114TH CONGRESS
1ST SESSION

S. 511

To amend the Federal Food, Drug, and Cosmetic Act to require that genetically engineered food and foods that contain genetically engineered ingredients be labeled accordingly.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2015

Mrs. BOXER (for herself, Mr. LEAHY, Mr. SANDERS, Mr. BLUMENTHAL, Mrs. FEINSTEIN, Mr. MURPHY, Mr. MERKLEY, Ms. MIKULSKI, Mr. REED, Mrs. SHAHEEN, Mr. HEINRICH, Ms. WARREN, Mr. TESTER, and Mr. BOOKER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that genetically engineered food and foods that contain genetically engineered ingredients be labeled accordingly.

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 ''Genetically Engineered Food Right-to-Know Act''.

SEC. 2. PURPOSE AND FINDINGS.

(a) PURPOSE.—The purposes of this Act are to—

(1) establish a consistent and enforceable standard for labeling of foods produced using genetic engineering, thereby providing consumers with knowledge of how their food is produced; and

(2) prevent consumer confusion and deception by prohibiting the labeling of products produced from genetic engineering as ''natural'', and by promoting the disclosure of factual information on food labels to allow consumers to make informed decisions.

(b) FINDINGS.—Congress finds that—

(1) the process of genetically engineering food organisms results in material changes and the fact that foods are genetically engineered is of material importance to consumers;

(2) the Food and Drug Administration requires the labeling of more than 3,000 ingredients, additives, and processes;

(3) individuals in the United States have a right to know if their food was produced with genetic engineering for a variety of reasons, including health, economic, environmental, religious, and ethical;

(4) more than 60 countries, including the United Kingdom and all other countries of the Euro-

pean Union, South Korea, Japan, Brazil, Australia, India, China, and other key United States trading partners have laws or regulations mandating disclosure of genetically engineered food on food labels;

(5) in 2011, Codex Alimentarius, the food standards organization of the United Nations, adopted a text that indicates that governments can decide on whether and how to label foods produced with genetic engineering;

(6) mandatory identification of food produced with genetic engineering can be a critical method of preserving the economic value of exports or domestically sensitive markets with labeling requirements for genetically engineered foods; and

(7) the cultivation of genetically engineered crops can have adverse effects on the environment in the form of cross-pollination of native plants, increased herbicide usage, and impacts on non-target and beneficial organisms, including the Monarch butterfly.

SEC. 3. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) IN GENERAL.—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) If it is a food that has been genetically engineered or contains 1 or more genetically engineered ingredients, unless the ingredients label clearly states that the food has been genetically engineered or identifies any genetically engineered ingredients, as applicable.

''(2) This paragraph does not apply to food that—

''(A) is served in restaurants or other similar eating establishments, such as cafeterias and carryouts;

''(B) is a medical food (as defined in section 5(b) of the Orphan Drug Act);

''(C) would be subject to this paragraph solely because it was produced using a genetically engineered vaccine or drug;

''(D) is a food or processed food that would be subject to this paragraph solely because it includes the use of a genetically engineered processing aid (including yeast) or enzyme; or

''(E) is a packaged food consisting of materials produced through genetic engineering that do not account for more than nine-tenths of 1 percent of the total weight of the packaged food.

''(3) In this paragraph and in paragraph (aa):

''(A) The term 'genetic engineering' means a process—

"(i) involving the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles;

"(ii) involving the application of fusion of cells beyond the taxonomic family; or

"(iii) that overcomes natural physiological, reproductive, or recombinant barriers and that is not a process used in traditional breeding and selection.

"(B) The term 'genetically engineered', used with respect to a food, means a material intended for human consumption that is—

"(i) an organism that is produced through the intentional use of genetic engineering; or

"(ii) the progeny of intended sexual or asexual reproduction (or both) of 1 or more organisms that is the product of genetic engineering.

"(C) The term 'genetically engineered ingredient' means a material that is an ingredient in a food that is derived from any part of an organism that has been genetically engineered, without regard to whether—

''(i) the altered molecular or cellular characteristics of the organism are detectable in the material; and

''(ii) the organism is capable for use as human food.''.

(b) RESTRICTIONS ON THE TERM ''NATURAL''.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343), as amended by subsection (a), is further amended by adding at the end the following:

''(aa) If it is a food intended for human consumption that has been produced using genetic engineering or that contains one or more genetically engineered ingredients and it bears a label, or for which there is signage or advertising, containing a claim that the food is 'natural', 'naturally made', 'naturally grown', 'all natural', or using any similar words that would be misleading to a consumer.''.

(c) GUARANTY.—

(1) IN GENERAL.—Section 303(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(d)) is amended—

(A) by striking ''(d)'' and inserting ''(d)(1)''; and

(B) by adding at the end the following:

''(2)(A) No person shall be subject to the penalties of subsection (a)(1) for a violation of sub-

section (a), (b), or (c) of section 301 involving food that is misbranded within the meaning of paragraph (z) or (aa) of section 403 if such person (referred to in this paragraph as the 'recipient') establishes a guaranty or undertaking that—

"(i) is signed by, and contains the name and address of, a person residing in the United States from whom the recipient received in good faith the food (including the receipt of seeds to grow raw agricultural commodities); and

"(ii) contains a statement to the effect that the food is not genetically engineered or does not contain a genetically engineered ingredient.

"(B) In the case of a recipient who, with respect to a food, establishes a guaranty or undertaking in accordance with subparagraph (A), the exclusion under such subparagraph from being subject to penalties applies to the recipient without regard to the manner in which the recipient uses the food, including whether the recipient is—

"(i) processing the food;

"(ii) using the food as an ingredient in a food product;

"(iii) repacking the food; or

''(iv) growing, raising, or otherwise producing the food.

''(C) No person may avoid responsibility or liability for a violation of subsection (a), (b), or (c) of section 301 involving food that is misbranded within the meaning of paragraph (z) or (aa) of section 403 by entering into a contract or other agreement that specifies that another person shall bear such responsibility or liability, except that a recipient may require a guaranty or undertaking as described in this subsection.

''(D) For purposes of this Act, food will be considered not to have been produced with the knowing or intentional use of genetic engineering if—

''(i) such food is lawfully certified to be labeled, marketed, and offered for sale as 'organic' pursuant to the Organic Foods Production Act of 1990; or

''(ii) an independent organization has determined that the food has not been knowingly or intentionally genetically engineered and has been segregated from, and not knowingly or intentionally commingled with, foods that may have been genetically engineered at any time, if

such a determination has been made pursuant to a sampling and testing procedure that—

"(I) is consistent with sampling and testing principles recommended by internationally recognized standards organizations; and

"(II) does not rely on testing processed foods in which no DNA is detectable.

"(E) In this subsection, the terms 'genetically engineered' and 'genetically engineered ingredient' have the meanings given the terms in section 403(z).".

(2) FALSE GUARANTY.—Section 301(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(h)) is amended by inserting "or 303(d)(2)" after "section 303(c)(2)".

(d) UNINTENDED CONTAMINATION.—Section 303(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(d)), as amended by subsection (b), is further amended by adding at the end the following:

"(3)(A) No person shall be subject to the penalties of subsection (a)(1) for a violation of subsection (a), (b), or (c) of section 301 involving food that is misbranded within the meaning of section 403(z) if—

"(i) such person is an agricultural producer and the violation occurs because food that is grown, raised, or otherwise produced by such producer, which food does not contain a genetically engineered material and was not produced with a genetically engineered material, is contaminated with a food that contains a genetically engineered material or was produced with a genetically engineered material; and

"(ii) such contamination is not intended by the agricultural producer.

"(B) Subparagraph (A) does not apply to an agricultural producer to the extent that the contamination occurs as a result of the negligence of the producer.".

(e) PROMULGATION OF REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary shall promulgate proposed regulations establishing labeling requirements for compliance in accordance with section 403(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

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