



(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

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

Mr. PALLONE introduced the following bill; which was referred to the Committee on _____

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 2021”.

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

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

1 dition to or inconsistent with the information required
2 under this subparagraph.

3 “(2) REQUIRED CRITERIA FOR IMPLEMENTING REG-
4 ULATIONS.—Final regulations regarding the summary nu-
5 trition information required under subparagraph (1) shall
6 meet the following criteria:

7 “(A) There shall be a standardized symbol sys-
8 tem that displays calorie information related to the
9 serving size determined under paragraph (q)(1)(A),
10 and information related to the content of saturated
11 and trans fats, sodium, added sugars, and any other
12 nutrients that the Secretary determines are strongly
13 associated with public health concerns.

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

17 “(i) a warning symbol or symbols for prod-
18 ucts high in saturated or trans fats, sodium,
19 added sugars, and any other nutrients the con-
20 sumption of which should be limited or discour-
21 aged; and

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

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

3 “(D) The information shall—

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

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

8 “(iii) be sufficiently large to be easily leg-
9 ible.

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

17 “(A) Consumers should be able to quickly and
18 easily comprehend the meaning of the system as an
19 indicator of a product’s contribution to a healthy
20 diet without requiring specific or sophisticated nutri-
21 tional knowledge.

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

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

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

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

14 (b) PERCENTAGE OF WHEAT AND GRAINS IN GRAIN-
15 BASED PRODUCTS, AND AMOUNT OF REAL FRUIT, VEGE-
16 TABLE, AND YOGURT IN PRODUCTS BEARING FRUIT,
17 VEGETABLE, AND YOGURT CLAIMS.—Section 403 of the
18 Federal Food, Drug, and Cosmetic Act, as amended by
19 subsection (a), is further amended by adding at the end
20 the following:

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

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

3 “(2) a declaration of the whole grain content by
4 weight,

5 “(3) the term ‘wheat’ on a wheat bread, pasta,
6 or similar product that is typically made from wheat,
7 or

8 “(4) any similar descriptive phrases, terms, or
9 representations suggesting the product contains
10 whole grains,

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

19 “(bb) AMOUNT OF FRUIT.—

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

22 “(A) the term ‘fruit’, ‘fruity’, ‘froot’,
23 ‘frooty’, or ‘fruit-flavored’,

24 “(B) representations, depictions, or images
25 of such ingredients, or

1 “(C) any similar descriptive phrases,
2 terms, or representations suggesting the prod-
3 uct contains fruit or any specific type of fruit,
4 unless the quantity per serving and form of fruit, in-
5 cluding only the nutrient-dense forms, is declared on
6 the principal display panel in a common household
7 measure that is appropriate to the food, conspicu-
8 ously, and in immediate proximity to the most
9 prominent term, representation, depiction, or image
10 of fruit.

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

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

23 “(cc) AMOUNT OF VEGETABLES.—

24 “(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
3 of such ingredients, or
4 “(C) any similar descriptive phrases,
5 terms, or representations suggesting the prod-
6 uct contains vegetables or any specific type of
7 vegetable,
8 unless the quantity per serving and form of vege-
9 table, including only the nutrient-dense form, is de-
10 clared on the principal display panel in a common
11 household measure that is appropriate to the food,
12 conspicuously, and in immediate proximity to the
13 most prominent term, representation, depiction, or
14 image of vegetable.

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

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

1 pulp, puree, 100-percent juice, or fully reconstituted
2 concentrates.

3 “(dd) AMOUNT OF YOGURT.—

4 “(1) If, in the case of food other than a dietary
5 supplement, the principal display panel bears the
6 term ‘yogurt’, unless—

7 “(A) the quantity per serving of yogurt is
8 declared on the principal display panel in a
9 common household measure that is appropriate
10 to the food, conspicuously, in immediate prox-
11 imity to the term; or

12 “(B) the first ingredient is cultured milk,
13 cultured cream, cultured partially skimmed
14 milk, or cultured skim milk.

15 “(2) The Secretary shall by regulation establish
16 quantities below which such declaration shall state
17 that the food does not contain any full serving of yo-
18 gurt.”.

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

23 “(ee) COLORING AND FLAVORING.—If, in the case of
24 food other than a dietary supplement, it bears or contains
25 any artificial dye, or any added artificial or natural fla-

1 voring, unless such fact is prominently stated on the prin-
2 cipal display panel of the packaging of the food. For the
3 purposes of this paragraph, the term ‘artificial dye’ refers
4 to a batch-certified dye certified under part 74 of title 21,
5 Code of Federal Regulations (or any successor regula-
6 tions).”.

7 (d) SWEETENERS.—Section 403 of the Federal Food,
8 Drug, and Cosmetic Act, as amended by subsection (c),
9 is further amended by adding at the end the following:

10 “(ff) SWEETENERS.—If, in the case of food other
11 than a dietary supplement, it bears or contains any added
12 artificial or natural noncaloric sweetener, unless such fact
13 is prominently stated on the principal display panel of the
14 packaging of the food.”.

15 (e) CONSTRUCTION.—Nothing in this section shall be
16 construed as—

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

23 (2) restricting the authority of the Secretary of
24 Health and Human Services to require additional in-

1 formation be disclosed on such a principal display
2 panel.

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

4 (a) HEALTH-RELATED CLAIMS.—

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

15 (2) SUBSTANTIATION OF CLAIM.—Section
16 403(r) of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 343(r)) is amended—

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

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

22 “(7) If the Secretary requests that a claim under sub-
23 paragraph (1)(B) for food (other than a dietary supple-
24 ment) be substantiated, then not later than 90 days after
25 the date on which the Secretary makes such request, the

1 manufacturer shall provide to the Secretary all docu-
2 mentation in the manufacturer's possession relating to the
3 claim.”.

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

13 (b) NUTRIENT CONTENT CLAIMS.—

14 (1) IN GENERAL.—Section 403(r)(2)(B) of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 343(r)(2)) is amended by striking paragraph (B)
17 and inserting the following:

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

1 (2) REVISIONS TO REGULATIONS.—In promul-
2 gating the regulations required by section 18, the
3 Secretary of Health and Human Services shall revise
4 section 101.13(h) of title 21, Code of Federal Regu-
5 lations, by—

6 (A) updating the level of sodium requiring
7 disclosure to align with the Daily Reference
8 Value for sodium established in the final rule
9 entitled “Food Labeling: Revision of the Nutri-
10 tion and Supplement Facts Labels” published
11 by the Food and Drug Administration in the
12 Federal Register on May 27, 2016 (81 Fed.
13 Reg. 33742 et seq.);

14 (B) including a level of added sugars re-
15 quiring disclosure based on the Daily Reference
16 Value for added sugars established in the final
17 rule referenced in subparagraph (A);

18 (C) eliminating the requirement that meal
19 products containing more than 26 grams of fat
20 and main dish products containing 19.5 grams
21 of fat per labeled serving must disclose that fat
22 is present in the food; and

23 (D) authorizing the use of express and im-
24 plied “low added sugar” claims on products
25 containing 3 grams of added sugars or less per

1 reference amount customarily consumed (or per
2 50 grams if the reference amount customarily
3 consumed is 30 grams or less or 2 tablespoons
4 or less).

5 (c) TRANS FATS.—Section 403(r)(2)(A) of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C.
7 343(r)(2)(A)) is amended—

8 (1) by redesignating subclauses (v) and (vi) as
9 subclauses (vi) and (vii), respectively; and

10 (2) by inserting after subclause (iv) the fol-
11 lowing new subclause:

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

22 (d) ADDED SUGARS.—Not more than 2 years after
23 the date of enactment of this Act, the Secretary of Health
24 and Human Services shall promulgate a final rule revising

1 section 101.14 of title 21, Code of Federal Regulations,
2 to include a disqualifying nutrient level for added sugars.

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

4 (a) USE OF THE TERM “NATURAL”.—

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

8 (A) relating to use of the term “natural”
9 on the labeling of food (other than a dietary
10 supplement);

11 (B) specifically addressing the use of such
12 term on the principal display panel and the in-
13 formation panel; and

14 (C) requiring that any such use includes a
15 prominent disclosure explaining what the term
16 “natural” does and does not mean in terms of
17 ingredients and manufacturing processes.

18 (2) DEFINITION.—The regulations promulgated
19 pursuant to paragraph (1) shall define the term
20 “natural”—

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

1 (B) based on data, including data on con-
2 sumers' understanding of the term as used in
3 connection with food.

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

7 (A) conduct consumer surveys and studies
8 and issue a timely call for relevant public sub-
9 missions regarding relevant consumer research,
10 including with respect to consumer under-
11 standing of the term “natural” in relation to
12 the term “organic”; and

13 (B) fully consider the results of such sur-
14 veys and studies, as well as such public submis-
15 sions.

16 (b) USE OF TERM “HEALTHY”.—

17 (1) ADDED SUGARS AND WHOLE GRAINS.—

18 (A) IN GENERAL.—In promulgating the
19 regulations required by section 18, the Sec-
20 retary of Health and Human Services shall in-
21 clude regulations to revise the regulations under
22 the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 301 et seq.) relating to the use of the
24 term “healthy” on the labeling of a food (other
25 than a dietary supplement) to take into account

1 the extent to which such food contains added
2 sugars or whole grains.

3 (B) REQUIREMENT.—In making the revi-
4 sions required by subparagraph (A) in the case
5 of a food (other than a dietary supplement)
6 that contains grains, the Secretary of Health
7 and Human Services shall not consider the food
8 to be “healthy” unless 100 percent of those
9 grains are whole grains.

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

19 (3) PRINCIPLES FOR IMPLEMENTING REGULA-
20 TIONS.—In promulgating regulations under para-
21 graphs (1) and (2) regarding the use of the term
22 “healthy”, the Secretary of Health and Human
23 Services shall—

24 (A) consider both food and nutrient cri-
25 teria; and

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

3 (i) consider only ingredients that
4 make up the core of a healthy eating pat-
5 tern; and

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

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

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

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

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

1 (b) **FORMAT REQUIREMENTS.**—The format require-
2 ments referred to in subsection (a) shall include require-
3 ments for font size, uppercase and lowercase characters,
4 serif and noncondensed font types, high-contrast between
5 text and background, and bullet points between adjacent
6 ingredients with appropriate exemptions for small pack-
7 ages or other considerations.

8 (c) **ENFORCEMENT OF INGREDIENT LIST.**—Not later
9 than 2 years after the enactment of this Act, and every
10 2 years thereafter, the Secretary of Health and Human
11 Services shall submit a report to the Congress on the Sec-
12 retary’s enforcement of—

13 (1) section 403(i) of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C. 343(i)), as amended
15 pursuant to subsection (a); and

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

19 **SEC. 6. DECLARATION OF PHOSPHORUS IN THE INGRE-**
20 **DIENT LIST.**

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

24 “(gg) If it is a food intended for human consumption
25 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 paragraphs (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.**

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

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

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

16 **SEC. 9. INFORMATION ABOUT MAJOR FOOD ALLERGENS**
17 **AND GLUTEN-CONTAINING GRAINS.**

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

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

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 each reference to “food allergen” in subpara-
21 graphs (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 “and
9 gluten-containing grains,” after “allergens,”; and

10 (2) in subsection (o)(3)(D), by inserting
11 “and 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 (popularly referred to as ‘nutrient-content
15 claims’);

16 “(F) claims under section 403(r)(1)(B)
17 (popularly referred to as ‘health-related
18 claims’); and

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

22 “(2) UPDATES.—The Secretary shall require
23 the manufacturer or importer of food to update or
24 supplement the information submitted under para-

1 graph (1) with respect to the food in order to keep
2 the information up-to-date and complete.

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

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

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

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

15 **SEC. 11. STANDARDS OF IDENTITY.**

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

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

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

24 (B) minimum levels of ingredients con-
25 taining high levels of such nutrients; and

1 (2) report to the Committee on Energy and
2 Commerce of the House of Representatives and the
3 Committee on Health, Education, Labor, and Pen-
4 sions of the Senate on the findings of such review.

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

9 (1) provide for the use of salt substitutes where
10 appropriate; and

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

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

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

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

2 Section 403 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 343), as amended by section 13, is further
4 amended by adding at the end the following:

5 “(ii) SALE OF FOOD ONLINE.—

6 “(1) If it is a food offered for sale online, un-
7 less all information required to appear on the label
8 or labeling under this section is available to con-
9 sumers at the online point of selection prior to pur-
10 chasing the food.

11 “(2) The Secretary shall by regulation specify
12 the format and manner in which the information re-
13 quired under subparagraph (1) is to be made avail-
14 able online to consumers.

15 “(3) Foods shall be exempt from the require-
16 ments of this paragraph if they are foods that are
17 offered for sale by a retailer with annual gross sales
18 of not more than \$500,000, or with annual gross
19 sales of foods or dietary supplements to consumers
20 of not more than \$50,000, so long as such retailers
21 do not provide nutrition information or make a nu-
22 trient content or health claim at the online point of
23 purchase.”.

24 **SEC. 17. DEFINITIONS.**

25 (a) DEFINITIONS APPLICABLE IN THIS ACT.—In this
26 Act, the terms “food” and “dietary supplement” have the

1 meanings given to such terms in section 201 of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 321).

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

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

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

12 “(2) food or an ingredient that has undergone
13 chemical changes through the introduction of syn-
14 thetic chemicals or processing aids (such as corn
15 syrup, high-fructose corn syrup, high-maltose corn
16 syrup, maltodextrin, chemically modified starch, and
17 cocoa processed with alkali), excluding—

18 “(A) food or an ingredient that has under-
19 gone traditional processes used to make food
20 edible, to preserve food, or to make food safe
21 for human consumption (such as smoking,
22 roasting, freezing, drying, and fermenting proc-
23 esses); or

24 “(B) food or an ingredient that has under-
25 gone traditional physical processes that do not

1 fundamentally alter the raw product or which
2 only separate a whole intact food into compo-
3 nent parts (such as grinding grains, separating
4 eggs into albumen and yolk, or pressing fruits
5 to produce juice); or

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

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

17 “(uu) The term ‘gluten-containing grains’ means any
18 one of the following grains (or any crossbred hybrid there-
19 of):

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

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

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

1 “(vv) The term ‘gluten’ means the proteins that—

2 “(1) naturally occur in a gluten-containing
3 grain; and

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

6 “(ww) The term ‘online’ means on or by any system
7 of data communication and transmission, such as the
8 internet.

9 “(xx) The term ‘online point of selection’ means any
10 space in which consumers are allowed to purchase food
11 online, including websites, e-commerce platforms, web ap-
12 plications, and mobile applications.”.

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

14 (a) REGULATIONS.—

15 (1) PROPOSED REGULATIONS.—Not later than
16 1 year after the date of enactment of this Act, the
17 Secretary of Health and Human Services, acting
18 through the Commissioner of Food and Drugs, shall
19 issue proposed regulations to carry out sections 2, 3,
20 4, 5(a), 6, 7, 9, 10, 11, 13, 14, 16, and 17(b) and
21 the amendments made by such sections.

22 (2) FINAL REGULATIONS.—Not later than 2
23 years after the date of enactment of this Act, the
24 Secretary of Health and Human Services, acting
25 through the Commissioner of Food and Drugs, shall

1 finalize the regulations proposed pursuant to para-
2 graph (1).

3 (3) FAILURE TO ISSUE FINAL REGULATION.—If
4 the Secretary of Health and Human Services does
5 not issue a final regulation as required by paragraph
6 (2) by the deadline specified in such paragraph, the
7 corresponding proposed regulation shall become final
8 on such deadline.

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