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H. R. 4432

To amend the Federal Food, Drug, and Cosmetic Act with respect to food produced from, containing, or consisting of a bioengineered organism, the labeling of natural foods, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 9, 2014

Mr. POMPEO (for himself, Mr. BUTTERFIELD, Mr. MATHESON, Mrs. BLACKBURN, and Mr. WHITFIELD) 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 with respect to food produced from, containing, or consisting of a bioengineered organism, the labeling of natural foods, 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.

This Act may be cited as the ''Safe and Accurate Food Labeling Act of 2014''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.
Sec. 3. Ensuring safety of food supply.

TITLE I—FOOD PRODUCED FROM, CONTAINING, OR CONSISTING OF A BIOENGINEERED ORGANISM

Sec. 101. Definitions.
Sec. 102. Mandatory premarket biotechnology notification program.
Sec. 103. Labeling of whether food is bioengineered.
Sec. 104. Preemption.

TITLE II—NATURAL FOODS

Sec. 201. Labeling of natural foods.
Sec. 202. Regulations.
Sec. 203. Preemption.
Sec. 204. Effective date.

SEC. 3. ENSURING SAFETY OF FOOD SUPPLY.

Nothing in this Act (or the amendments made by this Act) is intended to alter or affect the authorities or regulatory programs, policies, and procedures otherwise available to the Food and Drug Administration to ensure the safety of the food supply under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

TITLE I—FOOD PRODUCED FROM, CONTAINING, OR CONSISTING OF A BIOENGINEERED ORGANISM

SEC. 101. DEFINITIONS.

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 'bioengineered organism' refers to an organism if—

''(1) the organism is a plant (or a seed, a fruit, or any other part thereof);

''(2) the organism contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and

''(3) the modification could not otherwise be obtained using conventional breeding techniques.''.

SEC. 102. MANDATORY PREMARKET BIOTECHNOLOGY NOTIFICATION PROGRAM.

(a) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(ddd) The initial introduction or delivery for introduction in interstate commerce of a bioengineered organism intended for a food use or application, unless the developer of the organism has complied with the notification requirements, to the extent applicable, under section 424.''.

(b) NOTIFICATION PROGRAM.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 424. NOTIFICATION RELATING TO CERTAIN BIOENGINEERED ORGANISMS.

''(a) IN GENERAL.—A bioengineered organism shall not be introduced or delivered for introduction into interstate commerce for a food use or application unless—

''(1) the use or application of the bioengineered organism in food has been addressed by the developer of the bioengineered organism in a premarket biotechnology notification, to which the Secretary has responded under subsection (d)(2)(A) by stating no objections; or

''(2)(A) food produced from, containing, or consisting of the bioengineered organism was evaluated by the Secretary pursuant to the Food and Drug Administration's voluntary consultation process for foods and food products from genetically engineered plants in effect prior to the date of enactment of the Safe and Accurate Food Labeling Act of 2014; and

''(B) the Secretary informed the developer of the bioengineered organism that all questions about safety have been resolved.

''(b) EXCEPTIONS.—This section does not apply with respect to the introduction or delivery for introduction into interstate commerce of a bioengineered organism—

''(1) for the purpose of development or testing conducted to generate data and information that

could be used in a premarket biotechnology notification or other regulatory submission; or

''(2) solely because—

''(A) a processing aid or enzyme produced from the bioengineered organism is intended to be used to produce food; or

''(B) food produced from, containing, or consisting of the bioengineered organism is intended to be fed to an animal from which food is intended to be produced or derived.

''(c) PREMARKET BIOTECHNOLOGY NOTIFICATION.—

''(1) SUBMISSION.—At least 210 days before a bioengineered organism is first introduced or delivered for introduction into interstate commerce for a food use or application, a premarket biotechnology notification shall be submitted to the Secretary by the developer of the bioengineered organism. Such notification shall provide—

''(A) the basis for the notifier's determination that food produced from, containing, or consisting of such bioengineered organism is as safe for use by humans or animals, as applicable, as one or more comparable marketed foods that are not produced from, do not contain, or

do not consist of such bioengineered organism; and

"(B) whether any other Federal agency is conducting or has conducted any review of the bioengineered organism and the status or conclusions of any such review.

"(2) CONSULTATION PRIOR TO SUBMISSION.—A prospective notifier may consult informally with the Secretary concerning a bioengineered organism intended for a food use or application before submitting a premarket biotechnology notification.

"(d) RESPONSE TO A PREMARKET BIOTECHNOLOGY NOTIFICATION.—

"(1) PRELIMINARY RESPONSE.—Within 30 days of receipt of a premarket biotechnology notification, the Secretary shall—

"(A) inform the notifier in writing that the notification is complete and has been filed; or

"(B) inform the notifier in writing of any missing elements that prevent the Secretary from filing and reviewing the notification.

The Secretary shall limit any request under subparagraph (B) to data or information necessary to perform the evaluation specified in paragraph (2) and

shall not delay informing the notifier under paragraph (1)(A) for any other purpose.

"(2) SUBSTANTIVE RESPONSE.—Within 180 days of the Secretary informing the notifier under paragraph (1)(A) that the premarket biotechnology notification is complete, the Secretary—

"(A) shall respond in writing to the notifier that the Secretary has evaluated the notification and has no objections to the notifier's determination that food produced from, containing, or consisting of the bioengineered organism that is the subject of the notification is as safe for use by humans or animals, as applicable, as one or more comparable marketed foods that are not produced from, do not contain, or do not consist of such bioengineered organism; or

"(B) shall—

"(i) respond in writing to the notifier that the Secretary has evaluated the notification and has determined the notification does not provide an adequate basis for the notifier's determination; and

"(ii) include in such response the Secretary's basis for the Secretary's determination.

"(3) WITHDRAWAL BY NOTIFIER.—At any point before receiving a written response from the Secretary under subparagraph (A) or (B) of paragraph (2), the notifier may withdraw a premarket biotechnology notification without prejudice as to any future notifications.

"(4) EFFECTIVE DATE.—A notification submitted under subsection (c) shall become effective on the date that is 180 days after the Secretary informs the notifier under paragraph (1)(A) that the notification is complete, and as of such date the bioengineered organism that is the subject of the notification may be introduced or delivered for introduction into interstate commerce, unless the Secretary provides a response under paragraph (2)(B).

"(e) LABELING.—If the Secretary determines that there is a material difference between a food produced from, containing, or consisting of a bioengineered organism and its comparable marketed food and that disclosure of such difference is necessary to protect health and safety or to prevent the label or labeling of such food from being false or misleading, the Secretary may, in a response

under subsection (d)(2)(A), specify labeling that would adequately inform consumers of such material difference. The use of bioengineering does not, by itself, constitute a material difference.

''(f) PUBLIC DISCLOSURE.—The existence and contents of a premarket biotechnology notification shall be made available to the public as of the date the Secretary issues a written response under subsection (d)(2)(A), subject to review by the Secretary pursuant to the provisions on exemptions from disclosure under chapter 5 of title 5, United States Code.

''(g) DEFINITIONS.—In this section:

''(1)(A) The term 'comparable marketed food' means, with respect to the food produced from, containing, or consisting of a plant that is a bioengineered organism—

''(i) the parental variety of the plant;

''(ii) another commonly consumed variety of the plant; or

''(iii) a plant variety from which is derived a commonly consumed food with properties comparable to the food produced from, containing, or consisting of the plant that is a bioengineered organism.

''(B) A food produced from, containing, or consisting of a bioengineered organism may have more than one comparable marketed food.

''(2) The term 'notifier' means the person who submits a premarket biotechnology notification.

''(3) The term 'premarket biotechnology notification'—

''(A) means a submission to the Secretary under subsection (c); and

''(B) includes all scientific data and other information in the original submission and in any amendments to the original submission.

''(4) The term 'material difference' means a difference that—

''(A) significantly alters the characteristics, including the functional or compositional characteristics, of a food, such that the common or usual name no longer adequately describes the food;

''(B) results in a significantly different nutritional property in the food produced from, containing, or consisting of the bioengineered organism; or

''(C) results in the food containing an allergen that consumers would not expect to be present based upon the name of the food.''.

(c) APPLICABILITY.—The amendments made by this section apply beginning on the date that is 30 days after the date of enactment of this Act, irrespective of whether regulations or guidance have been finalized or issued by such date to carry out such amendments.

(d) PENDING SUBMISSIONS.—The Secretary shall—

(1) deem to be a premarket biotechnology notification under section 424 of the Federal Food, Drug, and Cosmetic Act, as added by this section, any submission that—

(A) is pending as of the date of enactment of this Act; and

(B) is for voluntary consultation with respect to food produced from, containing, or consisting of a bioengineered organism (as such term is used in section 301(ddd) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)); and

(2) evaluate such notifications expeditiously.

(e) PREEMPTION.—Section 403A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–2(a)) is amended—

(1) by striking ''or'' at the end of paragraph (4);

(2) by striking the period at the end of paragraph (5) and inserting a comma; and

(3) by adding at the end the following:

''(6) any requirement respecting, prohibition against, or restriction on, the sale, distribution, or marketing of—

''(A) a bioengineered organism intended for a food use or application, or

''(B) food produced from, containing, or consisting of a bioengineered organism, as such term is used in section 301(ddd), or''.

(f) TECHNICAL CORRECTIONS.—Section 403A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–1) is amended—

(1) by striking the section designation and enumerator and all that follows through ''(a) Except'' and inserting the following:

''SEC. 403A. STATE REQUIREMENTS.

''(a) IN GENERAL.—Except''; and

(2) in subsection (b), by striking ''(b) Upon petition'' and inserting the following:

''(b) PETITIONS FOR EXEMPTIONS.—Upon petition''.

SEC. 103. LABELING OF WHETHER FOOD IS BIOENGINEERED.

(a) MISBRANDING.—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) If it bears labeling (indicating that bioengineering was or was not used in the production of the food) in violation of section 425.''.

(b) LABELING REQUIREMENTS.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.), as amended by section 102 of this Act, is further amended by adding at the end the following:

''SEC. 425. LABELING OF WHETHER FOOD IS BIOENGINEERED.

''(a) CLAIMS THAT BIOENGINEERING WAS NOT USED.—

''(1) IN GENERAL.—If a claim in the labeling of food indicates, directly or indirectly, that bioengineering was not used in the production of the food, such claim shall be subject to this subsection.

''(2) REQUIREMENTS.—A claim described in paragraph (1)—

''(A) may be made only if the food bearing the claim is comprised of ingredients subject to supply chain process controls that address—

"(i) the producer planting a seed developed by means other than through the use of bioengineering;

"(ii) the producer keeping the crop separated during growth, harvesting, storage, and transportation; and

"(iii) persons in direct contact with such crop or foods derived from such crop during transportation, storage, or processing keeping the product separated from foods or food ingredients derived through bioengineering;

"(B) may be made for a food produced in accordance with subparagraph (A) in which food produced from, containing, or consisting of a bioengineered organism is inadvertently present;

"(C) may not suggest either expressly or by implication that foods developed without the use of bioengineering are safer than foods produced from, containing, or consisting of a bioengineered organism;

"(D) may be made on dairy products derived from cows or other milk-producing animals, on shell eggs derived from chickens and

other birds, and on products consisting of or derived from fish or animals (that are under the jurisdiction of the Food and Drug Administration) that consumed feed or a feed ingredient, or received a drug or biological product, that—

''(i) was developed with the use of bioengineering; and

''(ii) has been authorized for such use by the Secretary;

''(E) may be made on a food produced with a bioengineered processing aid or enzyme; and

''(F) shall comply with any other requirements established by the Secretary by regulation to ensure that the food's labeling is not false or misleading.

''(3) REGULATIONS.—

''(A) IN GENERAL.—The Secretary shall promulgate regulations to carry out this section. Such regulations shall specify a maximum permissible level of food produced from, containing, or consisting of a bioengineered organism that may be inadvertently present in food bearing claims under paragraph (1).

''(B) SEPARATE CATEGORIES.—Such regulations may specify different permissible levels for separate categories of food.

''(C) CLAIMS PRIOR TO FINALIZATION OF REGULATIONS.—This section does not limit the ability of persons to make claims described in paragraph (1) before the finalization of regulations under this paragraph.

''(D) INITIAL REGULATIONS.—The Secretary shall promulgate final regulations under this paragraph not later than 24 months after the date of enactment of the Safe and Accurate Food Labeling Act of 2014.

''(b) CLAIMS THAT BIOENGINEERING WAS USED.—

''(1) IN GENERAL.—If a claim in the labeling of food indicates, directly or indirectly, that bioengineering was used in the production of the food, such claim shall be subject to this subsection.

''(2) REGULATIONS.—A claim described in paragraph (1) may be made only in accordance with regulations promulgated by the Secretary. Such regulations—

''(A) shall not require the labeling to declare the use of bioengineering solely because

the food was developed with the use of bioengineering;

''(B) shall not allow the labeling to expressly or impliedly claim that food developed with the use of bioengineering is safer solely because the food is a food developed with the use of bioengineering;

''(C) shall allow any claims which the Secretary deems necessary under section 424(e); and

''(D) may contain other requirements established by the Secretary to ensure that the food's labeling is not false or misleading.

''(3) PROHIBITION AGAINST RESTRICTING CERTAIN DISCLOSURES.—The regulations under this subsection shall not prevent a person—

''(A) from disclosing voluntarily on the labeling of food developed with the use of bioengineering the manner in which the food has been modified to express traits or characteristics that differ from its comparable marketed food (as defined in section 424); or

''(B) from disclosing in advertisements, on the Internet, in response to consumer inquiries, or on other communications, other than in the

labeling, that a food was developed with the use of bioengineering.

''(c) DEFINITION.—The term 'bioengineered organism' means a bioengineered organism, as such term is used in section 301(ddd).''.

SEC. 104. PREEMPTION.

(a) IN GENERAL.—Section 403A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–2(a)) is amended by adding at the end the following:

''(7) any requirement for the labeling of food of the type described in subsection (a)(1) or (b)(1) of section 425 that is not identical to the requirement of such section, or''.

(b) PROHIBITION AGAINST MANDATORY LABELING.—Section 403A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–1) is amended by adding at the end the following:

''(c) PROHIBITIONS AGAINST MANDATORY LABELING OF FOOD DEVELOPED USING BIOENGINEERING.—Except for claims under subsection (a)(1) or (b)(1) of section 425, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement for the labeling of a food by virtue of its having been developed using bioengineering, including any require-

ments for claims that a food is or contains an ingredient that was developed using bioengineering.''.

TITLE II—NATURAL FOODS

SEC. 201. LABELING OF NATURAL FOODS.

Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343), as amended by section 103 of this Act, is further amended by adding at the end the following:

''(aa)(1) If its labeling contains an express or implied claim that the food is 'natural' unless the claim is made in accordance with subparagraph (2).

''(2) A claim described in subparagraph (1) may be made only if the claim uses terms that have been defined by, and the food meets the requirements that have been established in, regulations promulgated to carry out this paragraph.

''(3) Notwithstanding subparagraph (2), prior to the finalization of regulations to carry out this paragraph, the use of any claim that a food is 'natural' shall be allowed if consistent with the Secretary's existing policy for such claims.

''(4) In promulgating regulations to carry out this paragraph, the Secretary shall differentiate between food for human consumption and food intended for consumption by animals other than humans.

"(5) For purposes of subparagraph (1), a natural claim includes the use of—

"(A) the terms 'natural', '100% natural', 'naturally grown', 'all natural', and 'made with natural ingredients'; and

"(B) any other terms specified by the Secretary.".

SEC. 202. REGULATIONS.

(a) PROPOSED REGULATIONS.—Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(aa) of the Federal Food, Drug, and Cosmetic Act, as added by section 201 of this Act.

(b) FINAL REGULATIONS.—Not later than 24 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final regulations to implement such section 403(aa).

SEC. 203. PREEMPTION.

Section 403A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–1(a)), as amended by section 104 of this Act, is further amended by adding at the end the following:

''(8) any requirement for the labeling of food of the type required by section 403(aa) that is not identical to the requirement of such section.''.

SEC. 204. EFFECTIVE DATE.

The labeling requirements of section 403(aa) of the Federal Food, Drug, and Cosmetic Act, as added by section 201 of this Act, shall take effect on the effective date of final regulations promulgated under section 202(b) of this Act. The provisions of section 403A(a)(8) of the Federal Food, Drug, and Cosmetic Act, as added by section 203 of this Act, take effect on the date of enactment of this Act.

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