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112TH CONGRESS
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H. R. 3554

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

DECEMBER 2, 2011

Mr. KUCINICH (for himself, Mr. GRIJALVA, and Mr. STARK) 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

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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.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Genetically Engineered Safety Act''.

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

TITLE I—GENETICALLY ENGINEERED PHARMACEUTICAL AND INDUSTRIAL CROP SAFETY

SEC. 101. SHORT TITLE.

This title may be cited as the ''Genetically Engineered Pharmaceutical and Industrial Crop Safety Act of 2011''.

SEC. 102. FINDINGS.

Congress finds the following:

(1) A pharmaceutical crop or industrial crop is a plant that has been genetically engineered to produce a medical or industrial product, including a human or veterinary drug, biologic, industrial, or research chemical, or enzyme.

(2) The Department of Agriculture has issued more than 270 permits for more than 300 outdoor field trials of plants genetically engineered to produce experimental pharmaceuticals, industrial enzymes and novel proteins. More than 80 percent of the field trial permits involved feed crops, including corn, soybeans, rice, safflower, barley, alfalfa, mustard greens, peas, sugarcane, tomatoes, and wheat.

(3) Many of the novel substances produced in pharmaceutical crops and industrial crops exhibit

high levels of biological activity and are intended to be used for particular medical or industrial purposes, under very controlled circumstances. None of these substances is intended to be incorporated in food or to be spread into the environment.

(4) The magnitude of the risks posed by pharmaceutical crops and industrial crops depends on many factors, including the chemicals involved, the organisms or environments exposed, and the level and duration of the exposure. Humans, animals, and the environment at large could be at risk from contamination, a major concern of which is that bioactive nonfood substances, which have not been tested, will contaminate or otherwise adversely affect the food supply. Substances intended for use as human drugs are especially problematic because they are intended to be biologically active in people.

(5) Pharmaceutical crops and industrial crops also pose substantial liability and other economic risks to farmers, grain handlers, food companies, and other persons in the food and feed supply chain. These risks include liability for contamination episodes, costly food recalls, losses in export markets, reduced prices for a contaminated food or feed crop, and loss of confidence in the safety of the American

food supply among foreign importers and consumers of American agricultural commodities.

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

(7) While there presently exists a pro forma zero tolerance standard, the Department of Agriculture and experts in the field acknowledge that contamination of human food and animal feed is inevitable due to the inherent imprecision of biological and agricultural systems, as well as the laxity of the regulatory regime. This is illustrated, for example, in the Department of Agriculture's regulations, which aim not for prevention (recognized as unattainable), but rather mitigation of the gene flow that results in contamination of food/feed crops with these substances. Some experts in the field are calling for establishment of tolerances, despite the potential risks involved.

(8) The rapidly emerging field of synthetic biology is an extreme form of genetic engineering that has been heralded as a remedy for numerous societal ills ranging from climate change to environmental pollutants. The goal of synthetic biology is to create

life from scratch with synthetic DNA or without the use of DNA entirely. DNA is synthesized by a computer is then inserted into organisms. There are a range of practices which can be classified as synthetic biology, but such practices are more commonly defined as the design and construction of new biological parts, devices and systems that do not exist in the natural world and also the redesign of existing biological systems to perform specific tasks.

(9) Proponents of synthetic biology are developing products that they may soon seek approval for entry into the food supply of the United States.

(10) Therefore, appropriate regulatory controls, as established by this title, are urgently needed to ensure that the byproducts of pharmaceutical crops, industrial crops and organisms created as a result of synthetic biology, as well as their byproducts, do not enter human food or animal feed crops at any level.

SEC. 103. DEFINITIONS.

In this title:

(1) The term ''genetically engineered plant'' means a plant that contains a genetically engineered material or was produced from a genetically engineered seed. A plant shall be considered to contain a genetically engineered material if the plant has

been injected or otherwise treated with a genetically engineered material (except that the use of manure as a fertilizer for the plant may not be construed to mean that the plant is produced with a genetically engineered material).

(2) The term ''genetically engineered material'' means material 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, introducing a foreign gene, and changing the positions of genes), other than a means consisting exclusively of breeding, conjugation, fermentation, hybridization, in vitro fertilization, tissue culture, or mutagenesis.

(3) The term ''genetically engineered seed'' means a seed that contains a genetically engineered material or was produced with a genetically engineered material. A seed shall be considered to contain a genetically engineered material or to have been produced with a genetically engineered material if the seed (or the plant from which the seed is derived) has been injected or otherwise treated with a genetically engineered material (except that the use

of manure as a fertilizer for the plant may not be construed to mean that any resulting seeds are produced with a genetically engineered material).

(4) The term ''pharmaceutical crop'' means a genetically engineered plant that is designed to produce medical products, including human and veterinary drugs and biologics. The term includes a crop intentionally treated with genetically engineered material that, in turn, produces a medical substance.

(5) The term ''industrial crop'' means a genetically engineered plant that is designed to produce industrial products, including industrial and research chemicals and enzymes. The term includes a crop intentionally treated with genetically engineered material that, in turn, produces an industrial substance.

SEC. 104. REGULATION OF PRODUCTION OF PHARMACEUTICAL CROPS AND INDUSTRIAL CROPS.

(a) TEMPORARY MORATORIUM PENDING REGULATIONS.—No pharmaceutical crop or industrial crop may be grown, raised, or otherwise cultivated until the final regulations and tracking system required by this section are in effect.

(b) PROHIBITION ON OPEN-AIR CULTIVATION.—No person may grow, raise or otherwise cultivate a pharma-

ceutical crop or industrial crop in an open air environment.

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

(d) BIOTECH TRACKING SYSTEM.—The United States Department of Agriculture shall establish a tracking system to regulate the growing, handling, transportation, and disposal of all pharmaceutical and industrial crops and their byproducts to prevent contamination.

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

(1) to enforce the prohibitions imposed by subsections (b) and (c);

(2) to designate the foods commonly used for human food or domestic animal feed, the use of which as a source of a pharmaceutical crop or industrial crop is prohibited by subsection (c); and

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

SEC. 105. CIVIL PENALTIES FOR VIOLATION.

(a) AUTHORITY TO ACCESS PENALTIES.—The Secretary of Agriculture may assess, by written order, a civil

penalty against a person that violates a provision of section 105, including a regulation promulgated or order issued under such section. Each violation, and each day during which a violation continues, shall be a separate offense.

(b) AMOUNT AND FACTORS IN ACCESSING PENALTIES.—The maximum amount that may be accessed under this section for a violation may not exceed $1,000,000. In determining the amount of the civil penalty, the Secretary shall take into account—

(1) the gravity of the violation;

(2) the degree of culpability;

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

(4) any history of prior offenses under such section or other laws administered by the Secretary.

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

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

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

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

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

(e) COLLECTION ACTION FOR FAILURE TO PAY ASSESSMENT.—If a person fails to pay a civil penalty after the order assessing the civil penalty has become final and unappealable, the Secretary shall refer the matter to the Attorney General, who shall bring a civil action to recover the amount of the civil penalty in United States district court. In the collection action, the validity and appropriateness of the order of the Secretary imposing the civil penalty shall not be subject to review.

SEC. 106. REPORT TO CONGRESS ON ALTERNATIVE METHODS TO PRODUCE PHARMACEUTICAL AND INDUSTRIAL CROPS.

The National Academy of Sciences shall submit to Congress a report that explores alternative methods to

produce pharmaceuticals or industrial chemicals that have the advantage of being conducted in controlled production facilities and do not present the risk of contamination.

TITLE II—GENETICALLY ENGINEERED FOOD SAFETY

SEC. 201. SHORT TITLE.

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

SEC. 202. FINDINGS.

The Congress finds as follows:

(1) Genetic engineering is an artificial gene transfer process wholly 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 our food supply in this century.

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

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

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

(7) Federal agencies have failed to uphold congressional intent of the Food Additives Amendment of 1958 by allowing genetically engineered foods to be marketed, sold and otherwise used without requiring pre-market safety testing addressing their unique characteristics.

(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.

(9) Given the consensus among the scientific community that genetic engineering can potentially introduce hazards, such as allergens or toxins, genetically engineered foods need to be evaluated on a

case-by-case basis and cannot be presumed to be generally recognized as safe.

SEC. 203. 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 and below subparagraph (6) the following sentence:

''Such term includes the different genetic constructs, proteins of 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 (as defined in paragraph (ss)), other than a genetic construct, protein, vector, promoter, or marker system or other appropriate term for which an application under section 505 or 512 has been filed. For purposes of this Act, the term 'genetic food additive' means a genetic construct, protein, vector, promoter, or marker system or other appropriate term that is so included.''; and

(2) by adding at the end the following:

''(ss)(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, without regard to whether the altered molecular or cellular characteristics of the organism are detectable in the material.

''(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 but not limited to recombinant DNA and RNA techniques, cell fusion, microencapsulation, macroencapsulation, gene deletion and doubling, introducing a foreign gene, and changing the positions of genes), other than a means consisting exclusively of breeding, conjugation, fermentation, hybridization, in vitro fertilization, tissue culture, or mutagenesis; 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) For purposes of subparagraph (1), a food shall be considered to have been produced with a genetically en-

gineered material if the organism from which the food is derived has been injected or otherwise treated with a genetically engineered material (except that the use of manure as a fertilizer for raw agricultural commodities may not be construed to mean that such commodities are produced with a genetically engineered material).''.

(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 by adding after and below subparagraph (E) the following sentence:

''In the case of a genetic food additive, such reports shall include 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:

''(i) Promptly after providing the notice under subparagraph (A), the Secretary shall make available to the public all reports and data described in paragraph (2)(E) 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 the safety for use of the additive.

''(ii) 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 the safety for use of the additive. Any person may petition the Secretary for a reconsideration of such a determination.

''(C) In the case of genetic food additives:

''(i) The Secretary shall maintain and make available to the public through telecommunications a list of petitions that are pending under this subsection and a list of petitions for which regulations under subsection (c)(1)(A) have been established. 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, when 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)(i) In the case of a genetic food additive, an order under paragraph (1)(A) may not be issued regarding the petition involved before the expiration of the applicable

period under clause (ii). During such period, and continuing until an order under paragraph (1) is issued, the Secretary shall provide interested persons an opportunity to submit to the Secretary comments on the petition. In publishing such notice, the Secretary shall inform the public of such opportunity.

''(ii) For purposes of clause (i), the applicable period under this clause regarding a petition is the 30-day period beginning on the date on which the Secretary has under subparagraph (B)(i) of subsection (b)(5) made information available to the public regarding the petition, except that, if under subparagraph (B)(ii) of such subsection the Secretary finds in favor of a person who files for reconsideration (relating to a determination by the Secretary that information does not relate to safety), such 30-day period is extended by an additional period of 30-days. For purposes of the preceding sentence, a discrete 30-day extension applies to each such reconsideration for which the Secretary finds in favor of the person filing for reconsideration.''.

(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 (but not be limited to) the results of the following analyses:

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

''(B) Pleiotropic effects. The Secretary shall require tests to determine the potential for such effects (using molecular characterization, biochemical characterization, mRNA profiling, or other techniques, or as appropriate, combinations of such techniques).

''(C) Appearance of new toxins or increased levels of existing toxins.

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

''(E) Changes in the levels of important nutrients.

''(F) Changes in the levels of anti-nutrients.''.

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

''(7) In the case of genetic food additives:

''(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) if the petition under subsection (b)(1) 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) if the petition 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) For purposes of clause (i), the Secretary shall by regulation determine the best available biochemical and physiological protocols. In carrying out rulemaking under the preceding sentence, 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 amended by adding at the end the following paragraph:

''(8) In the case of a genetic food additive, the Secretary may not establish a regulation under paragraph (1)(A) if—

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

''(B) the additive is a protein and 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; or

''(C) effective June 1, 2006, 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 one or more antibiotics.''.

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

''(9)(A) In determining the safety for use of genetic food additives, the Secretary may (directly or through contract) conduct investigations of such additives for purposes of supplementing the information provided to the Secretary pursuant to petitions under subsection (b)(1).

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

(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 reference 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 petition filed under subsection (b)(1).''.

(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 (5) through (7) of subsection (f) 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 (5) through (7) apply with respect to a civil penalty under paragraph (1), (2), (3), (4), or (9) of subsection (f).''.

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

"SEC. 311. CITIZEN SUITS REGARDING GENETIC FOOD ADDITIVES.

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

"(1) a person who is alleged to have engaged in a violation of section 301(a), 301(b), or 301(c) involving the adulteration of food by reason of failing to comply with the provisions of section 409 that relate to genetic food additives; or

"(2) the Secretary where there is alleged a failure of the Secretary to perform any act or duty under section 409 that relates to such additives and is not discretionary.

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

"(1) enforce the compliance of a person with the applicable provisions referred to paragraph (1) of such subsection; or

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

"(c) LIMITATIONS.—

"(1) NOTICE TO SECRETARY.—A civil action may not be commenced under subsection (a)(1) prior

to 60 days after the plaintiff has provided to the Secretary notice of the violation involved.

''(2) RELATION TO ACTIONS OF SECRETARY.—A civil action may not be commenced under subsection (a)(2) if the Secretary has commenced and is diligently prosecuting a civil or criminal action in a district court of the United States to enforce compliance with the applicable provisions referred to in subsection (a)(1).

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

''(e) AWARD OF COSTS; FILING OF BOND.—In a civil action under subsection (a), the district court involved may award costs of litigation (including reasonable attorney and expert witness fees) to any party whenever the court determines such an award is appropriate. The court may, if a temporary restraining order or preliminary injunction is sought, require the filing of a bond or equivalent security in accordance with the Federal Rules of Civil Procedure.

''(f) SAVINGS PROVISION.—This section does not restrict any right that a person (or class of persons) may have under any statute or common law to seek enforcement of the provisions referred to subsection (a)(1), or to

seek any other relief (including relief against the Secretary).''.

(f) RULE OF CONSTRUCTION.—With respect to section 409 of the Federal Food, Drug, and Cosmetic Act as amended by this section, 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. 204. 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, is 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 rule required in section 206 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 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 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).

"(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 subsection (f)(2) for such fiscal year. Individual fees shall be assessed by the Secretary on the basis of an estimate by the Secretary of the amount necessary

to ensure that the sum of the fees collected for such fiscal year equals the amount so appropriated. In assessing the individual fees, the Secretary shall by regulation provide for the assessment of reduced fee amounts for entities that are small businesses, or nonprofit private entities, as defined by the Secretary for purposes of this section.

''(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 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).

''(e) ASSESSMENT OF FEES.—

''(1) LIMITATION.—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 fiscal year involved, except that in making determinations under

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

"(A) the amounts appropriated under subsection (f)(2) for the fiscal years involved; and

"(B) the amounts appropriated under sections 736(g), 738(h), 740(g), and 741(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 ex-

penses 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 four 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.

''(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 (as defined in subsection (i)).

''(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 during the preceding fiscal year in the Consumer Price Index for all urban consumers (all items; U.S. city average); or

"(ii) the total percentage change for such 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 where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it 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 genetic food additives be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(i) DEFINITION OF ADJUSTMENT FACTOR.—For purposes of this section, the term 'adjustment factor' applicable to a fiscal year is the lower of—

''(1) 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

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

quired under section 254(c) of the Balanced Budget and Emergency Deficit Control Act of 1985) 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).

For purposes of this subsection, the terms 'budget authority' and 'category' have the meaning given such terms in the Balanced Budget and Emergency Deficit Control Act of 1985.''.

SEC. 205. EMBARGO AUTHORITY.

(a) EMBARGO.—

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

(A) in the first sentence—

(i) by striking ''If during'' and all that follows through ''order the device or tobacco product detained'' and inserting the following: ''If, during an inspection conducted under section 704, an officer or employee of the Department has reason to believe that a food, device, or tobacco product is in violation of this Act, such officer

or employee may order the food, device, or tobacco product detained''; and

(ii) by striking ''he may authorize'' and inserting ''the Secretary may authorize'';

(B) in the second and third sentences, by striking ''device or tobacco product'' each place it appears and inserting ''food, device, or tobacco product'';

(C) by striking the fourth and fifth sentences; and

(D) by adding at the end the following sentence: ''A detention order under this paragraph shall be considered final agency action.''.

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

(A) in section 301(r)—

(i) by striking ''device or tobacco product'' the first place such term appears and inserting ''food, device, or tobacco product''; and

(ii) by striking ''the device or tobacco product'' and inserting ''such food, device, or tobacco product''; and

(B) in section 304(g)(2)—

(i) in subparagraph (A), by striking ''device or tobacco product'' and inserting ''food, device, or tobacco product''; and

(ii) in subparagraph (B), by striking ''device'' each place it appears and inserting ''food or device''.

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

(c) CONFIDENTIALITY.—For any food embargoed, seized, or recalled under the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration shall disclose all necessary information without regard to business confidentiality, if such disclosure is necessary to fully embargo, seize, or recall any adulterated food.

(d) FOOD RETAILER REGISTRATION.—All food retailers shall register with the Food and Drug Administra-

tion for the purpose of expediting recalls, embargoes, and seizures under the Federal Food, Drug, and Cosmetic Act.

SEC. 206. RULEMAKING; EFFECTIVE DATE; PREVIOUSLY UNREGULATED MARKETED ADDITIVES.

(a) RULEMAKING; EFFECTIVE DATE.—Not later than one year after the date of the enactment of this title, 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 in accordance with the amendments made by section 203, and criteria for carrying out section 409A of such Act (as added by section 204). Such amendments take effect upon the expiration of the 30-day period beginning on the date on which the Secretary promulgates the final rule under the preceding sentence, subject to subsection (b).

(b) PREVIOUSLY UNREGULATED MARKETED ADDITIVES.—

(1) IN GENERAL.—In the case of a genetic food additive (as defined pursuant to the amendments made by section 203) that in the United States was in commercial use in food as of the day before the date on which the final rule under subsection (a) is promulgated, the amendments made by this title apply to the additive upon the expiration of the two-

year period beginning on the date on which the final rule 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 under section 409(b)(1) of such Act that is filed before the expiration of the two-year period described in such paragraph.

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