

109TH CONGRESS
2D SESSION

H. R. 5267

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, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 2, 2006

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

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 exposure to genetically engineered pharmaceutical and industrial crops and their byproducts, 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 Pharmaceutical and Industrial Crop Safety Act of 2005”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

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

13 (2) The Department of Agriculture has issued
14 “split approval” permits to allow the cultivation of
15 10 food crops genetically engineered to produce bio-
16 pharmaceuticals or chemicals that are not approved
17 for human consumption. As of January 1, 2003,
18 more than 300 field trials have been conducted in
19 the United States. In nearly 70 percent of these
20 tests, corn has been the crop used, but other crops
21 tested include soybean, tobacco, rice, alfalfa, barley,
22 rapeseed (canola), wheat, tomato, safflower, and
23 sugercane.

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

1 high levels of biological activity and are intended to
2 be used for particular medical or industrial pur-
3 poses, under very controlled circumstances. None of
4 these substances is intended to be incorporated in
5 food or to be spread into the environment.

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

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

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

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

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

21 (8) Therefore, appropriate regulatory controls,
22 as established by this Act, are urgently needed to
23 ensure that pharmaceutical crops and industrial
24 crops and their byproducts do not enter human food
25 or animal feed crops at any level.

1 **SEC. 3. DEFINITIONS.**

2 In this Act:

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

13 (2) The term “genetically engineered material”
14 means material that has been altered at the molec-
15 ular or cellular level by means that are not possible
16 under natural conditions or processes (including re-
17 combinant DNA and RNA techniques, cell fusion,
18 microencapsulation, macroencapsulation, gene dele-
19 tion and doubling, introducing a foreign gene, and
20 changing the positions of genes), other than a means
21 consisting exclusively of breeding, conjugation, fer-
22 mentation, hybridization, in vitro fertilization, tissue
23 culture, or mutagenesis.

24 (3) The term “genetically engineered seed”
25 means a seed that contains a genetically engineered
26 material or was produced with a genetically engi-

1 neered material. A seed shall be considered to con-
 2 tain a genetically engineered material or to have
 3 been produced with a genetically engineered material
 4 if the seed (or the plant from which the seed is de-
 5 rived) has been injected or otherwise treated with a
 6 genetically engineered material (except that the use
 7 of manure as a fertilizer for the plant may not be
 8 construed to mean that any resulting seeds are pro-
 9 duced with a genetically engineered material).

10 (4) The term “pharmaceutical crop” means a
 11 genetically engineered plant that is designed to
 12 produce medical products, including human and vet-
 13 erinary drugs and biologics. The term includes a
 14 crop intentionally treated with genetically engineered
 15 material that, in turn, produces a medical substance.

16 (5) The term “industrial crop” means a geneti-
 17 cally engineered plant that is designed to produce in-
 18 dustrial products, including industrial and research
 19 chemicals and enzymes. The term includes a crop in-
 20 tentiously treated with genetically engineered mate-
 21 rial that, in turn, produces an industrial substance.

22 **SEC. 4. REGULATION OF PRODUCTION OF PHARMA-**
 23 **CEUTICAL CROPS AND INDUSTRIAL CROPS.**

24 (a) TEMPORARY MORATORIUM PENDING REGULA-
 25 TIONS.—No pharmaceutical crop or industrial crop may

1 be grown, raised, or otherwise cultivated until the final
2 regulations and tracking system required by this section
3 are in effect.

4 (b) PROHIBITION ON OPEN-AIR CULTIVATION.—No
5 person may grow, raise or otherwise cultivate a pharma-
6 ceutical crop or industrial crop in an open air environ-
7 ment.

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

13 (d) BIOTECH TRACKING SYSTEM.—The United
14 States Department of Agriculture shall establish a track-
15 ing system to regulate the growing, handling, transpor-
16 tation, and disposal of all pharmaceutical and industrial
17 crops and their byproducts to prevent contamination.

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

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

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

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

3 **SEC. 5. CIVIL PENALTIES FOR VIOLATION.**

4 (a) **AUTHORITY TO ACCESS PENALTIES.**—The Sec-
5 retary of Agriculture may assess, by written order, a civil
6 penalty against a person that violates a provision of sec-
7 tion 5, including a regulation promulgated or order issued
8 under such section. Each violation, and each day during
9 which a violation continues, shall be a separate offense.

10 (b) **AMOUNT AND FACTORS IN ACCESSING PEN-**
11 **ALTIES.**—The maximum amount that may be accessed
12 under this section for a violation may not exceed
13 \$1,000,000. In determining the amount of the civil pen-
14 alty, the Secretary shall take into account—

- 15 (1) the gravity of the violation;
16 (2) the degree of culpability;
17 (3) the size and type of the business; and
18 (4) any history of prior offenses under such sec-
19 tion or other laws administered by the Secretary.

20 (c) **NOTICE AND OPPORTUNITY FOR HEARING.**—The
21 Secretary shall not assess a civil penalty under this section
22 against a person unless the company is given notice and
23 opportunity for a hearing on the record before the Sec-
24 retary in accordance with sections 554 and 556 of title
25 5, United States Code.

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

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

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

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

16 (e) COLLECTION ACTION FOR FAILURE TO PAY AS-
17 SESSMENT.—If a person fails to pay a civil penalty after
18 the order assessing the civil penalty has become final and
19 unappealable, the Secretary shall refer the matter to the
20 Attorney General, who shall bring a civil action to recover
21 the amount of the civil penalty in United States district
22 court. In the collection action, the validity and appro-
23 priateness of the order of the Secretary imposing the civil
24 penalty shall not be subject to review.

1 **SEC. 6. REPORT TO CONGRESS ON ALTERNATIVE METHODS**
2 **TO PRODUCE PHARMACEUTICAL AND INDUS-**
3 **TRIAL CROPS.**

4 The National Academy of Sciences shall submit to
5 Congress a report that explores alternative methods to
6 produce pharmaceuticals or industrial chemicals that have
7 the advantage of being conducted in controlled production
8 facilities and do not present the risk of contamination.

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