

118TH CONGRESS
1ST SESSION

H. R. 2901

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 26, 2023

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 2023”.

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-package labeling for foods.
- Sec. 3. Claims for conventional foods.
- Sec. 4. Use of specific terms.

- Sec. 5. Format of ingredient list.
- Sec. 6. Declaration of phosphorus in the ingredient list.
- Sec. 7. Caffeine content on information panel.
- Sec. 8. Food allergen labeling.
- Sec. 9. Information about major food allergens and gluten-containing grains.
- Sec. 10. Submission and availability of food label information.
- Sec. 11. Standards of identity.
- Sec. 12. Study on fortification of corn masa flour.
- Sec. 13. Sugar alcohols and isolated fibers.
- Sec. 14. Infant and toddler beverages.
- Sec. 15. Formatting of information on principal display panels.
- Sec. 16. Sale of food online.
- Sec. 17. Definitions.
- Sec. 18. Regulations; delayed applicability.

1 **SEC. 2. ADDITIONAL REQUIREMENTS FOR FRONT-OF-PACK-**
 2 **AGE LABELING FOR FOODS.**

3 (a) INTERPRETIVE NUTRITION INFORMATION.—Sec-
 4 tion 403 of the Federal Food, Drug, and Cosmetic Act
 5 (21 U.S.C. 343) is amended by adding at the end the fol-
 6 lowing:

7 “(z)(1) Except as provided in subparagraphs (3), (4),
 8 and (5) of paragraph (q), if it is food (other than a dietary
 9 supplement) intended for human consumption and is of-
 10 fered for sale and otherwise required to bear nutrition la-
 11 beling, unless its principal display panel bears interpretive
 12 nutrition information.

13 “(2) Final regulations regarding the interpretive nu-
 14 trition information required under subparagraph (1) shall
 15 meet the following criteria:

16 “(A) There shall be a standardized symbol sys-
 17 tem that displays calorie information related to the
 18 serving size determined under paragraph (q)(1)(A),
 19 and interpretive nutrition information related to the

1 content of added sugars, sodium, saturated fat, and
2 any other nutrients that the Secretary determines
3 the highlighting of which will assist consumers in
4 maintaining healthy dietary practices, including by
5 highlighting products containing high levels of such
6 nutrients.

7 “(B) The system shall clearly distinguish be-
8 tween products of greater or lesser nutritional value.

9 “(C) The information shall—

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

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

14 “(iii) be sufficiently large to be easily leg-
15 ible.

16 “(3) In promulgating regulations regarding the inter-
17 pretive nutrition information required under subpara-
18 graph (1) and the standardized symbol system required
19 under subparagraph (2)(A), the Secretary shall take into
20 account published reports by the Health and Medicine Di-
21 vision of the National Academy of Sciences, Engineering,
22 and Medicine regarding interpretive nutrition information,
23 and base regulations on the following principles:

24 “(A) Consumers should be able to quickly and
25 easily comprehend the meaning of the system as an

1 indicator of a product’s contribution to a healthy
2 diet without requiring specific or sophisticated nutri-
3 tional knowledge.

4 “(B) The nutrition information should be con-
5 sistent with the Nutrition Facts Panel and with the
6 recommendations of the Dietary Guidelines for
7 Americans.

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

11 “(4) The Secretary should periodically evaluate the
12 standardized symbol system required under subparagraph
13 (2)(A) to assess its effectiveness in facilitating consumer
14 selection of healthy product options and the extent to
15 which manufacturers are offering healthier products as a
16 result of the disclosure.

17 “(5) The implementation of this paragraph should be
18 accompanied by appropriate consumer education and pro-
19 motion campaigns determined by the Secretary.”.

20 (b) PERCENTAGE OF WHEAT AND GRAINS IN GRAIN-
21 BASED PRODUCTS, AND AMOUNT OF REAL FRUIT, VEGE-
22 TABLE, AND YOGURT IN PRODUCTS BEARING FRUIT,
23 VEGETABLE, AND YOGURT CLAIMS.—Section 403 of the
24 Federal Food, Drug, and Cosmetic Act, as amended by

1 subsection (a), is further amended by adding at the end
2 the following:

3 “(aa) If, in the case of food other than a dietary sup-
4 plement, the principal display panel bears—

5 “(1) the term ‘whole wheat’, ‘whole grain’,
6 ‘made with whole grain’, or ‘multigrain’;

7 “(2) a declaration of the whole grain content by
8 weight;

9 “(3) the term ‘wheat’ on a wheat bread, pasta,
10 or similar product that is typically made from wheat;
11 or

12 “(4) any similar descriptive phrases, terms, or
13 representations suggesting the product contains
14 whole grains,

15 unless the amounts of whole grains and refined grains,
16 expressed as a percentage of total grains, are conspicu-
17 ously disclosed in immediate proximity to the most promi-
18 nent descriptive phrase, term, or representation using a
19 font color and formatting of equivalent prominence to the
20 descriptive phrase, term, or representation with respect to
21 whole grain content, or unless 100 percent of the grains
22 in the food are whole grains.

23 “(bb)(1) If, in the case of food other than a dietary
24 supplement, the principal display panel bears—

1 “(A) the term ‘fruit’, ‘fruity’, ‘froot’, ‘frooty’, or
2 ‘fruit-flavored’;

3 “(B) representations, depictions, or images of
4 such ingredients; or

5 “(C) any similar descriptive phrases, terms, or
6 representations suggesting the product contains fruit
7 or any specific type of fruit,

8 unless the quantity per serving and form of fruit, includ-
9 ing only the nutrient-dense forms, is declared on the prin-
10 cipal display panel in a common household measure that
11 is appropriate to the food, conspicuously, and in imme-
12 diate proximity to the most prominent term, representa-
13 tion, depiction, or image of fruit.

14 “(2) The Secretary shall by regulation establish
15 quantities below which such declaration shall state that
16 the food does not contain any full serving of fruit.

17 “(3) In this paragraph, the term ‘nutrient-dense’,
18 with respect to the form of an ingredient derived from a
19 fruit, means the whole, cut, dried, pulp, puree, 100-per-
20 cent juice, or fully reconstituted concentrate form, and not
21 concentrates, powders, and other ingredients that are not
22 whole, cut, dried, pulp, puree, 100-percent juice, or fully
23 reconstituted concentrates.

24 “(cc)(1) If, in the case of food other than a dietary
25 supplement, the principal display panel bears—

1 “(A) the term ‘vegetable’ or ‘veggie’;

2 “(B) representations, depictions, or images of
3 such ingredients; or

4 “(C) any similar descriptive phrases, terms, or
5 representations suggesting the product contains
6 vegetables or any specific type of vegetable,
7 unless the quantity per serving and form of vegetable, in-
8 cluding only the nutrient-dense form, is declared on the
9 principal display panel in a common household measure
10 that is appropriate to the food, conspicuously, and in im-
11 mediate proximity to the most prominent term, represen-
12 tation, depiction, or image of vegetable.

13 “(2) The Secretary shall by regulation establish
14 quantities below which such declaration shall state that
15 the food does not contain any full serving of vegetable.

16 “(3) In this paragraph, the term ‘nutrient-dense’,
17 with respect to the form of an ingredient derived from a
18 vegetable, means the whole, cut, dried, pulp, puree, 100-
19 percent juice, or fully reconstituted concentrate form, and
20 not concentrates, powders, and other ingredients that are
21 not whole, cut, dried, pulp, puree, 100-percent juice, or
22 fully reconstituted concentrates.

23 “(dd)(1) If, in the case of food other than a dietary
24 supplement, the principal display panel bears the term ‘yo-
25 gurt’, unless—

1 “(A) the quantity per serving of yogurt is de-
2 clared on the principal display panel in a common
3 household measure that is appropriate to the food,
4 conspicuously, in immediate proximity to the term;
5 or

6 “(B) the first ingredient is cultured milk, cul-
7 tured cream, cultured partially skimmed milk, or
8 cultured skim milk.

9 “(2) The Secretary shall by regulation establish
10 quantities below which such declaration shall state that
11 the food does not contain any full serving of yogurt.”.

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

16 “(ee) If, in the case of food other than a dietary sup-
17 plement, it bears or contains any artificial dye, or any
18 added artificial or natural flavoring, unless such fact is
19 prominently stated on the principal display panel of the
20 packaging of the food. For the purposes of this paragraph,
21 the term ‘artificial dye’ refers to a batch-certified dye cer-
22 tified under part 74 of title 21, Code of Federal Regula-
23 tions (or any successor regulations).”.

24 (d) SWEETENERS.—

1 (1) IN GENERAL.—Section 403 of the Federal
2 Food, Drug, and Cosmetic Act, as amended by sub-
3 section (c), is further amended by adding at the end
4 the following:

5 “(ff) If, in the case of food other than a dietary sup-
6 plement, it bears or contains any added artificial or nat-
7 ural noncaloric sweetener, unless such fact is prominently
8 stated on the principal display panel of the packaging of
9 the food.”.

10 (2) REPORT.—

11 (A) IN GENERAL.—Not later than 2 years
12 after the date of enactment of this Act, the Sec-
13 retary of Health and Human Services (referred
14 to in this Act as the “Secretary”) shall submit
15 to Congress a report that—

16 (i) evaluates whether—

17 (I) manufacturers have increased
18 the use of low- and no-calorie sweet-
19 eners; and

20 (II) the use of low- and no-cal-
21 orie sweeteners has risen to a level
22 that could result in negative health
23 consequences; and

24 (ii) describes actions that will be
25 taken by the Secretary to address any in-

1 creased use of low- and no-calorie sweet-
2 eners.

3 (B) MONITORING.—On completion of the
4 report described in subparagraph (A), the Sec-
5 retary shall—

6 (i) periodically monitor for increased
7 use of low- and no-calorie sweeteners; and

8 (ii) take action to address the use of
9 low- and no-calorie sweeteners if the use
10 has risen to a level that could result in
11 negative health consequences.

12 (e) CONSTRUCTION.—Nothing in this section, includ-
13 ing any amendment made by this section, shall be con-
14 strued as—

15 (1) affecting any requirement in regulation in
16 effect as of the date of the enactment of this Act
17 with respect to matters that are required to be stat-
18 ed on the principal display panel of a package or
19 container of food that is not required by an amend-
20 ment made by this section; or

21 (2) restricting the authority of the Secretary of
22 Health and Human Services to require additional in-
23 formation be disclosed on such a principal display
24 panel.

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

2 (a) HEALTH-RELATED CLAIMS.—

3 (1) IN GENERAL.—Section 403(r)(1)(B) of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 343(r)(1)(B)) is amended by inserting after “health-
6 related condition” the following: “, describes the ef-
7 fect that a nutrient may have on the structure or
8 function of the human body, characterizes the docu-
9 mented mechanism by which that nutrient acts to
10 maintain such structure or function, or describes
11 general well-being from consumption of that nutri-
12 ent,”.

13 (2) SUBSTANTIATION OF CLAIM.—Section
14 403(r) of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 343(r)) is amended—

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

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

20 “(7) If the Secretary requests that a claim under sub-
21 paragraph (1)(B) for food (other than a dietary supple-
22 ment) be substantiated, then not later than 90 days after
23 the date on which the Secretary makes such request, the
24 manufacturer shall provide to the Secretary all docu-
25 mentation in the manufacturer’s possession relating to the
26 claim.”.

1 (3) INCOMPATIBLE WITH MAINTAINING
2 HEALTHY DIETARY PRACTICES.—Section
3 403(r)(3)(A)(ii) of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 343(r)(2)(B)) is amended
5 by striking “increases to persons in the general pop-
6 ulation the risk of a disease or health-related condi-
7 tion which is diet related” and inserting “may not
8 be compatible with maintaining healthy dietary prac-
9 tices”.

10 (b) NUTRIENT CONTENT CLAIMS.—

11 (1) IN GENERAL.—Section 403(r)(2) of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 343(r)(2)) is amended by striking clause (B) and in-
14 serting the following:

15 “(B) If a claim described in subparagraph (1)(A) is
16 made with respect to a nutrient in a food and the Sec-
17 retary makes a determination that the food contains a nu-
18 trient at a level that may not be compatible with maintain-
19 ing healthy dietary practices, the label or labeling of such
20 food shall contain, prominently and in immediate prox-
21 imity to such claim, a statement which indicates the food
22 is high in such nutrient.”.

23 (2) REVISIONS TO REGULATIONS.—In promul-
24 gating the regulations required by section 18, the
25 Secretary of Health and Human Services shall revise

1 section 101.13(h) of title 21, Code of Federal Regu-
2 lations, by—

3 (A) updating the level of sodium requiring
4 disclosure to align with the Daily Reference
5 Value for sodium established in the final rule
6 entitled “Food Labeling: Revision of the Nutri-
7 tion and Supplement Facts Labels” published
8 by the Food and Drug Administration on May
9 27, 2016 (81 Fed. Reg. 33741);

10 (B) including a level of added sugars re-
11 quiring disclosure based on the Daily Reference
12 Value for added sugars established in the final
13 rule described in subparagraph (A);

14 (C) eliminating the requirement that meal
15 products containing more than 26 grams of fat
16 and main dish products containing 19.5 grams
17 of fat per labeled serving must disclose that fat
18 is present in the food; and

19 (D) authorizing the use of express and im-
20 plied “low added sugar” claims on products
21 containing 3 grams of added sugars or less per
22 reference amount customarily consumed (or per
23 50 grams if the reference amount customarily
24 consumed is 30 grams or less or 2 tablespoons
25 or less).

1 (c) TRANS FATS.—Section 403(r)(2)(A) of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C.
3 343(r)(2)(A)) is amended—

4 (1) by redesignating subclauses (v) and (vi) as
5 subclauses (vi) and (vii), respectively; and

6 (2) by inserting after subclause (iv) the fol-
7 lowing new subclause:

8 “(v) may not be made with respect to the level
9 of trans fats in the food, except on the Nutrition
10 Facts Panel, unless the food contains less than one
11 gram of saturated fat per serving or, if the food con-
12 tains more than one gram of saturated fat per serv-
13 ing, unless the label or labeling of the food discloses
14 the level of saturated fat in the food in immediate
15 proximity to such claim and with appropriate promi-
16 nence which shall be no less than one-half the size
17 of the claim with respect to the level of trans fats,”.

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

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

24 (a) USE OF THE TERM “NATURAL”.—

1 (1) IN GENERAL.—In promulgating the regula-
2 tions required by section 18, the Secretary of Health
3 and Human Services shall include regulations—

4 (A) relating to use of the term “natural”
5 on the labeling of food (other than a dietary
6 supplement);

7 (B) specifically addressing the use of such
8 term on the principal display panel and the in-
9 formation panel; and

10 (C) requiring that any such use includes a
11 prominent disclosure explaining what the term
12 “natural” does and does not mean in terms of
13 ingredients and manufacturing processes.

14 (2) DEFINITION.—The regulations promulgated
15 pursuant to paragraph (1) shall define the term
16 “natural”—

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

20 (B) based on data, including data on con-
21 sumers’ understanding of the term as used in
22 connection with food.

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

1 (A) conduct consumer surveys and studies
2 and issue a timely call for relevant public sub-
3 missions regarding relevant consumer research,
4 including with respect to consumer under-
5 standing of the term “natural” in relation to
6 the term “organic”; and

7 (B) fully consider the results of such sur-
8 veys and studies, as well as such public submis-
9 sions.

10 (b) USE OF TERM “HEALTHY”.—

11 (1) ADDED SUGARS AND WHOLE GRAINS.—

12 (A) IN GENERAL.—In promulgating the
13 regulations required by section 18, the Sec-
14 retary of Health and Human Services shall in-
15 clude regulations to revise the regulations under
16 the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 301 et seq.) relating to the use of the
18 term “healthy” on the labeling of a food (other
19 than a dietary supplement) to take into account
20 the extent to which such food contains added
21 sugars or whole grains.

22 (B) REQUIREMENT.—In making the revi-
23 sions required by subparagraph (A) in the case
24 of a food (other than a dietary supplement)
25 that contains grains, the Secretary of Health

1 and Human Services shall not consider the food
2 to be “healthy” unless 100 percent of the
3 grains are whole grains.

4 (2) SODIUM.—In promulgating the regulations
5 required by section 18, the Secretary of Health and
6 Human Services shall revise the regulations under
7 the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 301 et seq.) relating to the use of the term
9 “healthy” on the labeling of a food (other than a di-
10 etary supplement) to align labeling requirements re-
11 lated to sodium with the daily value for sodium in
12 the most recent Dietary Guidelines for Americans.

13 (3) PRINCIPLES FOR IMPLEMENTING REGULA-
14 TIONS.—In promulgating regulations under para-
15 graphs (1) and (2) regarding the use of the term
16 “healthy”, the Secretary of Health and Human
17 Services shall—

18 (A) consider both food and nutrient cri-
19 teria; and

20 (B) if requiring food labeled as “healthy”
21 to contain healthful ingredients—

22 (i) consider only ingredients that
23 make up the core of a healthy eating pat-
24 tern; and

1 (ii) consider these ingredients only in
2 their nutrient-dense forms (as such term in
3 defined in paragraphs (bb) and (cc) of sec-
4 tion 403 of the Federal Food, Drug, and
5 Cosmetic Act, as added by section 2(b) of
6 this Act).

7 **SEC. 5. FORMAT OF INGREDIENT LIST.**

8 (a) **IN GENERAL.**—In promulgating the regulations
9 required by section 18, the Secretary of Health and
10 Human Services shall include requirements for the format
11 of the information required under section 403(i) of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 343(i))—

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

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

20 (b) **FORMAT REQUIREMENTS.**—The format require-
21 ments described in subsection (a) shall include require-
22 ments for font size, uppercase and lowercase characters,
23 serif and noncondensed font types, high-contrast between
24 text and background, and bullet points between adjacent

1 ingredients with appropriate exemptions for small pack-
2 ages or other considerations.

3 (c) ENFORCEMENT OF INGREDIENT LIST.—Not later
4 than 2 years after the enactment of this Act, and every
5 2 years thereafter, the Secretary of Health and Human
6 Services shall submit a report to Congress on the Sec-
7 retary’s enforcement of—

8 (1) section 403(i) of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 343(i)), including with
10 respect to the regulations described in subsection
11 (a); and

12 (2) regulations of the Food and Drug Adminis-
13 tration on labeling of ingredients in section 101.4 of
14 title 21, Code of Federal Regulations.

15 **SEC. 6. DECLARATION OF PHOSPHORUS IN THE INGRE-**
16 **DIENT LIST.**

17 Section 403 of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 343), as amended by section 2(d), is fur-
19 ther amended by adding at the end the following:

20 “(gg) If it is a food intended for human consumption
21 that is offered for sale and contains phosphorus, unless—

22 “(1) the phrase ‘contains phosphorus’, along
23 with the quantity of phosphorus in the product, re-
24 ported in milligrams per serving, is printed imme-
25 diately after or is adjacent to the list of ingredients

1 required under paragraphs (g) and (i), in a type size
2 no smaller than the type size used in the list of in-
3 gredients; or

4 “(2) the quantity of phosphorus contained in
5 the product, in milligrams, is reported in the Nutri-
6 tion Facts Panel.”.

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

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

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

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

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

22 **SEC. 8. FOOD ALLERGEN LABELING.**

23 (a) IN GENERAL.—Section 201(qq) of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)) is
25 amended by adding at the end the following:

1 “(3) Any other food ingredient that the Sec-
2 retary determines by regulation to be a major food
3 allergen, based on the prevalence and severity of al-
4 lergic reactions to the food ingredient.”.

5 (b) UPDATE TO COMPLIANCE POLICY GUIDE.—Not
6 later than 2 years after the date of enactment of this Act,
7 the Secretary of Health and Human Services shall update
8 the Food and Drug Administration’s Compliance Policy
9 Guide, section 555.250, to conform with applicable laws
10 related to major food allergens and gluten-containing
11 grains, including requirements under sections 9 and 10
12 of this Act.

13 **SEC. 9. INFORMATION ABOUT MAJOR FOOD ALLERGENS**
14 **AND GLUTEN-CONTAINING GRAINS.**

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

18 (1) in subparagraph (1)(A), by striking “is
19 printed immediately after or is adjacent to the list
20 of ingredients (in a type size no smaller than the
21 type size used in the list of ingredients) required
22 under subsections (g) and (i)” and inserting “is
23 printed as specified in subparagraph (8)”;

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

4 (3) in subparagraph (3), by striking “The infor-
5 mation” and inserting “Subject to subparagraph
6 (8)(B), the information”;

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

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

10 “(A) printed immediately after or adjacent to
11 the list of ingredients (in a type size no smaller than
12 the type size used in the list of ingredients) required
13 under paragraphs (g) and (i); or

14 “(B) in the case of a nonpackaged food being
15 offered for sale at retail, and not subject to the re-
16 quirements of paragraphs (g) and (i), placed on a
17 sign adjacent to the food (in a type size no smaller
18 than the name of the food item).”;

19 (5) by inserting “or gluten-containing grain”
20 after “food allergen” each place it appears in sub-
21 paragraphs (1), (2), (4), and (7); and

22 (6) in subparagraph (7)(A)—

23 (A) by striking “paragraph (6)” and in-
24 serting “subparagraph (6)”; and

1 (B) by striking “allergen labeling require-
2 ments of this subsection” and inserting “aller-
3 gen and gluten-containing grain labeling re-
4 quirements of this paragraph”.

5 (b) HAZARD ANALYSIS AND PREVENTIVE CON-
6 TROLS.—Section 418 of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 350g) is amended—

8 (1) in subsection (b)(1)(A), by inserting “glu-
9 ten-containing grains,” after “allergens,”; and

10 (2) in subsection (o)(3)(D), by inserting “and
11 gluten-containing grain” after “allergen,”.

12 (c) INSPECTIONS RELATING TO FOOD ALLERGENS.—
13 Section 205 of the Food Allergen Labeling and Consumer
14 Protection Act of 2004 (21 U.S.C. 374a) is amended by
15 inserting “and gluten-containing grains,” after “aller-
16 gens” each place it appears.

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

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

22 **“SEC. 403D. SUBMISSION AND AVAILABILITY OF FOOD**
23 **LABEL INFORMATION.**

24 “(a) SUBMISSIONS.—

1 “(1) REQUIREMENT.—The Secretary shall re-
2 quire the manufacturer or importer of any food that
3 is introduced or delivered for introduction into inter-
4 state commerce in package form to submit to the
5 Secretary all information to be included in the label
6 of the food, including—

7 “(A) the nutrition facts panel;

8 “(B) the ingredients list;

9 “(C) an image of the principal display
10 panel;

11 “(D) major allergens and gluten-containing
12 grains;

13 “(E) claims under section 403(r)(1)(A)
14 (commonly known as ‘nutrient-content claims’);

15 “(F) claims under section 403(r)(1)(B)
16 (commonly known as ‘health-related claims’);

17 and

18 “(G) other relevant information required
19 by law to be published in the labeling of the
20 food.

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

1 “(3) CIVIL PENALTY.—Whoever knowingly vio-
2 lates paragraph (1) with respect to any food shall be
3 liable to the United States for a civil penalty in an
4 amount not to exceed \$10,000 for each day on which
5 such violation continues with respect to such food.

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

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

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

13 **SEC. 11. STANDARDS OF IDENTITY.**

14 (a) IN GENERAL.—Not later than 2 years after the
15 date of enactment of this Act, the Secretary of Health and
16 Human Services shall—

17 (1) review standards of identity prescribed by
18 regulation which require foods to contain—

19 (A) minimum levels of nutrients that the
20 Secretary determines are strongly associated
21 with public health concerns; or

22 (B) minimum levels of ingredients con-
23 taining high levels of such nutrients; and

24 (2) report to the Committee on Energy and
25 Commerce of the House of Representatives and the

1 Committee on Health, Education, Labor, and Pen-
2 sions of the Senate on the findings of such review.

3 (b) AMENDMENTS.—In promulgating the regulations
4 required by section 18, the Secretary of Health and
5 Human Services shall amend standards of identity regula-
6 tions to—

7 (1) provide for the use of salt substitutes where
8 appropriate; and

9 (2) require that yogurt, lowfat yogurt, and non-
10 fat yogurt contain a minimum level of live and active
11 cultures per gram.

12 **SEC. 12. STUDY ON FORTIFICATION OF CORN MASA FLOUR.**

13 Not later than 2 years after the date of enactment
14 of this Act, the Secretary of Health and Human Services
15 shall submit a report to Congress on the effect of the final
16 rule titled “Food Additives Permitted for Direct Addition
17 to Food for Human Consumption; Folic Acid” published
18 by the Food and Drug Administration on April 15, 2016
19 (81 Fed. Reg. 22176), on folic acid intake in the United
20 States population by race and ethnicity, comparing actual
21 exposure with modeled exposure estimates from the final
22 rule.

1 **SEC. 13. SUGAR ALCOHOLS AND ISOLATED FIBERS.**

2 Section 403 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 343), as amended by section 6, is further
4 amended by adding at the end the following:

5 “(hh) If it is a food intended for human consumption
6 that is offered for sale and contains allulose, polydextrose,
7 sugar alcohols, or isolated fibers, unless such fact is
8 prominently stated on the principal display panel of the
9 packaging of the food. The Secretary shall by regulation
10 establish quantities above which such labeling shall include
11 a warning that the food contains a level of allulose,
12 polydextrose, sugar alcohols, or isolated fibers per serving
13 determined by the Secretary to cause deleterious health
14 effects.”.

15 **SEC. 14. INFANT AND TODDLER BEVERAGES.**

16 In promulgating the regulations required by section
17 18, the Secretary of Health and Human Services shall re-
18 vise—

19 (1) section 101.3 of title 21, Code of Federal
20 Regulations, to prohibit any beverage in powder or
21 liquid form, other than infant formula, represented
22 or purported to be for use by children more than 12
23 months old, from being identified as “infant for-
24 mula” or use the term “formula” in combination
25 with any other term; and

1 (2) part 102 of title 21, Code of Federal Regu-
2 lations, so that—

3 (A) in the case of any powdered or liquid
4 milk-based beverage that claims to be for con-
5 sumption by children 12 to 36 months of age,
6 such beverage shall—

7 (i) use as its common or usual name
8 a descriptive term such as “milk-based
9 drink”; and

10 (ii) if the beverage contains added
11 sugars, nonnutritive sweeteners, or
12 flavorings, include in such common or
13 usual name a qualifying term such as
14 “sweetened” or “flavored”;

15 (B) in the case of any powdered or liquid
16 nondairy-milk-based beverage that claims to be
17 for consumption by children 12 to 36 months of
18 age, such beverage shall—

19 (i) use as its common or usual name
20 an appropriately descriptive term identi-
21 fying the source of protein, such as “soy-
22 based drink powder for 12–36 month
23 olds”; and

24 (ii) if the beverage contains added
25 sugars, nonnutritive sweeteners, or

1 flavorings, include in such common or
2 usual name qualifying terms such as
3 “sweetened” and “flavored” when applica-
4 ble; and

5 (C) the labeling of a beverage described in
6 subparagraph (A) or (B) shall—

7 (i) contain a disclaimer that—

8 (I) cautions against consumption
9 of the beverage by infants, such as
10 “DO NOT SERVE TO INFANTS
11 UNDER 12 MONTHS OLD”; and

12 (II) such beverages are not rec-
13 ommended for children 12 to 24
14 months of age and such consumption
15 of such beverages is not required for
16 a healthy diet, such as “This product
17 contains added sugars. The Dietary
18 Guidelines for Americans recommend
19 to avoid food and beverages with
20 added sugars for children younger
21 than 24 months of age.”; and

22 (ii) not contain any statement sug-
23 gesting a recommended intake of such bev-
24 erages, such as “one cup a day”.

1 **SEC. 15. FORMATTING OF INFORMATION ON PRINCIPAL**
2 **DISPLAY PANELS.**

3 The Secretary of Health and Human Services shall—

4 (1) not later than 2 years after the date of en-
5 actment of this Act, conduct a study on the legibility
6 of food labeling to determine updated recommenda-
7 tions for text size and color contrast that make food
8 labeling information visually accessible to the major-
9 ity of consumers;

10 (2) not later than 1 year after the completion
11 of the study under paragraph (1), issue proposed
12 regulations revising section 101.2(c) of title 21,
13 Code of Federal Regulations, to—

14 (A) set the scale of text size, taking into
15 consideration the results of the study conducted
16 under paragraph (1); and

17 (B) establish new requirements for text
18 and background color contrast, taking into con-
19 sideration the results of the study conducted
20 under paragraph (1); and

21 (3) not later than 2 years after the completion
22 of the study under paragraph (1), finalize such pro-
23 posed regulations.

24 **SEC. 16. SALE OF FOOD ONLINE.**

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

1 section 13, is further amended by adding at the end the
2 following:

3 “(ii)(1) If it is a food offered for sale online or by
4 other remote written electronic means, unless all informa-
5 tion required to appear on the label or labeling is available
6 to consumers at the point of selection prior to purchasing
7 the food.

8 “(2) The Secretary shall by regulation specify the for-
9 mat and manner in which the information required under
10 subparagraph (1) is to be made available online to con-
11 sumers. Such regulations shall include—

12 “(A) a requirement that the nutrition informa-
13 tion shall be in the same format as the nutrition in-
14 formation required under paragraph (q); and

15 “(B) a requirement that the nutrition informa-
16 tion required under paragraph (q), the ingredient in-
17 formation required under paragraphs (g) and (i),
18 and the allergen information required under para-
19 graph (w) shall—

20 “(i) appear on the first product informa-
21 tion page that appears for the product on a mo-
22 bile device, internet website, or other landing
23 page;

24 “(ii) appear prominently and conspicuously
25 (as compared with other words, statements, or

1 designs on the mobile device, internet website,
2 or other landing page) so as to render the infor-
3 mation likely to be read and understood by the
4 ordinary individual under customary conditions
5 of online purchase; and

6 “(iii) not contain intervening marketing in-
7 formation.”.

8 (b) PROHIBITED ACTS.—

9 (1) IN GENERAL.—Section 301 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is
11 amended by adding at the end the following:

12 “(jjj) In the case of a person providing a platform
13 for, or otherwise assisting, the sale of food online or by
14 other remote written electronic means, the prevention by
15 the person of the provision to consumers of information
16 required under section 403(z) or the charging by such per-
17 son of an additional fee for the provision of such informa-
18 tion.”.

19 (2) PENALTIES.—Section 303 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 333) is
21 amended by adding at the end the following:

22 “(h)(1) Notwithstanding subsection (a), any person
23 who violates section 301(jjj) shall be liable to the United
24 States for a civil penalty in an amount not to exceed
25 \$10,000 for each such violation, and not to exceed

1 \$1,000,000 for all such violations adjudicated in a single
2 proceeding.

3 “(2) The Secretary shall provide the person subject
4 to a penalty under paragraph (1) with a warning and op-
5 portunity to correct the violation prior to issuing the first
6 civil penalty under that paragraph.

7 “(3) In determining the amount of a civil penalty
8 under paragraph (1), the Secretary shall take into consid-
9 eration whether the person is making efforts to correct
10 the violation for which such person is subject to such civil
11 penalty.

12 “(4) No person shall be subject to criminal penalties
13 as described in subsection (a) for a violation of section
14 301(jjj).”.

15 (c) CIVIL MONETARY PENALTIES FOR VIOLATION OF
16 REQUIREMENTS FOR SALE OF FOOD ONLINE.—Section
17 303 of the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 333) (as amended by subsection (b)(2)) is amended
19 by adding at the end the following:

20 “(i)(1) Notwithstanding subsection (a), any person
21 who introduces into interstate commerce, delivers for in-
22 troduction into interstate commerce, receives in interstate
23 commerce, or manufactures a food that is misbranded as
24 described in section 403(z), or misbrands the food as de-
25 scribed in that section, shall be liable to the United States

1 for a civil penalty in an amount not to exceed \$10,000
2 for each such violation, and not to exceed \$1,000,000 for
3 all such violations adjudicated in a single proceeding.

4 “(2) The Secretary shall provide the person subject
5 to a penalty under paragraph (1) with a warning and op-
6 portunity to correct the violation prior to issuing the first
7 civil penalty under that paragraph.

8 “(3) In determining the amount of a civil penalty
9 under paragraph (1), the Secretary shall take into consid-
10 eration whether the person is making efforts to correct
11 the violation for which such person is subject to such civil
12 penalty.

13 “(4) No person shall be subject to criminal penalties
14 as described in subsection (a) for a violation described in
15 paragraph (1).”.

16 **SEC. 17. DEFINITIONS.**

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

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

1 “(tt) The term ‘artificial’, with respect to food or any
2 ingredient of food, means—

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

6 “(2) food or an ingredient that has undergone
7 chemical changes through the introduction of syn-
8 thetic chemicals or processing aids (such as corn
9 syrup, high-fructose corn syrup, high-maltose corn
10 syrup, maltodextrin, chemically modified starch, and
11 cocoa processed with alkali), excluding—

12 “(A) food or an ingredient that has under-
13 gone traditional processes used to make food
14 edible, to preserve food, or to make food safe
15 for human consumption (such as smoking,
16 roasting, freezing, drying, and fermenting proc-
17 esses); or

18 “(B) food or an ingredient that has under-
19 gone traditional physical processes that do not
20 fundamentally alter the raw product or which
21 only separate a whole intact food into compo-
22 nent parts (such as grinding grains, separating
23 eggs into albumen and yolk, or pressing fruits
24 to produce juice); or

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

4 “(uu) The term ‘synthetic’, with respect to a sub-
5 stance in food or any ingredient of food, means a sub-
6 stance that is formulated or manufactured by a chemical
7 process or by a process that chemically changes a sub-
8 stance extracted from a naturally occurring plant, animal,
9 or mineral source, except that such term does not apply
10 to a substance created by naturally occurring biological
11 processes.

12 “(vv) The term ‘gluten-containing grains’ means any
13 one of the following grains (or any crossbred hybrid there-
14 of):

15 “(1) Wheat, including any species belonging to
16 the genus *Triticum*.

17 “(2) Rye, including any species belonging to the
18 genus *Secale*.

19 “(3) Barley, including any species belonging to
20 the genus *Hordeum*.

21 “(ww) The term ‘gluten’ means the proteins that—

22 “(1) naturally occur in a gluten-containing
23 grain; and

24 “(2) may cause adverse health effects in per-
25 sons with celiac disease.

1 “(xx) The term ‘online’ means on or by any system
2 of data communication and transmission, such as the
3 internet.

4 “(yy) The term ‘online point of selection’ means any
5 space in which consumers are allowed to purchase food
6 online, including websites, e-commerce platforms, web ap-
7 plications, and mobile applications.”.

8 **SEC. 18. REGULATIONS; DELAYED APPLICABILITY.**

9 (a) REGULATIONS.—

10 (1) PROPOSED REGULATIONS.—Not later than
11 1 year after the date of enactment of this Act, the
12 Secretary of Health and Human Services, acting
13 through the Commissioner of Food and Drugs, shall
14 issue proposed regulations to carry out sections 2, 3,
15 4, 5(a), 6, 7, 9, 10, 11, 13, 14, 16, and 17(b) and
16 the amendments made by such sections.

17 (2) FINAL REGULATIONS.—Not later than 2
18 years after the date of enactment of this Act, the
19 Secretary of Health and Human Services, acting
20 through the Commissioner of Food and Drugs, shall
21 finalize the regulations proposed pursuant to para-
22 graph (1).

23 (3) FAILURE TO ISSUE FINAL REGULATION.—If
24 the Secretary of Health and Human Services does
25 not issue a final regulation as required by paragraph

1 (2) by the deadline specified in such paragraph, the
2 corresponding proposed regulation shall become final
3 on such deadline.

4 (b) **DELAYED APPLICABILITY.**—The amendments
5 made by sections 2, 3, 4, 5(a), 6, 7, 9, 10, 11, 13, 14,
6 16, and 17(b) apply beginning on the date that is 3 years
7 after the date of enactment of this Act.

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