

## CHAPTER 18F

### GENETICALLY ENGINEERED ORGANISMS

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#### 18F.01 PURPOSE.

The purpose of sections 18F.01 to 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.

**History:** 1991 c 250 s 1; 1994 c 454 s 1

#### 18F.02 DEFINITIONS.

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

Subd. 2. **Agency.** "Agency" means the Department of Agriculture.

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 18G.02, subdivision 17; 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.

Subd. 3. **Commissioner.** "Commissioner" means the commissioner of agriculture or an agent authorized by the commissioner.

Subd. 4. **Genetic engineering.** "Genetic engineering" means the introduction of new genetic material to an organism or the regrouping of an organism's genes using techniques or technology designed by humans. This does not include selective breeding, hybridization, or nondirected mutagenesis.

Subd. 5. **Genetically engineered organism.** "Genetically engineered organism" means an organism that has been modified directly or indirectly using genetic engineering.

Subd. 6. **Organism.** "Organism" means an animal, plant, bacterium, cyanobacterium, fungus, protist, or virus.

Subd. 7. [Repealed, 1994 c 454 s 14]

Subd. 8. **Release.** "Release" means the placement or use of a genetically engineered organism outside a contained laboratory, greenhouse, building, structure, or other similar facility or under other conditions not specifically determined by the commissioner to be adequately contained.

Subd. 9. **Unreasonable adverse effects on the environment.** "Unreasonable adverse effects on the environment" means an unreasonable risk to humans or the environment, taking into account the environmental costs and benefits of the use of a genetically engineered organism.

**History:** 1991 c 250 s 2; 1994 c 454 s 2-4; 2004 c 228 art 1 s 12

#### **18F.04 POWERS AND DUTIES OF COMMISSIONER.**

The commissioner shall administer, implement, and enforce sections 18F.01 to 18F.13. The Board of Animal Health shall be consulted on permits that relate to livestock and domestic animals.

**History:** 1991 c 250 s 3; 1994 c 454 s 5

#### **18F.07 GENETICALLY ENGINEERED AGRICULTURALLY RELATED ORGANISM PERMIT.**

Subdivision 1. **Requirement.** A person may not conduct a release of a genetically engineered agriculturally related organism until a permit for the release has been obtained from the commissioner. Each release of a genetically engineered agriculturally related organism requires a new permit until the commissioner determines by rule that the 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 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 agriculturally related organism permit, the amount or number of genetically engineered 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 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 agriculturally related organism permit if the commissioner determines that the use to be made of the 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 genetically engineered 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 agriculturally related organism;
- (4) the name, address, and telephone number of cooperators or participants in this state;
- (5) the amount 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 agriculturally related organism must be accompanied by a nonrefundable application fee of \$125.

**History:** 1991 c 250 s 4; 1994 c 454 s 6

#### **18F.12 RULES.**

The commissioner shall adopt rules governing the issuance of permits for proposed releases of genetically engineered 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.

**History:** 1991 c 250 s 5; 1994 c 454 s 7

#### **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.

**History:** 1994 c 454 s 8