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117TH CONGRESS
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H. R. 4917

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

AUGUST 3, 2021

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

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A BILL

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

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Food Labeling Modernization Act of 2021''.

(b) TABLE OF CONTENTS.—The table of contents of 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.

SEC. 2. ADDITIONAL REQUIREMENTS FOR FRONT-OF-PACKAGE LABELING FOR FOODS.

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

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

''(2) REQUIRED CRITERIA FOR IMPLEMENTING REGULATIONS.—Final regulations regarding the summary nutrition information required under subparagraph (1) shall meet the following criteria:

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

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

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

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

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

''(D) The information shall—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

unless the amounts of whole grains and refined grains, expressed as a percentage of total grains, are conspicuously disclosed in immediate proximity to the most prominent descriptive phrase, term, or representation using a font color and formatting of equivalent prominence to the descriptive phrase, term, or representation with respect to whole grain content, or unless 100 percent of the grains in the food are whole grains.

''(bb) AMOUNT OF FRUIT.—

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

''(A) the term 'fruit', 'fruity', 'froot', 'frooty', or 'fruit-flavored';

''(B) representations, depictions, or images of such ingredients; or

''(C) any similar descriptive phrases, terms, or representations suggesting the product contains fruit or any specific type of fruit, unless the quantity per serving and form of fruit, including only the nutrient-dense forms, is declared on the principal display panel in a common household measure that is appropriate to the food, conspicuously, and in immediate proximity to the most prominent term, representation, depiction, or image of fruit.

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

''(3) In this paragraph, the term 'nutrient-dense', with respect to the form of an ingredient derived from a fruit, means the whole, cut, dried, pulp, puree, 100-percent juice, or fully reconstituted concentrate form, and not concentrates, powders, and other ingredients that are not whole, cut, dried, pulp, puree, 100-percent juice, or fully reconstituted concentrates.

''(cc) AMOUNT OF VEGETABLES.—

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

"(A) the term 'vegetable' or 'veggie';

"(B) representations, depictions, or images of such ingredients; or

"(C) any similar descriptive phrases, terms, or representations suggesting the product contains vegetables or any specific type of vegetable,

unless the quantity per serving and form of vegetable, including only the nutrient-dense form, is declared on the principal display panel in a common household measure that is appropriate to the food, conspicuously, and in immediate proximity to the most prominent term, representation, depiction, or image of vegetable.

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

"(3) In this paragraph, the term 'nutrient-dense', with respect to the form of an ingredient derived from a vegetable, means the whole, cut, dried, pulp, puree, 100-percent juice, or fully reconstituted concentrate form, and not concentrates, powders, and other ingredients that are not whole, cut, dried,

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

''(dd) AMOUNT OF YOGURT.—

''(1) If, in the case of food other than a dietary supplement, the principal display panel bears the term 'yogurt', unless—

''(A) the quantity per serving of yogurt is declared on the principal display panel in a common household measure that is appropriate to the food, conspicuously, in immediate proximity to the term; or

''(B) the first ingredient is cultured milk, cultured cream, cultured partially skimmed milk, or cultured skim milk.

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

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

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

voring, unless such fact is prominently stated on the principal display panel of the packaging of the food. For the purposes of this paragraph, the term 'artificial dye' refers to a batch-certified dye certified under part 74 of title 21, Code of Federal Regulations (or any successor regulations).''.

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

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

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

(1) affecting any requirement in regulation in effect as of the date of the enactment of this Act with respect to matters that are required to be stated on the principal display panel of a package or container of food that is not required by an amendment made by this section; or

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

formation be disclosed on such a principal display panel.

SEC. 3. CLAIMS FOR CONVENTIONAL FOODS.

(a) HEALTH-RELATED CLAIMS.—

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

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

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

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

''(7) If the Secretary requests that a claim under subparagraph (1)(B) for food (other than a dietary supplement) be substantiated, then not later than 90 days after the date on which the Secretary makes such request, the

manufacturer shall provide to the Secretary all documentation in the manufacturer's possession relating to the claim.''.

(3) INCOMPATIBLE WITH MAINTAINING HEALTHY DIETARY PRACTICES.—Section 403(r)(3)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(2)(B)) is amended by striking ''increases to persons in the general population the risk of a disease or health-related condition which is diet related'' and inserting ''may not be compatible with maintaining healthy dietary practices''.

(b) NUTRIENT CONTENT CLAIMS.—

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

''(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that may not be compatible with maintaining healthy dietary practices, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, a statement which indicates the food is high in such nutrient.''.

(2) REVISIONS TO REGULATIONS.—In promulgating the regulations required by section 18, the Secretary of Health and Human Services shall revise section 101.13(h) of title 21, Code of Federal Regulations, by—

(A) updating the level of sodium requiring disclosure to align with the Daily Reference Value for sodium established in the final rule entitled ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' published by the Food and Drug Administration in the Federal Register on May 27, 2016 (81 Fed. Reg. 33742 et seq.);

(B) including a level of added sugars requiring disclosure based on the Daily Reference Value for added sugars established in the final rule referenced in subparagraph (A);

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

(D) authorizing the use of express and implied ''low added sugar'' claims on products containing 3 grams of added sugars or less per

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

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

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

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

''(v) may not be made with respect to the level of trans fats in the food, except on the Nutrition Facts Panel, unless the food contains less than one gram of saturated fat per serving or, if the food contains more than one gram of saturated fat per serving, unless the label or labeling of the food discloses the level of saturated fat in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of trans fats;''.

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

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

SEC. 4. USE OF SPECIFIC TERMS.

(a) USE OF THE TERM ''NATURAL''.—

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

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

(B) specifically addressing the use of such term on the principal display panel and the information panel; and

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

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

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

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

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

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

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

(b) USE OF TERM ''HEALTHY''.—

(1) ADDED SUGARS AND WHOLE GRAINS.—

(A) IN GENERAL.—In promulgating the regulations required by section 18, the Secretary of Health and Human Services shall include regulations to revise the regulations under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) relating to the use of the term ''healthy'' on the labeling of a food (other than a dietary supplement) to take into account

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

(B) REQUIREMENT.—In making the revisions required by subparagraph (A) in the case of a food (other than a dietary supplement) that contains grains, the Secretary of Health and Human Services shall not consider the food to be ''healthy'' unless 100 percent of those grains are whole grains.

(2) SODIUM.—In promulgating the regulations required by section 18, the Secretary of Health and Human Services shall revise the regulations under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) relating to the use of the term ''healthy'' on the labeling of a food (other than a dietary supplement) to align labeling requirements related to sodium with the daily value for sodium in the most recent Dietary Guidelines for Americans.

(3) PRINCIPLES FOR IMPLEMENTING REGULATIONS.—In promulgating regulations under paragraphs (1) and (2) regarding the use of the term ''healthy'', the Secretary of Health and Human Services shall—

(A) consider both food and nutrient criteria; and

(B) if requiring food labeled as ''healthy'' to contain healthful ingredients—

(i) consider only ingredients that make up the core of a healthy eating pattern; and

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

SEC. 5. FORMAT OF INGREDIENT LIST.

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

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

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

(b) FORMAT REQUIREMENTS.—The format requirements referred to in subsection (a) shall include requirements for font size, uppercase and lowercase characters, serif and noncondensed font types, high-contrast between text and background, and bullet points between adjacent ingredients with appropriate exemptions for small packages or other considerations.

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

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

(2) regulations of the Food and Drug Administration on labeling of ingredients in section 101.4 of title 21, Code of Federal Regulations.

SEC. 6. DECLARATION OF PHOSPHORUS IN THE INGREDIENT LIST.

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

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

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

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

SEC. 7. CAFFEINE CONTENT ON INFORMATION PANEL.

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

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

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

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

SEC. 8. FOOD ALLERGEN LABELING.

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

''(3) Any other food ingredient that the Secretary determines by regulation to be a major food allergen, based on the prevalence and severity of allergic reactions to the food ingredient.''.

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

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

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

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

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

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

(4) by adding at the end the following:

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

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

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

(5) by inserting ''or gluten-containing grain'' after each reference to ''food allergen'' in subparagraphs (1), (2), (4), and (7); and

(6) in subparagraph (7)(A)—

(A) by striking ''paragraph (6)'' and inserting ''subparagraph (6)''; and

(B) by striking ''allergen labeling requirements of this subsection'' and inserting ''allergen and gluten-containing grain labeling requirements of this paragraph''.

(b) HAZARD ANALYSIS AND PREVENTIVE CONTROLS.—Section 418 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g) is amended—

(1) in subsection (b)(1)(A), by inserting ''and gluten-containing grains,'' after ''allergens,''; and

(2) in subsubsection (o)(3)(D), by inserting ''and gluten-containing grain'' after ''allergen,''.

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

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

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

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

''(a) SUBMISSIONS.—

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

''(A) the nutrition facts panel;

''(B) the ingredients list;

''(C) an image of the principal display panel;

''(D) major allergens and gluten-containing grains;

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

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

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

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

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

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

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

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

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

SEC. 11. STANDARDS OF IDENTITY.

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

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

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

(B) minimum levels of ingredients containing high levels of such nutrients; and

(2) report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the findings of such review.

(b) AMENDMENTS.—In promulgating the regulations required by section 18, the Secretary of Health and Human Services shall amend standards of identity regulations to—

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

(2) require that yogurt, lowfat yogurt, and nonfat yogurt contain a minimum level of live and active cultures per gram.

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

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

SEC. 13. SUGAR ALCOHOLS AND ISOLATED FIBERS.

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

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

SEC. 14. INFANT AND TODDLER BEVERAGES.

In promulgating the regulations required by section 18, the Secretary of Health and Human Services shall revise—

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

(2) part 102 of title 21, Code of Federal Regulations, so that—

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

(i) use as its common or usual name a descriptive term such as ''milk-based drink''; and

(ii) if the beverage contains added sugars, nonnutritive sweeteners, or flavorings, include in such common or usual name a qualifying term such as ''sweetened'' or ''flavored'';

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

(i) use as its common or usual name an appropriately descriptive term identifying the source of protein, such as ''soy-based drink powder for 12–36 month olds''; and

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

flavorings, include in such common or usual name qualifying terms such as ''sweetened'' and ''flavored'' when applicable; and

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

(i) contain a disclaimer that—

(I) cautions against consumption of the beverage by infants, such as ''DO NOT SERVE TO INFANTS UNDER 12 MONTHS OLD''; and

(II) such beverages are not recommended for children 12 to 24 months of age and such consumption of such beverages is not required for a healthy diet, such as ''This product contains added sugars. The Dietary Guidelines for Americans recommend to avoid food and beverages with added sugars for children younger than 24 months of age.''; and

(ii) not contain any statement suggesting a recommended intake of such beverages, such as ''one cup a day''.

SEC. 15. FORMATTING OF INFORMATION ON PRINCIPAL DISPLAY PANELS.

The Secretary of Health and Human Services shall—

(1) not later than 2 years after the date of enactment of this Act, conduct a study on the legibility of food labeling to determine updated recommendations for text size and color contrast that make food labeling information visually accessible to the majority of consumers;

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

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

(B) establish new requirements for text and background color contrast, taking into consideration the results of the study conducted under paragraph (1); and

(3) not later than 2 years after the completion of the study under paragraph (1), finalize such proposed regulations.

SEC. 16. SALE OF FOOD ONLINE.

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

''(ii) SALE OF FOOD ONLINE.—

''(1) If it is a food offered for sale online, unless all information required to appear on the label or labeling under this section is available to consumers at the online point of selection prior to purchasing the food.

''(2) The Secretary shall by regulation specify the format and manner in which the information required under subparagraph (1) is to be made available online to consumers.

''(3) Foods shall be exempt from the requirements of this paragraph if they are foods that are offered for sale by a retailer with annual gross sales of not more than $500,000, or with annual gross sales of foods or dietary supplements to consumers of not more than $50,000, so long as such retailers do not provide nutrition information or make a nutrient content or health claim at the online point of purchase.''.

SEC. 17. DEFINITIONS.

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

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

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

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

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

''(2) food or an ingredient that has undergone chemical changes through the introduction of synthetic chemicals or processing aids (such as corn syrup, high-fructose corn syrup, high-maltose corn syrup, maltodextrin, chemically modified starch, and cocoa processed with alkali), excluding—

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

''(B) food or an ingredient that has undergone traditional physical processes that do not

fundamentally alter the raw product or which only separate a whole intact food into component parts (such as grinding grains, separating eggs into albumen and yolk, or pressing fruits to produce juice); or

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

''(tt) The term 'synthetic', with respect to a substance in food or any ingredient of food, means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal, or mineral source, except that such term does not apply to a substance created by naturally occurring biological processes.

''(uu) The term 'gluten-containing grains' means any one of the following grains (or any crossbred hybrid thereof):

''(1) Wheat, including any species belonging to the genus Triticum.

''(2) Rye, including any species belonging to the genus Secale.

''(3) Barley, including any species belonging to the genus Hordeum.

''(vv) The term 'gluten' means the proteins that—

''(1) naturally occur in a gluten-containing grain; and

''(2) may cause adverse health effects in persons with celiac disease.

''(ww) The term 'online' means on or by any system of data communication and transmission, such as the internet.

''(xx) The term 'online point of selection' means any space in which consumers are allowed to purchase food online, including websites, e-commerce platforms, web applications, and mobile applications.''.

SEC. 18. REGULATIONS; DELAYED APPLICABILITY.

(a) REGULATIONS.—

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

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

finalize the regulations proposed pursuant to paragraph (1).

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

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

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