

1 Department of Agriculture

2

3 Adopted Permanent Rules Relating to the Release of Genetically
4 Engineered Agriculturally Related Organisms

5

6 Rules as Adopted

7 1558.0010 SCOPE.

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

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

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

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

35 1558.0020 DEFINITIONS.

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

3 Subp. 2. Agriculturally related organism. "Agriculturally
4 related organism" means any organism that is used in
5 agricultural production or processing of agricultural products.
6 It includes livestock and livestock products; dairy animals and
7 dairy products; poultry and poultry products; domestic
8 fur-bearing animals; animal feeds; horticultural stock; nursery
9 stock, as detailed in Minnesota Statutes, section 18.46,
10 subdivision 3; ~~fruits~~ fruit; vegetables; forage; grain; wild
11 rice; seeds; bees; apiary products; and products for the control
12 or mitigation of noxious weeds. It excludes vaccines and drugs
13 for use in humans; genetic engineering of human germ cells and
14 human somatic cells intended for use in human gene therapy;
15 vaccines for use in livestock, dairy animals, poultry, domestic
16 fur-bearing animals, or private aquatic life; genetically
17 engineered wild animals; and forestry products.

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

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

26 Subp. 5. Commissioner. "Commissioner" means the
27 commissioner of agriculture or an agent authorized by the
28 commissioner.

29 Subp. 6. Containment facility. "Containment facility"
30 means a laboratory, greenhouse, building, structure, or other
31 similar facility that complies with the most recent applicable
32 National Institute of Health Guidelines for Research Involving
33 Recombinant DNA Molecules which is incorporated by reference and
34 published in the Federal Register or is certified by the USDA
35 Animal and Plant Health Inspection Service as a containment
36 facility. Such facilities must also be certified under part

1 1558.0080, subpart 2 1, or has been exempted by the commissioner
2 under part 1558.0080, subpart 3 2.

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

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

12 Subp. 8- 9. **Environmental impact statement; EIS.**
13 "Environmental impact statement" or "EIS" has the meaning given
14 in part 4410.0200, subpart 26.

15 Subp. 9- 10. **Environmental Quality Board; EQB.**
16 "Environmental Quality Board" or "EQB" means the Minnesota
17 Environmental Quality Board.

18 Subp. 10- 11. **Federal application.** "Federal application"
19 means an application, notification, or petition and supporting
20 documents submitted to any agency of the United States
21 government for the release of a genetically engineered organism.

22 Subp. 11- 12. **Genetic engineering.** "Genetic engineering"
23 means the introduction of new genetic material into an organism
24 or the regrouping of an organism's genes using techniques or
25 technology designed by humans or any progeny containing the new
26 genetic material or regrouping. This does not include selective
27 breeding, hybridization, or nondirected mutagenesis.

28 Subp. 12- 13. **Genetically engineered organism; GEO.**
29 "Genetically engineered organism" or "GEO" means an
30 agriculturally related organism that has been modified directly
31 or indirectly using genetic engineering, as defined in Minnesota
32 Statutes, section 18F.02, subdivision 5, experimental
33 genetically engineered pesticides, as defined in Minnesota
34 Statutes, section 18B.01, subdivision 10b, genetically
35 engineered fertilizer as defined in Minnesota Statutes, section
36 18C.005, subdivision 12b, genetically engineered plant

1 amendments, as defined in Minnesota Statutes, section 18C.005,
2 subdivision 12c, or genetically engineered soil amendments, as
3 defined in Minnesota Statutes, section 18C.005, subdivision 12d.

4 Subp. ~~13~~ 14. **Organism.** "Organism" means an animal,
5 plant, bacterium, cyanobacterium, fungus, protist, or virus.

6 Subp. ~~14~~ 15. **Release.** "Release" means the placement or
7 use of a GEO outside a containment facility or under any other
8 conditions not specifically determined by the commissioner to be
9 adequate containment pursuant to part 1558.0080, subpart 1 or 2.

10 Subp. ~~15~~ 16. **Release permit.** "Release permit" means the
11 terms, conditions, and authorization by the commissioner under
12 this chapter for the release of a genetically engineered
13 organism.

14 Subp. ~~16~~ 17. **Responsible person.** "Responsible person"
15 means a person who has custody of, control of, or responsibility
16 for an agriculturally related genetically engineered organism.

17 Subp. 18. **Unreasonable adverse effects.** "Unreasonable
18 adverse effects" means an unreasonable risk to humans or the
19 environment, taking into account the environmental costs and
20 benefits of the use of a genetically engineered organism.

21 Subp. ~~17~~ 19. **USDA.** "USDA" means the United States
22 Department of Agriculture.

23 1558.0030 CONSIDERATIONS.

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

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

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

1 C. the potential for the genetically engineered
2 organism to cause any adverse ~~environmental-effects,-including~~
3 ~~but-not-limited-to~~ effects on humans or the environment, such as:

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

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

10 (3) the extent of the changes to the genetically
11 engineered organism's competitiveness and survivability under
12 normal and environmentally stressful conditions ~~including,-but~~
13 ~~not-limited-to~~, such as resource base, dormancy, temperature
14 tolerance, fire resistance, drought resistance, or ability to
15 disperse in the environment, that have been made as a result of
16 the genetic engineering;

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

23 (5) the potential of the genetically engineered
24 organism to affect adversely ~~affect~~ the groundwater environment
25 or to pass ~~harmful-genes~~ transgenes to organisms found in
26 groundwater;

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

30 E. any previous risk assessments for the same or
31 similar organisms prepared by federal or state agencies and
32 their adequacy and relevance to the current proposal, ~~including,~~
33 ~~but-not-limited-to,~~ such as consideration of the following:

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

36 (2) whether the genetically engineered organisms

1 failed to demonstrate an ability to be self-reproducing or
2 competitive because of transient factors; and

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

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

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

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

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

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

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

21 1558.0040 RELEASE PERMIT PROCEDURES.

22 Subpart 1. Procedure and application. Release permits,
23 including EAWs prepared by the commissioner, are required from
24 the commissioner for all releases of GEOs except those exempted
25 under subpart 13, or those regulated under part 1558.0060,
26 1558.0070, or 1558.0080. The commissioner shall provide
27 application forms.

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

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

32 (2) name, address, and telephone number of
33 cooperators or participants in the state;

34 (3) origin, destination, name of responsible
35 person, and containment procedures for movement and storage of

1 GEOs;

2 (4) the amount or number of organisms, material,
3 cultures, or seeds to be shipped or used in this state;

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

6 (6) a statement certifying that the use of the
7 genetically engineered organism will be in accordance with this
8 chapter;

9 (7) all information required for an EAW, as given
10 in part 1558.0050;

11 (8) supporting documentation, including research
12 information and any United States Environmental Protection
13 Agency, USDA, or other federal agency regulatory application or
14 approval document, if requested to verify or substantiate
15 information given in the permit application or respond to public
16 comments; and

17 (9) any information needed for an experimental
18 use permit under Minnesota Statutes, chapter 18B.

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

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

30 If the commissioner rejects an application, the applicant
31 must be informed in writing of the deficiencies that exist and
32 requirements that, if corrected, will allow acceptance of the
33 application. The applicant may submit the additional
34 information or withdraw the application. Acceptance of the
35 application does not constitute issuance of the permit.

36 Subp. 3. **Application distribution.** Within 14 days of the

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

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

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

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

16 Subp. 6. Permit conditions. The commissioner may
17 prescribe terms and conditions ~~including, but not limited~~
18 ~~to,~~ such as the period for the GEO release permit, the amount or
19 number of GEOs to be released, monitoring activities, department
20 inspection schedules, reporting of experimental results, and
21 experiment termination procedures. The commissioner may impose
22 additional reasonable and appropriate release permit conditions
23 to mitigate or minimize the adverse effects of the release on
24 human health or the environment.

25 Subp. 7. Violation of the permit. A person ~~may~~ shall not
26 violate terms or conditions of a permit issued under this
27 section. The commissioner may modify, suspend, or revoke the
28 release permit at any time if the commissioner finds that its
29 terms or conditions are being violated or are inadequate to
30 avoid unreasonable adverse effects on human health or the
31 environment pursuant to Minnesota Statutes, section 18F.07,
32 subdivision 2. If adverse effects are observed, the permit will
33 be suspended. If adverse effects can be mitigated by
34 modification of the conditions for release, the permit may be
35 reinstated. Revocation ~~may~~ shall result in termination and
36 disposal of all GEOs if the commissioner determines that the

1 GEOs pose a significant environmental risk. Minnesota Statutes,
2 section 18D.301, subdivision 1, authorizes procedures and
3 penalties as outlined in Minnesota Statutes, chapter 18D, to be
4 applied to violations of Minnesota Statutes, chapter 18B, 18C,
5 or 18F.

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

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

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

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

24 A. the release permit identification number; and

25 B. methods of observation, resulting data, and
26 analysis or observations of adverse effects on human health or
27 the environment.

28 Subp. 12. **Access.** Access to the release site must be
29 allowed for state regulatory officials to inspect facilities or
30 the field test site, or both, and any records necessary to
31 evaluate compliance with this chapter. Records must be kept for
32 three years. Access of regulatory officials from state agencies
33 other than the Department of Agriculture must be coordinated
34 through the Department of Agriculture.

35 Subp. 13. **Partial or complete exemptions.** Partial or
36 complete exemptions from the permit procedures may be given by

1 the commissioner based on the considerations in part 1558.0030
2 and adequacy of alternative oversight as it relates to those
3 considerations.

4 A. The applicant may file a written request to the
5 commissioner for the exemption of an individual release or for a
6 class of releases. The request must include a copy of the
7 federal application or documentation and the information
8 necessary to determine if there is a potential for ~~significant~~
9 ~~adverse-environmental-effects~~ adverse effects on humans or the
10 environment. The determination must be based on the
11 considerations in part 1558.0030 and the adequacy of alternative
12 oversight as it relates to those considerations. The
13 commissioner shall make a determination within 30 days of the
14 receipt of the exemption request and documentation. Class
15 exemptions may be initiated by the commissioner.

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

22 1558.0050 ENVIRONMENTAL ASSESSMENT WORKSHEETS.

23 Subpart 1. Reason for EAWs. EAWs are prepared by the
24 Minnesota Department of Agriculture as part of the release
25 permit application in part 1558.0040. EAWs are designed to look
26 at environmental effects associated with a proposed release.
27 The EAW findings are used to determine if an EIS is needed, if
28 the permit should be granted, and if any permit conditions are
29 needed to mitigate or lower risks that have been identified by
30 the EAW. The EAW must be written in plain and objective
31 language and include a clear presentation of the proposed
32 release and issues of concern. Information for EAWs must be
33 submitted by the applicant on forms provided by the department
34 as part of the permit application. The EAW, which is prepared
35 by the department using information from the applicant and other

1 sources, is intended to be a summary of the considerations in
2 part 1558.0030 as they relate to the proposed release; however,
3 supporting documents must be referenced and available upon
4 request.

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

10 Subp. 3. EAW review. The EAW must be reviewed using an
11 interdisciplinary approach that will ensure the integrated use
12 of the natural and environmental sciences, including involvement
13 of the following disciplines as appropriate: microbiology,
14 ecology, public health, biological safety, agronomy, animal
15 science, plant biology, risk assessment, molecular biology,
16 biochemistry, entomology, vertebrate biology, physical and
17 biological containment, and other appropriate disciplines. The
18 notice of availability of the EAW and the a 30-day public
19 comment period must be published in the first available EQB
20 Monitor.

21 Subp. 4. EAW findings. The commissioner shall issue
22 findings of fact based on the EAW. The findings must determine
23 if there is a potential for significant environmental effects.
24 If there is a potential for significant environmental effects,
25 ~~an-EIS-must-be-prepared---The-findings-may-also-be-used-to~~
26 ~~determine-if-the-permit-should-be-granted-or-denied,-and-if-any~~
27 ~~permit-conditions-are-needed-to-mitigate-or-lower-risks-that~~
28 ~~have-been-identified-by-the-EAW~~ an EIS must be prepared, and no
29 permit may be issued until after preparation of an EIS. If
30 there is a finding of no potential for significant environmental
31 effects, and the commissioner chooses to decide on the permit
32 application at this stage, the commissioner must base the
33 decision to grant or deny the permit or impose conditions on
34 granting a permit on the findings made under this part.

35 Subp. 5. EIS preparation and review. An EIS, if required,
36 must be written and reviewed under the procedures in part parts

1 4410.2000 to 4410.2300.

2 1558.0060 NOTIFICATION PROCEDURES FOR CERTAIN GENETICALLY
3 ENGINEERED PLANTS.

4 Subpart 1. Genetically engineered plants eligible for
5 release under the notification procedure. In accordance with
6 Minnesota Statutes, section 116C.98, genetically engineered
7 plants that meet the eligibility criteria of items A to F and
8 whose release meets the performance standards in subpart 2 are
9 eligible for release under the notification procedure of subpart
10 3.

11 A. The genetically engineered plant is:

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

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

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

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

32 D. The genetically engineered material does not:

33 (1) cause the production of an infectious entity;

34 (2) encode substances that are known or likely to
35 be toxic to nontarget organisms known or likely to feed or live

1 on the plant species; or

2 (3) encode products intended for pharmaceutical
3 use.

4 E. To ensure that the introduced genetic sequences do
5 not pose a significant risk of the creation of any new plant
6 viruses they must be:

7 (1) noncoding regulatory sequences of known
8 function;

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

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

17 F. The plant has not been modified to contain the
18 following genetic material from ~~animals~~ animal or human
19 pathogens:

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

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

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

26 A. The performance standards in this subpart must be
27 met for any releases under the notification procedure.

28 B. If the genetically engineered plants or plant
29 materials are shipped, they must be shipped in such a way that
30 the viable plant material is unlikely to be disseminated while
31 in transit and must be maintained at the facility in such a way
32 that there is no release into the environment.

33 C. The genetically engineered plants must be planted
34 in such a way that they are not inadvertently mixed with
35 nonregulated plant materials of any species which are not part
36 of the release.

1 D. The plants and plant parts must be maintained in
2 such a way that the identity of the material is known while it
3 is in use, and the plant parts must be contained or devitalized
4 when no longer in use.

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

7 F. The field trial must be conducted so that:

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

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

12 G. Upon termination of the field test:

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

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

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

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

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

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

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

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

30 C. the names and locations of the origination and
31 destination facilities for movement or the field site location
32 for the environmental release, and the size of the use;

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

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

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

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

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

10 A. the release number;

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

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

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

20 Subp. 8. Access. Access must be allowed for state
21 regulatory officials to inspect facilities or the field test
22 site, or both, and any records necessary to evaluate compliance
23 with the provisions of subparts 1 to 6. Access of regulatory
24 officials from state agencies other than the Department of
25 Agriculture must be coordinated through the department.

26 Subp. 9. Administrative action in response to notification.

27 A. The commissioner shall publish notice of the
28 proposed release at the earliest opportunity in the EQB Monitor
29 and shall mail notice to the ~~chief-executive~~ chair of the county
30 board of the county and the tribal council of any reservation
31 within which the release will take place.

32 B. The commissioner shall grant or deny permission to
33 release the noticed genetically engineered plant within 30 days
34 of the receipt of the notification.

35 C. A person denied permission for use of a
36 genetically engineered plant under notification may apply for a

1 permit for release of that genetically engineered plant without
2 prejudice.

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

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

9 1558.0070 COMMERCIAL USE EXEMPTION.

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

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

21 A. An applicant must submit any federal documents
22 needed to address the considerations in part 1558.0030, subpart
23 1.

24 B. Supplemental notice of Federal Register items
25 regarding delisting or deregulation of agriculturally related
26 GEOs must be published in the EQB Monitor and sent to the
27 Minnesota Department of Agriculture GEO mailing list. The
28 Minnesota Department of Agriculture shall accept comments during
29 the federal comment period. Notice of the exemption of GEOs to
30 allow for commercial use must be published in the EQB Monitor at
31 least 30 days prior to ~~sale~~ commercial use.

32 C. The commissioner may require additional use
33 conditions or marketing limits to mitigate or lower risk for
34 ~~unreasonable~~ adverse effects on ~~human-health~~ humans or the
35 environment resulting from commercial use of a GEO.

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

7 E. The commissioner may reject an application for a
8 GEO commercial use exemption based on ~~unreasonable~~ adverse
9 effects on ~~human-health~~ humans or the environment.

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

13 1558.0080 USES NOT REQUIRING A RELEASE PERMIT, NOTIFICATION, OR
14 COMMERCIAL USE EXEMPTION.

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

24 Subp. 2. **Facility exemption.** The use of a GEO in a
25 facility that does not meet the requirements of a containment
26 facility~~7,~~ but~~7~~ has been found by the commissioner to provide
27 adequate containment, to prevent unreasonable risk of release
28 into the environment for the specific use proposed, is not a
29 release and does not require a release permit. The commissioner
30 retains the right to inspect facilities to ensure compliance.

31 Subp. 3. **Movement of GEOs.** GEOs must be moved in such a
32 way that the viable organism is unlikely to be disseminated in
33 transit and it must be maintained at the destination facility in
34 such a way that there is no release into the environment. All
35 GEOs must be clearly labeled. Movement of GEOs does not require

1 a permit but must comply with items A and B.

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

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

13 1558.0090 CONCURRENT REVIEW.

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