

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 1599  
OFFERED BY M. \_\_\_\_\_**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the  
3 “Safe and Accurate Food Labeling Act of 2015”.

4 (b) TABLE OF CONTENTS.—The table of contents of  
5 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Food safety affirmation.

**TITLE I—GENETICALLY ENGINEERED PLANTS INTENDED FOR A  
FOOD USE OR APPLICATION**

**Subtitle A—Food and Drug Administration**

- Sec. 101. Consultation process.
- Sec. 102. Misbranding.
- Sec. 103. Preemption.

**Subtitle B—Department of Agriculture**

- Sec. 111. Regulation.
- Sec. 112. Regulations.
- Sec. 113. Preemption.
- Sec. 114. Rule of construction.

**TITLE II—GENETIC ENGINEERING CERTIFICATION**

- Sec. 201. Genetic engineering certification.
- Sec. 202. Regulations.
- Sec. 203. Preemption.

1 **SEC. 2. FOOD SAFETY AFFIRMATION.**

2 Nothing in this Act (or the amendments made by this  
3 Act) is intended to alter or affect the authorities or regu-  
4 latory programs, policies, and procedures otherwise avail-  
5 able to the Food and Drug Administration under the Fed-  
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et  
7 seq.) or the Animal and Plant Health Inspection Service  
8 under the Plant Protection Act (7 U.S.C. 7701 et seq.),  
9 to ensure the safety of the food supply and the protection  
10 of plant health.

11 **TITLE I—GENETICALLY ENGI-**  
12 **NEERED PLANTS INTENDED**  
13 **FOR A FOOD USE OR APPLI-**  
14 **CATION**

15 **Subtitle A—Food and Drug**  
16 **Administration**

17 **SEC. 101. CONSULTATION PROCESS.**

18 Chapter IV of the Federal Food, Drug, and Cosmetic  
19 Act is amended by inserting after section 423 of such Act  
20 (21 U.S.C. 350l) the following:

21 **“SEC. 424. FOOD DERIVED FROM NEW PLANT VARIETIES.**

22 “(a) IN GENERAL.—The Secretary shall continue to  
23 administer the consultation process established under the  
24 Food and Drug Administration’s policy statement entitled  
25 ‘Statement of Policy: Food Derived from New Plant Vari-

1 eties' published in the Federal Register on May 29, 1992  
2 (57 Fed. Reg. 22,984).

3 “(b) DETERMINATION OF MATERIAL DIFFERENCE  
4 BETWEEN FOOD FROM GENETICALLY ENGINEERED  
5 PLANTS AND COMPARABLE MARKETED FOODS.—For  
6 purposes of subsection (a)—

7 “(1) the use of genetic engineering does not, by  
8 itself, constitute information that is material for  
9 purposes of determining whether there is a dif-  
10 ference between a food produced from, containing,  
11 or consisting of a genetically engineered plant and a  
12 comparable marketed food; and

13 “(2) the Secretary may specify labeling that  
14 would adequately inform consumers of such material  
15 difference if the Secretary determines that—

16 “(A) there is a material difference between  
17 a food produced from, containing, or consisting  
18 of a genetically engineered plant and its com-  
19 parable marketed food that—

20 “(i) significantly alters the character-  
21 istics of the food so produced, including  
22 the functional or compositional characteris-  
23 ties, such that the common or usual name  
24 no longer adequately describes the food;

1 “(ii) results in a significantly different  
2 nutritional property in the food so pro-  
3 duced; or

4 “(iii) results in the food so produced  
5 containing an allergen that consumers  
6 would not expect to be present based on  
7 the name of the food; and

8 “(B) disclosure of such material difference  
9 is necessary to protect health and safety or to  
10 prevent the label or labeling of the food so pro-  
11 duced from being false or misleading.”.

12 **SEC. 102. MISBRANDING.**

13 Section 403 of the Federal Food, Drug, and Cosmetic  
14 Act (21 U.S.C. 343) is amended by adding at the end the  
15 following:

16 “(z) If it bears labeling indicating that genetic engi-  
17 neering was or was not used in the production of the food,  
18 except in compliance with sections 291B and 291C of the  
19 Agricultural Marketing Act of 1946.”.

20 **SEC. 103. PREEMPTION.**

21 Section 403A(a) of the Federal Food, Drug, and Cos-  
22 metic Act (21 U.S.C. 343–1(a)) is amended—

23 (1) in paragraph (4), by striking “or” at the  
24 end;

1 (2) in paragraph (5), by striking the period at  
2 the end and inserting “, or”; and

3 (3) by inserting after paragraph (5) the fol-  
4 lowing:

5 “(6) any requirement for the labeling of food of  
6 the type described in section 403(z) that is not iden-  
7 tical to the requirements of such section.”.

8 **Subtitle B—Department of**  
9 **Agriculture**

10 **SEC. 111. REGULATION.**

11 (a) DEFINITIONS.—Section 403 of the Plant Protec-  
12 tion Act (7 U.S.C. 7702) is amended—

13 (1) by redesignating paragraphs (5) through  
14 (20) as paragraphs (6) through (21), respectively;

15 (2) by inserting after paragraph (4) the fol-  
16 lowing new paragraph:

17 “(5) FOOD.—The term ‘food’ has the meaning  
18 given such term in section 201(f) of the Federal  
19 Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)).”;

20 (3) by redesignating paragraphs (11) through  
21 (21) (as redesignated by paragraph (1)) as para-  
22 graphs (12) through (22), respectively; and

23 (4) by inserting after paragraph (9) the fol-  
24 lowing new paragraph:

1           “(10) NONREGULATED GENETICALLY ENGI-  
2           NEERED PLANT.—The term ‘nonregulated geneti-  
3           cally engineered plant’ means a genetically engi-  
4           neered plant (as defined in section 291 of the Agri-  
5           cultural Marketing Act of 1946) for which the Sec-  
6           retary of Agriculture has—

7                   “(A) approved a petition under section  
8                   340.6 of title 7, Code of Federal Regulations  
9                   (as in effect on June 1, 2015), for a determina-  
10                  tion that the genetically engineered plant is not  
11                  a plant pest; or

12                   “(B) has otherwise determined that such  
13                   plant is not subject to regulation as a plant  
14                   pest under this Act, including a determination  
15                   made by the Secretary on or after the date of  
16                   enactment of the Safe and Accurate Food La-  
17                   beling Act of 2015.”.

18           (b) COORDINATION OF FOOD SAFETY AND AGRI-  
19           CULTURE PROGRAMS.—The Plant Protection Act (7  
20           U.S.C. 7701 et seq.) is amended by adding at the end  
21           the following new subtitle:

1    **“Subtitle F—Coordination of Food**  
2    **Safety and Agriculture Programs**

3    **“SEC. 461. NOTIFICATION RELATING TO CERTAIN GENETI-**  
4                    **CALLY ENGINEERED PLANTS.**

5            “(a) IN GENERAL.—It shall be unlawful to introduce  
6 or deliver for introduction into interstate commerce a non-  
7 regulated genetically engineered plant or a food produced  
8 from, containing, or consisting of a genetically engineered  
9 plant for a food use or application unless—

10            “(1)(A) the Secretary of Health and Human  
11 Services notified the developer of the genetically en-  
12 gineered plant in writing that the Secretary of  
13 Health and Human Services has no objections to the  
14 developer’s determination that food produced from,  
15 containing, or consisting of the genetically engi-  
16 neered plant that is the subject of the notification is  
17 as safe for use by humans or animals, as applicable,  
18 as one or more comparable marketed foods; and

19            “(B) the developer of the genetically engineered  
20 plant submits to the Secretary of Agriculture—

21            “(i) the notification of the finding of the  
22 Secretary of Health and Human Services under  
23 subparagraph (A); and

1           “(ii) any documentation the Secretary of  
2           Health and Human Services issues to the devel-  
3           oper with respect to such finding; or

4           “(2)(A) the Secretary of Health and Human  
5           Services evaluated food produced from, containing,  
6           or consisting of the genetically engineered plant pur-  
7           suant to the consultation process referred to in sec-  
8           tion 424(a) of the Federal Food, Drug, and Cos-  
9           metic Act; and

10           “(B) the Secretary of Health and Human Serv-  
11           ices informed the developer of the genetically engi-  
12           neered plant that all questions with respect to the  
13           safety of the genetically engineered plant have been  
14           resolved.

15           “(b) EXCEPTIONS.—This section does not apply with  
16           respect to the introduction or delivery for introduction into  
17           interstate commerce of a genetically engineered plant—

18           “(1) for the purpose of research or development  
19           testing, including—

20           “(A) testing conducted to generate data  
21           and information that could be used in a notifi-  
22           cation submitted under subsection (a)(2)(A) or  
23           other regulatory submission;

24           “(B) research involving multiplication of  
25           seed or hybrid and variety development con-



1           ducted before submitting a notification to the  
2           Secretary of Agriculture under subsection  
3           (a)(2)(A); or

4           “(2) solely because a processing aid or enzyme  
5           produced from the genetically engineered plant is in-  
6           tended to be used to produce food.

7           “(c) RULE OF CONSTRUCTION.—Nothing in sub-  
8           section (b)(2)(B) may be construed as authorizing the in-  
9           troduction or delivery for introduction into interstate com-  
10          merce a nonregulated genetically engineered plant or a  
11          food produced from, containing, or consisting of a geneti-  
12          cally engineered plant for a food use or application.

13          “(d) PUBLIC DISCLOSURE.—

14                 “(1) IN GENERAL.—Subject to paragraph (2),  
15                 not later than 180 days after the date of the enact-  
16                 ment of the Safe and Accurate Food Labeling Act  
17                 of 2015, the Secretary of Agriculture shall publish  
18                 on the public Website of the Department of Agri-  
19                 culture, and update as necessary, a registry that  
20                 contains—

21                         “(A) a list of each nonregulated genetically  
22                         engineered plant intended for a food use or ap-  
23                         plication that may be introduced or delivered  
24                         for introduction in interstate commerce, in ac-  
25                         cordance with subsection (a);

1           “(B) the petitions submitted to, and deter-  
2           minations made by, the Secretary of Agri-  
3           culture with respect to such plants; and

4           “(C) the submissions made to, and notifi-  
5           cations of findings issued by, the Secretary of  
6           Health and Human Services, with respect to  
7           such plants.

8           “(2) TRADE SECRETS AND CONFIDENTIAL IN-  
9           FORMATION.—Notwithstanding paragraph (1), noth-  
10          ing in this section shall be construed to alter the  
11          protections offered by laws, regulations, and policies  
12          governing disclosure of confidential commercial or  
13          trade secret information, and any other information  
14          exempt from disclosure pursuant to section 552(b)  
15          of title 5, United States Code, as such provisions  
16          would be applied to consultation with individuals and  
17          organizations prior to the date of enactment of this  
18          section.”.

19 **SEC. 112. REGULATIONS.**

20          Not later than one year after the date of the enact-  
21          ment of this Act, the Secretary of Agriculture shall pro-  
22          mulgate final regulations to carry out the amendments  
23          made by section 111.

1 **SEC. 113. PREEMPTION.**

2       Regardless of whether regulations have been promul-  
3 gated under section 112, beginning on the date of the en-  
4 actment of this Act, no State or political subdivision of  
5 a State may directly or indirectly establish under any au-  
6 thority or continue in effect as to any food in interstate  
7 commerce any requirement with respect to the use of ge-  
8 netically engineered plants for a food use or application  
9 that is not identical to the requirement of section 461 of  
10 the Plant Protection Act (as added by section 111 of this  
11 Act).

12 **SEC. 114. RULE OF CONSTRUCTION.**

13       Nothing in the amendments made by this subtitle is  
14 intended to alter or affect the ability of—

15           (1) the Secretary of Health and Human Serv-  
16 ices to take enforcement actions with respect to a  
17 violation of the Federal Food, Drug, and Cosmetic  
18 Act (21 U.S.C. 301 et seq.), including section 301  
19 of such Act (21 U.S.C. 331); or

20           (2) the Secretary of Agriculture to take enforce-  
21 ment actions with respect to a violation of the Plant  
22 Protection Act (7 U.S.C. 7701 et seq.), including  
23 section 411 of such Act (7 U.S.C. 7711).

1                   **TITLE II—GENETIC**  
2                   **ENGINEERING CERTIFICATION**

3                   **SEC. 201. GENETIC ENGINEERING CERTIFICATION.**

4                   The Agricultural Marketing Act of 1946 (7 U.S.C.  
5                   1621 et seq.) is amended by adding at the end the fol-  
6                   lowing new subtitle:

7                   **“Subtitle E—Genetic Engineering**  
8                   **Certification**

9                   **“SEC. 291. DEFINITIONS.**

10                  “In this subtitle:

11                         “(1) The term ‘certifying agent’ means any per-  
12                         son (including a private entity) who is accredited by  
13                         the Secretary as a certifying agent for the purpose  
14                         of certifying a covered agricultural product as a  
15                         product to be labeled to indicate whether the product  
16                         is produced with or without the use of genetic engi-  
17                         neering.

18                         “(2) The term ‘covered agricultural product’  
19                         means any agricultural commodity or product,  
20                         whether raw or processed, including any commodity  
21                         or product derived from livestock that is marketed in  
22                         the United States for human or livestock consump-  
23                         tion and seed or other propagative material.

24                         “(3) The term ‘genetically engineered plant’ re-  
25                         fers to a plant (as defined in section 403 of the

1 Plant Protection Act (7 U.S.C. 7702)) or a seed, a  
2 fruit, or any other part thereof, if—

3 “(A) it contains genetic material that has  
4 been modified through in vitro recombinant  
5 deoxyribonucleic acid (DNA) techniques; and

6 “(B) the modification could not otherwise  
7 be obtained using conventional breeding tech-  
8 niques.

9 “(4) The term ‘comparable marketed food’  
10 means with respect to an agricultural product pro-  
11 duced from, containing, or consisting of a genetically  
12 engineered plant—

13 “(A) the parental variety of the plant;

14 “(B) another commonly consumed variety  
15 of the plant; or

16 “(C) a plant variety from which is derived  
17 a commonly consumed agricultural product with  
18 properties comparable to the agricultural prod-  
19 uct produced from, containing, or consisting of  
20 the plant that is a genetically engineered plant.

21 “(5) The term ‘handle’ means to sell, process or  
22 package covered agricultural products.

23 “(6) The term ‘producer’ means a person who  
24 engages in the business of growing or producing cov-  
25 ered agricultural products.

1           “(7) The term ‘Secretary’ means the Secretary  
2           of Agriculture, acting through the Agricultural Mar-  
3           keting Service.

4   **“SEC. 291A. NATIONAL GENETICALLY ENGINEERED FOOD**  
5           **CERTIFICATION PROGRAM.**

6           “(a) IN GENERAL.—The Secretary shall establish a  
7           genetically engineered food certification program for cov-  
8           ered agricultural products with respect to the use of ge-  
9           netic engineering in the production of such products, as  
10          provided for in this subtitle. The Secretary shall establish  
11          the requirements and procedures as the Secretary deter-  
12          mines are necessary to carry out such program.

13          “(b) CONSULTATION.—In developing the program  
14          under subsection (a), the Secretary shall consult with such  
15          other parties as are necessary to develop such program.

16          “(c) CERTIFICATION.—The Secretary shall imple-  
17          ment the program established under subsection (a)  
18          through certifying agents. Such certifying agents may cer-  
19          tify that covered agricultural products were or were not  
20          produced with the use of genetic engineering, in accord-  
21          ance with this subtitle.

1 **“SEC. 291B. NATIONAL STANDARDS FOR LABELING NON-GE-**  
2 **NETICALLY ENGINEERED FOOD.**

3 “(a) IN GENERAL.—To be sold or labeled as a cov-  
4 ered agricultural product produced without the use of ge-  
5 netic engineering—

6 “(1) the agricultural product shall—

7 “(A) be subject to supply chain process  
8 controls that address—

9 “(i) the producer planting a seed that  
10 is not a genetically engineered plant;

11 “(ii) the producer keeping the crop  
12 separated during growth, harvesting, stor-  
13 age, and transportation; and

14 “(iii) persons in direct contact with  
15 such crop or agricultural products derived  
16 from such crop during transportation, stor-  
17 age, or processing keeping the agricultural  
18 product separated from other agricultural  
19 products that are or are derived from ge-  
20 netically engineered plants; and

21 “(B) be produced and handled in compli-  
22 ance with a non-genetically engineered food  
23 plan developed and approved in accordance with  
24 subsection (c); and

25 “(2) a label or advertising material on, or in  
26 conjunction with, such covered agricultural product

1 may not suggest either expressly or by implication  
2 that covered agricultural products developed without  
3 the use of genetic engineering are safer or of higher  
4 quality than covered agricultural products produced  
5 from, containing, or consisting of a genetically engi-  
6 neered plant.

7 “(b) EXCEPTIONS.—A covered agricultural product  
8 shall not be considered as not meeting the criteria speci-  
9 fied in subsection (a) solely because the covered agricul-  
10 tural product—

11 “(1) is produced with a genetically engineered  
12 processing aid, enzyme, or microorganism; or

13 “(2) is derived from microorganisms that con-  
14 sumed a nutrient source produced from, containing,  
15 or consisting of a genetically engineered plant.

16 “(c) NON-GENETICALLY ENGINEERED FOOD  
17 PLAN.—

18 “(1) IN GENERAL.—A producer or handler  
19 seeking certification under this section shall submit  
20 a non-genetically engineered food plan to the certi-  
21 fying agent and such plan shall be reviewed by the  
22 certifying agent who shall determine if such plan  
23 meets the requirements of this section.

24 “(2) CONTENTS.—A non-genetically engineered  
25 food plan shall contain a description of—



1           “(A) the procedures that will be followed  
2 to assure compliance with this section;

3           “(B) a description of the monitoring  
4 records that will be maintained; and

5           “(C) any corrective actions that will be im-  
6 plemented in the event there is a deviation from  
7 the plan.

8           “(3) AVAILABILITY.—The non-genetically engi-  
9 neered food plan and the records maintained under  
10 the plan shall be available for review and copying by  
11 the Secretary or a certifying agent.

12 **“SEC. 291C. NATIONAL STANDARDS FOR LABELING GENETI-  
13 CALLY ENGINEERED FOOD.**

14           “(a) IN GENERAL.—To be sold or labeled as a cov-  
15 ered agricultural product produced with the use of genetic  
16 engineering—

17           “(1) the covered agricultural product shall be  
18 produced and handled in compliance with a geneti-  
19 cally engineered food plan developed and approved in  
20 accordance with subsection (b); and

21           “(2) the labeling of such covered agricultural  
22 product shall—

23           “(A) not expressly or impliedly claim that  
24 a covered agricultural product developed with  
25 the use of genetic engineering is safer or of

1 higher quality solely because the covered agri-  
2 cultural product is a product developed with the  
3 use of genetic engineering;

4 “(B) not make any claims that are false or  
5 misleading; and

6 “(C) contain such information as the Sec-  
7 retary considers appropriate.

8 “(b) GENETICALLY ENGINEERED FOOD PLAN.—

9 “(1) IN GENERAL.—A producer or handler  
10 seeking certification under this section shall submit  
11 a genetically engineered food plan to the certifying  
12 agent and such plan shall be reviewed by the certi-  
13 fying agent who shall determine if such plan meets  
14 the requirements of this section.

15 “(2) AVAILABILITY.—The genetically engi-  
16 neered food plan and the records maintained under  
17 the plan shall be available for review and copying by  
18 the Secretary or a certifying agent.

19 “(c) PROHIBITION AGAINST RESTRICTING CERTAIN  
20 DISCLOSURES.—With respect to a covered agricultural  
21 product that otherwise meets the criteria specified in sub-  
22 section (a), the Secretary may not prevent a person—

23 “(1) from disclosing voluntarily on the labeling  
24 of such a covered agricultural product developed  
25 with the use of genetic engineering the manner in

1 which the product has been modified to express  
2 traits or characteristics that differ from its com-  
3 parable marketed food; or

4 “(2) from disclosing in advertisements, on the  
5 Internet, in response to consumer inquiries, or on  
6 other communications, other than in the labeling,  
7 that a covered agricultural product was developed  
8 with the use of genetic engineering.

9 **“SEC. 291D. IMPORTED PRODUCTS.**

10 “Imported agricultural products may be sold or la-  
11 beled as produced with or without the use of genetic engi-  
12 neering if the Secretary determines that such products  
13 have been produced and handled under a genetic engineer-  
14 ing certification program that provides safeguards and  
15 guidelines governing the production and handling of such  
16 products that are at least equivalent to the requirements  
17 of this subtitle.”.

18 **SEC. 202. REGULATIONS.**

19 (a) IN GENERAL.—Not later than one year after the  
20 date of the enactment of this Act, the Secretary of Agri-  
21 culture shall, in consultation with stakeholders as the Sec-  
22 retary determines appropriate, promulgate final regula-  
23 tions to carry out the amendments made by section 201.

1 (b) CONSIDERATIONS.—In promulgating regulations  
2 to carry out the amendments made by section 201, the  
3 Secretary of Agriculture shall—

4 (1) provide a process to account for certified  
5 non-genetically engineered covered agricultural prod-  
6 ucts containing a genetically engineered plant due to  
7 the inadvertent presence of such plant;

8 (2) take into account other voluntary labeling  
9 programs administered by the Secretary, and, to the  
10 greatest extent practicable, establish consistency  
11 among such programs and the certification program  
12 established under subtitle E of the Agricultural Mar-  
13 keting Act of 1946 (as added by section 201); and

14 (3) with respect to regulations for covered agri-  
15 cultural products intended for consumption by ani-  
16 mals other than humans—

17 (A) take into account the inherent dif-  
18 ferences between food intended for animal and  
19 human consumption, including the essential vi-  
20 tamins, minerals, and micronutrients required  
21 to be added to animal food to formulate a com-  
22 plete and balanced diet; and

23 (B) provide a process for requesting and  
24 granting exemptions under conditions estab-  
25 lished by the Secretary.

1 **SEC. 203. PREEMPTION.**

2       Regardless of whether regulations have been promul-  
3 gated under section 202, beginning on the date of the en-  
4 actment of this Act, no State or political subdivision of  
5 a State may directly or indirectly establish under any au-  
6 thority or continue in effect as to any agricultural product  
7 in interstate commerce any requirement for the labeling  
8 of covered agricultural products of the type described in  
9 section 291B or 291C of the Agricultural Marketing Act  
10 of 1946 (as added by section 201 of this Act) that is not  
11 identical to the requirements of such respective section.

