

1558.0060 NOTIFICATION PROCEDURES FOR CERTAIN GENETICALLY ENGINEERED PLANTS.

Subpart 1. **Genetically engineered plants eligible for release under the notification procedure.** In accordance with Minnesota Statutes, section 116C.98, genetically engineered plants that meet the eligibility criteria of items A to F and whose release meets the performance standards in subpart 2 are eligible for release under the notification procedure of subpart 3.

A. 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) additional plant species that the commissioner, after public notice and after complying with Minnesota Statutes, chapter 18F, and the rules adopted under it, has determined may be safely used in accordance with the organism eligibility criteria in items B to F and the release performance standards in subpart 2. Supplemental notice of Federal Register items announcing changes in the list of plant species must be published in the EQB Monitor and sent to the Minnesota Department of Agriculture GEO mailing list. The Minnesota Department of Agriculture shall accept comments during the federal comment period.

B. The genetically engineered material is stably integrated into the plant genome.

C. The function of the genetically engineered material is known and its expression in the genetically engineered organism does not result in disease.

D. 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.

E. To ensure that the introduced genetic sequences do not pose a significant risk of the creation of any new plant viruses they 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.

F. 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.

Subp. 2. Performance standards for release under the notification procedure.

A. The performance standards in this subpart 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 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 the material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use.

E. There must be no viable vector agent associated with the genetically engineered plants.

F. The field trial must be conducted so 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 may remain which is likely to volunteer in subsequent seasons; or

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

Subp. 3. **Notification procedure.** Notification must be directed to the commissioner, including the following:

A. the name, title, address, telephone number, and signature of the responsible person;

B. information necessary to identify the genetically engineered plant or plants, including:

(1) the scientific, common, or trade name and the phenotype of the genetically engineered plant;

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

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

C. 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;

D. the expected date of release and the expected duration of the release; and

E. a statement that certifies that the use of the genetically engineered organism will comply with this chapter.

Subp. 4. **Federal notification as application.** A copy of the federal notification information including all confidential business information necessary to determine that the guidelines are met by the applicant as well as complete site identification may be used as the application.

Subp. 5. **Notification before release.** Notification must be submitted at least 30 days before the day of use.

Subp. 6. **Release reports.** Release reports, if required by the commissioner, must include:

A. the release number;

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

C. any other available information requested by the commissioner regarding the impact of the genetically engineered organism on human health or the environment.

Subp. 7. **Unexpected occurrences.** The commissioner must be notified of any unexpected occurrences relating to the release within 48 hours.

Subp. 8. **Access.** Access must 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 subparts 1 to 6. Access of regulatory officials from state agencies other than the Department of Agriculture must be coordinated through the department.

Subp. 9. Administrative action in response to notification.

A. The commissioner shall publish notice of the proposed release at the earliest opportunity in the EQB Monitor and shall mail notice to the chair of the county board of the county and the tribal council of any reservation within which the release will take place.

B. The commissioner 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 release of that genetically engineered plant without prejudice.

D. The commissioner shall notify the chair of the Environmental Quality Board of any unexpected occurrences relating to the release.

E. The commissioner has the right to rescind any notifications if there is evidence of unreasonable adverse effects on human health or the environment.

Statutory Authority: *MS s 18F.12*

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