

106TH CONGRESS
2D SESSION

H. R. 3883

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of genetically engineered foods.

IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2000

Mr. KUCINICH (for himself, Mr. METCALF, Mr. HINCHEY, Mr. CONYERS, Mr. SANDERS, Ms. WOOLSEY, and Ms. LEE) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of genetically engineered foods.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Genetically Engineered
5 Food Safety Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) Genetic engineering is an artificial gene
9 transfer process wholly different from traditional
10 breeding.

1 (2) Genetic engineering can be used to produce
2 new versions of virtually all plant and animal foods.
3 Thus, within a short time, the food supply could
4 consist almost entirely of genetically engineered
5 products.

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

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

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

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

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

1 (8) The food additive process gives the Food
2 and Drug Administration discretion in applying the
3 safety factors that are generally recognized as ap-
4 propriate to evaluate the safety of food and food in-
5 gredients.

6 **SEC. 3. FEDERAL DETERMINATION OF SAFETY OF GENETI-**
7 **CALLY ENGINEERED FOOD; REGULATION AS**
8 **FOOD ADDITIVE.**

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

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

14 “Such term includes the different genetic constructs, pro-
15 teins of such constructs, vectors, promoters, marker sys-
16 tems, and other appropriate terms that are used or cre-
17 ated as a result of the creation of a genetically engineered
18 food (as defined in paragraph (kk)), other than a genetic
19 construct, protein, vector, promoter, or marker system or
20 other appropriate term for which an application under sec-
21 tion 505 or 512 has been filed. For purposes of this Act,
22 the term ‘genetic food additive’ means a genetic construct,
23 protein, vector, promoter, or marker system or other ap-
24 propriate term that is so included.”; and

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

1 “(kk)(1) The term ‘genetically engineered food’
2 means food that contains or was produced with a geneti-
3 cally engineered material.

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

9 “(3) The term ‘genetically engineered organism’
10 means—

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

21 “(B) an organism made through sexual or asex-
22 ual reproduction (or both) involving an organism de-
23 scribed in clause (A), if possessing any of the altered
24 molecular or cellular characteristics of the organism
25 so described.

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

9 (b) PETITION TO ESTABLISH SAFETY.—

10 (1) DATA IN PETITION.—Section 409(b)(2)(E)
11 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 348(b)(2)(E)) is amended by adding at the
13 end the following sentence: “In the case of a genetic
14 food additive, such reports shall include all data that
15 was collected or developed pursuant to the investiga-
16 tions, including data that does not support the claim
17 of safety for use.”.

18 (2) NOTICES; PUBLIC AVAILABILITY OF INFOR-
19 MATION.—Section 409(b)(5) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)) is
21 amended—

22 (A) by striking “(5)” and inserting
23 “(5)(A)”; and

24 (B) by adding at the end the following sub-
25 paragraphs:

1 “(B) In the case of a genetic food additive, the Sec-
2 retary, promptly after providing the notice under subpara-
3 graph (A), shall make available to the public all reports
4 and data described in paragraph (2)(E) that are contained
5 in the petition involved, and all other information in the
6 petition to the extent that the information is relevant to
7 a determination of the safety for use of the additive. Such
8 notice shall state whether any information in the petition
9 is not being made available to the public because the Sec-
10 retary has made a determination that the information does
11 not relate to the safety for use of the additive. Any person
12 may petition the Secretary for a reconsideration of such
13 a determination, and if the Secretary finds in favor of such
14 person, the period for public comment under subsection
15 (c)(2)(B) shall be extended accordingly.

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

17 “(i) The Secretary shall maintain and make
18 available to the public through telecommunications a
19 list of petitions that are pending under this sub-
20 section and a list of petitions for which regulations
21 under subsection (c)(1)(A) have been established.
22 Such list shall include information on the additives
23 involved, including the source of the additives, and
24 including any information received by the Secretary
25 pursuant to clause (ii).

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

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

19 (A) by striking “(2)” and inserting
20 “(2)(A)”; and

21 (B) by adding at the end the following sub-
22 paragraph:

23 “(B) In the case of a genetic food additive, an order
24 under paragraph (1)(A) may not be issued before the expi-
25 ration of the 30-day period beginning on the date on which

1 the Secretary has under subsection (b)(5) made informa-
2 tion available to the public pursuant to a notification
3 under such subsection regarding the petition involved.
4 During such period (or such longer period as the Secretary
5 may designate), the Secretary shall provide interested per-
6 sons an opportunity to submit to the Secretary comments
7 on the petition. In publishing such notice, the Secretary
8 shall inform the public of such opportunity.”.

9 (3) CONSIDERATION OF CERTAIN FACTORS.—

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

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

17 “(A) Allergenicity effects resulting from the
18 added proteins, including proteins not found in the
19 food supply.

20 “(B) Pleiotropic effects. The Secretary shall re-
21 quire tests to determine the potential for such ef-
22 fects (using molecular characterization, biochemical
23 characterization, mRNA profiling, or other tech-
24 niques, or as appropriate, combinations of such tech-
25 niques).

1 “(C) Appearance of new toxins or increased lev-
2 els of existing toxins.

3 “(D) Changes in the functional characteristics
4 of food.

5 “(E) Changes in the levels of important nutri-
6 ents.”.

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

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

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

21 “(B)(i) If a genetic food additive is a protein
22 that has not undergone the investigations described
23 in subparagraph (A), the Secretary may not estab-
24 lish a regulation under paragraph (1)(A) if the peti-
25 tion under subsection (b)(1) fails to include full re-

1 ports of investigations that used the best available
2 biochemical and physiological protocols to evaluate
3 whether it is likely that the protein involved is an al-
4 lergen.

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

11 (5) PROHIBITED ADDITIVES.—Section 409(c) of
12 the Federal Food, Drug, and Cosmetic Act, as
13 amended by paragraph (4), is amended by adding at
14 the end the following paragraph:

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

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

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

1 “(C) effective June 1, 2004, a selective marker
2 is used with respect to the additive, the selective
3 marker will remain in the food involved when the
4 food is marketed, and the selective marker inhibits
5 the function of one or more antibiotics.”.

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

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

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

1 “(C) In the case of genetic food additives, petitions
2 under subsection (b)(1) may not be categorically excluded
3 for purposes of the National Environmental Policy Act.”.

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

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

10 (2) by adding at the end the following para-
11 graph:

12 “(2) The provisions of subsections (b) and (c) that
13 expressly reference genetic food additives apply with re-
14 spect to a regulation proposed by the Secretary under
15 paragraph (1) to the same extent and in the same manner
16 as such provisions apply with respect to a petition filed
17 under subsection (b)(1).”.

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

21 “(h)(1) With respect to a violation of section 301(a),
22 301(b), or 301(c) involving the adulteration of food by rea-
23 son of failure to comply with the provisions of section 409
24 that relate to genetic food additives, any person engaging
25 in such a violation shall be liable to the United States for

1 a civil penalty in an amount not to exceed \$100,000 for
2 each such violation.

3 “(2) Paragraphs (3) through (5) of subsection (g)
4 apply with respect to a civil penalty under paragraph (1)
5 of this subsection to the same extent and in the same man-
6 ner as such paragraphs (3) through (5) apply with respect
7 to a civil penalty under paragraph (1) or (2) of subsection
8 (g).”.

9 (e) **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. 4. USER FEES REGARDING DETERMINATION OF SAFE-**
17 **TY 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 “USER FEES REGARDING SAFETY OF GENETIC FOOD
22 ADDITIVES

23 “SEC. 409A. (a) **IN GENERAL.**—In the case of ge-
24 netic food additives, the Secretary shall in accordance with
25 this section assess and collect a fee on each petition that
26 is filed under section 409(b)(1). The fee shall be collected

1 from the person who submits the petition, is due upon sub-
2 mission of the petition, and shall be assessed in an amount
3 determined under subsection (c). This section applies as
4 of the first fiscal year that begins after the date of promul-
5 gation of the final rule required in section 5 of the Geneti-
6 cally Engineered Food Safety Act (referred to in this sec-
7 tion as the ‘first applicable fiscal year’).

8 “(b) PURPOSE OF FEES.—

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

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

18 “(B) To provide for a program of basic
19 and applied research on the safety of genetic
20 food additives (to be carried out by the Com-
21 missioner of Food and Drugs). The program
22 shall address fundamental questions and prob-
23 lems that arise repeatedly during the process of
24 reviewing petitions under section 409(b)(1) with
25 respect to genetic food additives, and shall not

1 directly support the development of new geneti-
2 cally engineered foods.

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

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

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

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

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

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

24 “(c) TOTAL FEE REVENUES; INDIVIDUAL FEE
25 AMOUNTS.—The total fee revenues collected under sub-

1 section (a) for a fiscal year shall be the amounts appro-
2 priated under subsection (f)(2) for such fiscal year. Indi-
3 vidual fees shall be assessed by the Secretary on the basis
4 of an estimate by the Secretary of the amount necessary
5 to ensure that the sum of the fees collected for such fiscal
6 year equals the amount so appropriated.

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

14 “(e) ASSESSMENT OF FEES.—

15 “(1) LIMITATION.—Fees may not be assessed
16 under subsection (a) for a fiscal year beginning after
17 the first applicable fiscal year unless the amount ap-
18 propriated for salaries and expenses of the Food and
19 Drug Administration for such fiscal year is equal to
20 or greater than the amount appropriated for salaries
21 and expenses of the Food and Drug Administration
22 for the first applicable fiscal year multiplied by the
23 adjustment factor applicable to the fiscal year in-
24 volved, except that in making determinations under

1 this paragraph for the fiscal years involved there
2 shall be excluded—

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

5 “(B) the amounts appropriated under sec-
6 tion 736(g) for such fiscal years.

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

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

17 “(1) IN GENERAL.—Fees collected for a fiscal
18 year pursuant to subsection (a) shall be credited to
19 the appropriation account for salaries and expenses
20 of the Food and Drug Administration and shall be
21 available in accordance with appropriation Acts until
22 expended without fiscal year limitation. Such sums
23 as may be necessary may be transferred from the
24 Food and Drug Administration salaries and ex-
25 penses appropriation account without fiscal year lim-

1 itation to such appropriation account for salaries
2 and expenses with such fiscal year limitation. The
3 sums transferred shall be available solely for the
4 purposes described in paragraph (1) of subsection
5 (b), and the sums are subject to allocations under
6 paragraph (2) of such subsection.

7 “(2) AUTHORIZATION OF APPROPRIATIONS.—

8 “(A) FIRST FISCAL YEAR.—For the first
9 applicable fiscal year—

10 “(i) there is authorized to be appro-
11 priated for fees under subsection (a) an
12 amount equal to the amount of increase
13 determined under subsection (b)(1) by the
14 Secretary (which amount shall be pub-
15 lished in the Federal Register); and

16 “(ii) in addition, there is authorized to
17 be appropriated for fees under subsection
18 (a) an amount determined by the Secretary
19 to be necessary to carry out the purpose
20 described in subsection (b)(2) (which
21 amount shall be so published).

22 “(B) SUBSEQUENT FISCAL YEARS.—For
23 each of the four fiscal years following the first
24 applicable fiscal year—

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

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

15 “(3) ADJUSTMENTS.—

16 “(A) AGENCY COST OF RESOURCES.—For
17 each fiscal year other than the first applicable
18 fiscal year, the amount that applied under para-
19 graph (2)(A)(i) for the first applicable fiscal
20 year shall be multiplied by the adjustment fac-
21 tor (as defined in subsection (i)).

22 “(B) RESEARCH PROGRAM.—For each fis-
23 cal year other than the first applicable fiscal
24 year, the amount that applied under paragraph
25 (2)(A)(ii) for the first applicable fiscal year

1 shall be adjusted by the Secretary (and as ad-
2 justed shall be published in the Federal Reg-
3 ister) to reflect the greater of—

4 “(i) the total percentage change that
5 occurred during the preceding fiscal year
6 in the Consumer Price Index for all urban
7 consumers (all items; U.S. city average); or

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

16 “(4) OFFSET.—Any amount of fees collected
17 for a fiscal year under subsection (a) that exceeds
18 the amount of fees specified in appropriation Acts
19 for such fiscal year shall be credited to the appro-
20 priation account of the Food and Drug Administra-
21 tion as provided in paragraph (1), and shall be sub-
22 tracted from the amount of fees that would other-
23 wise be authorized to be collected under this section
24 pursuant to appropriation Acts for a subsequent fis-
25 cal year.

1 “(g) COLLECTION OF UNPAID FEES.—In any case
2 where the Secretary does not receive payment of a fee as-
3 sessed under subsection (a) within 30 days after it is due,
4 such fee shall be treated as a claim of the United States
5 Government subject to subchapter II of chapter 37 of title
6 31, United States Code.

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

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

17 “(1) the Consumer Price Index for all urban
18 consumers (all items; United States city average) for
19 April of the preceding fiscal year divided by such
20 Index for April of the first applicable fiscal year; or

21 “(2) the total of discretionary budget authority
22 provided for programs in categories other than the
23 defense category for the immediately preceding fiscal
24 year (as reported in the Office of Management and
25 Budget sequestration preview report, if available, re-

1 (1) IN GENERAL.—In the case of a genetic food
2 additive (as defined pursuant to the amendments
3 made by section (3)) that in the United States was
4 in commercial use in food as of the day before the
5 date on which the final rule under subsection (a) is
6 promulgated, the amendments made by this Act
7 apply to the additive upon the expiration of the two-
8 year period beginning on the date on which the final
9 rule is promulgated, subject to paragraph (2).

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

○