Donnelly#1

| AM.  | ENDMENT NO. Calendar No.   |
|------|--|
| Pur  | pose: In the nature of a substitute.   |
| IN T | THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.  |
|      | S  |
| Тоз  | amend the Agricultural Marketing Act of 1946 to require<br>the Secretary of Agriculture to establish a national vol-<br>untary labeling standard for bioengineered foods, and<br>for other purposes. |
| Re   | ferred to the Committee on and ordered to be printed   |
|      | Ordered to lie on the table and to be printed  |
| Ax   | MENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Mr. Donnelly   |
| Viz: |  |
| 1    | Strike all after the enacting clause and insert the fol-   |
| 2    | lowing:  |
| 3    | SECTION 1. NATIONAL VOLUNTARY BIOENGINEERED FOOD   |
| 4    | LABELING STANDARD.   |
| 5    | The Agricultural Marketing Act of 1946 (7 U.S.C.   |
| 6    | 1621 et seq.) is amended by adding at the end the fol-   |
| 7    | lowing:  |

S.L.C.

2

| 1  | "Subtitle E—National Voluntary                                |  |  |  |  |  |
|----|---|--|--|--|--|--|
| 2  | Bioengineered Food Labeling                                   |  |  |  |  |  |
| 3  | Standard  |  |  |  |  |  |
| 4  | "SEC. 291. DEFINITIONS.                                       |  |  |  |  |  |
| 5  | "In this subtitle:  |  |  |  |  |  |
| 6  | "(1) FOOD.—The term 'food' has the meaning                    |  |  |  |  |  |
| 7  | given the term in section 201 of the Federal Food,            |  |  |  |  |  |
| 8  | Drug, and Cosmetic Act (21 U.S.C. 321).                       |  |  |  |  |  |
| 9  | "(2) Secretary.—The term 'Secretary' means                    |  |  |  |  |  |
| 10 | the Secretary of Agriculture.                                 |  |  |  |  |  |
| 11 | "SEC. 292. APPLICABILITY.                                     |  |  |  |  |  |
| 12 | "This subtitle shall apply to any claim in the labeling       |  |  |  |  |  |
| 13 | of food that indicates, directly or indirectly, that the food |  |  |  |  |  |
| 14 | is a bioengineered food or bioengineering was used in the     |  |  |  |  |  |
| 15 | development or production of the food, including a claim      |  |  |  |  |  |
| 16 | that a food is or contains an ingredient that was developed   |  |  |  |  |  |
| 17 | or produced using bioengineering.                             |  |  |  |  |  |
| 18 | "SEC. 293. ESTABLISHMENT OF NATIONAL VOLUNTARY BIO-           |  |  |  |  |  |
| 19 | ENGINEERED FOOD LABELING STANDARD.                            |  |  |  |  |  |
| 20 | "(a) Establishment of Standard.—Not later                     |  |  |  |  |  |
| 21 | than 1 year after the date of enactment of this subtitle,     |  |  |  |  |  |
| 22 | the Secretary shall—  |  |  |  |  |  |
| 23 | "(1) establish a national voluntary bioengi-                  |  |  |  |  |  |
| 24 | neered food labeling standard with respect to—                |  |  |  |  |  |
| 25 | "(A) any bioengineered food; and                              |  |  |  |  |  |

| 1  | "(B) any food that may be bioengineered              |
|----|--|
| 2  | or may have been produced or developed using         |
| 3  | bioengineering; and                                  |
| 4  | "(2) establish such requirements and proce-          |
| 5  | dures as the Secretary determines necessary to carry |
| 6  | out the standard.                                    |
| 7  | "(b) Regulations.—                                   |
| 8  | "(1) In general.—A food may be labeled as            |
| 9  | bioengineered only in accordance with regulations    |
| 0  | promulgated by the Secretary in accordance with      |
| 11 | this subtitle.                                       |
| 12 | "(2) Requirements.—A regulation promul-              |
| 13 | gated by the Secretary in carrying out this subtitle |
| 14 | shall  |
| 15 | $``(\Lambda)$ prohibit any express or implied claim  |
| 16 | that a food is or is not safer or of higher qual-    |
| 17 | ity solely based on whether the food is or is        |
| 18 | not  |
| 19 | "(i) bioengineered; or                               |
| 20 | "(ii) produced or developed with the                 |
| 21 | use of bioengineering;                               |
| 22 | "(B) determine the amounts of a bioengi-             |
| 23 | neered substance that may be present in food,        |
| 24 | as appropriate, in order for the food to be la-      |
| 25 | beled as a bioengineered food;                       |

| 1  | "(C) require a disclosure on the label                      |  |  |  |  |  |
|----|---|--|--|--|--|--|
| 2  | that—   |  |  |  |  |  |
| 3  | "(i) clearly indicates to consumers                         |  |  |  |  |  |
| 4  | that more information regarding the con-                    |  |  |  |  |  |
| 5  | tent or ingredients is available; and                       |  |  |  |  |  |
| 6  | "(ii) provides direct access to informa-                    |  |  |  |  |  |
| 7  | tion regarding whether food is or is not                    |  |  |  |  |  |
| 8  | bioengineered or whether bioengineering                     |  |  |  |  |  |
| 9  | was or was not used in the development or                   |  |  |  |  |  |
| 10 | production of the food; and                                 |  |  |  |  |  |
| 11 | "(D) establish a process for requesting and                 |  |  |  |  |  |
| 12 | granting a determination by the Secretary re-               |  |  |  |  |  |
| 13 | garding other factors and conditions under                  |  |  |  |  |  |
| 14 | which a food may be labeled as a bioengineered              |  |  |  |  |  |
| 15 | food.   |  |  |  |  |  |
| 16 | "(e) STATE FOOD LABELING STANDARDS.—Notwith-                |  |  |  |  |  |
| 17 | standing section 295, no State or political subdivision of  |  |  |  |  |  |
| 18 | a State may directly or indirectly establish under any au-  |  |  |  |  |  |
| 19 | thority or continue in effect as to any food in interstate  |  |  |  |  |  |
| 20 | commerce any requirement for a food that is the subject     |  |  |  |  |  |
| 21 | of the bioengineered food labeling standard under this sec- |  |  |  |  |  |
| 22 | tion that is not identical to that voluntary standard.      |  |  |  |  |  |
| 23 | "SEC. 294. MEASURING ACCESS AND AWARENESS OF INFOR-         |  |  |  |  |  |
| 24 | MATION.   |  |  |  |  |  |
| 25 | "(a) Mandatory Report; Publication.—                        |  |  |  |  |  |

| 1  | (1) IN GENERAL.—Not later than I year after              |
|----|--|
| 2  | the date on which the Secretary promulgates regula-      |
| 3  | tions under section 293 and annually thereafter, the     |
| 4  | Secretary and the Secretary of Health and Human          |
| 5  | Services shall—  |
| 6  | "(A) submit to Congress a report on—                     |
| 7  | "(i) the availability of information re-                 |
| 8  | garding whether food is or is not bioengi-               |
| 9  | neered or whether bioengineering was or                  |
| 10 | was not used in the development or pro-                  |
| 11 | duction of the food; and                                 |
| 12 | "(ii) consumer awareness of how to                       |
| 13 | access the information described in sub-                 |
| 14 | paragraph (A); and                                       |
| 15 | "(B) make the report publicly available.                 |
| 16 | "(2) Availability of information stand-                  |
| 17 | ARD.—In carrying out the report under paragraph          |
| 18 | (1), the Secretary and the Secretary of Health and       |
| 19 | Human Services shall consider only marks and la-         |
| 20 | bels that meet the requirements under section            |
| 21 | 293(b)(2)(C) to meet the standard of availability of     |
| 22 | information referred to in paragraph $(1)(\Lambda)(i)$ . |
| 23 | "(b) Survey.—The Secretary shall—                        |
| 24 | "(1) conduct a survey of consumers to deter-             |
| 25 | mine—  |

| Ţ  | "(A) the availability of information regard          |
|----|--|
| 2  | ing whether food is or is not bioengineered o        |
| 3  | whether bioengineering was or was not used in        |
| 4  | the development or production of food; and           |
| 5  | "(B) the awareness of consumers on how               |
| 6  | to access the information described in subpara       |
| 7  | graph (A); and                                       |
| 8  | "(2) make the survey publicly available.             |
| 9  | "(e) Improving Consumer Awareness.—                  |
| 10 | "(1) In General.—Not later than 1 year after         |
| 11 | the date on which the Secretary promulgates regula   |
| 12 | tions under section 293, the Secretary shall make a  |
| 13 | determination as to whether consumers have suffi     |
| 14 | cient awareness of how to access the available infor |
| 15 | mation regarding whether a food is or is not bioengi |
| 16 | necred or whether bioengineering was or was no       |
| 17 | used in the development or production of the food    |
| 18 | "(2) RECOMMENDATIONS.—If the Secretary de            |
| 19 | termines that an insufficient percentage of con      |
| 20 | sumers have awareness of how to access the infor-    |
| 21 | mation described in paragraph (1), the Secretary     |
| 22 | shall issue recommendations for improving consumer   |
| 23 | awareness.   |
| 24 | "(3) Ensuring consumer awareness.—To                 |
| 25 | the maximum extent practicable, the Secretary shall  |

1 ensure that a sufficient percentage of consumers 2 have awareness of how to access the information de-3 scribed in paragraph (1). 4 "(d) Improving Access to Information.— 5 "(1) IN GENERAL.—Not later than 1 year after 6 the date on which the Secretary promulgates regula-7 tions under section 293, the Secretary shall make a 8 determination as to whether at least 65 percent of 9 relevant products provide information regarding 10 whether a food is or is not bioengineered or whether 11 bioengineering was or was not used in the develop-12 ment or production of the food. 13 "(2) Recommendations.—If the Secretary determines that less than 65 percent of relevant prod-14 15 ucts provide information as described in paragraph 16 (1), the Secretary shall issue recommendations for 17 improving access to that information. 18 "SEC. 294A, NATIONAL MANDATORY BIOENGINEERED FOOD 19 LABELING STANDARD. 20 "(a) REQUIREMENT FOR ESTABLISHMENT OF MAN-21 DATORY Electronic STANDARD.—The mandatory standard under subsection (b) shall be established only if, by the date that is 3 years after the date on which the 23 Secretary promulgates regulations under section 293, less than 85 percent of relevant products provide information

| 1  | to consumers in accordance with the voluntary standard |
|----|--|
| 2  | under section 293.                                     |
| 3  | "(b) ESTABLISHMENT OF MANDATORY ELECTRONIC             |
| 4  | STANDARD.—   |
| 5  | "(1) IN GENERAL.—If the Secretary determines           |
| 6  | that the standard under subsection (a) has been        |
| 7  | met, the Secretary shall—                              |
| 8  | "(A) establish a national mandatory elec-              |
| 9  | tronic bioengineered food labeling standard with       |
| 10 | respect to—  |
| 11 | "(i) labeled bioengineered food; and                   |
| 12 | "(ii) labeled food that may be bioengi-                |
| 13 | neered or may have been produced or de-                |
| 14 | veloped using bioengineering; and                      |
| 15 | "(B) establish such requirements and pro-              |
| 16 | cedures as the Secretary determines necessary          |
| 17 | to carry out the standard.                             |
| 18 | "(2) Application.—The mandatory standard               |
| 19 | under this subsection shall not apply to food served   |
| 20 | in a restaurant or similar establishment.              |
| 21 | "(e) REGULATIONS.—                                     |
| 22 | "(1) In general.—If the Secretary establishes          |
| 23 | a mandatory standard under subsection (b), a food      |
| 24 | may be labeled as bioengineered only in accordance     |

| 1          | with regulations promulgated by the Secretary in ac-   |
|------------|--|
| 2          | cordance with this section.                            |
| 3          | "(2) Requirements.—A regulation promul-                |
| 4          | gated by the Secretary in carrying out this section—   |
| 5          | "(A) may permit different methods of dis-              |
| 6          | closure, including electronic scannable links,         |
| 7          | phone numbers, or website information; and             |
| 8          | "(B) shall require an explicit direction or            |
| 9          | disclosure to consumers that clearly indicates         |
| 10         | that more information regarding whether a food         |
| 11         | is or is not bioengineered or whether bio-             |
| 12         | engineering was or was not used in the develop-        |
| 13         | ment or production of the food is available.           |
| 14         | "(3) Public comment.—In establishing the               |
| 15         | mandatory standard under subsection (b) and regu-      |
| 16         | lations to carry out the mandatory standard, the       |
| <u>1</u> 7 | Secretary shall—                                       |
| 8          | $``(\Lambda)$ provide an opportunity for public        |
| 19         | comment; and   |
| 20         | "(B) consider any public comments and                  |
| 21         | other relevant factors.                                |
| 22         | "(d) Enforcement.—                                     |
| 23         | "(1) WARNING.—If the Secretary determines              |
| 24         | that a person subject to this subtitle is in violation |
| 25         | of this section, the Secretary shall—                  |

| 1  | "(A) provide to the person a written notice            |
|----|--|
| 2  | of the determination of the Secretary; and             |
| 3  | "(B) provide a 30-day period, beginning on             |
| 4  | the date on which the person receives the notice       |
| 5  | under paragraph $(\Lambda)$ , during which the person  |
| 6  | may take steps to comply with this section.            |
| 7  | "(2) NOTICE AND HEARING.—A person who re-              |
| 8  | ceives a warning under paragraph (1) shall be pro-     |
| 9  | vided notice of and opportunity for a hearing before   |
| 10 | the Secretary regarding the violation described in     |
| 11 | paragraph (1).   |
| 12 | "(3) Fines.—After the 30-day period described          |
| 13 | in paragraph (1)(B) and the notice of and oppor-       |
| 14 | tunity for a hearing under paragraph (2), the Sec-     |
| 15 | retary may fine the person in an amount of not         |
| 16 | more than \$1,000 for each violation, if the Secretary |
| 17 | determines that the person—                            |
| 18 | $``(\Lambda)$ has not made a good faith effort to      |
| 19 | comply with this section, and;                         |
| 20 | "(B) continues to willfully violate this sec-          |
| 21 | tion with respect to the violation about which         |
| 22 | the person received notification under para-           |
| 23 | graph $(1)(\Lambda)$ .                                 |
| 24 | "(e) STATE FOOD LABELING STANDARDS.—If the             |
| 25 | Secretary establishes a mandatory standard under sub-  |

- 1 section (b), notwithstanding section 295, no State or polit-
- 2 ical subdivision of a State may directly or indirectly estab-
- 3 lish under any authority or continue in effect as to any
- 4 food in interstate commerce any requirement for a food
- 5 that is the subject of the bioengineered food labeling
- 6 standard under this section that is not identical to that
- 7 mandatory standard.

## 8 "SEC. 294B. MANDATORY ON-PACKAGE LABELING.

- 9 "(a) IN GENERAL.—Notwithstanding sections 293,
- 10 294, and 294A and consistent with existing authority, the
- 11 Secretary or the Administrator of the Food and Drug Ad-
- 12 ministration (referred to in this section as the 'Adminis-
- 13 trator'), as appropriate, may require on-package labeling
- 14 regarding whether a food is or is not bioengineered or
- 15 whether bioengineering was or was not used in the devel-
- 16 opment or production of the food if—
- 17 "(1) the Secretary or the Administrator deter-
- mines that mandatory on-package labeling is sci-
- 19 entifically warranted for health and safety; or
- 20 "(2) the Secretary or the Administrator deter-
- 21 mines that there is a material different between con-
- ventional breeding and bioengineering.
- 23 "(b) RECOMMENDATION.—Beginning 4 years after
- 24 the date on which the Secretary promulgates regulations
- 25 under section 293, if less than 85 percent of relevant prod-

- 1 ucts provide information in accordance with the voluntary
- 2 standard under section 293, and the Secretary determines
- 3 that the voluntary standard is insufficient to meet a nec-
- 4 essary level of consumer awareness of how to access avail-
- 5 able information regarding whether a food is or is not bio-
- 6 engineered or whether bioengineering was or was not used
- 7 in the development or production of the food, the Sec-
- 8 retary shall submit to Congress a report on the need for
- 9 and ways to improve the voluntary standard, including a
- 10 recommendation as to whether Congress should require
- 11 on-package labeling.
- 12 "(c) REQUIREMENT.—The Secretary and the Admin-
- 13 istrator may not take any action to require mandatory on-
- 14 package labeling as described in subsection (a) unless the
- 15 Secretary or the Administrator of the Food and Drug Ad-
- 16 ministration makes a determination as described in sub-
- 17 section (a).

## 18 "Subtitle F—Labeling of Certain

## 19 **Food**

- 20 "SEC. 295. FEDERAL PREEMPTION.
- 21 "(a) Definition of Food.—In this subtitle, the
- 22 term 'food' has the meaning given the term in section 201
- 23 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
- 24 321).

| 1  | "(b) FEDERAL PREEMPTION.—No State or a polit-                 |
|----|---|
| 2  | ical subdivision of a State may directly or indirectly estab- |
| 3  | lish under any authority or continue in effect as to any      |
| 4  | food or seed in interstate commerce any requirement relat-    |
| 5  | ing to the labeling of whether a food (including food served  |
| 6  | in a restaurant or similar establishment) or seed is geneti-  |
| 7  | cally engineered (which shall include such other similar      |
| 8  | terms as determined by the Secretary of Agriculture) or       |
| 9  | was developed or produced using genetic engineering, in-      |
| 10 | cluding any requirement for claims that a food or seed        |
| 11 | is or contains an ingredient that was developed or pro-       |
| 12 | duced using genetic engineering.                              |
| 13 | "SEC. 296. NO PREEMPTION OF COMMON LAW OR STATU-              |
| 14 | TORY CAUSES OF ACTION.  |
| 15 | "Nothing in this subtitle or subtitle E, or any regula-       |
| 16 | tion promulgated pursuant to this subtitle or subtitle E,     |
| 17 | preempts, displaces, or supplants—                            |
| 18 | "(1) any common law right; or                                 |
| 19 | "(2) any Federal or State law creating a rem-                 |
| 20 | edy for civil relief, including for civil damage or pen-      |
| 21 | alty for evininal conduct "                                   |