8/26/91

MINNESOTA ENVIRONMENTAL QUALITY BOARD
300 Centennial Building · 658 Cedar Street · St. Paul, Minnesota 55155
612-296-2603

Proposed Permanent Rules Relating to the Release of Genetically Engineered Organisms into the Environment

Notice of Intent to Adopt Rules With a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Environmental Quality Board (Board) intends to adopt the above-referenced rules with a public hearing following the procedures set forth in the Administrative Procedures Act for adopting rules pursuant to Minnesota Statutes, sections 14.131 to 14.20 (1990), on September 27, in room 301 of the Centennial Building, 658 Cedar Street, St. Paul, Minnesota, commencing at 9:00 a.m. Additional days may be scheduled as needed. All interested or affected persons will have an opportunity to participate, and may present their views either orally at the hearing or in writing at any time prior to the close of the hearing record. All evidence submitted should be pertinent to the matter at hand.

Written material not submitted at the time of the hearing which is to be included in the hearing record may be mailed to Allen E. Giles, Administrative Law Judge, Office of Administrative Hearings, 500 Flour Exchange Building, 310 Fourth Avenue South, Minneapolis, Minnesota, 55415, telephone 612/349-2543, either before or within five days after the hearing ends. The Administrative Law Judge may, at the hearing, order the record kept open for a longer period not to exceed 20 calendar days. Written material received during this period will be available for review at the Office of Administrative Hearings. After the close of the comment period, the EQB and interested persons have three business days to respond in writing to any new information submitted during the comment period. No additional evidence may be submitted during the three-day period. This rule hearing procedure is governed by Minnesota Statutes, sections 14.131 to 14.20 (1986) and by Minnesota Rules, parts 1400.0200 to 1400.1200. Questions about procedures may be directed to the Administrative Law Judge.

The proposed permanent rules would regulate the placement or use of a genetically engineered organism outside a containment facility. The proposed rules contain amendments to the Board's environmental review rules chapter 4410 and new rules perscribing the circumstances, procedures, and conditions by which environmental review and the issuance of a permit for the release of a genetically engineered organism must be conducted.

The proposed rules are authorized by Minnesota Statutes, section 116C.94. A free copy of the proposed rules may be obtained by writing or telephoning: John P. Hynes, Environmental Quality Board, 300 Centennial Office Building, 658 Cedar Street, St. Paul, MN 55155, telephone 612/296-2871.

The proposed rules may be modified as a result of the rule hearing process if the modifications do not result in a substantial change in the proposed rules as noticed. Those who are potentially affected by the substance of the proposed rules are therefore advised and encouraged to participate in the process.

Notice is hereby given that a statement of need and reasonableness is available for review at the EQB offices and at the Office of Administrative Hearings. This document describes the need for and

reasonableness of each proposed rule and identifies the information relied upon to support the proposed rules. Copies may be obtained from the Office of Administrative Hearings at the cost of reproduction.

The proposed rules will not require the expenditure of public money by local public bodies, therefore the requirements of Minnesota Statutes, section 14.11, subdivision 1, do not apply.

The proposed rules will not have a direct and substantial impact on agricultural land in the state, therefore the requirements of Minnesota Statutes, sections 17.80 to 17.84 do not apply.

The proposed rules will not have a direct impact on small businesses, therefore the requirements of Minnesota Statutes, section 14.115 (1986) do not apply.

Please note that any person may request notification of the date on which the Administrative Law Judge's report will be available, after which date the EQB may not take any final action on the proposed rules for a period of five business days. If you wish to be so notified, you may do so at the hearing. After the hearing, you may request notification by writing to the Administrative Law Judge.

Any person may request notification of the date on which the proposed rules were adopted and filed with the Secretary of State. The notice will be mailed to any person requesting this notice on the same day the rule is filed. If you wish to be so notified, you may so indicate at the hearing or send a written request to the EQB at any time prior to the filing of the rule with the Secretary of State.

Minnesota Statutes, Chapter 10A requires each lobbyist to register with the State Ethical Practices Board with five days after he or she commences lobbying. A lobbyist is defined in Minnesota Statutes, section 10A.01, subd. 11 as any individual:

(a) Engaged for pay or other consideration, or authorized by another individual or association to spend money, who spends more than five hours in any given month or more that $250.00, not including his own travel expenses and membership dues, in any year for the purpose of attempting to influence legislation or administrative action by communicating or urging others to communicate with public officials; or

(b) Who spends more that $250.00 not including his own travel expenses and membership dues, in any year for the purpose of attempting to influence legislation or administrative action by communicating or urging others to communicate with public officials.

The statute provides certain exceptions. Questions should be directed to the Ethical Practices Board, 41 State Office Building, St. Paul, Minnesota, 55155, telephone (612) 296-5615.

Date

Robert Dunn, Chair

STATE OF MINNESOTA
COUNTY OF RAMSEY

MINNESOTA ENVIRONMENTAL
QUALITY BOARD

In the Matter of the Proposed Permanent Rules Relating to Release of Genetically Engineered Organisms

STATEMENT OF NEED AND REASONABLENESS

I. INTRODUCTION

In 1987, the Environmental Quality Board (board) solicited public opinion on changes to the environmental review program. Several commentators asked that mandatory review categories for biotechnology products be established. Their primary concern was the release into the environment of organisms or products developed through genetic engineering techniques.

Genetic engineering is a relatively new, powerful tool for modifying the genetic material of living organisms. Some view it as a technique that will lead to major improvements in medicine, agriculture, and industry. Others view it as a major threat to all parts of the environment and to existing social and economic structures. As with nuclear energy, the potential environmental effects are enormous if proper precautions are not taken.

The National Institutes of Health has developed strict rules for laboratory experiments funded by the federal government. Industry has voluntarily used these rules as guidelines for its laboratory research.

Federal regulation of releases of genetically engineered organisms into the environment is administered by various agencies under the authority of a number of different laws. None of the laws were written specifically to regulate releases of genetically engineered organisms. In spite of the involvement of multiple agencies, there are major gaps in the federal regulation.

Over the last three years, the board appointed a series of three committees, a 1987 work group, a 1988 task force, and a 1989-90 advisory committee, to advise the board on this issue and each has further developed recommendations on the state's role. The 1988 task force reported to the board in February 1989. The task force stated that:

> *Minnesota must have the opportunity to require and review information on any environmentally relevant genetically engineered organisms; and*
>
> *Minnesota must maintain and establish adequate authority to prohibit projects where there are significant questions about public health or environmental safety.*

The task force's primary recommendations were that:

- The board be designated the coordinating agency for Minnesota state regulatory activities relating to genetically engineered organisms;
- An environmental assessment worksheet be required for any proposed release;
- Minnesota establish a permitting system under the board for all releases;
- An advisory committee be established to provide advice on both general issues of genetic engineering and on issues of specific proposals; and
- Minnesota be proactive in developing and obtaining the knowledge base needed for meaningful regulation.

In response to the task force report, the 1989 Minnesota legislature enacted an amendment to the Environmental Quality Board Statute (Minnesota Statutes, §§ 116C.91 through 116C.95) which requires: 1) a permit for the release of genetically engineered organisms into the environment; 2) an environmental assessment worksheet (EAW) for all such releases in Minnesota; and directs the board to adopt rules to give effect to these requirements.

Rulemaking was initiated on July 31, 1989 with the publication of Notice of Intent to Solicit Outside Opinion in the State Register. To provide additional means of receiving outside opinions, an advisory committee, as required by Minn. Stat. § 116C.93, was appointed on September 12, 1989. During the committee process oral or written comments were received from members of the public.

The board Advisory Committee on Genetically Engineered Organisms was appointed on September 12, 1989 after solicitation of applications through the Secretary of State's Open Application Process and after a notice of vacancies published in the State Register on July 31, 1989.

The advisory committee included members from industry, public interest and environmental groups, the academic community, state agencies, and the general public. It held nine meetings between October 1989 and September 1990, reviewed information from a number of sources including the National Academy of Sciences, the Ecology Society of America, the American Fisheries Society, and the Congressional Office of Technology Assessment.

The Genetic Engineering Advisory Committee determined that 120 days was a reasonable compromise between enough time to process a relatively non-controversial permit, i.e. one that did not require a contested case hearing or an environmental impact statement and yet be timely for the proposer of a release. Many permit requests will be for releases to be initiated in the spring of the year at the start of a growing season and the results will not be known until after harvest in the fall. The results would need to be analyzed before a new application for a release the next spring could be prepared. If the release should be done in May the application must be made in January. The usual permitting schedule of the U.S. Department of Agriculture for the release of genetically engineered organisms is also 120 days.

The advisory committee reviewed and debated other substantive parts of the proposed rules, such as the considerations contained in Part 4420.0035 Subpart 3, and has provided useful suggestions for improvement throughout the rule development. The committee provided the board with its report in the form of draft rules dated October 1, 1990 and in an oral report at a board meeting. On December 20, 1990, the board authorized the Chair to order a hearing for the purpose of adopting rules.

The 1991 Legislature gave the Department of Agriculture the authority and responsibility to issue a permit for the release into the environment of genetically engineered plants, fertilizers, pesticides, plant amendments, and soil amendments. The Legislature also clarified that the board has the authority to place conditions on a permit and to deny, modify, suspend, or revoke a permit, defined a "significant environmental permit", provided for reimbursement by the proposer of a release of the necessary and reasonable costs of processing exemptions or applications. (See Attachment A)

As a result of the 1991 legislation, the Department of Agriculture proposed several amendments to the draft rules. The Committee met on July 2, 1991, reviewed the amendments and suggested some changes to which the Department agreed. On July 18, 1991 the board approved the amendments. On August 9, 1991, the Chair ordered the hearing to be held on September 27, 1991. Notice was published in the State Register on August 26, 1991.

II. STATEMENT OF BOARD'S AUTHORITY

Minn. Stat. § 116C.94 establishes the board's authority to adopt rules requiring a permit for the release of genetically engineered organisms and an Environmental Assessment Worksheet (EAW). The board's rule making authority for environmental review is in Minn. Stat. § 116D.04.

III. STATEMENT OF NEED AND REASONABLENESS
GENERAL COMMENTS

Minnesota Statutes, chapter 14 [ADMINISTRATIVE PROCEDURE] (1990) requires the board to make an affirmative presentation of facts establishing the need for and reasonableness of the rules as proposed for adoption. In general terms, this means that the board must set forth the reasons for its proposal, and the reasons must not be arbitrary or capricious. To the extent that need and reasonableness are separate tests, "need" means identification of the problem requiring administrative attention and "reasonableness" means that the solution proposed by the board has a rational basis underlying the specific solutions proposed to remedy the identified problem.

The proposed rules for the release of genetically engineered organisms are contained in proposed chapter 4420. The EAW requirements for the release of genetically engineered organisms will be included as modifications to chapter 4410. This statement of need and reasonableness discusses both.

The statement of need and reasonableness and the proposed rules are two separate documents, which must be read together. The part and subpart identification numbers in the statement of need and reasonableness correspond to part and subpart identification numbers in the proposed rules.

IV. STATEMENT OF NEED AND REASONABLENESS
CHAPTER 4420
ENVIRONMENTAL QUALITY BOARD RULES
PERTAINING TO PERMITTING THE RELEASE OF GENETICALLY ENGINEERED ORGANISMS

These rules are needed to provide an orderly and timely permitting process for the release of genetically engineered organisms. The Chapter contains the following parts:

4420.0010	Definitions	4420.0015	Authority, Scope, Objectives
4420.0020	Applicability	4420.0025	Application Procedures and Requirements
4420.0030	Release Permit Procedures and Requirements	4420.0035	Basis for Decision
4420.0040	Advisory Committee	4420.0045	Application Contents
4420.0050	Permit Modification, Suspension, and Revocation Not Initiated by the Permittee	4420.0055	Permit Modification Initiated by the Permittee
4420.0060	Mailing List	4420.0070	General Responsibilities

The proposed rules establish a process with the following steps:

14 days	Application acceptance or rejection, 4420.0025 subp. 2;
45 days	Preparation of draft release permit documents, 4420.0030 subp. 3 and preparation of the Environmental Assessment Worksheet, 4410.4300 subp. 35 and 4410.8000 subp. 1A.
30 days	Comment period on the draft release permit documents, 4420.0030 subp. 6 and for the EAW 4410.1600; and
30 days	board decision on the potential for significant environmental effect, 4410.1700 and 4410.8000 subp. 1C, on the need for a contested case hearing, 4420.0030 subp. 10, and on the issuance of a permit, 4420.0035.

Total time for the process is 119 days. If a contested case hearing is necessary or if an environmental impact statement is ordered then the board decision is delayed until after the report of the administrative law judge or the final EIS is issued.

4420.0010 DEFINITIONS.

The definitions in part 4415.0010 are needed to clarify reference to specific terms in the proposed rules. Some of the definitions are taken from Minn. Stat. § 116C.91 [Definitions], others correspond to the definitions provided in the environmental review rules and the board's operating rules. Where possible these definitions are incorporated by reference. Technical definitions are primarily based on federal genetic engineering regulations and on reports by the National Academy of Science. The use of existing definitions when possible provides for consistency among all regulations that apply to genetic engineering releases.

The following definitions are needed so that one word or a short phrase can be used throughout the chapter to identify a person, organization, or thing. Their reasonableness is obvious and no further comment will be made:

Subp. 1. Scope.
Subp. 2. Agency.
Subp. 3. Applicant.
Subp. 4. Application.
Subp. 5. Board.
Subp. 6. Chair.
Subp. 8. Draft release permit documents.
Subp. 9. EAW.
Subp. 10. EIS.
Subp. 16. Genetic engineering advisory committee.
Subp. 17. Local governmental unit.

The need and reasonableness for the remaining definitions are as follows:

Subp. 7. Containment facility.

Minn. Stat. § 116C.91 Subd. 6 defines a "release" as the placement or use of a genetically engineered organism outside a contained facility. The statute is silent on the definition of a contained facility. The definition of a containment facility in needed to determine if a release is occurring or being proposed and thus if a permit is needed or not.

The definition proposes two standards for containment. The first is compliance with the National Institutes of Health (NIH) guidelines and a self certification to the board that the facility is in compliance. The second is a finding by the board that a facility provides adequate containment.

The standards are reasonable because the NIH guidelines are required for research using federal funds and because the industry also follows these guidelines when federal funds are not being used. The second part allows for exceptions on a case by case basis.

Subp. 11. Environment.

The definition of environment used here is the same as used in the Environmental Review (ER) rules, 4410.0200 Subp. 23. It is repeated here to assist the public in understanding the rule.

Subp. 12. Federal application.

This definition is needed to identify the federal documents requested in several parts of the rule. It is reasonable because it restricts the documents to those relating to the release of genetically engineered organisms and minimizes duplication.

Subp. 13. File.

This definition is needed to identify the point in time when any applicant initiates an action requiring board action. An application must be received at the board office before it is considered filed. In several cases within the chapter, filing starts a limited time period. Five copies are needed for review.

Subp. 14. Genetically engineered organism.

This term is defined in the enabling legislation at Minn. Stat. § 116C.91 Subd. 4. and is a combination of genetic engineering and organism as defined by Minn. Stat. § 116C.91 Subds. 3 and 5. This term is used frequently and is repeated for the purpose of assisting the public in understanding these rules.

Subp. 15. Genetic engineering.

This term is defined in Minn. Stat. § 116C.91 Subd. 3. and is repeated here for the purpose of assisting the public in understanding what genetic engineering is and what it is not. Examples of selective breeding, hybridization, or nondirected mutagenesis are included to clarify what techniques are not considered genetic engineering.

Subp. 18. Organism.

This term is defined in Minn. Stat. § 116C.91 Subd. 5. and is essential to other rule definitions used throughout the rules. It is repeated here for assisting the public in understanding these rules.

Subp. 19. Release.

This term is defined in Minn. Stat. § 116C.91 Subd. 6. and is essential to other rule definitions used throughout the rules. It is repeated here for assisting the public in understanding these rules.

Subp. 20. Release permit.

This term is necessary as the release permit is the document issued by the board authorizing the release of a genetically engineered organism. This document also details the terms and conditions of the permit.

Subp. 21. Significant environmental permit.

The 1991 Legislature has defined this term (Minn. Stat. § 116C.91 Subd. 7. See attachment A.) The term is repeated in the rules for the purpose of assisting the public in understanding the Legislature's standards for exempting a release from the board's permit when the release is subject to another agencies permit.

4420.0015 AUTHORITY, SCOPE, PURPOSE

This part provides reference and introductory statements that address the need for a permit to release genetically organisms into the environment. Subparts 1. through 4. are comprised of statements which are treated in additional detail within the rules.

It is legislative intent to exercise state jurisdiction in protecting human health and the environment from any significant or material adverse impacts that could result from the release of genetically engineered organisms. Therefore, it is necessary to establish a prudent and orderly review procedure prior to authorizing the release of genetically engineered organisms.

This chapter also insures that an open, public review process is available to all governmental units and the general public.

4420.0020 APPLICABILITY OF RULES.

Part 4415.0020 describes under what conditions a release permit from the board is required and exceptions to these requirements.

Subpart 1. Release permit required. This part reflects the specific intent of Minn. Stat. § 116C.94 to require a board permit for all releases with certain specific exceptions. This language is necessary to provide clarification regarding applicability of the rules. It also requires certain minimum notice for board meetings considering exemptions.

Subp. 2. Exemption for a significant environmental permit.
Subp. 3. Exemption for other agency permits.

Minn. Stat. § 116C.94 states that "The rules shall provide that a permit from the board is not required if the proposer can demonstrate to the board that a significant environmental permit is required for the proposal by another state agency." Minn. Stat. § 116C.91 Subdivision 7, which was added by the 1990 Legislature, defines a significant environmental permit as "a permit issued by a state agency with the authority to deny, modify, revoke, or place conditions on the permit in compliance with the requirements of sections 116C.91 to 116C.96, chapter 116D, and the rules adopted under them."

Subpart 2 establishes the necessary and reasonable procedures and standards to determine if a permit required by another state agency for a release is a significant environmental permit and what the applicant must do to be exempt from the board's permit.

Item B. requires the board to identify agency permits that would be considered significant environmental permits. It also allows an agency to request the board to find that a permit is a significant environmental permit.

Item C. requires that the board find a permit a significant environmental permit when it meets four criteria. The criteria are environmental review, evaluation of the application using an interdisciplinary approach, full authority over the permit, and inclusion of the considerations contained in part 4420.0035, subpart 3 in the issuance or denial of the permit. The Advisory Committee discussed these criteria and others at considerable length. They found that these four embodied the safeguards necessary to protect human health and the environment.

Item D. requires publication of the list of significant environmental permits. This is necessary to inform those proposing a release and reasonable in that the board Monitor and the State Register are commonly known sources of regulatory information.

Subpart 3 is necessary to reduce duplication of efforts when another agency permit is required for the release and the permit is not on the list of significant environmental permits, but, under which permit, full review could take place. This is intended to be used on a case by case basis where an agency's laws and rules do not meet the criteria of subp. 2, but the applicant and agency agree to meet the equivalent criteria in item B. It also provides oversight of the procedures by the board and the standard and time limits for revocation of the exemption.

Exemptions from the board's permit under both subparts 2 and 3 are not exempt from environmental review under chapter 4410.

Subp. 4. Exemption for use in a facility not a containment facility.

The use of a genetically engineered organism in a facility other than a containment facility is considered a release and requires a release permit unless exempted under this part. Minn. Stat. § 116C.91 Subd. 6. provides the board with authority to determine adequate containment. The definition of containment facility requires compliance with the National Institutes of Health "Guidelines for Research involving Recombinant DNA Molecules" and certification under 4420.0020 subp. 5 or a finding of adequate containment by the board.

It is conceivable that there may be facilities that do not meet the NIH guidelines yet the facility may provide adequate containment for specific organisms under the specific conditions provided by the facility. Requiring a board release permit could be considered unnecessary regulation. This part provides an exemption process for such a situation.

The part includes requirements with which the proposer must comply, the notice required, and time allowed for the board to take action on the request are included. When an exemption is denied the board must notify the proposer in writing of its reasons for denying the exemption. The proposer may file a revised request for exemption or a release permit. When an exemption is obtained, environmental review of the use of the genetically engineered organism in the facility is not required.

Subp. 5. Containment facility certification.

This subpart is necessary to determine which uses of genetically engineered organisms are releases and which are not. Minn. Stat. § 116C.91 Subd. 6 and Part 4400.0020 subp. 7 provide the authority and the definition for the determination of a release.

This subpart provides a reasonable process for an initial self certification, the authorization of the board to inspect a facility to determine compliance, and the options the board may use to correct violations.

The self certification is reasonable because most researchers are aware of and comply with the NIH standards and many containment facilities have been inspected by a federal agency. In many of these inspections a state agency has accompanied the federal agency. Duplication of these inspections is unnecessary. However, if it is alleged that a facility is being operated in violation of the NIH guidelines the rule provides the board with the authority to inspect for violations and the options to correct the violations.

4420.0025 APPLICATION PROCEDURES AND REQUIREMENTS.

Part 4420.0025 sets forth the procedures and requirements to initiate the request for a release permit. It includes subparts addressing the application form, application acceptance, notice of application, and application distribution. These are needed to initiate an orderly and timely review process.

Subp. 1. Application form.

Because the field of biotechnology is evolving rapidly, the form the application should take is also evolving. The rule simply requires that the application be filed in a form approved by the chair and that it contain the information required in part 4420.0045 [Application Content]. This allows potential applicants and staff the opportunity to improve the form as needed.

Subp. 2. Application acceptance.

In order to complete the processing of the application within the time requirements established in subsequent parts the application must contain adequate information. The time allowed for review and processing does not begin until the chair formally accepts the application under part 4420.0025. This rule provides for rejection of the application if it 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 environmental assessment worksheet. Fourteen days are allowed to review the adequacy of the application.

If the application is rejected, the applicant must be informed of the deficiencies in writing so they can be corrected. The rule also provides an appeal process to the board after a second rejection.

The rule also recognizes that even after acceptance there may be additional information necessary to process the application and requires the applicant to provide, in a timely manner, any additional information the chair considers necessary to process the application. This is reasonable because the review for acceptance may not be as thorough as the evaluation which occurs after acceptance.

Subp. 3 Notice of application acceptance.

This subpart provides for public notice when an application is accepted by the chair. This first notice includes a notice published in the board Monitor and in a newspaper in the area where the release is proposed and mailed notice to persons on the general mailing list maintained by the chair for this purpose. Notice requirements are needed to clearly identify what the chair and what the applicant must do to assure timely and reasonable public awareness of the review process.

It is reasonable that the newspaper notice and the mailed notice of application acceptance is a requirement placed on the applicant because it is to the applicant's advantage that the staff use its limited time for review of the application and preparation of a an EAW and draft release permit.

The published notice is intended to conform with Minn. Stat. § 645.11, Published Notice, and Minn. Stat. § 331A, Newspapers. This requirement is also found in the board's pipeline routing rules (chapter 4415).

The fourteen day period is reasonable to allow for publication requirements of weekly newspapers. The information requirements for the notice are simple and necessary to assure public awareness.

It is reasonable for the Chair to publish the notice in the Monitor because the Monitor is the publication of the board for such notices.

Subp. 4 Application distribution.

The application distribution requirements are needed to clearly identify the places where members of the public can review or obtain a copy of the application thus allowing full public participation. The proposed distribution requirements are reasonable for full public participation and are consistent with the requirements of other rules administered by the board. The application distribution requirement is placed on the applicant to expedite distribution and minimize expenditure of public funds. Since the application is prepared by the applicant, the applicant has the master copy to make whatever additional copies are necessary. It is also reasonable to require the applicant to provide additional copies to the Chair so that timely review may take place and so that the public can obtain copies from the Chair.

4420.0030 RELEASE PERMIT PROCEDURES AND REQUIREMENTS.

This part details release permit procedures the board must follow in making a determination on whether to grant or deny a release permit.

Subpart 1. Scope of release permit conditions.

This part is needed to outline the board's authority to impose conditions on a release permit. The conditions are limited to: mitigating or minimizing the adverse impact of the release on human health or the environment; providing information necessary for monitoring compliance; and providing information for analysis relating to subsequent release applications. Many early applications will be for experimental releases to the environment and as a result of these experiments other experiments will be designed that may require additional release permits. There may be information that could be collected on the early releases that could affect the issuance of subsequent applications. This part allows the board to collect the information necessary to fully evaluate subsequent applications.

Subp. 2. Evaluation and preparation.

This subpart requires an interdisciplinary approach in the review of the application and preparation of the release permit documents. It is needed to indicate to the public the type of review that can be expected. It is reasonable because the complexity of the release of a genetically engineered organism into the environment requires the background information from many disciplines to thoroughly review the proposed release.

Subp. 3. Draft release permit documents.

This subpart specifies that the chair will prepare and distribute the draft release documents within 45 days of application acceptance, that notice will be published in the board Monitor and identifies who the draft release permit will be distributed to.

This subpart also states under what conditions the board may delay, for up to an additional 30 days, the preparation and notice of the draft permit. This part is needed to assure that additional time is available when warranted by special circumstances. The conditions include:

If the application is for a release on multiple sites or for multiple years; or

If the application is for multiple organisms, each having different ecological impacts; or

If the board determines that more time is needed because of the complexity of the application.

Subp. 4. Notice content.

Identifies the minimum information which will be included in notice of the draft release documents. Notice requirements are needed to clearly identify the information necessary to assure public awareness.

Subp. 5. Notice distribution.

Identifies persons that will receive a copy of the notice of the draft release documents. Included is the applicant, persons who registered their names on the mailing list pursuant to part 4420.0060 subp. 1. and any interested person on request. This notice is provided by the board.

Subp. 6. Comment period.

Provides a 30 day period for review and comment on the draft release permit and establishes the day of notice publication in the board Monitor as the starting day. This is necessary to prevent unnecessary delay in the review process and to insure that comments are provided in a timely manner in the decision making process. Comments not received within the 30 day comment period need not be considered by the board. However, this does not preclude the board from considering the comments if they wish to do so. All comments received by the board within the 30 day comment period must be considered by the board.

Subp. 7. Comments.

Provides guidance for providing written comments that will assist the board in making their determination on the permit. The purpose of this subpart is to focus attention on matters that are of critical importance. If the rules were to provide no guidance, persons interested in commenting may not know what sort of comments would be appropriate or useful to the board. Also requested, is information relating to the person's interest in the application, a statement of action that they want the board to take, the reasons supporting the person's position and the need for a contested case hearing.

Subp. 8. Public meetings.

This subpart is necessary to indicate that public meetings may be held if the chair determines that it would be useful or helpful. As written the requirement for a meeting is discretionary rather than mandatory. On all initial applications the board may hold public meeting if they will be useful to the board. However, after processing a number of applications, it is anticipated that certain applications will generate little or no public interest. When that is the case, it is not reasonable to hold a public information meeting.

When a public meeting is held, published notice will be provided and notice mailed to persons on the mailing list in accordance with 4420.0060 subp. 2. This noticing requirement is reasonable and consistent with the requirements of other rules administered by the board.

Subp. 9. Contested case hearing.

This subpart requires the board to hold a contested case hearing when it finds that all of the conditions in Sub. 9. A. subitems 1 through 3. have been met; prescribes the notice content requirements in item B.; and distribution of the notice in item C. These requirements are necessary to determine when a contested case hearing should be held. The notice content and distribution requirements also insure that all affected or interested persons will be notified.

Item A. specifies that the board must hold a contested case hearing when it finds that all conditions have been met. The subitems in A. identify specific standards, relating to material issue of fact or of application of law to fact, jurisdiction, and a reasonable basis, that must be met. The subitems are reasonable and provide guidance to the board and to the public.

Item B. specifies the contested case notice requirements. The subitems are clear and direct and comport with other program notice requirements administered by the board.

Item C. specifies that the requirements of notice, distribution and conduct of the hearing are governed by other statutes and rules.

Subp. 10. Release permit action.

This subpart provides the board 30 days after the close of the comment period to respond to the comments, review the record and make a decision unless a contested case hearing or the preparation of an EIS is ordered.

4420.0035 BASIS FOR DECISION.

This part is needed to provide standards and considerations that the board must consider in making a decision regarding the release of genetically engineered organisms. This part is necessary and reasonable in rendering a decision and provides the board with a basis for making decisions.

Subpart 1. Criteria for issuing a release permit.

This subpart contains the standards needed to determine when the board must issue a release permit or modify a release permit. The standard requires compliance or anticipates compliance with the conditions of the release permit and all applicable board rules and Minnesota Statutes. These standards have been used in other rules and are considered reasonable.

Subp. 2. Criteria for denying or revoking a release permit.

This subpart contains the standards which constitute justification to deny or revoke a release permit. A positive finding by the board with respect to:

i) non-compliance with the permit or law;
ii) failure to disclose all facts or submitting false information;
iii) significant adverse effects caused by the release; or
vi) non-fulfillment of the statutory provisions and rules promulgated under Minn. Stat. § 116D;

are grounds for release permit denial or revocation. These standards provide the board with a reasonable means to assure compliance with the law and allows the board to protect the general public interest. These standards have been used in other rules.

Subp. 3. Considerations.

This part contains the special considerations relating to genetically engineered organisms, which the board will evaluate in determining if a release permit should be issued or modified and in specifying the conditions for issuance or modification or if a release permit should be denied or revoked.

A report providing guidance was written by the National Academy of Sciences in 1989 at the request of the federal regulatory agencies. Other professional scientific organizations have also developed guidance documents for federal regulators. Addressing these considerations in rule insures that decisions are made in a consistent manner and based on scientific factors.

The considerations in this subpart were developed by the board's 1989-90 Advisory Committee on Genetically Engineered Organisms. The committee reviewed the 1988 report of the National Academy of Sciences. This report includes recommendations on consideration for releases of genetically engineered organisms related to familiarity with the organism, degree of control of the release, and potential effects of the release. The committee also reviewed the 1988 report of the Ecological Society of America that includes a list of factors to be considered and a 1990 report of the American Fisheries Society that outlined types of ecosystem impacts. The committee developed the list of considerations proposed for inclusion in this subpart, taking into account the recommendations of both reports and their own expertise.

Items A. & B. both relate to the familiarity and predictability of the genetically engineered organism. In applying consideration A., the more familiar and predictable the donor organism, the recipient organism, and the final product is, the less likely it is that the release will cause unexpected effects. Item B. relates to the most direct evidence of familiarity and predictability possible--previous experience with the engineered organism in other environmental uses and the observed effect of those experiences.

Item C. relates to the methods of predicting potential adverse effect of a proposed release.

Subitem 1. Whether the recipient organism is native or non-native to the release area will affect potential risk. If it is non-native, it may have less natural enemies, could result in uncontrolled spread (for example, non-engineered introduced species such as purple loosestrife, kudzu, Eurasian Watermillfoil) and increase the potential risk of an adverse effect. If it is a non-native that can not survive in the local climate, the risk would be lower. The latter would not be true if the engineering of the non-native organism improved its survivability in the local climate.

Subitem 2. There is an increased risk if the pathogenicity or toxicity of the engineered organism to other organisms in the release area is altered. If it is increased the other organisms may not survive. If it is decreased the other organisms may spread.

Subitem 3. There is an increased risk of disrupting existing interactions among local organisms if the ability of the engineered organism to compete with other organisms, survive environmental stress, or disperse in the environment is altered. Such disruptions might threaten the survival of environmentally and economically important species.

Subitem 4. There is a risk if genetic engineering has altered the organism's resource base (e.g., increased or decreased the types of "food" it can use). If the resource base is increased the organism could have an advantage over other non-engineered organisms and take over an environmental niche or expand its range. If the resource base is decreased the existing interactions among local organisms may be disrupted, which might threaten the survival of environmental and economically important species.

Subitem 5. If the engineered genes can again easily transfer to another organism during the field release, this could result in changes in the competitiveness or survivability of the other organism and would increase the risks of the field release.

Subitem 6. If the genetically engineered organism can enter or adversely affect the groundwater environment or if unusual genes could enter that environment, specific review of potential effects on the groundwater would be warranted, because it would be difficult or even impossible to eradicate unwanted organisms from groundwater.

Item D. relates directly to the plans for confinement of the genetically engineered organism to the release site. The potential risks increase with the increased likelihood that the organism could spread beyond the test site.

Item E. Considers any previous risk assessments on the same or similar organism. In applying previous risk assessments, care must be taken to determine if changes in the locations, scope, or timing of the release could change the risk.

Subitem 1. Changes related to the location must be considered. Are there changes in the type of soil that could affect survivability or spread of the organism? Are there changes in the climate that could affect the result? As an example, did the organism fail to survive a winter because of numerous freeze-thaw cycles with no snow cover? Will the native species of organism in a different area affect the risks?

Subitem 2. Were the results related to factors that may not occur during the new release? For example, did the organism fail to survive due to an unusual drought, or other climate condition or due to unusual competition from a transient increase in a competing organism?

Subitem 3. Was the scale of release in the previous study adequate to assess potential adverse risk?

Items F. and G. recognizes previous work and cuts down on duplication.

Item F. Consideration of conditions placed on the proposed release by federal agencies.

Item G. Consideration of conclusions or conditions by federal or state agencies on previous releases in Minnesota or elsewhere.

4420.0040 ADVISORY COMMITTEE.

Minn. Stat. § 116C.93 requires the board to establish an advisory committee on genetically engineered organisms to provide advice at the request of the board on general issues involving genetic engineering and on issues relating to specific proposals, including the identification of research needed for adequate regulation of field trials. This part is necessary as it fulfills that requirement in the following subparts:

Subpart 1. General.

This subpart provides that the board or chair shall provide guidance to the committee in the form of a charge. It also restricts committee members from receiving a trade secret version copy of the application, if that person is in any business or enterprise in competition or when that information could be used for product development purposes. This requirement is necessary and reasonable to provide protection for the applicant and is consistent with federal requirements.

Subp. 2. Release review.

This subpart identifies the activities that the chair may request of the committee. The chair may direct the committee to assist in the review of applications and other aspects of releases. This requirement is reasonable and necessary because of the short time for review. It is more efficient to have the chair direct the advisory committee regarding the level of participation needed on a specific application or other item that has been delegated to the chair by rule or the operating rules of the board.

Subp. 3. Program review.

This subpart identifies that the board may direct the committee regarding development, revision, and enforcement of these rules and programs. This part is needed for clarification and is reasonable.

4420.0045 APPLICATION CONTENTS.

This part is needed to provide a standard for submitting the required information in an application for a release permit and also addresses trade secret information requirements.

Subpart 1. Release permit application.

This requirement is necessary to identify the specific information that the applicant is required to supply.

These requirements are identified as items A. through F. and are clear and direct. The information requested in item E. subitem 4. requests information as it relates to the considerations identified at part 4420.0035 Subp. 3. The information required here will also be used in preparation of the EAW under the requirements of Chapter 4410.

Subp. 2. Trade Secret Information.

This subpart requires that information submitted by the applicant that qualifies as trade secret information pursuant to Minn. Stat. § 13.37 be treated as non-public data in accordance with Minn. Stat. chapter 13. The applicant has the burden to demonstrate that the information qualifies as trade secret information.

When an application contains trade secret information, the applicant is required to submit a modified application with the trade secret information deleted. The trade secret deleted version is the version that is distributed to the public under Part 4420.0025 subp. 4. When the applicant submits a trade secret deleted version, that application must contain sufficient information necessary for public review of the adverse effects on human health and the environment. This requirement is reasonable because it protects trade secret information but still provides the information necessary to evaluate adverse effects.

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

Minn. Stat. § 116C.94(a) provides the authority for the board to modify, suspension or revoke a release permit. Procedures and standards for permit modification, suspension, and revocation are necessary to protect human health and the environment and to provide due process for the permittee and the public.

This part provides the procedures and standards by which the board can modify, suspend, or revoke a release permit at the request of a person other than the permittee. The procedures and standards of this part have been adapted from similar provisions in the board's pipeline routing permit rules and the Minnesota Pollution Control Agency's general permit rules.

A permit is issued to an applicant on the basis of stated intent to conduct a release according to specific terms and conditions identified in the permit. In the event the applicant fails to comply with those terms and conditions, or in the event that a serious threat to human health or the environment arises that is not controlled by the terms or conditions of the permit, a process is needed by which the board can act to protect the environment and public health and to resolve the problem. This part provides three remedies to the board, depending on the nature of the problem and its solution.

Modification of a permit allows the action to continue, but under altered conditions; this remedy is appropriate where the original terms and conditions prove inadequate in practice to prevent possible harm to the environment or public health.

Suspension of a permit involves a temporary suspension of the authorization to conduct the project. Suspension is needed and reasonable in cases where imminent and substantial harm to the environment or public health is occurring or may occur, thus, it is necessary for the board to order the project to cease while an investigation of the situation is conducted to determine how best to resolve the problem.

Revocation is a permanent cancellation of the authorization to conduct the project.

Subpart 1. Initiation.

Subpart 1 provides the basic procedural and substantive requirements for initiating modification, suspension, or revocation proceedings by the board. Initiation is by a prima facia showing by any person or agency that at least one of three conditions has occurred. These three conditions are each a reasonable basis for modifying, suspending, or revoking a permit, and have been adapted from the general permit rules of the Minnesota Pollution Control Agency. They are: violation of the permit; having secured a permit upon a false or misleading factual basis; or the need to alter the conditions of the permit to protect the environment from unreasonable or material adverse effects. The subpart provides that the board must consider the matter at its next regular or a special meeting, in order to expedite consideration.

Subp. 2. Notice.

This subpart is intended to provide adequate notice (in non-emergency cases, 10 days) to the proposer of the allegations that have been brought to the attention of the board in order to provide opportunity for the proposer to prepare a response. It also provides notice to all persons who have registered their interest in the specific permit in question so that they may have opportunity to share any information or opinions about the matter with the board. In the event of an imminent and substantial danger, the chair is authorized to call a special board meeting with less than 10 days notice.

Subp. 3. Emergency corrective action.

This subpart authorizes the chair of the board to act immediately to correct or prevent actual, imminent damage without following the procedures of subpart 2. The text provides a high threshold ("clear and immediate danger requiring immediate action") for action under this part to safeguard the due process rights of the permittee under subparts 1 and 2 except when immediate action is clearly necessary.

Subp. 4. Contested case hearing.

This subpart allows a person to request a contested case hearing. The board must hold a hearing when the standards in part 4420.0030 subp. 9A are met.

Subp. 5. Board action.

This subpart sets forth the substantive standards for board action to modify, suspend, or revoke a release permit. It provides that if the board finds that any of the three conditions of subpart 1, item A. exists, it may modify, suspend, or revoke the permit, whichever is appropriate under the circumstances. Since, as provided in subpart 1B, this decision would be made at a regular or special meeting of the board, the decision must be reached according to the board's operating rules, chapter 4405.

The subpart also allows the board to terminate or suspend its action on the permit upon determination that the permittee has effectively resolved the problem.

Subp. 6. Scope of suspension.

This subpart is necessary to protect the permittee from abuse of the suspension provision. It restricts the duration of a suspension to the time necessary for the board to determine what corrective action must be undertaken and for the permittee to complete that action.

Subp. 7. Scope of modification.

This subpart is necessary to restrict modifications of a permit to only those additional or altered conditions necessary to provide mitigation or minimization of significant or material adverse effects. These conditions must relate to the considerations set forth in part 4420.0035 as relevant to genetic engineering releases.

Subpart 7. Scope of revocation.

This subpart specifies the standards for revocation, which are the same standards for denial of a permit, and which are contained in part 4420.0035, subpart 2.

PART 4420.0055 RELEASE PERMIT MODIFICATION REQUESTED BY PERMITTEE.

This part provides a systematic process for the modification of a release permit as requested by the permittee, and assures adequate notice of such proposed modifications to interested persons.

Subpart 1. Initiation.

This subpart provides guidance to the permittee regarding the information that must be submitted to support a modification request and provides for a determination at a regular or special board meeting in accordance with board operating rules, chapter 4405.

Subp. 2. Notice.

This provision defines the persons and governmental units that must be notified of the permittee's request for the permit modification. This is needed to provide an opportunity for potentially affected persons or units to prepare a response to the request to be presented to the board.

In a case of the need for emergency action (where there exists an "imminent and substantial danger to human health or the environment") the chair would be allowed to call a special board meeting with less than 10 days notice. Alternatively, if all persons who commented on the draft permit and all affected local governmental units agree to a shorter timeframe, the 10 day notice may be waived.

Subp. 3. Board action.

The standard for granting a modification requested by the permittee is given in this subpart, and is the same as the standard for setting permit conditions as specified at part 4420.0035.

PART 4420.0060 MAILING LISTS

This part describes two mailing lists which the board proposes to use as the basic mechanism to make the public aware of pending actions regarding release permits.

Subpart 1. General mailing list.

Persons registered on this mailing list will receive notice of the acceptance of all applications for release permits and general notices relating to this chapter. Upon receipt of a notice of acceptance of an application, persons may request that they be registered on the special mailing list of subpart 2 to receive specific notices of the rest of the events that would occur during the permitting and permit duration for that specific release (e.g., notice of the draft permit).

Subp. 2. Specific release mailing lists.

Persons registering their names on a specific release list would receive all future notices relating to the specific release in question, including any notices after permit issuance, such as notice of proposed modification.

4420.0070 GENERAL RESPONSIBILITIES.

This part is standard language in state agency rules requiring the board to make improvements in the rules as necessary and to assist anyone in understanding the rules.

V. STATEMENT OF NEED AND REASONABLENESS
AMENDMENTS TO CHAPTER 4410
ENVIRONMENTAL REVIEW PROGRAM RULES
PERTAINING TO RELEASES OF GENETICALLY ENGINEERED ORGANISMS

4410.0200 DEFINITIONS AND ABBREVIATIONS.

The following four definitions are needed to clarify specific terms in the proposed amendments and to provide consistent definitions between the permitting of the release of genetically engineered organisms into the environment (Chapter 4420), and the environmental review of the proposed releases (Chapter 4410).

In each case the definition is the same as proposed in chapter 4420 and applies only to these amendments.

Subpart 35a. Genetically engineered organism.

This term is defined in the enabling legislation at Minn. Stat. § 116C.91 Subd. 4. and is a combination of genetic engineering and organism as defined by Minn. Stat. § 116C.91 Subds. 3 and 5. This term is essential to these amendments.

Subp. 35b. Genetic engineering.

This term is defined in Minn. Stat. § 116C.91 Subd. 3. and is essential to these amendments. Additional language is included to further elucidate what is meant by selective breeding, hybridization, or nondirected mutagenesis.

Subp. 55a. Organism.

This term is defined in Minn. Stat. § 116C.91 Subd. 5. and is essential to these amendments.

Subp. 71b. Release.

This term is defined in Minn. Stat. § 116C.91 Subd. 6. and is essential to these amendments.

4410.4300 MANDATORY EAW CATEGORIES.

Subp. 35. Release of genetically engineered organisms.

This new mandatory EAW category is proposed to carry out the statutory mandate of Minn. Stat. § 116C.94 that the board adopt rules to require an EAW for the proposed release of genetically engineered organisms.

The requirement for an EAW for the release of a genetically engineered organism is needed because a number of potentially serious environmental impacts could result from such activities, if not properly conducted. These environmental impacts could include but are not limited to:

(1) a genetically engineered organism could be better suited to the environment than natives species and consequently could take over an ecological niche;
(2) genetically engineered organisms could evolve and become more adapted to their environment, resulting in increased competition for native organisms or increased risks to native organisms; and
(3) undesirable traits could be transferred to pests (e.g., insects or weeds) making them more resistant to pesticides or other methods of control.

The applicability of this category is based on the definitions of "release" and "genetically engineered organism" as defined in proposed chapter 4420, rules for an board permit for releases of genetically engineered organisms; the definitions of these terms proposed to be added to chapter 4410 are identical to those proposed in chapter 4420.

The RGU for an EAW for the release of a genetically engineered organism may be either the board or another state agency, depending on whether the release requires a permit from another state agency which substitutes for an board release permit. If an board release permit is required, the board will be the RGU;, but if no board release permit is required because another state agency must issue a permit that deals with the relevant environmental issues, in accordance with the procedures and criteria of chapter 4420, the permitting state agency will be the RGU. This division of RGU responsibility is consistent with the basic environmental review principle that the agency with the greatest responsibility for approving the project should be the RGU (see part 4410.0500, subp. 5, item B).

4410.8000. SPECIAL RULES FOR RELEASE OF GENETICALLY ENGINEERED ORGANISMS.

Because of some unique features of the review of the environmental effects of a proposed release of a genetically engineered organism, there is a need to make several modifications to the normal EAW process. The method chosen by the board to accommodate these differences is to adopt "special rules" for this review, following the examples of the review of power plants and high voltage transmission lines (see parts 4410.7000 to 4410.7800). What the proposed special rules do, in effect, is spell out exceptions to the normal EAW process.

Subp. 1. Exceptions.

This subpart describes three exceptions to the normal EAW process which are needed for the review of genetically engineered organisms. The first two exceptions apply only if the board is the RGU, and relate to timing issues associated with the concurrent preparation of a draft board release permit under proposed chapter 4420. The third exception applies to all RGUs and concerns special criteria for determining whether a proposed release of a genetically engineered organism has the potential for significant environmental effects.

Item A. The board release permit process under proposed chapter 4420 and the board's proposed EAW process for genetic engineering releases have been developed to proceed concurrently to avoid duplication of effort and confusion for the applicant and the public. Since the board proposed permit rules provide that the draft release permit must be prepared for public review within 45 days from the acceptance of the application (which includes the information necessary for the EAW), and since it is desirable for the draft permit and the EAW to be available for review on the same schedule, it is appropriate for the EAW to also be prepared within 45 days of acceptance of the application. While the regular environmental review rules provide for only 30 days for the RGU to complete the EAW from the submission of complete information by the proposer, it makes little sense for the board to complete the EAW in 30 days in circumstances where it will not be distributed for review until 45 days.

Item B. Subp. 2a of part 4410.1700 provides that an RGU may delay the decision on the need for an EIS for up to 30 days if information needed for the EIS decision is lacking. The proposed special rules would delete this postponement provision in cases where the board is the RGU. This deletion is needed in order to prevent the board release permit process from becoming too long. According to the discussions of the Genetic Engineering Advisory Committee, it is important for the board to be able to issue its permit within 120 days. (This is based on the assumption that many applications will be follow ups to work done the previous summer, and that if the timeframe of the board's release permit process is longer than 120 days, there would not be sufficient time between the end of one growing season and the following spring planting to allow an applicant to analyze the data, prepare an application and secure a new permit.) If the board were to delay its decision for 30 days, the overall estimated timeframe would be 150 days.

It is reasonable to eliminate the postponement provision in the case of the board being the RGU because the board has several mechanisms for assuring that adequate information is available that are not usually available to an RGU. First, the board chair will not accept the application for the release permit, which is accompanied by the EAW information, until the chair believes that it contains adequate information. Furthermore, the application will have very specific information requirements pertinent to genetic engineering releases, so it is likely that information gaps will be identified and corrected early on. It is the board's experience that in most cases where an RGU postpones the EIS need decision because of insufficient information, the primary cause was that the original EAW was lacking in basic information. Second, the board will have 15 days more to prepare the EAW than would normally be the case, so there is less chance that important information will be left out. If despite these safeguards, it should turn out that critical information is lacking, whether or not the rule provides for a postponement, the applicant has the right to ask the board to delay action to give the opportunity to develop the missing information, and the board has provisions within its operating rules (chapter 4405) to postpone action until the next board meeting.

Item C. Subitems 1 through 7 of item C are special considerations which a RGU must use to evaluate a proposed release of genetically engineered organisms in order to ascertain whether or not it has potential for significant environmental effects. These seven factors are identical to the considerations in chapter 4420.0035 which must be used by the board to determine whether to grant a release permit and to determine the conditions of such permits. The considerations were developed by the board's Genetic Engineering Advisory Committee, and as such represent a consensus among varied interests on the special information needed to review the impacts of genetically engineered organisms on the environment and human health.

Subitems 8, 9, and 10 are identical to criteria A, B, and C of the regular EIS need decision process of part 4410.1700, and supplement the special genetic engineering factors of 1 through 7. Note that criteria D of part 4410.1700 is replaced by subitems 6 and 7, which are more specific to the subject of genetic engineering.

Subpart 2. EAW and EIS preparation.

Item A. The intent of item A is to make clear the need to prepare EAWs for releases of genetically engineered organisms with an interdisciplinary approach if all potential impacts are to be adequately identified and assessed. The language used was recommended by the board's Genetic Engineering Advisory Committee and parallels a similar directive regarding review of the release permit application in chapter 4420.0030 subp. 2

Item B. This item is a reminder to the RGU that care must be taken in preparing the EAW so that the general public can understand the documents. This is particularly important with a highly technical area such as genetic engineering releases, and therefore merits being pointed out in this fashion in the rules. The text is adapted from a similar requirement in chapter 4410 regarding EIS preparation.

Item C. In order to accomplish the interdisciplinary review called for in item A, the board must have access to technical expertise beyond that of its own staff. An efficient mechanism to provide this assistance on the short notice inherent in the permit review process would be to call on the expertise of the standing Genetic Engineering Advisory Committee, and to have the ability to add additional members as needed to expand the range of expertise.