

111TH CONGRESS
2^D SESSION

H. R. 5578

To prohibit the open-air cultivation of genetically engineered pharmaceutical and industrial crops, to prohibit the use of common human food or animal feed as the host plant for a genetically engineered pharmaceutical or industrial chemical, to establish a tracking system to regulate the growing, handling, transportation, and disposal of pharmaceutical and industrial crops and their byproducts to prevent human, animal, and general environmental exposure to genetically engineered pharmaceutical and industrial crops and their byproducts, to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of genetically engineered foods, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 23, 2010

Mr. KUCINICH (for himself, Mr. DEFAZIO, Mr. FRANK of Massachusetts, Mr. GRIJALVA, Mr. STARK, and Ms. WOOLSEY) introduced the following bill; which was referred to the Committee on Agriculture, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To prohibit the open-air cultivation of genetically engineered pharmaceutical and industrial crops, to prohibit the use of common human food or animal feed as the host plant for a genetically engineered pharmaceutical or industrial chemical, to establish a tracking system to regulate the growing, handling, transportation, and disposal of pharmaceutical and industrial crops and their byproducts to prevent human, animal, and general environmental expo-

sure to genetically engineered pharmaceutical and industrial crops and their byproducts, to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of genetically engineered foods, and for other purposes.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
 5 “Genetically Engineered Safety Act”.

6 (b) TABLE OF CONTENTS.—The table of contents for
 7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—GENETICALLY ENGINEERED PHARMACEUTICAL AND
 INDUSTRIAL CROP SAFETY

Sec. 101. Short title.

Sec. 102. Findings.

Sec. 103. Definitions.

Sec. 104. Regulation of production of pharmaceutical crops and industrial
 crops.

Sec. 105. Civil penalties for violation.

Sec. 106. Report to Congress on alternative methods to produce pharmaceutical
 and industrial crops.

TITLE II—GENETICALLY ENGINEERED FOOD SAFETY

Sec. 201. Short title.

Sec. 202. Findings.

Sec. 203. Federal determination of safety of genetically engineered food; regula-
 tion as food additive.

Sec. 204. User fees regarding determination of safety of genetic food additives.

Sec. 205. Embargo authority.

Sec. 206. Rulemaking; effective date; previously unregulated marketed addi-
 tives.

1 **TITLE I—GENETICALLY ENGI-**
2 **NEERED PHARMACEUTICAL**
3 **AND INDUSTRIAL CROP SAFE-**
4 **TY**

5 **SEC. 101. SHORT TITLE.**

6 This title may be cited as the “Genetically Engi-
7 neered Pharmaceutical and Industrial Crop Safety Act of
8 2010”.

9 **SEC. 102. FINDINGS.**

10 Congress finds the following:

11 (1) A pharmaceutical crop or industrial crop is
12 a plant that has been genetically engineered to
13 produce a medical or industrial product, including a
14 human or veterinary drug, biologic, industrial, or re-
15 search chemical, or enzyme.

16 (2) The Department of Agriculture has issued
17 “split approval” permits to allow the cultivation of
18 10 food crops genetically engineered to produce bio-
19 pharmaceuticals or chemicals that are not approved
20 for human consumption. As of January 1, 2003,
21 more than 300 field trials have been conducted in
22 the United States. In nearly 70 percent of these
23 tests, corn has been the crop used, but other crops
24 tested include soybean, tobacco, rice, alfalfa, barley,

1 rapeseed (canola), wheat, tomato, safflower, and
2 sugercane.

3 (3) Many of the novel substances produced in
4 pharmaceutical crops and industrial crops exhibit
5 high levels of biological activity and are intended to
6 be used for particular medical or industrial pur-
7 poses, under very controlled circumstances. None of
8 these substances is intended to be incorporated in
9 food or to be spread into the environment.

10 (4) The magnitude of the risks posed by phar-
11 maceutical crops and industrial crops depends on
12 many factors, including the chemicals involved, the
13 organisms or environments exposed, and the level
14 and duration of the exposure. Humans, animals, and
15 the environment at large could be at risk from con-
16 tamination, a major concern of which is that bio-
17 active nonfood substances, which have not been test-
18 ed, will contaminate or otherwise adversely affect the
19 food supply. Substances intended for use as human
20 drugs are especially problematic because they are in-
21 tended to be biologically active in people.

22 (5) Pharmaceutical crops and industrial crops
23 also pose substantial liability and other economic
24 risks to farmers, grain handlers, food companies,
25 and other persons in the food and feed supply chain.

1 These risks include liability for contamination epi-
2 sodes, costly food recalls, losses in export markets,
3 reduced prices for a contaminated food or feed crop,
4 and loss of confidence in the safety of the American
5 food supply among foreign importers and consumers
6 of American agricultural commodities.

7 (6) These risks necessitate a zero tolerance
8 standard for the presence of pharmaceutical crops
9 and industrial crops and their byproducts in crops
10 used to produce human food or animal feed.

11 (7) While there presently exists a pro forma
12 zero tolerance standard, the Department of Agri-
13 culture and experts in the field acknowledge that
14 contamination of human food and animal feed is in-
15 evitable due to the inherent imprecision of biological
16 and agricultural systems, as well as the laxity of the
17 regulatory regime. This is illustrated, for example, in
18 the Department of Agriculture's regulations, which
19 aim not for prevention (recognized as unattainable),
20 but rather mitigation of the gene flow that results
21 in contamination of food/feed crops with these sub-
22 stances. Some experts in the field are calling for es-
23 tablishment of tolerances, despite the potential risks
24 involved.

1 (8) Therefore, appropriate regulatory controls,
2 as established by this title, are urgently needed to
3 ensure that pharmaceutical crops and industrial
4 crops and their byproducts do not enter human food
5 or animal feed crops at any level.

6 **SEC. 103. DEFINITIONS.**

7 In this title:

8 (1) The term “genetically engineered plant”
9 means a plant that contains a genetically engineered
10 material or was produced from a genetically engi-
11 neered seed. A plant shall be considered to contain
12 a genetically engineered material if the plant has
13 been injected or otherwise treated with a genetically
14 engineered material (except that the use of manure
15 as a fertilizer for the plant may not be construed to
16 mean that the plant is produced with a genetically
17 engineered material).

18 (2) The term “genetically engineered material”
19 means material that has been altered at the molec-
20 ular or cellular level by means that are not possible
21 under natural conditions or processes (including re-
22 combinant DNA and RNA techniques, cell fusion,
23 microencapsulation, macroencapsulation, gene dele-
24 tion and doubling, introducing a foreign gene, and
25 changing the positions of genes), other than a means

1 consisting exclusively of breeding, conjugation, fer-
2 mentation, hybridization, in vitro fertilization, tissue
3 culture, or mutagenesis.

4 (3) The term “genetically engineered seed”
5 means a seed that contains a genetically engineered
6 material or was produced with a genetically engi-
7 neered material. A seed shall be considered to con-
8 tain a genetically engineered material or to have
9 been produced with a genetically engineered material
10 if the seed (or the plant from which the seed is de-
11 rived) has been injected or otherwise treated with a
12 genetically engineered material (except that the use
13 of manure as a fertilizer for the plant may not be
14 construed to mean that any resulting seeds are pro-
15 duced with a genetically engineered material).

16 (4) The term “pharmaceutical crop” means a
17 genetically engineered plant that is designed to
18 produce medical products, including human and vet-
19 erinary drugs and biologics. The term includes a
20 crop intentionally treated with genetically engineered
21 material that, in turn, produces a medical substance.

22 (5) The term “industrial crop” means a geneti-
23 cally engineered plant that is designed to produce in-
24 dustrial products, including industrial and research
25 chemicals and enzymes. The term includes a crop in-

1 tentionally treated with genetically engineered mate-
2 rial that, in turn, produces an industrial substance.

3 **SEC. 104. REGULATION OF PRODUCTION OF PHARMA-**
4 **CEUTICAL CROPS AND INDUSTRIAL CROPS.**

5 (a) TEMPORARY MORATORIUM PENDING REGULA-
6 TIONS.—No pharmaceutical crop or industrial crop may
7 be grown, raised, or otherwise cultivated until the final
8 regulations and tracking system required by this section
9 are in effect.

10 (b) PROHIBITION ON OPEN-AIR CULTIVATION.—No
11 person may grow, raise or otherwise cultivate a pharma-
12 ceutical crop or industrial crop in an open air environ-
13 ment.

14 (c) PROHIBITION ON USE OF COMMON HUMAN
15 FOODS OR ANIMAL FEEDS.—No person may grow, raise,
16 or otherwise cultivate a pharmaceutical crop or industrial
17 crop in a food commonly used for human food or domestic
18 animal feed.

19 (d) BIOTECH TRACKING SYSTEM.—The United
20 States Department of Agriculture shall establish a track-
21 ing system to regulate the growing, handling, transpor-
22 tation, and disposal of all pharmaceutical and industrial
23 crops and their byproducts to prevent contamination.

24 (e) REGULATIONS.—The Secretary of Agriculture
25 shall issue regulations—

1 (1) to enforce the prohibitions imposed by sub-
2 sections (b) and (c);

3 (2) to designate the common foods whose use as
4 a source of a pharmaceutical crop or industrial crop
5 is prohibited by subsection (c); and

6 (3) to establish the tracking system required by
7 subsection (d).

8 **SEC. 105. CIVIL PENALTIES FOR VIOLATION.**

9 (a) **AUTHORITY TO ACCESS PENALTIES.**—The Sec-
10 retary of Agriculture may assess, by written order, a civil
11 penalty against a person that violates a provision of sec-
12 tion 105, including a regulation promulgated or order
13 issued under such section. Each violation, and each day
14 during which a violation continues, shall be a separate of-
15 fense.

16 (b) **AMOUNT AND FACTORS IN ACCESSING PEN-**
17 **ALTIES.**—The maximum amount that may be assessed
18 under this section for a violation may not exceed
19 \$1,000,000. In determining the amount of the civil pen-
20 alty, the Secretary shall take into account—

21 (1) the gravity of the violation;

22 (2) the degree of culpability;

23 (3) the size and type of the business; and

24 (4) any history of prior offenses under such sec-
25 tion or other laws administered by the Secretary.

1 (c) NOTICE AND OPPORTUNITY FOR HEARING.—The
2 Secretary shall not assess a civil penalty under this section
3 against a person unless the company is given notice and
4 opportunity for a hearing on the record before the Sec-
5 retary in accordance with sections 554 and 556 of title
6 5, United States Code.

7 (d) JUDICIAL REVIEW.—(1) An order assessing a
8 civil penalty against a person under subsection (a) may
9 be reviewed only in accordance with this subsection. The
10 order shall be final and conclusive unless the person—

11 (A) not later than 30 days after the effective
12 date of the order, files a petition for judicial review
13 in the United States court of appeals for the circuit
14 in which the person resides or has its principal place
15 of business or in the United States Court of Appeals
16 for the District of Columbia; and

17 (B) simultaneously sends a copy of the petition
18 by certified mail to the Secretary.

19 (2) The Secretary shall promptly file in the court a
20 certified copy of the record on which the violation was
21 found and the civil penalty assessed.

22 (e) COLLECTION ACTION FOR FAILURE TO PAY AS-
23 SESSMENT.—If a person fails to pay a civil penalty after
24 the order assessing the civil penalty has become final and
25 unappealable, the Secretary shall refer the matter to the

1 Attorney General, who shall bring a civil action to recover
2 the amount of the civil penalty in United States district
3 court. In the collection action, the validity and appro-
4 priateness of the order of the Secretary imposing the civil
5 penalty shall not be subject to review.

6 **SEC. 106. REPORT TO CONGRESS ON ALTERNATIVE METH-**
7 **ODS TO PRODUCE PHARMACEUTICAL AND IN-**
8 **DUSTRIAL CROPS.**

9 The National Academy of Sciences shall submit to
10 Congress a report that explores alternative methods to
11 produce pharmaceuticals or industrial chemicals that have
12 the advantage of being conducted in controlled production
13 facilities and do not present the risk of contamination.

14 **TITLE II—GENETICALLY**
15 **ENGINEERED FOOD SAFETY**

16 **SEC. 201. SHORT TITLE.**

17 This title may be cited as the “Genetically Engi-
18 neered Food Safety Act”.

19 **SEC. 202. FINDINGS.**

20 The Congress finds as follows:

21 (1) Genetic engineering is an artificial gene
22 transfer process wholly different from traditional
23 breeding.

24 (2) Genetic engineering can be used to produce
25 new versions of virtually all plant and animal foods.

1 Thus, within a short time, the food supply could
2 consist almost entirely of genetically engineered
3 products.

4 (3) This conversion from a food supply based
5 on traditionally bred organisms to one based on or-
6 ganisms produced through genetic engineering could
7 be one of the most important changes in our food
8 supply in this century.

9 (4) Genetically engineered foods present new
10 issues of safety that have not been adequately stud-
11 ied.

12 (5) The Congress has previously required that
13 food additives be analyzed for their safety prior to
14 their placement on the market.

15 (6) Adding new genes into a food should be
16 considered adding a food additive, thus requiring an
17 analysis of safety factors.

18 (7) Federal agencies have failed to uphold con-
19 gressional intent of the Food Additives Amendment
20 of 1958 by allowing genetically engineered foods to
21 be marketed, sold and otherwise used without re-
22 quiring pre-market safety testing addressing their
23 unique characteristics.

24 (8) The food additive process gives the Food
25 and Drug Administration discretion in applying the

1 safety factors that are generally recognized as ap-
2 propriate to evaluate the safety of food and food in-
3 gredients.

4 (9) Given the consensus among the scientific
5 community that genetic engineering can potentially
6 introduce hazards, such as allergens or toxins, ge-
7 netically engineered foods need to be evaluated on a
8 case-by-case basis and cannot be presumed to be
9 generally recognized as safe.

10 **SEC. 203. FEDERAL DETERMINATION OF SAFETY OF GE-**
11 **NETICALLY ENGINEERED FOOD; REGULA-**
12 **TION AS FOOD ADDITIVE.**

13 (a) INCLUSION IN DEFINITION OF FOOD ADDI-
14 TIVE.—Section 201 of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 321) is amended—

16 (1) in paragraph (s), by adding after and below
17 subparagraph (6) the following sentence:

18 “Such term includes the different genetic constructs, pro-
19 teins of such constructs, vectors, promoters, marker sys-
20 tems, and other appropriate terms that are used or cre-
21 ated as a result of the creation of a genetically engineered
22 food (as defined in paragraph (ss)), other than a genetic
23 construct, protein, vector, promoter, or marker system or
24 other appropriate term for which an application under sec-
25 tion 505 or 512 has been filed. For purposes of this Act,

1 the term ‘genetic food additive’ means a genetic construct,
2 protein, vector, promoter, or marker system or other ap-
3 propriate term that is so included.”; and

4 (2) by adding at the end the following:

5 “(ss)(1) The term ‘genetically engineered food’ means
6 food that contains or was produced with a genetically engi-
7 neered material.

8 “(2) The term ‘genetically engineered material’
9 means material derived from any part of a genetically en-
10 gineered organism, without regard to whether the altered
11 molecular or cellular characteristics of the organism are
12 detectable in the material.

13 “(3) The term ‘genetically engineered organism’
14 means—

15 “(A) an organism that has been altered at the
16 molecular or cellular level by means that are not
17 possible under natural conditions or processes (in-
18 cluding but not limited to recombinant DNA and
19 RNA techniques, cell fusion, microencapsulation,
20 macroencapsulation, gene deletion and doubling, in-
21 troducing a foreign gene, and changing the positions
22 of genes), other than a means consisting exclusively
23 of breeding, conjugation, fermentation, hybridiza-
24 tion, in vitro fertilization, tissue culture, or
25 mutagenesis; and

1 “(B) an organism made through sexual or asex-
2 ual reproduction (or both) involving an organism de-
3 scribed in clause (A), if possessing any of the altered
4 molecular or cellular characteristics of the organism
5 so described.

6 “(4) For purposes of subparagraph (1), a food shall
7 be considered to have been produced with a genetically en-
8 gineered material if the organism from which the food is
9 derived has been injected or otherwise treated with a ge-
10 netically engineered material (except that the use of ma-
11 nure as a fertilizer for raw agricultural commodities may
12 not be construed to mean that such commodities are pro-
13 duced with a genetically engineered material).”.

14 (b) PETITION TO ESTABLISH SAFETY.—

15 (1) DATA IN PETITION.—Section 409(b)(2) of
16 the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 348(b)(2)) is amended by adding after and
18 below subparagraph (E) the following sentence:

19 “In the case of a genetic food additive, such reports shall
20 include all data that was collected or developed pursuant
21 to the investigations, including data that does not support
22 the claim of safety for use.”.

23 (2) NOTICES; PUBLIC AVAILABILITY OF INFOR-
24 MATION.—Section 409(b)(5) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)) is
2 amended—

3 (A) by striking “(5)” and inserting
4 “(5)(A)”; and

5 (B) by adding at the end the following sub-
6 paragraphs:

7 “(B) In the case of a genetic food additive:

8 (i) Promptly after providing the notice under
9 subparagraph (A), the Secretary shall make avail-
10 able to the public all reports and data described in
11 paragraph (2)(E) that are contained in the petition
12 involved, and all other information in the petition to
13 the extent that the information is relevant to a de-
14 termination of the safety for use of the additive.

15 (ii) Such notice shall state whether any infor-
16 mation in the petition is not being made available to
17 the public because the Secretary has made a deter-
18 mination that the information does not relate to the
19 safety for use of the additive. Any person may peti-
20 tion the Secretary for a reconsideration of such a de-
21 termination.

22 “(C) In the case of genetic food additives:

23 (i) The Secretary shall maintain and make
24 available to the public through telecommunications a
25 list of petitions that are pending under this sub-

1 section and a list of petitions for which regulations
2 under subsection (c)(1)(A) have been established.
3 Such list shall include information on the additives
4 involved, including the source of the additives, and
5 including any information received by the Secretary
6 pursuant to clause (ii).

7 “(ii) If a regulation is in effect under sub-
8 section (c)(1)(A) for a genetic food additive, any
9 person who manufactures such additive for commer-
10 cial use shall submit to the Secretary a notification
11 of any knowledge of data that relate to the adverse
12 health effects of the additive, when knowledge is ac-
13 quired by the person after the date on which the
14 regulation took effect. If the manufacturer is in pos-
15 session of the data, the notification shall include the
16 data. The Secretary shall by regulation establish the
17 scope of the responsibilities of manufacturers under
18 this clause, including such limits on the responsibil-
19 ities as the Secretary determines to be appropriate.”.

20 (3) EFFECTIVE DATE OF REGULATION REGARD-
21 ING SAFE USE; OPPORTUNITY FOR PUBLIC COM-
22 MENT.—Section 409(c)(2) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 348(c)(2)) is
24 amended—

1 (A) by striking “(2)” and inserting
2 “(2)(A)”; and

3 (B) by adding at the end the following sub-
4 paragraph:

5 “(B)(i) In the case of a genetic food additive, an
6 order under paragraph (1)(A) may not be issued regarding
7 the petition involved before the expiration of the applicable
8 period under clause (ii). During such period, and con-
9 tinuing until an order under paragraph (1) is issued, the
10 Secretary shall provide interested persons an opportunity
11 to submit to the Secretary comments on the petition. In
12 publishing such notice, the Secretary shall inform the pub-
13 lic of such opportunity.

14 “(ii) For purposes of clause (i), the applicable period
15 under this clause regarding a petition is the 30-day period
16 beginning on the date on which the Secretary has under
17 subparagraph (B)(i) of subsection (b)(5) made informa-
18 tion available to the public regarding the petition, except
19 that, if under subparagraph (B)(ii) of such subsection the
20 Secretary finds in favor of a person who files for reconsid-
21 eration (relating to a determination by the Secretary that
22 information does not relate to safety), such 30-day period
23 is extended by an additional period of 30 days. For pur-
24 poses of the preceding sentence, a discrete 30-day exten-
25 sion applies to each such reconsideration for which the

1 Secretary finds in favor of the person filing for reconsider-
2 ation.”.

3 (4) CONSIDERATION OF CERTAIN FACTORS.—

4 Section 409(c) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 348(c)) is amended by adding
6 at the end the following paragraph:

7 “(6) In the case of a genetic food additive, the factors
8 considered by the Secretary regarding safety for use shall
9 include (but not be limited to) the results of the following
10 analyses:

11 “(A) Allergenicity effects resulting from the
12 added proteins, including proteins not found in the
13 food supply.

14 “(B) Pleiotropic effects. The Secretary shall re-
15 quire tests to determine the potential for such ef-
16 fects (using molecular characterization, biochemical
17 characterization, mRNA profiling, or other tech-
18 niques, or as appropriate, combinations of such tech-
19 niques).

20 “(C) Appearance of new toxins or increased lev-
21 els of existing toxins.

22 “(D) Changes in the functional characteristics
23 of food.

24 “(E) Changes in the levels of important nutri-
25 ents.

1 “(F) Changes in the levels of anti-nutrients.”.

2 (5) CERTAIN TESTS.—Section 409(c) of the
3 Federal Food, Drug, and Cosmetic Act, as amended
4 by paragraph (4), is amended by adding at the end
5 the following paragraph:

6 “(7) In the case of genetic food additives:

7 “(A) If a genetic food additive is a protein from
8 a commonly or severely allergenic food, the Sec-
9 retary may not establish a regulation under para-
10 graph (1)(A) if the petition under subsection (b)(1)
11 fails to include full reports of investigations that
12 used serum or skin tests (or other advanced tech-
13 niques) on a sensitive population to determine
14 whether such additive is commonly or severely aller-
15 genic.

16 “(B)(i) If a genetic food additive is a protein
17 that has not undergone the investigations described
18 in subparagraph (A), the Secretary may not estab-
19 lish a regulation under paragraph (1)(A) if the peti-
20 tion under subsection (b)(1) fails to include full re-
21 ports of investigations that used the best available
22 biochemical and physiological protocols to evaluate
23 whether it is likely that the protein involved is an al-
24 lergen.

1 “(ii) For purposes of clause (i), the Secretary
2 shall by regulation determine the best available bio-
3 chemical and physiological protocols. In carrying out
4 rulemaking under the preceding sentence, the Sec-
5 retary shall consult with the Director of the Na-
6 tional Institutes of Health.”.

7 (6) PROHIBITED ADDITIVES.—Section 409(c) of
8 the Federal Food, Drug, and Cosmetic Act, as
9 amended by paragraph (5), is amended by adding at
10 the end the following paragraph:

11 “(8) In the case of a genetic food additive, the Sec-
12 retary may not establish a regulation under paragraph
13 (1)(A) if—

14 “(A) the additive is a protein and a report of
15 an investigation finds that the additive is likely to be
16 commonly or severely allergenic;

17 “(B) the additive is a protein and a report of
18 an investigation that uses a protocol described in
19 paragraph (7)(B) fails to find with reasonable cer-
20 tainty that the additive is unlikely to be an allergen;
21 or

22 “(C) effective June 1, 2006, a selective marker
23 is used with respect to the additive, the selective
24 marker will remain in the food involved when the

1 food is marketed, and the selective marker inhibits
2 the function of one or more antibiotics.”.

3 (7) ADDITIONAL PROVISIONS.—Section 409(c)
4 of the Federal Food, Drug, and Cosmetic Act, as
5 amended by paragraph (6), is amended by adding at
6 the end the following paragraph:

7 “(9)(A) In determining the safety for use of genetic
8 food additives, the Secretary may (directly or through con-
9 tract) conduct investigations of such additives for pur-
10 poses of supplementing the information provided to the
11 Secretary pursuant to petitions under subsection (b)(1).

12 “(B) To provide the Congress with a periodic inde-
13 pendent, external review of the Secretary’s formulation of
14 the approval process under paragraph (1)(A) that relates
15 to genetic food additives, the Secretary shall enter into
16 an agreement with the Institute of Medicine. Such agree-
17 ment shall provide that, if the Institute of Medicine has
18 any concerns regarding the approval process, the Institute
19 of Medicine will submit to the Congress a report describ-
20 ing such concerns.”.

21 (c) REGULATION ISSUED ON SECRETARY’S INITIA-
22 TIVE.—Section 409(d) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 348(d)) is amended—

1 (1) by striking “(d) The Secretary” and insert-
2 ing “(d)(1) Subject to paragraph (2), the Sec-
3 retary”; and

4 (2) by adding at the end the following para-
5 graph:

6 “(2) The provisions of subsections (b) and (c) that
7 expressly reference genetic food additives apply with re-
8 spect to a regulation proposed by the Secretary under
9 paragraph (1) to the same extent and in the same manner
10 as such provisions apply with respect to a petition filed
11 under subsection (b)(1).”.

12 (d) CIVIL PENALTIES.—Section 303 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amend-
14 ed by adding at the end the following subsection:

15 “(h)(1) With respect to a violation of section 301(a),
16 301(b), or 301(c) involving the adulteration of food by rea-
17 son of failure to comply with the provisions of section 409
18 that relate to genetic food additives, any person engaging
19 in such a violation shall be liable to the United States for
20 a civil penalty in an amount not to exceed \$100,000 for
21 each such violation.

22 “(2) Paragraphs (5) through (7) of subsection (f)
23 apply with respect to a civil penalty under paragraph (1)
24 of this subsection to the same extent and in the same man-
25 ner as such paragraphs (5) through (7) apply with respect

1 to a civil penalty under paragraph (1), (2), (3), (4), or
2 (9) of subsection (f).”.

3 (e) CITIZEN SUITS.—Chapter III of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 331 et seq.)
5 is amended by adding at the end the following section:

6 **“SEC. 311. CITIZEN SUITS REGARDING GENETIC FOOD AD-**
7 **DITIVES.**

8 “(a) IN GENERAL.—Except as provided in subsection
9 (c), any person may on his or her behalf commence a civil
10 action in an appropriate district court of the United States
11 against—

12 “(1) a person who is alleged to have engaged in
13 a violation of section 301(a), 301(b), or 301(c) in-
14 volving the adulteration of food by reason of failing
15 to comply with the provisions of section 409 that re-
16 late to genetic food additives; or

17 “(2) the Secretary where there is alleged a fail-
18 ure of the Secretary to perform any act or duty
19 under section 409 that relates to such additives and
20 is not discretionary.

21 “(b) RELIEF.—In a civil action under subsection (a),
22 the district court involved may, as the case may be—

23 “(1) enforce the compliance of a person with
24 the applicable provisions referred to paragraph (1)
25 of such subsection; or

1 “(2) order the Secretary to perform an act or
2 duty referred to in paragraph (2) of such subsection.

3 “(c) LIMITATIONS.—

4 “(1) NOTICE TO SECRETARY.—A civil action
5 may not be commenced under subsection (a)(1) prior
6 to 60 days after the plaintiff has provided to the
7 Secretary notice of the violation involved.

8 “(2) RELATION TO ACTIONS OF SECRETARY.—

9 A civil action may not be commenced under sub-
10 section (a)(2) if the Secretary has commenced and
11 is diligently prosecuting a civil or criminal action in
12 a district court of the United States to enforce com-
13 pliance with the applicable provisions referred to in
14 subsection (a)(1).

15 “(d) RIGHT OF SECRETARY TO INTERVENE.—In any
16 civil action under subsection (a), the Secretary, if not a
17 party, may intervene as a matter of right.

18 “(e) AWARD OF COSTS; FILING OF BOND.—In a civil
19 action under subsection (a), the district court involved
20 may award costs of litigation (including reasonable attor-
21 ney and expert witness fees) to any party whenever the
22 court determines such an award is appropriate. The court
23 may, if a temporary restraining order or preliminary in-
24 junction is sought, require the filing of a bond or equiva-

1 lent security in accordance with the Federal Rules of Civil
2 Procedure.

3 “(f) SAVINGS PROVISION.—This section does not re-
4 strict any right that a person (or class of persons) may
5 have under any statute or common law to seek enforce-
6 ment of the provisions referred to subsection (a)(1), or to
7 seek any other relief (including relief against the Sec-
8 retary).”.

9 (f) RULE OF CONSTRUCTION.—With respect to sec-
10 tion 409 of the Federal Food, Drug, and Cosmetic Act
11 as amended by this section, compliance with the provisions
12 of such section 409 that relate to genetic food additives
13 does not constitute an affirmative defense in any cause
14 of action under Federal or State law for personal injury
15 resulting in whole or in part from a genetic food additive.

16 **SEC. 204. USER FEES REGARDING DETERMINATION OF**
17 **SAFETY OF GENETIC FOOD ADDITIVES.**

18 Chapter IV of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 341 et seq.) is amended by inserting after
20 section 409 the following section:

21 **“SEC. 409A. USER FEES REGARDING SAFETY OF GENETIC**
22 **FOOD ADDITIVES.**

23 “(a) IN GENERAL.—In the case of genetic food addi-
24 tives, the Secretary shall in accordance with this section
25 assess and collect a fee on each petition that is filed under

1 section 409(b)(1). The fee shall be collected from the per-
2 son who submits the petition, is due upon submission of
3 the petition, and shall be assessed in an amount deter-
4 mined under subsection (c). This section applies as of the
5 first fiscal year that begins after the date of promulgation
6 of the final rule required in section 206 of the Genetically
7 Engineered Food Safety Act (referred to in this section
8 as the ‘first applicable fiscal year’).

9 “(b) PURPOSE OF FEES.—

10 “(1) IN GENERAL.—The purposes of fees under
11 subsection (a) are as follows:

12 “(A) To defray increases in the costs of
13 the resources allocated for carrying out section
14 409 for the first applicable fiscal year over the
15 costs of carrying out such section for the pre-
16 ceding fiscal year, other than increases that are
17 not attributable to the responsibilities of the
18 Secretary with respect to genetic food additives.

19 “(B) To provide for a program of basic
20 and applied research on the safety of genetic
21 food additives (to be carried out by the Com-
22 missioner). The program shall address funda-
23 mental questions and problems that arise re-
24 peatedly during the process of reviewing peti-
25 tions under section 409(b)(1) with respect to

1 genetic food additives, and shall not directly
2 support the development of new genetically en-
3 gineered foods.

4 “(2) ALLOCATIONS BY SECRETARY.—Of the
5 total fee revenues collected under subsection (a) for
6 a fiscal year, the Secretary shall reserve and ex-
7 pend—

8 “(A) 95 percent for the purpose described
9 in paragraph (1)(A); and

10 “(B) 5 percent for the purpose described
11 in paragraph (1)(B).

12 “(3) CERTAIN PROVISIONS REGARDING IN-
13 CREASED ADMINISTRATIVE COSTS.—With respect to
14 fees under subsection (a):

15 “(A) Increases referred to in paragraph
16 (1)(A) include the costs of the Secretary in pro-
17 viding for investigations under section
18 409(c)(9)(A).

19 “(B) Increases referred to in paragraph
20 (1)(A) include increases in costs for an addi-
21 tional number of full-time equivalent positions
22 in the Department of Health and Human Serv-
23 ices to be engaged in carrying out section 409
24 with respect to genetic food additives.

1 “(c) TOTAL FEE REVENUES; INDIVIDUAL FEE
2 AMOUNTS.—The total fee revenues collected under sub-
3 section (a) for a fiscal year shall be the amounts appro-
4 priated under subsection (f)(2) for such fiscal year. Indi-
5 vidual fees shall be assessed by the Secretary on the basis
6 of an estimate by the Secretary of the amount necessary
7 to ensure that the sum of the fees collected for such fiscal
8 year equals the amount so appropriated. In assessing the
9 individual fees, the Secretary shall by regulation provide
10 for the assessment of reduced fee amounts for entities that
11 are small businesses, or nonprofit private entities, as de-
12 fined by the Secretary for purposes of this section.

13 “(d) FEE WAIVER OR REDUCTION.—The Secretary
14 shall grant a waiver from or a reduction of a fee assessed
15 under subsection (a) if the Secretary finds that the fee
16 to be paid will exceed the anticipated present and future
17 costs incurred by the Secretary in carrying out the pur-
18 poses described in subsection (b) (which finding may be
19 made by the Secretary using standard costs).

20 “(e) ASSESSMENT OF FEES.—

21 “(1) LIMITATION.—Fees may not be assessed
22 under subsection (a) for a fiscal year beginning after
23 the first applicable fiscal year unless the amount ap-
24 propriated for salaries and expenses of the Food and
25 Drug Administration for such fiscal year is equal to

1 or greater than the amount appropriated for salaries
2 and expenses of the Food and Drug Administration
3 for the first applicable fiscal year multiplied by the
4 adjustment factor applicable to the fiscal year in-
5 volved, except that in making determinations under
6 this paragraph for the fiscal years involved there
7 shall be excluded—

8 “(A) the amounts appropriated under sub-
9 section (f)(2) for the fiscal years involved; and

10 “(B) the amounts appropriated under sec-
11 tions 736(g), 738(h), 740(g), and 741(g) for
12 such fiscal years.

13 “(2) AUTHORITY.—If under paragraph (1) the
14 Secretary does not have authority to assess fees
15 under subsection (a) during a portion of a fiscal
16 year, but does at a later date in such fiscal year
17 have such authority, the Secretary, notwithstanding
18 the due date under such subsection for fees, may as-
19 sess and collect such fees at any time in such fiscal
20 year, without any modification in the rate of the
21 fees.

22 “(f) CREDITING AND AVAILABILITY OF FEES.—

23 “(1) IN GENERAL.—Fees collected for a fiscal
24 year pursuant to subsection (a) shall be credited to
25 the appropriation account for salaries and expenses

1 of the Food and Drug Administration and shall be
2 available in accordance with appropriation Acts until
3 expended without fiscal year limitation. Such sums
4 as may be necessary may be transferred from the
5 Food and Drug Administration salaries and ex-
6 penses appropriation account without fiscal year lim-
7 itation to such appropriation account for salaries
8 and expenses with such fiscal year limitation. The
9 sums transferred shall be available solely for the
10 purposes described in paragraph (1) of subsection
11 (b), and the sums are subject to allocations under
12 paragraph (2) of such subsection.

13 “(2) AUTHORIZATION OF APPROPRIATIONS.—

14 “(A) FIRST FISCAL YEAR.—For the first
15 applicable fiscal year—

16 “(i) there is authorized to be appro-
17 priated for fees under subsection (a) an
18 amount equal to the amount of increase
19 determined under subsection (b)(1)(A) by
20 the Secretary (which amount shall be pub-
21 lished in the Federal Register); and

22 “(ii) in addition, there is authorized to
23 be appropriated for fees under subsection
24 (a) an amount determined by the Secretary
25 to be necessary to carry out the purpose

1 described in subsection (b)(1)(B) (which
2 amount shall be so published).

3 “(B) SUBSEQUENT FISCAL YEARS.—For
4 each of the four fiscal years following the first
5 applicable fiscal year—

6 “(i) there is authorized to be appro-
7 priated for fees under subsection (a) an
8 amount equal to the amount that applied
9 under subparagraph (A)(i) for the first ap-
10 plicable fiscal year, except that such
11 amount shall be adjusted under paragraph
12 (3)(A) for the fiscal year involved; and

13 “(ii) in addition, there is authorized to
14 be appropriated for fees under subsection
15 (a) an amount equal to the amount that
16 applied under subparagraph (A)(ii) for the
17 first applicable fiscal year, except that such
18 amount shall be adjusted under paragraph
19 (3)(B) for the fiscal year involved.

20 “(3) ADJUSTMENTS.—

21 “(A) AGENCY COST OF RESOURCES.—For
22 each fiscal year other than the first applicable
23 fiscal year, the amount that applied under para-
24 graph (2)(A)(i) for the first applicable fiscal

1 year shall be multiplied by the adjustment fac-
2 tor (as defined in subsection (i)).

3 “(B) RESEARCH PROGRAM.—For each fis-
4 cal year other than the first applicable fiscal
5 year, the amount that applied under paragraph
6 (2)(A)(ii) for the first applicable fiscal year
7 shall be adjusted by the Secretary (and as ad-
8 justed shall be published in the Federal Reg-
9 ister) to reflect the greater of—

10 “(i) the total percentage change that
11 occurred during the preceding fiscal year
12 in the Consumer Price Index for all urban
13 consumers (all items; U.S. city average); or

14 “(ii) the total percentage change for
15 such fiscal year in basic pay under the
16 General Schedule in accordance with sec-
17 tion 5332 of title 5, United States Code,
18 as adjusted by any locality-based com-
19 parability payment pursuant to section
20 5304 of such title for Federal employees
21 stationed in the District of Columbia.

22 “(4) OFFSET.—Any amount of fees collected
23 for a fiscal year under subsection (a) that exceeds
24 the amount of fees specified in appropriation Acts
25 for such fiscal year shall be credited to the appro-

1 priation account of the Food and Drug Administra-
2 tion as provided in paragraph (1), and shall be sub-
3 tracted from the amount of fees that would other-
4 wise be authorized to be collected under this section
5 pursuant to appropriation Acts for a subsequent fis-
6 cal year.

7 “(g) COLLECTION OF UNPAID FEES.—In any case
8 where the Secretary does not receive payment of a fee as-
9 sessed under subsection (a) within 30 days after it is due,
10 such fee shall be treated as a claim of the United States
11 Government subject to subchapter II of chapter 37 of title
12 31, United States Code.

13 “(h) CONSTRUCTION.—This section may not be con-
14 strued as requiring that the number of full-time equivalent
15 positions in the Department of Health and Human Serv-
16 ices, for officers, employers, and advisory committees not
17 engaged in carrying out section 409 with respect to ge-
18 netic food additives be reduced to offset the number of
19 officers, employees, and advisory committees so engaged.

20 “(i) DEFINITION OF ADJUSTMENT FACTOR.—For
21 purposes of this section, the term ‘adjustment factor’ ap-
22 plicable to a fiscal year is the lower of—

23 “(1) the Consumer Price Index for all urban
24 consumers (all items; United States city average) for

1 April of the preceding fiscal year divided by such
2 Index for April of the first applicable fiscal year; or
3 “(2) the total of discretionary budget authority
4 provided for programs in categories other than the
5 defense category for the immediately preceding fiscal
6 year (as reported in the Office of Management and
7 Budget sequestration preview report, if available, re-
8 quired under section 254(c) of the Balanced Budget
9 and Emergency Deficit Control Act of 1985) divided
10 by such budget authority for the first applicable fis-
11 cal year (as reported in the Office of Management
12 and Budget final sequestration report submitted for
13 such year).

14 For purposes of this subsection, the terms ‘budget author-
15 ity’ and ‘category’ have the meaning given such terms in
16 the Balanced Budget and Emergency Deficit Control Act
17 of 1985.”.

18 **SEC. 205. EMBARGO AUTHORITY.**

19 (a) EMBARGO.—

20 (1) TEMPORARY DETENTION.—Section
21 304(g)(1) of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 334(g)(1)) is amended—

23 (A) in the first sentence—

24 (i) by striking “If during” and all
25 that follows through “order the device or

1 tobacco product detained” and inserting
2 the following: “If, during an inspection
3 conducted under section 704, an officer or
4 employee of the Department has reason to
5 believe that a food, device, or tobacco prod-
6 uct is in violation of this Act, such officer
7 or employee may order the food, device, or
8 tobacco product detained”; and

9 (ii) by striking “he may authorize”
10 and inserting “the Secretary may author-
11 ize”;

12 (B) in the second and third sentences, by
13 striking “device or tobacco product” each place
14 it appears and inserting “food, device, or to-
15 bacco product”;

16 (C) by striking the fourth and fifth sen-
17 tences; and

18 (D) by adding at the end the following sen-
19 tence: “A detention order under this paragraph
20 shall be considered final agency action.”.

21 (2) CONFORMING AMENDMENTS.—Chapter III
22 of the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 331 et seq.) is amended—

24 (A) in section 301(r)—

1 (i) by striking “device or tobacco
2 product” the first place such term appears
3 and inserting “food, device, or tobacco
4 product”; and

5 (ii) by striking “the device or tobacco
6 product” and inserting “such food, device,
7 or tobacco product”; and

8 (B) in section 304(g)(2)—

9 (i) in subparagraph (A), by striking
10 “device or tobacco product” and inserting
11 “food, device, or tobacco product”; and

12 (ii) in subparagraph (B), by striking
13 “device” each place it appears and insert-
14 ing “food or device”.

15 (b) DATE CERTAIN FOR PROPOSED AND FINAL
16 RULES.—Within six months of the date of the enactment
17 of this title, the Secretary of Health and Human Services
18 shall propose a revision to the regulations in effect on such
19 date under section 304(g) of the Federal Food, Drug, and
20 Cosmetic Act to include food. Within three months of the
21 date such proposed revision is published in the Federal
22 Register, the Secretary shall issue a final revision of such
23 regulations.

24 (c) CONFIDENTIALITY.—For any food embargoed,
25 seized, or recalled under the Federal Food, Drug, and Cos-

1 metic Act, the Food and Drug Administration shall dis-
2 close all necessary information without regard to business
3 confidentiality, if such disclosure is necessary to fully em-
4 bargo, seize, or recall any adulterated food.

5 (d) **FOOD RETAILER REGISTRATION.**—All food re-
6 tailers shall register with the Food and Drug Administra-
7 tion for the purpose of expediting recalls, embargoes, and
8 seizures under the Federal Food, Drug, and Cosmetic Act.

9 **SEC. 206. RULEMAKING; EFFECTIVE DATE; PREVIOUSLY**
10 **UNREGULATED MARKETED ADDITIVES.**

11 (a) **RULEMAKING; EFFECTIVE DATE.**—Not later
12 than one year after the date of the enactment of this title,
13 the Secretary of Health and Human Services shall by reg-
14 ulation establish criteria for carrying out section 409 of
15 the Federal Food, Drug, and Cosmetic Act in accordance
16 with the amendments made by section 203, and criteria
17 for carrying out section 409A of such Act (as added by
18 section 204). Such amendments take effect upon the expi-
19 ration of the 30-day period beginning on the date on which
20 the Secretary promulgates the final rule under the pre-
21 ceding sentence, subject to subsection (b).

22 (b) **PREVIOUSLY UNREGULATED MARKETED ADDI-**
23 **TIVES.**—

24 (1) **IN GENERAL.**—In the case of a genetic food
25 additive (as defined pursuant to the amendments

1 made by section 203) that in the United States was
2 in commercial use in food as of the day before the
3 date on which the final rule under subsection (a) is
4 promulgated, the amendments made by this title
5 apply to the additive upon the expiration of the two-
6 year period beginning on the date on which the final
7 rule is promulgated, subject to paragraph (2).

8 (2) USER FEES.—With respect to a genetic
9 food additive described in paragraph (1), such para-
10 graph does not waive the applicability of section
11 409A of the Federal Food, Drug, and Cosmetic Act
12 to a petition under section 409(b)(1) of such Act
13 that is filed before the expiration of the two-year pe-
14 riod described in such paragraph.

○