

1558.0040 RELEASE PERMIT PROCEDURES.

Subpart 1. **Procedure and application.** Release permits, including EAWs prepared by the commissioner, are required from the commissioner for all releases of GEOs except those exempted under subpart 13, or those regulated under part 1558.0060, 1558.0070, or 1558.0080. The commissioner shall provide application forms.

A. Applications for release permits for GEOs must be submitted to the commissioner and must contain:

- (1) name, title, address, telephone number, and signature of the responsible person;
- (2) name, address, and telephone number of cooperators or participants in the state;
- (3) origin, destination, name of responsible person, and containment procedures for movement and storage of GEOs;
- (4) the amount or number of organisms, material, cultures, or seeds to be shipped or used in this state;
- (5) the expected date of release and the expected duration of the release;
- (6) a statement certifying that the use of the genetically engineered organism will be in accordance with this chapter;
- (7) all information required for an EAW, as given in part 1558.0050;
- (8) supporting documentation, including research information and any United States Environmental Protection Agency, USDA, or other federal agency regulatory application or approval document, if requested to verify or substantiate information given in the permit application or respond to public comments; and
- (9) any information needed for an experimental use permit under Minnesota Statutes, chapter 18B.

B. During the permit process, the commissioner may request additional information necessary to determine the potential for adverse effects on human health or the environment of the proposed release.

Subp. 2. **Application submission.** An application must be accepted or rejected by the commissioner within 14 days of its receipt. The commissioner may reject an application if the regulation of the genetically engineered organism is not authorized under Minnesota Statutes, chapter 18B, 18C, or 18F, or if the application does not contain all the required information.

If the commissioner rejects an application, the applicant must be informed in writing of the deficiencies that exist and requirements that, if corrected, will allow acceptance

of the application. The applicant may submit the additional information or withdraw the application. Acceptance of the application does not constitute issuance of the permit.

Subp. 3. **Application distribution.** Within 14 days of the application acceptance, a copy of the application with not public data deleted, including the EAW prepared by the Minnesota Department of Agriculture, must be distributed to: the chair of the EQB, the Legislative Reference Library, local government units within whose boundaries the release is proposed, and any other person upon request to the commissioner. Those persons shall be added to the mailing list maintained by the commissioner of persons interested in receiving information on the release of GEOs. EAWs must be distributed according to the EQB distribution list. Not public data is available for review by any state agency according to provisions of Minnesota Statutes, section 13.05, subdivision 9, of the Minnesota Government Data Practices Act.

Subp. 4. **Application review.** The application must be reviewed using an interdisciplinary approach that will ensure the integrated use of the natural and environmental sciences, including involvement of the following disciplines as appropriate: microbiology, ecology, public health, biological safety, agronomy, animal science, plant biology, risk assessment, molecular biology, biochemistry, entomology, vertebrate biology, physical and biological containment, and other appropriate disciplines. Application review must address the considerations in part 1558.0030, including federal documents, and evidence from laboratory studies and previous releases. After reviewing a completed release permit application including the EAW and comments from reviewers, the commissioner may issue a release permit for GEOs if the commissioner determines that the applicant has adequately demonstrated that the proposed release does not have the potential for unreasonable adverse effects on human health or the environment. The commissioner may deny issuance of a GEO release permit if the release of the GEO under proposed terms and conditions of the release permit may cause unreasonable adverse effects on human health or the environment.

The Board of Animal Health must be consulted during the review on permits that relate to livestock and domestic animals.

Subp. 5. [Repealed, 27 SR 1820]

Subp. 6. **Permit conditions.** The commissioner may prescribe terms and conditions such as the period for the GEO release permit, the amount or number of GEOs to be released, monitoring activities, department inspection schedules, reporting of experimental results, and experiment termination procedures. The commissioner may impose additional reasonable and appropriate release permit conditions to mitigate or minimize the adverse effects of the release on human health or the environment.

Subp. 7. **Violation of the permit.** A person shall not violate terms or conditions of a permit issued under this section. The commissioner may modify, suspend, or revoke

the release 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 human health or the environment pursuant to Minnesota Statutes, section 18F.07, subdivision 2. If adverse effects are observed, the permit will be suspended. If adverse effects can be mitigated by modification of the conditions for release, the permit may be reinstated. Revocation shall result in termination and disposal of all GEOs if the commissioner determines that the GEOs pose a significant environmental risk. Minnesota Statutes, section 18D.301, subdivision 1, authorizes procedures and penalties as outlined in Minnesota Statutes, chapter 18D, to be applied to violations of Minnesota Statutes, chapter 18B, 18C, or 18F.

Subp. 8. **Adverse effects.** It is the responsibility of the applicant to notify the commissioner of any unexpected occurrences or adverse effects within 48 hours.

Subp. 9. **Application fee.** An application for a release permit for a GEO must be accompanied by a nonrefundable application fee of \$125 in accordance with Minnesota Statutes, section 18F.07, subdivision 4, or \$150 if an experimental use permit is required under Minnesota Statutes, section 18B.28, subdivision 4.

Subp. 10. **Permit renewal.** Releases that are substantially the same as a previous release may be eligible for a permit renewal. The applicant must submit a written permit renewal request to the commissioner at least 30 days before release of the GEO. A request may be denied based on evidence of unreasonable adverse effects on human health or the environment.

Subp. 11. **Release reports.** Release reports are required by the commissioner for all releases. Release reports must include:

- A. the release permit identification number; and
- B. methods of observation, resulting data, and analysis or observations of adverse effects on human health or the environment.

Subp. 12. **Access.** Access to the release site 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 this chapter. Records must be kept for three years. Access of regulatory officials from state agencies other than the Department of Agriculture must be coordinated through the Department of Agriculture.

Subp. 13. **Partial or complete exemptions.** Partial or complete exemptions from the permit procedures may be given by the commissioner based on the considerations in part 1558.0030 and adequacy of alternative oversight as it relates to those considerations.

A. The applicant may file a written request to the commissioner for the exemption of an individual release or for a class of releases. The request must include a copy of the federal application or documentation and the information necessary to determine if there is a potential for adverse effects on humans or the environment. The determination must be

based on the considerations in part 1558.0030 and the adequacy of alternative oversight as it relates to those considerations. The commissioner shall make a determination within 30 days of the receipt of the exemption request and documentation. Class exemptions may be initiated by the commissioner.

B. There will be public notice of the request in the first available EQB Monitor and a 30-day public comment period for class exemptions. The determination must be based on the considerations in part 1558.0030, the adequacy of alternative oversight as it relates to those considerations, and review of comments.

Statutory Authority: *MS s 18F.12*

History: *20 SR 1037; 27 SR 1820*

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