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S. 2594

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 SENATE OF THE UNITED STATES

AUGUST 3, 2021

Mr. BLUMENTHAL (for himself, Mr. WHITEHOUSE, and Mr. MARKEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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-
17 dition to or inconsistent with the information required
18 under this subparagraph.

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

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

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

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

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

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

1 “(D) The information shall—

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

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

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

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

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

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

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 effec-
6 tiveness in facilitating consumer selection of healthy
7 product options and the extent to which manufactur-
8 ers are offering healthier products as a result of the
9 disclosure.

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) IN GENERAL.—If, in the case of food other
21 than a dietary supplement, the principal display
22 panel bears—

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

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

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

13 “(2) QUANTITIES.—The Secretary shall by reg-
14 ulation establish quantities below which such dec-
15 laration shall state that the food does not contain
16 any full serving of fruit.

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

25 “(cc) AMOUNT OF VEGETABLES.—

1 “(1) IN GENERAL.—If, in the case of food other
2 than a dietary supplement, the principal display
3 panel bears—

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

5 “(B) representations, depictions, or images
6 of such ingredients; or

7 “(C) any similar descriptive phrases,
8 terms, or representations suggesting the prod-
9 uct contains vegetables or any specific type of
10 vegetable,

11 unless the quantity per serving and form of vege-
12 table, including only the nutrient-dense form, is de-
13 clared on the principal display panel in a common
14 household measure that is appropriate to the food,
15 conspicuously, and in immediate proximity to the
16 most prominent term, representation, depiction, or
17 image of vegetable.

18 “(2) QUANTITIES.—The Secretary shall by reg-
19 ulation establish quantities below which such dec-
20 laration shall state that the food does not contain
21 any full serving of vegetable.

22 “(3) NUTRIENT-DENSE.—In this paragraph,
23 the term ‘nutrient-dense’, with respect to the form
24 of an ingredient derived from a vegetable, means the
25 whole, cut, dried, pulp, puree, 100-percent juice, or

1 fully reconstituted concentrate form, and not con-
2 centrates, powders, and other ingredients that are
3 not whole, cut, dried, pulp, puree, 100-percent juice,
4 or fully reconstituted concentrates.

5 “(dd) AMOUNT OF YOGURT.—

6 “(1) IN GENERAL.—If, in the case of food other
7 than a dietary supplement, the principal display
8 panel bears the term ‘yogurt’, unless—

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

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

17 “(2) QUANTITIES.—The Secretary shall by reg-
18 ulation establish quantities below which such dec-
19 laration shall state that the food does not contain
20 any full serving of yogurt.”.

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

1 “(ee) COLORING AND FLAVORING.—If, in the case of
 2 food other than a dietary supplement, it bears or contains
 3 any artificial dye, or any added artificial or natural fla-
 4 voring, unless such fact is prominently stated on the prin-
 5 cipal display panel of the packaging of the food. For the
 6 purposes of this paragraph, the term ‘artificial dye’ refers
 7 to a batch-certified dye certified under part 74 of title 21,
 8 Code of Federal Regulations (or any successor regula-
 9 tions).”.

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

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

18 (e) CONSTRUCTION.—Nothing in this section, includ-
 19 ing any amendment made by this section, shall be con-
 20 strued as—

21 (1) affecting any requirement in regulation in
 22 effect as of the date of the enactment of this Act
 23 with respect to matters that are required to be stat-
 24 ed on the principal display panel of a package or

1 container of food that is not required by an amend-
 2 ment made by this section; or

3 (2) restricting the authority of the Secretary of
 4 Health and Human Services to require additional in-
 5 formation be disclosed on such a principal display
 6 panel.

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

8 (a) HEALTH-RELATED CLAIMS.—

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

19 (2) SUBSTANTIATION OF CLAIM.—Section
 20 403(r) of the Federal Food, Drug, and Cosmetic Act
 21 (21 U.S.C. 343(r)) is amended—

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

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

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

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

17 (b) NUTRIENT CONTENT CLAIMS.—

18 (1) IN GENERAL.—Section 403(r)(2) of the
 19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 20 343(r)(2)) is amended by striking clause (B) and in-
 21 serting the following:

22 “(B) If a claim described in subparagraph (1)(A) is
 23 made with respect to a nutrient in a food and the Sec-
 24 retary makes a determination that the food contains a nu-
 25 trient at a level that may not be compatible with maintain-

1 ing healthy dietary practices, the label or labeling of such
 2 food shall contain, prominently and in immediate prox-
 3 imity to such claim, a statement which indicates the food
 4 is high in such nutrient.”.

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

10 (A) updating the level of sodium requiring
 11 disclosure to align with the Daily Reference
 12 Value for sodium established in the final rule
 13 entitled “Food Labeling: Revision of the Nutri-
 14 tion and Supplement Facts Labels” published
 15 by the Food and Drug Administration on May
 16 27, 2016 (81 Fed. Reg. 33741);

17 (B) including a level of added sugars re-
 18 quiring disclosure based on the Daily Reference
 19 Value for added sugars established in the final
 20 rule described in subparagraph (A);

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

1 (D) authorizing the use of express and im-
2 plied “low added sugar” claims on products
3 containing 3 grams of added sugars or less per
4 reference amount customarily consumed (or per
5 50 grams if the reference amount customarily
6 consumed is 30 grams or less or 2 tablespoons
7 or less).

8 (c) TRANS FATS.—Section 403(r)(2)(A) of the Fed-
9 eral Food, Drug, and Cosmetic Act (21 U.S.C.
10 343(r)(2)(A)) is amended—

11 (1) by redesignating subclauses (v) and (vi) as
12 subclauses (vi) and (vii), respectively; and

13 (2) by inserting after subclause (iv) the fol-
14 lowing new subclause:

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

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

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

7 (a) USE OF THE TERM “NATURAL”.—

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

11 (A) relating to use of the term “natural”
12 on the labeling of food (other than a dietary
13 supplement);

14 (B) specifically addressing the use of such
15 term on the principal display panel and the in-
16 formation panel; and

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

21 (2) DEFINITION.—The regulations promulgated
22 pursuant to paragraph (1) shall define the term
23 “natural”—

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

4 (B) based on data, including data on con-
5 sumers' understanding of the term as used in
6 connection with food.

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

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

16 (B) fully consider the results of such sur-
17 veys and studies, as well as such public submis-
18 sions.

19 (b) USE OF TERM “HEALTHY”.—

20 (1) ADDED SUGARS AND WHOLE GRAINS.—

21 (A) IN GENERAL.—In promulgating the
22 regulations required by section 18, the Sec-
23 retary of Health and Human Services shall in-
24 clude regulations to revise the regulations under
25 the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 301 et seq.) relating to the use of the
2 term “healthy” on the labeling of a food (other
3 than a dietary supplement) to take into account
4 the extent to which such food contains added
5 sugars or whole grains.

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

13 (2) SODIUM.—In promulgating the regulations
14 required by section 18, the Secretary of Health and
15 Human Services shall 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 term
18 “healthy” on the labeling of a food (other than a di-
19 etary supplement) to align labeling requirements re-
20 lated to sodium with the daily value for sodium in
21 the most recent Dietary Guidelines for Americans.

22 (3) PRINCIPLES FOR IMPLEMENTING REGULA-
23 TIONS.—In promulgating regulations under para-
24 graphs (1) and (2) regarding the use of the term

1 “healthy”, the Secretary of Health and Human
2 Services shall—

3 (A) consider both food and nutrient cri-
4 teria; and

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

7 (i) consider only ingredients that
8 make up the core of a healthy eating pat-
9 tern; and

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

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

17 (a) IN GENERAL.—In promulgating the regulations
18 required by section 18, the Secretary of Health and
19 Human Services shall include requirements for the format
20 of the information required under section 403(i) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 343(i))—

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

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

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

11 (c) **ENFORCEMENT OF INGREDIENT LIST.**—Not later
12 than 2 years after the enactment of this Act, and every
13 2 years thereafter, the Secretary of Health and Human
14 Services shall submit a report to Congress on the Sec-
15 retary’s enforcement of—

16 (1) section 403(i) of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 343(i)), including with
18 respect to the regulations described in subsection
19 (a); and

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

1 **SEC. 6. DECLARATION OF PHOSPHORUS IN THE INGRE-**
 2 **DIENT LIST.**

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

6 “(gg) PHOSPHORUS CONTENT.—If it is a food in-
 7 tended for human consumption that is offered for sale and
 8 contains phosphorus, unless—

9 “(1) the phrase ‘contains phosphorus’, along
 10 with the quantity of phosphorus in the product, re-
 11 ported in milligrams per serving, is printed imme-
 12 diately after or is adjacent to the list of ingredients
 13 required under paragraphs (g) and (i), in a type size
 14 no smaller than the type size used in the list of in-
 15 gredients; or

16 “(2) the quantity of phosphorus contained in
 17 the product, in milligrams, is reported in the Nutri-
 18 tion Facts Panel.”.

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

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

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

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

25 (3) by inserting “, and (4) if the food is food
 26 other than a dietary supplement and contains at

1 least 10 milligrams of caffeine from all sources per
2 serving, a statement (with appropriate prominence
3 near the statement of ingredients required by this
4 paragraph) of the number of milligrams of caffeine
5 contained in one serving of the food and the size of
6 such serving” after “vegetable juice contained in the
7 food”.

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

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

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

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

1 **SEC. 9. INFORMATION ABOUT MAJOR FOOD ALLERGENS**
2 **AND GLUTEN-CONTAINING GRAINS.**

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

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

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

15 (3) in subparagraph (3), by striking “The infor-
16 mation” and inserting “Subject to subparagraph
17 (8)(B), the information”; and

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

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

21 “(A) printed immediately after or adjacent to
22 the list of ingredients (in a type size no smaller than
23 the type size used in the list of ingredients) required
24 under paragraphs (g) and (i); or

25 “(B) in the case of a nonpackaged food being
26 offered for sale at retail, and not subject to the re-

1 requirements of paragraphs (g) and (i), placed on a
 2 sign adjacent to the food (in a type size no smaller
 3 than the name of the food item).”;

4 (5) by inserting “or gluten-containing grain”
 5 after each reference to “food allergen” in subpara-
 6 graphs (1), (2), (4), and (7); and

7 (6) in subparagraph (7)(A)—

8 (A) by striking “paragraph (6)” and in-
 9 serting “subparagraph (6)”; and

10 (B) by striking “allergen labeling require-
 11 ments of this subsection” and inserting “aller-
 12 gen and gluten-containing grain labeling re-
 13 quirements of this paragraph”.

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

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

19 (2) in subsubsection (o)(3)(D), by inserting
 20 “and gluten-containing grain” after “allergen,”.

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

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

3 The Federal Food, Drug, and Cosmetic Act is amend-
 4 ed by inserting after section 403C of such Act (21 U.S.C.
 5 343–3) the following:

6 **“SEC. 403D. SUBMISSION AND AVAILABILITY OF FOOD**
 7 **LABEL INFORMATION.**

8 “(a) SUBMISSIONS.—

9 “(1) REQUIREMENT.—The Secretary shall re-
 10 quire the manufacturer or importer of any food that
 11 is introduced or delivered for introduction into inter-
 12 state commerce in package form to submit to the
 13 Secretary all information to be included in the label
 14 of the food, including—

15 “(A) the nutrition facts panel;

16 “(B) the ingredients list;

17 “(C) an image of the principal display
 18 panel;

19 “(D) major allergens and gluten-containing
 20 grains;

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

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

25 and

1 “(G) other relevant information required
2 by law to be published in the labeling of the
3 food.

4 “(2) UPDATES.—The Secretary shall require
5 the manufacturer or importer of food to update or
6 supplement the information submitted under para-
7 graph (1) with respect to the food in order to keep
8 the information up-to-date and complete.

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

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

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

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

21 **SEC. 11. STANDARDS OF IDENTITY.**

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

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

3 (A) minimum levels of nutrients that the
 4 Secretary determines are strongly associated
 5 with public health concerns; or

6 (B) minimum levels of ingredients con-
 7 taining high levels of such nutrients; and

8 (2) report to the Committee on Energy and
 9 Commerce of the House of Representatives and the
 10 Committee on Health, Education, Labor, and Pen-
 11 sions of the Senate on the findings of such review.

12 (b) AMENDMENTS.—In promulgating the regulations
 13 required by section 18, the Secretary of Health and
 14 Human Services shall amend standards of identity regula-
 15 tions to—

16 (1) provide for the use of salt substitutes where
 17 appropriate; and

18 (2) require that yogurt, lowfat yogurt, and non-
 19 fat yogurt contain a minimum level of live and active
 20 cultures per gram.

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

22 Not later than 2 years after the date of enactment
 23 of this Act, the Secretary of Health and Human Services
 24 shall submit a report to Congress on the effect of the final
 25 rule titled “Food Additives Permitted for Direct Addition

1 to Food for Human Consumption; Folic Acid” published
2 by the Food and Drug Administration on April 15, 2016
3 (81 Fed. Reg. 22176) on folic acid intake in the United
4 States population by race and ethnicity, comparing actual
5 exposure with modeled exposure estimates from the final
6 rule.

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

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

11 “(hh) ALLULOSE, POLYDEXTROSE, SUGAR ALCO-
12 HOLS, AND ISOLATED FIBERS.—If it is a food intended
13 for human consumption that is offered for sale and con-
14 tains allulose, polydextrose, sugar alcohols, or isolated fi-
15 bers, unless such fact is prominently stated on the prin-
16 cipal display panel of the packaging of the food. The Sec-
17 retary shall by regulation establish quantities above which
18 such labeling shall include a warning that the food con-
19 tains a level of allulose, polydextrose, sugar alcohols, or
20 isolated fibers per serving determined by the Secretary to
21 cause deleterious health effects.”.

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

23 In promulgating the regulations required by section
24 18, the Secretary of Health and Human Services shall re-
25 vise—

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

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

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

14 (i) use as its common or usual name
15 a descriptive term such as “milk-based
16 drink”; and

17 (ii) if the beverage contains added
18 sugars, nonnutritive sweeteners, or
19 flavorings, include in such common or
20 usual name a qualifying term such as
21 “sweetened” or “flavored”;

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

1 (i) use as its common or usual name
2 an appropriately descriptive term identi-
3 fying the source of protein, such as “soy-
4 based drink powder for 12–36 month
5 olds”; and

6 (ii) if the beverage contains added
7 sugars, nonnutritive sweeteners, or
8 flavorings, include in such common or
9 usual name qualifying terms such as
10 “sweetened” and “flavored” when applica-
11 ble; and

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

14 (i) contain a disclaimer that—

15 (I) cautions against consumption
16 of the beverage by infants, such as
17 “DO NOT SERVE TO INFANTS
18 UNDER 12 MONTHS OLD”; and

19 (II) such beverages are not rec-
20 ommended for children 12 to 24
21 months of age and such consumption
22 of such beverages is not required for
23 a healthy diet, such as “This product
24 contains added sugars. The Dietary
25 Guidelines for Americans recommend

1 to avoid food and beverages with
 2 added sugars for children younger
 3 than 24 months of age.”; and
 4 (ii) not contain any statement sug-
 5 gesting a recommended intake of such bev-
 6 erages, such as “one cup a day”.

7 **SEC. 15. FORMATTING OF INFORMATION ON PRINCIPAL**
 8 **DISPLAY PANELS.**

9 The Secretary of Health and Human Services shall—
 10 (1) not later than 2 years after the date of en-
 11 actment of this Act, conduct a study on the legibility
 12 of food labeling to determine updated recommenda-
 13 tions for text size and color contrast that make food
 14 labeling information visually accessible to the major-
 15 ity of consumers;
 16 (2) not later than 1 year after the completion
 17 of the study under paragraph (1), issue proposed
 18 regulations revising section 101.2(c) of title 21,
 19 Code of Federal Regulations, to—
 20 (A) set the scale of text size, taking into
 21 consideration the results of the study conducted
 22 under paragraph (1); and
 23 (B) establish new requirements for text
 24 and background color contrast, taking into con-

1 sideration the results of the study conducted
 2 under paragraph (1); and
 3 (3) not later than 2 years after the completion
 4 of the study under paragraph (1), finalize such pro-
 5 posed regulations.

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

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

10 “(ii) SALE OF FOOD ONLINE.—

11 “(1) IN GENERAL.—If it is a food offered for
 12 sale online, unless all information required to appear
 13 on the label or labeling under this section is avail-
 14 able to consumers at the online point of selection
 15 prior to purchasing the food.

16 “(2) FORM AND MANNER.—The Secretary shall
 17 by regulation specify the format and manner in
 18 which the information required under subparagraph
 19 (1) is to be made available online to consumers.

20 “(3) EXEMPTION.—A food shall be exempt
 21 from the requirements of this paragraph if it is a
 22 food that is offered for sale by a retailer with annual
 23 gross sales of not more than \$500,000, or with an-
 24 nual gross sales of foods or dietary supplements to
 25 consumers of not more than \$50,000, so long as

1 such retailers do not provide nutrition information
 2 or make a nutrient content or health claim at the
 3 online point of purchase.”.

4 **SEC. 17. DEFINITIONS.**

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

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

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

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

18 “(2) food or an ingredient that has undergone
 19 chemical changes through the introduction of syn-
 20 thetic chemicals or processing aids (such as corn
 21 syrup, high-fructose corn syrup, high-maltose corn
 22 syrup, maltodextrin, chemically modified starch, and
 23 cocoa processed with alkali), excluding—

24 “(A) food or an ingredient that has under-
 25 gone traditional processes used to make food

1 edible, to preserve food, or to make food safe
2 for human consumption (such as smoking,
3 roasting, freezing, drying, and fermenting proc-
4 esses); or

5 “(B) food or an ingredient that has under-
6 gone traditional physical processes that do not
7 fundamentally alter the raw product or which
8 only separate a whole intact food into compo-
9 nent parts (such as grinding grains, separating
10 eggs into albumen and yolk, or pressing fruits
11 to produce juice); or

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

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

23 “(uu) The term ‘gluten-containing grains’ means any
24 one of the following grains (or any crossbred hybrid there-
25 of):

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

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

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

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

8 “(1) naturally occur in a gluten-containing
9 grain; and

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

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

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

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

20 (a) REGULATIONS.—

21 (1) PROPOSED REGULATIONS.—Not later than
22 1 year after the date of enactment of this Act, the
23 Secretary of Health and Human Services, acting
24 through the Commissioner of Food and Drugs, shall
25 issue proposed regulations to carry out sections 2, 3,

1 4, 5(a), 6, 7, 9, 10, 11, 13, 14, 16, and 17(b) and
2 the amendments made by such sections.

3 (2) FINAL REGULATIONS.—Not later than 2
4 years after the date of enactment of this Act, the
5 Secretary of Health and Human Services, acting
6 through the Commissioner of Food and Drugs, shall
7 finalize the regulations proposed pursuant to para-
8 graph (1).

9 (3) FAILURE TO ISSUE FINAL REGULATION.—If
10 the Secretary of Health and Human Services does
11 not issue a final regulation as required by paragraph
12 (2) by the deadline specified in such paragraph, the
13 corresponding proposed regulation shall become final
14 on such deadline.

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

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