
HOUSE BILL 2839

State of Washington 52nd Legislature 1992 Regular Session

By Representatives Brekke, Valle and Rust

Read first time 01/29/92. Referred to Committee on Environmental Affairs/Appropriations.

1 AN ACT Relating to the release and commercial use of genetically
2 engineered organisms and the products of genetically engineered
3 organisms; adding a new chapter to Title 15 RCW; creating a new
4 section; prescribing penalties; making an appropriation; and providing
5 an effective date.

6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

7 NEW SECTION. **Sec. 1.** The legislature finds that biotechnology
8 has the potential to benefit many fields of human endeavor, including
9 agriculture, health care, and environmental protection. The state of
10 Washington is recognized as a center for agricultural, chemical, forest
11 products, and food processing industries and as such may gain from
12 advances in biotechnology.

13 The legislature further finds that as products of biotechnology
14 move from contained laboratories into the environment for testing and

1 commercialization, the citizens of Washington will have concerns about
2 the potential effects of planned environmental introductions of
3 genetically engineered organisms and the products of genetically
4 engineered organisms on agriculture, public health and safety, the
5 economy, and the social well-being of the state. While many of these
6 releases may be benign, the introduction of new entities may pose
7 unknown risks and, therefore, require appropriate oversight.

8 The legislature therefore determines that it is incumbent upon the
9 state, working in concert with the federal regulatory authorities, to
10 take responsible, timely, and minimally burdensome measures to protect
11 agriculture, public health and safety, the environment, the economy,
12 and the social well-being of the state, and to address concerns
13 regarding the impact of biotechnology while at the same time allowing
14 research to continue and advance with proper safeguards.

15 To these ends the department of ecology shall create a
16 biotechnology review board responsible for reviewing and, where
17 appropriate, approving proposed introductions of genetically engineered
18 organisms or the products of genetically engineered organisms into the
19 environment. The board shall cooperate with the federal authorities to
20 assess the potential risks and effects of releases of genetically
21 engineered organisms and the products of genetically engineered
22 organisms without undue governmental interference with the progress and
23 development of biotechnology.

24 NEW SECTION. **Sec. 2.** As used in this chapter, the following
25 terms have the meanings indicated unless the context clearly requires
26 otherwise.

27 (1) "Adverse effect" means an injury to or an impact to the
28 detriment of agriculture, the public's health and safety, the
29 environment, the economy, or the social well-being of the state.

1 (2) "Board" means the biotechnology review board.

2 (3) "Department" means the department of ecology.

3 (4) "Director" means the director of the department of ecology.

4 (5) "Environment" includes all the land, air, and water, and all
5 the living organisms in association with land, air, and water.

6 (6) "Federal coordinated framework" means the coordinated framework
7 for the regulation of biotechnology described in 51 C.F.R. Secs. 23302-
8 23350.

9 (7) "Genetic engineering" means the introduction of new genetic
10 material to an organism or the regrouping of an organism's genes,
11 except for the breeding of plants, animals, and other organisms by
12 traditional methods, such as artificial insemination or hand
13 pollination, and other methods as may be designated by the board under
14 section 4 of this act.

15 (8) "Genetically engineered organism" means a living organism or
16 dormant stage of life derived from genetic engineering.

17 (9) "Local government" means a county, city, or town.

18 (10) "Organism" includes any animal, plant, bacterium, fungus,
19 mycoplasma, mycoplasma-like organism, protist, virus, or any entity
20 related to the foregoing.

21 (11) "Person" means an individual, firm, organization, corporation,
22 association, partnership, consortium, joint venture, commercial entity,
23 state government agency, unit of local government, or federal
24 government agency.

25 (12) "Release" means the placement or use of a genetically
26 engineered organism, or the placement or use of a product of a
27 genetically engineered organism, outside a contained laboratory,
28 fermentation facility, greenhouse, or other structure or contained
29 facility, or under other conditions not specifically determined by the
30 board to be adequately contained.

1 Members designated by an ex officio member shall serve at the pleasure
2 of that ex officio member.

3 (4) The board shall elect a chair from among its members for a one-
4 year term but who shall serve no more than two consecutive terms. The
5 director may appoint a member of the board to serve as interim chair
6 for one year or until the board elects a chair, whichever is sooner.

7 (5) A vacancy shall be filled by the appropriate appointing
8 authority. An appointment to fill a vacancy on the board created by
9 any cause shall be for the balance of the unexpired term.

10 (6) An appointed member of the board may be removed by the
11 appointing authority for misfeasance, malfeasance, or nonfeasance.

12 (7) The members of the board who are not otherwise paid for the
13 time expended on the board shall receive per diem and travel expenses
14 as provided by law under RCW 43.03.050 and 43.03.060.

15 (8) All clerical and other services required by the board shall be
16 supplied by the department of ecology.

17 (9) A majority of the board shall constitute a quorum for the
18 transaction of business.

19 (10) Rule-making and administrative proceedings shall be governed
20 by chapter 34.05 RCW.

21 NEW SECTION. **Sec. 4.** (1) The board shall:

22 (a) Adopt regulations designating those activities that are not
23 treated as genetic engineering for the purposes of this chapter;

24 (b) Establish criteria for environmental impact statements to
25 accompany applications for permits granted under this chapter;

26 (c) Set fines for the transgression of any of its rules and for the
27 release of genetically engineered materials or their products without
28 a license;

1 (d) Charge fees for actions taken under section 6(6) of this act
2 equal to the actual cost necessary to review each permit;

3 (e) Delegate to the director any of its duties, other than
4 rulemaking, but including issuance of permits, as the board deems
5 necessary for the administration and enforcement of this chapter; and

6 (f) Keep the public informed and, where possible, involved in the
7 work of the board.

8 (2) The director and members of the board, employees of the
9 department of ecology, the state and its political subdivisions, and
10 other state entities and employees involved with issuing a permit under
11 section 6 of this act are immune from civil liability, whether direct
12 or derivative, for issuing the permit. The permit certifies only that
13 the holder met all state requirements for the purposes of issuing the
14 permit.

15 (3) The board may:

16 (a) Adopt, amend, or revoke rules to implement and carry out the
17 purposes of this chapter;

18 (b) Establish advisory committees to assist the board in carrying
19 out its duties; and

20 (c) Either (i) establish a fund to which all applicants shall
21 contribute a designated amount and from which may be drawn the costs of
22 cleanup of unforeseen and undesirable consequences of environmental
23 release, the fund being a designated fund and therefore not to be used
24 for other purposes, or (ii) require of permit applicants a bond or
25 proof of financial ability to pay for potential accidents and
26 consequences of release, with full liability payment to victims and all
27 cleanup costs to be paid by the involved parties.

28 NEW SECTION. **Sec. 5.** (1) The director shall enforce this
29 chapter, administer the permit process, and exercise the powers and

1 duties imposed on him or her by this chapter or by the rules adopted
2 under this chapter.

3 (2) The director may designate employees of the department of
4 ecology to assist him or her and enter into cooperative agreements with
5 federal and state agencies necessary to carry out the duties and
6 exercise the powers provided by this chapter.

7 NEW SECTION. **Sec. 6.** (1)(a) A genetically engineered organism
8 or a product of a genetically engineered organism may not be released
9 into the environment, or sold, offered for sale, or distributed for
10 release into the environment unless a permit for the release has been
11 issued by the board. Release without a permit is governed by the fines
12 and penalties established in section 9 of this act.

13 (b) Prior to an intended release of a genetically engineered
14 organism or a product of a genetically engineered organism into the
15 environment, or the sale, offer for sale, or distribution in this state
16 of a genetically engineered organism or its product for release into
17 the environment, a person shall apply in writing to the board for a
18 permit.

19 (i) If federal notification is required prior to release, a person
20 shall apply to the board within seven working days of submitting an
21 application, or other written notice, to the federal coordinated
22 framework or federal regulatory agency.

23 (ii) If no federal notification is required, a person shall apply
24 to the board at least one hundred twenty days prior to the proposed
25 release of a genetically engineered organism or its product into the
26 environment, or the sale, offer for sale, or distribution of a
27 genetically engineered organism or its product for release into the
28 environment.

1 (c) The board may provide, by rule, for general permits for classes
2 of activities for which individual permits are not required.

3 (2) Permit applications must be on forms or in the format
4 prescribed by the board, and include an environmental impact statement
5 and other information deemed necessary by the board in order to
6 determine compliance with this chapter. To the extent feasible, the
7 board shall authorize the use of forms or format required by the
8 federal government for actions similar to those regulated under this
9 chapter. Applicants, upon request by the board, shall submit copies of
10 data submitted with corresponding federal permit applications.

11 (3) The board may require additional data it deems necessary to
12 determine potential adverse effects of the release of a genetically
13 engineered organism or its products. To the extent possible, the board
14 shall accept for review and base its decision on data submitted with
15 the federal application.

16 (4) If the board finds it necessary for the protection against
17 potential adverse effects of the release of a genetically engineered
18 organism or the product of a genetically engineered organism, the board
19 may:

20 (a) Restrict the number and location of organisms or products
21 released and method of release, prescribe the training of persons
22 involved with the release, regulate the disposal of organisms or
23 products or organisms, and other conditions of use;

24 (b) Require measures to limit dispersal of released organisms or
25 products of organisms or spread of inserted genes or gene products;

26 (c) Require monitoring of the abundance and dispersal of the
27 released organisms or products of organisms or inserted genes or gene
28 products; or

29 (d) Deny, suspend, modify, or revoke the permit.

1 (5) The board may submit written comments to any federal agency
2 reviewing a proposed or completed release, and otherwise participate in
3 those reviews. The board may issue a permit under this chapter based
4 on the federal review and approval of the proposed release if the board
5 determines that the federal regulation of the release sufficiently
6 protects agriculture, public health and safety, the environment, social
7 well-being, and the economy of Washington. The board shall minimize
8 duplication of federal regulatory requirements to the extent possible.
9 This section is in addition to and does not supplant the requirements
10 of other provisions of law, including, but not limited to, the state
11 environmental policy act, chapter 43.21C RCW, and the administrative
12 procedure act, chapter 34.05 RCW.

13 (6) The board may deny, suspend, modify, or revoke a permit for
14 failure to comply with this chapter or any rule adopted by the board
15 in accordance with chapter 34.05 RCW. The board may summarily suspend
16 a permit if it determines that an adverse effect is occurring or is
17 likely to occur because of a release authorized by a permit.

18 (7) The board shall make a decision on a permit application within
19 ninety days from the date the completed application is received by the
20 board unless a public hearing is held pursuant to section 8 of this
21 act. The board may, for good cause, extend the time for making a
22 decision by no more than ninety days, by notifying the applicant in
23 writing.

24 (8) The application may be withdrawn at any time by written notice
25 to the board.

26 NEW SECTION. **Sec. 7.** (1) In submitting data pursuant to this
27 chapter, an applicant for a permit shall:

28 (a) Clearly mark portions of the material that the applicant
29 believes are entitled to treatment as trade secrets as defined in RCW

1 19.108.010 or commercial or financial confidential business information
2 that are exempt from disclosure under RCW 42.17.310; and

3 (b) Submit the marked material separately from other material
4 required to be submitted under this chapter.

5 Material not clearly marked as a trade secret or as confidential
6 may be released by the department to the public.

7 (2) Except as otherwise provided by this subsection, the board may
8 not make public material marked as provided in subsection (1) of this
9 section or material that in the board's judgment should be privileged
10 or confidential because it contains or relates to trade secrets or
11 confidential commercial or financial information. The board may,
12 however, reveal information acquired under this chapter at a public
13 hearing or in findings of fact issued by the board when it deems such
14 disclosure necessary to carry out the purposes of this chapter.

15 (3)(a) A person engaged in the review of the effects of a proposed
16 release of a genetically engineered organism or the products of a
17 genetically engineered organism who believes that access to undisclosed
18 confidential business information is necessary in order to perform a
19 review effectively may request the disclosure of material designated as
20 confidential business information by submitting a written petition to
21 the board. The petition must state the reasons that such confidential
22 business information is necessary to the performance of the
23 petitioner's review. In addition, the petitioner shall sign an
24 affidavit affirming that the petitioner does not represent in any
25 capacity a person engaged in business or enterprise in competition with
26 the applicant or in which the confidential business information could
27 be utilized for commercial or product development purposes.

28 (b) The applicant must be notified of the petition and have an
29 opportunity to respond to the petition. The response may include an
30 offer by the applicant to produce the confidential business information

1 for the petitioner under terms expressed in a written agreement between
2 the applicant and the petitioner and an explanation by the applicant as
3 to why the petitioner does not need the confidential business
4 information, or an offer by the applicant to provide the petitioner
5 with other information that is not confidential and responds to the
6 petitioner's reasons for requesting the confidential business
7 information. By written stipulation of the petitioner and the
8 applicant, the board may delay a decision on the petition until further
9 written notice by the petitioner.

10 (c) The board shall make a determination as to whether the
11 petitioner requires access to some or all of the confidential business
12 information requested by the petitioner in order to make an effective,
13 independent review of the proposed release. Where the board determines
14 that the petitioner requires access to some or all of the confidential
15 business information requested by the petitioner, the board shall
16 notify the applicant and the petitioner of its decision whereupon the
17 applicant shall provide that confidential business information to the
18 petitioner or withdraw its application. If the board's decision is
19 appealed, the applicant is not required to disclose the confidential
20 business information pending appeal. If the application is withdrawn,
21 all confidential business information must be returned to the applicant
22 and shall not be disclosed.

23 (4) If the board proposes to release for inspection information
24 that the applicant believes to be protected from disclosure under
25 subsection (2) of this section, the applicant shall notify the board by
26 certified mail and provide a statement that explains why the particular
27 information should not be released. The board shall not release this
28 data until thirty days after receipt of the notice by the applicant.
29 During this period, the applicant may institute an action in the
30 superior court of Thurston county for declaratory judgment as to

1 whether the information is subject to protection under this subsection.
2 In deciding whether to allow the information to be released, the court
3 shall balance the interests of the applicant in the confidentiality of
4 the material against the public's interest in access to the material to
5 determine the impact of the proposed release on agriculture, public
6 health and safety, the environment, and the social well-being and
7 economy of the state.

8 (5) Except as provided by this section, a person may not reveal or
9 use for his or her own benefit any confidential business information
10 received pursuant to this chapter.

11 (6) Nothing in this section, or in rules adopted pursuant to this
12 section, authorizes the board or any person to withhold from the public
13 information regarding the adverse effects of a proposed release of any
14 genetically engineered organism or the product of such an organism.

15 NEW SECTION. **Sec. 8.** (1) Within fifteen days of receiving a
16 completed application for a proposed release, the board shall publish
17 notice and a brief description of the proposed release. The board
18 shall also notify any person who has filed a written request to be
19 notified of releases. The board shall prescribe the form, content, and
20 extent of the notice. However, at a minimum, the notice must be
21 published once in a newspaper having a general circulation in the
22 county where the release is proposed to be made. In addition, subject
23 to section 7 of this act, any documents submitted as part of the
24 application must be available for public inspection or copying at or
25 near the site of the proposed release and at the offices of the board.
26 A person may submit written comments to the board regarding the
27 proposed release.

28 (2) The local government having jurisdiction where a person
29 proposes to release a genetically engineered organism or its product,

1 or ten or more citizens residing within the government's jurisdiction,
2 may request a public hearing by filing a written request with the board
3 within thirty days following the last date notice of the application
4 was published. The hearing, if requested, must be held within the
5 boundaries of the local government and the board shall provide, except
6 in emergency circumstances, a minimum of twenty days' public notice of
7 the hearing by publication in a newspaper of general circulation.
8 Notice must be provided to any person who has filed written request to
9 be notified of such hearings.

10 The board may order a public hearing even if no hearing has been
11 requested.

12 (3) If a public hearing is held, the board shall accept or deny the
13 permit application within one hundred twenty days from the date the
14 completed application is received by the board. The board may, for
15 good cause, extend the time for making a decision by not more than
16 sixty days by notifying the applicant in writing.

17 (4) If no public hearing is held, the board shall accept or deny
18 the permit application within sixty days from the date the completed
19 application is received by the board. The board may, for good cause,
20 extend the time for making a decision by not more than thirty days by
21 notifying the applicant in writing.

22 (5) The board may, with the written consent of the applicant,
23 extend the period to review the application.

24 NEW SECTION. **Sec. 9.** (1) The board may assess a civil penalty
25 of not more than ten thousand dollars against a person who violates a
26 provision of this chapter or a rule of the board. In determining the
27 amount of the penalty, the board may consider the degree and extent of
28 the harm caused by the violation. Each and every violation is a

1 separate and distinct offense. Each day's violation is a separate
2 offense.

3 (2) Every person who, through an act of commission or omission,
4 procures, aids, or abets in the violation, violates this section and
5 may be subject to the civil penalty provided in this section. A public
6 employee who willfully releases a genetically engineered organism or
7 the product of a genetically engineered organism in violation of this
8 chapter is subject to the civil penalty provided in this section and
9 may also be subject to dismissal.

10 (3) A person who interferes with or attempts to interfere with the
11 director or any of his or her agents while engaged in the performance
12 of their duties under this chapter, or who violates any provision of
13 this chapter or any rule of the board adopted under this chapter is
14 guilty of a misdemeanor and subject to a fine of not less than two
15 hundred dollars nor more than one thousand dollars for each offense.
16 Each day's violation is a separate offense.

17 (4) A person who releases a genetically engineered organism or the
18 product of a genetically engineered organism in violation of this
19 chapter is liable for the consequences and costs of remediation and
20 cleanup of the effects of such a release.

21 (5) The director may bring an action to enjoin the violation or
22 threatened violation of any provision of this chapter or any rule
23 adopted under this chapter in a court of competent jurisdiction of the
24 county in which the violation occurs or is about to occur.

25 NEW SECTION. **Sec. 10.** This chapter does not apply to
26 genetically engineered organisms not proposed for release, and not
27 released, to the environment.

1 NEW SECTION. **Sec. 11.** Section 6 of this act shall take effect
2 September 1, 1992.

3 NEW SECTION. **Sec. 12.** The biotechnology review account is
4 created in the state treasury. All receipts from fees charged under
5 section 4 of this act, and from fines assessed under section 9 of this
6 act shall be deposited into the account. Moneys in the account may be
7 spent only after appropriation. Expenditures may be used only for the
8 purposes of this chapter.

9 NEW SECTION. **Sec. 13.** The sum of one hundred ten thousand
10 dollars, or as much thereof as may be necessary, is appropriated for
11 the biennium ending June 30, 1993, from the biotechnology review
12 account to the department of ecology for the purposes of this act.

13 NEW SECTION. **Sec. 14.** Sections 2 through 10 and 12 of this act
14 shall constitute a new chapter in Title 15 RCW.