

AMENDMENT NO. _____ Calendar No. _____

Purpose: To improve the amendment.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

S. 764

To reauthorize and amend the National Sea Grant College Program Act, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. SANDERS to the amendment (No. 4935) proposed by Mr. ROBERTS

Viz:

1 In lieu of the matter proposed to be inserted, insert

2 the following:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “GMO Labeling Act

5 of 2016”.

6 **SEC. 2. PURPOSES.**

7 The purposes of this Act are to—

8 (1) establish a system by which people may

9 make informed decisions about the food they pur-

10 chase and consume and by which, if they choose,

11 people may avoid food produced from genetic engi-

12 neering;

1 (2) inform the purchasing decisions of con-
2 sumers who are concerned about the potential envi-
3 ronmental effects of the production of food from ge-
4 netic engineering;

5 (3) reduce and prevent consumer confusion and
6 deception by prohibiting the labeling of products
7 produced from genetic engineering as “natural” and
8 by promoting the disclosure of factual information
9 on food labels to allow consumers to make informed
10 decisions; and

11 (4) provide consumers with data from which
12 they may make informed decisions for religious rea-
13 sons.

14 **SEC. 3. LABELING REQUIREMENTS.**

15 (a) IN GENERAL.—Chapter IV of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
17 ed by adding at the end the following:

18 **“SEC. 424. LABELING OF FOOD PRODUCED WITH GENETIC**
19 **ENGINEERING.**

20 “(a) IN GENERAL.—Except as provided in subsection
21 (d), any food that is entirely or partially produced with
22 genetic engineering and offered for retail sale after Janu-
23 ary 1, 2017, shall be labeled or shall be displayed, as appli-
24 cable, in accordance with subsection (b).

1 “(b) LABELING REQUIREMENTS.—In the case of a
2 food described in subsection (a), the manufacturer or re-
3 tailer shall ensure that such food is labeled or displayed
4 in accordance with the following:

5 “(1) MANUFACTURERS.—

6 “(A) RAW AGRICULTURAL COMMOD-
7 ITIES.—In the case of a packaged raw agricul-
8 tural commodity, the manufacturer shall label
9 the package offered for retail sale, in a clear
10 and conspicuous manner, with the words ‘pro-
11 duced with genetic engineering’.

12 “(B) PROCESSED FOOD.—In the case of
13 any processed food that contains a product or
14 products of genetic engineering, the manufac-
15 turer shall label the package in which the proc-
16 essed food is offered for sale, in a clear and
17 conspicuous manner, with the words: ‘Partially
18 produced with genetic engineering’, ‘May be
19 produced with genetic engineering’, or ‘Pro-
20 duced with genetic engineering’, as applicable.

21 “(2) RETAILERS.—In the case of any raw agri-
22 cultural commodity that is not separately packaged,
23 the retailer shall post a label appearing on the retail
24 store shelf or bin in which the commodity is dis-

1 played for sale, in a clear and conspicuous manner,
2 with the words ‘produced with genetic engineering’.

3 “(c) PROHIBITED LABELING.—Except as provided in
4 subsection (d), a manufacturer or retailer of a food pro-
5 duced entirely or in part from genetic engineering shall
6 not label the product on the package, in signage, or in
7 advertising as ‘natural’, ‘naturally made’, ‘naturally
8 grown’, ‘all natural’, or using any words of similar import
9 that would have a tendency to mislead a consumer.

10 “(d) EXEMPTIONS.—The labeling requirements of
11 subsection (b) shall not apply with respect to the following:

12 “(1) Food consisting entirely of, or derived en-
13 tirely from, an animal that has not itself been pro-
14 duced with genetic engineering, regardless of wheth-
15 er the animal has been fed or injected with any food,
16 drug, or other substance produced with genetic engi-
17 neering.

18 “(2) A raw agricultural commodity or processed
19 food derived from a raw agricultural commodity that
20 has been grown, raised, or produced without the
21 knowing or intentional use of food or seed produced
22 with genetic engineering, except that the exception
23 described in this paragraph shall apply only if the
24 person otherwise responsible for complying with the
25 requirements of subsection (b) with respect to a raw

1 agricultural commodity or processed food obtains,
2 from whomever sold the raw agricultural commodity
3 or processed food to that person, a sworn statement
4 that the raw agricultural commodity or processed
5 food has not been knowingly or intentionally pro-
6 duced with genetic engineering and has been seg-
7 regated from and has not been knowingly or inten-
8 tionally commingled with food that may have been
9 produced with genetic engineering at any time. In
10 providing such a sworn statement, any person may
11 rely on a sworn statement from a direct supplier
12 that contains such an affirmation.

13 “(3) Animal feed.

14 “(4) A processed food that would be subject to
15 such requirements solely because such food includes
16 one or more processing aids or enzymes produced
17 with genetic engineering.

18 “(5) Alcoholic beverages.

19 “(6) A processed food that would be subject to
20 such requirements solely because such food includes
21 one or more materials that have been produced with
22 genetic engineering, provided that the genetically en-
23 gineered materials in the aggregate do not account
24 for more than 0.9 percent of the total weight of the
25 processed food.

1 “(7) Food that an independent organization has
2 verified has not been knowingly or intentionally pro-
3 duced from or commingled with food or seed pro-
4 duced with genetic engineering. The Secretary, shall
5 approve, by regulation, any independent organiza-
6 tions from which verification shall be acceptable
7 under this paragraph.

8 “(8) Food that is not packaged for retail sale
9 and that is—

10 “(A) a processed food prepared and in-
11 tended for immediate human consumption; or

12 “(B) served, sold, or otherwise provided in
13 a restaurant or other establishment in which
14 food is served for immediate human consump-
15 tion.

16 “(9) Medical food, as that term is defined in
17 section 5(b) of the Orphan Drug Act.

18 “(e) DISCLAIMER.—The Secretary may, through reg-
19 ulation, require that labeling required under this section
20 include a disclaimer that the Food and Drug Administra-
21 tion does not consider foods produced from genetic engi-
22 neering to be materially different from other foods.

23 “(f) DEFINITIONS.—In this section—

24 “(1) the term ‘enzyme’ means a protein that
25 catalyzes chemical reactions of other substances

1 without itself being destroyed or altered upon com-
2 pletion of the reactions;

3 “(2) the term ‘genetic engineering’ is a process
4 by which a food is produced from an organism or or-
5 ganisms in which the genetic material has been
6 changed through the application of—

7 “(A) in vitro nucleic acid techniques, in-
8 cluding recombinant deoxyribonucleic acid
9 (DNA) techniques and the direct injection of
10 nucleic acid into cells or organelles; or

11 “(B) fusion of cells (including protoplast
12 fusion) or hybridization techniques that over-
13 come natural physiological, reproductive, or re-
14 combination barriers, where the donor cells or
15 protoplasts do not fall within the same taxo-
16 nomic group, in a way that does not occur by
17 natural multiplication or natural recombination;

18 “(3) the term ‘in vitro nucleic acid techniques’
19 means techniques, including recombinant DNA or ri-
20 bonucleic acid techniques, that use vector systems
21 and techniques involving the direct introduction into
22 the organisms of hereditary materials prepared out-
23 side the organisms such as micro-injection,
24 chemoporation, electroporation, micro-encapsulation,
25 and liposome fusion;

1 “(4) the term ‘organism’ means any biological
2 entity capable of replication, reproduction, or trans-
3 ferring of genetic material;

4 “(5) the term ‘processing aid’ means—

5 “(A) a substance that is added to a food
6 during the processing of the food but that is re-
7 moved in some manner from the food before the
8 food is packaged in its finished form;

9 “(B) a substance that is added to a food
10 during processing, is converted into constituents
11 normally present in the food, and does not sig-
12 nificantly increase the amount of the constitu-
13 ents naturally found in the food; or

14 “(C) a substance that is added to a food
15 for its technical or functional effect in the proc-
16 essing but is present in the finished food at lev-
17 els that do not have any technical or functional
18 effect in that finished food.

19 “(g) RULES OF CONSTRUCTION.—This section shall
20 not be construed to require—

21 “(1) the listing or identification of any ingre-
22 dient or ingredients that were genetically engineered;
23 or

1 “(2) the placement of the term ‘genetically en-
2 gineered’ immediately preceding any common name
3 or primary product descriptor of a food.”.

4 (b) PENALTIES.—Section 303 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 333) is amended by
6 adding at the end the following:

7 “(h)(1) A manufacturer who introduces or delivers
8 for introduction into interstate commerce any food, the la-
9 beling of which is not in compliance with the applicable
10 requirements of section 424, or a retailer who sells or of-
11 fers for retail sale a food, the display for which is not in
12 compliance with the applicable requirements of section
13 424, shall be liable for a civil penalty of not more than
14 \$1,000 per day, for each uniquely named, designated, or
15 marketed food with respect to which such manufacturer
16 or retailer is not in compliance. Calculation of the civil
17 penalty shall not be made or multiplied by the number
18 of individual packages of the same product introduced or
19 delivered for introduction into interstate commerce, or dis-
20 played or offered for retail sale.

21 “(2) A person who knowingly provides a false state-
22 ment under section 424(d)(4) that a raw agricultural com-
23 modity or processed food has not been knowingly or inten-
24 tionally produced with genetic engineering and has been
25 segregated from and has not been knowingly or inten-

1 tionally commingled with food that may have been pro-
2 duced with genetic engineering at any time shall be liable
3 for a civil penalty of not more than \$100,000.”.