to 2-4 percent of food items. Certain retailers carry significantly higher SKUs and proportionately more food items are not labeled. Many of the items in bakeries and delis are already labeled. All par baked items, defrosted cakes and deli items in consumer packages, must be labeled.

<sup>14</sup> Progressive Grocer, 78<sup>th</sup> Annual Report of the Grocery Industry, April 2011; 2011 Chain Store Guide, Directory of Supermarket, Grocery and Convenience Store Chains.

<sup>15</sup> Id. at 26.



required to carry nutrition labeling under the NLEA to be labeled. Rather than having half of the menu items of an average restaurant, supermarkets have 6 to hundreds of times more items. FMI members have reported anywhere from 500 to 15,000 items being covered. If the scope of the Proposed Rule were limited to restaurant food only—and not restaurant-type food—then the estimate of 40 items would be closer to reality. The definition of restaurant-type foods includes all foods that are processed or prepared in a retail establishment and are ready for consumption, but not sold for immediate consumption. Existing FDA policy takes a very broad view of what constitutes “processed or prepared” in a retail establishment.<sup>16</sup> There is no indication that Congress intended that food not served for immediate consumption should be covered under the law. State sales tax laws distinguish what FDA categorizes as “restaurant-type” foods from true restaurant foods as FMI discussed at length in comments submitted previously to FDA.

FMI estimates that on average, 1,000 to 2,000 items will be covered with some retailers having to label thousands more.

### **B. Cost per Item**

FDA has estimated that the average cost of a full nutrition analysis is \$269 per item. FMI believes this is significantly underestimating the cost to the grocery industry. FMI has consulted laboratories and polled its membership, and this is simply not the case. While a handful of retailers may have existing staff who can handle this responsibility, many retailers will be required to hire additional staff at a large cost. Adding or reallocating a single full-time employee for this task has been estimated to cost \$70,000-\$120,000. Retailers may be required to hire several new employees to comply with this new regulatory requirement.

Many retailers will need to enlist the help of outside labs and labeling firms to comply with the requirement. These firms generally charge \$500-\$1,000 per item. A lab analysis of an item will far exceed the \$269 estimate. It will likely cost \$750-\$1,000 per item. Only for items with simple ingredients where there is comprehensive supplier-provided information available to the lab or labeling firm, will the cost of conducting an analysis by an outside firm be near the \$269 estimate.

Even retailers that conduct their own calculations internally are likely to utilize outside lab testing to verify the accuracy for numerous products. Furthermore, calculating nutrition information

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<sup>16</sup> To meet the criteria for being “primarily processed and prepared on-site”, the food must be augmented on site in a manner that changes the nutrient profile of the food (i.e., filling, icing, enrobing). Washing and garnishing with nuts, onions or seeds would fall under the definition of “primarily processed and prepared” if the added foods change the nutrition profile of the finished product. Foods which are not prepared on premises and that are portioned to consumer specifications on-site . . . (e.g., 1 lb of potato salad; 2 lb cheese, 1 lb assorted cookies, 5 rolls) are considered processed pursuant to 21 CFR 101.9(j)(3).

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/UCM064904#away>

internally will consume significant staff resources and, for many retailers, require the hiring of additional employees at the salaries described above.

### **C. Number of Stores Grossly Underestimated by FDA—PRIA Inconsistent with Rule**

In the PRIA, FDA estimates that only 11,200 grocery establishments will be affected by the Proposed Rule because the Census Bureau's 2007 Economic Census data reports that 36 percent of total establishments report sales of "meals or beverages for immediate consumption." This estimate misses the mark because it fails to consider that the Proposed Rule regulates stores that not only sell food for immediate consumption,<sup>17 18</sup> but also food not sold for immediate consumption, but ready for human consumption and processed or prepared in a retail establishment.<sup>19</sup> The definition of similar retail food establishment will generally cover every supermarket. While many supermarkets offer some form of food for immediate consumption, not all do. However, every supermarket offers what FDA has defined as "restaurant-type food." Only a handful of limited assortment chains (nontraditional retailers) do not. Essentially every supermarket has a bakery, deli or other facility where items are processed or prepared as defined by FDA. The number of grocery establishments affected by the Proposed Rule exceeds 35,000.

### **D. Menu Boards**

FDA has estimated that 2 hours of time will be needed to change each menu board and that grocery and convenience stores average 1 menu board per establishment. FMI believes both figures are too low. Redesigning menu boards can be a complex task, especially when significantly more text must be placed on a limited space. Many retailers will have to do major redesigns of their menu boards. FMI estimates that for most retailers it will take 8-15 hours to redesign each menu board to accommodate the information required by § 4205. Furthermore, the average supermarket is likely to have 5 menu boards, with a significant number of retailers having as many as 30 or more.

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<sup>17</sup> *Restaurant or similar retail food establishment* means a retail establishment that offers for sale **restaurant or restaurant-type food** (emphasis added), where the sale of food is the primary business activity of the establishment. The sale of food is the retail establishment's primary business activity if the establishment presents itself, or has presented itself publicly as a restaurant, or a total of more than 50 percent of that retail establishment's gross floor area is used for the preparation, purchase, service, consumption or storage of food. 76 Fed. Reg. 19233 (April 6, 2011).

<sup>18</sup> Restaurant food is defined as "food that is served in restaurants or other establishments in which food is served for immediate human consumption, *i.e.*, to be consumed either on the premises where that food is purchased or while walking away; or which is sold for sale or use in such establishments." 76 Fed. Reg. 19197 (April 6, 2011).

<sup>19</sup> Restaurant-type food is defined as "food of the type described in the definition of "restaurant food" that is ready for human consumption, offered for sale to consumers but not for immediate consumption, processed and prepared primarily in a retail establishment, and not offered for sale outside of that establishment." 76 Fed. Reg. 19197 (April 6, 2011).

### **E. Cost of Menu Boards**

FDA has estimated the average cost of a menu board to be \$550. While this will be accurate for some retailers, particularly those who have already installed boards which permit flexibility to accommodate changing offerings, for many other retailers the costs are likely to be greater—approximately \$1,000 to \$1,500 or more per menu board. A number of retailers have reported to FMI that the cost of redesigning and replacing their menu boards will amount to several million dollars.

### **F. Recordkeeping Costs**

The recordkeeping burdens of the Proposed Rule are enormous and as FMI discusses in the attached comments<sup>20</sup>, inconsistent with the statute. A number of retailers have reported to FMI that these provisions alone will impose millions of dollars of costs per year. These burdens are needless and vastly outweigh any benefits of the Proposed Rule.

### **G. Training Costs**

Training store level associates and developing training materials will cost \$150,000,000 across the industry. FDA estimates that total training costs will amount to only \$1.8 to \$12.2 million. This estimate does not reflect the realities of the burden the Proposed Rule will impose on supermarkets.

## **Congressional Concern**

The House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Subcommittee Report for the Fiscal Year 2012 Agriculture and Related Agencies funding bill includes report language expressing concern about the scope of the Proposed Rule:

*Nutrition Labeling.*—The Committee is concerned with the proposed rule that FDA issued on April 6, 2011, on nutrition labeling of standard menu items in restaurants and similar retail food establishments. The proposed rule would include establishments that are not primarily in the business of selling food for immediate consumption or selling food that is prepared or processed on the premises. These establishments are not similar to restaurants. . . . The Committee urges FDA to use the proposed alternative definition in the rule that would encompass only establishments where the

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<sup>20</sup> FMI Comments on Proposed Rule Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (July 5, 2011) pp. 34-37.

primary business is the selling of food for immediate consumption or selling food that is prepared and processed on the premises.<sup>21</sup>

OMB should consider this language and require FDA to adopt Option 2. “[W]hile the views of subsequent Congresses cannot override the unmistakable intent of the enacting one, such views are entitled to significant weight, and particularly so when the precise intent of the enacting Congress is obscure.”<sup>22</sup>

In addition, members of the House and Senate have sent letters to FDA regarding their concern with the fact that the Proposed Rule regulates supermarkets and urging the Agency to adopt Option 2 which would exclude them.

FMI greatly appreciates OMB’s consideration of these matters. Please contact me at (202) 220-0614 or [elieberman@fmi.org](mailto:elieberman@fmi.org) if you have any additional questions or need further information.

Sincerely,



Erik R. Lieberman  
Regulatory Counsel

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<sup>21</sup> H.R. Report No. 112-101 (June 3, 2011).

<sup>22</sup> *Seatrains Shipbuilding Corp. v. Shell Oil Co.*, 444 U.S. 572 (1980).

# **Exhibit A**



# Comments on Proposed FDA Menu Labeling Rule

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July 5, 2011

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***Submitted Electronically***

The Honorable Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
White Oak Building 1  
10903 New Hampshire Avenue  
Room 2217  
Silver Spring, MD20993

**RE: Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Proposed Rule**

**Docket No. FDA-2011-F-0172**

Dear Commissioner Hamburg:

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the Food and Drug Administration's (FDA or the Agency) request for comments on the proposed rule implementing § 4205 of the Affordable Care Act<sup>1</sup> (ACA), which requires restaurants and "similar retail food establishments" that are part of a chain with 20 or more locations doing business under the same name to provide calorie and other nutrition information for standard menu items (the Proposed Rule).<sup>2</sup> Section 4205 is codified in sections 403(q)(5)(A) and 403(q)(5)(H) of the Federal Food Drug and Cosmetic Act (FD&C Act).<sup>3</sup>

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of \$680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

We appreciate the opportunity to comment on this important matter.

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<sup>1</sup> Pub. L. No. 111-48.

<sup>2</sup> 76 Fed. Reg. 19192

<sup>3</sup> 21 U.S.C. §§ 301 et seq.

## Key Points

- FMI believes the plain language and legislative history of the statute requires the Proposed Rule to be narrow in scope and exclude supermarkets.
- Executive Order 13563 requires FDA to exclude supermarkets from the scope of the Proposed Rule.
- FDA has grossly underestimated the number of items required to be labeled at the typical supermarket under the Proposed Rule at 40. In fact, most chains will be required to label hundreds of items, some will be required to label several thousand. Several FMI members indicate they expect to be required to label 9,000-15,000 items on a company-wide basis. Most of these items fall within the definition of “restaurant-type” foods.
- If FDA proceeds to regulate the supermarket industry despite the plain language and legislative history of the statute and Executive Order 12866 and 13563, excluding “restaurant-type” foods from the scope of the final rule would provide significant relief to the supermarket industry.
- The plain language of the statute does not require additional written nutrition information to be provided to consumers for self-service items and foods on display contrary to FDA’s position.
- All foods that possess a Nutrition Facts panel disclosing the information required in § 101.11(b)(2)(ii)—regardless of whether the product is required to be labeled with a Nutrition Facts panel under § 403(q)(1) or the label is placed on the item voluntarily—should be excluded from the scope of the Proposed Rule so long as the consumer can view the information before purchasing the item.
- The Agency should use a “reasonable basis” test for nutrient declarations.
- Implementation of the Proposed Rule will be very costly and complex for the supermarket industry. If FDA determines that any aspect of the statute is applicable in supermarket environments, FMI believes the Agency should give the supermarket industry at least 24 months to comply following publication of the final rule.



## Table of Contents

Key Points.....	2
I. Introduction .....	5
II. Legal Analysis.....	6
A. The Plain Meaning of the Text Does Not Cover All Supermarkets as FDA has Construed It.....	6
B. Supermarkets are Generally Not Similar Retail Food Establishments .....	6
C. Regulated Establishments Must Be Similar to Restaurants .....	7
D. The Definition FDA Has Proposed Fails to Make Any Distinction Between Retail Food Establishments and Retail Food Establishments That Are “Similar” To Restaurants .....	7
E. Statutory Construction: § 403(q)(5)(H) Requires FDA to Make a Distinction Between All Retail Food Establishments and Retail Food Establishments That Are Similar to Restaurants .....	9
1. Section Heading .....	10
2. Legislative History.....	10
a. Restaurants Supported § 4205 to Preempt State Laws Regulating Them.....	11
b. House Agricultural Appropriations Subcommittee Expresses Concern About Scope of Menu Labeling.....	12
c. Language Modeled After New York City Code .....	12
III. Executive Order 13563 .....	13
A. Least Burdensome Tools for Achieving Regulatory Ends.....	13
B. Accounting for Quantitative Benefits .....	14
C. Burden of Cumulative Regulations .....	14
IV. Burden Estimate.....	16
A. Number of Items Grossly Underestimated By FDA .....	16
B. Cost per item .....	17
C. Menu Boards .....	17
D. Cost of Menu Boards .....	18
E. Recordkeeping Costs .....	18
V. The Burden Imposed On Supermarkets is Significantly Greater than Restaurants .....	18
A. Larger Variety of Items.....	18
B. New Items .....	19
C. Ingredients are Less Standardized.....	19

D. More Signage/Displays Impacted .....	20
VI. Comments on Specific Provisions of Proposed Rule .....	20
A. Defining the Term “Restaurant and Similar Retail Food Establishment” .....	20
B. “Primary Business Activity” Test .....	22
C. Doing Business Under the Same Name .....	22
D. Menu and Menu Board .....	23
E. Food Covered .....	23
1. Restaurant-Type Food.....	23
2. Standard Menu Item.....	25
F. Foods to Which the Requirements of Section 4205 Do Not Apply .....	25
1. Temporary Menu Items.....	25
G. Foods on Display .....	25
H. Custom Order .....	26
I. Information that Must Be Declared by Covered Establishments .....	26
J. Determination of Calories for Standard Menu Items that Come in Different Flavors, Varieties, or Combinations .....	27
K. Succinct Statement Concerning Suggested Daily Caloric Intake Required on Menus and Menu Boards .....	27
L. Nutrition Information that Must be Made Available in a Written Form.....	28
M. Display of Calories for Self-Service Foods or Foods on Display .....	28
N. Applicability of 403(q)(5)(H)(ii) to Self-Service Food and Food on Display .....	30
1. Calorie Declarations.....	30
2. Additional Written Nutrition Information for Self-Service Food and Food on Display .....	30
O. Packaged Foods that Bear the Nutrition Information Required by Section 403(q)(1) of the FD&C Act.....	31
P. Determination of Nutrient Content.....	33
Q. Substantiation Documentation .....	34
R. Proposed Effective Date.....	37

## I. Introduction

The supermarket industry is committed to providing consumers with nutrition information and, as discussed in these comments, has been held up as a model for other segments of the food industry to follow. The supermarket industry has seen robust competition among retailers as they battle to win over consumers with innovative new ways of providing nutritional information. More than 74 percent of retailers compete on the basis of consumer wellness and family health.<sup>4</sup> These innovations are benefitting consumers by making it easier for them to identify nutritious foods. Consumers are demanding nutrition information and supermarkets are responding. No less than 89 percent of Americans say that they are either somewhat or very concerned about the nutritional content of their food intake.<sup>5</sup> In the most recent study on shopper trends conducted by FMI, 72 percent of shoppers surveyed rated the availability of nutrition and health information as being a somewhat or very important factor in selecting a primary grocery store, and 73 percent of consumers stated that their primary store does a good or excellent job of providing nutrition and health information.<sup>6</sup> Sixty-three percent of consumers use this resource at least once a month and 30 percent use it once a week.<sup>7</sup> Supermarkets are responding to consumers' demands. More than 95 percent of food items sold in the typical supermarket bear nutrition labeling.

Regarding menu labeling shopper opinion is different. In fact, 56 percent of consumers were indifferent or opposed government efforts to require that calorie and ingredient information be posted for restaurant foods and prepared foods sold in supermarkets.<sup>8</sup> Seventy percent of consumers stated that the posting of calorie information would not make a difference in the amount of supermarket prepared foods that they eat.<sup>9</sup>

Section 4205 of the ACA amended the FD&C Act to require chain restaurants and certain "similar retail food establishments" to post calorie and other nutrition information for standard menu items. FDA has acknowledged that § 4205 does not require the Agency to regulate supermarkets and is contemplating an alternative within preamble of the Proposed Rule ("Option 2"), which would exclude supermarkets from the scope of the law. We submit that the language of § 4205 requires FDA to adopt this alternative, particularly in light of its legislative history. Executive Order 12866 and 13563 also require FDA to adopt Option 2. FDA recognizes that Option 2 would reduce the burden of the rule on the economy by tens of millions of dollars. FMI knows the burden reductions of the alternative would be much more. It would reduce the regulatory burden of § 4205 on the industry by hundreds of millions of dollars, if not billions of dollars. This would allow FMI members to use that money to expand their businesses and create

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<sup>4</sup> Food Marketing Institute, 2011 The Food Retailing Industry Speaks

<sup>5</sup> Food Marketing Institute, 2011 U.S. Grocery Shopper Trends.

<sup>6</sup>Id.

<sup>7</sup>Id.

<sup>8</sup> Food Marketing Institute, 2011 U.S. Grocery Shopper Trends.

<sup>9</sup>Id.

jobs. While supermarket retailers bear much of the regulatory cost, the rest are ultimately borne by consumers in the form of higher prices. Option 2 will save supermarket shoppers from these very substantial regulatory costs. FMI believes FDA should adopt Option 2 for the reasons outlined in these comments. Headings that are italicized reference text from the rule on specific requests for information posed by FDA.

## II. Legal Analysis

### A. The Plain Meaning of the Text Does Not Cover All Supermarkets as FDA has Construed It

Section 403(q)(5)(H) applies only to certain foods sold at restaurants and “similar retail establishments.” Unlike the Nutrition Labeling and Education Act<sup>10</sup> (NLEA), which applies to foods generally,<sup>11</sup> the application of § 403(q)(5)(H) is dependent on the type of establishment serving the food. FMI believes Congress chose such wording because it contemplated the challenges establishments like supermarkets face in determining nutrition content for and labeling items prepared and processed at the retail level. FMI will describe these challenges in greater detail later in this document.

### B. Supermarkets are Generally Not Similar Retail Food Establishments

Congress used the term “similar retail food establishment” but did not define it. It is essential then to view the term in the context of the statute § 4205 modifies, 21 U.S.C. §343(q). Within paragraph (q) the term “food retailer” is used to describe entities that are subject to nutrition labeling of meat and fish and this term is generally understood and has been construed to apply to supermarkets. Also within paragraph (q) the term “retail establishment” is used to describe certain foods that are exempt from the NLEA.<sup>12</sup> Supermarkets certainly fall within the definition of retail establishments, as do restaurants. Instead of using these terms, however, Congress chose to use “similar retail food establishment.” It is always appropriate to assume that Congress knows the law.<sup>13</sup> “Where Congress includes particular language in one section of a statute, but omits it in another . . . it is generally assumed that Congress acts intentionally and purposefully in

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<sup>10</sup> Pub. L. No. 101-535

<sup>11</sup> NLEA applies to “. . . food intended for human consumption and is offered for sale . . .,” 21 U.S.C. §343(q)(1), whereas § 4205 applies to “. . . food that is a standard menu item that is 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 . . .”

<sup>12</sup> 21 U.S.C. §343(q)(5).

<sup>13</sup> “It is always appropriate to assume that our elected representatives, like other citizens, know the law;” *Cannon v. University of Chicago*, 441 U.S. 677 (1979). The Court presumes Congress is aware of existing law when it passes legislation. *South Dakota v. Yankton Sioux Tribe*, 522 U.S. 329 (1998).

the disparate inclusion or exclusion.”<sup>14</sup> “It is accepted lore that when Congress uses certain words in one part of a statute but omits them in another, an inquiring court should presume that this differential draftsmanship was deliberate.”<sup>15</sup>

FDA must assume that Congress did not intend for “similar retail food establishments” and “food retailers” or “retail establishments” to have the same meanings.<sup>16</sup>

### **C. Regulated Establishments Must Be Similar to Restaurants**

Congress could have simply used the term “retail food establishment”—which is defined by FDA to include grocery stores<sup>17</sup> or “retail establishment” as in the NLEA—but instead qualified it with the word “similar.” This implies that being a retail food establishment alone does not bring the business under the ACA § 4205 regime; the retail food establishment must be similar to a restaurant. As the term establishment means “a place of business,”<sup>18</sup> FMI believes FDA must assess the establishment as a whole when evaluating whether it is similar to a restaurant. FDA’s purpose in crafting the Proposed Rule is to capture all food excluded by the gap in the NLEA. FMI believes this is not a proper construction of the statute. If Congress had intended for FDA to do so, it would have used the term *retail establishment* as used in NLEA rather than using the term *similar retail food establishment*.

### **D. The Definition FDA Has Proposed Fails to Make Any Distinction Between Retail Food Establishments and Retail Food Establishments That Are “Similar” To Restaurants**

FDA has proposed defining similar retail food establishments in the following manner:

*Restaurant or similar retail food establishment* means a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of the establishment. The sale of food is the retail establishment’s primary business activity if the establishment presents itself, or has presented itself publicly as a restaurant, or a total of more than 50 percent of that retail establishment’s gross floor area is used for the preparation, purchase, service, consumption or storage of food.<sup>19</sup>

FDA notes that “the statutory text focuses explicitly on restaurants and retail food establishments that are ‘similar’ to restaurants, rather than on all establishments where

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<sup>14</sup> *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

<sup>15</sup> *United States v. Ahlers*, 305 F.3d 54, 60 (1st Cir. Me. 2002).

<sup>16</sup> “If Congress uses one term in one place and a different term in another place, the court presumes that each term has a distinct meaning.” *Bailey v. U.S.*, 516 U.S. 137 (1995).

<sup>17</sup> 21 C.F.R § 1.227(b)(11).

<sup>18</sup> <http://www.merriam-webster.com/dictionary/establishment>.

<sup>19</sup> 76 Fed. Reg. 19233 (April 6, 2011).

food is sold (often incidentally to or quite separately from the establishment's primary purpose).”<sup>20</sup> However, the definition in the Proposed Rule makes no distinction between retail food establishments and retail food establishments that are similar to restaurants. All supermarkets are not restaurants. FDA must make this distinction, and this definition does not. It covers every supermarket and grocery store. FDA has said as such:

TABLE 1—ARE THE FOLLOWING ESTABLISHMENTS “RESTAURANTS OR SIMILAR RETAIL FOOD ESTABLISHMENTS” UNDER THE PROPOSED RULE?

Generally yes	Generally no
Table service dining establishments Quick service (fast food) establishments Cafeterias Pastry and retail confectionary stores Coffee shops Snack bars Ice cream parlors Multi-purpose establishments that have presented themselves publicly as restaurants Establishments within larger establishments that are part of a chain with locations outside of the larger establishment's chain (e.g., chain coffee shop in a bookstore; see discussion below) Grocery stores Convenience stores	Movie theaters Amusement parks General merchandise stores Hotels Trains Planes

Restaurant food is defined as “food that is served in restaurants or other establishments in which food is served for immediate human consumption, *i.e.*, to be consumed either on the premises where that food is purchased or while walking away; or which is sold for sale or use in such establishments.”<sup>21</sup>

Restaurant-type food is defined as “food of the type described in the definition of “restaurant food” that is ready for human consumption, offered for sale to consumers but not for immediate consumption, processed and prepared primarily in a retail establishment, and not offered for sale outside of that establishment.”<sup>22</sup>

The definition of similar retail food establishment will generally cover every supermarket. While many supermarkets offer some form of food for immediate consumption, not all do. However, every supermarket offers what FDA has defined as “restaurant-type food.” Only a handful of limited assortment chains (nontraditional retailers) do not. Essentially every supermarket has either a bakery, deli or other facility where items are processed or prepared. FDA considers “processed and prepared” pursuant to 21 CFR 101.9(j)(3) in a very broad fashion in the retail context:

To meet the criteria for being ‘primarily processed and prepared on-site’, the food must be augmented on site in a manner that changes the nutrient profile of the food (*i.e.*, filling, icing, enrobing). Washing and garnishing with nuts, onions or seeds would fall under the definition of “primarily processed and prepared” if the added foods change the nutrition profile of the finished product. Custom cakes are exempt . . . Foods which are not prepared on premises and that are portioned to consumer specifications on-site are not

<sup>20</sup> 76 Fed. Reg. 19197.

<sup>21</sup> 76 Fed. Reg. 19197.

<sup>22</sup> *Id.*

required to have nutrition labeling (e.g., 1 lb of potato salad; 2 lb cheese, 1 lb assorted cookies, 5 rolls).<sup>23</sup>

FDA has stated that every grocery store is generally subject to the regulation. The trigger for coverage is the selling of a single item of restaurant-type food. Does a single act of portioning chicken salad from a deli case all of a sudden make a grocer a restaurant? Under the Proposed Rule it does. It is hard to conceive that this was the intent of Congress. This logic is dubious particularly in light of FDA's exclusion of sliced deli meats and cheeses on the basis that "there is an ordinary expectation that the consumer will further prepare those foods before consumption, e.g., by using the meat and cheese to make a sandwich."<sup>24</sup> Deli salads are generally eaten as part of a sandwich or with crackers as well. This logic should extend to other items in the deli case including cold prepared foods which require the consumer to take an additional step (heating up) before they are ready for consumption. It should also include bread, rolls and bagels as they are generally eaten as part of a sandwich or spread with butter or cream cheese.

The Proposed Rule fails to make any distinction between retail food establishments and retail food establishments that are similar to restaurants. It must—the law requires FDA to make such a distinction. Congress contemplated this because it used the term food retailer or retail establishment elsewhere in the same section but chose to use "similar retail food establishment" in § 403(q)(5)(H).

#### **E. Statutory Construction: § 403(q)(5)(H) Requires FDA to Make a Distinction Between All Retail Food Establishments and Retail Food Establishments That Are Similar to Restaurants**

Under FDA's proposed definition of similar retail food establishment, all retail food establishments are subject to the Proposed Rule. This is not permissible under the language of the law. Congress has required FDA to make a distinction between retail food establishments, retail establishments, food retailers and similar retail food establishments.

If the term used in the statute "similar retail food establishment" were replaced with "food retailer" or "retail establishment," the Proposed Rule would still be compatible with the statute. It would also be compatible with the statute if the word "similar" was stricken. This Proposed Rule would similarly apply if the Congress used the term "retail food establishment" rather than the term "similar retail food establishment." FDA must craft a regulation that contemplates a distinction between "similar retail food establishments" and all retail food establishments. "It is an elementary rule of

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<sup>23</sup><http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/UCM064904#away>.

<sup>24</sup> 76 Fed. Reg. 19204 (April 6, 2011).

construction that effect must be given, if possible, to every word, clause and sentence of a statute.”<sup>25</sup> A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous.<sup>26</sup>

Contending that a supermarket becomes similar to a restaurant the instant it sells one item—whether it be a ½ lb of potato salad, a store-made roll or cookie—does not reflect the intent of Congress or the language of the law.

Option 2 does contemplate such a distinction. We believe the law requires FDA to implement this option.

## 1. Section Heading

The heading of the § 4205 should inform FDA’s rule. The heading is entitled “Nutrition Labeling of Standard Menu Items at Chain Restaurants.” Because the heading refers only to restaurants, FDA should construe the term “similar retail food establishment” narrowly.<sup>27</sup> “Even though a section heading is not part of the law, it can aid interpretation when an ambiguity exists.”<sup>28</sup> FDA acknowledges that the term “. . . is ambiguous. It is possible to imagine a range of interpretations, calling for relatively narrow coverage (including only restaurants and those establishments that are closely analogous to restaurants) or relatively broad coverage (including a range of establishments that sell food at retail.)”<sup>29</sup> The title and heading of sections in an act can shed light on an ambiguous phrase.<sup>30</sup> Option 2 is a construction of the statute which is consistent with the heading. The Proposed Rule as written is not.

## 2. Legislative History

The primary champion of menu labeling in the Senate, Senator Tom Harkin, has repeatedly held up supermarkets as the model for providing nutrition information to consumers. As the sponsor of the bill that served as the basis for § 4205, Senator Harkin’s statements are particularly probative in determining Congress’s legislative intent.<sup>31</sup> In his floor statement introducing the MEAL Act (S. 1048), Senator Harkin

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<sup>25</sup> *Plaut v. Spendthrift Farm, Inc.* 514 U.S. 211 (1995).

<sup>26</sup> *ErieNet, Inc. v. Velocity Net, Inc.*, 156 F. 3d 513 (3d Cir. 1998) (quoting *Pennsylvania Medical Soc’y v. Snider*, 29 F.3d 886, 895 (3d Cir. 1994)).

<sup>27</sup> Although a heading is not part of a statute, it may be relevant to the legislative history if it was present in the bill during the legislative process. Sutherland Statutes §21.4 7<sup>th</sup> Edition (2009) vol. 1A citing *U.S. v. Buckand*, 277 F. 3d 1173 (9th Cir. 2002).

<sup>28</sup> *Id.* citing *Lazaro v. U.S. Dept. of Agriculture*, 186 F. Supp. 2d 1203 (M.D. Fla. 2001), *Pudenz v. Littlefuse, Inc.* 177 F.3d 1204 (11th Cir. 1999).

<sup>29</sup> 76 Fed. Reg. 19196.

<sup>30</sup> *Brotherhood of R.R. Trainmen v. Baltimore & O.R. Co.* 331 U.S. 519 (1947).

<sup>31</sup> *Nat’l Woodwork Mfgs. Assn. v. NLRB*, 386 U.S. 612, 640 (1967) (“It is the sponsors that we look to when the meaning of the statutory words is in doubt.” (quoting *Schwegmann Bros. v. Calvert Distillers Corp.*, 341 U.S. 384 (1951))); *NLRB v. St. Francis Hosp. of Lynwood*, 601 F.2d 404, 415 n. 12 (9th Cir. 1979) (“[W]e would look to the language of the sponsors of the bill as being more demonstrative of the



stated: “Consumers say that they would like nutrition information provided when they order their food at restaurants, yet, while they have good information in supermarkets, at restaurants they can only guess.”<sup>32</sup> Furthermore, Senator Harkin cited several laws and initiatives and municipalities in his statement—none of which regulate supermarkets.<sup>33</sup> In Senator Harkin’s past press releases he also praised supermarkets: “It makes no sense that American consumers can go to a grocery store and find nutrition information on just about anything, but then they are totally in the dark when they go to a restaurant for dinner.”<sup>34</sup> “[I]nformation is lacking in our restaurants. Even though consumers have ready access to nutritional information at grocery stores, they are left to guess and estimate when they go out to eat.”<sup>35</sup> Nowhere in the legislative history is there an indication that Congress contemplated regulating supermarkets under § 4205.

### **a. Restaurants Supported § 4205 to Preempt State Laws Regulating Them**

The restaurant industry promoted § 4205 because it provided them with national uniformity with menu labeling:

The chain restaurant industry led the effort to enact a uniform national standard for menu labeling of nutrition information in *chain restaurants*, (emphasis added) which will ensure that nutrition information is provided to consumers in a consistent and understandable format in all States and localities. Congress enacted Section 4205 of the Affordable Care Act which creates this national standard . . . chain restaurant operators . . . deserve the certainty of a Federal standard that preempts all other menu labeling regulations.<sup>36</sup>

Consumers deserve to know the nutritional content of their food. And chain restaurant operators, including thousands of small business franchisees across the country, deserve the certainty of a Federal standard that preempts all other menu labeling regulations. Chain restaurants had become burdened with a patchwork of differing state and city menu labeling rules and thus sought a federal law that would preempt them. FMI did not ask for this law and never was it mentioned in any hearing or debate that the provision would confer broad authority on FDA to essentially regulate every supermarket chain in America with 20 or more locations. State laws and municipal codes generally do not cover supermarkets and the purpose of § 4205 was to preempt these laws.

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congressional intent rather than the other comments made on the Senate floor.”). See, e.g., *Public Employees Retirement Sys. of Ohio v. Betts*, 492 U.S. 158, 178 (1989) (relying on the statement of the Age Discrimination in Employment Act sponsor, Senator Javits, when interpreting the statute).

<sup>32</sup> 155 Cong. Rec. S5522 (May 14, 2009) (statement of Senator Harkin).

<sup>33</sup> Id.

<sup>34</sup> Press Release, Senator Tom Harkin, “Harkin Introduces Restaurant Labeling Initiative” (June 8, 2006) <http://harkin.senate.gov/press/release.cfm?i=256693>.

<sup>35</sup> Press Release, Senator Tom Harkin, “Statement of Senator Tom Harkin on Ruby Tuesday’s Decision to Provide Nutrition Information” (April 27, 2004) <http://harkin.senate.gov/press/release.cfm?i=256693>.

<sup>36</sup> <http://www.nccr.net/sites/nccr.net/files/NCCR%20Public%20Policy%20Positions.pdf>

## **b. House Agricultural Appropriations Subcommittee Expresses Concern About Scope of Menu Labeling**

The House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Subcommittee Report for the Fiscal Year 2012 Agriculture and Related Agencies funding bill includes report language expressing concern about the scope of the Proposed Rule:

*Nutrition Labeling.*—The Committee is concerned with the proposed rule that FDA issued on April 6, 2011, on nutrition labeling of standard menu items in restaurants and similar retail food establishments. The proposed rule would include establishments that are not primarily in the business of selling food for immediate consumption or selling food that is prepared or processed on the premises. These establishments are not similar to restaurants. . . . The Committee urges FDA to use the proposed alternative definition in the rule that would encompass only establishments where the primary business is the selling of food for immediate consumption or selling food that is prepared and processed on the premises.<sup>37</sup>

FDA should consider this language and adopt Option 2. “[W]hile the views of subsequent Congresses cannot override the unmistakable intent of the enacting one, such views are entitled to significant weight, and particularly so when the precise intent of the enacting Congress is obscure.”<sup>38</sup>

## **c. Language Modeled After New York City Code**

Section 4205 is modeled after Section 81.50 of the New York City Health Code.<sup>39 40</sup> Section 81.50 does not regulate supermarkets. “Where a meaning of a statute is in doubt, reference to legislation in other states and jurisdictions which pertains to the same subject matter . . . may be a helpful source of interpretive guidance.”<sup>41</sup> Where courts look to another jurisdiction for clarification or guidance, the phraseology and language of similar legislation in other jurisdictions deserves special consideration not only in the interests of uniformity but also for the purpose of determining the general policy and objectives of a particular course of action.<sup>42</sup> The New York Code was the first—and most extensively discussed—law cited by Senator Harkin in introducing the MEAL Act. FDA must consider this fact and thus should adopt Option 2.

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<sup>37</sup> H.R. Report No. 112-101 (June 3, 2011).

<sup>38</sup> *Seatrains Shipbuilding Corp. v. Shell Oil Co.*, 444 U.S. 572 (1980).

<sup>39</sup> The measure was modeled after one that has already taken effect in New York City. . . .”  
[http://www.foodconsumer.org/newsite/Politics/32/health\\_care\\_legislation\\_calories\\_restaurant\\_menus\\_2703100932.html](http://www.foodconsumer.org/newsite/Politics/32/health_care_legislation_calories_restaurant_menus_2703100932.html)

<sup>40</sup> Title 24 Rules of the City of New York § 81.50.

<http://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-50.pdf>.

<sup>41</sup> *Sutherland Statutes 52.3 Jamison v. Encarnacion*, 281 U.S. 635 (1930), *Taber v. Maine*, 45 F. 3d 598 (2d Cir. 1995).

<sup>42</sup> *Overstreet v. North Shore Corp.*, 318 U.S. 125 (1943).

### **III. Executive Order 13563**

Earlier this year, President Obama issued Executive Order 13563 which states:

Our regulatory system . . . must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. . . As stated in (Executive Order 12866) . . . each agency must . . . propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs. . . (and) tailor its regulations to impose the least burden on society.<sup>43</sup>

It is hard to conceive of a more perfect circumstance than the one presented in the Proposed Rule of which the principles of E.O 13563 should be applied. E.O. 13563 requires FDA to adopt Option 2. FMI challenges FDA and the Office of Management and Budget to do so.

#### **A. Least Burdensome Tools for Achieving Regulatory Ends**

FDA has acknowledged that § 403(q)(5) does not obligate the Agency to regulate supermarkets. The Agency has tentatively decided to do so in the Proposed Rule, but is considering Option 2 that would generally exclude supermarkets from the scope of the law. Option 2 is the least burdensome tool FDA has expressed in the Proposed Rule that would permit the Agency to achieve its regulatory ends. The Agency has estimated that the Proposed Rule would impose compliance costs of \$76.8 million, assuming a discount rate of 3 percent, or \$82.3 million, assuming a discount rate of 7 percent. The Agency's high estimate of compliance costs is \$120.5 million, assuming a discount rate of 3 percent and \$130.1 million, assuming a discount rate of 7 percent. FMI believes the compliance costs of Option 1 will be far higher for the reasons outlined later in these comments. Option 2 reduces the compliance costs of the Proposed Rule by more than 12.5 percent while the proportional dollar sales of restaurant or restaurant-type food not covered by the label drops by only 5 percent. For every dollar of restaurant food not covered, FDA saves the economy \$2.50 in compliance costs according to the preliminary regulatory impact analysis conducted by the Agency.<sup>44</sup> FMI can attest that this cost savings will be much greater. According to our estimate it will result in approximately \$20.00 in compliance costs saved for every dollar of restaurant food not covered. These dollars will be put back into the economy to create jobs and reduce costs to consumers.

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<sup>43</sup> Exec. Order No. 13563 (January 18, 2011).

<sup>44</sup> Department of Health and Human Services, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments Notice of Proposed Rulemaking, Preliminary Regulatory Impact Analysis (March 2011).

## B. Accounting for Quantitative Benefits

E.O. 13563 requires agencies to “take into account benefits and costs, both quantitative and qualitative.”<sup>45</sup> FDA has not bothered to quantify any benefits of the Proposed Rule in spite of E.O. 13563 and the fact that the Proposed Rule will cost the supermarket industry hundreds of millions of dollars.

TABLE 5a—ACCOUNTING STATEMENT: ANNUALIZED COST AND BREAK-EVEN BENEFIT POINT FOR THE PROPOSED REQUIREMENTS

	Primary estimate	Low estimate	High estimate	Year dollar	Discount rate	Period covered
<b>Benefits</b>						
Annualized Monetized (\$millions/year) .....	Not quantified					
Annualized Quantified:						
Qualitative: FDA estimates that at least 0.06 percent of the adult obese population would need to reduce caloric intake by at least 100 calories per week in order for benefits from the proposed requirements to reach a break even point on annualized costs (at either 3% or 7%).						
<b>Costs</b>						
Annualized Monetized (\$millions/year) .....	\$82.3 76.8	\$34.9 33.4	\$130.1 120.5	2009 2009	7% 3%	10 10

Indeed, FDA has acknowledged in the PRIA that “Two of the most recent studies of local calories disclosure laws, one of calorie disclosure use in a taco chain in King County, Washington and another studying child and adolescent fast-food choice in New York City, found no significant change in calorie intake.”<sup>46</sup>

## C. Burden of Cumulative Regulations

E.O. 13563 reaffirms the principles governing regulatory review that were established in E.O. 12866, which requires each agency to “tailor its regulations to impose the least burden on society. . . taking into account . . . the costs of cumulative regulations.”<sup>47</sup> Supermarkets face a profoundly larger array of regulations than restaurants. Compliance staff at supermarket firms are already being stretched thin coping with these existing rules, and the burden imposed by the Proposed Rule is going to push them to the brink.

<sup>45</sup>Exec. Order No. 13563 (January 18, 2011).

<sup>46</sup> Department of Health and Human Services, Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments Notice of Proposed Rulemaking, Preliminary Regulatory Impact Analysis (March 2011).

<sup>47</sup> Exec. Order No. 13563 (January 18, 2011).

**Regulations that supermarkets must comply with that restaurants do not:**

<b>Regulatory Burdens Faced by Supermarkets and Restaurants</b>		
<b>Regulation</b>	<b>Compliance Required by Supermarkets</b>	<b>Compliance Required by Restaurants</b>
Country of Origin Labeling (7 C.F.R. pt. 60; 21 U.S.C §§ 301-399)	Yes	No
Identity Statement (21 C.F.R. § 101.3; 21 U.S.C. § 343(i)(1))	Yes	No
Net Quantity of Contents (21 C.F.R. § 101.105; 21 U.S.C. § 343(e)(2))	Yes	No
Ingredient Labeling (21 C.F.R. §§ 101.4; 21 U.S.C. § 343(i)(1))	Yes	No
Use By Dating	Yes	No
Nutrition Labeling (FDA) (21 C.F.R. § 101.9; 21 U.S.C. § 343(q))	Yes	Pending
Nutrition Labeling of Raw Meat and Poultry (9 C.F.R. §§ 317.300-345 and 381.400-445; 21 U.S.C. § 343(q))	Yes	No
Allergen Labeling (Pub. L. No. 108-282)	Yes	No
Presence of Artificial Colors, Chemical Preservatives and Artificial Flavors (21 C.F.R. 101.22; 21 U.S.C. § 343(i)(1))	Yes	No
Signature Line (21 C.F.R. § 101.5; 21 U.S.C. § 343(e)(1))	Varies by state	No
Safe Handling Instructions (21 C.F.R. § 101.17)	Yes	No
Bioterrorism Act Recordkeeping (21 C.F.R. § 1.327; Pub.L. No.107-188)	Yes	No
Recall Notification (Pub. L. 111-353)	Yes	No

The supermarket industry faces hundreds of millions of more regulatory burdens annually than the restaurant industry. E.O. 13563 and E.O. 12866 require FDA to consider this and adopt Option 2.

The fact of the matter is that more than 95 percent of the food items sold at the typical chain supermarket already carry nutrition labeling.<sup>48</sup> The cost incurred in capturing the remaining 5 percent vastly exceeds any benefit obtained.

## **IV. Burden Estimate**

FMI estimates that 150 chains<sup>49</sup> will be impacted with an average of 1,500 items covered by the Proposed Rule. FMI estimates that the cost of determining the nutrition information for each item will be \$1,000. The cost of getting the nutrition information initially will be at least \$225,000,000 for the industry. Menu boards and signs will be \$1,000,000 for each retailer leading to a cost of \$150,000,000. New scale/software investments will be \$1,500,000 per retailer or \$225,000,000. Training store level associates and developing training materials will cost \$150,000,000 across the industry. Recordkeeping is estimated to cost \$2,000,000 per chain annually for a total of \$300,000,000. The total burden on the industry will be more than \$1 billion for the first year alone. Ongoing costs will amount to the hundreds of millions of dollars.

### **A. Number of Items Grossly Underestimated By FDA**

“Because of the more limited offerings for restaurant or restaurant-type foods at grocery and convenience stores, FDA estimates that these establishments have on average approximately one half the number of menu items of an average restaurant, or 40 menu items.”<sup>50</sup> FDA has grossly underestimated the number of items covered. Here the estimate and the Proposed Rule simply don’t match. The Proposed Rule requires virtually every food item in a supermarket that is not required to carry nutrition labeling under the NLEA to be labeled. Rather than having half of the menu items of an average restaurant, supermarkets have 6 to hundreds of times more items. FMI members have reported anywhere from 500 to 15,000 items being covered. If FDA limited the scope of the Proposed Rule to restaurant food only—and not restaurant-type food—then the

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<sup>48</sup> The average store in the industry carries about 39,000 stock keeping units according to FMI’s latest survey, the Food Retailing Industry Speaks.. 10- 15 percent of those items are non-food items. Assuming an average of 12.5 percent on non-food items, the typical chain supermarket carries 34,125 food items. Of these 700-1500 will not be labeled with nutrition labeling which equates to 2-4 percent of food items. Certain retailers carry significantly higher SKUs and proportionately more food items are not labeled. Many of the items in bakeries and delis are already labeled. All par baked items, defrosted cakes and deli items in consumer packages, must be labeled.

<sup>49</sup> Progressive Grocer, 78<sup>th</sup> Annual Report of the Grocery Industry, April 2011; 2011 Chain Store Guide, Directory of Supermarket, Grocery and Convenience Store Chains.

<sup>50</sup> Id. at 26.

estimate of 40 items would be closer to reality. If the Agency proceeds with regulating the supermarket industry, we believe that only restaurant food should be covered. There is no indication that Congress intended that food not served for immediate consumption should be covered under the law. State sales tax laws distinguish what FDA categorizes as “restaurant-type” foods from true restaurant foods as FMI discussed at length in comments submitted previously to FDA.

FMI estimates that on average, 1,000 to 2,000 items will be covered with some retailers having to label thousands more.

### **B. Cost per item**

FDA has estimated that the average cost of a full nutrition analysis is \$269 per item. FMI believes this is significantly underestimating the cost to the grocery industry. FMI has consulted laboratories and polled its membership, and this is simply not the case. While a handful of retailers may have existing staff who can handle this responsibility, many retailers will be required to hire additional staff at a large cost. Adding or reallocating a single full-time employee for this task has been estimated to cost \$70,000-\$120,000. Retailers may be required to hire several new employees to comply with this new regulatory requirement.

Many retailers will need to enlist the help of outside labs and labeling firms to comply with the requirement. These firms generally charge \$500-\$1,000 per item. A lab analysis of an item will far exceed the \$269 estimate. It will likely cost \$750-\$1,000 per item. Only for items with simple ingredients where there is comprehensive supplier-provided information available to the lab or labeling firm, will the cost of conducting an analysis by an outside firm be near the \$269 estimate.

### **C. Menu Boards**

FDA has estimated that 2 hours of time will be needed to change each menu board and that grocery and convenience stores average 1 menu board per establishment. FMI believes both figures are too low. Redesigning menu boards can be a complex task, especially when significantly more text must be placed on a limited space. Many retailers will have to do major redesigns of their menu boards. FMI estimates that for most retailers it will take 8-15 hours to redesign each menu board to accommodate the information required by § 4205. Furthermore, the average supermarket is likely to have 5 menu boards, with a significant number of retailers having as many as 30 or more.

#### **D. Cost of Menu Boards**

FDA has estimated the average cost of a menu board to be \$550. While this will be accurate for some retailers, particularly those who have already installed boards which permit flexibility to accommodate changing offerings, for many other retailers the costs are likely to be greater—approximately \$1,000 to \$1,500 or more per menu board. A number of retailers have reported to FMI that the cost of redesigning and replacing their menu boards will amount to several million dollars.

#### **E. Recordkeeping Costs**

The recordkeeping burdens of the Proposed Rule are enormous and as FMI discusses later, inconsistent with the statute. A number of retailers have reported to FMI that these provisions alone will impose millions of dollars of costs per year. These burdens are needless and vastly outweigh any benefits of the Proposed Rule.

### **V. The Burden Imposed On Supermarkets is Significantly Greater than Restaurants**

#### **A. Larger Variety of Items**

FDA has estimated that the typical supermarket carries half the number of items covered by the Proposed Rule than the typical restaurant. If the Proposed Rule was limited to restaurant food—rather than both restaurant food and “restaurant-type food”—this might be the case. FDA however has included restaurant-type food within the scope of the Proposed Rule, thus every loaf of bread, roll, cake, bagel and pie made within the store must be labeled. Even items that are not prepared within the store, but are portioned at the customer’s request, are all covered. Essentially every deli item not already labeled (except cold cuts and sliced cheese) is covered under the Proposed Rule. The Proposed Rule also touches the seafood department and produce department for many retailers. Cooked shrimp and cut produce appear to be covered under the Proposed Rule.

While a restaurant will manage a limited set menu under the control of a chef or Sous Chef, a retail supermarket merchandises foods in a variety of formats: service, self-service, cold or hot in various departments throughout the store. The types of foods offered can vary throughout the year depending on season, holiday, and promotions. There is not a set menu used by all stores within a supermarket chain.

A retail supermarket is designed and set up to sell primarily packaged foods. The majority of those items are sold in compliance with the NLEA and FPLA. The items that



are affected by the menu regulation were specifically exempted by the NLEA because of the complexity and variation that occurs with store preparation.

Due to the variety and number of items many stores carry, including numerous ready-to-eat items that are processed in the retail store, retailers have reported it would take years and considerable expenditures to send all of these items to an outside laboratory to analyze the nutrition content of all items and set them up in a system to ensure the accuracy guidelines are met as set forth in the Proposed Rule. Retailers have reported that additional positions would need to be added to support the analysis, system entry and set up for each item, in addition to maintaining current information after initial set up.

Supermarkets have a greater variety of items not only in terms of the number of different items offered for sale, but also on how items might be displayed in different ways. Examples include the same cake and pie displayed whole, sliced in half, sliced in quarters, etc.; rotisserie chicken, fried chicken tenders, served both hot and cold; a salad displayed in the service case and pre-packed in containers, muffins sold in a bulk bin, 2 pack container and 4 pack container. All of these items would have to be labeled separately.

## **B. New Items**

Many retailers have hundreds of new items that are added to their product mix each year, many of which would be covered under the Proposed Rule because they are ready to eat and require some retail processing. Items are being added and deleted constantly based on the needs and wants of the customer. The Proposed Rule, adding significant new tasks and requirements to the introduction of a new item, would create a barrier to allowing new items into the market due to the analysis and system entry and setup requirements. It would diminish innovation in stores and limit consumer choices.

## **C. Ingredients are Less Standardized**

Unlike a chain restaurant with prescribed recipes and ingredients, many retailers give stores the flexibility to adapt recipes to the local regional taste profiles. For example, there may be multiple formulas of potato salad that are sold throughout the different regions. Another good example is a crab cake. Crab cakes sold in Mid-Atlantic stores may have different amounts of seasoning than those sold in New England.

Unlike restaurants, stores often serve as their own suppliers for prepared foods. The meat department supplies the meat for items, the produce department supplies fresh fruits and vegetables and packaged foods may also be used in creating prepared items. Stores have discretion in using these ingredients based on availability. For example, stores have the flexibility to use different brand yogurts when assembling a fruit and yogurt meal based on the availability of product in the store. Labeling and determining calorie information

for these items will be profoundly difficult. Retailers make items based on product availability in the store from a wide variety of items. Restaurants do not. The availability of products is affected by seasonality in making fruit and vegetable platters. Each ingredient change may impact the calorie or nutritional values of the finished product. Items may vary across divisions, regions and even by store, as offerings are customized based on customer demographics and trade area profile. A great deal of variation can occur based on ingredient availability, demographics and seasonality.

Each store has multiple formats and departments involving numerous associates in food preparation across a broad spectrum of hours from early morning to late evening. The complexity of the assortment and product offering makes standardization very difficult.

#### **D. More Signage/Displays Impacted**

A restaurant operation does not compare to a retail supermarket. The lineal footage of display cases and menu boards for each department far exceed any restaurant operation. Restaurants typically identify their offered foods and pricing through a single menu board and/or menu. Supermarkets typically identify and price offered products through individual product shelf tags or product signs. Each and every one of these individual product shelf tags and product signs for items covered under the Proposed Rule would have to be changed to incorporate the required nutrition information. Some retailers may have thousands of items covered so thousands of signs will have to be changed. Examples are signs at soup kettles, signs at hot bars, signs at olive bars, signs at salad bars, signs at donut cases, and signs at bagel/pastry bins. Retailers do not maintain a master menu listing for the entire product offering as do restaurants.

### **VI. Comments on Specific Provisions of Proposed Rule**

FMI believes that § 403(q)(5)(H) does not cover supermarkets generally, and E. O. 13563 and 12866 require as well as case law require FDA to exclude supermarkets from the scope of the Proposed Rule and FDA should adopt Option 2. However as FDA has regulated supermarkets in the Proposed Rule as written, FMI feels compelled to respond to the following items:

#### **A. Defining the Term “Restaurant and Similar Retail Food Establishment”**

*The 1990 NLEA amendments which exempted two categories of food: (1) Food “which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or used in such establishments,”<sup>51</sup> and (2) food “which is processed and prepared primarily in a retail establishment, which is*

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<sup>51</sup> 21 U.S.C. § 343(q)(5)(A)(i)

*ready for human consumption, which is the type described in [(1)] and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.”<sup>52</sup>“Section 4205 amended the statutory exemption from Federal nutrition labeling requirements for restaurant and restaurant-type food.”<sup>53</sup>*

However, Section 4205 regulates food served by certain types of *establishments*, not all restaurant and restaurant-type food is covered. Restaurant and restaurant-type food sold by establishments that are not similar to restaurants is not covered. FMI believes that if Congress had intended to broadly apply menu labeling to firms selling restaurant and restaurant-type food, the statute would have been crafted in a manner in which 21 U.S.C. § 343(q)(5)(A)(i) and (ii) would be overhauled rather than letting those sections stand with a new subparagraph (H) being added.

Furthermore, if Congress had intended to completely close the gap in the NLEA, it would have written the § 4205 to reference “restaurants and retail establishments,” the precise language used in the NLEA. Instead, Congress used the term “similar retail food establishments.” Thus, not all retail establishments are covered under the law, only retail food establishments that are similar to restaurants.

FDA has proposed defining “similar retail food establishments” in the following manner:

*Restaurant or similar retail food establishment means a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of the establishment. The sale of food is the retail establishment’s primary business activity if the establishment presents itself, or has presented itself publicly as a restaurant, or a total of more than 50 percent of that retail establishment’s gross floor area is used for the preparation, purchase, service, consumption or storage of food.*<sup>54</sup>

As explained previously, FMI believes this definition is inconsistent with the language of the statute, congressional intent and E.O. 13563 and E.O. 12866. We believe that the alternative definition proposed by FDA whereby the Agency would consider the sale of restaurant or restaurant-type food to be a retail establishment’s primary business activity if either “(1) the establishment presents itself or has presented itself publicly as a restaurant, or (2) a total of more than 50 percent of a retail establishment’s gross floor area is used for the preparation, purchase, service, consumption, or storage of restaurant or restaurant-type food or its ingredients”<sup>55</sup> is consistent with the statute, the intent of Congress and E.O. 13563 and 12866 and thus should be adopted by FDA in the final rule. Adopting this option will remove billions of dollars of regulatory burden on the supermarket industry.

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<sup>52</sup> 21 U.S.C. § 343(q)(5)(A)(ii)

<sup>53</sup> 76 Fed. Reg. 19196.

<sup>54</sup> 76 Fed. Reg. 19233 (April 6, 2011).

<sup>55</sup> 76 Fed. Reg. 19198.

### Suggested Regulatory Change

#### §101.11(a) *Definitions.*

*Restaurant or similar retail food establishment* means a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of that establishment. The sale of food is the retail establishment's primary business activity if the establishment presents itself, or has presented itself publicly as a restaurant, or a total of more than 50 percent of that retail establishment's gross floor area is used for the preparation, purchase, service, consumption, or storage of **restaurant or restaurant-type food or its ingredients.**

#### **B. “Primary Business Activity” Test**

*We are also interested in comments on whether we should use “primary business activity,” or a different test, as a basis for determining whether an establishment is a restaurant or similar retail food establishment.*

FMI believes a primary business activity test is appropriate for purposes of determining the scope of the Proposed Rule. As discussed previously in the comments, Option 2 captures establishments that are similar to restaurants whereas the Proposed Rule as written brings in a range of businesses that are not similar to restaurants. The Proposed Rule as written is inconsistent with the statute and Congressional intent and E.O. 12866 and 13563.

FMI believes a percentage revenue test would also achieve this goal as we set forth in earlier comments.

#### **C. Doing Business Under the Same Name**

A number of food retailers are members of cooperatives. The cooperative structure allows independent retailers to take advantage of economies of scale for supply chain and joint marketing, among other things. However, members of the co-op remain separate corporate entities that operate more or less independently and have their own recipes and prepared food offerings. While a co-op may be comprised of 100 stores operating under the same banners, it may actually be a grouping of 50 separate owners that operate two stores each. Store owners enjoy—and exercise—vastly more independence than owners of franchise restaurants. Stores in co-ops may operate under completely different banners, may have different banners but display a common logo, or may share all aspects of the same banner. FMI believes stores that belong to a co-op but are independently

owned, separate corporate entities should not be aggregated by FDA for purposes of determining the applicability of § 403(q)(5)(H).

#### **D. Menu and Menu Board**

Section 403(q)(5)(H)(xi) provides that “the term ‘menu’ or ‘menu board’ means the primary writing of the restaurant or similar retail food establishment from which a consumer makes an order selection.” In the Proposed Rule, FDA has defined the term as:

*Menu or menu board* means the primary writing of the restaurant or similar retail food establishment from which a customer makes an order selection, including, but not limited to, breakfast, lunch and dinner menus; dessert menus; beverage menus, children’s menus, other specialty menus, electronic menus, and menus on the Internet. The menus may be in different forms, e.g., booklets, pamphlets, or single sheets of paper. Menu boards include those inside a restaurant or similar retail food establishment as well as drive-through menu boards at restaurants or similar retail food establishments.

Supermarkets do not generally have menus. Many supermarkets have menu boards for sub/deli sandwiches. FDA should not view ad circulars as menus. In virtually all circumstances they are not the “primary writing” from which a consumer makes an order selection. Some supermarkets do offer delivery service, but generally orders must be placed online. When consumers receive ad circulars in their local newspaper or the mail they generally cannot make an order selection from them. Often copies of ad circulars are distributed within a store, but these are not the “primary writing” from which a consumer makes an order selection. Other signs, tags or menu boards within the store identify the item for the consumer and are used by shoppers to make an order selection.

Supermarkets do utilize signs throughout the store to highlight the attributes of a particular product. These signs should not be considered menus or menu boards. A menu board lists multiple items from which a consumer can make an order selection.

#### **E. Food Covered**

##### **1. Restaurant-Type Food**

The language of § 403(q)(5)(H) regulates only “standard menu items” sold at restaurants or similar retail food establishments. FMI believes Congress did not intend for foods that are not served for immediate consumption to be covered by the §403(q)(5)(H). FDA’s definition of “restaurant-type” food will pull in hundreds of items for most supermarkets and thousands of items for many. There is no indication in the legislative history that Congress intended for this law to apply to these items.

As discussed earlier in these comments, §403(q)(5)(H) was largely inspired by and modeled after the New York City Health Code, which states in its preamble: “Of course, in order for the calorie information to be accurate, such a requirement can only be implemented for food items that are standardized with regard to **portion size**, formulation and ingredients” (emphasis added). As FMI reads the Proposed Rule, this definition of “restaurant-type” food will apply to virtually every item in the store that is not already labeled. It will apply to all foods processed and prepared in the store and these items are by no means in a standard portion size. Supermarkets are not restaurants and do not have the standardized ingredients that chain restaurants do. Thousands of items within the store may be utilized as ingredients for prepared foods. Portion sizes vary.

FDA considers “processed and prepared” in a very broad fashion in the retail context:

To meet the criteria for being ‘primarily processed and prepared on-site’, the food must be augmented on site in a manner that changes the nutrient profile of the food (i.e., filling, icing, enrobing). Washing and garnishing with nuts, onions or seeds would fall under the definition of “primarily processed and prepared” if the added foods change the nutrition profile of the finished product. Custom cakes are exempt . . . Foods which are not prepared on premises and that are portioned to consumer specifications on-site are not required to have nutrition labeling (e.g., 1 lb of potato salad; 2 lb cheese, 1 lb assorted cookies, 5 rolls).<sup>56</sup>

The definition FDA is proposing will include every deli-salad served from the case, every bread, cookie, roll, pie, and bun. FDA has estimated that the Proposed Rule would only affect on average about 40 items in the typical supermarket. That may apply to restaurant foods in a store, but it by no means would it apply to “restaurant-type” food. FMI has documentation that this definition will result in 9,000 items being covered for one supermarket chain on a companywide basis and 10,000-15,000 SKUs being covered for another. FDA should eliminate the term Restaurant-Type Food and apply the regulation to only Restaurant Food. If FDA does not adopt Option 2, this change would save the industry hundreds of millions of dollars.

### Suggested Regulatory Change

#### §101.11 (a) *Definitions*

~~*Restaurant-type food* means food of the type described in the definition of “restaurant food” that is ready for human consumption, offered for sale to consumers but not for immediate consumption, processed and prepared primarily in a retail establishment, and not offered for sale outside of that establishment.~~

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<sup>56</sup><http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/UCM064904#away>.

## 2. Standard Menu Item

FMI seeks clarification from FDA whether a “standard menu item” must contain the same ingredients. For instance “potato salad” can include a very wide range of recipes, and as explained previously, individual stores within a chain may alter recipes to appeal to regional and seasonal tastes. FMI believes that if an item has different ingredients in less than 20 outlets within a chain, it should not be covered by the Proposed Rule. For example, a large national retailer may sell a standard potato salad nationwide, but in ten outlets in Louisiana sell a potato salad with different ingredients. There are many other items where several ingredients may be different based on regional tastes but they still have the same name. Consumers benefit from regional items and FDA should not implement a policy which could reduce consumer choice and limit innovation leading to more formulaic items.

The definition of “standard menu item” should also contemplate that an item must have the same general recipe.

### Suggested Regulatory Change

#### §101.11 (a) *Definitions*

Standard menu item means a restaurant or restaurant-type food **with the same general recipe prepared in substantially the same way with the substantially the same food components** that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display **at 20 or more locations**.

## F. Foods to Which the Requirements of Section 4205 Do Not Apply

### 1. Temporary Menu Items

FDA does not apply the temporary menu item exclusion to foods on display or self-service items. We believe it should be applied here. We see public policy justification why not. If FDA cannot apply it in the light of the statutory language, we believe they should use enforcement discretion

## G. Foods on Display

*FDA is proposing to define the term “food on display” to mean restaurant or restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption.<sup>57</sup> Food on display would not encompass meats and cheeses sold at delicatessens in grocery stores, given that there is an ordinary expectation that the*

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<sup>57</sup> 76 Fed. Reg. 19233.

*consumer will further prepare those foods before consumption, e.g., by using the meat and cheese to make a sandwich.*<sup>58</sup>

FMI believes this logic should also apply to deli platters with sliced cold cuts; olives, pickled vegetables, hummus, dips and other spreads, wedges of cheese and similar items which are eaten not alone, but with further preparation. Hummus and cheese are generally eaten with crackers and/or bread. Deli platters are typically used to make sandwiches or eaten with crackers.

## **H. Custom Order**

*FDA is defining “custom order” in §101.11(a) as “a food that is prepared in a specific manner based on an individual customer’s request which requires the restaurant or similar retail food establishment to deviate from its usual preparation of a menu item . . .”*

For some items prepared in supermarkets—like made-to-order birthday cakes—there is no usual preparation. FMI believes that custom ordered birthday cakes should fall within the definition of “custom order” and seeks clarification from FDA that this is indeed the case. Similarly, sub sandwiches and salads may be presented to consumers in a manner in which there is no usual preparation. For example, a menu board for subs may list bread options, meat and cheese options and topping options but not list any particular sandwiches. FMI believes these should be considered custom orders. In addition, some supermarkets offer catering services, and these too should be considered custom orders since the purchaser selects which items will be included in the order. Deli platters should generally be considered custom orders. FMI also believes they should be excluded on the basis that they are eaten with further preparation as explained above.

## **I. Information that Must Be Declared by Covered Establishments**

*Section 403(q)(5)(H)(ii) requires covered establishments to disclose on menus and menu boards, in a clear and conspicuous manner, the number of calories contained in standard menu items as usually offered and prepared for sale. FDA has tentatively concluded in the Proposed Rule that calorie declarations must be provided on all menus and menu boards of covered establishments.*

### Size of Calorie Declaration

*FDA is proposing in § 101.11 that a calorie declaration must be no smaller than the type size of the name or price of the associated standard menu item on the menu or menu board whichever is smaller.*

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<sup>58</sup> 76 Fed. Reg. 19204.



FMI supports this position as it provides a degree of flexibility.

*FDA is proposing in § 101.11 that the term “Calories” or “Cal” must appear as a heading above a column listing the number of calories for each standard menu item, or adjacent to the number of calories for each standard menu item.*

FMI supports the flexibility to use “Calories” or “Cal” as there are often significant space constraints on menus and menu boards.

#### **J. Determination of Calories for Standard Menu Items that Come in Different Flavors, Varieties, or Combinations**

*FDA is proposing in §101.11 that the calories must be declared as a range for standard menu items that come in different flavors, varieties, or combinations but are listed as a single menu item. The calorie information for these items would be declared in a format “xx-yy” where “xx” is the caloric content of the lowest calorie flavor or combination and “yy” is the caloric content of the highest calorie flavor or combination.*

FMI believes a calorie declaration range is the most workable system of the options presented in the Proposed Rule.

#### **K. Succinct Statement Concerning Suggested Daily Caloric Intake Required on Menus and Menu Boards**

*FDA has tentatively concluded in the Proposed Rule that the statement: “A 2,000 calorie daily diet is used as the basis for general nutrition advice; however, individual calorie needs may vary” satisfies the requirements of Section 403(q).*

FMI supports this position.

*FDA is proposing in § 101.11 that the suggested daily calorie intake statement appear in a type size no smaller than the smallest type size for any calorie declaration appearing on the same menu or menu board.*

Due to limited space on menu boards, and the amount of text required to be included in the statement, FMI believes FDA should permit for a smaller type size for the statement.

FMI also believes that when there are multiple menu boards that may be viewed simultaneously when a shopper is making an order selection, only one such board should be required to display the daily calorie intake statement. Requiring redundant disclosures would provide no benefit to consumers but would take up valuable space on menus and menu boards, reducing the number of items that can be displayed.

## **L. Nutrition Information that Must be Made Available in a Written Form**

*Section 403(q) requires that covered establishments must provide, in a written form and upon consumer request, the nutrition information required under clauses (C) and (D) of section 403 (q)(1) of the FD&C Act. Section 403(q)(5)(H)(ii)(III) states that the information must be “available on the premises.” FDA is seeking comment on interpreting this phrase for menus appearing on the internet.*

Premises is defined by Merriam-Webster as “(a) a tract of land with the buildings thereon; (b) a building or part of a building usually with its appurtenances (as grounds).” The term “premises” refers to a physical location and FMI believes that FDA should interpret the phrase to require only that written nutrition information be made available to consumers at store locations. Retailers should be given the option of voluntarily providing the written nutrition information on-line for menus appearing on the internet, but should not be required to do so.

*FDA is proposing in § 101.11 that the statement of availability of written nutrition information appear in a type size no smaller than the smallest type size for any calorie declaration appearing on the same menu or menu board.*

Due to limited space on menu boards, and the amount of text required to be included in the statement, FMI believes FDA should permit a smaller type size for the statement.

*FDA states that it recognizes that some restaurants or SIMILAR RETAIL FOOD ESTABLISHMENTS have relatively few standard menu items, and as a result, may have menu boards that list relatively few items in very large font. FDA is requesting comment on whether it is appropriate in these cases to tie the font size of the two statements required to appear at the bottom of the menu board to the calorie disclosures.*

FMI believes that these statements should not be tied to the larger text for the reasons outlined previously.

## **M. Display of Calories for Self-Service Foods or Foods on Display**

*FDA requests comment on whether establishments that already provide an individual sign identifying each food on display or self-service food with its name, price, or both should have the option of providing a separate individual sign for each food on display or self-service food for the calorie declaration, so long as the sign with the calorie declaration is adjacent to and clearly associated with its corresponding food.*

FMI believes that these establishments should have the flexibility to put information on a separate sign if they so choose.

*Often, self-service food or food on display is displayed per item, such that the customer generally takes one item or is generally served one item (e.g., a baked potato at a buffet, a cupcake at a bakery, a cup of pudding at a cafeteria). FDA tentatively concludes that for self-service food or food on display that is displayed per item, where an item represents one serving, the calorie declaration should be per item.*

While the nutrient content for a cup of pudding may be relatively easy to ascertain since the serving size is regimented, for an item such as a baked potato, fish fillet, or chicken breast, size may vary considerably. FMI has concerns about declaring accurate nutrient values for such items with significant variations in size and believes that retailers should have the option of including a serving size for the item or the nutrition information should be based off of a standard serving size for such item. FMI seeks clarification as to whether or how the Reference Amounts Customarily Consumed would apply in these situations. FMI would recommend to FDA that serving sizes similar to those in the NLEA listing for single ingredient fruits, vegetables, meats, poultry, fish, and seafood be considered.

*For self-service food or food on display that is not displayed per item (e.g., potato salad at a buffet or ice cream at an ice cream parlor), FDA tentatively concludes that the calorie declaration should be per serving. Covered establishments may use the size of the serving utensil as the serving measure (e.g. 300 calories per single scoop of ice cream), or they may use common household measurements (e.g., 400 calories per cup of potato salad). FDA requests comment on the appropriate measurement units for declaring calories per serving for self-service foods and foods on display.*

FMI agrees with FDA that retailers should have the flexibility of using common household measurements or serving utensils in declaring calories per serving. FDA should keep in mind that many retailers will wish to keep serving sizes on items consistent with those of packaged foods so as not to implement dueling serving size regimes. FDA should ensure that retailers that wish to align serving sizes for foods covered by 403(q)(5)(H) be able to do so.

*With respect to multiple-serving foods, FDA tentatively concludes that if the food on display or self-service food is a discrete item such as a whole rotisserie chicken, and it is sold as such, then the calories must be displayed for the whole item.*

FMI believes that requiring total calories to be displayed for a multiple serving item (e.g. a whole pizza or a whole cake) will only serve to confuse consumers and not provide them with useful information. These items are not consumed whole. FDA rejected this approach for packaged foods, and FMI sees no need for it here. FDA should justify a need for this change. It is inconsistent with the NLEA labeling regime consumers have been familiar with for decades and will confuse shoppers. FMI is perplexed why FDA is utilizing this approach. It would be akin to labeling a box of cereal or a bag of potato

chips with 2,000 calories. Information provided pursuant to 403(q)(5)(H) should be meaningful to consumers and total calorie values for multiple serving foods is not.

## **N. Applicability of 403(q)(5)(H)(ii) to Self-Service Food and Food on Display**

### **1. Calorie Declarations**

*FDA proposes to define “menu” or “menu board” as the primary writing of the covered establishment from which a consumer makes an order selection. Under this definition, most self-service food and food on display would not appear on menus or menu boards. However, some would. For example, an ice cream parlor might list all of its flavors on a menu board and also have bulk containers of ice cream on display and visible to customers in a display case. In this situation, calorie declarations must be provided adjacent to the ice cream flavors on the menu board under 403(q)(5)(H)(ii)(II)(aa) and on signs adjacent to the individual ice cream bulk containers themselves under 403(q)(5)(H)(iii).*

FMI believes that if a consumer can simultaneously view a menu board listing a standard menu item and a tag for the same menu item on display, only one calorie disclosure should be required. The Proposed Rule will result in a redundant disclosure and an unnecessary burden. For purposes of displaying the succinct statement of daily caloric intake and notice of written nutrition information, FDA has stated that only one disclosure is required when both a menu board and signs are viewable at the same time.<sup>59</sup> This logic should also apply to calorie disclosures.

### **2. Additional Written Nutrition Information for Self-Service Food and Food on Display**

*Section 403(q)(5)(H)(ii)(iii) requires certain additional nutrition information to be available to the consumer in written form upon request. Because section 403(q)(5)(H)(i) states that covered establishments must disclose the information in section 403(q)(5)(H)(ii) for standard menu items, FDA tentatively concludes that covered establishments must provide the additional written nutrition information described in section 403(q)(5)(H)(ii)(III) for self-service foods and food on display that are standard menu items.*

FMI respectfully disagrees with FDA’s interpretation of section 403(q)(5)(H)(i). The section reads “in the case of food that is a standard menu item that is offered for sale in a restaurant or similar retail food establishment . . . the restaurant or similar retail food establishment shall disclose the information described in subclauses (ii) and (iii).”

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<sup>59</sup> 76 Fed. Reg. 19217.

Subclause (ii) provides that standard menu items appearing on menus and menu boards list calorie information for each item, a succinct statement regarding daily caloric intake, and additional written nutrition information.

Section 403(q)(5)(H)(ii)(I)(bb) reads that a restaurant or SIMILAR RETAIL FOOD ESTABLISHMENT shall disclose “. . . a succinct statement concerning suggested daily caloric intake . . . posted prominently on the menu” (emphasis added). Similarly Section 403(q)(5)(H)(ii)(II)(bb) reads “a succinct statement concerning suggested daily caloric intake . . . posted prominently on the menu board” (emphasis added). Section 405(q)(5)(H)(ii)(IV) reads “on the menu or menu board, a prominent clear, and conspicuous statement regarding the availability of (written nutrition information).”

Self-service food and food on display was included in a wholly different subclause that makes no mention of additional written nutrition information or a statement of daily caloric intake. It would have been simple for Congress to have included self-service food and food on display in subclause (ii), but it deliberately omitted them. While every word of a statute must be presumed to have been used for a purpose, it is also the case that every word excluded from a statute must be presumed to have been excluded for a purpose.<sup>60</sup>

It follows then that not only does the written nutrition information requirement not apply to self-service foods and foods on display, but also the signage for written nutrition information and statement of daily caloric intake. To apply the requirements of subclause (ii) to subclause (iii) does not work in practice and is not a rational construction of the statute.

#### **O. Packaged Foods that Bear the Nutrition Information Required by Section 403(q)(1) of the FD&C Act**

*Some packaged food, such as bags of chips or packages of cookies, are offered for sale in covered establishments individually or as parts of combination meals. A packaged food that is required to bear nutrition information on its label under 403(q)(1) of the FD&C Act and FDA's implementing regulations § 101.9 would not be a restaurant or restaurant-type food, because restaurant or restaurant-type food includes only food previously exempt from those nutrition labeling requirements. Therefore such food would not be covered by the proposed menu labeling requirements. However, FDA tentatively concludes that some packaged food offered for sale in covered establishments is “food served in restaurants or other establishments in which food is served for immediate consumption or that is sold for sale or use in such establishments.” While it happens to bear Nutrition Facts, it is not required to do so.*

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<sup>60</sup> *Chickasaw Nation v. U.S.*, 534 U.S. 84 (2001).

*So long as the consumer is able to examine the nutrition information on the label of the packaged food before purchasing the food and the food complies with the nutrition labeling requirements set forth in 403(q)(1) of the FD&C Act and § 101.9, the label for the packaged food will provide to consumers, in written form, the nutrition information that FDA is proposing be required in the written nutrition information. Therefore, FDA tentatively concludes that this type of packaged food would satisfy the requirements of § 101.11(b)(2)(ii), so long as consumers are able to examine the nutrition information on the label of the packaged food before purchasing the food. . . . FDA tentatively concludes that a packaged food that is a self-service food or food on display that bears the nutrition information required by 403(q)(1) of the FD&C Act and § 101.9 satisfies the calorie disclosure requirement for self-service food or food on display in section 403(q)(5)(H)(iii) of the FD&C Act, so long as a consumer is able to examine the calorie information on the label prior to purchase.*

Unlike restaurants, supermarkets generally place a label on individual items requested by a shopper. For example, when a consumer orders a store-prepared or processed cooked chicken breast from a deli case, the item is removed from the case, placed in a container and a label is affixed to the container so it may be scanned at the check-out line. The labeled item is given to the consumer before the consumer has to purchase the food at check out. Although these items are currently not required to bear a Nutrition Facts panel, in some instances a Nutrition Facts panel is printed from the scale and placed on the container. In these circumstances consumers see all of the information required to be disclosed in § 101.11(b)(2)(ii) before they purchase the item. FMI believes that all items that bear a Nutrition Facts panel compliant with § 101.9—**regardless of whether the item is required to be labeled under § 403(q)(1) or not**—should not be subject to the Proposed Rule.

This would provide relief to the supermarket industry while giving consumers all of the same information required by the Proposed Rule.

Labels are often preprinted or previously affixed on packaging for items (e.g. a paper bag for a sub sandwich of bread) to improve efficiency and save costs. Preprinted Nutrition Facts panels will contain nutrient information based on the standard preparation of a menu item. Undoubtedly consumers will request that toppings will be added or removed to a standard menu item (e.g. a made-to-order sandwich). Although FMI understands this would be considered a custom item and thus exempt from the Proposed Rule, FMI seeks clarification from FDA that such an item would not be misbranded if the packaging contained nutrition information based on the standard preparation.

In addition, FMI believes that if a retailer displays all of the information required to be disclosed in § 101.11(b)(2)(ii) on a laminated card, poster, or other display or makes it available in a binder before a consumer purchases the item, such item should be exempt from the Proposed Rule.

## **P. Determination of Nutrient Content**

*FDA is proposing in § 101.11 an approach for determining compliance modeled after § 101.9(g). Proposed § 101.11(c)(2) provides for two classes of nutrients for purposes of compliance: Class I (added nutrients) and Class II (naturally occurring (indigenous) nutrients). FDA is proposing that for Class I protein or dietary fiber, the nutrient content of an appropriate composite sample must be at least equal to the value for that nutrient declared in the nutrition information in the written form. Other requirements would include that the amount of calories, sugars, total fat, saturated fat, trans fat, cholesterol and sodium contained in an appropriate composite of a standard menu item must not be more than 20 percent in excess of the declared value. Additionally, the amount of protein, total carbohydrates and dietary fiber contained in an appropriate composite of a standard menu item must not be less than 80 percent of the declared value.*

FMI believes it is unrealistic for FDA to impose the same standards applicable to packaged foods to foods processed and prepared in restaurants and retail establishments. These items were carved out of the NLEA because Congress recognized the challenges inherent to producing items in a decentralized manner.

Section 403(q)(5)(H)(iv) plainly states that a restaurant or similar retail food establishment “shall have a **reasonable basis** for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in section 101.10 of title 21, Code of Federal Regulations (or any successor regulation) or in a related guidance” by FDA. FDA proposal to apply the standards for packaged foods to restaurant and restaurant-type foods is clearly inconsistent with the statute and the Agency must correct the final rule to use reasonable basis standard.

FDA’s Guidance clearly explains the “reasonable basis” standard:

FDA does not intend to impose an unrealistic regime (e.g., to require exacting measurements or strict portion controls) in restaurants. However the agency is requiring that a restaurant have a reasonable basis for believing that a food meets the nutrient requirements for a claim, and that it be able to provide reasonable assurance that the preparation of the food adheres to the basis for the claims.<sup>61</sup>

Restaurateurs will need to employ preparation methods that are sufficiently consistent, including weight and volume measurements to provide reasonable assurance that the preparation method adheres to the basis for the claim.

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<sup>61</sup> FDA Guidance for Industry: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-from-Home Foods (April 2008).

In addition, the Guidance also discusses how FDA will evaluate compliance in a restaurant situation:

For compliance purposes, FDA will look at the recipe, nutrient information source, and any calculations used by a restaurant as its “reasonable basis” for believing that a food meets the requirements for a claim or other nutrition information. ... FDA may also request that a restaurant provide reasonable assurance that the method of preparation used adheres to the restaurant’s basis for the claim.”<sup>62</sup>

FDA’s Guidance clearly establishes that the “reasonable basis” standard does not impose “exacting measurements” and that compliance is to be evaluated by reviewing the documents that underlie the basis for the claim.

Food processing and preparation at retail is not, and can never be, as standardized as that which occurs in a central manufacturing facility. FMI believes that FDA should follow the “reasonable basis” standard. If the Agency does not, we believe FDA should expand the tolerance for declared values by 10 percent on both ends. Namely, the amount of calories, sugars, total fat, saturated fat, trans fat, cholesterol and sodium contained in an appropriate composite of a standard menu item must not be more than 30 percent in excess of the declared value and the amount of protein, total carbohydrates and dietary fiber contained in an appropriate composite of a standard menu item must not be less than 70 percent of declared value. FDA must also consider that the nutrient values for hot food bar items change over time as moisture leaves the item making it very difficult to precisely declare the nutrient content. Stores using purchased recipe books that provide nutrition information may easily find that the nutrition information provided by the author will deviate considerably from the actual values of the item as prepared.

#### **Q. Substantiation Documentation**

FMI believes the recordkeeping requirements in the Proposed Rule are excessive and will impose hundreds of millions of dollars of regulatory burdens on the industry. FMI believes FDA should only require records that are kept in the ordinary course of business to substantiate nutrient values similar to NLEA requirements. It makes no sense to require documentation for restaurant and restaurant-type foods that exceeds the requirements for packaged foods.

Suppliers of items are not currently required to provide nutrition information to retailers, which makes compliance with the Proposed Rule challenging. FDA should consider requiring that such nutrition information be provided.

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<sup>62</sup> Although technically this applies to food-related claims in restaurants, nutrition labeling per se is not required under this provision as Congress specifically referred FDA to this section, the Agency should consider it.



FDA's proposal for "Identical" substantiation is unworkable and inconsistent with the statute.

Section 101.11(c)(6) requires establishments covered by the ACA requirements to retain and provide to FDA substantiation of the nutrient values that the establishment provides under the law and further lists specific information that must be retained depending on the source.

For nutrient databases, analyses, and "other reasonable means," FDA requires the recipe used to determine nutrient content to be "identical" to the recipe used to prepare the food and further requires a signed statement from the person who prepared the food that the recipe used on any given day is "identical" to that provided in the documentation. As discussed previously, because , it is unreasonable for FDA to expect them to be "identical" and inconsistent with the statute.

Congress directed FDA to consider several factors related to the variability inherent in the preparation of restaurant and restaurant-type food as the Agency promulgated its regulations including "reasonable variation in serving size and formulation of menu items . . . inadvertent human error, training of food service workers, variations in ingredients, and other factors."<sup>63</sup>

FMI recommends that FDA delete the specific requirements regarding substantiation and instead rely on the "reasonable basis" standard articulated in the statute.

#### Suggested Regulatory Change

##### *§ 101.11(c) Determination of nutrient content*

(6) A restaurant or similar retail food establishment must provide to FDA, within a reasonable period of time upon request, information substantiating nutrient values including the method and data used to derive these nutrient levels. This information must include the following:

(i) For nutrient databases:

(A) The identity of the database used.

(B) The recipe or formula used as a basis for the nutrient declarations. ~~The recipe posted on the database must be identical to that used by the restaurant or similar retail food establishment to prepare the menu item.~~ [minor variations to a recipe will not likely result in significant nutrient shift, e.g. spices, adding parsley, decorative sprinkles]

(C) ~~For the specified amounts of each ingredient identified in the recipe, a detailed listing (e.g., printout) of the amount of each~~

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<sup>63</sup> 21 USC Section 403(q)(5)(H)(x)

nutrient that that ingredient contributes to the menu item.

~~—(D) If this information is not available because the nutrition information was derived from a computer program, which is designed to provide only a final list of nutrient values for the recipe, a certificate of validation attesting to the accuracy of the computer program.~~

(E) A detailed listing (e.g., printout) of the nutrient values determined for each menu item.

~~(F) If this information is not derived through the aid of a computer program which provides a final nutrient analysis for the menu item, worksheets used to determine the nutrient values for each of these menu items.~~

(G) Any other information pertinent to the final nutrient levels of the menu item (e.g., information about what might cause slight variations in the nutrient profile such as moisture variations).

~~(H) A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.~~

(ii) For published cookbooks that contain nutritional information for recipes in the cookbook:

(A) The name, author and publisher of the cookbook used.

(B) If available, information provided by the cookbook about how the nutrition information for the recipes was obtained.

~~—(C) A copy of the recipe used to prepare the menu item and a copy of the nutrition information for that menu item as provided by the cookbook.~~

~~(D) A statement signed by a responsible individual employed by the covered establishment certifying that the recipe used to prepare the menu item by the restaurant or similar retail food establishment is the same recipe provided in the cookbook. (Recipes may be divided as necessary to accommodate differences in the portion size derived from the recipe and that are served as the menu item but no changes may be made to the proportion of ingredients used.)~~

(iii) For analyses:

(A) A copy of the recipe for the menu item used for the nutrient analysis.

(B) The identity of the laboratory performing the analysis.

(C) Copies of analytical worksheets used to determine and verify nutrition information.

~~(D) A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and an additional signed statement certifying that the recipe used to prepare the menu~~

~~item is identical to that used for the nutrient analysis.~~

(iv) For nutrition information provided by other reasonable means:

(A) A ~~detailed~~ description of the method used to determine the nutrition information.

~~(B) Documentation of the validity of that method.~~

(C) A recipe or formula used as a basis for the nutrient determination. The recipe used in determining these nutrient values must be the same recipe used by the restaurant and similar retail food establishment to prepare the item.

(D) Any data derived in determining the nutrient values for the menu item.

~~(E) A statement signed by a responsible individual employed by the covered establishment that can certify that the information contained in the nutrient analysis is complete and accurate and that the recipe used to prepare the menu item is identical to that used for the nutrient analysis.~~

## **R. Proposed Effective Date**

*FDA is proposing that the final rule become effective six months from the date of its publication . . . FDA recognizes, however, the potential difficulties of implementing the rule in this timeframe, and we request comment on whether the effective date should be extended for a greater period of time after the publication of the final rule.*

Implementation of § 403(q)(5)(H) will be very costly and complex for the supermarket industry. It will pose enormous logistical and operational challenges and will require intensive and time consuming training of staff. If FDA determines that any aspect of the statute is applicable in supermarket environments, FMI believes the Agency should give the supermarket industry at least 24 months to comply with § 403(q)(5)(H) following publication of the final rule implementing the provisions. The 24 month effective date is what FDA granted the food industry for compliance with the NLEA and as § 403(q)(5)(H) will have a similarly large impact on the supermarket industry, we believe it is the appropriate timeframe here.

FMI greatly appreciates the Agency's consideration of these comments.

Sincerely,



Erik R. Lieberman  
Regulatory Counsel