

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.

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

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.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Food Labeling Modernization Act of 2018”.

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

Sec. 1. Short title; table of contents.

Sec. 2. Additional requirements for front-of-packaging (FOP) labeling for processed foods.

Sec. 3. Claims for conventional foods.

- Sec. 4. Use of specific terms.
- Sec. 5. Nutrition facts panel compliance date.
- Sec. 6. Ingredient labels.
- Sec. 7. Caffeine content on information panel.
- Sec. 8. Food allergen labeling for sesame.
- Sec. 9. Information about major food allergens in nonprepackaged foods.
- Sec. 10. Submission and availability of food label information.
- Sec. 11. Definitions.
- Sec. 12. Applicability; regulations.

1 **SEC. 2. ADDITIONAL REQUIREMENTS FOR FRONT-OF-PACK-**
 2 **AGING (FOP) LABELING FOR PROCESSED**
 3 **FOODS.**

4 (a) SUMMARY NUTRITION LABELING INFORMA-
 5 TION.—Section 403 of the Federal Food, Drug, and Cos-
 6 metic Act (21 U.S.C. 343) is amended by adding at the
 7 end the following:

8 “(z)(1) SUMMARY NUTRITION INFORMATION.—Ex-
 9 cept as provided in subparagraphs (3), (4), and (5) of
 10 paragraph (q), if it is food (other than a dietary supple-
 11 ment) intended for human consumption and is offered for
 12 sale and otherwise required to bear nutrition labeling, un-
 13 less its principal display panel bears summary nutrition
 14 information that reflects the overall nutritional value of
 15 the food or specified ingredients, as specified in accord-
 16 ance with regulations of the Secretary, and does not con-
 17 tain any summary nutritional information which is in ad-
 18 dition to or inconsistent with the information required
 19 under this subparagraph.

20 “(2) REQUIRED CRITERIA FOR IMPLEMENTING REG-
 21 ULATIONS.—Final regulations regarding the summary nu-

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

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

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

13 “(i) a warning symbol or symbols for prod-
14 ucts high in saturated or trans fats, sodium,
15 added sugars, or other nutrients the consump-
16 tion of which should be limited or discouraged;
17 or

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

22 “(C) The information shall appear on all prod-
23 ucts that are required to bear nutrition labeling.

24 “(D) The information shall—

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

3 “(ii) have a prominent design that visually
4 contrasts with existing packaging design; and

5 “(iii) be sufficiently large to be easily leg-
6 ible.

7 “(3) PRINCIPLES FOR IMPLEMENTING REGULA-
8 TIONS.—In promulgating regulations regarding the sum-
9 mary nutrition information required under subparagraph
10 (1), the Secretary shall take into account published re-
11 ports by the Health and Medicine Division of the National
12 Academy of Sciences regarding such information, and base
13 regulations on the following principles:

14 “(A) Consumers should be able to quickly and
15 easily comprehend the meaning of the symbol system
16 as an indicator of a product’s contribution to a
17 healthy diet without requiring specific or sophisti-
18 cated nutritional knowledge.

19 “(B) The nutrition information should be con-
20 sistent with the Nutrition Facts Panel and with the
21 recommendations of the Dietary Guidelines of Amer-
22 icans.

23 “(C) The information should aim to facilitate
24 consumer selection of healthy product options, in-
25 cluding among nutritionally at-risk subpopulations.

1 “(D) The Secretary should periodically evaluate
2 the front-of-package information to assess its ability
3 to help facilitate consumer selection of healthy prod-
4 uct options and the extent to which manufacturers
5 are offering healthier products as a result of the dis-
6 closure.

7 “(E) The implementation of the information
8 disclosure should be accompanied by appropriate
9 consumer education and promotion campaigns deter-
10 mined by the Secretary.”.

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

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

19 “(1) the terms ‘whole wheat’, ‘whole grain’,
20 ‘made with whole grain’, or ‘multigrain’;

21 “(2) a declaration of the whole grain content by
22 weight;

23 “(3) the term ‘wheat’ on a wheat bread, pasta,
24 or similar product that is typically made from wheat;
25 or

1 “(4) any similar descriptive phrases, terms, or
2 representations suggesting the product contains
3 whole grains,
4 unless the amount of whole grains, expressed as a percent-
5 age of total grains, is conspicuously disclosed in immediate
6 proximity to the descriptive phrase, term, or representa-
7 tion, using a font, color, and formatting of equivalent
8 prominence to the descriptive phrase, term, or representa-
9 tion with respect to whole grain content.”.

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

14 “(bb) SWEETENERS, COLORING, AND FLAVORING.—
15 If, in the case of food other than a dietary supplement,
16 it bears or contains any added artificial or natural color-
17 ing, any added artificial or natural non-caloric sweetener,
18 or any added artificial or natural flavoring, unless such
19 fact is prominently stated on the principal display panel
20 of a package or container of the food.”.

21 (d) CONFORMING AMENDMENT.—The second sen-
22 tence of section 403(k) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 343(k)) is amended by striking
24 “and (i)” and inserting “, (i), (z), (aa), and (bb)”.

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

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

11 (a) HEALTH-RELATED CLAIMS.—

12 (1) IN GENERAL.—Section 403(r)(1)(B) of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 343(r)(1)(B)) is amended by inserting after “health-
15 related condition” the following: “, describes the ef-
16 fect that a nutrient may have on the structure or
17 function of the human body, characterizes the docu-
18 mented mechanism by which that nutrient acts to
19 maintain such structure or function, or describes
20 general well-being from consumption of that nutri-
21 ent,”.

22 (2) SUBSTANTIATION OF CLAIM.—Section
23 403(r) of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 343(r)) is amended—

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

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

5 “(7) If the Secretary requests that a claim
6 under subparagraph (1)(B) for food (other than a
7 dietary supplement) be substantiated, then not later
8 than 90 days after the date on which the Secretary
9 makes such request, the manufacturer shall provide
10 to the Secretary all documentation in the manufac-
11 turer’s possession relating to the claim.”.

12 (b) TRANS FATS.—Section 403(r)(2)(A) of the Fed-
13 eral Food, Drug, and Cosmetic Act (21 U.S.C.
14 343(r)(2)(A)) is amended—

15 (1) in subclause (iii)—

16 (A) in the matter before item (I), by strik-
17 ing “fat or saturated fat” and inserting “fat,
18 saturated fat, or trans fats”; and

19 (B) in item (II), by striking “fat or satu-
20 rated fat” and inserting “fat, saturated fat, or
21 trans fats”;

22 (2) in subclause (iv), by striking “saturated
23 fat” and inserting “saturated fat or trans fats” each
24 place it appears;

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

3 (4) by inserting after subclause (iv) the fol-
4 lowing new subclause:

5 “(v) may not be made with respect to the level
6 of trans fats in the food unless the food contains less
7 than one gram of saturated fat per serving or, if the
8 food contains more than one gram of saturated fat
9 per serving, unless the label or labeling of the food
10 discloses the level of saturated fat in the food in im-
11 mediate proximity to such claim and with appro-
12 priate prominence which shall be no less than one-
13 half the size of the claim with respect to the level
14 of trans fats,”.

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

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

21 (a) USE OF THE TERM “NATURAL”.—

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

1 (A) relating to use of the term “natural”
2 on the labeling of food (other than a dietary
3 supplement); and

4 (B) including provisions to specifically ad-
5 dress the use of such term on the principal dis-
6 play panel and the information panel.

7 (2) DEFINITION.—The rule promulgated pursu-
8 ant to paragraph (1) shall define the term “nat-
9 ural”—

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

13 (B) based on data, including data on con-
14 sumers’ understanding of the term as used in
15 connection with food.

16 (3) PROCESS.—In promulgating the rule re-
17 quired by paragraph (1), the Secretary of Health
18 and Human Services shall—

19 (A) conduct consumer surveys and studies
20 and issue a timely call for relevant public sub-
21 missions regarding relevant consumer research,
22 including with respect to consumer under-
23 standing of the term “natural” in relation to
24 the term “organic”; and

1 (B) fully consider the results of such sur-
2 veys and studies, as well as such public submis-
3 sions.

4 (b) USE OF TERM “HEALTHY”.—

5 (1) ADDED SUGARS AND WHOLE GRAINS.—The
6 Secretary of Health and Human Services shall revise
7 the regulations under the Federal Food, Drug, and
8 Cosmetic Act relating to the use of the term
9 “healthy” on the labeling of a food (other than a di-
10 etary supplement) to take into account the extent to
11 which such food contains added sugars or whole
12 grains.

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

15 (A) in the case of a food (other than a die-
16 tary supplement) that contains grains, the Sec-
17 retary shall not consider the food to be
18 “healthy” unless at least half of those grains,
19 by weight, are whole grains; and

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

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

2 The Secretary of Health and Human Services shall
3 not extend the compliance dates in the final rule entitled
4 “Food Labeling: Revision of the Nutrition and Supple-
5 ment Facts Labels” published by the Food and Drug Ad-
6 ministration in the Federal Register on May 27, 2016 (or
7 any successor rule), beyond the compliance dates proposed
8 in the proposed rule entitled rule entitled “Food Labeling:
9 Revision of the Nutrition and Supplement Facts Labels
10 and Serving Sizes of Foods That Can Reasonably Be Con-
11 sumed at One Eating Occasion; Dual-Column Labeling;
12 Updating, Modifying, and Establishing Certain Reference
13 Amounts Customarily Consumed; Serving Size for Breath
14 Mints; and Technical Amendments; Proposed Extension of
15 Compliance Dates” published by the Food and Drug Ad-
16 ministration in the Federal Register on October 2, 2017.

17 **SEC. 6. INGREDIENT LABELS.**

18 (a) **FORMAT OF INGREDIENT LABELS.**—

19 (1) **IN GENERAL.**—The Secretary of Health and
20 Human Services shall include requirements for the
21 format of the information required under section
22 403(i) of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 343(i))—

24 (A) for the purpose of improving the read-
25 ability of such information on the label of the
26 food (other than a dietary supplement); and

1 (B) that are, as determined by the Sec-
2 retary, necessary to assist consumers in main-
3 taining healthy dietary practices.

4 (2) FORMAT REQUIREMENTS.—The format re-
5 quirements referred to in paragraph (1) shall include
6 requirements for upper- and lower-case characters,
7 serif and noncondensed font types, high-contrast be-
8 tween text and background, and bullet points be-
9 tween adjacent ingredients with appropriate exemp-
10 tions for small packages or other considerations.

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

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

17 “(cc) If the name or primary display panel of the food
18 (other than a dietary supplement) refers to any character-
19 izing ingredient or component of the food, unless—

20 “(1) the characterizing ingredient or component
21 is a predominant ingredient in the food; or

22 “(2) the primary display panel of the food in-
23 cludes, in letters not less than one-half the height of
24 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 “(1) the phrase ‘contains phosphorus’, along
2 with the quantity of phosphorus in the product, re-
3 ported in milligrams per serving, is printed imme-
4 diately after or is adjacent to the list of ingredients
5 required under subsections (g) and (i), in a type size
6 no smaller than the type size used in the list of in-
7 gredients; or

8 “(2) the quantity of phosphorus contained in
9 the product, in milligrams, is reported in the Nutri-
10 tion Facts Panel.”.

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

12 Section 403(i) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 343(i)) is amended—

14 (1) by striking “and (2)” and inserting “(2)”;

15 (2) by striking “and if the food purports” and
16 inserting “, (3) if the food purports”; and

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

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

2 Section 201(qq)(1) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 321(qq)(1)) is amended by strik-
4 ing “and soybeans” and inserting “soybeans, and ses-
5 ame”.

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

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

11 (1) in subparagraph (1)(A), by striking “is
12 printed immediately after or is adjacent to the list
13 of ingredients (in a type size no smaller than the
14 type size used in the list of ingredients) required
15 under subsections (g) and (i)” and inserting “is
16 printed as specified in subparagraph (8)”;

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

20 (3) in subparagraph (3), by striking “The infor-
21 mation” and inserting “Subject to subparagraph
22 (8)(B), the information”; and

23 (4) by adding at the end the following:

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

1 “(A) printed immediately after or adjacent to
 2 the list of ingredients (in a type size no smaller than
 3 the type size used in the list of ingredients) required
 4 under subsections (g) and (i); or

5 “(B) in the case of a nonpackaged food being
 6 offered for sale at retail, and not subject to the re-
 7 quirements of subsections (g) and (i), placed on a
 8 sign adjacent to the food (in a type size no smaller
 9 than the name of the food item).”.

10 (b) APPLICABILITY.—The amendments made by sub-
 11 section (a) apply beginning on the date that is 3 years
 12 after the date of enactment of this Act.

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

15 The Federal Food, Drug, and Cosmetic Act is amend-
 16 ed by inserting after section 403C of such Act (21 U.S.C.
 17 343–3) the following:

18 **“SEC. 403D. SUBMISSION AND AVAILABILITY OF FOOD**
 19 **LABEL INFORMATION.**

20 “(a) SUBMISSIONS.—

21 “(1) REQUIREMENT.—The Secretary shall re-
 22 quire the manufacturer or importer of any food that
 23 is introduced or delivered for introduction into inter-
 24 state commerce in package form to submit to the

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

3 “(A) the nutrition facts panel;

4 “(B) ingredients;

5 “(C) an image of the primary display
6 panel;

7 “(D) allergy warnings or information;

8 “(E) claims under section 403(r)(1)(A)
9 (popularly referred to as ‘nutrient-content
10 claims’);

11 “(F) claims under section 403(r)(1)(B)
12 (popularly referred to as ‘health-related
13 claims’); and

14 “(G) other relevant information required
15 by law to be published in the labeling of the
16 food.

17 “(2) UPDATES.—The Secretary shall require
18 the manufacturer or importer of food to update or
19 supplement the information submitted under para-
20 graph (1) with respect to the food in order to keep
21 the information up-to-date and complete.

22 “(3) CIVIL PENALTY.—Whoever knowingly vio-
23 lates paragraph (1) with respect to any food shall be
24 liable to the United States for a civil penalty in an

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

3 “(b) PUBLIC DATABASE.—The Secretary shall estab-
4 lish and maintain a public database containing the infor-
5 mation submitted under this section that—

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

8 “(2) allows members of the public to easily
9 search and sort information.”.

10 **SEC. 11. DEFINITIONS.**

11 (a) DEFINITIONS APPLICABLE IN THIS ACT.—In this
12 Act, the terms “food” and “dietary supplement” have the
13 meanings given to such terms in section 201 of the Fed-
14 eral Food, Drug, and Cosmetic Act (21 U.S.C. 321).

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

19 “(ss) The term ‘artificial’, with respect to food or any
20 ingredient of food, means—

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

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

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

5 “(A) food or an ingredient that has under-
6 gone traditional processes used to make food
7 edible, to preserve food, or to make food safe
8 for human consumption (such as smoking,
9 roasting, freezing, drying, and fermenting proc-
10 esses); or

11 “(B) food or ingredient that has undergone
12 traditional physical processes that do not fun-
13 damentally alter the raw product or which only
14 separate a whole intact food into component
15 parts (such as grinding grains, separating eggs
16 into albumen and yolk, or pressing fruits to
17 produce juice); or

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

21 “(tt) The term ‘synthetic’, with respect to a sub-
22 stance, means a substance that is formulated or manufac-
23 tured by a chemical process or by a process that chemi-
24 cally changes a substance extracted from a naturally oc-
25 curring plant, animal, or mineral source, except that such

1 term does not apply to a substance created by naturally
2 occurring biological processes.”.

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

4 (a) APPLICABILITY.—The amendments made by—

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

10 (2) sections 2 and 9 shall apply beginning on
11 the date that is 3 years after such date of enact-
12 ment.

13 (b) REGULATIONS.—

14 (1) PROPOSED REGULATIONS.—The Secretary
15 of Health and Human Services shall propose regula-
16 tions—

17 (A) not later than 1 year after the date of
18 enactment of this Act, to implement the amend-
19 ments made by subsections (a) and (b) of sec-
20 tion 3, subsections (b)(1) and (c) of section 6,
21 and sections 7, 8, 9, 10, and 11(b); and

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

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

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

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

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

○