

114TH CONGRESS  
2D SESSION

# S. 2621

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

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IN THE SENATE OF THE UNITED STATES

MARCH 2, 2016

Mr. MERKLEY (for himself, Mr. LEAHY, Mr. TESTER, Mrs. FEINSTEIN, and  
Mr. SANDERS) introduced the following bill; which was read twice and re-  
ferred to the Committee on Health, Education, Labor, and Pensions

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## 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”.

1 **SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**  
2 **COSMETIC ACT.**

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

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

10 “(2) The provisions of this paragraph shall not  
11 apply—

12 “(A) if it is a processed food and the ingredi-  
13 ents produced from genetic engineering do not, in  
14 the aggregate, account for more than nine-tenths of  
15 1 percent of the total weight of the processed food;

16 “(B) if the food would be subject to this para-  
17 graph solely because a genetically engineered vaccine  
18 was used at any point in the production of the food  
19 or the lifecycle of its agricultural inputs; or

20 “(C) if it is a food or processed food that would  
21 be subject to this paragraph solely because it was  
22 produced using a processing aid (including yeast) or  
23 enzyme that was produced or derived from genetic  
24 engineering.

1       “(3) In the case of a food that is not a food described  
2 in paragraph (4), a producer shall meet the labeling re-  
3 quirement under this paragraph by inserting either—

4           “(A) the words ‘genetically engineered’ or the  
5 abbreviation ‘GE’ in parenthesis immediately fol-  
6 lowing the common or usual name of each geneti-  
7 cally engineered ingredient;

8           “(B) an asterisk next to the common or usual  
9 name of each genetically engineered ingredient with  
10 a statement, in a font size no smaller than the words  
11 ‘Ingredient List’, at the bottom of the ingredient list  
12 that denotes that the ingredient or ingredients are  
13 genetically engineered;

14           “(C) a statement, established by the Secretary  
15 of Health and Human Services, at the bottom of the  
16 ingredient list (or if there is no such ingredient list,  
17 on the information panel of the food) that would dis-  
18 close that the food is produced or partially produced  
19 with genetic engineering or contains genetically engi-  
20 neered ingredients; or

21           “(D) a symbol, established by the Secretary,  
22 that would disclose the presence of a genetically en-  
23 gineered ingredient or genetically engineered ingredi-  
24 ents in the food in a clear and conspicuous manner.

1       “(4) In the case of a food or an ingredient of a food  
2 that is produced or derived from genetic engineering and  
3 is a raw agricultural commodity either unpackaged or  
4 packaged for retail sale, the producer complies with label-  
5 ing regulations established by the Secretary of Health and  
6 Human Services, in consultation with the Secretary of Ag-  
7 riculture.

8       “(5) For purposes of this paragraph, whether a food  
9 or ingredient of a food was produced or derived from a  
10 genetically engineered plant variety or animal shall, by  
11 itself, constitute information that is material within the  
12 meaning of section 201(n).”.

13 **SEC. 3. REGULATIONS.**

14       (a) INTERIM RULE.—Not later than December 31,  
15 2016, the Secretary of Health and Human Services shall  
16 issue an interim final rule regarding the implementation  
17 of section 403(z) of the Federal Food, Drug, and Cosmetic  
18 Act, as added by section 2 of this Act.

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

1           (1) include definitions of all relevant terms in  
2           such section 403(z);

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

5           (3) be updated as needed.

6           (c) FINAL REGULATIONS.—Not later than 24 months  
7           after the date of enactment of this Act, the Secretary of  
8           Health and Human Services shall issue final regulations  
9           described in subsection (b).

10 **SEC. 4. FEDERAL PREEMPTION.**

11           (a) IN GENERAL.—No State or political subdivision  
12           of a State shall impose different or additional require-  
13           ments to state the presence of the same genetically engi-  
14           neered food or ingredients covered by this Act under the  
15           laws, regulations, requirements, or standards of such  
16           State or political subdivision of a State.

17           (b) SCOPE.—Nothing in this Act, nor any amend-  
18           ment, regulation, rule, or requirement promulgated pursu-  
19           ant to this Act, shall be construed to preempt or otherwise  
20           affect the authority of a State or political subdivision of  
21           a State to enforce any action taken or requirement im-  
22           posed pursuant to the authority of a State, political sub-  
23           division of a State, or local law, regulation, requirement  
24           or standard that otherwise relates to food labeling and is  
25           not described in subsection (a).

1       (c) NO PREEMPTION OF COMMON LAW OR STATU-  
2 TORY CAUSES OF ACTION.—Nothing in this Act, nor any  
3 amendment, regulation, rule, or requirement promulgated  
4 pursuant to this Act, shall be construed to preempt, dis-  
5 place, or supplant any State or Federal common law rights  
6 or any State or Federal statute creating a remedy for civil  
7 relief, including those for civil damage, or a penalty for  
8 a criminal conduct.

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