

COMMON SENSE NUTRITION DISCLOSURE ACT OF 2015

FEBRUARY 2, 2016.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 2017]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2017) to amend the Federal Food, Drug, and Cosmetic Act to improve and clarify certain disclosure requirements for restaurants and similar retail food establishments, and to amend the authority to bring proceedings under section 403A, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Common Sense Nutrition Disclosure Act of 2015”.

**SEC. 2. AMENDING CERTAIN DISCLOSURE REQUIREMENTS FOR RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS.**

(a) IN GENERAL.—Section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)) is amended—

(1) in subclause (ii)—

(A) in item (I)(aa), by striking “the number of calories contained in the standard menu item, as usually prepared and offered for sale” and inserting “the number of calories contained in the whole standard menu item, or the number of servings (as reasonably determined by the restaurant or similar retail food establishment) and number of calories per serving, or the number of calories per the common unit division of the standard menu item, such as for a multiserving item that is typically divided before presentation to the consumer”;

(B) in item (II)(aa), by striking “the number of calories contained in the standard menu item, as usually prepared and offered for sale” and inserting “the number of calories contained in the whole standard menu item, or the number of servings (as reasonably determined by the restaurant or similar retail food establishment) and number of calories per serving, or the number of calories per the common unit division of the standard menu item, such as for a multiserving item that is typically divided before presentation to the consumer”; and

(C) by adding at the end the following flush text:

“In the case of restaurants or similar retail food establishments where the majority of orders are placed by customers who are off-premises at the time such order is placed, the information required to be disclosed under items (I) through (IV) may be provided by a remote-access menu (such as a menu available on the Internet) as the sole method of disclosure instead of on-premises writings.”;

(2) in subclause (iii)—

(A) by inserting “either” after “a restaurant or similar retail food establishment shall”; and

(B) by inserting “or comply with subclause (ii)” after “per serving”;

(3) in subclause (iv)—

(A) by striking “For the purposes of this clause” and inserting the following:

“(I) IN GENERAL.—For the purposes of this clause”;

(B) by striking “and other reasonable means” and inserting “or other reasonable means”;

(C) by adding at the end the following:

“(II) REASONABLE BASIS DEFINED.—For the purposes of this subclause, with respect to a nutrient disclosure, the term ‘reasonable basis’ means that the nutrient disclosure is within acceptable allowances for variation in nutrient content. Such acceptable allowances shall include allowances for variation in serving size, inadvertent human error in formulation or preparation of menu items, and variations in ingredients.”;

(4) by amending subclause (v) to read as follows:

“(v) MENU VARIABILITY AND COMBINATION MEALS.—The Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children’s combination meals. Such standards shall allow a restaurant or similar retail food establishment to choose whether to determine and disclose such content for the whole standard menu item, for a serving or common unit division thereof, or for a serving or common unit division thereof accompanied by the number of servings or common unit divisions in the whole standard menu item. Such standards shall allow a restaurant or similar retail food establishment to determine and disclose such content by using any of the following methods: ranges, averages, individual labeling of flavors or components, or labeling of one preset standard build. In addition to such methods, the Secretary may allow the use of other methods, to be determined by the Sec-

retary, for which there is a reasonable basis (as such term is defined in subclause (iv)(II)).”;

(5) in subclause (x)—

(A) by striking “Not later than 1 year after the date of enactment of this clause, the Secretary shall promulgate proposed regulations to carry out this clause.” and inserting “Not later than 1 year after the date of enactment of the Common Sense Nutrition Disclosure Act of 2015, the Secretary shall issue proposed regulations to carry out this clause, as amended by such Act. Any final regulations that are promulgated pursuant to the Common Sense Nutrition Disclosure Act of 2015, and any final regulations that were promulgated pursuant to this clause before the date of enactment of the Common Sense Nutrition Disclosure Act of 2015, shall not take effect earlier than 2 years after the promulgation of final regulations pursuant to the Common Sense Nutrition Disclosure Act of 2015.”; and

(B) by adding at the end the following:

“(IV) CERTIFICATIONS.—Restaurants and similar retail food establishments shall not be required to provide certifications or similar signed statements relating to compliance with the requirements of this clause.”;

(6) by amending subclause (xi) to read as follows:

“(xi) DEFINITIONS.—In this clause:

“(I) MENU; MENU BOARD.—The term ‘menu’ or ‘menu board’ means the one listing of items which the restaurant or similar retail food establishment reasonably believes to be, and designates as, the primary listing from which customers make a selection in placing an order. The ability to order from an advertisement, coupon, flyer, window display, packaging, social media, or other similar writing does not make the writing a menu or menu board.

“(II) PRESET STANDARD BUILD.—The term ‘preset standard build’ means the finished version of a menu item most commonly ordered by consumers.

“(III) STANDARD MENU ITEM.—The term ‘standard menu item’ means a food item of the type described in subclause (i) or (ii) of subparagraph (5)(A) with the same recipe prepared in substantially the same way with substantially the same food components that—

“(aa) 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 doing business under the same name; and

“(bb) is not a food referenced in subclause (vii).”; and

(7) by adding at the end the following:

“(xii) OPPORTUNITY TO CORRECT VIOLATIONS.—Any restaurant or similar retail food establishment that the Secretary determines is in violation of this clause shall have 90 days after receiving notification of the violation to correct the violation. The Secretary shall take no enforcement action, including the issuance of any public letter, for violations that are corrected within such 90-day period.”.

(b) NATIONAL UNIFORMITY.—Section 403A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 1(b)) is amended by striking “may exempt from subsection (a)” and inserting “may exempt from subsection (a) (other than subsection (a)(4))”.

**SEC. 3. LIMITATION ON LIABILITY FOR DAMAGES ARISING FROM NONCOMPLIANCE WITH NUTRITION LABELING REQUIREMENTS.**

Section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)), as amended by section 2, is further amended by adding at the end the following:

“(xiii) LIMITATION ON LIABILITY.—A restaurant or similar retail food establishment shall not be liable in any civil action in Federal or State court (other than an action brought by the United States or a State) for any claims arising out of an alleged violation of—

“(I) this clause; or

“(II) any State law permitted under section 403A(a)(4).”.

**PURPOSE AND SUMMARY**

H.R. 2017, the Common Sense Nutrition Disclosure Act of 2015, addresses the Food and Drug Administration’s (FDA) final menu labeling regulations that are burdensome and inappropriate for food establishments such as convenience stores, supermarkets, grocery stores and pizza restaurants. H.R. 2017 would provide a flexible approach to calorie disclosures by allowing for food establishments to provide consumers with caloric information in the most

helpful way, such as online or on a digital table rather than a traditional menu board. Additionally, H.R. 2017 eliminates the criminal penalties and allows restaurants and retailers to take corrective action, and preempts civil litigation for violations of the federal menu labeling law and any state laws that may exist. Employees would no longer be penalized for inadvertent human error while preparing foods.

#### BACKGROUND AND NEED FOR LEGISLATION

H.R. 2017, authored by Rep. Cathy McMorris-Rodgers (R-WA), would amend section 4205 of the Patient Protection and Affordable Care Act, which requires calorie and other nutrition information to be provided to consumers in restaurants and other similar retail food establishments that have twenty or more locations.

The FDA's final rule implementing section 4205 was issued on November 25, 2014, three and a half years after FDA published the proposed rule. The final rule, which will go into effect on December 1, 2015, requires restaurants and similar retail food establishments to provide calorie and other nutrition information to consumers. According to the final rule, similar retail establishments include:

. . . bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities located within entertainment venues (such as amusement parks, bowling alleys, and movie theaters), food service vendors (e.g., ice cream shops and mall cookie counters), food take out and/or delivery establishments), grocery stores, retail confectionary stores, superstores, quick service restaurants and table service restaurants.<sup>1</sup>

The bill revises the federal menu labeling requirements to allow covered restaurants and retail food establishments to determine how calorie information should be displayed for menu items including serving size, change the definition of 'reasonable basis' to allow for variation in nutrient content due to inadvertent human error in formulation or preparation of a menu item, permit nutrition information to be posted solely via remote-access menu, and require FDA to establish by regulation how nutrient content for variable menu items and combination meals should be determined and disclosed, among other modifications.

#### HEARINGS

The Subcommittee on Health held a hearing on H.R. 2017 on June 4, 2015. The Subcommittee received testimony from:

- Ms. Sonja Yates Hubbard, Chief Executive Officer, E-Z Mart Stores, Inc., *on behalf of* the National Association of Convenience Stores;
- Mr. Israel O'Quinn, Director of Strategic Initiatives, Food City, *on behalf of* the Food Marketing Institute and the National Grocer's Association;
- Ms. Lynn Liddle, Executive Vice President, Communications, Legislative Affairs and Investor Relations, Domino's, *on behalf of* the American Pizza Community;

<sup>1</sup> <https://www.federalregister.gov/articles/2014/12/01/2014-27833/food-labeling-nutrition-labeling-of-standard-menu-items-in-restaurants-and-similar-retail-food>.

- Ms. Karen Raskopf, Chief Communications Officer, Dunkin' Brands, Inc.;
- Ms. Margo G. Wootan, D.Sc., Director, Nutrition Policy, Center for Science in the Public Interest.

COMMITTEE CONSIDERATION

On November 3 and 4, 2015, the Subcommittee on Health met in open markup session and forwarded H.R. 2017 to the full Committee, as amended, by a voice vote. On November 17 and 18, 2015, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 2017 reported to the House, as amended, by a record vote of 36 yeas, 12 nays, and 1 present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

**COMMITTEE ON ENERGY AND COMMERCE -- 114TH CONGRESS  
ROLL CALL VOTE # 43**

**BILL: H.R. 2017**, Common Sense Nutrition Disclosure Act of 2015

**AMENDMENT:** A motion by Mr. Upton to order H.R. 2017 favorably reported to the House, as amended. (Final Passage)

**DISPOSITION: AGREED TO**, by a roll call vote of 36 yeas, 12 nays, 1 present.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton	X			Mr. Pallone		X	
Mr. Barton	X			Mr. Rush	X		
Mr. Whitfield	X			Ms. Eshoo		X	
Mr. Shimkus	X			Mr. Engel			
Mr. Pitts	X			Mr. Green		X	
Mr. Walden				Ms. DeGette		X	
Mr. Murphy				Ms. Capps		X	
Mr. Burgess	X			Mr. Doyle	X		
Mrs. Blackburn	X			Ms. Schakowsky		X	
Mr. Scalise				Mr. Butterfield	X		
Mr. Latta	X			Ms. Matsui	X		
Mrs. McMorris Rodgers	X			Ms. Castor		X	
Mr. Harper	X			Mr. Sarbanes		X	
Mr. Lance	X			Mr. McNerney		X	
Mr. Guthrie	X			Mr. Welch	X		
Mr. Olson	X			Mr. Lujan	X		
Mr. McKinley	X			Mr. Tonko	X		
Mr. Pompeo	X			Mr. Yarmuth			X
Mr. Kinzinger	X			Ms. Clarke		X	
Mr. Griffith	X			Mr. Loeb sack		X	
Mr. Bilirakis	X			Mr. Schrader		X	
Mr. Johnson	X			Mr. Kennedy	X		
Mr. Long	X			Mr. Cardenas	X		
Mrs. Ellmers	X						
Mr. Bucshon	X						
Mr. Flores	X						
Mrs. Brooks	X						
Mr. Mullin	X						
Mr. Hudson	X						
Mr. Collins	X						
Mr. Cramer							

11/18/2015

## COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings that are reflected in this report.

## STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of H.R. 2017 is to amend the Federal menu labeling requirements that allow covered restaurants and retail food establishments to determine how nutrition information should be disclosed to consumer.

## NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2017 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

## EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 2017 contains no earmarks, limited tax benefits, or limited tariff benefits.

## COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, February 1, 2016.*

Hon. FRED UPTON,  
*Chairman, Committee on Energy and Commerce,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2017, the Common Sense Nutrition Disclosure Act of 2015.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Ellen Werble.

Sincerely,

KEITH HALL.

Enclosure.

*H.R. 2017—Common Sense Nutrition Disclosure Act of 2015*

Summary: H.R. 2017 would amend the Federal Food, Drug, and Cosmetics Act to revise the information certain restaurants and retail food establishments must disclose about nutrition to the consumer. CBO estimates that implementing H.R. 2017 would cost \$9 million over the 2016–2021 period, assuming appropriation of the necessary amounts. Enacting H.R. 2017 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

CBO estimates that enacting H.R. 2017 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

H.R. 2017 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary effect of H.R. 2017 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—						
	2016	2017	2018	2019	2020	2021	2016–2021
CHANGES IN SPENDING SUBJECT TO APPROPRIATION							
Estimated Authorization Level .....	0	2	2	1	1	1	9
Estimated Outlays .....	0	2	2	1	1	1	9

Note: Components may not sum to totals because of rounding.

Basis of estimate: H.R. 2017 would modify the labeling requirements for nutrition information displayed by restaurants and other retail food establishments. The Food and Drug Administration (FDA) issued a final rule on such labeling in December 2014, and subsequently several guidances to implement those requirements. The legislation would require the Secretary of Health and Human Services to issue new proposed regulations within a year to modify the current requirements. Some of those modifications would include:

- Providing options for displaying the number of calories for menu items, such as displaying the number of servings and calories per serving for each item;
- Defining a reasonable basis to allow for acceptable variations, such as serving size and inadvertent human error in formulation or preparation of the menu item; and
- Allowing restaurants or similar retail food establishments where the majority of orders are placed by customers who are off-premises at the time to post nutrition information on a remote-access menu, such as the Internet, as the sole method of disclosure.

CBO estimates those modifications would take several years to fully implement because they would significantly change the current regulation. CBO expects FDA would have to develop and publish a new regulation and additional guidance to comply with modifications. Based on information provided by FDA, historical spending on similar activities, and assuming appropriation of the necessary amounts, CBO estimates that those activities would cost FDA \$9 million over the 2016–2021 period.

Pay-As-You-Go considerations: None.

Increase in long term direct spending and deficits: CBO estimates that enacting H.R. 2017 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

Intergovernmental and private sector impact: H.R. 2017 contains no intergovernmental or private-sector mandates as defined in UMRA and would not impose costs on state, local, or tribal governments. Section 2(b) of the bill would remove the ability of states to petition the FDA to enforce their own nutrition labeling requirements on food sold in some chain restaurants or similar retail food establishments. The ability of states to enforce such requirements without FDA approval is already preempted by federal law. Because existing law provides FDA with broad authority over state nutrition laws, the removal of the option for states to petition FDA for the ability to enforce their own laws is not considered a new mandate.

Estimate prepared by: Federal Costs: Ellen Werble; Impact on State, Local, and Tribal Governments: J'nell Blanco Suchy; Impact on the Private Sector: Amy Petz.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

#### FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

#### DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 2017 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

#### DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 2017 specifically directs to be completed one rule making within the meaning of 5 U.S.C. 551.

#### ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

#### APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

## SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

*Section 1. Short title*

This section provides the short title of “Common Sense Nutrition Disclosure Act of 2015.”

*Section 2. Amending certain disclosure requirements for restaurants and similar retail food establishments*

Subsection (A) would allow covered restaurants and retail food establishments to determine how calorie information will be disclosed, including determining the serving size of a menu item. Subsection (B) would allow covered restaurants and retail food establishments to list calorie information for a whole standard menu item, serving amount as determined by the covered establishment, or common unit if a standard menu item on a menu board on a per item or serving amount. Subsection (C) would allow businesses to list the calorie information by remote access if the majority of customers were ordering from off the premises. Additionally, the section would define “reasonable basis” to ensure that there are allowances for variations in serving size, inadvertent human error in formulation or preparation of menu items, and variations in ingredients. The Secretary would also be required to issue a regulation regarding standards for disclosure of nutrition information for variable menu items and combination meals. Further, this section prohibits the FDA from requiring covered restaurants and retail food establishments to provide certifications or similar signed statements related to compliance with federal menu labeling requirements. This section also modifies the definitions of “menu” and “menu board” to allow covered establishments to designate the primary listing customers order from, establishes a definition of “present standard build” to include finished menu items commonly ordered by consumers, and amends the definition of “standard menu item” to limit the definition to items that are prepared in substantially the same way with substantially the same food components. This section also would provide restaurants and similar retail establishments 90 days to correct a violation before enforcement action is taken. Finally, this section would preempt the ability of States and localities to petition FDA to require menu labeling that is different from the federal labeling requirements for covered establishments.

*Section 3. Limitation on liability for damages arising from non-compliance with nutrition labeling requirements*

This section states that an establishment shall not be liable in any civil litigation in Federal or State court for claims arising out of an alleged violation of the federal menu labeling law or any State menu label law.

## CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

**FEDERAL FOOD, DRUG, AND COSMETIC ACT**

\* \* \* \* \*

**CHAPTER IV—FOOD**

\* \* \* \* \*

**MISBRANDED FOOD**

SEC. 403. A food shall be deemed to be misbranded—

(a) If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2).

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(3) a food that is pasteurized unless—

(A) such food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation promulgated under this Act; or

(B)(i) such food has been subjected to a safe process or treatment that—

(I) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food;

(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(III) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

(IV) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

(ii) at least 120 days have passed after the date of receipt of such notification by the Secretary without the Secretary making a determination that the process or treatment involved has not been shown to meet the requirements of subclauses (I) through (III) of clause (i).

For purposes of paragraph (3), a determination by the Secretary that a process or treatment has not been shown to meet the requirements of subclauses (I) through (III) of subparagraph (B)(i) shall constitute final agency action under such subclauses.

(i) Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 721(c) unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used

in or on a raw agricultural commodity which is the produce of the soil.

(l) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical, except that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 721.

(n) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(q)(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(C) the total number of calories—

(i) derived from any source, and

(ii) derived from the total fat,

in each serving size or other unit of measure of the food,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this Act before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

(2)(A) If the Secretary determines that a nutrient other than a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to subparagraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require

that information relating to such additional nutrient be included in the label or labeling of such food.

(B) If the Secretary determines that the information relating to a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) or clause (A) of this subparagraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement.

(3) For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale.

(4)(A) The Secretary shall provide for furnishing the nutrition information required by subparagraphs (1) and (2) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines, as provided by clause (B) or by issuing regulations that are mandatory as provided by clause (D).

(B)(i) Upon the expiration of 12 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990, the Secretary, after providing an opportunity for comment, shall issue guidelines for food retailers offering raw agricultural commodities or raw fish to provide nutrition information specified in subparagraphs (1) and (2). Such guidelines shall take into account the actions taken by food retailers during such 12-month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. Such guidelines shall only apply—

(I) in the case of raw agricultural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year, and

(II) to the 20 varieties of raw fish most frequently consumed during a year.

The vegetables, fruits, and raw fish to which such guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply such guidelines regionally.

(ii) Upon the expiration of 12 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990, the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under subclause (i). The regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial-compliance standard has been met.

(C)(i) Upon the expiration of 30 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990, the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under clause (A). Such report shall include a determination of whether there is substantial compliance with the guidelines.

(ii) If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in subclause (i) every two years.

(D)(i) If the Secretary determines that there is not substantial compliance with the guidelines issued under clause (A), the Secretary shall at the time such determination is made issue proposed regulations requiring that any person who offers raw agricultural commodities or raw fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by subparagraphs (1) and (2). The Secretary shall issue final regulations imposing such requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their promulgation.

(ii) Regulations issued under subclause (i) may require that the nutrition information required by subparagraphs (1) and (2) be provided for more than 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of such products are frequently consumed. Such regulations shall permit such information to be provided in a single location in each area in which raw agricultural commodities and raw fish are offered for sale. Such regulations may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural commodity or raw fish. The Secretary shall develop and make available to the persons who offer such food to consumers the information required by subparagraphs (1) and (2).

(iii) Regulations issued under subclause (i) shall permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for sale. The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information. Such regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media which the Secretary approves.

(E) For purposes of this subparagraph, the term “fish” includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(F) No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this subparagraph if there has been substantial compliance with the requirements of this paragraph.

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—

(i) except as provided in clause (H)(ii)(III), which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

(ii) except as provided in clause (H)(ii)(III), which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), 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,

- (iii) which is an infant formula subject to section 412,
- (iv) which is a medical food as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)), or
- (v) which is described in section 405(2).

(B) Subparagraphs (1) and (2) shall not apply to the label of a food if the Secretary determines by regulations that compliance with such subparagraphs is impracticable because the package of such food is too small to comply with the requirements of such subparagraphs and if the label of such food does not contain any nutrition information.

(C) If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

(D) If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than \$500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than \$50,000, the requirements of subparagraphs (1), (2), (3), and (4) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

(E)(i) During the 12-month period for which an exemption from subparagraphs (1) and (2) is claimed pursuant to this subclause, the requirements of such subparagraphs shall not apply to any food product if—

(I) the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r),

(II) the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 100 full-time equivalent employees,

(III) such person provided the notice described in subclause (iii), and

(IV) in the case of a food product which was sold in the 12-month period preceding the period for which an exemption was claimed, fewer than 100,000 units of such product were sold in the United States during such preceding period, or in the case of a food product which was not sold in the 12-month period preceding the period for which such exemption is claimed, fewer than 100,000 units of such product are reasonably anticipated to be sold in the United States during the period for which such exemption is claimed.

(ii) During the 12-month period after the applicable date referred to in this sentence, the requirements of subparagraphs (1) and (2) shall not apply to any food product which was first introduced into interstate commerce before May 8, 1994, if the labeling for such product does not provide nutrition information or make a claim

subject to paragraph (r), if such person provided the notice described in subclause (iii), and if—

(I) during the 12-month period preceding May 8, 1994, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 600,000 units of such product were sold in the United States,

(II) during the 12-month period preceding May 8, 1995, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 400,000 units of such product were sold in the United States, or

(III) during the 12-month period preceding May 8, 1996, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 200 full-time equivalent employees and fewer than 200,000 units of such product were sold in the United States.

(iii) The notice referred to in subclauses (i) and (ii) shall be given to the Secretary prior to the beginning of the period during which the exemption under subclause (i) or (ii) is to be in effect, shall state that the person claiming such exemption for a food product has complied with the applicable requirements of subclause (i) or (ii), and shall—

(I) state the average number of full-time equivalent employees such person employed during the 12 months preceding the date such person claims such exemption,

(II) state the approximate number of units the person claiming the exemption sold in the United States,

(III) if the exemption is claimed for a food product which was sold in the 12-month period preceding the period for which the exemption was claimed, state the approximate number of units of such product which were sold in the United States during such preceding period, and, if the exemption is claimed for a food product which was not sold in such preceding period, state the number of units of such product which such person reasonably anticipates will be sold in the United States during the period for which the exemption was claimed, and

(IV) contain such information as the Secretary may require to verify the information required by the preceding provisions of this subclause if the Secretary has questioned the validity of such information.

If a person is not an importer, has fewer than 10 full-time equivalent employees, and sells fewer than 10,000 units of any food product in any year, such person is not required to file a notice for such product under this subclause for such year.

(iv) In the case of a person who claimed an exemption under subclause (i) or (ii), if, during the period of such exemption, the number of full-time equivalent employees of such person exceeds the number in such subclause or if the number of food products sold in the United States exceeds the number in such subclause, such exemption shall extend to the expiration of 18 months after the date the number of full-time equivalent employees or food products sold exceeded the applicable number.

(v) For any food product first introduced into interstate commerce after May 8, 2002, the Secretary may by regulation lower

the employee or units of food products requirement of subclause (i) if the Secretary determines that the cost of compliance with such lower requirement will not place an undue burden on persons subject to such lower requirement.

(vi) For purposes of subclauses (i), (ii), (iii), (iv), and (v)—

(I) the term “unit” means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers,

(II) the term “food product” means food in any sized package which is manufactured by a single manufacturer or which bears the same brand name, which bears the same statement of identity, and which has similar preparation methods, and

(III) the term “person” in the case of a corporation includes all domestic and foreign affiliates of the corporation.

(F) A dietary supplement product (including a food to which section 411 applies) shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary which shall provide that—

(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;

(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.

(G) Subparagraphs (1), (2), (3), and (4) shall not apply to food which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.

(H) RESTAURANTS, RETAIL FOOD ESTABLISHMENTS, AND VENDING MACHINES.—

(i) GENERAL REQUIREMENTS FOR RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS.—Except for food described in subclause (vii), in the case of 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, the restaurant or similar retail food establishment shall disclose the information described in subclauses (ii) and (iii).

(ii) INFORMATION REQUIRED TO BE DISCLOSED BY RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—Except as pro-

vided in subclause (vii), the restaurant or similar retail food establishment shall disclose in a clear and conspicuous manner—

(I)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu listing the item for sale, **the number of calories contained in the standard menu item, as usually prepared and offered for sale** *the number of calories contained in the whole standard menu item, or the number of servings (as reasonably determined by the restaurant or similar retail food establishment) and number of calories per serving, or the number of calories per the common unit division of the standard menu item, such as for a multiserving item that is typically divided before presentation to the consumer;* and

(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu and designed to enable the public to understand, in the context of a total daily diet, the significance of the caloric information that is provided on the menu;

(II)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu board, including a drive-through menu board, **the number of calories contained in the standard menu item, as usually prepared and offered for sale** *the number of calories contained in the whole standard menu item, or the number of servings (as reasonably determined by the restaurant or similar retail food establishment) and number of calories per serving, or the number of calories per the common unit division of the standard menu item, such as for a multiserving item that is typically divided before presentation to the consumer;* and

(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu board, designed to enable the public to understand, in the context of a total daily diet, the significance of the nutrition information that is provided on the menu board;

(III) in a written form, available on the premises of the restaurant or similar retail establishment and to the consumer upon request, the nutrition information required under clauses (C) and (D) of subparagraph (1); and

(IV) on the menu or menu board, a prominent, clear, and conspicuous statement regarding the availability of the information described in item (III).

*In the case of restaurants or similar retail food establishments where the majority of orders are placed by customers who are off-premises at the time such order is placed, the information required to be disclosed under items (I) through (IV) may be provided by a remote-access menu (such as a menu available on the Internet) as the sole method of disclosure instead of on-premises writings.*

(iii) SELF-SERVICE FOOD AND FOOD ON DISPLAY.—Except as provided in subclause (vii), in the case of food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display and that is visible to customers, a restaurant or similar retail food establishment shall *either* place adjacent to each food offered a sign that lists calories per displayed food item or per serving or *comply with subclause (ii)*

(iv) REASONABLE BASIS.—**[For the purposes of this clause]**

(I) *IN GENERAL.*—*For the purposes of this clause, 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] or 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 of the Food and Drug Administration.*

(II) *REASONABLE BASIS DEFINED.*—*For the purposes of this subclause, with respect to a nutrient disclosure, the term “reasonable basis” means that the nutrient disclosure is within acceptable allowances for variation in nutrient content. Such acceptable allowances shall include allowances for variation in serving size, inadvertent human error in formulation or preparation of menu items, and variations in ingredients.*

**[(v) MENU VARIABILITY AND COMBINATION MEALS.—The Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children’s combination meals, through means determined by the Secretary, including ranges, averages, or other methods.]**

*(v) MENU VARIABILITY AND COMBINATION MEALS.—The Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children’s combination meals. Such standards shall allow a restaurant or similar retail food establishment to choose whether to determine and disclose such content for the whole standard menu item, for a serving or common unit division thereof, or for a serving or common unit division thereof accompanied by the number of servings or common unit divisions in the whole standard menu item. Such standards shall allow a restaurant or similar retail food establishment to determine and disclose such content by using any of the following methods: ranges, averages, individual labeling of flavors or components, or labeling of one preset standard build. In addition to such methods, the Secretary may allow the use of other methods, to be determined by the Secretary, for which there is a reasonable basis (as such term is defined in subclause (iv)(II)).*

(vi) ADDITIONAL INFORMATION.—If the Secretary determines that a nutrient, other than a nutrient required under sub-

clause (ii)(III), should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary may require, by regulation, disclosure of such nutrient in the written form required under subclause (ii)(III).

(vii) NONAPPLICABILITY TO CERTAIN FOOD.—

(I) IN GENERAL.—Subclauses (i) through (vi) do not apply to—

(aa) items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use);

(bb) daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, or custom orders; or

(cc) such other food that is part of a customary market test appearing on the menu for less than 90 days, under terms and conditions established by the Secretary.

(II) WRITTEN FORMS.—Subparagraph (5)(C) shall apply to any regulations promulgated under subclauses (ii)(III) and (vi).

(viii) VENDING MACHINES.—

(I) IN GENERAL.—In the case of an article of food sold from a vending machine that—

(aa) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and

(bb) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines,

the vending machine operator shall provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.

(ix) VOLUNTARY PROVISION OF NUTRITION INFORMATION.—

(I) IN GENERAL.—An authorized official of any restaurant or similar retail food establishment or vending machine operator not subject to the requirements of this clause may elect to be subject to the requirements of such clause, by registering biannually the name and address of such restaurant or similar retail food establishment or vending machine operator with the Secretary, as specified by the Secretary by regulation.

(II) REGISTRATION.—Within 120 days of enactment of this clause, the Secretary shall publish a notice in the Federal Register specifying the terms and conditions for implementation of item (I), pending promulgation of regulations.

(III) RULE OF CONSTRUCTION.—Nothing in this subclause shall be construed to authorize the Secretary to require an application, review, or licensing process for any entity to register with the Secretary, as described in such item.

(x) REGULATIONS.—

(I) PROPOSED REGULATION.—[Not later than 1 year after the date of enactment of this clause, the Secretary shall

promulgate proposed regulations to carry out this clause.】  
*Not later than 1 year after the date of enactment of the Common Sense Nutrition Disclosure Act of 2015, the Secretary shall issue proposed regulations to carry out this clause, as amended by such Act. Any final regulations that are promulgated pursuant to the Common Sense Nutrition Disclosure Act of 2015, and any final regulations that were promulgated pursuant to this clause before the date of enactment of the Common Sense Nutrition Disclosure Act of 2015, shall not take effect earlier than 2 years after the promulgation of final regulations pursuant to the Common Sense Nutrition Disclosure Act of 2015.*

(II) CONTENTS.—In promulgating regulations, the Secretary shall—

(aa) consider standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors, as the Secretary determines; and

(bb) specify the format and manner of the nutrient content disclosure requirements under this subclause.

(III) REPORTING.—The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a quarterly report that describes the Secretary’s progress toward promulgating final regulations under this subparagraph.

(IV) CERTIFICATIONS.—*Restaurants and similar retail food establishments shall not be required to provide certifications or similar signed statements relating to compliance with the requirements of this clause.*

【(xi) DEFINITION.—In this clause, the term “menu” or “menu board” means the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection.】

(xi) DEFINITIONS.—*In this clause:*

(I) MENU; MENU BOARD.—*The term “menu” or “menu board” means the one listing of items which the restaurant or similar retail food establishment reasonably believes to be, and designates as, the primary listing from which customers make a selection in placing an order. The ability to order from an advertisement, coupon, flyer, window display, packaging, social media, or other similar writing does not make the writing a menu or menu board.*

(II) PRESET STANDARD BUILD.—*The term “preset standard build” means the finished version of a menu item most commonly ordered by consumers.*

(III) STANDARD MENU ITEM.—*The term “standard menu item” means a food item of the type described in subclause (i) or (ii) of subparagraph (5)(A) with the same recipe prepared in substantially the same way with substantially the same food components that—*

(aa) *is routinely included on a menu or menu board or routinely offered as a self-service food or food on dis-*

*play at 20 or more locations doing business under the same name; and*

*(bb) is not a food referenced in subclause (vii).*

*(xii) OPPORTUNITY TO CORRECT VIOLATIONS.—Any restaurant or similar retail food establishment that the Secretary determines is in violation of this clause shall have 90 days after receiving notification of the violation to correct the violation. The Secretary shall take no enforcement action, including the issuance of any public letter, for violations that are corrected within such 90-day period.*

*(xiii) LIMITATION ON LIABILITY.—A restaurant or similar retail food establishment shall not be liable in any civil action in Federal or State court (other than an action brought by the United States or a State) for any claims arising out of an alleged violation of—*

*(I) this clause; or*

*(II) any State law permitted under section 403A(a)(4).*

(r)(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)—

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,

(ii) may not state the absence of a nutrient unless—

(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or

(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food,

(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which is diet related unless—

(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and a requirement that the statement disclose that cholesterol is not usually present in the food, and

(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of cholesterol,

(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat,

(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of dietary fiber, and

(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: "See nutrition information for \_\_\_\_\_ content." The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.

(C) Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

(D) Subparagraph (2) does not apply to a claim described in subparagraph (1)(A) which uses the term "diet" and is contained in the label or labeling of a soft drink if (i) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25, 1989, and (iii) the use of the term "diet" was in conformity with section 105.66 of title 21 of the

Code of Federal Regulations. Such a claim is subject to paragraph (a).

(E) Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 201(n); and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(H) A claim submitted under the requirements of clause (G) may be made until—

(i) such time as the Secretary issues a regulation—

- (I) prohibiting or modifying the claim and the regulation has become effective, or
  - (II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or
  - (ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.
- (3)(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made—
- (i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and
  - (ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).
- (B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.
- (ii) A regulation described in subclause (i) shall describe—
    - (I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease or health-related condition, and
    - (II) the significance of each such nutrient in affecting such disease or health-related condition.
  - (iii) A regulation described in subclause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.
- (C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—
- (i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is cur-

rently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(D) A claim submitted under the requirements of clause (C) may be made until—

(i) such time as the Secretary issues a regulation under the standard in clause (B)(i)—

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph (2)(A)(i) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary denies the petition or the petition is deemed to be denied, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision.

If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue a regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days.

(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this paragraph and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

(5)(A) This paragraph does not apply to infant formulas subject to section 412(h) and medical foods as defined in section 5(b) of the Orphan Drug Act.

(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to 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 use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 401 shall not be subject to subparagraph (2)(A)(i) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such

disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

(i) enable consumers to develop and maintain healthy dietary practices;

(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.

(s) If—

(1) it is a dietary supplement; and

(2)(A) the label or labeling of the supplement fails to list—

(i) the name of each ingredient of the supplement that is described in section 201(ff); and

(ii)(I) the quantity of each such ingredient; or

(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;

(B) the label or labeling of the dietary supplement fails to identify the product by using the term "dietary supplement", which term may be modified with the name of such an ingredient;

(C) the supplement contains an ingredient described in section 201(ff)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;

- (D) the supplement—
  - (i) is covered by the specifications of an official compendium;
  - (ii) is represented as conforming to the specifications of an official compendium; and
  - (iii) fails to so conform; or
- (E) the supplement—
  - (i) is not covered by the specifications of an official compendium; and
  - (ii)(I) fails to have the identity and strength that the supplement is represented to have; or
  - (II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.

A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.

(t) If it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae.

(u) If it purports to be or is represented as ginseng, unless it is an herb or herbal ingredient derived from a plant classified within the genus *Panax*.

(v) If—

(1) it fails to bear a label required by the Secretary under section 801(n)(1) (relating to food refused admission into the United States);

(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

(3) upon or after notifying the owner or consignee involved that the label is required under section 801, the Secretary informs the owner or consignee that the food presents such a threat.

(w)(1) If it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either—

(A) the word “Contains”, followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under subsections (g) and (i); or

(B) the common or usual name of the major food allergen in the list of ingredients required under subsections (g) and (i) is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when—

(i) the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived; or

(ii) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the

name of a food ingredient that is not a major food allergen under section 201(qq)(2)(A) or (B).

(2) As used in this subsection, the term “name of the food source from which the major food allergen is derived” means the name described in section 201(qq)(1); provided that in the case of a tree nut, fish, or Crustacean shellfish, the term “name of the food source from which the major food allergen is derived” means the name of the specific type of nut or species of fish or Crustacean shellfish.

(3) The information required under this subsection may appear in labeling in lieu of appearing on the label only if the Secretary finds that such other labeling is sufficient to protect the public health. A finding by the Secretary under this paragraph (including any change in an earlier finding under this paragraph) is effective upon publication in the Federal Register as a notice.

(4) Notwithstanding subsection (g), (i), or (k), or any other law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen shall be subject to the labeling requirements of this subsection.

(5) The Secretary may by regulation modify the requirements of subparagraph (A) or (B) of paragraph (1), or eliminate either the requirement of subparagraph (A) or the requirements of subparagraph (B) of paragraph (1), if the Secretary determines that the modification or elimination of the requirement of subparagraph (A) or the requirements of subparagraph (B) is necessary to protect the public health.

(6)(A) Any person may petition the Secretary to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection.

(B) The Secretary shall approve or deny such petition within 180 days of receipt of the petition or the petition shall be deemed denied, unless an extension of time is mutually agreed upon by the Secretary and the petitioner.

(C) The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.

(D) A determination regarding a petition under this paragraph shall constitute final agency action.

(E) The Secretary shall promptly post to a public site all petitions received under this paragraph within 14 days of receipt and the Secretary shall promptly post the Secretary’s response to each.

(7)(A) A person need not file a petition under paragraph (6) to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection, if the person files with the Secretary a notification containing—

(i) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or

(ii) a determination by the Secretary that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409.

(B) The food ingredient may be introduced or delivered for introduction into interstate commerce as a food ingredient that is not a major food allergen 90 days after the date of receipt of the notification by the Secretary, unless the Secretary determines within the 90-day period that the notification does not meet the requirements of this paragraph, or there is insufficient scientific evidence to determine that the food ingredient does not contain allergenic protein or does not cause an allergenic response that poses a risk to human health.

(C) The Secretary shall promptly post to a public site all notifications received under this subparagraph within 14 days of receipt and promptly post any objections thereto by the Secretary.

(x) Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.

(y) If it is a dietary supplement that is marketed in the United States, unless the label of such dietary supplement includes a domestic address or domestic phone number through which the responsible person (as described in section 761) may receive a report of a serious adverse event with such dietary supplement.

SEC. 403A. (a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g), except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 401 and 403(g),

(2) any requirement for the labeling of food of the type required by section 403(c), 403(e), 403(i)(2), 403(w), or 403(x) that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(c) and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(h)(1) and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q), except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not 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 unless such restaurant or similar retail food establishment

complies with the voluntary provision of nutrition information requirements under section 403(q)(5)(H)(ix), or

(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r), except a requirement respecting a claim made in the label or labeling of food which is exempt under section 403(r)(5)(B).

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(b) Upon petition of a State or a political subdivision of a State, the Secretary **【may exempt from subsection (a)】** *may exempt from subsection (a) (other than subsection (a)(4))*, under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a).

\* \* \* \* \*

## DISSENTING VIEWS

We oppose the passage of H.R. 2017, the *Common Sense Nutrition Disclosure Act of 2015*, a bill that would amend the Federal Food, Drug, and Cosmetic Act to revise how calorie and other nutritional information is displayed in restaurants and other retail food establishments. Disclosure of this type of nutritional information was initially placed into law by the Affordable Care Act over six years ago. We have significant concern that this legislation would undermine the intent of federal menu labeling requirements to provide consumers with transparency regarding the calorie information for menu items in restaurants and retail food establishments as well as interfere with the Food and Drug Administration's ability to implement this law as Congress intended.

### I. BACKGROUND

In recent years, obesity and diet related chronic diseases have risen to become a prominent public health issue. Presently, more than two-thirds of adults and one-third of children are considered to be overweight or obese.<sup>1</sup> The primary driver of this epidemic, most experts believe, is an increase in caloric intake. Importantly, research shows that Americans spend nearly half of their food dollars on foods prepared outside the home, and most consumers either do not know or underestimate the calorie counts of their meals.<sup>2</sup> Therefore, access to nutritional information at the point of purchase is an important tool for consumers to make informed nutrition choices.

As a result of increasing awareness of the role diet plays in the obesity epidemic, states and localities began independently implementing menu labeling requirements. Since 2006, five states and dozens of major cities and counties have adopted menu labeling laws. Included in these municipalities are some of the nation's most populous, including Philadelphia and New York City.<sup>3</sup> These measures held broad support amongst public health, health professional and industry groups such as the American Heart Association, the American Medical Association and National Association of County and City Health Officials.

One concern with the rapid spread of independent menu labeling laws was the broad variation in local laws. Chain restaurants found it difficult to comply and sought uniform standards. As a result, the National Restaurant Association has supported uniform menu-labeling requirements. To address these concerns and to im-

<sup>1</sup>National Institute of Diabetes and Digestive and Kidney Diseases, *Overweight and Obesity Statistics* (online at <http://www.niddk.nih.gov/health-information/health-statistics/Pages/overweight-obesity-statistics.aspx>).

<sup>2</sup>Jason P. Block et al., *Consumer's Estimation of Calorie Content at Fast Food Restaurants: Cross Sectional Observational Study*, *British Medical Journal* 346, (2013):f2907

<sup>3</sup>Center for Science and the Public Interest, *State and Local Menu Labeling Policies* (April 2011) (online at [http://cspinet.org/new/pdf/ml\\_map.pdf](http://cspinet.org/new/pdf/ml_map.pdf)).

prove consumer access to menu labeling provisions, the Affordable Care Act (ACA) included a provision that mandated nutrition labeling for standard menu items in restaurants and retail food establishments with 20 or more locations.<sup>4</sup>

## II. IMPLEMENTATION OF ACA MENU LABELING REQUIREMENTS

Since passage of the ACA in 2010, FDA has engaged in robust stakeholder engagement in the promulgation of the subsequent regulations. Per the ACA, the agency was tasked with establishing standards for determining and disclosing nutrition information for standard menu items and variable menu items as well as other provisions. Thus, in April 2011, FDA published a proposed menu labeling rule, which garnered over 1,100 comments. Subsequently, the agency included a number of changes to address stakeholder concerns, and released the final rule in December 2014.<sup>5</sup> FDA allowed restaurants and food establishments one year to become compliant with menu labeling requirements, establishing an effective date of December 1, 2015.

The agency also released menu labeling guidance in September 2015 intended to help covered restaurants and retail food establishments to better understand the federal menu labeling requirements and assist in the implementation of these requirements.<sup>6</sup> With the release of this draft guidance, FDA announced that it would provide covered establishments with an additional year to comply with the federal menu labeling requirements setting an effective date of December 1, 2016.<sup>7</sup> Section 747 of the Consolidated Appropriations Act of 2016 further delayed the effective date of the federal menu labeling requirements until the later of December 1, 2016, or until one year after FDA publishes Level 1 guidance, or final guidance, on menu labeling requirements.<sup>8</sup>

## III. H.R. 2017 DECREASES CONSUMER ACCESS TO ACCURATE NUTRITIONAL INFORMATION

H.R. 2017 contains numerous provisions that both decrease consumer access to nutritional information and increase the likelihood of inconsistent or confusing menu labels. Current law requires that the number of calories contained in the standard menu item, as usually prepared and offered for sale, to be displayed. The bill as amended would change this requirement to allow restaurants and retail food establishments to choose how the calorie information is displayed—either in the whole standard menu item, or the number of servings as determined by the establishment and number of calories per serving, or the number of calories per the common unit

<sup>4</sup>The Affordable Care Act, Section 4205, *Nutrition Labeling of Restaurant Menus and Food Sold in Vending Machines*, (online at <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW111publ148.pdf>).

<sup>5</sup>FDA, *Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Calorie Labeling of Articles of Food in Vending Machines; Final Rule*, (Dec 1, 2014) (online at <https://www.federalregister.gov/articles/2014/12/01/2014-27833/food-labeling-nutrition-labeling-of-standard-menu-items-in-restaurants-and-similar-retail-food>).

<sup>6</sup>FDA, *Draft Guidance for Industry: A Labeling Guide for Restaurants and Retail Food Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11*, (Sept 2015) (online at <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM461963.pdf>).

<sup>7</sup>FDA, *Statement on Release of Menu Labeling Guidance*, (September 11, 2-15) (online at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm217762.htm>).

<sup>8</sup>P.L. 114–113

of division of the standard menu item. Practically speaking, this allows businesses to create deceptive serving sizes. For example, a business could list the calories for a serving size of a portion of a sandwich, when the average consumer may mistakenly assume the calorie count is for the entire sandwich. It may also result in covered establishments setting serving sizes that are different between restaurants and retail food establishments and between similar menu items. These provisions could also create an uneven playing field amongst covered restaurants and retail food industries in how menu labeling applies within the industry.

Beyond the allowance of unintuitive serving sizes, the bill also weakens requirements for locations where consumers can access nutritional information. It is my belief that consumers should be able to access nutritional information regardless of the location where they purchase the food, whether it is in-store or online. The authors of the ACA menu labeling provision agree with this intent in the original legislation.<sup>9</sup> However, as amended, H.R. 2017 would allow restaurants and retail food establishments to limit disclosure of calorie information to one menu or menu board designated by the establishment as the primary listing from which customers order. Further, the bill would allow covered establishments to disclose calorie information in the location in which the majority of food orders are placed. Hence, if a business receives 51 percent of its orders online, no calorie information would be required on menu boards for customers who make an in-store purchase and would instead only be available remotely. Both of these provisions would deny customers access to calorie information at the point of order.

Additionally, the bill contains technical provisions that create a potential loophole that may allow establishments to avoid menu labeling all together. Under the current FDA rule, all items that routinely appear on the menu are subject to menu labeling requirements. However, under H.R. 2017, this definition is changed to include only menu items that are routinely offered in at least 20 locations *with the same recipe*. Although on its face, this provision sounds innocuous, in practice it creates a potential loophole to avoid menu labeling. Given the nature of cooking, the seasonal nature of various ingredients and other factors, under this definition, companies could either intentionally or unintentionally escape menu labeling requirements due to minor alterations in recipes. Additionally, this change in definition is unnecessary, given that current FDA rules exclude restaurant “specials” or menu items that appear fewer than 60 days per calendar year.

#### IV. H.R. 2017 DECREASES CONSUMER PROTECTIONS

H.R. 2017 includes several provisions which decrease the likelihood of business compliance with the menu labeling and remove consumer protections in the event that a business does not comply with the requirements. Under current law, covered restaurants and retail food establishments are required to provide the FDA with a certification or signed statement that they are in compliance with

<sup>9</sup>Letter from Representative Rosa DeLauro and former Senator Tom Harkin to The Honorable Shaun Donovan, Director of the Office of Management and Budget (August 15, 2014) (online at <http://www.help.senate.gov/ranking/newsroom/press/harkin-de-lauro-call-on-administration-to-issue-strong-menu-labeling-rule>).

menu labeling requirements upon request. However, the bill as amended removes this important mechanism that allows the FDA to ensure that someone at each establishment is responsible for complying with the menu labeling requirements.

In addition, the bill also shields covered establishments from any civil lawsuits (except those brought by federal or state governments) for not complying with federal menu labeling requirements. It also shields establishments not subject to the menu labeling requirements (e.g., because they are not part of a chain with 20 or more locations) from civil lawsuits for not complying with state menu labeling requirements to which they are subject. This removes a critical tool for communities and consumers to ensure that the establishments in their communities are compliant with the law.

Further, H.R. 2017 would also preempt States and Localities from petitioning FDA to require menu labeling for food sold in covered establishments that is different than the federal menu labeling requirements. In effect, this provision would prevent States and Localities from requiring and implementing menu labeling requirements that goes farther than the federal requirements inhibiting their ability to offer consumers greater access to nutrition and calorie information for foods purchased out of the home.

#### V. LEGISLATION IS THE INCORRECT APPROACH

Finally, H.R. 2017 is an overly prescriptive, permanent legislative approach that is unnecessary at this time. FDA has engaged in considerable dialogue with stakeholders from all perspectives including consumers, industry, and public health professionals. After its initial comment period, the agency made substantial changes to accommodate industry concerns on a variety of topics. Overall, the regulatory process has worked well. For this reason, over 100 nutrition and health professional individuals and organizations oppose H.R. 2017. Additionally, the National Restaurant Association concurs and also opposes H.R. 2017 as passed out of Committee.

Although a small subset of the food industry seeks additional changes to menu labeling requirements, additional legislation is not only unnecessary, but would be counterproductive to current efforts. Undoubtedly, producers of craft foods with unique and varying recipes, such as pizza parlors, will experience more complicated decisions to deliver accurate, understandable nutrition information to consumers. However, these issues are easily addressed under current law through the rule-making process.

It also is counter to what the majority of consumers want—the inclusion of nutrition information on restaurant menus. Nearly 70 percent of consumers support the government requiring restaurants to post calorie information at the point of purchase.<sup>10</sup> Six years have passed since the enactment of federal menu labeling requirements as a part of the ACA. Yet, this bill would extend these requirements an additional two years after the promulgation of final regulations pursuant to the Common Sense Nutrition Disclosure Act of 2015, further delaying consumer access to important

<sup>10</sup>Sara N. Bleich and Keshia M. Pollack, *The Public's Understanding of Daily Caloric Recommendations and Their Perspective of Calorie Posting in Chain restaurants*, (2010), BMC Public Health (10) 121.

nutrition information. Businesses are already prepared to enact menu labeling requirements and a last-minute change is simply unnecessary. The American people stand ready to improve the public health. Unfortunately H.R. 2017 acts as an unnecessary, misguided approach that would interfere with the FDA's well-executed implementation of existing law and delay consumer access to critical nutritional information. Instead of passing H.R. 2017, Congress should be further facilitate guidance and education to covered establishments in how nutrition information can be made available to consumers in a transparent manner.

FRANK PALLONE, JR.  
GENE GREEN.

