

109TH CONGRESS
2^D SESSION

H. R. 5268

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

MAY 2, 2006

Mr. KUCINICH (for himself, Mr. CONYERS, Ms. LEE, Mr. SANDERS, Ms. WATERS, Mr. OLVER, Mr. NADLER, and Mr. GEORGE MILLER of California) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

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.**

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

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) Genetic engineering is an artificial gene
2 transfer process wholly different from traditional
3 breeding.

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

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

14 (4) Genetically engineered foods present new
15 issues of safety that have not been adequately stud-
16 ied.

17 (5) The Congress has previously required that
18 food additives be analyzed for their safety prior to
19 their placement on the market.

20 (6) Adding new genes into a food should be
21 considered adding a food additive, thus requiring an
22 analysis of safety factors.

23 (7) Federal agencies have failed to uphold con-
24 gressional intent of the Food Additives Amendment
25 of 1958 by allowing genetically engineered foods to

1 be marketed, sold and otherwise used without re-
2 quiring pre-market safety testing addressing their
3 unique characteristics.

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

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

15 **SEC. 3. FEDERAL DETERMINATION OF SAFETY OF GENETI-**
16 **CALLY ENGINEERED FOOD; REGULATION AS**
17 **FOOD ADDITIVE.**

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

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

23 “Such term includes the different genetic constructs, pro-
24 teins of such constructs, vectors, promoters, marker sys-
25 tems, and other appropriate terms that are used or cre-

1 ated as a result of the creation of a genetically engineered
2 food (as defined in paragraph (rr)), other than a genetic
3 construct, protein, vector, promoter, or marker system or
4 other appropriate term for which an application under sec-
5 tion 505 or 512 has been filed. For purposes of this Act,
6 the term ‘genetic food additive’ means a genetic construct,
7 protein, vector, promoter, or marker system or other ap-
8 propriate term that is so included.”; and

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

10 “(rr)(1) The term ‘genetically engineered food’ means
11 food that contains or was produced with a genetically engi-
12 neered material.

13 “(2) The term ‘genetically engineered material’
14 means material derived from any part of a genetically en-
15 gineered organism, without regard to whether the altered
16 molecular or cellular characteristics of the organism are
17 detectable in the material.

18 “(3) The term ‘genetically engineered organism’
19 means—

20 “(A) an organism that has been altered at the
21 molecular or cellular level by means that are not
22 possible under natural conditions or processes (in-
23 cluding but not limited to recombinant DNA and
24 RNA techniques, cell fusion, microencapsulation,
25 macroencapsulation, gene deletion and doubling, in-

1 roducing a foreign gene, and changing the positions
2 of genes), other than a means consisting exclusively
3 of breeding, conjugation, fermentation, hybridiza-
4 tion, in vitro fertilization, tissue culture, or
5 mutagenesis; and

6 “(B) an organism made through sexual or asex-
7 ual reproduction (or both) involving an organism de-
8 scribed in clause (A), if possessing any of the altered
9 molecular or cellular characteristics of the organism
10 so described.

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

19 (b) PETITION TO ESTABLISH SAFETY.—

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

24 “In the case of a genetic food additive, such reports shall
25 include all data that was collected or developed pursuant

1 to the investigations, including data that does not support
2 the claim of safety for use.”.

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

7 (A) by striking “(5)” and inserting
8 “(5)(A)”; and

9 (B) by adding at the end the following sub-
10 paragraphs:

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

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

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

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

2 “(i) The Secretary shall maintain and make
3 available to the public through telecommunications a
4 list of petitions that are pending under this sub-
5 section and a list of petitions for which regulations
6 under subsection (c)(1)(A) have been established.
7 Such list shall include information on the additives
8 involved, including the source of the additives, and
9 including any information received by the Secretary
10 pursuant to clause (ii).

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

24 (3) EFFECTIVE DATE OF REGULATION REGARD-
25 ING SAFE USE; OPPORTUNITY FOR PUBLIC COM-

1 MENT.—Section 409(c)(2) of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 348(c)(2)) is
3 amended—

4 (A) by striking “(2)” and inserting
5 “(2)(A)”; and

6 (B) by adding at the end the following sub-
7 paragraph:

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

17 “(ii) For purposes of clause (i), the applicable period
18 under this clause regarding a petition is the 30-day period
19 beginning on the date on which the Secretary has under
20 subparagraph (B)(i) of subsection (b)(5) made informa-
21 tion available to the public regarding the petition, except
22 that, if under subparagraph (B)(ii) of such subsection the
23 Secretary finds in favor of a person who files for reconsid-
24 eration (relating to a determination by the Secretary that
25 information does not relate to safety), such 30-day period

1 is extended by an additional period of 30-days. For pur-
2 poses of the preceding sentence, a discrete 30-day exten-
3 sion applies to each such reconsideration for which the
4 Secretary finds in favor of the person filing for reconsider-
5 ation.”.

6 (4) CONSIDERATION OF CERTAIN FACTORS.—
7 Section 409(c) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 348(c)) is amended by adding
9 at the end the following paragraph:

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

14 “(A) Allergenicity effects resulting from the
15 added proteins, including proteins not found in the
16 food supply.

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

23 “(C) Appearance of new toxins or increased lev-
24 els of existing toxins.

1 “(D) Changes in the functional characteristics
2 of food.

3 “(E) Changes in the levels of important nutri-
4 ents.

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

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

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

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

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

1 biochemical and physiological protocols to evaluate
2 whether it is likely that the protein involved is an al-
3 lergen.

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

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

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

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

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

1 “(C) effective June 1, 2006, 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 (7) ADDITIONAL PROVISIONS.—Section 409(c)
7 of the Federal Food, Drug, and Cosmetic Act, as
8 amended by paragraph (6), 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) REGULATION ISSUED ON SECRETARY’S INITIA-
2 TIVE.—Section 409(d) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 348(d)) is amended—

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

7 (2) by adding at the end the following para-
8 graph:

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

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

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

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

3 “(1) enforce the compliance of a person with
4 the applicable provisions referred to paragraph (1)
5 of such subsection; or

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

8 “(c) LIMITATIONS.—

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

13 “(2) RELATION TO ACTIONS OF SECRETARY.—
14 A civil action may not be commenced under sub-
15 section (a)(2) if the Secretary has commenced and
16 is diligently prosecuting a civil or criminal action in
17 a district court of the United States to enforce com-
18 pliance with the applicable provisions referred to in
19 subsection (a)(1).

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

23 “(e) AWARD OF COSTS; FILING OF BOND.—In a civil
24 action under subsection (a), the district court involved
25 may award costs of litigation (including reasonable attor-

1 ney and expert witness fees) to any party whenever the
2 court determines such an award is appropriate. The court
3 may, if a temporary restraining order or preliminary in-
4 junction is sought, require the filing of a bond or equiva-
5 lent security in accordance with the Federal Rules of Civil
6 Procedure.

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

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

20 **SEC. 4. USER FEES REGARDING DETERMINATION OF SAFE-**
21 **TY OF GENETIC FOOD ADDITIVES.**

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

1 **“SEC. 409A. USER FEES REGARDING SAFETY OF GENETIC**
2 **FOOD ADDITIVES.**

3 “(a) IN GENERAL.—In the case of genetic food addi-
4 tives, the Secretary shall in accordance with this section
5 assess and collect a fee on each petition that is filed under
6 section 409(b)(1). The fee shall be collected from the per-
7 son who submits the petition, is due upon submission of
8 the petition, and shall be assessed in an amount deter-
9 mined under subsection (c). This section applies as of the
10 first fiscal year that begins after the date of promulgation
11 of the final rule required in section 6 of the Genetically
12 Engineered Food Safety Act (referred to in this section
13 as the ‘first applicable fiscal year’).

14 “(b) PURPOSE OF FEES.—

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

17 “(A) To defray increases in the costs of
18 the resources allocated for carrying out section
19 409 for the first applicable fiscal year over the
20 costs of carrying out such section for the pre-
21 ceding fiscal year, other than increases that are
22 not attributable to the responsibilities of the
23 Secretary with respect to genetic food additives.

24 “(B) To provide for a program of basic
25 and applied research on the safety of genetic
26 food additives (to be carried out by the Com-

1 missioner). The program shall address funda-
2 mental questions and problems that arise re-
3 peatedly during the process of reviewing peti-
4 tions under section 409(b)(1) with respect to
5 genetic food additives, and shall not directly
6 support the development of new genetically en-
7 gineered foods.

8 “(2) ALLOCATIONS BY SECRETARY.—Of the
9 total fee revenues collected under subsection (a) for
10 a fiscal year, the Secretary shall reserve and ex-
11 pend—

12 “(A) 95 percent for the purpose described
13 in paragraph (1)(A) and

14 “(B) 5 percent for the purpose described
15 in paragraph (1)(B).

16 “(3) CERTAIN PROVISIONS REGARDING IN-
17 CREASED ADMINISTRATIVE COSTS.—With respect to
18 fees under subsection (a):

19 “(A) Increases referred to in paragraph
20 (1)(A) include the costs of the Secretary in pro-
21 viding for investigations under section
22 409(c)(9)(A).

23 “(B) Increases referred to in paragraph
24 (1)(A) include increases in costs for an addi-
25 tional number of full-time equivalent positions

1 in the Department of Health and Human Serv-
2 ices to be engaged in carrying out section 409
3 with respect to genetic food additives.

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

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

23 “(e) ASSESSMENT OF FEES.—

24 “(1) LIMITATION.—Fees may not be assessed
25 under subsection (a) for a fiscal year beginning after

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

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

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

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

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

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

16 “(2) AUTHORIZATION OF APPROPRIATIONS.—

17 “(A) FIRST FISCAL YEAR.—For the first
18 applicable fiscal year—

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

1 “(ii) in addition, there is authorized to
2 be appropriated for fees under subsection
3 (a) an amount determined by the Secretary
4 to be necessary to carry out the purpose
5 described in subsection (b)(1)(B) (which
6 amount shall be so published).

7 “(B) SUBSEQUENT FISCAL YEARS.—For
8 each of the four fiscal years following 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 that applied
13 under subparagraph (A)(i) for the first ap-
14 plicable fiscal year, except that such
15 amount shall be adjusted under paragraph
16 (3)(A) for the fiscal year involved; and

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

24 “(3) ADJUSTMENTS.—

1 “(A) AGENCY COST OF RESOURCES.—For
2 each fiscal year other than the first applicable
3 fiscal year, the amount that applied under para-
4 graph (2)(A)(i) for the first applicable fiscal
5 year shall be multiplied by the adjustment fac-
6 tor (as defined in subsection (i)).

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

14 “(i) the total percentage change that
15 occurred during the preceding fiscal year
16 in the Consumer Price Index for all urban
17 consumers (all items; U.S. city average); or

18 “(ii) the total percentage change for
19 such fiscal year in basic pay under the
20 General Schedule in accordance with sec-
21 tion 5332 of title 5, United States Code,
22 as adjusted by any locality-based com-
23 parability payment pursuant to section
24 5304 of such title for Federal employees
25 stationed in the District of Columbia.

1 “(4) OFFSET.—Any amount of fees collected
2 for a fiscal year under subsection (a) that exceeds
3 the amount of fees specified in appropriation Acts
4 for such fiscal year shall be credited to the appro-
5 priation account of the Food and Drug Administra-
6 tion as provided in paragraph (1), and shall be sub-
7 tracted from the amount of fees that would other-
8 wise be authorized to be collected under this section
9 pursuant to appropriation Acts for a subsequent fis-
10 cal year.

11 “(g) COLLECTION OF UNPAID FEES.—In any case
12 where the Secretary does not receive payment of a fee as-
13 sessed under subsection (a) within 30 days after it is due,
14 such fee shall be treated as a claim of the United States
15 Government subject to subchapter II of chapter 37 of title
16 31, United States Code.

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

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

4 “(1) the Consumer Price Index for all urban
5 consumers (all items; United States city average) for
6 April of the preceding fiscal year divided by such
7 Index for April of the first applicable fiscal year; or

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

19 For purposes of this subsection, the terms ‘budget author-
20 ity’ and ‘category’ have the meaning given such terms in
21 the Balanced Budget and Emergency Deficit Control Act
22 of 1985.”.

23 **SEC. 5. EMBARGO AUTHORITY.**

24 (a) EMBARGO.—

1 (1) TEMPORARY DETENTION.—Section
2 304(g)(1) of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 334(g)(1)) is amended—

4 (A) in the first sentence—

5 (i) by striking “If during” and all
6 that follows through “order the device de-
7 tained” and inserting the following: “If,
8 during an inspection conducted under sec-
9 tion 704, an officer or employee of the De-
10 partment has reason to believe that a food
11 or device is in violation of this Act, such
12 officer or employee may order the food or
13 device detained”; and

14 (ii) by striking “he may authorize”
15 and inserting “the Secretary may author-
16 ize”;

17 (B) in the second and third sentences, by
18 striking “device” each place such term appears
19 and inserting “food or device”;

20 (C) by striking the fourth and fifth sen-
21 tences; and

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

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

4 (A) in section 301(r)—

5 (i) by striking “device” the first place
6 such term appears and inserting “food or
7 device”; and

8 (ii) by striking “the device” and in-
9 serting “such food or device”; and

10 (B) in section 304(g)(2), by striking “de-
11 vice” each place such term appears and insert-
12 ing “food or device”.

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

22 (c) CONFIDENTIALITY.—For any food embargoed,
23 seized, or recalled under the Federal Food, Drug, and Cos-
24 metic Act, the Food and Drug Administration shall dis-
25 close all necessary information without regard to business

1 confidentiality, if such disclosure is necessary to fully em-
2 bargo, seize, or recall any adulterated food.

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

7 **SEC. 6. RULEMAKING; EFFECTIVE DATE; PREVIOUSLY UN-**
8 **REGULATED MARKETED ADDITIVES.**

9 (a) **RULEMAKING; EFFECTIVE DATE.**—Not later
10 than one year after the date of the enactment of this Act,
11 the Secretary of Health and Human Services shall by reg-
12 ulation establish criteria for carrying out section 409 of
13 the Federal Food, Drug, and Cosmetic Act in accordance
14 with the amendments made by section 3, and criteria for
15 carrying out section 409A of such Act (as added by section
16 4). Such amendments take effect upon the expiration of
17 the 30-day period beginning on the date on which the Sec-
18 retary promulgates the final rule under the preceding sen-
19 tence, subject to subsection (b).

20 (b) **PREVIOUSLY UNREGULATED MARKETED ADDI-**
21 **TIVES.**—

22 (1) **IN GENERAL.**—In the case of a genetic food
23 additive (as defined pursuant to the amendments
24 made by section (3)) that in the United States was
25 in commercial use in food as of the day before the

1 date on which the final rule under subsection (a) is
2 promulgated, the amendments made by this Act
3 apply to the additive upon the expiration of the two-
4 year period beginning on the date on which the final
5 rule is promulgated, subject to paragraph (2).

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

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