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115TH CONGRESS
2D SESSION

# H. R. 5425

To amend the Federal Food, Drug, and Cosmetic Act to strengthen requirements related to nutrient information on food labels, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

APRIL 2, 2018

Mr. PALLONE (for himself and Ms. DELAURO) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# A BILL

To amend the Federal Food, Drug, and Cosmetic Act to strengthen requirements related to nutrient information on food labels, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

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

(a) SHORT TITLE.—This Act may be cited as the ''Food Labeling Modernization Act of 2018''.

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

**SEC. 2. ADDITIONAL REQUIREMENTS FOR FRONT-OF-PACKAGING (FOP) LABELING FOR PROCESSED FOODS.**

(a) SUMMARY NUTRITION LABELING INFORMATION.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(z)(1) SUMMARY NUTRITION INFORMATION.—Except as provided in subparagraphs (3), (4), and (5) of paragraph (q), if it is food (other than a dietary supplement) intended for human consumption and is offered for sale and otherwise required to bear nutrition labeling, unless its principal display panel bears summary nutrition information that reflects the overall nutritional value of the food or specified ingredients, as specified in accordance with regulations of the Secretary, and does not contain any summary nutritional information which is in addition to or inconsistent with the information required under this subparagraph.

''(2) REQUIRED CRITERIA FOR IMPLEMENTING REGULATIONS.—Final regulations regarding the summary nu-

trition information required under subparagraph (1) shall meet the following criteria:

''(A) There shall be a single, simple, standard symbol system that displays calorie information related to the serving size determined under paragraph (q)(1)(A), and information related to the content of saturated and trans fats, sodium, added sugars, and any other nutrients that the Secretary determines are strongly associated with public health concerns.

''(B) The system shall employ an approach that clearly distinguishes between products of greater or lesser nutritional value. This system may include—

''(i) a warning symbol or symbols for products high in saturated or trans fats, sodium, added sugars, or other nutrients the consumption of which should be limited or discouraged; or

''(ii) a stop-light, points, star, or other commonly recognized signaling system to scale or rank foods according to their overall health value.

''(C) The information shall appear on all products that are required to bear nutrition labeling.

''(D) The information shall—

"(i) appear in a consistent location on the principal display panels across products;

"(ii) have a prominent design that visually contrasts with existing packaging design; and

"(iii) be sufficiently large to be easily legible.

"(3) PRINCIPLES FOR IMPLEMENTING REGULATIONS.—In promulgating regulations regarding the summary nutrition information required under subparagraph (1), the Secretary shall take into account published reports by the Health and Medicine Division of the National Academy of Sciences regarding such information, and base regulations on the following principles:

"(A) Consumers should be able to quickly and easily comprehend the meaning of the symbol system as an indicator of a product's contribution to a healthy diet without requiring specific or sophisticated nutritional knowledge.

"(B) The nutrition information should be consistent with the Nutrition Facts Panel and with the recommendations of the Dietary Guidelines of Americans.

"(C) The information should aim to facilitate consumer selection of healthy product options, including among nutritionally at-risk subpopulations.

''(D) The Secretary should periodically evaluate the front-of-package information to assess its ability to help facilitate consumer selection of healthy product options and the extent to which manufacturers are offering healthier products as a result of the disclosure.

''(E) The implementation of the information disclosure should be accompanied by appropriate consumer education and promotion campaigns determined by the Secretary.''.

(b) PERCENTAGE OF WHEAT AND GRAINS IN GRAIN-BASED PRODUCTS.—Section 403 of the Federal Food, Drug, and Cosmetic Act, as amended, is further amended by adding at the end the following:

''(aa) PERCENTAGE OF WHEAT AND GRAINS IN GRAIN-BASED PRODUCTS.—If, in the case of food other than a dietary supplement, the principal display panel bears—

''(1) the terms 'whole wheat', 'whole grain', 'made with whole grain', or 'multigrain';

''(2) a declaration of the whole grain content by weight;

''(3) the term 'wheat' on a wheat bread, pasta, or similar product that is typically made from wheat; or

''(4) any similar descriptive phrases, terms, or representations suggesting the product contains whole grains,

unless the amount of whole grains, expressed as a percentage of total grains, is conspicuously disclosed in immediate proximity to the descriptive phrase, term, or representation, using a font, color, and formatting of equivalent prominence to the descriptive phrase, term, or representation with respect to whole grain content.''.

(c) SWEETENERS, COLORING, AND FLAVORING.—Section 403 of the Federal Food, Drug, and Cosmetic Act, as amended, is further amended by adding at the end the following:

''(bb) SWEETENERS, COLORING, AND FLAVORING.—If, in the case of food other than a dietary supplement, it bears or contains any added artificial or natural coloring, any added artificial or natural non-caloric sweetener, or any added artificial or natural flavoring, unless such fact is prominently stated on the principal display panel of a package or container of the food.''.

(d) CONFORMING AMENDMENT.—The second sentence of section 403(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(k)) is amended by striking ''and (i)'' and inserting '', (i), (z), (aa), and (bb)''.

(e) CONSTRUCTION.—Nothing in this section shall be construed as affecting any requirement in regulation in effect as of the date of the enactment of this Act with respect to matters that are required to be stated on the principal display panel of a package or container of food that is not required by an amendment made by this section or as restricting the authority of the Secretary of Health and Human Services to require additional information be disclosed on such a principal display panel.

**SEC. 3. CLAIMS FOR CONVENTIONAL FOODS.**

(a) HEALTH-RELATED CLAIMS.—

(1) IN GENERAL.—Section 403(r)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(1)(B)) is amended by inserting after ''health-related condition'' the following: '', describes the effect that a nutrient may have on the structure or function of the human body, characterizes the documented mechanism by which that nutrient acts to maintain such structure or function, or describes general well-being from consumption of that nutrient,''.

(2) SUBSTANTIATION OF CLAIM.—Section 403(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)) is amended—

(A) by redesignating subparagraph (7) as subparagraph (8); and

(B) by inserting after subparagraph (6) the following:

''(7) If the Secretary requests that a claim under subparagraph (1)(B) for food (other than a dietary supplement) be substantiated, then not later than 90 days after the date on which the Secretary makes such request, the manufacturer shall provide to the Secretary all documentation in the manufacturer's possession relating to the claim.''.

(b) TRANS FATS.—Section 403(r)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(2)(A)) is amended—

(1) in subclause (iii)—

(A) in the matter before item (I), by striking ''fat or saturated fat'' and inserting ''fat, saturated fat, or trans fats''; and

(B) in item (II), by striking ''fat or saturated fat'' and inserting ''fat, saturated fat, or trans fats'';

(2) in subclause (iv), by striking ''saturated fat'' and inserting ''saturated fat or trans fats'' each place it appears;

(3) by redesignating subclauses (v) and (vi) as subclauses (vi) and (vii), respectively; and

(4) by inserting after subclause (iv) the following new subclause:

''(v) may not be made with respect to the level of trans fats in the food unless the food contains less than one gram of saturated fat per serving or, if the food contains more than one gram of saturated fat per serving, unless the label or labeling of the food discloses the level of saturated fat 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 trans fats,''.

(c) ADDED SUGARS.—Not more than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate a final rule revising section 101.14 of title 21, Code of Federal Regulations, to include a disqualifying nutrient level for added sugars.

**SEC. 4. USE OF SPECIFIC TERMS.**

(a) USE OF THE TERM ''NATURAL''.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate a final rule—

(A) relating to use of the term ''natural'' on the labeling of food (other than a dietary supplement); and

(B) including provisions to specifically address the use of such term on the principal display panel and the information panel.

(2) DEFINITION.—The rule promulgated pursuant to paragraph (1) shall define the term ''natural''—

(A) to exclude, at a minimum, the use of any artificial food or ingredient (including any artificial flavor or added color); and

(B) based on data, including data on consumers' understanding of the term as used in connection with food.

(3) PROCESS.—In promulgating the rule required by paragraph (1), the Secretary of Health and Human Services shall—

(A) conduct consumer surveys and studies and issue a timely call for relevant public submissions regarding relevant consumer research, including with respect to consumer understanding of the term ''natural'' in relation to the term ''organic''; and

(B) fully consider the results of such surveys and studies, as well as such public submissions.

(b) USE OF TERM ''HEALTHY''.—

(1) ADDED SUGARS AND WHOLE GRAINS.—The Secretary of Health and Human Services shall revise the regulations under the Federal Food, Drug, and Cosmetic Act relating to the use of the term ''healthy'' on the labeling of a food (other than a dietary supplement) to take into account the extent to which such food contains added sugars or whole grains.

(2) REQUIREMENTS.—In making the revisions to regulations required by paragraph (1)—

(A) in the case of a food (other than a dietary supplement) that contains grains, the Secretary shall not consider the food to be ''healthy'' unless at least half of those grains, by weight, are whole grains; and

(B) the Secretary shall not allow a food to be labeled ''healthy'' if the food contains more than 10 percent of the daily value of added sugar per serving.

**SEC. 5. NUTRITION FACTS PANEL COMPLIANCE DATE.**

The Secretary of Health and Human Services shall not extend the compliance dates in the final rule entitled ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' published by the Food and Drug Administration in the Federal Register on May 27, 2016 (or any successor rule), beyond the compliance dates proposed in the proposed rule entitled rule entitled ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Proposed Extension of Compliance Dates'' published by the Food and Drug Administration in the Federal Register on October 2, 2017.

**SEC. 6. INGREDIENT LABELS.**

(a) FORMAT OF INGREDIENT LABELS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall include requirements for the format of the information required under section 403(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(i))—

(A) for the purpose of improving the readability of such information on the label of the food (other than a dietary supplement); and

(B) that are, as determined by the Secretary, necessary to assist consumers in maintaining healthy dietary practices.

(2) FORMAT REQUIREMENTS.—The format requirements referred to in paragraph (1) shall include requirements for upper- and lower-case characters, serif and noncondensed font types, high-contrast between text and background, and bullet points between adjacent ingredients with appropriate exemptions for small packages or other considerations.

(b) CHARACTERIZING INGREDIENTS IN NAME OR PRIMARY DISPLAY PANEL.—

(1) IN GENERAL.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343), as amended, is further amended by adding at the end the following:

''(cc) If the name or primary display panel of the food (other than a dietary supplement) refers to any characterizing ingredient or component of the food, unless—

''(1) the characterizing ingredient or component is a predominant ingredient in the food; or

''(2) the primary display panel of the food includes, in letters not less than one-half the height of the letters used in the name of the food, the percent-

age of each characterizing ingredient or component contained in the food.''.

(2) ENFORCEMENT OF CHARACTERIZING INGREDIENTS.—Not later than 2 years after the date of enactment of this Act and every 2 years thereafter, the Secretary of Health and Human Services shall submit a report to the Congress on the Secretary's enforcement of—

(A) section 403(cc) of the Federal Food, Drug, and Cosmetic, as added by paragraph (1); and

(B) regulations of the Food and Drug Administration on characterizing ingredients and components, including section 102.5 of title 21, Code of Federal Regulations (and any successor regulations).

(c) DECLARATION OF PHOSPHORUS ON THE INGREDIENT LABEL.—

(1) IN GENERAL.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 ), as amended, is further amended by adding at the end the following:

''(dd) If it is a food intended for human consumption that is offered for sale and contains phosphorus, unless—

''(1) the phrase 'contains phosphorus', along with the quantity of phosphorus in the product, reported in milligrams per serving, is printed immediately after or is adjacent to the list of ingredients required under subsections (g) and (i), in a type size no smaller than the type size used in the list of ingredients; or

''(2) the quantity of phosphorus contained in the product, in milligrams, is reported in the Nutrition Facts Panel.''.

**SEC. 7. CAFFEINE CONTENT ON INFORMATION PANEL.**

Section 403(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(i)) is amended—

(1) by striking ''and (2)'' and inserting ''(2)'';

(2) by striking ''and if the food purports'' and inserting '', (3) if the food purports''; and

(3) by inserting '', and (4) if the food is food other than a dietary supplement and contains at least 10 milligrams of caffeine from all sources per serving, a statement (with appropriate prominence near the statement of ingredients required by this paragraph) of the number of milligrams of caffeine contained in one serving of the food and the size of such serving'' after ''vegetable juice contained in the food''.

**SEC. 8. FOOD ALLERGEN LABELING FOR SESAME.**

Section 201(qq)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)(1)) is amended by striking ''and soybeans'' and inserting ''soybeans, and sesame''.

**SEC. 9. INFORMATION ABOUT MAJOR FOOD ALLERGENS IN NONPREPACKAGED FOODS.**

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

(1) in subparagraph (1)(A), by striking ''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)'' and inserting ''is printed as specified in subparagraph (8)'';

(2) in subparagraph (1)(B), by striking ''in the list of ingredients required under subsections (g) and (i)'' and inserting ''as so printed'';

(3) in subparagraph (3), by striking ''The information'' and inserting ''Subject to subparagraph (8)(B), the information''; and

(4) by adding at the end the following:

''(8) The information required by subparagraph (1) to be conveyed to the consumer shall be—

''(A) printed immediately after or 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) in the case of a nonpackaged food being offered for sale at retail, and not subject to the requirements of subsections (g) and (i), placed on a sign adjacent to the food (in a type size no smaller than the name of the food item).''.

(b) APPLICABILITY.—The amendments made by subsection (a) apply beginning on the date that is 3 years after the date of enactment of this Act.

**SEC. 10. SUBMISSION AND AVAILABILITY OF FOOD LABEL INFORMATION.**

The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 403C of such Act (21 U.S.C. 343–3) the following:

**''SEC. 403D. SUBMISSION AND AVAILABILITY OF FOOD LABEL INFORMATION.**

''(a) SUBMISSIONS.—

''(1) REQUIREMENT.—The Secretary shall require the manufacturer or importer of any food that is introduced or delivered for introduction into interstate commerce in package form to submit to the

Secretary all information to be included in the label of the food, including—

"(A) the nutrition facts panel;

"(B) ingredients;

"(C) an image of the primary display panel;

"(D) allergy warnings or information;

"(E) claims under section 403(r)(1)(A) (popularly referred to as 'nutrient-content claims');

"(F) claims under section 403(r)(1)(B) (popularly referred to as 'health-related claims'); and

"(G) other relevant information required by law to be published in the labeling of the food.

"(2) UPDATES.—The Secretary shall require the manufacturer or importer of food to update or supplement the information submitted under paragraph (1) with respect to the food in order to keep the information up-to-date and complete.

"(3) CIVIL PENALTY.—Whoever knowingly violates paragraph (1) with respect to any food shall be liable to the United States for a civil penalty in an

amount not to exceed $10,000 for each day on which such violation continues with respect to such food.

''(b) PUBLIC DATABASE.—The Secretary shall establish and maintain a public database containing the information submitted under this section that—

''(1) is available to the public through the website of the Food and Drug Administration; and

''(2) allows members of the public to easily search and sort information.''.

**SEC. 11. DEFINITIONS.**

(a) DEFINITIONS APPLICABLE IN THIS ACT.—In this Act, the terms ''food'' and ''dietary supplement'' have the meanings given to such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(b) DEFINITIONS APPLICABLE IN THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(ss) The term 'artificial', with respect to food or any ingredient of food, means—

''(1) food or an ingredient that is synthetically produced whether or not it has the same chemical structure as a naturally occurring food or ingredient;

''(2) food or an ingredient that has undergone chemical changes through the introduction of syn-

thetic chemicals or processing aids (such as corn syrup, high-fructose corn syrup, high-maltose corn syrup, maltodextrin, chemically modified starch, and cocoa processed with alkali), excluding—

''(A) food or an ingredient that has undergone traditional processes used to make food edible, to preserve food, or to make food safe for human consumption (such as smoking, roasting, freezing, drying, and fermenting processes); or

''(B) food or ingredient that has undergone traditional physical processes that do not fundamentally alter the raw product or which only separate a whole intact food into component parts (such as grinding grains, separating eggs into albumen and yolk, or pressing fruits to produce juice); or

''(3) any food or ingredient that the Secretary specifies by regulation to be artificial for purposes of this Act.

''(tt) The term 'synthetic', with respect to a substance, means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal, or mineral source, except that such

term does not apply to a substance created by naturally occurring biological processes.''.

**SEC. 12. APPLICABILITY; REGULATIONS.**

(a) APPLICABILITY.—The amendments made by—

(1) subsections (a) and (b) of section 3, subsections (b)(1) and (c) of section 6, and sections 7, 8, 10, and 11(b) shall apply beginning on the date that is 2 years after the date of enactment of this Act; and

(2) sections 2 and 9 shall apply beginning on the date that is 3 years after such date of enactment.

(b) REGULATIONS.—

(1) PROPOSED REGULATIONS.—The Secretary of Health and Human Services shall propose regulations—

(A) not later than 1 year after the date of enactment of this Act, to implement the amendments made by subsections (a) and (b) of section 3, subsections (b)(1) and (c) of section 6, and sections 7, 8, 9, 10, and 11(b); and

(B) not later than 2 years after such date of enactment, to implement the amendments made by section 2.

(2) FINAL REGULATIONS.—The Secretary of Health and Human Services shall promulgate final regulations—

(A) not later than 2 years after the date of enactment of this Act, to implement the amendments made by subsections (a) and (b) of section 3, subsections (b)(1) and (c) of section 6, and sections 7, 8, 9, 10, and 11(b); and

(B) not later than 3 years after such date of enactment to implement the amendments made by section 2.

(3) DEADLINE.—If the Secretary of Health and Human Services does not issue a final regulation by the deadline specified in subparagraph (A) or (B) of paragraph (2), the corresponding proposed regulation under subparagraph (A) or (B) of paragraph (1) shall become final on the respective deadline.

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