CHAPTER 4420
ENVIRONMENTAL QUALITY BOARD
GENETICALLY ENGINEERED ORGANISMS

4420.0010 DEFINITIONS.

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

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

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

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

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

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

Subp. 7. **Containment facility.** "Containment facility" means a laboratory, greenhouse, building, structure, or other similar facility that complies with applicable NIH guidelines, regardless of whether the facility receives any support from NIH, and is certified pursuant to part 4420.0070, subpart 1, or that has been exempted by the board under part 4420.0070, subpart 3.

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

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

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

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

Subp. 12. **Federal application.** "Federal application" means any applications or notifications and supporting documents submitted to any agency of the United States government for the release of a genetically engineered organism.

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

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

Subp. 15. **Genetic engineering.** "Genetic engineering" means the introduction of new genetic material to an organism or the regrouping of an organism's genes using techniques or technology designed by humans. Genetic engineering does not include selective breeding, hybridization, or nondirected mutagenesis, such as hand pollination, procedures based on sexual reproduction that have not involved molecular level manipulation of the genetic ma-

terial, hybridization where the parent strains do not include genetic material that has been manipulated on the molecular level, mutagenesis induced by chemical, radiation, or heat, embryo rescue, selection of spontaneous mutants, somaclonal variant selection, and artificial insemination.

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

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

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

Subp. 19. **Release.** "Release" means the placement or use of a genetically engineered organism outside a containment facility or under any other conditions not specifically determined by the board to be adequate containment pursuant to part 4420.0070, subpart 3.

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

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0015 AUTHORITY, SCOPE, PURPOSE.

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

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

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

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

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

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

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

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0020 APPLICABILITY OF RULES.

Subpart 1. **Release permit required.** A release permit is required for all releases of genetically engineered organisms except as provided in parts 4420.0070, subpart 3; 4420.0075; and 4420.0080, and Minnesota Statutes, section 116C.94, paragraph (c).

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

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

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

Subp. 5. **Use of genetically engineered organisms after August 3, 1992.** After August 3, 1992, any person who proposes to use a genetically engineered organism must comply with this chapter.

Subp. 6. **1992 exemption.** Any person who by July 1, 1992, has received a declaration of no potential for significant environmental effects from the Minnesota Department of Agriculture for a proposed release or who has had prepared an environmental assessment worksheet by the Minnesota Department of Agriculture for a proposed release need not comply with this chapter for the proposed release in calendar year 1992.

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0025 APPLICATION PROCEDURES AND REQUIREMENTS.

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

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

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

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

Subp. 3. **Notice of application acceptance.** Within 15 days of the application acceptance, the applicant must publish notice of application acceptance and availability in a newspaper of general circulation in the area where the release is proposed and mail notice to persons registered under part 4420.0060, subpart 1, and governmental units with approval authority over the release. The chair must publish the notice of application acceptance and availability in the EQB Monitor.

The notice must include:

A. identification of the applicant;

B. the date of acceptance;

C. a brief description of the proposed release including, but not limited to, size, type, and location;

D. availability of the application;

E. telephone number and address of the office of the chair; and

F. information on how a person can receive the trade secret deleted version of the application and all notices pertaining to this release.

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0030 RELEASE PERMIT PROCEDURES AND REQUIREMENTS.

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

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

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

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

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

A. the identification of the applicant;

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

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

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

E. locations where documents are available for public review;

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

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

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

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

A. mailed to the applicant;

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

C. to any interested person upon request.

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

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

Written comments shall include the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0035 BASIS FOR DECISION.

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

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

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

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

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

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

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

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

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

C. the potential for the genetically engineered organisms to cause adverse environmental effects including, but not limited to:

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

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

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

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

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

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

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

E. any previous risk assessment for the release of the same or similar organisms prepared by federal or state agencies and the risk assessment adequacy and relevance to the current proposal including, but not limited to:

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

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

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

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

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

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

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

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0040 GENETIC ENGINEERING ADVISORY COMMITTEE.

Subpart 1. **General.** The board or chair must provide guidance to the genetic engineering advisory committee in the form of a charge and through specific requests. No member of the advisory committee may receive the trade secret information contained in an application if that person is, or represents in any capacity, a person engaged in any business or enterprise in competition with the applicant or in which the trade secret information could be used for product development purposes. If an advisory committee member receives a copy of an application that contains information that has been determined to be trade secret information pursuant to Minnesota Statutes, chapter 13, that advisory committee member must treat that information as nonpublic data pursuant to Minnesota Statutes, chapter 13.

Subp. 2. **Release review.** The chair may direct the genetic engineering advisory committee to provide advice and comment about applications and of requests for exemptions and the preparation of draft release permit documents or any other aspect relating to a release pursuant to this chapter. The chair may appoint special members to the advisory committee to advise and comment on specific applications.

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0045 APPLICATION CONTENTS.

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

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

B. a title page and a table of contents;

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

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

E. a description of the proposed release including:

(1) location;

(2) use and purpose;

(3) release date and duration of release;

(4) the information necessary to evaluate the proposed release using the considerations identified in part 4420.0035, subpart 3; and

(5) any other information relevant to the release requested by the chair;

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

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

Subp. 2. **Trade secret information.** An applicant shall identify in the application any information that the applicant believes is trade secret information which should not be made available to the public. The applicant has the burden to establish that the information in question qualifies as trade secret information. In the event the chair disagrees with the applicant, the chair shall notify the applicant of the chair's decision at least five working days prior to making the information public. The applicant may withdraw the application or seek judicial recourse.

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

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

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

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

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

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

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

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

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

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

Subp. 3. **Emergency corrective action.** To assure an adequate response to an emergency, the chair may order corrective action without following the procedures of subpart 2 if the

chair determines that the release constitutes a clear and immediate danger requiring immediate action to prevent, minimize, or mitigate damage to human health or the environment.

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

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

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

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

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

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

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0055 RELEASE PERMIT MODIFICATION REQUESTED BY PERMITTEE.

Subpart 1. **Initiation.** The permittee may request the board to modify the terms or conditions of the release permit on or before the expiration date of the permit. The permittee must file a written request for modification that includes:

A. the modification to the terms or conditions;

B. the purpose of the modification;

C. the information necessary to evaluate the release with the modification pursuant to part 4420.0035;

D. any potential change in the effects on human health and the environment that could result from the release with the modification; and

E. the reasons for requesting the modification.

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

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

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0060 MAILING LISTS.

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

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0070 CONTAINMENT FACILITIES.

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

Subp. 2. **Inspection.** The board or an agency with authority to inspect may inspect the containment facility to determine if the facility and its operation comply with the certified level of biosafety and if the level of biosafety is appropriate for the genetically engineered organisms being used. If it is found that the facility does not comply with the certified level of biosafety or that the biosafety level is inappropriate for the genetically engineered organisms being used, the responsible person must be ordered to comply with the guidelines or to cease using the genetically engineered organism or to file an application for a release permit or exemption. Reasonable and appropriate conditions may be placed on the use of the genetically engineered organism while an application for a release permit or exemption is pending.

Subp. 3. **Exemption.**

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

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

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

(2) a description and location of the facility;

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

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

(5) any relevant submittals to the federal government.

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

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

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

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

Subp. 4. **Facilities existing on August 3, 1992.** On August 3, 1992, any person who is using a genetically engineered organism in a containment facility, or in a facility that is not a containment facility and for which the person will seek an exemption, must file with the board, within 90 days, either the certification required under subpart 1 or the exemption request required under subpart 3.

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0075 SIGNIFICANT ENVIRONMENTAL PERMIT.

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

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

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

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

A. a requirement for an environmental assessment worksheet for the proposed release, and compliance with Minnesota Statutes, chapter 116D, and rules adopted under it;

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

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

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

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0080 EXEMPTION FOR OTHER AGENCY PERMITS.

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

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

A. a requirement for an environmental assessment worksheet for the proposed release and compliance with Minnesota Statutes, chapter 116D, and rules adopted under it;

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

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

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

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

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4420.0085 GENERAL RESPONSIBILITIES.

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

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*