

JAN 19 2007

A BILL FOR AN ACT

RELATING TO GENETICALLY ENGINEERED CROPS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 SECTION 1. The legislature finds that pharmaceutical crops
2 and industrial crops are plants that have been genetically
3 engineered to produce a medical or industrial product, including
4 a human or veterinary drug, and a biological, industrial, or
5 research chemical or enzyme.

6 The legislature further finds that the department of
7 agriculture has issued sixteen permits to allow the cultivation
8 of food crops that are genetically engineered to produce
9 biopharmaceuticals or chemicals that are not approved for human
10 consumption in the State. Many of the novel substances produced
11 in pharmaceutical crops and industrial crops exhibit high levels
12 of biological activity and are intended to be used for
13 particular medical or industrial purposes under very controlled
14 circumstances. None of these substances is intended to be
15 incorporated in food or to be spread into the environment.

16 The legislature further finds that the magnitude of the
17 risks posed by pharmaceutical crops and industrial crops depends



1 on many factors, including the chemicals involved, the organisms
2 or environments exposed to those crops, and the level and
3 duration of exposure. Humans, animals, and the environment at
4 large could be at risk from contamination. A major
5 contamination concern is that bioactive nonfood substances,
6 which have not been tested, will contaminate or otherwise
7 adversely affect the general food supply. Substances intended
8 for use as human drugs are especially problematic because they
9 are intended to be biologically active in people.

10 Pharmaceutical crops and industrial crops also pose
11 substantial liability and other economic risks to farmers, grain
12 handlers, food companies, and other persons in the food and feed
13 supply chain. These risks may include liability for
14 contamination episodes, costly food recalls, losses in export
15 markets, reduced prices for a contaminated food or feed crops,
16 and loss of confidence in the safety of Hawaii's food supply
17 between importers and consumers of agricultural commodities from
18 Hawaii. These risks necessitate a zero tolerance standard for
19 the presence of pharmaceutical crops and industrial crops and
20 their byproducts in crops used to produce human food or animal
21 feed.



1 The legislature further finds that while a pro forma zero
2 tolerance standard exists, the department of agriculture and
3 experts in the field acknowledge that contamination of human
4 food and animal feed is inevitable due to the inherent
5 imprecision of biological and agricultural systems, as well as
6 the relaxed regulatory regime. For example, the department of
7 agriculture's regulations aim not for prevention -- which may be
8 unattainable -- but rather for mitigation of the gene flow that
9 results in contamination of food and feed crops with these
10 substances. Some experts in the field are calling for the
11 establishment of tolerances, despite the potential risks
12 involved. Under these circumstances, appropriate regulatory
13 controls are urgently needed to ensure that pharmaceutical crops
14 and industrial crops and their byproducts do not enter human
15 food or animal feed crops at any level.

16 The purpose of this Act is to regulate the production of
17 pharmaceutical crops and industrial crops.

18 SECTION 2. Chapter 145, Hawaii Revised Statutes, is
19 amended by adding a new part to be appropriately designated and
20 to read as follows:

21 **"PART . GENETICALLY ENGINEERED PHARMACEUTICAL**
22 **AND INDUSTRIAL CROP SAFETY ACT**



1 **§145- Definitions.** As used in this part:

2 "Genetically engineered material" means material that has
3 been altered at the molecular or cellular level by means that
4 are not possible under natural conditions or by processes
5 (including recombinant DNA and RNA techniques, cell fusion,
6 microencapsulation, macroencapsulation, gene deletion and
7 doubling, introducing a foreign gene, and changing the positions
8 of genes) other than a means consisting exclusively of breeding,
9 conjugation, fermentation, hybridization, in vitro
10 fertilization, tissue culture, or mutagenesis.

11 "Genetically engineered plant" means a plant that contains
12 a genetically engineered material or was produced from a
13 genetically engineered seed. A plant shall be considered to
14 contain genetically engineered material if the plant has been
15 injected or otherwise treated with a genetically engineered
16 material, except that the use of manure as a fertilizer for the
17 plant shall not be construed to mean that the plant is produced
18 with a genetically engineered material.

19 "Genetically engineered seed" means a seed that contains or
20 was produced with genetically engineered material. A seed shall
21 be considered to contain genetically engineered material or to
22 have been produced with genetically engineered material if the



1 seed (or the plant from which the seed is derived) has been
2 injected or otherwise treated with genetically engineered
3 material, except that the use of manure as a fertilizer for the
4 plant shall not be construed to mean that any resulting seeds
5 are produced with a genetically engineered material.

6 "Industrial crop" means a genetically engineered plant that
7 is designed to produce industrial products, including industrial
8 and research chemicals and enzymes. The term includes a crop
9 intentionally treated with genetically engineered material that,
10 in turn, produces an industrial substance.

11 "Pharmaceutical crop" means a genetically engineered plant
12 that is designed to produce medical products, including human
13 and veterinary drugs and biologics. The term includes a crop
14 intentionally treated with genetically engineered material that,
15 in turn, produces a medical substance.

16 **§145- Regulation of production of pharmaceutical crops**
17 **and industrial crops.** (a) It shall be prohibited to:

18 (1) Grow, raise, or cultivate pharmaceutical crops and
19 industrial crops utilizing plants commonly used for
20 human food or domestic animal feed; or

21 (2) Conduct open air testing of pharmaceutical crops and
22 industrial crops.



1 (b) In order to prevent contamination, the department of
2 agriculture shall establish a tracking system to regulate the
3 growing, handling, transportation, and disposal of all
4 pharmaceutical and industrial crops and their byproducts.

5 **§145- Civil penalties for violation.** (a) The
6 department of agriculture, under chapter 91, may assess a civil
7 penalty against a person who violates this part, including any
8 rule adopted or order issued under this part. Each violation,
9 and each day during which a violation continues, shall
10 constitute a separate offense.

11 (b) The civil penalty shall be in an amount up to a
12 maximum of \$1,000,000 for each violation. In determining the
13 amount of the civil penalty, factors to be considered include
14 the following:

- 15 (1) The gravity of the violation;
16 (2) The degree of culpability;
17 (3) The size and type of business; and
18 (4) Any history of prior offenses of other laws
19 administered by the department of agriculture.

20 (c) A civil penalty under this section shall not be
21 assessed against a person unless the person is given notice and
22 an opportunity for a hearing on the record.



1 (d) An appeal of a penalty assessment may be made pursuant
2 to section 91-14.

3 (e) If a person fails to pay a civil penalty after the
4 order assessing the civil penalty has become final and
5 unappealable, the department shall refer the matter to the
6 attorney general, who shall bring a civil action to recover the
7 amount of the civil penalty. In the collection action, the
8 validity and appropriateness of the order of the department
9 imposing the civil penalty shall not be subject to review.

10 §145- Rules. The department of agriculture shall adopt
11 rules pursuant to chapter 91 for the purposes of this part."

12 SECTION 3. Growing, raising, or otherwise cultivating a
13 pharmaceutical crop or industrial crop as defined in section 2
14 of this Act shall be prohibited until the rules and tracking
15 system required by this Act are in effect.

16 SECTION 4. This Act shall take effect upon its approval.

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INTRODUCED BY: Ray L. Aar

Report Title:

GMOs; Pharmaceutical and Industrial Crops

Description:

Regulates production of pharmaceutical crops and industrial crops. Imposes civil penalties for violations.

