

1 Environmental Quality Board

2

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

5

6 Rules as Adopted

7 4410.0200 DEFINITIONS AND ABBREVIATIONS.

8 [For text of subps 1 to 35, see M.R.]

9 Subp. 35a. Genetically engineered organism. "Genetically  
10 engineered organism" has the meaning given in part 4420.0010,  
11 subpart 14.

12 Subp. 35b. Genetic engineering. "Genetic engineering" has  
13 the meaning given in part 4420.0010, subpart 15.

14 [For text of subps 36 to 55, see M.R.]

15 Subp. 55a. Organism. "Organism" has the meaning given in  
16 part 4420.0010, subpart 18.

17 [For text of subps 56 to 71a, see M.R.]

18 Subp. 71b. Release. "Release" has the meaning given in  
19 part 4420.0010, subpart 19.

20 [For text of subps 73 to 96, see M.R.]

21 4410.4300 MANDATORY EAW CATEGORIES.

22 [For text of subps 1 to 34, see M.R.]

23 Subp. 35. Release of genetically engineered organisms.

24 For the release of a genetically engineered organism that  
25 requires a release permit from the EQB under chapter 4420, the  
26 EQB is the RGU. For all other releases of genetically  
27 engineered organisms, the RGU is the permitting state  
28 agency. This subpart does not apply to the direct medical  
29 application of genetically engineered organisms to humans or  
30 animals.

31 4410.8000 SPECIAL RULES FOR RELEASE OF GENETICALLY ENGINEERED  
32 ORGANISMS.

33 Subpart 1. Generally. Environmental review for the  
34 release of genetically engineered organisms shall be conducted

1 according to the procedures in parts 4410.1200 to 4410.3000  
2 except as provided in items A to C.

3 A. In part 4410.1400 when the EQB is the RGU, it  
4 shall have 45 days to add supplementary material, if necessary,  
5 and to approve the EAW for distribution.

6 B. In part 4410.1700 when the EQB is the RGU, part  
7 4410.1700, subpart 2a, does not apply.

8 C. In deciding whether a project has the potential  
9 for significant environmental effects, the criteria in part  
10 4410.1700, subpart 7, shall be replaced by the following factors:

11 (1) the familiarity and predictability of the  
12 ~~donor~~ ecologically relevant biological properties of the  
13 introduced DNA, the vector if one exists, the recipient, and  
14 engineered organisms;

15 (2) the history of any previous environmental  
16 uses of the genetically engineered organism;

17 (3) the potential for the genetically engineered  
18 organisms to cause adverse environmental effects including, but  
19 not limited to:

20 (a) whether the recipient organism is native  
21 or nonnative to the release area;

22 (b) whether the genetically engineered  
23 organism is pathogenic or toxic to target or nontarget organisms  
24 and to what extent this trait has been introduced or altered as  
25 a result of the genetic engineering;

26 (c) the extent to which the genetically  
27 engineered organism's competitiveness and survivability under  
28 environmental stress including, but not limited to, dormancy,  
29 temperature tolerance, fire resistance, drought resistance, or  
30 ability to disperse in the environment have been changed or  
31 potentially changed as a result of the genetic engineering. The  
32 determination of potential changes must be based ~~upon~~  
33 ~~consideration-of~~ minimally on the natural history of the  
34 recipient organism and subsequent the potential effects on of  
35 natural selection on the genetically engineered organism;

36 (d) the extent of change or potential change

1 to the recipient organism's resource base including, but not  
2 limited to, the ability of plants to grow on new soil types, of  
3 bacteria to metabolize new nutrients, and of fish to eat new  
4 foods;

5 (e) the potential for the genetically  
6 engineered organism's genes to transfer to other hosts and the  
7 resultant effects on other hosts' competitiveness, dispersal,  
8 dormancy, pathogenicity or toxicity, and expansion of their  
9 resource bases; and

10 (f) the potential of the genetically  
11 engineered organism to enter or adversely affect the groundwater  
12 environment or to pass unusual genes to a microorganism resident  
13 in the groundwater;

14 (4) the adequacy and appropriateness of proposed  
15 measures, if any, for confinement of the genetically engineered  
16 organism;

17 (5) any previous risk assessments for the same or  
18 similar organisms prepared by federal or state agencies and  
19 their adequacy and relevance to the current proposal including,  
20 but not limited to, consideration of the following:

21 (a) the range of soils, ecological biotypes,  
22 and meteorological conditions that existed in previous field  
23 releases and their relationship to the proposed release area;

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

28 (c) whether the scale of the assessment was  
29 adequate to assess potential for establishing ~~an-ecological~~  
30 ~~foothold~~ a self-reproducing population;

31 (6) the conclusions reached and conditions  
32 imposed by federal agencies with jurisdiction over the proposed  
33 release;

34 (7) the conclusions reached or conditions imposed  
35 by federal or state agencies on previous environmental releases  
36 in Minnesota or elsewhere and their adequacy and relevance to

1 the current proposal;

2 (8) the type, extent, and reversibility of  
3 environmental effects;

4 (9) the cumulative potential effects of related  
5 or anticipated future projects; and

6 (10) the extent to which the environmental  
7 effects are subject to mitigation by ongoing public regulatory  
8 authority.

9 Subp. 2. **EAW and EIS preparation.**

10 A. The EAW shall be prepared, using an  
11 interdisciplinary approach that will ensure the integrated use  
12 of the natural and environmental sciences. The review should  
13 include involvement of the following disciplines, as  
14 appropriate: microbiology, ecology, public health, biological  
15 safety, agronomy, plant biology, risk assessment, molecular  
16 biology, biochemistry, entomology, vertebrate biology, physical  
17 and biological containment, and other appropriate disciplines.

18 B. The EAW shall be written in plain and objective  
19 language and include clear presentation of the proposed release  
20 and of the issues of concern.

21 C. When the EQB is the RGU, the EQB chair may direct  
22 the EQB genetic engineering advisory committee to ~~assist-in-the~~  
23 ~~preparation-of~~ provide advice and comment on the EAW or EIS.  
24 The chair may appoint special members to the advisory committee  
25 to assist with specific EAWs or EISs.

26 PERMITTING PROCESS; RELEASES

27 4420.0010 DEFINITIONS.

28 Subpart 1. **Scope.** For the purpose of this chapter, the  
29 following terms and abbreviations have the meanings given them  
30 unless otherwise provided.

31 Subp. 2. **Agency.** "Agency" means a department, board, or  
32 agency of the state of Minnesota.

33 Subp. 3. **Applicant.** "Applicant" means a person or persons  
34 who file an application with the board for a release permit to  
35 release a genetically engineered organism.

1 Subp. 4. **Application.** "Application" means the document  
2 filed by a person or persons with the board for a release permit  
3 to release a genetically engineered organism.

4 Subp. 5. **Board.** "Board" means the Environmental Quality  
5 Board.

6 Subp. 6. **Chair.** "Chair" is the chairperson of the board  
7 as defined in part 4405.0100, subpart 4.

8 Subp. 7. **Containment facility.** "Containment facility"  
9 means a laboratory, greenhouse, building, structure, or other  
10 similar facility that complies with applicable ~~National~~  
11 ~~Institutes-of-Health-(NIH)-"guidelines for Research Involving~~  
12 ~~Recombinant-DNA-Molecules"-1986~~, regardless of whether the  
13 facility receives any support from NIH, and is certified  
14 pursuant to part ~~4420-0020~~ 4420.0070, subpart 6 1, or that has  
15 been ~~found~~ exempted by the board ~~to-be-an-adequate-containment~~  
16 ~~facility~~ under part ~~4420-0020~~ 4420.0070, subpart 4 3.

17 Subp. 8. **Draft release permit documents.** "Draft release  
18 permit documents" means the documents prepared by the chair  
19 under part 4420.0030, subpart 3, that include the chair's  
20 preliminary recommendation to the board to issue or modify a  
21 release permit and the proposed terms and conditions of the  
22 release permit, or the chair's preliminary recommendation to the  
23 board to deny or to revoke a release permit.

24 Subp. 9. **EAW.** "EAW" means environmental assessment  
25 worksheet and has the meaning given in part 4410.0200, subpart  
26 24.

27 Subp. 10. **EIS.** "EIS" means environmental impact statement  
28 and has the meaning given in part 4410.0200, subpart 26.

29 Subp. 11. **Environment.** "Environment" means the physical  
30 conditions existing in the area that may be affected by a  
31 proposed release. It includes land, air, water, minerals,  
32 flora, fauna, ambient noise, energy resources, and manmade  
33 objects or natural features of historic, geologic, or aesthetic  
34 significance.

35 Subp. 12. **Federal application.** "Federal application"  
36 means any applications or notifications and supporting documents

1 submitted to any agency of the United States government for the  
2 release of a genetically engineered organism.

3 Subp. 13. **File.** "File" means to deliver or mail five  
4 copies to the office of the chair.

5 Subp. 14. **Genetically engineered organism.** "Genetically  
6 engineered organism" means an organism derived from genetic  
7 engineering.

8 Subp. 15. **Genetic engineering.** "Genetic engineering"  
9 means the introduction of new genetic material to an organism or  
10 the regrouping of an organism's genes using techniques or  
11 technology designed by humans. Genetic engineering does not  
12 include selective breeding, hybridization, or nondirected  
13 mutagenesis, such as hand pollination, procedures based on  
14 sexual reproduction that have not involved molecular level  
15 manipulation of the genetic material, hybridization where the  
16 parent strains do not include genetic material that has been  
17 manipulated on the molecular level, mutagenesis induced by  
18 chemical, radiation, or heat, embryo rescue, selection of  
19 spontaneous mutants, somaclonal variant selection, and  
20 artificial insemination.

21 Subp. 16. **Local governmental unit.** "Local governmental  
22 unit" has the meaning given in part 4410.0200, subpart 43.

23 Subp. 17. **NIH guidelines.** "NIH guidelines" means the  
24 National Institutes of Health (NIH) "Guidelines for Research  
25 Involving Recombinant DNA Molecules," Federal Register, volume  
26 51, page 16958 (May 7, 1986), and NIH actions under the  
27 guidelines in Federal Register, volume 52, page 31848 (August  
28 24, 1987); volume 53, page 28819 (July 29, 1988); volume 53,  
29 page 43410 (October 26, 1988); volume 54, page 10508 (March 13,  
30 1989); volume 55, page 7438 (March 1, 1990); volume 55, page  
31 37565 (September 12, 1990); and volume 56, page 33174 (July 18,  
32 1991). The guidelines and actions are available at the office  
33 of the board and at the Minnesota Law Library.

34 Subp. 18. Organism. "Organism" means any animal, plant,  
35 bacterium, cyanobacterium, fungus, protist, or virus.

36 Subp. ~~18~~ 19. **Release.** "Release" means the placement or

1 use of a genetically engineered organism outside a containment  
2 facility or under any other conditions not specifically  
3 determined by the board to be adequate containment pursuant to  
4 part ~~4420.0020~~ 4420.0070, subpart 4 3.

5 Subp. ~~19~~ 20. **Release permit.** "Release permit" means the  
6 terms, conditions, and authorization by the board under this  
7 chapter for the release of a genetically engineered organism.

8 Subp. ~~20~~ 21. **Significant environmental permit.**  
9 "Significant environmental permit" means a permit issued by a  
10 state agency with the authority to deny, modify, revoke, or  
11 place conditions on the permit in compliance with Minnesota  
12 Statutes, sections 116C.91 to 116C.96, chapter 116D, and the  
13 rules adopted under them.

14 4420.0015 AUTHORITY, SCOPE, PURPOSE.

15 Subpart 1. **Authority.** This chapter is adopted under  
16 authority granted in Minnesota Statutes, section 116C.94, and  
17 chapter 116D to implement a permit procedure for the releases of  
18 genetically engineered organisms.

19 Subp. 2. **Scope.** This chapter applies to all releases of  
20 genetically engineered organisms, except that this chapter does  
21 not apply to the direct medical application of genetically  
22 engineered organisms to humans or animals.

23 Subp. 3. **Purpose.** The purpose of the release permit  
24 process created by this chapter is to:

25 A. protect human health and the environment from any  
26 significant or material adverse impacts that could result from  
27 the release of genetically engineered organisms;

28 B. allow for the orderly and safe development and use  
29 of released genetically engineered organisms;

30 C. provide information to the board and the public  
31 concerning proposed releases of genetically engineered  
32 organisms; and

33 D. provide an orderly and timely process for making  
34 decisions on permits for the release of genetically engineered  
35 organisms.

1 Subp. 4. Cooperative process. The board shall cooperate  
 2 with state and federal agencies to the fullest extent possible  
 3 to reduce duplication between implementation of this chapter and  
 4 the various state and federal regulatory and review programs  
 5 regarding genetically engineered organisms.

6 4420.0020 APPLICABILITY OF RULES.

7 Subpart 1. Release permit required. A release permit is  
 8 required for all releases of genetically engineered organisms  
 9 except as provided in ~~subparts 2 to 4. Notice of regular or~~  
 10 ~~special board meetings considering exemptions pursuant to~~  
 11 ~~subpart 2, 3, or 4 must include persons registered under part~~  
 12 ~~4420.0060, subpart 1~~ parts 4420.0070, subpart 3; 4420.0075; and  
 13 4420.0080, and Minnesota Statutes, section 116C.94, paragraph  
 14 (c).

15 ~~Subp. 2. Exemption for a significant environmental permit.~~

16 ~~A. A permit from the board is not required for a~~  
 17 ~~proposed release if a significant environmental permit is~~  
 18 ~~required by another agency.~~

19 ~~B. The board shall conduct a survey and evaluation of~~  
 20 ~~agency permits to determine which permits would be considered~~  
 21 ~~significant environmental permits for the release of genetically~~  
 22 ~~engineered organisms under this chapter. An agency may request~~  
 23 ~~the board to find that a permit is a significant environmental~~  
 24 ~~permit for the release of genetically engineered organisms.~~

25 ~~C. The board shall find that the permit is a~~  
 26 ~~significant environmental permit if the rules and laws applied~~  
 27 ~~in the issuance of the permit include all of the following:~~

28 ~~(1) a requirement for an environmental assessment~~  
 29 ~~worksheet for the proposed release, and compliance with~~

30 ~~Minnesota Statutes, chapter 116B, and rules adopted under it;~~

31 ~~(2) an evaluation of the application using an~~  
 32 ~~interdisciplinary approach that will ensure the integrated use~~  
 33 ~~of the natural and environmental sciences, including involvement~~  
 34 ~~of the following disciplines, as appropriate: microbiology,~~  
 35 ~~ecology, public health, biological safety, agronomy, plant~~



1 biology, risk-assessment, molecular-biology, biochemistry,  
2 entomology, vertebrate-biology, physical-and-biological  
3 containment, and other appropriate disciplines,

4 (3) the authority to prescribe terms and/or place  
5 conditions on the permit, and the authority to deny, modify,  
6 suspend, or revoke the permit, and

7 (4) considerations for permit issuance or denial  
8 substantially the same or equivalent to those listed in part  
9 4420.0035, subpart 3.

10 D.--When the board finds that a permit is a  
11 significant environmental permit, the permit must be placed on  
12 the list of significant environmental permits for the release of  
13 genetically engineered organisms and the list must be published  
14 in the EQB Monitor and the State Register.

15 Subp. 3.--Exemption for other agency permits.

16 A.--Any person or entity proposing a release requiring  
17 an agency permit not on the list of significant environmental  
18 permits may request an exemption from the board release permit.  
19 The proposer must file with the board a written request for  
20 exemption that includes the reasons the proposed release should  
21 be exempted from a release permit, a declaration that the laws,  
22 rules, and procedures applied in issuing the agency permit meet  
23 the requirements in item B, and a copy of the application for  
24 the agency permit.

25 B.--The board may exempt a release from a release  
26 permit if an agency permit not on the list of significant  
27 environmental permits is required and the board finds that the  
28 laws, rules, and procedures to be applied in the issuance of the  
29 permit include all of the following:

30 (1) a requirement for an environmental assessment  
31 worksheet for the proposed release and compliance with Minnesota  
32 Statutes, chapter 116B, and rules adopted under it;

33 (2) an evaluation of the application using an  
34 interdisciplinary approach that will ensure the integrated use  
35 of the natural and environmental sciences, including involvement  
36 of the following disciplines, as appropriate:--microbiology,

1 ecology, public health, biological safety, agronomy, plant  
 2 biology, risk assessment, molecular biology, biochemistry,  
 3 entomology, vertebrate biology, physical and biological  
 4 containment, and other appropriate disciplines;

5 (3) the authority or an agreement with the  
 6 proposer for the agency to place conditions on a permit to  
 7 mitigate or minimize the adverse impacts of the release on human  
 8 health or the environment and to provide the agency with  
 9 information adequate to monitor compliance with the permit, and

10 (4) considerations for permit issuance or denial  
 11 substantially the same or equivalent to those listed in part  
 12 4420.0035, subpart 3.

13 C.--The board must deny or conditionally grant the  
 14 exemption at its first regularly scheduled meeting after the  
 15 request for exemption is filed, provided that the exemption is  
 16 filed at least 21 calendar days before that meeting.

17 D.--The conditional exemption must be revoked if,  
 18 prior to 20 days after the issuance of the other agency permit,  
 19 the board finds that the requirements of item B have not been  
 20 met.--The conditional exemption is no longer conditional if the  
 21 board does not act by 20 days after the issuance of the other  
 22 agency permit.

23 Subp. 4.--Exemption for use in a facility not a containment  
 24 facility.--The procedure for obtaining an exemption from the  
 25 requirement for a release permit is described in items A to E.

26 A.--Any person or agency proposing the use of a  
 27 genetically engineered organism in a facility other than a  
 28 containment facility may request the board to find that the  
 29 facility provides adequate containment for the specific use  
 30 under Minnesota Statutes, section 116C.91, subdivision 6, and  
 31 part 4420.0010, subpart 7, and to exempt the specific use of the  
 32 genetically engineered organism in the facility from a release  
 33 permit.

34 The proposer must file with the board a written request for  
 35 exemption that includes:

36 (1) a description of the genetically engineered

1 organism-and-the-use;

2 (2)-a-description-of-the-facility;

3 (3)-the-reasons-why-the-facility-provides

4 adequate-containment-for-this-genetically-engineered-organism

5 and-this-use;-and

6 (4)-any-relevant-submittals-to-the-federal

7 government.

8 B.--Within-five-days-of-the-filing,-the-chair-must

9 mail-notice-of-the-request-to-the-local-governmental-units

10 within-whose-jurisdiction-the-facility-is-located,-governmental

11 units-with-approval-authority-over-the-use-of-the-facility,-and

12 the-mailing-list-of-part-4420.0060,-subpart-1.

13 C.--The-board-must-grant-or-deny-the-exemption-at-its

14 first-regularly-scheduled-meeting-after-the-request-for

15 exemption-is-filed,-provided-that-the-request-is-filed-at-least

16 21-calendar-days-before-that-meeting.

17 D.--If-the-board-denies-an-exemption,-the-board-must

18 inform-the-proposer-in-writing-of-its-reasons.--The-proposer-may

19 refile-a-revised-request-for-exemption-or-may-apply-for-a

20 release-permit.

21 E.--A-use-of-the-genetically-engineered-organism

22 allowed-in-an-exemption-granted-under-this-subpart-is-exempt

23 from-environmental-review-under-chapter-4410.

24 Subp.-5.--Containment-facility-certification.--The-use-of-a

25 genetically-engineered-organism-in-a-containment-facility-is-not

26 a-release-and-does-not-require-a-release-permit.

27 To-certify-a-facility-as-a-containment-facility,-the-owner

28 or-operator-of-the-facility-must-file-with-the-board-a

29 certification-stating-the-level-of-biosafety-maintained-at-the

30 facility-and-demonstrating-with-supporting-documentation-that

31 the-facility-complies-with-the-National-Institutes-of-Health

32 "Guidelines-for-Research-Involving-Recombinant-DNA-Molecules"

33 1986,-and-that-the-level-of-biosafety-maintained-is-appropriate

34 for-the-genetically-engineered-organisms-being-used.

35 The-board-may-inspect-the-containment-facility-to-determine

36 if-the-facility-and-its-operation-comply-with-the-certified

1 ~~level-of-biosafety-and-if-the-level-of-biosafety-is-appropriate~~  
 2 ~~for-the-genetically-engineered-organisms-being-used.--If-the~~  
 3 ~~board-finds-that-the-facility-does-not-comply-with-the-certified~~  
 4 ~~level-of-biosafety-or-if-the-board-finds-that-level-is~~  
 5 ~~inappropriate-for-the-level-of-biosafety-required-for-the~~  
 6 ~~genetically-engineered-organisms-being-used,-it-must-order-the~~  
 7 ~~responsible-person-or-agency-to-comply-with-the-guidelines-or-to~~  
 8 ~~cease-using-the-genetically-engineered-organism-or-to-file-an~~  
 9 ~~application-for-a-release-permit-or-exemption.--In-addition,-the~~  
 10 ~~board-may-place-reasonable-and-appropriate-conditions-on-the-use~~  
 11 ~~of-the-genetically-engineered-organism-while-an-application-for~~  
 12 ~~a-release-permit-or-exemption-is-pending.~~

13       Subp. 2. Containment facility. The use of a genetically  
 14 engineered organism in a containment facility is not a release  
 15 and does not require a release permit.

16       Subp. 3. Facility exemption. The use of a genetically  
 17 engineered organism in a facility that does not meet the  
 18 requirements of a containment facility but has been found by the  
 19 board to provide adequate containment for the specific use  
 20 proposed is not a release and does not require a release permit.

21       Subp. 4. Containment determined by another agency. The  
 22 use of a genetically engineered organism in a facility that does  
 23 not meet the requirements of a containment facility but has been  
 24 found, by an agency with a significant environmental permit and  
 25 the authority under law to determine adequate containment, to  
 26 provide adequate containment for the specific use proposed is  
 27 not a release and does not require a release permit.

28       Subp. 5. Use of genetically engineered organisms after the  
 29 effective date of chapter. After the effective date of this  
 30 chapter, any person who proposes to use a genetically engineered  
 31 organism must comply with this chapter.

32       Subp. 6. 1992 exemption. Any person who by July 1, 1992,  
 33 has received a declaration of no potential for significant  
 34 environmental effects from the Minnesota Department of  
 35 Agriculture for a proposed release or who has had prepared an  
 36 environmental assessment worksheet by the Minnesota Department

1 of Agriculture for a proposed release need not comply with this  
2 chapter for the proposed release in calendar year 1992.

3 Subp. 7. Exemptions for licensed animal vaccines. Chapter  
4 4410 and this chapter do not apply to any animal vaccine  
5 containing a genetically engineered organism that has received a  
6 license from the United States Department of Agriculture prior  
7 to January 1, 1992, and any person may utilize such licensed  
8 product without a release permit.

9 4420.0025 APPLICATION PROCEDURES AND REQUIREMENTS.

10 Subpart 1. **Application.** An application for a release  
11 permit for the release of genetically engineered organisms must  
12 be filed in the form approved by the chair. The application  
13 shall contain the information required in part 4420.0045.

14 Subp. 2. **Application acceptance.** The chair shall accept  
15 or reject an application within 14 calendar days after receipt  
16 of the application. The chair shall reject an application if  
17 the application does not contain the information required in  
18 part 4420.0045 or if the information is not sufficient to carry  
19 out the requirements of this chapter or to prepare an EAW under  
20 chapter 4410.

21 If the chair rejects an application, the chair shall inform  
22 the applicant in writing of the deficiencies that, if corrected,  
23 will allow the application to be accepted. If the application  
24 is revised and resubmitted, the chair shall accept or reject the  
25 revised application within 14 calendar days from receipt of the  
26 revised application. If there is a second rejection by the  
27 chair, the applicant may resubmit a revised application to the  
28 chair or appeal to the board for acceptance of the application.

29 After acceptance of an application, the applicant must, in  
30 a timely manner, provide the additional information the chair  
31 considers necessary to process the application. If the  
32 applicant does not provide the information in a timely manner,  
33 the chair may delay the preparation and notice of the draft  
34 release permit documents until the information is provided.

35 Subp. 3. **Notice of application acceptance.** Within 15 days

1 of the application acceptance, the applicant must publish notice  
2 of application acceptance and availability in a newspaper of  
3 general circulation in the area where the release is proposed  
4 and mail notice to persons registered under part 4420.0060,  
5 subpart 1, and governmental units with approval authority over  
6 the release. The chair must publish the notice of application  
7 acceptance and availability in the EQB Monitor.

8 The notice must include:

- 9 A. identification of the applicant;  
10 B. the date of acceptance;  
11 C. a brief description of the proposed release  
12 including, but not limited to, size, type, and location;  
13 D. availability of the application;  
14 E. telephone number and address of the office of the  
15 chair; and  
16 F. information on how a person can receive the trade  
17 secret deleted version of the application and all notices  
18 pertaining to this release.

19 Subp. 4. **Application distribution.** Within 21 days of the  
20 application acceptance, the applicant must provide a copy of the  
21 trade secret deleted version of the accepted application to:  
22 each member of the EQB, the Environmental Conservation Library,  
23 the Legislative Reference Library, the regional development  
24 commission and regional development library for the region in  
25 which the release is proposed, and local governmental units  
26 within whose boundaries the release is proposed, and any other  
27 person upon written request. If a board member requests and  
28 receives a copy of an application that contains information that  
29 has been determined to be trade secret information pursuant to  
30 Minnesota Statutes, chapter 13, that board member must treat  
31 that information as nonpublic data pursuant to Minnesota  
32 Statutes, chapter 13. Copies of the complete application shall  
33 be made available to board members upon request. The applicant  
34 must provide additional copies of either version of the accepted  
35 application to the chair upon request.

1 4420.0030 RELEASE PERMIT PROCEDURES AND REQUIREMENTS.

2 Subpart 1. **Scope of release permit conditions.** The board  
3 may impose reasonable and appropriate release permit conditions  
4 to mitigate or minimize the adverse impacts of the release on  
5 human health or the environment and to provide the board with  
6 information adequate to monitor compliance with the release  
7 permit and for analysis relating to future applications.

8 Subp. 2. **Evaluation and preparation.** The application must  
9 be evaluated, and the draft release permit documents must be  
10 prepared, using an interdisciplinary approach that will ensure  
11 the integrated use of the natural and environmental sciences.  
12 The review shall include involvement of the following  
13 disciplines, as appropriate: microbiology, ecology, public  
14 health, biological safety, agronomy, plant biology, risk  
15 assessment, molecular biology, biochemistry, entomology,  
16 vertebrate biology, physical and biological containment, and  
17 other appropriate disciplines.

18 Subp. 3. **Draft release permit documents.** Within 45 days  
19 of acceptance of the application, the chair must prepare the  
20 draft release permit documents and publish notice of their  
21 availability in the EQB Monitor. The chair must provide a copy  
22 of the draft release permit documents to: each member of the  
23 EQB, the Environmental Conservation Library, the Legislative  
24 Reference Library, the regional development commission and  
25 regional development library for the region in which the release  
26 is proposed, governmental units with approval authority over the  
27 release, and local governmental units within whose boundaries  
28 the release is proposed, and any other person upon written  
29 request.

30 The board may order that the preparation and notice of the  
31 draft release permit documents be delayed for not more than 30  
32 days if the application is for a release on multiple sites, for  
33 multiple years, or for organisms with different ecological  
34 impacts, or if the board determines that more time is needed to  
35 complete the preparation and notice of the draft release permit  
36 documents due to the complexity of the application.

1 Subp. 4. **Notice content.** The notice of the draft release  
2 permit documents must include, but is not limited to:

3 A. the identification of the applicant;

4 B. the comment period and the requirements of subpart  
5 7;

6 C. a concise description and location of the proposed  
7 release;

8 D. the preliminary decision of the chair to propose  
9 issuance or denial of the release permit;

10 E. locations where documents are available for public  
11 review;

12 F. the address and telephone number of the office of  
13 the chair; and

14 G. information on how a person can receive all  
15 notices pertaining to this release.

16 This notice may be combined with the notice of EAW availability  
17 required under part 4410.1500.

18 Subp. 5. **Notice distribution.** The chair must distribute  
19 the notice of the draft release permit documents in the  
20 following manner:

21 A. mailed to the applicant;

22 B. mailed to all persons who have registered their  
23 names and addresses on the mailing list under part 4420.0060,  
24 subpart 1; and

25 C. to any interested person upon request.

26 Subp. 6. **Comment period.** A 30-day period for review and  
27 comment on the draft release permit documents begins the day  
28 notice of the draft release permit documents is published in the  
29 EQB Monitor. Comments received after the close of the comment  
30 period need not be considered by the board.

31 Subp. 7. **Comments.** Written comments may address the  
32 accuracy and completeness of the material contained in the  
33 application, potential impacts that may warrant further  
34 investigation before the release is approved, the adequacy of  
35 the draft release permit documents, additional permit  
36 conditions, and the need for a contested case hearing.



1 Written comments shall include the following:

2 A. a statement of the person's interest in the  
3 application or the draft release permit documents;

4 B. a statement of the action the person wishes the  
5 board to take;

6 C. the reasons supporting the person's position; and

7 D. if a person requests a contested case hearing, the  
8 comments must include a statement of the rationale and facts  
9 supporting findings that meet the requirements of subpart 9,  
10 item A, to hold a contested case hearing and an identification  
11 of the issues that the person proposes to address at the hearing.

12 Subp. 8. **Public meetings.** One or more public meetings may  
13 be held during the public comment period to gather comments on  
14 the application and draft release permit documents if the chair  
15 determines that a meeting is necessary or useful. Public notice  
16 of the meetings shall be given prior to the meetings including  
17 mailed notice to persons registered pursuant to part 4420.0060,  
18 subpart 2, governmental units with approval authority over the  
19 release, and publication in a newspaper of general circulation  
20 in the county where the proposed release would take place. All  
21 meetings shall be open to the public.

22 Subp. 9. **Standard for contested case hearing.** The board  
23 must hold a contested case hearing when it finds all of the  
24 following:

25 A. that the person requesting the contested case  
26 hearing has raised a material issue of fact or of the  
27 application of law to facts related to the chair's preliminary  
28 determination or the draft release permit documents;

29 B. that the board has jurisdiction to make  
30 determinations on the issues of fact or of the application of  
31 law to facts raised by the person requesting the contested case  
32 hearing; and

33 C. that there is a reasonable basis underlying issues  
34 of fact or law raised by the person who requests the contested  
35 case hearing such that the holding of the contested case hearing  
36 would aid the board in making a determination on the release

1 permit.

2 Subp. 10. **Requirements for contested case hearing.** When  
3 the board decides to hold a contested case hearing, the chair  
4 must prepare a notice of and an order for hearing, that includes:

5 A. the information required by part 1400.5600 of the  
6 Office of Administrative Hearings;

7 B. a reference to the public notice of the  
8 application and the draft release permit documents, including  
9 any identification numbers on the draft release permit  
10 documents, and the dates of issuance of the public notice and  
11 draft release permit documents;

12 C. identification of the existing parties and a  
13 concise description of the issues that have been raised by any  
14 party;

15 D. the address and telephone number of the office of  
16 the chair; and

17 E. information on how a person can receive all  
18 notices pertaining to this release.

19 The notice of hearing, distribution of the notice, and the  
20 conduct of the contested case hearing are governed by Minnesota  
21 Statutes, sections 14.57 to 14.62, and the rules of the Office  
22 of Administrative Hearings, parts 1400.5100 to 1400.8402.

23 Subp. 11. **Release permit action.** The board shall review  
24 the record and issue, modify and issue, deny, or order a hearing  
25 on the release permit within 30 days of the close of the comment  
26 period unless:

27 A. if a contested case hearing is ordered pursuant to  
28 subpart 9, then a decision on the release permit must be made  
29 within 30 days after the issuance of the report of the  
30 administrative law judge; and

31 B. if an EIS is ordered pursuant to part 4410.1700, a  
32 decision on the release permit must be made within 30 days after  
33 the determination of adequacy of a final EIS.

34 4420.0035 BASIS FOR DECISION.

35 Subpart 1. **Standard for issuing a release permit.** Except

1 as provided in subpart 2, the board must issue or modify a  
2 release permit if the board determines that the applicant will,  
3 with respect to the release, comply or will undertake a schedule  
4 of compliance to achieve compliance with the conditions of the  
5 release permit and all applicable Minnesota statutes and rules  
6 administered by the board, and that all applicable requirements  
7 of Minnesota Statutes, chapter 116D, and the rules adopted under  
8 chapter 116D, have been fulfilled.

9       **Subp. 2. Standard for denying or revoking a release**  
10 **permit.** The following findings by the board constitute  
11 justification for the board to deny or to revoke a release  
12 permit or to deny a modification to a release permit:

13           A. that the applicant will not comply or has not  
14 complied with the conditions of the release permit or applicable  
15 law;

16           B. that the applicant has failed to disclose fully  
17 all facts relevant to the release or has submitted false or  
18 misleading information to the board;

19           C. that the release will result or has resulted in  
20 significant or material adverse effects on human health or the  
21 environment; or

22           D. that all applicable requirements of Minnesota  
23 Statutes, chapter 116D, and the rules adopted under chapter  
24 116D, have not been fulfilled.

25       **Subp. 3. Considerations.** In determining pursuant to  
26 subparts 1 and 2 whether a release permit should be issued or  
27 denied, modified, or revoked and in specifying or modifying  
28 permit conditions, the board must consider the following:

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

33           B. the history of any previous environmental uses of  
34 the genetically engineered organism;

35           C. the potential for the genetically engineered  
36 organisms to cause adverse environmental effects including, but

1 not limited to:

2 (1) whether the recipient organism is native or  
3 nonnative to the release area;

4 (2) whether the genetically engineered organism  
5 is pathogenic or toxic to target or nontarget organisms and to  
6 what extent has this trait been introduced or altered as a  
7 result of the genetic engineering;

8 (3) the extent to which the genetically  
9 engineered organism's competitiveness, survivability under  
10 environmental stress including, but not limited to, dormancy,  
11 temperature tolerance, fire resistance, and drought resistance,  
12 or ability to disperse in the environment has been changed or  
13 potentially changed as a result of the genetic engineering. The  
14 determination of potential changes must be based ~~upon~~  
15 ~~consideration-of~~ minimally on the natural history of the  
16 recipient organism and ~~subsequent~~ the potential effects on of  
17 natural selection on the genetically engineered organism;

18 (4) the extent of change or potential change to  
19 the recipient organism's resource base including, but not  
20 limited to, the ability of plants to grow on new soil types, of  
21 bacteria to metabolize new nutrients, and of fish to eat new  
22 foods;

23 (5) the potential for the genetically engineered  
24 organism's genes to transfer to other hosts and the resultant  
25 effects on the other hosts' competitiveness, dispersal,  
26 dormancy, pathogenicity or toxicity, or on the expansion of  
27 their resource bases; and

28 (6) the potential of the genetically engineered  
29 organism to enter or adversely affect the groundwater  
30 environment or to pass unusual genes to a microorganism resident  
31 in the groundwater;

32 D. the adequacy and appropriateness of proposed  
33 measures, if any, for confinement of the genetically engineered  
34 organism;

35 E. any previous risk assessment for the release of  
36 the same or similar organisms prepared by federal or state

1 agencies and the risk assessment adequacy and relevance to the  
2 current proposal including, but not limited to:

3 (1) the range of soils, ecological biotypes, and  
4 meteorological conditions that existed in previous field  
5 releases and their relationship to the proposed release area;

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

9 (3) whether the scale of the release was adequate  
10 to assess potential for establishing an-ecological-foothold a  
11 self-reproducing population;

12 F. the conclusions reached and conditions imposed by  
13 federal agencies with jurisdiction over the proposed release and  
14 their adequacy and relevance to the current proposal; and

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

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

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

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

25 4420.0040 GENETIC ENGINEERING ADVISORY COMMITTEE.

26 Subpart 1. **General.** The board or chair must provide  
27 guidance to the genetic engineering advisory committee in the  
28 form of a charge and through specific requests. No member of  
29 the advisory committee may receive the trade secret information  
30 contained in an application if that person is, or represents in  
31 any capacity, a person engaged in any business or enterprise in  
32 competition with the applicant or in which the trade secret  
33 information could be used for product development purposes. If  
34 an advisory committee member receives a copy of an application  
35 that contains information that has been determined to be trade

1 secret information pursuant to Minnesota Statutes, chapter 13,  
2 that advisory committee member must treat that information as  
3 nonpublic data pursuant to Minnesota Statutes, chapter 13.

4 Subp. 2. **Release review.** The chair may direct the genetic  
5 engineering advisory committee to ~~assist-in-the-review-of~~  
6 provide advice and comment about applications and of requests  
7 for exemptions and the preparation of draft release permit  
8 documents or any other aspect relating to a release pursuant to  
9 this chapter. The chair may appoint special members to the  
10 advisory committee to ~~assist-with~~ advise and comment on specific  
11 applications.

12 Subp. 3. **Program review.** The board may direct the genetic  
13 engineering advisory committee to provide advice and make  
14 recommendations concerning development, revision, and  
15 enforcement of any rule or program initiated under chapter 4420  
16 and Minnesota Statutes, sections 116C.92 to 116C.96.

17 4420.0045 APPLICATION CONTENTS.

18 Subpart 1. **Release permit application.** Each application  
19 for a release permit shall contain the following information in  
20 a form approved by the chair:

21 A. a cover letter signed by an authorized  
22 representative or agent of the applicant requesting a release  
23 permit and identifying the proposed release organism and the  
24 location of the release;

25 B. a title page and a table of contents;

26 C. the applicant's complete name, address, and  
27 telephone number;

28 D. the complete name, title, address, and telephone  
29 number of the authorized representative to be contacted  
30 concerning the applicant's filing;

31 E. a description of the proposed release including:

32 (1) location;

33 (2) use and purpose;

34 (3) release date and duration of release;

35 (4) the information necessary to evaluate the

1 proposed release using the considerations identified in part  
2 4420.0035, subpart 3; and

3 ~~(5) the estimated cost, and~~  
4 ~~(6) any other information relevant to the release~~  
5 requested by the chair;

6 F. a list of all the known federal, state, and local  
7 agencies or authorities and titles of the permits they issue  
8 that are required for the proposed release; and

9 G. the federal application and the federal  
10 Confidential Business Information Deleted application if they  
11 have been prepared. The applicant may make reference to the  
12 federal application in completing the release permit application.

13 Subp. 2. Trade secret information. ~~Information submitted~~  
14 ~~that qualifies as trade secret information under Minnesota~~  
15 ~~Statutes, section 13.37, subdivision 1, paragraph (b), must be~~  
16 ~~treated as nonpublic data in accordance with Minnesota Statutes,~~  
17 ~~chapter 13. At the time of submittal, the applicant has the~~  
18 ~~burden to demonstrate that the information in question qualifies~~  
19 ~~as trade secret information. Information regarding the effects~~  
20 ~~of a release on human health or the environment must not be~~  
21 ~~included as trade secret information.~~

22 ~~When the application contains information that qualifies as~~  
23 ~~trade secret information, the applicant shall submit a second~~  
24 ~~version of the application with the trade secret information~~  
25 ~~deleted. An applicant shall identify in the application any~~  
26 information that the applicant believes is trade secret  
27 information which should not be made available to the public.  
28 The applicant has the burden to establish that the information  
29 in question qualifies as trade secret information. In the event  
30 the chair disagrees with the applicant, the chair shall notify  
31 the applicant of the chair's decision at least five working days  
32 prior to making the information public. The applicant may  
33 withdraw the application or seek judicial recourse.

34 4420.0050 RELEASE PERMIT MODIFICATION, SUSPENSION, AND  
35 REVOCATION NOT INITIATED BY PERMITTEE.

1 Subpart 1. **Initiation.** Any person or agency may request  
2 the board to modify, suspend, or revoke a release permit. The  
3 requester must file a written request including:

4 A. a prima facie showing by affidavit or other  
5 documentation that:

6 (1) a violation of the terms and conditions of a  
7 release permit to release genetically engineered organisms has  
8 occurred or is likely to occur;

9 (2) a failure to disclose fully all facts or the  
10 submission of false or misleading information by the permittee;  
11 or

12 (3) the terms and conditions of the release  
13 permit are inadequate to avoid unreasonable or material adverse  
14 effects on human health or the environment; and

15 B. the action the person or agency is requesting the  
16 board to take.

17 The chair must place the matter on the agenda of the next  
18 regular or special meeting of the board according to part  
19 4405.0600 for consideration of an action to modify, suspend, or  
20 revoke the release permit.

21 Subp. 2. **Notice.** The chair must notify in writing the  
22 permittee, local governmental units within whose boundaries the  
23 release is permitted, governmental units with approval authority  
24 over the release, and the persons registered pursuant to part  
25 4420.0060, subpart 2, of the allegations and proposed action.  
26 The permittee must be given at least ten days from receipt of  
27 the notice to prepare a response to the allegation and proposed  
28 action for presentation at the board meeting unless the  
29 permittee requests or agrees that the board meeting be held less  
30 than ten days after notification. However, the chair may  
31 determine that there is imminent and substantial danger to human  
32 health or the environment requiring immediate board action and  
33 call a special meeting of the board less than ten days after  
34 notification.

35 Subp. 3. **Emergency corrective action.** To assure an  
36 adequate response to an emergency, the chair may order



1 corrective action without following the procedures of subpart 2  
2 if the chair determines that the release constitutes a clear and  
3 immediate danger requiring immediate action to prevent,  
4 minimize, or mitigate damage to human health or the environment.

5       **Subp. 4. Contested case hearing.** The person or agency  
6 initiating the action or the permittee may request the board to  
7 hold a contested case hearing pursuant to Minnesota Statutes,  
8 sections 14.57 to 14.62, and the rules of the Office of  
9 Administrative Hearings, parts 1400.5100 to 1400.8402. The  
10 board must determine the need for a contested case hearing  
11 according to part 4420.0030, subpart 9.

12       **Subp. 5. Board action.** When the board makes a finding of  
13 subpart 1, item A, subitem (1), (2), or (3), it may take action  
14 to modify, suspend, or revoke the permit. The board may, at any  
15 time, consider suspension or termination of its action if the  
16 permittee has undertaken effective corrective or mitigative  
17 measures to correct the violations or potential problems.

18       **Subp. 6. Scope of suspension.** An action by the board to  
19 suspend a release permit must be limited to the following:

20           A. the determination of the corrective or mitigative  
21 measures necessary to correct the violations or potential  
22 problems; and

23           B. the time period necessary for the permittee to  
24 complete the required corrective or mitigative measures.

25       **Subp. 7. Scope of modification.** An action by the board to  
26 modify the release permit must be according to part 4420.0035  
27 and be limited to the addition or modification of conditions to  
28 provide mitigation or minimization of significant or material  
29 adverse impacts on human health or the environment.

30       **Subp. 8. Scope of revocation.** When the board finds any  
31 item of part 4420.0035, subpart 2, the board may revoke a  
32 release permit.

33 4420.0055 RELEASE PERMIT MODIFICATION REQUESTED BY PERMITTEE.

34       **Subpart 1. Initiation.** The permittee may request the  
35 board to modify the terms or conditions of the release permit on

1 or before the expiration date of the permit. The permittee must  
2 file a written request for modification that includes:

- 3           A. the modification to the terms or conditions;  
4           B. the purpose of the modification;  
5           C. the information necessary to evaluate the release  
6 with the modification pursuant to part 4420.0035;  
7           D. any potential change in the effects on human  
8 health and the environment that could result from the release  
9 with the modification; and  
10           E. the reasons for requesting the modification.

11           When the permittee files a request, the chair must place  
12 the matter on the agenda of the next regular meeting of the  
13 board or may call a special meeting of the board according to  
14 part 4405.0600 and subject to the notice requirements of subpart  
15 2 for consideration of an action to modify the release permit.

16           **Subp. 2. Notice.** The permittee must mail notice of the  
17 request for modification to persons who commented on the draft  
18 release permit documents, the mailing list of part 4420.0060,  
19 subpart 2, the governmental units with approval authority over  
20 the release, and the local governmental units within whose  
21 boundaries the release is permitted. The persons who commented  
22 on the draft release and local governmental units must be given  
23 at least ten working days from receipt of the notice to prepare  
24 a response to the requested modification for presentation at the  
25 board meeting. However, the chair may determine that there is  
26 imminent and substantial danger to human health or the  
27 environment requiring immediate board action and call a special  
28 meeting of the board or the persons who commented on the draft  
29 release permit documents and local governmental units may  
30 request or agree that the board meeting be held less than ten  
31 working days after notification.

32           **Subp 3. Board action.** If the board determines that the  
33 requested modification is in accordance with part 4420.0035, the  
34 board may approve the modification.

35 4420.0060 MAILING LISTS.

1 Subpart 1. **General mailing list.** A person who desires to  
2 receive copies of general public notices issued by the chair or  
3 board relating to this chapter and notices of application issued  
4 by an applicant shall submit to the chair a written request that  
5 the person's name and address be placed on a mailing list kept  
6 by the chair for the purpose of issuing general public notices.

7 Subp. 2. **Specific release mailing list.** A person who  
8 desires to receive copies of all public notices for a specific  
9 proposed or permitted release shall submit to the chair a  
10 written request that the person's name and address be placed on  
11 that specific mailing list kept by the chair for the purpose of  
12 issuing public notices on each specific proposed or permitted  
13 release.

14 4420.0070 CONTAINMENT FACILITIES.

15 Subpart 1. Certification. To certify a facility as a  
16 containment facility, the owner or operator of the facility or  
17 the institutional biosafety committee, as defined in the NIH  
18 guidelines, for the facility must file with the board a  
19 certification stating the level of biosafety maintained at the  
20 facility and certifying that the facility complies with the  
21 applicable NIH guidelines and that the level of biosafety  
22 maintained is appropriate for the genetically engineered  
23 organisms being used in the facility. The board shall forward  
24 the containment facility certification documents to agencies  
25 with a significant environmental permit for review within the  
26 agency's authority.

27 Subp. 2. Inspection. The board or an agency with  
28 authority to inspect may inspect the containment facility to  
29 determine if the facility and its operation comply with the  
30 certified level of biosafety and if the level of biosafety is  
31 appropriate for the genetically engineered organisms being  
32 used. If it is found that the facility does not comply with the  
33 certified level of biosafety or that the biosafety level is  
34 inappropriate for the genetically engineered organisms being  
35 used, the responsible person must be ordered to comply with the

1 guidelines or to cease using the genetically engineered organism  
2 or to file an application for a release permit or exemption.  
3 Reasonable and appropriate conditions may be placed on the use  
4 of the genetically engineered organism while an application for  
5 a release permit or exemption is pending.

6 Subp. 3. Exemption.

7 A. Any person proposing the use of a genetically  
8 engineered organism in a facility that does not meet the  
9 requirements of a containment facility, but provides adequate  
10 containment for the specific organism, may apply for an  
11 exemption from the requirement to obtain a release permit.

12 B. The proposer must file with the board a written  
13 request for exemption that includes:

14 (1) a description of the genetically engineered  
15 organism and its use;

16 (2) a description and location of the facility;

17 (3) the reasons why the facility provides  
18 adequate containment for the genetically engineered organism and  
19 its use;

20 (4) a list of governmental units with approval  
21 authority over the use of the facility; and

22 (5) any relevant submittals to the federal  
23 government.

24 C. Within five days of the filing, the chair must  
25 mail notice of the request to the local governmental units  
26 within whose jurisdiction the facility is located, governmental  
27 units with approval authority over the use of the facility, and  
28 the mailing list identified in part 4420.0060, subpart 1.

29 D. The board must grant or deny the exemption at its  
30 first regularly scheduled meeting after the request for  
31 exemption is filed, provided that the request is filed at least  
32 21 calendar days before that meeting.

33 E. If the board denies an exemption, the board must  
34 inform the proposer in writing of its reasons. The proposer may  
35 refile a revised request for exemption or may apply for a  
36 release permit.

1           F. The use of the genetically engineered organism  
2 allowed in an exemption granted under this subpart is exempt  
3 from environmental review for a release under chapter 4410.

4           Subp. 4. Facilities existing on the effective date of  
5 chapter. On the effective date of this chapter, any person who  
6 is using a genetically engineered organism in a containment  
7 facility, or in a facility that is not a containment facility  
8 and for which the person will seek an exemption, must file with  
9 the board, within 90 days, either the certification required  
10 under subpart 1 or the exemption request required under subpart  
11 3.

12 4420.0075 SIGNIFICANT ENVIRONMENTAL PERMIT.

13           Subpart 1. No board action. A release permit from the  
14 board is not required for a proposed release if a significant  
15 environmental permit is required for the release by another  
16 agency. With respect to any release issued a significant  
17 environmental permit by another agency, the board retains its  
18 statutory authorities as the state coordinating organization for  
19 state and federal regulatory activities relating to genetically  
20 engineered organisms.

21           Subp. 2. Request for finding of significant environmental  
22 permit. An agency or a proposer may request the board to find  
23 that a permit issued by an agency is a significant environmental  
24 permit for the release of certain genetically engineered  
25 organisms.

26           Subp. 3. Notice of finding consideration. Notice of  
27 regular or special board meetings considering the request for a  
28 finding of a significant environmental permit must include  
29 persons registered under part 4420.0060, subpart 1.

30           Subp. 4. Approval of request for finding of significant  
31 environmental permit. The board shall approve the request of an  
32 agency or proposer if the board finds that all of the following  
33 exist:

34           A. a requirement for an environmental assessment  
35 worksheet for the proposed release, and compliance with

1 Minnesota Statutes, chapter 116D, and rules adopted under it;

2 B. an evaluation of an application using an  
3 interdisciplinary approach that will ensure the integrated use  
4 of the natural and environmental sciences, including involvement  
5 of the following disciplines, as appropriate: microbiology,  
6 ecology, public health, biological safety, agronomy, plant  
7 biology, risk assessment, molecular biology, biochemistry,  
8 entomology, vertebrate biology, physical and biological  
9 containment, and other appropriate disciplines;

10 C. the authority to prescribe terms and/or place  
11 conditions on the permit, and the authority to deny, modify,  
12 suspend, or revoke the permit; and

13 D. considerations substantially the same or  
14 equivalent to those the board would apply under part 4420.0035,  
15 subpart 3, in determining whether to issue or deny a permit.

16 Subp. 5. Notice of finding. When the board finds that a  
17 permit is a significant environmental permit, the board shall  
18 publish notice of the finding in the EQB Monitor and the State  
19 Register.

20 4420.0080 EXEMPTION FOR OTHER AGENCY PERMITS.

21 Subpart 1. Exemption request. Any person or entity  
22 proposing a release requiring an agency permit may request an  
23 exemption from the board release permit. The proposer must file  
24 with the board a written request for exemption that includes the  
25 reasons the proposed release should be exempted from a release  
26 permit; a declaration that the laws, rules, and procedures  
27 applied in issuing the agency permit meet the requirements in  
28 subpart 2; and a copy of the application for the agency permit.

29 Subp. 2. Exemption standards. The board may exempt a  
30 release from a release permit if an agency permit is required  
31 and the board finds that the laws, rules, and procedures to be  
32 applied in the issuance of the permit include all of the  
33 following:

34 A. a requirement for an environmental assessment  
35 worksheet for the proposed release and compliance with Minnesota

1 Statutes, chapter 116D, and rules adopted under it;

2 B. an evaluation of the application using an  
 3 interdisciplinary approach that will ensure the integrated use  
 4 of the natural and environmental sciences, including involvement  
 5 of the following disciplines, as appropriate: microbiology,  
 6 ecology, public health, biological safety, agronomy, plant  
 7 biology, risk assessment, molecular biology, biochemistry,  
 8 entomology, vertebrate biology, physical and biological  
 9 containment, and other appropriate disciplines;

10 C. the authority or an agreement with the proposer  
 11 for the agency to place conditions on a permit to mitigate or  
 12 minimize the adverse impacts of the release on human health or  
 13 the environment and to provide the agency with information  
 14 adequate to monitor compliance with the permit; and

15 D. considerations for permit issuance or denial  
 16 substantially the same or equivalent to those listed in part  
 17 4420.0035, subpart 3.

18 Subp. 3. Board action. Notice of regular or special board  
 19 meetings considering an exemption must include persons  
 20 registered under part 4420.0060, subpart 1. The board must deny  
 21 or grant the exemption at its first regularly scheduled meeting  
 22 after the request for exemption is filed, provided that the  
 23 exemption is filed at least 21 calendar days before that meeting.

24 Subp. 4. Exemption revocation. The exemption must be  
 25 revoked if, prior to 20 days after the issuance of the other  
 26 agency permit, the board finds that the requirements of subpart  
 27 2 have not been met.

28 ~~4420-0070~~ 4420.0085 GENERAL RESPONSIBILITIES.

29 The board shall monitor the effectiveness of this chapter  
 30 and shall take appropriate measures to modify and improve the  
 31 effectiveness of this chapter. The board shall assist  
 32 governmental units and interested persons in understanding the  
 33 rules.