

GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1989

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HOUSE BILL 748
Committee Substitute Favorable 5/9/89

Short Title: Genetic Engineering Act.

(Public)

Sponsors:

Referred to:

March 20, 1989

1 A BILL TO BE ENTITLED
2 AN ACT TO REGULATE THE RELEASE AND COMMERCIAL USE OF
3 GENETICALLY ENGINEERED ORGANISMS.

4 The General Assembly of North Carolina enacts:

5 Section 1. Chapter 106 of the General Statutes is amended by adding a new
6 Article to read:

7 **“ARTICLE 63.**

8 **“GENETICALLY ENGINEERED ORGANISMS ACT.**

9 **“§ 106-755. Declaration of findings.**

10 The General Assembly of North Carolina finds and declares that biotechnology has
11 enormous potential to benefit many fields of human endeavor, including agriculture,
12 health care, and environmental protection, and that North Carolina, as a center for the
13 agricultural, pharmaceutical, health care, fermentation, chemical, and food processing
14 industries has much to gain from advances in biotechnology and genetic engineering.

15 The General Assembly further finds that as products of biotechnology move from
16 contained laboratories into the environment for testing and commercialization, the
17 citizens of North Carolina may have concerns about the potential effects of planned
18 introductions of new genetically engineered organisms on agriculture, public health, and
19 the natural environment. While the majority of these introductions will be
20 environmentally benign and comparable to the introduction of new genetic entities
21 derived from selective breeding, certain introductions might pose unknown risks and, as
22 such, require appropriate oversight.

1 The General Assembly therefore determines that it is incumbent upon the State,
2 working in concert with the federal regulatory authorities, to take responsible, timely
3 and minimally burdensome measures to ensure that the public and the environment are
4 protected and that risks from the environmental use of new genetically engineered
5 organisms are promptly addressed, while simultaneously allowing biotechnological
6 research and product development to advance. To do so, the State will create, in the
7 Department of Agriculture, a Genetic Engineering Review Board responsible for
8 reviewing and approving proposed introductions of genetically engineered organisms
9 into the environment. This Board will allow the State, in cooperation with the federal
10 authorities, to assess the potential risks and effects of releases of genetically engineered
11 organisms without undue governmental interference with the progress and commercial
12 development of biotechnology.

13 **"§ 106-756. Title.**

14 This Article shall be known as the 'Genetically Engineered Organisms Act.'

15 **"§ 106-757. Purpose.**

16 The purpose of this Article is to regulate the release and commercial use of
17 genetically engineered organisms in order to protect agriculture, public health, and the
18 environment. This Article does not apply to the breeding of plants, animals, and other
19 organisms by traditional methods, such as artificial insemination or hand pollination.

20 **"§ 106-758. Definitions.**

21 As used in this Article:

- 22 (1) 'Adverse effect' means physical injury to agriculture, public health, or
23 the environment.
24 (2) 'Board' means the Genetic Engineering Review Board.
25 (3) 'Commercial use' means the sale, offering for sale, or distribution of a
26 genetically engineered organism.
27 (4) 'Commissioner' means the Commissioner of Agriculture.
28 (5) 'Department' means the Department of Agriculture.
29 (6) 'Genetic engineering' means the introduction of new genetic material
30 to an organism or the regrouping of an organism's genes, except for the
31 breeding of plants, animals, and other organisms by traditional
32 methods, such as artificial insemination or hand pollination, and such
33 other methods as may be designated by the Board under G.S. 106-760.
34 (7) 'Genetically engineered organism' means a living organism derived
35 from genetic engineering.
36 (8) 'Organism' means any animal, plant, bacterium, cyanobacterium,
37 fungus, protist, or virus.
38 (9) 'Release' means the placement or use of a genetically engineered
39 organism outside a contained laboratory, fermentation facility,
40 greenhouse, building, structure, or other similar facility or under any
41 other conditions not specifically determined by the Board to be
42 adequately contained.

43 **"§ 106-759. Genetic Engineering Review Board.**

1 (a) There is created the Genetic Engineering Review Board in the Department of
2 Agriculture. The Board shall consist of nine members as follows:

- 3 (1) The Secretary of the Department of Natural Resources and Community
4 Development or his designee;
5 (2) The Secretary of Human Resources or his designee;
6 (3) The Commissioner of Agriculture or his designee;
7 (4) The President of the North Carolina Biotechnology Center or his
8 designee;
9 (5) The Dean of the College of Agriculture and Life Sciences at North
10 Carolina State University or his designee;
11 (6) The Dean of the School of Public Health of The University of North
12 Carolina at Chapel Hill or his designee;
13 (7) A practicing farmer who is an active member of a farm organization,
14 appointed by the General Assembly upon the recommendation of the
15 Speaker of the House of Representatives;
16 (8) A representative of a nonprofit public interest organization appointed
17 by the General Assembly upon the recommendation of the President
18 Pro Tempore of the Senate; and
19 (9) A representative of the biotechnology industry appointed by the
20 Governor.

21 (b) The appointed members of the Board shall serve for three-year terms.
22 Members designated by an ex officio member shall serve at the pleasure of the ex
23 officio member. Appointments and designations shall be made within 60 days after the
24 effective date of this Article.

25 (c) A chairman shall be elected by the Board from among its members for a one-
26 year term, and shall serve no more than two consecutive terms. The Commissioner of
27 Agriculture may appoint a member of the Board to serve as interim chairman for one
28 year or until the Board elects a chairman, whichever is sooner.

29 (d) Any vacancies shall be filled by the appropriate appointing authority. Any
30 appointment to fill a vacancy on the Board created by resignation, dismissal, death,
31 disability or any cause shall be for the balance of the unexpired term. Vacancies in
32 appointments made by the General Assembly shall be filled in accordance with G.S.
33 120-122. Any appointed member of the Board may be removed by the appointing
34 authority for misfeasance, malfeasance or nonfeasance.

35 (e) The members of the Board who are not State employees shall receive per
36 diem and travel and subsistence allowances as provided by law. All clerical and other
37 services required by the Board shall be supplied by the Department of Agriculture. A
38 majority of the Board shall constitute a quorum for the transaction of business. Rule
39 making and administrative proceedings shall be governed by the North Carolina
40 Administrative Procedure Act.

41 **"§ 106-760. Board's powers and duties.**

42 (a) The Board shall:

- 43 (1) Delegate to the Commissioner any of its duties, other than rule
44 making, but including issuance of permits, as the Board deems

- 1 necessary or convenient for the administration and enforcement of this
2 Article; and
3 (2) Adopt regulations designating those activities that will not be treated
4 as genetic engineering for the purposes of this Article.
5 (b) The Board may:
6 (1) Grant, deny, suspend, modify or revoke permits as provided by this
7 Article, and charge fees for such permits, not to exceed two hundred
8 fifty dollars (\$250.00);
9 (2) Adopt, amend, or revoke regulations to implement and carry out the
10 purposes of this Article; and
11 (3) Establish advisory committees to assist the Board in carrying out its
12 duties.

13 **"§ 106-761. Commissioner's powers and duties.**

14 The Commissioner may:

- 15 (1) Enforce this Article, administer the permit process, and exercise the
16 powers and duties imposed upon him by this Article or by rules
17 adopted in accordance with this Article; and
18 (2) Designate such employees of the North Carolina Department of
19 Agriculture, and enter into cooperative agreements with federal and
20 State agencies, as may be necessary to carry out the duties and exercise
21 the powers provided by this Article.

22 **"§ 106-762. Permits required; applications; federal review; permit revocation.**

- 23 (a) A genetically engineered organism may not be released into the environment,
24 or sold, offered for sale, or distributed for release into the environment unless a permit
25 for its release has been issued pursuant to this Article. The Board may, by regulation,
26 provide for general permits for classes of activities for which individual permits will not
27 be required.
28 (b) Permit applications shall be on forms or in the format prescribed by the
29 Board, and shall include such information as the Board deems necessary in order to
30 determine compliance with this Article. To the extent feasible, the Board shall
31 authorize the use of forms or formats required by the federal government for actions
32 similar to those regulated under this Article. Applicants shall, upon request by the
33 Board, submit copies of data submitted with corresponding federal permit applications.
34 (c) The Board may require such additional data as it deems necessary to
35 determine potential adverse effects of the release of the organism on agriculture, public
36 health, and the environment. To the extent possible, the Board shall accept for review
37 and base its decision on the data submitted with the federal application.
38 (d) The Board may, if it deems it necessary to protect agriculture, public health,
39 or the environment from potential adverse effects of the release of a genetically
40 engineered organism:
41 (1) Place restrictions on the number and location of organisms released,
42 method of release, training of persons involved with the release of
43 organisms, disposal of organisms, and other conditions of use;

- 1 (2) Require measures to limit dispersal of released organisms or spread of
2 inserted genes or gene products;
3 (3) Require monitoring of the abundance and dispersal of the released
4 organism or inserted genes or gene products; and
5 (4) Deny, suspend, modify, or revoke the permit.

6 (e) The Board may submit written comments to any federal agency reviewing a
7 proposed or completed release, and otherwise participate in any such reviews. The
8 Board may issue a permit under this Article based on the federal review and approval of
9 the proposed release if the Board determines that federal regulation of the release
10 sufficiently protects agriculture, public health, and the environment in North Carolina.
11 The Board shall minimize duplication of federal regulatory requirements to the extent
12 possible.

13 (f) The Board may deny, suspend, modify, or revoke a permit for failure to
14 comply with this Article or with any rule adopted in accordance with this Article. Such
15 proceedings shall be in accordance with the Administrative Procedure Act. The Board
16 may summarily suspend a permit in accordance with G.S. 150B-3, pending further
17 proceedings, if the Board determines that an adverse effect is occurring or is likely to
18 occur because of a release authorized by such permit.

19 (g) A decision shall be made on a permit application within 90 days from the date
20 the completed application is received by the Board, unless a public hearing is held
21 pursuant to G.S. 106-763. The Board may, for good cause, extend the time for making
22 a decision by no more than 30 days.

23 (h) Issuance of permits under this Article is not subject to the provisions of
24 Article I of Chapter 113A.

25 (i) An application may be withdrawn at any time by written notice to the Board.

26 **"§ 106-763. Public notice of releases; public hearing.**

27 (a) Within 15 days after receiving a completed application for a proposed release,
28 the Board shall publish notice and a brief description of the proposed release, unless the
29 Board intends to deny the application. Notice shall also be provided to any person who
30 has filed a written request to be notified of such releases. The Board shall prescribe the
31 form, content and extent of the notice. However, at a minimum, notice shall be given
32 by publication one time in a newspaper having general circulation in each county where
33 the release is proposed to be made. In addition, subject to the provisions of this Article
34 regarding confidential business information, any documents submitted as part of the
35 application shall be available for public inspection or copying at or near the site of the
36 proposed release and at the offices of the Board. Any person may submit written
37 comments to the Board regarding the proposed release.

38 (b) Any person may request a public hearing on a permit application by filing a
39 written request with the Board within 30 days after the date of the notice of the
40 application. The Board shall consider all such requests for hearing and, if it determines
41 that there is significant public interest and justification for holding such a hearing, a
42 hearing shall be held in the county where the release is proposed to be made. If the
43 Board determines that a public hearing should be held, it may do so even though no
44 hearing has been requested. Notice of the hearing shall be published at least 30 days

1 before the hearing date. The Board shall prescribe the form, content, and extent of the
2 notice. However, at a minimum, notice shall be given by publication one time in a
3 newspaper having general circulation in each county where the release is proposed to be
4 made.

5 (c) If a public hearing is held, a decision shall be made on the permit application
6 within 120 days after the date the completed application is received by the Board. The
7 Board may, for good cause, extend the time for making a decision by no more than 30
8 additional days.

9 (d) The Board may, with the written consent of the applicant, extend the period
10 to review the application.

11 **"§ 106-764. Confidential business information.**

12 (a) In submitting information pursuant to this Article, an applicant for a permit
13 may designate as 'confidential' any portions of which the applicant believes are entitled
14 to treatment as confidential business information. A designation of confidentiality shall
15 be made in writing and in such manner as the Board may prescribe. Information
16 designated as 'confidential' may be submitted separately from other material submitted.

17 (b) Any person engaged in the review of the effects of a proposed release of a
18 genetically engineered organism who believes that access to undisclosed confidential
19 business information is necessary in order to perform such review effectively may
20 request the disclosure of material designated as confidential business information by
21 submitting a written petition to the Board. Such a petition shall state the reason(s) that
22 such confidential business information is necessary to the performance of the
23 petitioner's review. In addition, the petitioner shall sign an affidavit affirming that the
24 petitioner is not nor does petitioner represent in any capacity a person engaged in any
25 business or enterprise in competition with the applicant or in which the confidential
26 business information could be utilized for commercial or product development
27 purposes. The applicant shall be notified of the petition and shall have an opportunity to
28 respond to the petition. Such response may include an offer by the applicant to produce
29 the confidential business information to the petitioner pursuant to terms to be expressed
30 in a written agreement between the applicant and the petitioner, an explanation by the
31 applicant as to why the petitioner does not need the confidential business information in
32 order to perform such review or an offer by the applicant to provide the petitioner with
33 other information which is not confidential and responds to the petitioner's reasons for
34 requesting the confidential business information. By mutual written agreement of the
35 petitioner and the applicant, the Board may delay a decision on the petition until further
36 written notice by the petitioner. The Board shall then make a determination as to
37 whether the petitioner does require access to any or all of the confidential business
38 information requested by the petitioner in order to make an effective, independent
39 review of the proposed release. Where the Board determines that the petitioner does
40 require access to some or all of the confidential business information requested by the
41 petitioner, the Board shall notify the applicant and the petitioner of its decision, and the
42 applicant shall provide that confidential business information which is required by the
43 petitioner as determined by the Board to the petitioner or withdraw its application. If
44 the Board's decision is appealed, the applicant shall not be required to disclose the

1 confidential business information pending appeal. If the application is withdrawn, all
2 confidential business information shall be returned to the applicant and shall not be
3 disclosed.

4 (c) Except as provided in this Article, no person may reveal or use for his own
5 benefit any confidential business information received pursuant to this Article.

6 (d) Nothing in this section, or in rules adopted under this section, authorizes the
7 Board or any person to withhold from the public information regarding the adverse
8 effects of a proposed release of any organism.

9 **"§ 106-765. Local regulation.**

10 No county or municipality shall enact any regulation or ordinance regulating the
11 release of genetically engineered organisms.

12 **"§ 106-766. Unlawful acts; penalties; injunctions.**

13 (a) No genetically engineered organism may be released, sold, offered for sale, or
14 distributed in violation of this Article or rules adopted in accordance with this Article.

15 (b) A civil penalty of not more than ten thousand dollars (\$10,000) may be
16 assessed by the Board against any person who violates any provision of this Article or
17 any rule of the Board. In determining the amount of the penalty, the Board may
18 consider the degree and extent of harm caused by the violation. No civil penalty may be
19 assessed under this section unless the person has been given the opportunity for a
20 hearing pursuant to the Administrative Procedure Act. Each day's violation shall
21 constitute a separate offense.

22 (c) A person who interferes with or attempts to interfere with the Commissioner
23 or any of his agents while engaged in the performance of their duties under this Article,
24 or violates any provision of this Article or any rule of the Board, is guilty of a
25 misdemeanor and is punishable by a fine of not less than two hundred fifty dollars
26 (\$250.00) nor more than one thousand dollars (\$1,000) for each offense. Each day's
27 violation shall constitute a separate offense.

28 (d) Notwithstanding any remedy at law, the Commissioner is authorized to apply
29 to the superior court, and the court shall have jurisdiction upon hearing and for cause
30 shown, to grant a temporary or permanent injunction to prevent or stop a violation of
31 this Article.

32 (e) Any public employee who willfully releases a genetically engineered
33 organism in violation of this Article shall be subject to dismissal."

34 Sec. 2. There is appropriated from the General Fund to the Department of
35 Agriculture the sum of \$238,514 for the 1989-90 fiscal year and the sum of \$177,585
36 for the 1990-91 fiscal year for implementation and enforcement of this act.

37 Sec. 3. This act is effective upon ratification, but no permits shall be required
38 under G.S. 106-762 until July 1, 1990. This act shall expire on September 30, 1995,
39 unless the General Assembly amends this section prior to that date.