

Presented to the governor April 14, 1994

Signed by the governor April 18, 1994, 3:06 p.m.

CHAPTER 454—H.F.No. 2212

An act relating to the environment; genetically engineered organisms; authorizing the department of agriculture to exempt certain federally monitored releases; authorizing the environmental quality board to adopt rules relating to certain releases; providing for certain exemptions; amending Minnesota Statutes 1992, sections 18F.01; 18F.02, subdivisions 1, 5, and by adding a subdivision; 18F.04; 18F.07; 18F.12; 116C.91, subdivision 1; 116C.94; and 116C.96; proposing coding for new law in Minnesota Statutes, chapters 18F; and 116C; repealing Minnesota Statutes 1992, section 18F.02, subdivision 7.

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

Section 1. Minnesota Statutes 1992, section 18F.01, is amended to read:

18F.01 PURPOSE.

The purpose of sections 18F.01 to ~~18F.12~~ 18F.13 is to establish permits for the release of certain genetically engineered agriculturally related organisms to protect humans and the environment from the potential for significant adverse effects of those releases.

Sec. 2. Minnesota Statutes 1992, section 18F.02, subdivision 1, is amended to read:

Subdivision 1. **SCOPE.** As used in sections 18F.01 to ~~18F.12~~ 18F.13, the terms defined in this section have the meanings given them.

Sec. 3. Minnesota Statutes 1992, section 18F.02, is amended by adding a subdivision to read:

Subd. 2a. AGRICULTURALLY RELATED ORGANISM. "Agriculturally related organism" means any organism that is used in agricultural production or processing of agricultural products. It includes livestock and livestock products; dairy animals and dairy products; poultry and poultry products; domestic fur-bearing animals; animal feeds; horticultural stock; nursery stock, as defined in section 18.46, subdivision 3; fruit; vegetables; forage grain; wild rice; seeds; bees; apiary products; and products for the control or mitigation of noxious weeds. It excludes vaccines and drugs for use in humans; genetic engineering of human germ cells and human somatic cells intended for use in human gene therapy; vaccines for use in livestock, dairy animals, poultry, domestic fur-bearing animals, or private aquatic life; genetically engineered wild animals; and forestry products.

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Sec. 4. Minnesota Statutes 1992, section 18F.02, subdivision 5, is amended to read:

Subd. 5. **GENETICALLY ENGINEERED PLANT ORGANISM.** "Genetically engineered plant organism" means a plant an organism that has been modified directly or indirectly using genetic engineering.

Sec. 5. Minnesota Statutes 1992, section 18F.04, is amended to read:

18F.04 POWERS AND DUTIES OF THE COMMISSIONER.

The commissioner shall administer, implement, and enforce sections 18F.01 to ~~18F.12~~ 18F.13. The board of animal health shall be consulted on permits that relate to livestock and domestic animals.

Sec. 6. Minnesota Statutes 1992, section 18F.07, is amended to read:

18F.07 GENETICALLY ENGINEERED PLANT AGRICULTURALLY RELATED ORGANISM PERMIT.

Subdivision 1. **REQUIREMENT.** A person may not conduct a release of a genetically engineered plant agriculturally related organism until a permit for the release has been obtained from the commissioner. Each release of a plant genetically engineered agriculturally related organism requires a new permit until the commissioner determines by rule that the plant proposed use of the agriculturally related organism is no longer subject to regulation under this chapter.

Subd. 2. **PERMIT APPLICATION AND REVIEW.** (a) After reviewing a completed application, the commissioner may issue a genetically engineered plant agriculturally related organism permit if the commissioner determines that the applicant has adequately demonstrated that the proposed release does not have the potential for unreasonable adverse effects on the environment. The commissioner may prescribe terms and conditions including, but not limited to, the period for the genetically engineered plant agriculturally related organism permit, the amount or number of genetically engineered plants agriculturally related organisms to be used, monitoring activities, department inspection schedules, reporting of experiment results, and experiment termination procedures. A person may not violate terms or conditions of a permit issued under this section. After a genetically engineered plant agriculturally related organism permit is issued, the commissioner may revoke or change the permit at any time if the commissioner finds that its terms or conditions are being violated or are inadequate to avoid unreasonable adverse effects on the environment.

(b) The commissioner may deny issuance of a genetically engineered plant agriculturally related organism permit if the commissioner determines that the use to be made of the plant agriculturally related organisms under the proposed terms and conditions may cause unreasonable adverse effects on the environment.

Subd. 3. **APPLICATION.** A person shall file an application for a geneti-

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cally engineered ~~plant~~ agriculturally related organism permit with the commissioner. The application must include:

- (1) the name and address of the applicant;
- (2) any United States Environmental Protection Agency, United States Department of Agriculture, or other federal agency regulatory application or approval document, if required under federal law or rule;
- (3) the purpose or objectives of the ~~plant~~ agriculturally related organism;
- (4) the name, address, and telephone number of cooperators or participants in this state;
- (5) the amount of ~~plants, plant material or number of organisms, materials, cultures,~~ or seeds to be shipped or used in this state; and
- (6) other information requested by the commissioner.

Subd. 4. **APPLICATION FEE.** An application for a permit for a genetically engineered ~~plant~~ agriculturally related organism must be accompanied by a nonrefundable application fee of \$125.

Sec. 7. Minnesota Statutes 1992, section 18F.12, is amended to read:

18F.12 RULES.

The commissioner shall adopt rules governing the issuance of permits for proposed releases of genetically engineered ~~plants~~ agriculturally related organisms, experimental genetically engineered pesticides, and genetically engineered fertilizers, genetically engineered soil amendments, and genetically engineered plant amendments. The rules must include a requirement for environmental review subject to the provisions of chapter 116D and rules adopted under it. The rules must also include provisions requiring concurrent permit review for proposed releases that would require more than one permit under this chapter, chapter 18B or 18C.

Sec. 8. [18F.13] EXEMPTIONS.

(a) The commissioner may provide exemptions to the requirements to prepare an environmental assessment worksheet and obtain a permit for release of genetically engineered agriculturally related organisms for which substantial evidence, including past releases, has shown that the organism can be released without adverse effects on humans and the environment.

(b) The commissioner may provide exemptions from the requirements to prepare an environmental assessment worksheet and obtain a permit for release of genetically engineered agriculturally related organisms for which substantial evidence, including past releases, has shown that the organism can be released under alternative oversight without adverse effects to humans and the environment.

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Sec. 9. Minnesota Statutes 1992, section 116C.91, subdivision 1, is amended to read:

Subdivision 1. **SCOPE.** As used in sections 116C.91 to ~~116C.95~~ 116C.98, the terms defined in this section have the meanings given them.

Sec. 10. Minnesota Statutes 1992, section 116C.94, is amended to read:

116C.94 RULES.

(a) Subdivision 1. GENERAL AUTHORITY. The board shall adopt rules consistent with sections 116C.91 to 116C.96 that require an environmental assessment worksheet and otherwise comply with chapter 116D and rules adopted under it for a proposed release and a permit for a release. The board may place conditions on a permit and may deny, modify, suspend, or revoke a permit.

(b) Subd. 2. SIGNIFICANT ENVIRONMENTAL PERMIT. The rules shall provide that a permit from the board is not required if the proposer can demonstrate to the board that a significant environmental permit is required for the proposal by another state agency the board shall authorize an agency with a significant environmental permit to administer the regulatory oversight for the release of certain genetically engineered organisms.

(c) A person proposing a release for which a federal permit is required may apply to the board for an exemption from the board's permit or to an agency with a significant environmental permit for the proposed release for an exemption from the agency's permit. The proposer must file with the board or agency, within 14 days of filing a federal application, a written request for exemption with a copy of the federal application and the information necessary to determine if there is a potential for significant environmental effects under chapter 116D and rules adopted under it. The board or agency shall give public notice of the request in the first available issue of the EQB Monitor and shall provide an opportunity for public comment on the environmental review process consistent with chapter 116D and rules adopted under it. The board or agency may grant the exemption if the board or agency finds that the federal permit issued is in compliance with the requirements of chapter 116D and rules adopted under it and any other requirement of the board's or agency's authority regarding the release of genetically engineered organisms. The board or agency must grant or deny the exemption within 45 days after the receipt of the federal permit.

(d) Subd. 3. COMMERCIALIZATION. The board may adopt rules providing exemptions to the requirements to prepare an environmental assessment worksheet and obtain a permit for releases of genetically engineered organisms for which substantial evidence from past releases has shown to the board's satisfaction that the organism can be released without jeopardizing public health or the environment.

(e) Subd. 4. ALTERNATIVE REGULATORY OVERSIGHT. The board may adopt rules providing alternative regulatory oversight to the requirements to prepare an environmental assessment worksheet and obtain a permit for

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releases of genetically engineered organisms for which substantial evidence from past experience, including releases and laboratory data, has shown to the board's satisfaction that the alternative oversight will protect public health and the environment.

(f) Subd. 5. RULES; FEDERAL OVERSIGHT. The board may adopt rules to implement the authorities granted to it in section 116C.97, subdivision 2.

(g) Subd. 6. CONSULTATION. The board shall consult with local units of government and with private citizens before adopting any rules.

Sec. 11. Minnesota Statutes 1992, section 116C.96, is amended to read:

116C.96 COST REIMBURSEMENT.

The board shall assess the proposer of a release for the necessary and reasonable costs of processing exemptions from a release permit under rules authorized by sections 116C.94, subdivisions 1, 3, and 4, and 116C.97, subdivision 2, paragraph (c), or applications for a release permit. An estimated budget shall be prepared for each exemption or application by the chair of the board. The proposer must remit 25 percent of the estimated budget within 14 days of the receipt of the estimated budget from the chair. The unpaid balance shall be billed in periodic installments, due upon receipt of an invoice from the chair. Costs in excess of the estimated budget must be certified by the board and upon certification constitute prima facie evidence that the expenses are reasonable and necessary and shall be charged to the proposer. The proposer may review all actual costs and present objections to the board, which may modify the cost or determine that the cost assessed is reasonable. The assessment paid by the proposer shall not exceed the sum of the costs incurred. All money received under this section shall be deposited in the special account established under section 116D.045, subdivision 3, for the purpose of paying costs incurred in processing exemptions and applications.

Sec. 12. [116C.97] EXEMPTIONS.

Subdivision 1. HUMAN GENE THERAPY. The requirements of sections 116C.91 to 116C.96 and of the rules of the board adopted pursuant to section 116C.94 do not apply to genetic engineering of human germ cells and human somatic cells intended for use in human gene therapy.

Subd. 2. FEDERAL OVERSIGHT. (a) If the board determines, upon its own volition or at the request of any person, that a federal program exists for regulating the release of certain genetically engineered organisms and the federal oversight under the program is adequate to protect human health or the environment, then any person may release such genetically engineered organisms after obtaining the necessary federal approval and without obtaining a state release permit or a significant environmental permit or complying with the other requirements of sections 116C.91 to 116C.96 and the rules of the board adopted pursuant to section 116C.94.

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(b) If the board determines the federal program is adequate to meet only certain requirements of sections 116C.91 to 116C.96 and the rules of the board adopted pursuant to section 116C.94, the board may exempt such releases from those requirements.

(c) A person proposing a release for which a federal authorization is required may apply to the board for an exemption from the board's permit or to a state agency with a significant environmental permit for the proposed release for an exemption from the agency's permit. The proposer must file with the board or state agency a written request for exemption with a copy of the federal application and the information necessary to determine if there is a potential for significant environmental effects under chapter 116D and rules adopted under it. The board or state agency shall give public notice of the request in the first available issue of the EQB Monitor and shall provide an opportunity for public comment on the environmental review process consistent with chapter 116D and rules adopted under it. The board or state agency may grant the exemption if the board or state agency finds that the federal authorization issued is adequate to meet the requirements of chapter 116D and rules adopted under it and any other requirement of the board's or state agency's authority regarding the release of genetically engineered organisms. The board or state agency must grant or deny the exemption within 45 days after the receipt of the written request and the information required by the board or state agency.

Sec. 13. [116C.98] NOTIFICATION FOR THE RELEASE OF CERTAIN GENETICALLY ENGINEERED PLANTS.

Subdivision 1. GENERAL. Certain genetically engineered plants may be released without the regulatory oversight under section 116C.94, provided that the release is in compliance with the requirements of this section. Any other release of genetically engineered organisms requires regulatory oversight under section 116C.94 unless it is exempt under section 116C.97.

Subd. 2. GENETICALLY ENGINEERED PLANTS ELIGIBLE FOR USE UNDER THE NOTIFICATION PROCEDURE. (a) Genetically engineered plants which meet the eligibility criteria of paragraphs (b) to (g) and whose release meets the performance standards in subdivision 3 are eligible for release under the notification procedure of subdivision 4.

(b) The genetically engineered plant is:

(1) one of the following species: corn (*Zea mays* L.), cotton (*Gossypium hirsutum* L.), potato (*Solanum tuberosum* L.), soybean (*Glycine max* (L.) Merr.), tobacco (*Nicotiana tabacum* L.), or tomato (*Lycopersicon esculentum* L.); or

(2) any additional plant species that the commissioner of agriculture, after public notice and after complying with chapter 116D and the rules adopted under it, has determined may be safely used in accordance with the organism eligibility criteria set forth in paragraphs (c) to (g) and the release performance standards set forth in subdivision 3.

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(c) The genetically engineered material is stably integrated in the plant genome.

(d) The function of the genetically engineered material is known and its expression in the genetically engineered organism does not result in plant disease.

(e) The genetically engineered material does not:

(1) cause the production of an infectious entity;

(2) encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species; or

(3) encode products intended for pharmaceutical use.

(f) The genetically engineered sequences must be:

(1) noncoding regulatory sequences of known function;

(2) sense or antisense genetic constructs derived from viral coat protein genes from plant viruses that are prevalent and endemic in the area where the use will occur and that infect plants of the same host species; or

(3) antisense genetic constructs derived from noncapsid viral genes from plant viruses that are prevalent and endemic in the area where the use will occur and that infect plants of the same host species.

(g) The plant has not been modified to contain the following genetic material from animal or human pathogens:

(1) any nucleic acid sequence derived from an animal or human virus; or

(2) coding sequences whose products are known or likely causal agents of disease in animals or humans.

Subd. 3. PERFORMANCE STANDARDS FOR RELEASES UNDER THE NOTIFICATION PROCEDURE. (a) The performance standards in this subdivision must be met for any releases under the notification procedure.

(b) If the genetically engineered plants or plant materials are shipped, they must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment.

(c) The genetically engineered plants must be planted in such a way that they are not inadvertently mixed with nonregulated plant materials of any species which are not part of the release.

(d) The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use.

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(e) There must be a viable vector agent associated with the genetically engineered plants.

(f) The field trial must be conducted such that:

(1) the genetically engineered plants will not persist in the environment; and

(2) no offspring can be produced that could persist in the environment.

(g) Upon termination of the field test:

(1) no viable material shall remain which is likely to volunteer in subsequent seasons; or

(2) plant volunteers shall be managed to prevent persistence in the environment.

Subd. 4. NOTIFICATION PROCEDURE. (a) Notification shall be directed to the commissioner of agriculture.

(b) The notification shall include the following:

(1) name, title, address, telephone number, and signature of the responsible person;

(2) information necessary to identify the genetically engineered plant or plants, including:

(i) the scientific, common, or trade names, and phenotype of the genetically engineered plant;

(ii) the designations for the genetic loci, the encoded proteins or functions, and donor organisms for all genes from which used genetic material was derived; and

(iii) the method by which the recipient was transformed;

(3) the names and locations of the origination and destination facilities for movement or the field site location for the environmental release, and the size of the use;

(4) the expected date of release and the expected duration of the release; and

(5) a statement that certifies that use of the genetically engineered organism will be in accordance with the provisions of this section.

(c) Notification must be submitted at least 30 days prior to the day of use.

(d) Release reports may be required by the commissioner of agriculture. Release reports shall include:

(1) the release identification number;

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(2) methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment; and

(3) any other available information requested by the commissioner of agriculture or the chair of the board regarding the impact of the genetically engineered organism on human health or the environment.

(c) The commissioner of agriculture shall be notified of any unexpected occurrences relating to the release.

(f) Access shall be allowed for state regulatory officials to inspect facilities or the field test site, or both, and any records necessary to evaluate compliance with the provisions of subdivisions 2 and 3.

Subd. 5. ADMINISTRATIVE ACTION IN RESPONSE TO NOTIFICATION. (a) The commissioner of agriculture shall publish notice of the proposed release at the earliest opportunity in the EQB Monitor and shall mail notice to the chief executive of the county within which the release will take place.

(b) The commissioner of agriculture shall grant or deny permission to release the noticed genetically engineered plant within 30 days of the receipt of the notification.

(c) A person denied permission for use of a genetically engineered plant under notification may apply for a permit for use of that genetically engineered plant without prejudice.

(d) The commissioner of agriculture shall notify the chair of the board of any unexpected occurrences relating to the release.

Subd. 6. REPEALER. When the commissioner of agriculture adopts rules under section 8, paragraph (b), this section is repealed.

Sec. 14. REPEALER.

Minnesota Statutes 1992, section 18F.02, subdivision 7, is repealed.

Sec. 15. EFFECTIVE DATE.

This act is effective the day following final enactment.

Presented to the governor April 14, 1994

Signed by the governor April 18, 1994, 3:07 p.m.

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