

110TH CONGRESS  
2D SESSION

# S. 3575

To amend the Federal Food, Drug, and Cosmetic Act with respect to nutrition labeling of food offered for sale in food service establishments.

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## IN THE SENATE OF THE UNITED STATES

SEPTEMBER 25 (legislative day, SEPTEMBER 17), 2008

Mr. CARPER (for himself and Ms. MURKOWSKI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to nutrition labeling of food offered for sale in food service establishments.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Labeling Education and Nutrition Act of 2008” or the  
6 “LEAN Act of 2008”.

7 (b) TABLE OF CONTENTS.—The table of contents of  
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

- Sec. 3. Definitions.
- Sec. 4. Nutrition labeling exemption.
- Sec. 5. Voluntary nutrition labeling.
- Sec. 6. Mandatory nutrition labeling.
- Sec. 7. National uniformity.
- Sec. 8. Implementing regulations.
- Sec. 9. Effective dates.
- Sec. 10. Technical and conforming amendments.

1 **SEC. 2. FINDINGS.**

2 Congress finds that—

3 (1) a healthy lifestyle includes a balanced diet  
4 as well as physical activity;

5 (2) approximately more than 60 percent of  
6 American adults and 30 percent of American chil-  
7 dren suffer from being overweight and obese, which  
8 can lead to many chronic health risks, including dia-  
9 betes, heart disease, and hypertension;

10 (3) the United States ranks last in reducing the  
11 number of preventable deaths resulting from obesity-  
12 related chronic illnesses;

13 (4) during the 2-decade period preceding the  
14 date of enactment of this Act, there has been a sig-  
15 nificant increase in the number of meals prepared or  
16 eaten outside the home;

17 (5) nutrition labeling pursuant to the Nutrition  
18 Labeling and Education Act of 1990 has increased  
19 significantly American consumers' access to nutri-  
20 tion information regarding the foods they consume;

1           (6) the Department of Agriculture and leading  
2 health groups recognize that many individuals re-  
3 quire different information based on individual and  
4 specific health needs and risks;

5           (7) the nutrients provided pursuant to the Nu-  
6 trition Labeling and Education Act of 1990 provides  
7 consumers with all the tools needed to make healthy  
8 choices;

9           (8) as of 2008, nutrition information for stand-  
10 ard food items is voluntarily provided by various de-  
11 livery methods at many major chains of food service  
12 establishments;

13           (9) the nutrient content of a food offered for  
14 sale in a food service establishment can be deter-  
15 mined with appropriate accuracy by consulting nu-  
16 trient databases, cookbooks, laboratory analyses, or  
17 other sources that provide a reasonable basis for in-  
18 formation regarding the nutrient content of a food,  
19 notwithstanding variability in the portion size, for-  
20 mulation, and other characteristics of such food or  
21 its preparation method; and

22           (10) public health and welfare are advanced if  
23 food service establishment nutrition information is  
24 not subject to frivolous litigation.

1 **SEC. 3. DEFINITIONS.**

2 Section 403(q) of the Federal Food, Drug, and Cos-  
3 metic Act (21 U.S.C. 343(q)) is amended by adding at  
4 the end the following:

5 “(6) DEFINITIONS.—For purposes of subpara-  
6 graphs (7) and (8):

7 “(A) The term ‘standard food item’ means  
8 a food offered for sale at least 90 days per cal-  
9 endar year, but does not include food not sepa-  
10 rately offered for sale or food exempt under  
11 subparagraph (5)(C).

12 “(B) The term ‘menu’ or ‘menu board’  
13 means the primary writing on the premises of  
14 the food service establishment from which con-  
15 sumers make their order selection.

16 “(C) The term ‘reasonable basis’ means  
17 any means of determining nutrition information  
18 for a standard food item made without an in-  
19 tent to deceive, including nutrient databases,  
20 cookbooks, laboratory analyses, and other rea-  
21 sonable means.

22 “(D) The term ‘food service establishment’  
23 means an establishment that offers for sale food  
24 described in subclause (i) or (ii) of subpara-  
25 graph (5)(A).”.

1 **SEC. 4. NUTRITION LABELING EXEMPTION.**

2 Section 403(q)(5)(A) of the Federal Food, Drug, and  
3 Cosmetic Act (21 U.S.C. 343(q)(5)(A)) is amended—

4 (1) by adding at the end of subclause (i) the  
5 following: “except that such food shall not be consid-  
6 ered exempt under this subclause for purposes of  
7 providing nutrition information under subparagraph  
8 (7) or (8).”; and

9 (2) by adding at the end of subclause (ii) the  
10 following: “except that such food shall not be consid-  
11 ered exempt under this subclause for purposes of  
12 providing nutrition information under subparagraph  
13 (7) or (8).”.

14 **SEC. 5. VOLUNTARY NUTRITION LABELING.**

15 Section 403(q) of the Federal Food, Drug, and Cos-  
16 metic Act (21 U.S.C. 343(q)), as amended by section 3,  
17 is further amended by adding at the end the following:

18 “(7) VOLUNTARY NUTRITION LABELING OF  
19 FOOD SERVICE ESTABLISHMENT FOOD.—A food  
20 service establishment may provide nutrition informa-  
21 tion for a food item under this subparagraph by  
22 meeting the following requirements:

23 “(A) Providing nutrition information for  
24 all of the nutrients required by subparagraphs  
25 (1)(C) and (1)(D), determined with a reason-  
26 able basis.

1           “(B) Disclosing such information in writ-  
2           ten form on the premises of the food service es-  
3           tablishment.

4           “(C) Making such disclosure available  
5           upon request prior to purchase.”.

6 **SEC. 6. MANDATORY NUTRITION LABELING.**

7           Section 403(q) of the Federal Food, Drug, and Cos-  
8           metic Act (21 U.S.C. 343(q)), as amended by section 5,  
9           is further amended by adding at the end the following:

10           “(8) IN GENERAL.—The labeling of a standard  
11           food item served or offered for sale in a food service  
12           establishment that is part of a chain that operates  
13           20 or more establishments under the same trade  
14           name (regardless of the type of ownership of the es-  
15           tablishments) shall, except as provided in clause (E),  
16           disclose, in a clear and conspicuous manner in ac-  
17           cordance with paragraph (f), the following informa-  
18           tion, determined with a reasonable basis, as follows:

19           “(A) DISCLOSURE OF CALORIES.—

20           “(i) CALORIES ON THE MENU  
21           BOARD.—The number of calories shall be  
22           disclosed prior to the point of purchase by  
23           1 of the following means:

24           “(I) On the menu board.

1                   “(II) On a sign presenting stand-  
2                   ard food items in a manner similar to  
3                   the menu board and located on the  
4                   same wall as the menu board.

5                   “(III) On a sign at eye level in  
6                   the consumer queue prior to the point  
7                   of purchase.

8                   “(ii) CALORIES ON THE MENU.—The  
9                   number of calories shall be disclosed prior  
10                  to the point of purchase by 1 of the fol-  
11                  lowing means:

12                   “(I) In the menu.

13                   “(II) In an insert that accom-  
14                   panies the menu.

15                   “(III) In an appendix that is at-  
16                   tached to the back of the menu.

17                   “(IV) In a supplemental menu  
18                   that accompanies the menu.

19                   “(B) ADDITIONAL NUTRITION INFORMA-  
20                   TION.—The nutrition information for all nutri-  
21                   ents required by subparagraphs (1)(C) and  
22                   (1)(D) shall be located on the premises of the  
23                   food service establishment, in writing, and  
24                   available to the consumer upon request prior to  
25                   the point of purchase.

1           “(C) REFERRAL STATEMENT.—A menu,  
2 menu board, or other writing prior to the point  
3 of purchase shall bear a statement directing the  
4 consumer to the availability of additional nutri-  
5 tion information required under clause (B).

6           “(D) CALORIE INFORMATION STATE-  
7 MENT.—If calories are not listed directly on a  
8 menu or menu board pursuant to subclause  
9 (i)(I), (i)(II), or (ii)(I) of clause (A), then the  
10 menu or menu board shall state the suggested  
11 daily caloric intake as 2000 calories or an alter-  
12 native statement prescribed by the Secretary  
13 through guidance.

14           “(E) APPLICABILITY.—This subparagraph  
15 shall not apply to—

16           “(i) food offered for sale in a non-  
17 profit food service establishment;

18           “(ii) food that is not food described in  
19 subclause (i) or (ii) of subparagraph  
20 (5)(A); and

21           “(iii) such other food as the Secretary  
22 may exempt by regulation.

23           “(F) VIOLATIONS.—A person shall have  
24 knowingly or willfully violated the requirements  
25 of this paragraph if the person—

1 “(i) purposefully failed to make a dis-  
2 closure required by this paragraph; or

3 “(ii) made a disclosure under this  
4 paragraph with an intent to deceive.

5 “(G) ONE DETERMINATION PER ITEM.—A  
6 reasonable basis determination of nutrition in-  
7 formation shall be required only once per stand-  
8 ard food item if the portion size is reasonably  
9 consistent and the food service establishment  
10 follows a standardized recipe and trains to a  
11 consistent method of preparation.”.

12 **SEC. 7. NATIONAL UNIFORMITY.**

13 Section 403A(a)(4) of the Federal Food, Drug, and  
14 Cosmetic Act (21 U.S.C. 343–1(a)(4)) is amended to read  
15 as follows:

16 “(4) any requirement for nutrition labeling of  
17 food that is not identical to the requirement of sec-  
18 tion 403(q), except a requirement for nutrition label-  
19 ing of food which is exempt under subclause (i) or  
20 (ii) of section 403(q)(5)(A), other than food served  
21 in an establishment that is not part of a chain that  
22 operates 20 or more establishments under the same  
23 trade name, or”.

1 **SEC. 8. IMPLEMENTING REGULATIONS.**

2 The Secretary of Health and Human Services (re-  
3 ferred to in this section as the “Secretary”) shall carry  
4 out the following:

5 (1) Not later than 1 year after the date of en-  
6 actment of this Act, the Secretary shall promulgate  
7 proposed regulations to mandate nutrition labeling  
8 of food service establishment food in accordance with  
9 section 403(q)(8) of the Federal Food, Drug, and  
10 Cosmetic Act (21 U.S.C. 343(q)(8)) (as added by  
11 section 6).

12 (2) Not later than 2 years after the date of en-  
13 actment of this Act, the Secretary shall promulgate  
14 final regulations to mandate nutrition labeling of  
15 food service establishment food in accordance with  
16 section 403(q)(8) of the Federal Food, Drug, and  
17 Cosmetic Act (21 U.S.C. 343(q)(8)) (as added by  
18 section 6).

19 (3) If the Secretary determines that a nutrient  
20 other than a nutrient required by section 403(q)(8)  
21 of the Federal Food, Drug, and Cosmetic Act (21  
22 U.S.C. 343(q)(8)) should be included in the labeling  
23 of food menu items subject to such section 403(q)(8)  
24 for purposes of providing information regarding the  
25 nutritional value of such food that will assist con-  
26 sumers in maintaining healthy dietary practices, the

1 Secretary may by regulation require that informa-  
2 tion relating to such an additional nutrient be in-  
3 cluded in the labeling of such food items.

4 (4) If the Secretary determines that the infor-  
5 mation relating to a nutrient required by section  
6 403(q)(8) of the Federal Food, Drug, and Cosmetic  
7 Act (21 U.S.C. 343(q)(8)) or paragraph (3) of this  
8 section to be included in the labeling of food menu  
9 items is not necessary to assist consumers in main-  
10 taining healthy dietary practices, the Secretary may  
11 by regulation strike the requirement to include such  
12 information relating to such nutrient.

13 (5) The Secretary may prescribe by regulation  
14 alternative clear and conspicuous means of meeting  
15 the requirements of section 403(q)(8)(A) of the Fed-  
16 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
17 343(q)(8)(A)) (as added by section 6).

18 **SEC. 9. EFFECTIVE DATES.**

19 The amendments made by this Act shall take effect  
20 on the date of enactment of this Act, except that the  
21 amendment made by section 6 shall take effect 180 days  
22 after the Secretary of Health and Human Services pro-  
23 mulgates final regulations under section 8(2).

1 **SEC. 10. TECHNICAL AND CONFORMING AMENDMENTS.**

2 (a) Section 403(q)(1) of the Federal Food, Drug, and  
3 Cosmetic Act (21 U.S.C. 343(q)(1)) is amended by strik-  
4 ing “subparagraphs (3), (4), and (5)” and inserting “sub-  
5 paragraphs (3), (4), (5), (7), and (8).”

6 (b) Section 403(q)(5)(G) of the Federal Food, Drug,  
7 and Cosmetic Act (21 U.S.C. 343(q)(5)(G)) is amended  
8 by striking “Subparagraphs (1), (2), (3) and (4)” and in-  
9 serting “Subparagraphs (1), (2), (3), (4), (7) and (8).”

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