

CHAPTER 1558
DEPARTMENT OF AGRICULTURE
GENETICALLY ENGINEERED ORGANISMS

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1558.0010 SCOPE.

Subpart 1. **Regulatory authority.** The Minnesota Department of Agriculture is authorized to regulate the release of agriculturally related genetically engineered organisms in Minnesota. The requirement for environmental review is subject to Minnesota Statutes, chapter 116D, and rules adopted under it. The categories of releases are as follows: releases requiring permits, notifications, and commercial use.

Subp. 2. **Releases requiring permits.** All releases of agriculturally related genetically engineered organisms, pesticides, fertilizers, soil amendments, or plant amendments, that do not fall under the notification process or that have not been exempted for commercial use, require a release permit. The procedure for filing a release permit application is outlined in part 1558.0040.

Subp. 3. **Notification.** Corn, soybeans, cotton, tobacco, tomato, potato, and any other plants designated by the commissioner under part 1558.0060, subpart 1, may follow the notification procedure in part 1558.0060, provided that they meet all the eligibility criteria in part 1558.0060, subpart 1, and the performance standards in part 1558.0060, subpart 2.

Subp. 4. **Commercial use exemption.** Agriculturally related genetically engineered organisms, pesticides, fertilizers, soil amendments, or plant amendments that have passed the USDA procedure for delisting by petition, or similar procedures of the USDA or other federal regulatory agencies, may be considered for a commercial use exemption in Minnesota if they meet the guidelines and procedures in part 1558.0070.

Statutory Authority: *MS s 18F.12*

History: *20 SR 1037*

1558.0020 DEFINITIONS.

Subpart 1. **Scope.** The definitions in this part apply to this chapter.

Subp. 2. **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 detailed in Minnesota Statutes, 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.

Subp. 3. **Applicant.** "Applicant" means a person who files an application with the commissioner for a release permit, notification, or exemption for an agriculturally related genetically engineered organism.

Subp. 4. **Application.** "Application" means the document filed by the person or persons with the commissioner for a release permit, notification, or exemption for an agriculturally related genetically engineered organism.

Subp. 5. **Commissioner.** "Commissioner" means the commissioner of agriculture or an agent authorized by the commissioner.

Subp. 6. **Containment facility.** "Containment facility" means a laboratory, greenhouse, building, structure, or other similar facility that complies with the most recent applicable National Institute of Health Guidelines for Research Involving Recombinant DNA Molecules which is incorporated by reference and published in the Federal Register or is certified by the USDA Animal and Plant Health Inspection Service as a containment facility. Such facilities must also be certified under part 1558.0080, subpart 1, or has been exempted by the commissioner under part 1558.0080, subpart 2.

Subp. 7. **Environment.** "Environment" means the physical conditions existing in the area that may be affected by a proposed release. It includes land, air, water, minerals, flora, fauna, ambient noise, energy resources, and artifacts or natural features of historic, geologic, or aesthetic significance.

Subp. 8. **Environmental assessment worksheet; EAW.** "Environmental assessment worksheet" or "EAW" means a document complying with part 4410.0200, subpart 24.

Subp. 9. **Environmental impact statement; EIS.** "Environmental impact statement" or "EIS" has the meaning given in part 4410.0200, subpart 26.

Subp. 10. **Environmental Quality Board; EQB.** "Environmental Quality Board" or "EQB" means the Minnesota Environmental Quality Board.

Subp. 11. **Federal application.** "Federal application" means an application, notification, or petition and supporting documents submitted to any agency of the United States government for the release of a genetically engineered organism.

Subp. 12. **Genetic engineering.** "Genetic engineering" means the introduction of new genetic material into an organism or the regrouping of an organism's genes using techniques or technology designed by humans or any progeny containing the new genetic material or regrouping. This does not include selective breeding, hybridization, or nondirected mutagenesis.

Subp. 13. **Genetically engineered organism; GEO.** "Genetically engineered organism" or "GEO" means an agriculturally related organism that has been modified directly or indirectly using genetic engineering, as defined in Minnesota Statutes, section 18F.02, subdivision 5, experimental genetically engineered pesticides, as defined in Minnesota Statutes, section 18B.01, subdivision 10b, genetically engineered fertilizer as defined in Minnesota Statutes, section 18C.005, subdivision 12b, genetically engineered plant amendments, as defined in Minnesota Statutes, section 18C.005, subdivision 12c, or genetically engineered soil amendments, as defined in Minnesota Statutes, section 18C.005, subdivision 12d.

Subp. 14. **Organism.** "Organism" means an animal, plant, bacterium, cyanobacterium, fungus, protist, or virus.

Subp. 15. **Release.** "Release" means the placement or use of a GEO outside a containment facility or under any other conditions not specifically determined by the commissioner to be adequate containment pursuant to part 1558.0080, subpart 1 or 2.

Subp. 16. **Release permit.** "Release permit" means the terms, conditions, and authorization by the commissioner under this chapter for the release of a genetically engineered organism.

Subp. 17. **Responsible person.** "Responsible person" means a person who has custody of, control of, or responsibility for an agriculturally related genetically engineered organism.

Subp. 18. **Unreasonable adverse effects.** "Unreasonable adverse effects" 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.

Subp. 19. **USDA.** "USDA" means the United States Department of Agriculture.

Statutory Authority: *MS s 18F.12*

History: *20 SR 1037*

1558.0030 CONSIDERATIONS.

Subpart 1. **Considerations.** In determining whether a release permit, notification, or exemption for commercial use should be issued, denied, modified, suspended, or revoked, and in specifying or modifying conditions of release, the commissioner must consider the following:

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A. the familiarity and predictability of the ecologically relevant biological properties of the introduced DNA, the vector if one exists, the recipient, and the engineered organisms;

B. the history of previous environmental releases, evidence from laboratory studies, or other uses of the genetically engineered organisms;

C. the potential for the genetically engineered organism to cause any adverse effects on humans or the environment, such as:

(1) whether the organism is native, currently found in the area, or nonnative to the release area;

(2) whether the genetically engineered organism is pathogenic to target or nontarget organisms and to what extent this trait has been changed from the nontransgenic parents;

(3) the extent of the changes to the genetically engineered organism's competitiveness and survivability under normal and environmentally stressful conditions, such as resource base, dormancy, temperature tolerance, fire resistance, drought resistance, or ability to disperse in the environment, that have been made as a result of the genetic engineering;

(4) the potential for the genetically engineered organisms' genes to transfer to other organisms and the resultant effects on other organisms' competitiveness, dispersal, dormancy, pathogenicity or toxicity, fertility, expansion of their resource base or range, and any other fitness characteristics; and

(5) the potential of the genetically engineered organism to affect adversely the groundwater environment or to pass transgenes to organisms found in groundwater;

D. the adequacy of and appropriateness of the measures, if any are needed, for confinement of the genetically engineered organism;

E. any previous risk assessments for the same or similar organisms prepared by federal or state agencies and their adequacy and relevance to the current proposal, such as consideration of the following:

(1) the environmental conditions that existed in previous releases and their relationship to the proposed use;

(2) whether the genetically engineered organisms failed to demonstrate an ability to be self-reproducing or competitive because of transient factors; and

(3) whether the scale of the assessment was adequate to assess potential for establishing a self-reproducing population;

F. the conclusions reached and conditions imposed by federal agencies with jurisdiction over the proposed release;

G. the conclusions reached or conditions imposed by federal or state agencies on previous releases in Minnesota or elsewhere and their adequacy and relevance to the current proposal;

H. the type, extent, and reversibility of adverse environmental effects;

I. the cumulative potential effects of related or anticipated future projects; and

J. the extent to which the environmental effects are subject to mitigation by ongoing public regulatory authority.

Subp. 2. **Federal documents.** Relevant federal documents may be used to address some or all of the considerations in subpart 1.

Statutory Authority: *MS s 18F.12*

History: *20 SR 1037*

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. **Data privacy.** Information submitted as part of the permit application, which meets one of the definitions in Minnesota Statutes, section 13.37, subdivision 1, paragraph (a) or (b), of the Minnesota Government Data Practices Act, may be designated as such in the application by clearly and conspicuously marking it as "security information" or "trade secret information." Information that is submitted and marked "confidential business information" must be considered not public data under the federal Freedom of Information Act, United States Code, title 5, section 552, as amended, and Minnesota Statutes, section 13.03, subdivision 4. This information may be provided to interdisciplinary reviewers if they sign a nondisclosure agreement and they do not represent in any capacity any business or enterprise engaged in competition with the applicant.

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*

1558.0050 ENVIRONMENTAL ASSESSMENT WORKSHEETS.

Subpart 1. Reason for EAWs. EAWs are prepared by the Minnesota Department of Agriculture as part of the release permit application in part 1558.0040. EAWs are designed to look at environmental effects associated with a proposed release. The EAW findings are used to determine if an EIS is needed, if the permit should be granted, and if any permit conditions are needed to mitigate or lower risks that have been identified by the EAW. The EAW must be written in plain and objective language and include a clear presentation of the proposed release and issues of concern. Information for EAWs must be submitted by the applicant on forms provided by the department as part of the permit application. The EAW, which is prepared by the department using information from the applicant and other sources, is intended to be a summary of the considerations in part 1558.0030 as they relate to the proposed release; however, supporting documents must be referenced and available upon request.

Subp. 2. EAW considerations. The applicant for a release permit must provide information addressing the considerations in part 1558.0030, subpart 1, so that a draft EAW can be prepared for any proposed release requiring an EAW. Federal documents may be used to address the considerations.

Subp. 3. EAW review. The EAW 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. The notice of availability of the EAW and a 30-day public comment period must be published in the first available EQB Monitor.

Subp. 4. EAW findings. The commissioner shall issue findings of fact based on the EAW. The findings must determine if there is a potential for significant environmental effects. If there is a potential for significant environmental effects, an EIS must be prepared, and no permit may be issued until after preparation of an EIS. If there is a finding of no potential for significant environmental effects, and the commissioner chooses to decide on the permit application at this stage, the commissioner must base the decision to grant or deny the permit or impose conditions on granting a permit on the findings made under this part.

Subp. 5. EIS preparation and review. An EIS, if required, must be written and reviewed under the procedures in parts 4410.2000 to 4410.2300.

Statutory Authority: *MS s 18F.12*

History: *20 SR 1037*

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:

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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*

History: *20 SR 1037*

1558.0070 COMMERCIAL USE EXEMPTION.

Subpart 1. Commercial use. Any GEO that has passed the USDA procedure for delisting by petition, or similar procedures of the USDA or other federal regulatory agencies, may be considered for a commercial use exemption. Releases where the primary goal is experimental or developmental do not fall in this category.

Subp. 2. **Procedures.** Granting of exemptions must be based on federal delisting or deregulation, experience from past releases, and the considerations in part 1558.0030, subpart 1. GEOs that have a commercial use exemption need not obtain a release permit.

A. An applicant must submit any federal documents needed to address the considerations in part 1558.0030, subpart 1.

B. Supplemental notice of Federal Register items regarding delisting or deregulation of agriculturally related GEOs 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. Notice of the exemption of GEOs to allow for commercial use must be published in the EQB Monitor at least 30 days prior to commercial use.

C. The commissioner may require additional use conditions or marketing limits to mitigate or lower risk for adverse effects on humans or the environment resulting from commercial use of a GEO.

D. The commissioner may allow an exemption from item A, B, or C for commercial use of individual GEOs or classes of GEOs based on a history of past releases. There will be public notice in the first available EQB Monitor for individual exemptions. For class exemptions there must be a 30-day public comment period.

E. The commissioner may reject an application for a GEO commercial use exemption based on adverse effects on humans or the environment.

F. The commissioner may modify, suspend, or revoke the commercial use exemption should any evidence of unreasonable adverse effects on human health or the environment be observed.

Statutory Authority: *MS s 18F.12*

History: *20 SR 1037*

1558.0080 USES NOT REQUIRING A RELEASE PERMIT, NOTIFICATION, OR COMMERCIAL USE EXEMPTION.

Subpart 1. **Containment facility.** The use of a GEO in a containment facility is not a release and does not require a release permit. A containment facility must meet applicable guidelines of the National Institute of Health Guidelines for Research Involving Genetically Engineered Organisms or USDA Animal and Plant Health Inspection Service Standard and Supplemental Conditions for Containment of Plant Pests Under Permit as certified by the commissioner. The commissioner retains the right to inspect facilities to ensure compliance.

Subp. 2. **Facility exemption.** The use of a GEO in a facility that does not meet the requirements of a containment facility, but has been found by the commissioner to provide adequate containment, to prevent unreasonable risk of release into the environment for the specific use proposed, is not a release and does not require a release permit. The commissioner retains the right to inspect facilities to ensure compliance.

Subp. 3. **Movement of GEOs.** GEOs must be moved in such a way that the viable organism is unlikely to be disseminated in transit and it must be maintained at the destination facility in such a way that there is no release into the environment. All GEOs must be clearly labeled. Movement of GEOs does not require a permit but must comply with items A and B.

A. Interstate movement of GEOs is governed by the most recent NIH shipment guidelines, which are incorporated by reference and published in the Federal Register, with state concurrence. The commissioner retains the right to inspect facilities to ensure compliance or otherwise modify the movement permit issued by the federal agency to ensure proper containment.

B. Intrastate movement of GEOs requires notification to the commissioner of the intent to move the GEOs and adherence to NIH shipment guidelines. The commissioner retains the right to inspect facilities to ensure compliance or otherwise modify the movement permit to ensure proper containment.

Statutory Authority: *MS s 18F.12*

History: *20 SR 1037*

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Multiple permits are not required under this chapter. The commissioner shall review permit requirements concurrently if more than one permit is required from the commissioner under this chapter or Minnesota Statutes, chapter 18B, 18C, or 18F. GEOs requiring a permit under Minnesota Statutes, chapter 18F, are exempt from obtaining a permit under Minnesota Statutes, chapter 18B or 18C, but are not exempt from the requirements of those permits if they are different than Minnesota Statutes, chapter 18F. The additional information must be submitted with the application for a release permit, notification, or exemption under Minnesota Statutes, chapter 18F. Only one permitting fee may be charged under this chapter.

Statutory Authority: *MS s 18F.12*

History: *20 SR 1037*