106TH CONGRESS
2D SESSION

S. 2315

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

IN THE SENATE OF THE UNITED STATES

MARCH 29, 2000

Mr. MOYNIHAN (for himself, Mr. REID, and Mrs. BOXER) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Genetically Engineered Food Safety Act''.

SEC. 2. FINDINGS.

Congress finds the following:

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

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

(3) This conversion from a food supply based on traditionally bred organisms to one based on organisms produced through genetic engineering could be one of the most important changes in the food supply in this century.

(4) Genetically engineered foods present new issues of safety that have not been adequately studied.

(5) United States consumers are increasing concerned that food safety issues regarding genetically engineered foods are not being adequately addressed.

(6) Congress has previously required that food additives be analyzed for their safety prior to their placement on the market.

(7) Adding new genes, and the substances that the genes code for, into a food should be considered adding a food additive, thus requiring an analysis of safety factors.

(8) The food additive process gives the Food and Drug Administration discretion in applying the safety factors that are generally recognized as appropriate to evaluate the safety of food and food ingredients.

SEC. 3. FEDERAL DETERMINATION OF SAFETY OF GENETICALLY ENGINEERED FOOD; REGULATION AS FOOD ADDITIVE.

(a) INCLUSION IN DEFINITION OF FOOD ADDITIVE.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) in paragraph (s), by adding after subparagraph (6) the following:

''Such term includes the different genetic constructs, proteins of or other substances produced by such constructs, vectors, promoters, marker systems, and other appropriate terms that are used or created as a result of the creation of a genetically engineered food, other than a genetic construct, protein or other substance, vector, promoter, marker system, or other appropriate term for which an application has been filed under section 505 or 512.''; and

(2) by adding at the end the following:

''(kk)(1) The term 'genetically engineered food' means food that contains or was produced with a genetically engineered material.

''(2) The term 'genetically engineered material' means material derived from any part of a genetically engineered organism.

''(3) The term 'genetically engineered organism' means—

''(A) an organism that has been altered at the molecular or cellular level by means that are not possible under natural conditions or processes (including recombinant DNA and RNA techniques, cell fusion, microencapsulation, macroencapsulation, gene deletion and doubling, introduction of a foreign gene, and a process that changes the positions of genes), other than a means consisting exclusively of breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture; and

''(B) an organism made through sexual or asexual reproduction (or both) involving an organism described in clause (A), if possessing any of the altered molecular or cellular characteristics of the organism so described.

''(4) The term 'genetic food additive' means a genetic construct, protein or other substance, vector, promoter, marker system, or other appropriate term that is a food additive.''.

(b) PETITION TO ESTABLISH SAFETY.—

(1) DATA IN PETITION.—Section 409(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(2)) is amended—

(A) in subparagraph (D), by striking ''and'' at the end;

(B) in subparagraph (E), by striking the period and inserting ''; and''; and

(C) by adding at the end the following:

''(F) in the case of a genetic food additive, all data that was collected or developed pursuant to the investigations, including data that does not support the claim of safety for use.''.

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

(A) by striking ''(5)'' and inserting ''(5)(A)''; and

(B) by adding at the end the following subparagraphs:

''(B) In the case of a genetic food additive, the Secretary, promptly after providing the notice under subparagraph (A), shall make available to the public all reports and data described in subparagraphs (E) and (F) of paragraph (2) that are contained in the petition involved, and

all other information in the petition to the extent that the information is relevant to a determination of safety for use of the additive. Such notice shall state whether any information in the petition is not being made available to the public because the Secretary has made a determination that the information does not relate to safety for use of the additive. Any person may petition the Secretary for a reconsideration of such a determination, and if the Secretary finds in favor of such person, the information shall be made available to the public and the period for public comment described in subsection (c)(2)(B) shall be extended until the end of the 30th day after the information is made available.

''(C) In the case of a genetic food additive, the following rules shall apply:

''(i) The Secretary shall maintain and make available to the public through electronic and non-electronic means a list of petitions that are pending under this subsection and a list of petitions for which regulations have been established under subsection (c)(1)(A). Such list shall include information on the additives involved, including the source of the additives, and including any information received by the Secretary pursuant to clause (ii).

''(ii) If a regulation is in effect under subsection (c)(1)(A) for a genetic food additive, any person who manufactures such additive for commercial use shall submit to the Secretary a notification of any knowledge of data that relate to the adverse health effects of the additive, in a case in which the knowledge is acquired by the person after the date on which the regulation took effect. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this clause, including such limits on the responsibilities as the Secretary determines to be appropriate.''.

(3) EFFECTIVE DATE OF REGULATION REGARDING SAFE USE; OPPORTUNITY FOR PUBLIC COMMENT.—Section 409(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(2)) is amended—

(A) by striking ''(2)'' and inserting ''(2)(A)''; and

(B) by adding at the end the following subparagraph:

''(B) In the case of a genetic food additive, an order may not be issued under paragraph (1)(A) before the expi-

ration of the 30-day period beginning on the date on which the Secretary has made information available to the public under subsection (b)(5)(B) regarding the petition involved. During such period (or such longer period as the Secretary may designate), the Secretary shall provide interested persons an opportunity to submit to the Secretary comments on the petition. In publishing a notice for the additive under subsection (b)(5), the Secretary shall inform the public of such opportunity.''.

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

''(6) In the case of a genetic food additive, the factors considered by the Secretary regarding safety for use shall include the following:

''(A) Allergenicity effects resulting from added proteins, including proteins not found in the food supply.

''(B) Appropriate types of toxicity of proteins or other substances added to genetically engineered foods.

''(C) Pleiotropic effects. The Secretary shall require tests to determine the potential for such ef-

fects, including increased levels of toxins, or changes in the levels of nutrients.

''(D) Changes in the functional characteristics of food.''.

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

''(7) In the case of a genetic food additive, the following rules shall apply:

''(A) If a genetic food additive is a protein from a commonly or severely allergenic food, the Secretary may not establish a regulation under paragraph (1)(A) for the additive if the petition filed under subsection (b)(1) for the additive fails to include full reports of investigations that used serum or skin tests (or other advanced techniques) on a sensitive population to determine whether such additive is commonly or severely allergenic.

''(B)(i) If a genetic food additive is a protein that has not undergone the investigations described in subparagraph (A), the Secretary may not establish a regulation under paragraph (1)(A) for the additive if the petition filed under subsection (b)(1) fails to include full reports of investigations that

used the best available biochemical and physiological protocols to evaluate whether it is likely that the protein involved is an allergen.

''(ii)(I) For purposes of clause (i), the Secretary shall by regulation determine the best available biochemical and physiological protocols.

''(II) In carrying out rulemaking under subclause (I), the Secretary shall consult with the Director of the National Institutes of Health.''.

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

''(8)(A) In the case of a genetic food additive, the Secretary may only establish a regulation under paragraph (1)(A) for the additive if the regulation requires that a food containing the additive meet the requirements of subparagraph (C), in a case in which—

''(i) the additive is a protein and a report of an investigation described in subsection (b)(2)(E) finds that the additive is likely to be commonly or severely allergenic; or

''(ii) the additive is a protein and such a report of an investigation that uses a protocol described in

paragraph (7)(B) fails to find with reasonable certainty that the additive is unlikely to be an allergen.

''(B) Effective June 1, 2004, in the case of a genetic food additive, the Secretary may not establish a regulation under paragraph (1)(A), and shall repeal any regulation in effect under that paragraph, for the additive if a selective marker is used with respect to the additive, the selective marker will remain in the food involved when the food is marketed, and the selective marker inhibits the function of 1 or more antimicrobial drugs.

''(C) In a case described in clause (i) or (ii) of subparagraph (A), in order to meet the requirements of this subparagraph, a food that contains a genetic food additive shall—

''(i) bear a label or labeling that clearly and conspicuously states the name of the allergen involved; or

''(ii) be offered for sale under a name that includes the name of the allergen.''.

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

''(9)(A) In determining the safety for use of a genetic food additive under this subsection, the Secretary may (di-

rectly or through contract) conduct an investigation of such additive for purposes of supplementing the information provided to the Secretary pursuant to a petition filed under subsection (b)(1).

''(B) To provide Congress with a periodic independent, external review of the Secretary's formulation of the approval process carried out under paragraph (1)(A) that relates to genetic food additives, the Secretary shall enter into an agreement with the Institute of Medicine of the National Academy of Sciences. Such agreement shall provide that, if the Institute of Medicine has any concerns regarding the approval process, the Institute of Medicine will submit to Congress a report describing such concerns.

''(C) In the case of genetic food additives, petitions filed under subsection (b)(1) may not be categorically excluded from the application of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.).''.

(c) REGULATION ISSUED ON SECRETARY'S INITIATIVE.—Section 409(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(d)) is amended—

(1) by striking ''(d) The Secretary'' and inserting ''(d)(1) Subject to paragraph (2), the Secretary''; and

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

''(2) The provisions of subsections (b) and (c) that expressly refer to genetic food additives apply with respect to a regulation proposed by the Secretary under paragraph (1) to the same extent and in the same manner as such provisions apply with respect to a regulation issued under subsection (c) in response to a petition filed under subsection (b)(1). For purposes of this subsection, references in such provisions to information contained in such a petition shall be considered to be references to similar information in the possession of the Secretary.''.

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

''(h)(1) With respect to a violation of section 301(a), 301(b), or 301(c) involving the adulteration of food by reason of failure to comply with the provisions of section 409 that relate to genetic food additives, any person engaging in such a violation shall be liable to the United States for a civil penalty in an amount not to exceed $100,000 for each such violation.

''(2) Paragraphs (3) through (5) of subsection (g) apply with respect to a civil penalty under paragraph (1) of this subsection to the same extent and in the same manner as such paragraphs (3) through (5) apply with respect

to a civil penalty under paragraph (1) or (2) of subsection (g).''.

(e) RULE OF CONSTRUCTION.—With respect to section 409 of the Federal Food, Drug, and Cosmetic Act, compliance with the provisions of such section 409 that relate to genetic food additives does not constitute an affirmative defense in any cause of action under Federal or State law for personal injury resulting in whole or in part from a genetic food additive.

SEC. 4. USER FEES REGARDING DETERMINATION OF SAFETY OF GENETIC FOOD ADDITIVES.

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

''SEC. 409A. USER FEES REGARDING SAFETY OF GENETIC FOOD ADDITIVES.

''(a) IN GENERAL.—In the case of genetic food additives, the Secretary shall, in accordance with this section, assess and collect a fee on each petition that is filed under section 409(b)(1). The fee shall be collected from the person who submits the petition, shall be due upon submission of the petition, and shall be assessed in an amount determined under subsection (c). This section applies as of the first fiscal year that begins after the date of promulgation of the final regulation required in section 5 of the

Genetically Engineered Food Safety Act (referred to in this section as the 'first applicable fiscal year').

''(b) PURPOSE OF FEES.—

''(1) IN GENERAL.—The purposes of fees required under subsection (a) are as follows:

''(A) To defray increases in the costs of the resources allocated for carrying out section 409 for the first applicable fiscal year over the costs of carrying out such section for the preceding fiscal year, other than increases that are not attributable to the responsibilities of the Secretary with respect to genetic food additives.

''(B) To provide for a program of basic and applied research on the safety of genetic food additives (to be carried out by the Commissioner). The program shall address fundamental questions and problems that arise repeatedly during the process of reviewing petitions under section 409(b)(1) with respect to genetic food additives, and shall not directly support the development of new genetically engineered foods.

''(2) ALLOCATIONS BY SECRETARY.—Of the total fee revenues collected under subsection (a) for

a fiscal year, the Secretary shall reserve and expend—

"(A) 95 percent for the purpose described in paragraph (1)(A); and

"(B) 5 percent for the purpose described in paragraph (1)(B).

"(3) CERTAIN PROVISIONS REGARDING INCREASED ADMINISTRATIVE COSTS.—With respect to fees required under subsection (a)—

"(A) increases referred to in paragraph (1)(A) include the costs of the Secretary in providing for investigations under section 409(c)(9)(A); and

"(B) increases referred to in paragraph (1)(A) include increases in costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in carrying out section 409 with respect to genetic food additives.

"(c) TOTAL FEE REVENUES; INDIVIDUAL FEE AMOUNTS.—The total fee revenues collected under subsection (a) for a fiscal year shall be the amounts appropriated under subparagraph (A) or (B) of subsection (f)(2) for such fiscal year. Individual fees shall be assessed by the Secretary on the basis of an estimate by the Sec-

retary of the amount necessary to ensure that the sum of the fees collected for such fiscal year equals the amount so appropriated.

''(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of a fee assessed under subsection (a) if the Secretary finds that—

''(1) the fee to be paid will exceed the anticipated present and future costs incurred by the Secretary in carrying out the purposes described in subsection (b) (which finding may be made by the Secretary using standard costs); or

''(2) collection of the fee would result in substantial hardship for the person assessed for the fee.

''(e) ASSESSMENT OF FEES.—

''(1) LIMITATION.—

''(A) IN GENERAL.—Fees may not be assessed under subsection (a) for a fiscal year beginning after the first applicable fiscal year unless the amount appropriated for salaries and expenses of the Food and Drug Administration for such fiscal year is equal to or greater than the amount appropriated for salaries and expenses of the Food and Drug Administration for the first applicable fiscal year multiplied by

the adjustment factor applicable to the later fiscal year.

''(B) DETERMINATIONS.—In making determinations under this paragraph for the fiscal years involved, the Secretary shall exclude—

''(i) the amounts appropriated under subsection (f)(2) for the fiscal years involved; and

''(ii) the amounts appropriated under section 736(g) for such fiscal years.

''(2) AUTHORITY.—If under paragraph (1) the Secretary does not have authority to assess fees under subsection (a) during a portion of a fiscal year, but does at a later date in such fiscal year have such authority, the Secretary, notwithstanding the due date under such subsection for fees, may assess and collect such fees at any time in such fiscal year, without any modification in the rate of the fees.

''(f) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until

expended without fiscal year limitation. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purposes described in paragraph (1) of subsection (b), and the sums are subject to allocations under paragraph (2) of such subsection.

''(2) AUTHORIZATION OF APPROPRIATIONS.—

''(A) FIRST FISCAL YEAR.—For the first applicable fiscal year—

''(i) there is authorized to be appropriated for fees under subsection (a) an amount equal to the amount of increase determined under subsection (b)(1)(A) by the Secretary (which amount shall be published in the Federal Register); and

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

"(B) SUBSEQUENT FISCAL YEARS.—For each of the 4 fiscal years following the first applicable fiscal year—

"(i) there is authorized to be appropriated for fees under subsection (a) an amount equal to the amount that applied under subparagraph (A)(i) for the first applicable fiscal year, except that such amount shall be adjusted under paragraph (3)(A) for the fiscal year involved; and

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

"(C) SUPPLEMENTAL AUTHORIZATION OF APPROPRIATIONS.—In addition to sums authorized to be appropriated under subparagraphs (A) and (B), there are authorized to be appropriated, for the purposes described in subsection (b)(1)(A), such sums as may be necessary for the first applicable fiscal year and each of the 4 subsequent fiscal years.

''(3) ADJUSTMENTS.—

''(A) AGENCY COST OF RESOURCES.—For each fiscal year other than the first applicable fiscal year, the amount that applied under paragraph (2)(A)(i) for the first applicable fiscal year shall be multiplied by the adjustment factor.

''(B) RESEARCH PROGRAM.—For each fiscal year other than the first applicable fiscal year, the amount that applied under paragraph (2)(A)(ii) for the first applicable fiscal year shall be adjusted by the Secretary (and as adjusted shall be published in the Federal Register) to reflect the greater of—

''(i) the total percentage change that occurred since the beginning of the first applicable fiscal year in the Consumer Price Index for All Urban Consumers (all items; United States city average); or

''(ii) the total percentage change that occurred since the beginning of the first applicable fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based

comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

''(4) OFFSET.—Any amount of fees collected for a fiscal year under subsection (a) that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

''(g) COLLECTION OF UNPAID FEES.—In any case in which the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after the fee is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(h) CONSTRUCTION.—This section may not be construed as requiring that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in carrying out section 409 with respect to ge-

netic food additives be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(i) DEFINITION OF ADJUSTMENT FACTOR.—

''(1) IN GENERAL.—In this section, the term 'adjustment factor' applicable to a fiscal year means the lower of—

''(A) the Consumer Price Index for All Urban Consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April of the first applicable fiscal year; or

''(B) the total of discretionary budget authority provided for programs in categories other than the defense category for the preceding fiscal year (as reported in the Office of Management and Budget sequestration preview report, if available, required under section 254(c) of the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 904(c))) divided by such budget authority for the first applicable fiscal year (as reported in the Office of Management and Budget final sequestration report submitted for such year under section 254(f) of such Act).

''(2) BUDGET AUTHORITY; CATEGORY.—In this subsection, the terms 'budget authority' and 'category' have the meanings given such terms in section 250 of the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 900).''.

SEC. 5. RULEMAKING; EFFECTIVE DATE; PREVIOUSLY UNREGULATED MARKETED ADDITIVES.

(a) RULEMAKING; EFFECTIVE DATE.—

(1) RULEMAKING.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall by regulation establish criteria for carrying out section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 349) in accordance with the amendments made by section 3, and criteria for carrying out section 409A of such Act (as added by section 4).

(2) EFFECTIVE DATE.—Such amendments take effect on the first day of the first fiscal year that begins after the date of promulgation of the final regulation described in paragraph (1).

(b) PREVIOUSLY UNREGULATED MARKETED ADDITIVES.—

(1) IN GENERAL.—In the case of a genetic food additive (as defined in section 201(kk)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

321(kk)(4))) that in the United States was in commercial use in food as of the day before the date on which the final regulation described in subsection (a) is promulgated, the amendments made by this Act apply to the additive on the expiration of the 2-year period beginning on the date on which the final regulation is promulgated, subject to paragraph (2).

(2) USER FEES.—With respect to a genetic food additive described in paragraph (1), such paragraph does not waive the applicability of section 409A of the Federal Food, Drug, and Cosmetic Act to a petition filed under section 409(b)(1) of such Act (21 U.S.C. 348(b)(1)) that is filed before the expiration of the 2-year period described in such paragraph.

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