114TH CONGRESS 2D Session



To amend the Federal Food, Drug, and Cosmetic Act with respect to genetically engineered food transparency and uniformity.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to genetically engineered food transparency and uniformity.

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.

- 4 This Act may be cited as the "Biotechnology Food
- 5 Labeling Uniformity Act".

6 SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND 7 COSMETIC ACT.

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

 $\mathbf{2}$

"(z)(1) If the food or an ingredient of the food is
 produced or derived from genetic engineering, unless it
 bears labeling stating that fact in accordance with para graphs (3) and (4).

5 "(2) The provisions of this paragraph shall not6 apply—

7 "(A) if it is a processed food and the ingredi-8 ents produced from genetic engineering do not, in 9 the aggregate, account for more than nine-tenths of 10 1 percent of the total weight of the processed food; 11 "(B) if the food would be subject to this para-12 graph solely because a genetically engineered vaccine 13 was used at any point in the production of the food 14 or the life cycle of its agricultural inputs; or

15 "(C) if it is a food or processed food that would 16 be subject to this paragraph solely because it was 17 produced using a processing aid (including yeast) or 18 enzyme that was produced or derived from genetic 19 engineering.

"(3) In the case of a food that is not a food described
in paragraph (4), a producer shall meet the labeling requirement under this paragraph by inserting either—

23 "(A) the words 'genetically engineered' in pa24 renthesis immediately following the common or usual
25 name of each genetically engineered ingredient;

BOM16194

S.L.C.

3

"(B) an asterisk next to the common or usual
name of each genetically engineered ingredient with
a statement, in a font size no smaller than the words
'Ingredient List', at the bottom of the ingredient list
that denotes that the ingredient or ingredients are
genetically engineered;

"(C) a statement, established by the Secretary
of Health and Human Services, at the bottom of the
ingredient list (or if there is no such ingredient list,
on the information panel of the food) that would disclose that the food is produced or partially produced
with genetic engineering or contains genetically engineered ingredients; or

14 "(D) a symbol, established by the Secretary, 15 that would disclose the presence of a genetically en-16 gineered ingredient or genetically engineered ingredi-17 ents in the food in a clear and conspicuous manner. 18 "(4) In the case of a food or an ingredient of a food that is produced or derived from genetic engineering and 19 20 is a raw agricultural commodity either unpackaged or 21 packaged for retail sale, the producer complies with label-22 ing regulations established by the Secretary of Health and 23 Human Services, in consultation with the Secretary of Agriculture. 24

4

1 "(5) For purposes of this paragraph, whether a food 2 or ingredient of a food was produced or derived from a 3 genetically engineered plant variety or animal shall, by 4 itself, constitute information that is material within the 5 meaning of section 201(n).".

6 SEC. 3. REGULATIONS.

7 (a) INTERIM RULE.—Not later than December 31,
8 2016, the Secretary of Health and Human Services shall
9 issue an interim final rule regarding the implementation
10 of section 403(z) of the Federal Food, Drug, and Cosmetic
11 Act, as added by section 2 of this Act.

(b) PROPOSED REGULATIONS.—Not later than 18
months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue proposed
regulations to implement section 403(z) of the Federal
Food, Drug, and Cosmetic Act, as added by section 2 of
this Act, which shall—

18 (1) include definitions of all relevant terms in19 such section 403(z);

20 (2) be based on existing Federal regulations,
21 State law, and international standards; and

22 (3) be updated as needed.

23 (c) FINAL REGULATIONS.—Not later than 24 months24 after the date of enactment of this Act, the Secretary of

BOM16194

5

Health and Human Services shall issue final regulations
 described in subsection (b).

3 SEC. 4. FEDERAL PREEMPTION.

4 (a) IN GENERAL.—No State or political subdivision
5 of a State shall impose different or additional require6 ments to state the presence of the same genetically engi7 neered food or ingredients covered by this Act under the
8 laws, regulations, requirements, or standards of such
9 State or political subdivision of a State.

10 (b) SCOPE.—Nothing in this Act, nor any amend-11 ment, regulation, rule, or requirement promulgated pursu-12 ant to this Act, shall be construed to preempt or otherwise 13 affect the authority of a State or political subdivision of a State to enforce any action taken or requirement im-14 15 posed pursuant to the authority of a State, political subdivision of a State, or local law, regulation, requirement 16 17 or standard that otherwise relates to food labeling and is not described in subsection (a). 18

(c) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION.—Nothing in this Act, nor any
amendment, regulation, rule, or requirement promulgated
pursuant to this Act, shall be construed to preempt, displace, or supplant any State or Federal common law rights
or any State or Federal statute creating a remedy for civil

BOM16194

- 1 relief, including those for civil damage, or a penalty for
- 2 a criminal conduct.