Department : Agriculture

STATE OF MINNESOTA

Office Memorandum

Date : September 9, 1994

To : Maryanne Hruby, Director
LCRAR

From : Carol Milligan
Agriculture Planning Division

Phone : 296-6906

Subject : **Submittal of Statement of Need and Reasonableness**

As required by Minnesota Statutes, sections 14.131 and 14.23, attached is the Statement of Need and Reasonableness for rules governing genetically engineered organisms. The Notice of Intent to Adopt and the rules will be published in the *State Register* on 9/26/94.

Attachment

STATE OF MINNESOTA
DEPARTMENT OF AGRICULTURE

**IN THE MATTER OF THE PROPOSED)
RULES OF THE DEPARTMENT OF)
AGRICULTURE GOVERNING AGRICULTURALLY)
RELATED GENETICALLY ENGINEERED) STATEMENT OF NEED
ORGANISMS MINNESOTA RULES PART) AND REASONABLENESS
1558.0010 TO 1558.0090)**

I. INTRODUCTION

The subject of this rule making is the proposed adoption by the Minnesota Department of Agriculture (MDA) of a rule governing the release of agriculturally related genetically engineered organisms. This rule is proposed for adoption pursuant to Minnesota Statutes section 18F.12 which authorizes the MDA to promulgate rules for the release of agriculturally related genetically engineered organisms (GEOs). A law that was passed in 1991 amended Minnesota Statutes sections 18B.01 and 18B.285 to include authority to regulate the release of genetically engineered pesticides; Minnesota Statutes sections 18C.005 and 18C.310 to include authority to regulate the release of genetically engineered fertilizers, and plant and soil amendments; Minnesota Statutes section 18D.01 to include authority to imposes penalties and procedures for dealing with violations relating to GEOs; and added Minnesota Statutes chapter 18F which governed the release of genetically engineered plants. Minnesota Statutes chapter 18F was amended in 1994 to reflect the rapid development in the field of genetic engineering. The 1994 amendments expanded Minnesota Statutes chapter 18F to cover all agriculturally related genetically engineered organisms for field releases, notifications, and commercial use. This expanded the coverage beyond plants but limited all coverage to agriculturally related organisms. In the 1991 statute there was no provision for commercial use or for reduced regulation of organisms found to be safe when they were released under certain guidelines. The amendments address these areas and reflect changing needs in the area of regulation of genetic engineering.

There has been enough experience with some plants that have specific types of alterations to allow for a shortened regulatory procedure known as notification. This procedure was adopted by USDA/APHIS in 1993 and it was included in Laws of Minnesota 1994 chapter 454 which amends Minnesota Statutes chapters 18F and 116C. Minnesota Statutes chapter 116C is the EQB law regarding release of genetically engineered organisms. The amendments specify that the notification section will be included in the rules and will than be repealed from the statute.

In 1994, the first genetically engineered plant became available for commercial use. There are several products that will be available in 1995 and the number should increase rapidly in the following years. A recent estimate suggests that 50 products will be on the market in the next five years; therefore, it is important to address commercial use as a separate issue in the rules.

The authority for regulation of agriculturally related genetically engineered organisms is linked to the overall EQB authority for regulation of all genetically engineered organisms. Some of the rules are necessary in order to conform to EQB rules promulgated under Minnesota Statutes chapters 116C and 116D. This is particularly true for being designated as an agency that issues a "significant environmental permit". Laws of Minnesota 1994 chapter 454 amended 116C.91 subdivision 1 to read "the board shall authorize an agency with a significant environmental permit to administer the regulatory oversight for the release of certain genetically engineered organisms". Under EQB rules an agency may be considered to have such a permit if the release permit includes an Environmental Assessment Worksheet, interdisciplinary review, authority to apply terms and conditions to the permit, and the authority to deny, modify, suspend, or revoke the permit. The agency is required to use considerations that are the same or equivalent to the EQB in determining whether to issue or deny a permit.

The MDA has determined that the rules are non-controversial in nature because they are supported by industry, and have been reviewed by the genetic engineering advisory committee to the Environmental Quality Board (EQB). This committee is made up of industry, environmental groups, citizens, university, state agency and other technical representatives. The broad based support for the changes in legislation led to the rules as they are proposed.

II. GENERAL OVERVIEW

The proposed rules will provide for a comprehensive set of requirements and procedures to permit the release of GEOs outside of a containment facility, partial or complete release permit exemptions, notification procedures for certain plants, and a procedure to allow for the commercial use of GEOs.

MDA has circulated copies of the proposed rules to all interested parties to gain input and comment so that they will be workable for industry and MDA, while preventing unreasonable adverse effects on human health or the environment. The increased complexity in the law makes it imperative that clear easily followed rules are developed. The continuing rapid changes in the area of genetic engineering and biotechnology also makes it important to have rules that allow for flexibility as the industry changes.

In accordance with Minnesota Statutes section 14.23, this Statement of Need and Reasonableness was prepared and completed prior to the date that the proposed rules were published in the State Register.

III. NEED FOR AND REASONABLENESS OF PROPOSED RULES

1558.0010 SCOPE

The section on scope is needed in order to define the limits of the rules, avoid confusion about the various sections, and to direct readers to the proper section of the rules. It is reasonable to include this section at the beginning of the rules to make the rules easier to use.

Subp. 1. Regulatory authority. Not all genetically engineered organisms are covered under MDA authority. Additionally not all uses are considered releases. It is necessary to delineate what organisms and what types of uses are covered by the rules. It is also important to note that the rules must include a requirement for environmental review subject to the provisions of chapter 116D and the rules adopted under it. It is reasonable to include that information in the scope section in order to avoid confusion about what is covered under the rules.

Subp. 2. Releases requiring permits. This section describes the genetically engineered organisms, covered under Minnesota Statute chapters 18B, 18C, and 18F, which are required to obtain a release permit prior to release. It also directs the reader to the appropriate section in the rules that gives the procedures for applying for the release permit. Releases requiring permits are one of the major types of releases covered under the regulatory authority in chapters 18B, 18C, and 18F; therefore, it is reasonable to include an overview in this section which directs applicants to the appropriate place in the rules where they can find the details of applying for a release permit.

Subp. 3. Notifications. Applicants wishing to release certain plants, that meet certain eligibility criteria and performance standards, can follow an abbreviated notification procedure rather than obtaining a release permit. It was necessary to list those plants in this section so the applicant will know what procedures they must follow and where to find the appropriate section of the rules. Many of the plant releases are covered under the notification procedure; therefore, it is reasonable to include this information in the section directing applicants to the appropriate rules.

Subp. 4. Commercial use exemptions. Commercial use of genetically engineered organisms was not allowed prior to the amendments to Minnesota Statutes chapters 18F and 116C found in Laws of Minnesota 1994 chapter 454. This section alerts the applicant to the fact that exemptions for commercial use are now

available and to the section where the procedure can be found. The section on commercial use exemptions will not be used a great deal immediately but it is reasonable to include an explanation here because the number of commercial products is rapidly increasing and it is important for applicants to know what section of the rules deals with commercial use.

1558.0020 DEFINITIONS

Definitions in part 1558.0020 are needed to clarify specific words and phrases used in the proposed rules. Some of the definitions are taken from statutory language in Minnesota Statute chapters 18B, 18C, 18F, or 116C, others are technical definitions primarily based on federal genetic engineering regulations. The use of existing definitions, where possible, provides for consistency among all regulations that apply to genetic engineering releases. The definitions that are included are words or phrases that might otherwise be misinterpreted; therefore, it is reasonable that these particular words and phrases were included in the rules.

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. 3. Applicant.
Subp. 4. Application.
Subp. 5. Commissioner.
Subp. 7. Environmental Assessment Worksheet; EAW.
Subp. 8. Environmental Impact Statement; EIS.
Subp. 9. Environmental Quality Board; EQB.

Subp. 2. Agriculturally related organism. Minnesota Statute section 18F.3, subdivision 1a. defines agriculturally related organisms. This definition is needed to clearly delineate which organisms the commissioner has authority over, and which are regulated by other state agencies or are exempt under the law. The definition does not define each group of organisms, such as livestock, separately. These are primarily self explanatory; but, if there is any question about what is included there are separate statutory definitions for most of the organisms.

Subp. 6. Containment facility. A release permit is only needed if the genetically engineered organism is to be placed or used outside of a containment facility. This definition is needed to clarify what constitutes a release and thus requires a release permit.

The definition contains two standards for containment. Compliance with the National Institute of Health (NIH) Guidelines or United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS). NIH guidelines are periodically updated and published in the federal register. The rule

references the most current version. It was felt that it was reasonable to reference it in this way because of the large number of modifications that have been made in the past. Additions or changes have been published in the federal register as often as every 6 months. The USDA/APHIS standards are on a case by case basis; thus no citation is offered for USDA/APHIS standards. NIH defers to USDA for containment facility certification falling under USDA authority; so it was necessary to include that as an option for certification.

The standard is reasonable because the NIH and USDA guidelines are required to obtain federal funding and because the industry voluntarily follows these guidelines as well.

Subp. 10. Federal application. This definition is needed to identify the federal documents that are requested in several parts of the rules. It is reasonable because it restricts the documents to those relating to the release of genetically engineered organisms and minimizes duplication.

Subp. 11. Genetic engineering. This term is defined in Minnesota Statute sections 18B.01, 18C.005, and 18F.02 and is repeated here for the purposes of clarification. Examples of what is not considered genetic engineering are reasonably included in order to assist the reader in understanding the rules.

Subp. 12. Genetically engineered organism; GEO. This term is defined in the enabling legislation in Minnesota Statute sections 18B.01, 18C.005, and 18F.02 and is a combination of genetically engineered and organism. This term is used frequently and is repeated for the purpose of assisting the reader in understanding the rules.

Subp. 13. Organism. This term is defined in Minnesota Statute section 18B.01, 18C.005, and 18F.02 and is needed here in order to explain what is meant by this term throughout the rules. It is repeated here for the purposes of clarification to the reader in understanding the rules.

Subp. 14. Release. This term is defined in Minnesota Statute section 18B.01, 18C.005, and 18F.02 and is essential to understanding the rules. The term is used throughout to define what is covered under the rules. It is reasonable to repeat that definition here in order to assist the reader in understanding the rules.

Subp. 15. Release permit. This term is needed to describe the document that is issued by the commissioner to allow for the release of agriculturally related genetically engineered organisms. It is reasonable to define the term here to make it clear that the document may also contain terms and conditions related to release.

Subp. 16. Responsible person. A definition of responsible party is needed because the term is used in the application process. It is reasonable to define it

here so that it is clear to the applicant what is meant by the term and so that the proper party will be listed in the application.

1558.0030 CONSIDERATIONS

This section is needed to clearly delineate the considerations that are used to judge environmental concerns associated with release of GEOs. These considerations are used to help make a determination regarding release. The considerations are also used to determine various exemptions that may be given under the statute and the rules. The considerations are adapted from the Environmental Quality Board rules to meet the needs of agriculturally related genetically engineered organisms. Using these considerations as part of the determination also meets one of the requirements for an agency to be designated as issuing a "significant environmental permit".

Subp. 1. Considerations. It is necessary for the considerations to thoroughly examine the organism, the genetic changes in the organism, its relationship to its environment, and its relationship to or effects on other organisms. It is also important to look at federal assessments and any possible mitigation that might be required. This information is needed in order to assess whether the release will result in unreasonable adverse effects on human health or the environment. The considerations that are listed give a reasonable assessment of the factors listed above.

Previous releases are an important source of information in determining the behavior of an organism during release or in a commercial use situation. This information is requested as part of the considerations. It is necessary to have as much information as possible in order to make an adequate assessment of the proposed release. Information from release reports may be used to address this section of the rules. In some instances this information is not available due to the fact that there are no previous releases. Greenhouse information, laboratory studies, or information from releases that are similar may be helpful in these cases. It is reasonable to request this information in that environmental effects, positive or adverse, seen in previous releases, are an important factor in assessing behavior of an organism during a release.

The considerations are also consistent with the EQB considerations with minor changes designed to make the considerations fit agriculturally related organisms and to be more generic in order to cover all organisms not just plants or microorganisms. It is necessary and reasonable to be consistent with EQB in order to qualify as a "significant environmental permit". It is reasonable that the considerations used in assessing environmental effects of releases are written in some detail in order to inform the public and the applicant of exactly what criteria are used in making a determination.

Subp. 2. Federal documents. It is important to avoid duplication of the federal process wherever possible. In order to prevent duplication of federal oversight, the applicant may use federal documents to address some of all of the considerations. The considerations that are not addressed in federal documents must be addressed separately. Whenever possible the information will be taken from existing documents.

1558.0040 RELEASE PERMIT PROCEDURES

Release permits are required for all releases of GEOs not specifically covered under notifications, commercial use exemptions, or under 1558.0080 as uses not requiring release permits; thus, this section is needed to explain the procedure used for applications for GEO release permits, application review, issuance or denial of release permits, and other requirements for release. It is necessary to outline the specific procedures in order to clearly guide the applicant through the process. The specific procedures outlined in the rules reasonably meet the criteria of avoiding unreasonable adverse effects on human health or the environment.

Subp. 1. Procedure and application. This section lists the information that is required to properly complete the permit application. The information that is requested is needed in that it identifies the responsible person, participants, type of release, movement of GEOs, and the information needed to complete a Environmental Assessment Worksheet (EAW). The EAW is designed to address the considerations found in section 1558.0030. This is an important feature in that this is one of the criteria under EQB rules for an agency to be declared as issuing a "significant environmental permit". It is reasonable to have the authority to request this information and to follow the procedure outlined because the information is required for clearly identifying the participants, type of test to be conducted, and in making a determination of unreasonable adverse effects on human health or the environment.

This section also allows the commissioner the flexibility to ask for additional information needed to determine any adverse effects on human health or the environment. The wide range of organisms that might be covered and the broad range of uses of GEOs makes it difficult to anticipate all of the information that might be needed in making a determination; thus, authority to request **related** information is necessary in making an accurate determination. The ability to request additional information is clearly limited to information needed to make a determination. This is done to prevent requests for unnecessary information that does not directly relate to the issues raised for a particular project. The commissioner may also request input from various agencies and other sources to address specific issues. The range of issues that might be addressed for a particular release is broad and it is important to have input from other agencies and other sources regarding those issues. It is reasonable to have the authority to

request additional information if it directly relates to adverse effects on human health or the environment and is therefore needed for making an accurate assessment.

Subp. 2. Application submission. This section is needed to give procedures for accepting or rejecting an application. The time period of 14 days gives the commissioner adequate time to determine if the application is for a GEO that is regulated under chapter 18b, 18C or 18F and if the application contains all the relevant information. The 14 day time period is also reasonable for the applicant because that period is short enough to allow the applicant time to reapply in time for planting or other seasonal activities; or to apply to another agency with regulatory authority without unduly delaying the project. This section also outlines the procedure for rejecting an application and for resubmitting the application with additional information.

Subp. 3. Application distribution. This section is needed to show the distribution of the applications so all interested parties, including the public, can review or obtain copies of the applications, thus allowing full public participation in the review process. Other agencies receive copies of the applications by being members of the EQB. The EAW distribution list includes agencies as well. It is important to have other agencies and the EQB on the distribution list for EAWs in order to make sure that issues affecting other agencies are brought to the attention of those agencies and that other agencies have an opportunity to comment on the applications. The applications and projects are complicated and wide review is needed to ensure that unreasonable adverse effects on human health or the environment are identified.

The distribution list for EAWs is the same as the list mandated under EQB rules for chapter 116C. The distribution list includes state and federal agencies. This is reasonable in that the complex issues involved in some projects need as wide a review as possible. It is necessary and reasonable to have the same distribution in order to be considered as an agency that issues a "significant environmental permit". The designation of an agency having a "significant environmental permit" is important under EQB guidelines for agency participation.

Not public data is often a part of an application. Much of the information appropriately falls under guidelines for not public data. Access to not public data is often critical in completely assessing a projects effects on human health or the environment. The rules state that other agencies may receive this information in order to complete the review of proposed releases of GEOs. It is necessary to allow access to this information and to note this in the rules so that applicants are aware of the use of not public data allowed under the rules, and so agency reviewers and the general public are aware that the reviewers will have all the information needed in order to completely review the application.

Subp. 4. Application review. It is necessary to have interdisciplinary review to ensure that issues are identified and addressed in the permit process. Interdisciplinary review is required under EQB guidelines for a "significant environmental permit". This rule is consistent with the interdisciplinary review process found in the EQB rules. It is necessary to be consistent with the EQB rules in order to avoid confusion and to be considered as an agency that can issue a "significant environmental permit". It is also important to indicate to the public the type of review that can be expected. It is reasonable to have an interdisciplinary review because of the complexity of the permit applications requires background information from many different areas to thoroughly assess the application. This list can be used as appropriate to a project, which also gives the flexibility to match the type of reviewers needed with the type of release that is being proposed. The rule also states that other disciplines will be consulted as needed. Disciplines not listed can and will be consulted as appropriate to the project and the issues raised.

Many of the projects are very complex and issues relating to the projects may overlap with authority and expertise of other agencies. These agencies will be consulted on matters in their area of expertise. An example would be projects where there may be a significant health issue would be brought to the specific attention of the Department of Health. The Department of Health as well as many other agencies are on the distribution list but they will be consulted earlier in the application process on issues relating to their areas of expertise.

This section clearly states what criteria the commissioner uses to determine whether or not to issue the permit. It is necessary to identify the criteria to establish what should and should not be considered in the review and determination for reviewers, the public, and the applicant. It is reasonable to include these criteria in the section on permit review.

Minnesota Statutes section 18F.13 mandates that the Board of Animal Health will be consulted on all permits relating to livestock and domestic animals. It is necessary and reasonable to include a statement regarding that in the section on permit review.

Subp. 5. Data privacy. One of the areas that has caused confusion in the past is the use and availability of not public data; therefore, a section was needed to clearly explain the use of not public data. This information is defined using the terms "security information" or "trade secret information" on the state level; however many of the documents will be documents submitted to federal regulatory agencies. This information is known as "confidential business information" on the federal level. That terminology will be acceptable in the application forms to avoid confusion and to allow for the use of federal documents. This information can be made available to the interdisciplinary reviewers and other state agencies should it be required for reviewing a project. The conditions that allow for the release of the information are outlined. It is reasonable to include this information so that

reviewers know the conditions for obtaining the information and so the public is aware that the information is available to reviewers.

Subp. 6. Permit conditions. When an application is submitted, much of the information is related to specific guidelines and procedures that are going to be followed in conducting the project. Many or all of the terms and conditions that are listed are part of the project proposal and are used as a basis to prepare the EAW and make a determination; thus, it is reasonable to include those specific terms and conditions as part of the release permit terms and conditions. Examples of this would the size of the trial or the distance that must be maintained between the trial and fields of the same species are specified in the application. There may be special circumstances that require additional terms or conditions. Sometimes these are identified during the comment and review process or occasionally during a site visit. These additional terms and conditions are imposed to reduce the possibility of unreasonable adverse effects on human health or the environment. This section gives the commissioner reasonable authority in imposing additional terms and conditions; but, clearly limits them to those needed to mitigate or minimize unreasonable adverse effects on human health or the environment. This is reasonable in that it does not allow for additional terms and conditions that do not directly relate to specific concerns about the project.

Subp. 7. Violation of the permit. A permit is issued based on the stated intent of the applicant to follow certain procedures, and the terms and conditions of the permit reflect that understanding. In the event the applicant does not comply or if there are unexpected occurrences that cause unreasonable adverse effects to the environment, the commissioner needs to have a method to address and resolve the problem. Under Minnesota Statute section 18F.07 subdivision 2 the commissioner has the authority to revoke, suspend or modify the permit at any time if the commissioner finds that the terms or conditions are being violated or are inadequate to avoid unreasonable adverse effects on human health or the environment. It is necessary to outline the consequences of a violation and to reference Minnesota Statute chapter 18D for the penalties and procedures which apply to the violation of a release permit.

A suspension would give the commissioner time to assess the problem and see if there is any way to modify the permit to mitigate the adverse effects. A modification would allow the permit to continue, but under alternate or additional terms and conditions. The modifications would result in mitigation of the circumstances that led to the violation. This may be used in cases where unexpected occurrences resulted in possible adverse effects to human health or the environment. If there are no modifications that would result in mitigation of the problem the permit could be revoked. A revocation would result in a permanent cancellation of the project release permit. It is reasonable to have several levels of intervention when a problem is identified. This allows for the appropriate level of response based on the actual problem.

It is necessary and reasonable to include the section on violations in the release permit procedures section so that the applicants understand the consequences of a violation and so the public is assured that there are procedures to prevent unreasonable adverse effects on human health or the environment. It is also important to include a reference to Minnesota Statute chapter 18D so that all parties are aware that the procedures and penalties found in Minnesota Statute chapter 18D can be applied to violations of a release permit issued under Minnesota Statute chapters 18B, 18C, and 18F.

Subp. 8. Adverse effects. It is possible that unexpected occurrences or adverse effects may be seen in a project; therefore, it is necessary and reasonable to include procedures for dealing with problems. Should there be unexpected occurrences or adverse effects seen in the field release at any time during the project or during the monitoring period following the project, the responsible person, as identified in the application, must report to the commissioner within 48 hours. It is impossible to list what all of the possible adverse effects might be; therefore, it is necessary to report any unusual occurrences or possible adverse effects. The 48 hour time period is reasonable in that it gives the responsible person adequate time to notify the commissioner without causing additional problems due to delays in reporting.

Subp. 9. Application fee. An application fee of $125 is mandated in Minnesota Statute section 18F.07 subdivision 4. There is a fee of $150 mandated under Minnesota Statute section 18B.28 subdivision 4 for Experimental Use Permits (EUP). Many projects would require both a release permit and an EUP, however, duplicate permitting is restricted under 1558.0090. Under this rule only one permit fee will be charged for any single project. This is reasonable based on the restrictions on duplicate permitting.

Subp. 10 Permit renewal. Releases that are substantially the same as a previous release may apply for a renewal. This rule is needed to prevent unnecessary paper work and duplication. The 30 day waiting period is reasonable in that it gives the commissioner ample time to determine if there are any reasons to deny the renewal, but it is not so long as to unduly prevent applicants from performing seasonable projects or applying under other sections of this rule should the renewal be denied. A request for a renewal would be denied if there is evidence of unreasonable adverse effects on human health or the environment or if the project is substantially different from the previous years project. It is necessary to have criteria that would deny renewals if there have been problems with previous tests. It is reasonable to use the standard of adverse effects to make a determination on renewing a release permit. It is also reasonable to exclude permits from renewal if there has been a substantial change in the experiment protocol or location, because that could have an effect on the Environmental Assessment and the terms and conditions.

Subp. 11. Release reports. Release reports are a method of determining the environmental effects of the project and compliance with permit conditions and terms. The release reports request information on adverse effects or any significant effects on human health or the environment. This information is very important in determining future permits, renewals, exemptions and commercial use of the GEO in the project. In fact this is one of the most important sources of information on the actual behavior of a GEO in a field situation; thus, it is reasonable to make a request for this type of information in order make an informed decision regarding future uses.

Subp. 12 Access. It is necessary to have access to the site in order to determine compliance with terms and conditions of the release permit and to investigate reports of problems. At times questions may arise or specific concerns might be raised regarding a project. It is necessary to have records regarding the project in order to answer those questions and to document compliance with the terms and conditions of the permit. It is reasonable to have the records maintained for three years in order to answer any questions that may come up after the project is terminated. It may be necessary to have other agencies involved in monitoring specific projects. It is reasonable to give other agencies access and to coordinate the access through the commissioner in order to prevent unneeded visits and miscommunication between the parties.

Subp. 13. Partial or complete exemption. The number of releases has increased substantially in the last two years. Many of those releases are for the six plant species that are covered under the notification procedures. There may be organisms that are not covered under the notification procedure but which have substantial information regarding environmental considerations. Some of those organisms may be eligible for partial or complete exemptions based on the environmental considerations in 1558.0030, alternative oversight as it relates to those considerations, and evidence from laboratory studies and previous releases. This type of exemption is provided for in Minnesota Statutes Section 18F.13. This is one of the sections that was needed in order to add flexibility to accommodate rapidly changing technical advances and increased numbers of releases of genetically engineered organisms. The procedures as they are outlined are reasonable to meet requirements of the statute to prevent unreasonable adverse effects to human health or the environment, and to prevent needless duplication when there is alternative oversight. It is anticipated that most of the alternative oversight would be federal regulation, but there may be some exceptions.

The 30 day period for making a determination is needed and reasonable. It gives the commissioner ample time to look at the considerations in 1558.0030, but allows sufficient time for the applicant to apply for a release permit under other sections of the rule should the exemption be denied.

There may be exemptions for classes of organisms. In the case of class exemptions the commissioner will provide for notice in the EQB Monitor and a public comment period. It is reasonable to have a comment period on class exemptions in order to ensure public participation in the review process for a class exemption. Class exemptions may result in exemptions covering projects over many locations and even projects occurring in different years, thus it is necessary to allow extra time for public comment for the broader exemption.

Individual projects that might be exempted would most likely be similar to other projects that have already been conducted in Minnesota. An example would be a project that has been conducted at many sites, now wanting to add one additional site. If there have been no problems in the previous trials and all the considerations are addressed in earlier reviews the project may be issued an individual exemption. Additional public comment would not be necessary for this type of exemption. In the case of a class exemption, because of the scale of the exemption, it is important that the public comment period will be maintained.

1558.0050 ENVIRONMENTAL ASSESSMENT WORKSHEETS

An EAW is needed in order to assess the environmental impact of a proposed release and to meet statutory requirements for being designated as an agency that issues a "significant environmental permit" under Minnesota Statutes chapter 116C and the rules promulgated under that statute. The EAW guidelines that are presented will meet the general needs of the above requirement and the specific needs of the MDA in order to assess whether an unreasonable risk of adverse effects to human health or the environment exists.

Subp. 1. Reason for EAWs. This section of the rules is needed in order to explain what an EAW is, the uses of an EAW, and how an EAW is prepared. It is reasonable to ask that an EAW be prepared using language that can be understood as much as possible by the general public. Public involvement is an important part of the review process and if the document is written in language that is highly scientific it will be difficult for members of the public to read. This does present some difficulties in preparation because the science is fairly complicated and in some cases there is no easily understood substitute for the scientific term. What is important is that the issues are clearly presented so that the public can comment on areas of concern, thus it is reasonable to include these guidelines for preparation.

It is also important that the public and the applicant understand the preparation process. The EAW is prepared by the department of agriculture using information supplied by the applicant, input from other agencies, and from other sources of expertise. This is particularly important for projects that may have significant human health or environmental issues where input from other agencies, university, or other sources as appropriate is crucial. It is necessary and reasonable to include this information to avoid confusion about EAW preparation and to assure the

public that the information is scrutinized for accuracy and completeness, and that issues are addressed.

The EAW is intended to be a summary document. All of the data is not included in the EAW. This information is included so that applicants and reviewers understand that there may be supporting documentation and references for information in the EAW, and that the supporting information can be made available if it is needed for the review. It is reasonable to request supporting documentation from the applicant in that it is needed to substantiate statements in the EAW, and in some cases to complete the review of the permit application or answer comments from the reviewers.

Subp. 2. EAW considerations. This section is needed to clearly state that the EAW must address the considerations in 1558.0030 subp. 1. It is necessary and reasonable to include this so that the considerations are consistent with EQB rules under Minnesota Statutes chapter 116C, and the applicant understands why particular questions are part of the EAW.

Subp. 3. EAW review. The EAW must be reviewed using an interdisciplinary approach in order assure that issues are properly addressed and to be considered as a significant environmental permit under EQB rules promulgated under Minnesota Statute chapter 116C; thus, it necessary to include this section even though it is mentioned in 1558.0040, subpart 4. This section reiterates that procedure both for the applicant and for the public. The review process mentions interdisciplinary review but review from the various agencies that receive the EAW is also expected and would be considered as part of the interdisciplinary review process. It is reasonable to add this section of the rules in order to avoid confusion about the review process.

Subp. 4. EAW Findings. The purpose of an EAW is to look at environmental issues. The findings of fact are a public document that addresses issues and comments from reviewers, and is used to determine if there is a potential for significant environmental effects. It is important to issue a public findings of fact to address public comments and other issues that have been identified through the EAW. If the findings show that there is a potential for significant environmental effects than an EIS must be prepared. The findings are also part of the determination process for granting or denying a permit. In some cases the EAW will identify areas which need to be mitigated by additional permit terms and conditions. It is reasonable to use the EAW in this way since it is one of the primary sources of information and it has been subject to interdisciplinary review.

Subp. 5. EIS preparation and review. An EIS is required if the EAW finds that there could be significant adverse effects on the environment, thus it is necessary to reference those procedures. The EIS procedures are those used in the EQB rules in part 4410.2000. The EIS will be done using EQB guidelines so it is

reasonable to include only a reference to the procedure rather than the complete procedure.

1558.0060 NOTIFICATION PROCEDURES FOR CERTAIN GENETICALLY ENGINEERED PLANTS

The USDA/APHIS has outlined a procedure called notification that allows for the release of certain genetically engineered plants that meet specific guidelines without requiring that they follow the full permit procedure. The statutory changes in Laws of Minnesota 1994 chapter 454 (Minnesota Statutes section 116C.98) adopt the notification procedure. This section of the rules is needed because the Minnesota statute section 116C.98 subdivision 6 calls for the repeal of this section once rules are adopted by the commissioner of agriculture. It was originally written into statute so that it could go into effect upon passage. It is reasonable to include the sections as written in statute for the notification procedure. This section is reasonable in light of the whole rule in that these organisms have been shown to be safe for release if the eligibility criteria and performance standards are met.

Subp. 1, 2, and 3. USDA/APHIS has adopted a shortened procedure for the release of corn, cotton, potato, soybean, tobacco, and tomato. Additional plants may be added if they can meet the standards that are set forth in the rule 1558.0060 subp. 1 and 2. The notification procedure is important in that many of the current releases would fall under this provision. Notification was added under Minnesota statute section 116C.98 and will be automatically repealed as soon as rules on notification are adopted by the commissioner of agriculture. The legislation is very specific on exactly what must be covered in the notification procedure. It includes eligibility criteria, performance standards, and procedures for application, thus it is necessary to include those sections.

The eligibility criteria and performance standards are essentially the same as USDA/APHIS. USDA/APHIS has interpreted the eligibility criteria and performance standards in the broadest sense. MDA will follow that precedent and use a broad interpretation as well. In reviewing applications MDA will also consult agencies, university, and other groups if questions arise about issues relating either to appropriateness of using the notification procedure or other issues. This is reasonable in that it allows the commissioner to accept the federal application and to essentially follow the federal notification procedure, but it also allows the commissioner the opportunity for independent review of the federal process and for an opportunity to address issues identified during the review. The notification process will substantially reduce paperwork and duplication in the permitting process.

Subp. 4. Federal notification as application. It is necessary to have adequate information to see if the proposed release meets the eligibility criteria and the

performance standards. The eligibility criteria and performance standards for the state are the same as those for the USDA/APHIS notification process; therefore, it is reasonable to use the federal documents as a source for the information needed to make a determination. It is important to have all of the data labeled bin the federal documents as "confidential business information" in order to make a determination, thus it is necessary and reasonable to request that this information be include in the documents that are submitted. In general two sets of documents are submitted to the federal government. One set without the confidential business information and one set with that information. The rule merely specifies that the state requires the confidential business information to be included in the notification. The use of federal documents reduces unnecessary paperwork and expedites the process. It is necessary to request a complete site description in order to properly monitor the project. It is reasonable to ask for this in addition to the federal documents. The site is not usually completely identified in the federal documents.

Subp. 5. Notification before release. The thirty day notification period is the same as the federal waiting period. It is necessary to have time to examine the application to ensure that it meets the eligibility criteria and performance standards in the rules. The thirty day period is reasonable in that it gives adequate time to examine the notification, is consistent with the federal waiting period, and will not unduly delay the release.

Subp. 6. Release reports. Release reports are required for the same reasons as those mentioned in 1558.0040 subp. 12.

Subp. 7. Unexpected occurrences. It is possible that unexpected occurrences or adverse effects may be seen in a project; therefore, it is necessary and reasonable to include procedures for dealing with problems. The 48 hour time period gives the responsible person adequate time to notify the commissioner without causing additional problems due to delays in reporting.

Subp. 7. Access. It is necessary to have access to the site in order to determine compliance with terms and conditions of the notification. It is also necessary to have records regarding the project in order to document compliance. It is reasonable to have the records maintained for three years in order to answer any questions that may come up after the project is terminated. It may be necessary to have other agencies involved in specific projects, thus it is reasonable to allow access to the project to other agencies. It is also reasonable to coordinate the access through the commissioner in order to a prevent unneeded visits and miscommunication between the parties.

Subp. 8. Administrative action in response to notification. This section is needed in order to outline the procedures that are used in the notification process. Some of the procedures are needed to conform to the legislative mandates. This

would include the public notice in the EQB Monitor and the notification of the EQB of any unexpected occurrences. The other procedures are needed to inform the applicant of the time period required prior to planting, the right to apply under other sections of the rule should the notification be denied, and the right to rescind the notification should there be unreasonable adverse effects on human health or the environment. It is reasonable to include a 30 day time period in that it allows ample opportunity to review the notification but should also be short enough to allow the applicant to reapply under another section if necessary. The 30 day time period is consistent with USDA procedures as well. It is important to keep the time period relatively short due to the seasonal nature of many of the releases.

1558.0070 COMMERCIAL USE EXEMPTION

This section outlines the exemption procedures used to release organisms for commercial use. Exemptions for commercial use are authorized under Minnesota Statutes section 18F.13a. The rule is written to allow for release without a permit if the requirements are met, class exemptions when there are many similar releases, and the right to rescind the exemption should there be any unreasonable adverse effects on human health or the environment associated with the commercial use.

Subp. 1. Commercial use. This section defines commercial use. It is needed in order to clearly delineate which releases fall in this category. There are cases where an organism is delisted after an applicant has petitioned the USDA. This delisting may be the final regulatory action on the federal level. The organism may not be available in a form or quantity that is needed for commercial sale, but it is clearly beyond the release permit stage. It is reasonable to include those items that might be considered pre-commercial in that the law is written in such a way that they validly fall under the section allowing exemptions under Minnesota Statute section 18F.13a. It is reasonable to exclude experimental or developmental releases from this section because they properly fall under 1558.0040, releases requiring permits or 1558.0060, notification. This section of the rules is intended to allow commercialization, but it is also intended to act as a safeguard for the commercial use of genetically engineered organisms. In the vast majority of the cases the federal procedures will adequately address the considerations in section 1558.0030 subp. 1; therefore, it is likely that in most cases where an GEO has obtained federal approval the state will concur.

Subp. 2. Procedures. Commercial use exemptions are based on the federal delisting or deregulation and the considerations in 1558.0030 subp. 1. Items that meet this standard need not obtain a release permit. This standard is reasonable in that it uses the same considerations that have been identified for other environmental review under this chapter.

Subp. 2A. This section of the rules indicates that federal documentation will be used as the source of information for the considerations. This is reasonable in that it will reduce duplication and paperwork for all parties.

Subp. 1B allows for public notice prior to commercialization. The public notice is important part to make sure that the public is informed about the commercial use of genetically engineered organisms. The 30 day time period is reasonable in that it allows for adequate time to address any additional issues that might be raised by the public prior to sale.

Subp. 1C allows the commissioner to impose additional limits on commercialization in order to mitigate the risk of unreasonable adverse effects on human health or the environment. This is reasonable in that there may be state concerns that were not addressed completely by the federal procedure. An example might be protection to a state threatened species that was not on federal protected lists.

Subp. 1D gives procedures for exempting certain individual organisms or classes of genetically engineered organisms from the procedures in 1558.0070 subp. 2A, B, or C. This section is reasonable in that many of commercial products will likely be similar and it may be possible to look at individual GEOs or a whole class of GEOs and exempt them from additional regulation. This will be particularly important as the number of products increases. An example of a class exemption might be an exemption for corn carrying a particular insect resistance gene. Each corn variety would not have to be exempted separately but they could be exempted as a class and commercial use allowed for the entire group. This is reasonable in that the considerations would still be met and public comment would be allowed on class exemptions. The public comment on class exemptions is important in that it gives an opportunity for public review of the broader exemption.

Subp. 1E. There may be cases where there are specific concerns that are not addressed by the federal procedure. This section will give the flexibility to accept the federal ruling if the considerations are met, but it will still give the commissioner the authority to reject an application for commercial use should there be unreasonable adverse effects on human health or the environment.

1558.0070 subp. 1F allows for suspension, modification, or revocation of the exemption should any unreasonable adverse effects on human health or the environment be found at a later date. It is necessary and reasonable to have a means of addressing unforeseen problems. Suspensions, modifications, and revocations are discussed under 1558.0040 subp. 7.

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

This section is needed to delineate the specific uses that do not require a release permit, notification, or commercial use exemption. These uses are exempted under the rules because they do not constitute a release under Minnesota Statute chapter 18B, 18C, or 18F. It is reasonable to include them in the rule to avoid any confusion about what is considered a release under the law.

Subp. 1. Containment facility. This section describes a containment facility. It is necessary to include this description so that the reader will be able to determine if a release permit, notification or commercial use exemption is needed. The use of USDA/APHIS and NIH guidelines is reasonable in that grant funding depends on compliance and industry is also voluntarily complying with the guidelines. It is reasonable to have the commissioner certify and inspect such facilities to ensure compliance and to determine that the use is not a release.

Subp. 2. Facility exemption. One of the problems with the NIH or USDA/APHIS guidelines is they do not cover all the facilities that might be used; thus, a method for looking at case by case use is an important part of determining containment. Additionally there may be facilities that do not meet the exact requirements but which may provide adequate containment for specific projects. These facilities must be judged on a case by case basis. An example of this might be the use of a greenhouse that did not meet all the requirements might be considered adequate containment if it was used only during the winter months. It is necessary to have a mechanism to determine if these facilities provide adequate containment or if a release permit, notification or commercial use exemption is required under the statute. It is reasonable to include this standard because there are many cases where this could be applied. It is also reasonable to include the right to inspect facilities to insure adequate containment.

Subp. 3. Movement of GEOs. GEOs must be moved in order to get them to the area where a release is proposed. The process of moving them must include adequate containment to prevent release into the environment during transport; therefore, it is necessary to include guidelines on movement. Federal guidelines govern interstate movement and are designed to prevent release into the environment; thus it is reasonable that movement falls into this section of the rules. It is reasonable that the same standards are used for both inter- and intra-state movement. This will help prevent confusion and result in standard movement procedures for all types of movement. It is also necessary and reasonable to allow for inspections to ensure compliance with those guidelines.

1558.0090 CONCURRENT PERMIT REVIEW

Concurrent permit review is mandated under Minnesota Statute section 18F.12. Multiple permits may be required under Chapter 18B, 18C, or 18F; thus, this section is needed to adhere to the statutory guidelines. It is important to avoid unnecessary paperwork and duplication of applications. It is reasonable to have the section written in this manner to prevent the applicant from having to submit multiple applications and obtain multiple permits. It is reasonable to have one application that would supply all the relevant information for all sections of the statutes governing release of genetically engineered organisms. This will prevent duplication and confusion for the applicant.

IV. COST TO PUBLIC BODIES

As prescribed by Minnesota Statute section 14.11 subd. 1 a statement regarding the fiscal impact on local public bodies is required. This rule will not result in the expenditure of public money by local public bodies.

V. SMALL BUSINESS IMPACT

As prescribed by Minnesota Statute section 14.115 subd. 1 and 2, the MDA has considered the degree of impact on small businesses and the alternative methods for lessening that impact.

The MDA has determined that small businesses should benefit from the proposed rule in that it will eliminate previous duplication and unneeded paperwork. The rule proposes using existing information and documents wherever possible. These documents are already required by the federal regulatory process. In the past, the state regulatory process resulted in duplication and additional waiting periods in many cases. It is likely that the new rules will actually result in an easier, less time consuming procedure for all businesses.

Minnesota Statute section 14.1115 subdivision 2 provides that an agency shall consider several mechanisms for reducing the impact on small businesses. Each of those mechanisms is examined separately as it relates to the rules on the release of agriculturally related genetically engineered organisms.

A. The establishment of less stringent compliance or reporting requirements for small businesses.

The Minnesota Department of Agriculture (MDA) has looked at the compliance and reporting requirements as they relate to small business. The compliance and reporting requirements are based on the nature of the GEO, the environment into which it is released, and other factors unrelated to the size of the company. In

some cases a commercial use exemption will be granted or reduced regulatory oversight will be allowed. The less restrictive compliance and reporting requirements in these cases are due to factors relating to the release and not to the company requesting the release; thus, less restrictive requirements based on the size of the company would not be appropriate.

B. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The agency has established schedules and deadlines that will result in sufficient time to review applications and address issues related to the release. The time allowances are short enough to allow for timely project initiation and seasonal activities related to field projects. Most of the deadlines in the rules are for agency review and response. The applicant controls the start of the process by filing an application. The length of time needed to review an application is related to the type of application, public notice and comment periods, and to the issues related to the project. These factors are not affected by the size of the company; thus, reduction in time schedules for small businesses is inappropriate.

C. The consolidation or simplification of compliance or reporting requirements for small businesses.

The agency has established procedures that allow for review of a release permit application, notification, or commercial use exemption in a timely manner. None of the timelines should delay projects or commercial use. The rule allows for reduced reporting or compliance for particular uses and types of GEOs. The reduced compliance is based on factors other than the size of the business. The rule has tried to minimize the impact on all businesses. Additional reduction for small businesses would not be appropriate since the release conditions are not affected by the size of the business.

D. The establishment of performance standards for small businesses to replace design or operational standards required in the rule.

The agency has not proposed any specific design or operational standards for releases of GEOs in the rules. The test for the release of a GEO under Minnesota Statute section 18F.07 subdivision 2 is that it does not cause unreasonable adverse effects or human health or the environment. This is already a performance based standard; therefore, all applicants including small businesses have only performance standards to meet.

Those persons who are maintaining containment facilities must adhere to National Institute of Health guidelines. The NIH guidelines do not distinguish between the size of the facilities. These guidelines are commonly used by industry and

academia and it is not appropriate to substitute reduced guidelines for containment.

E. The exemption of small businesses from any or all requirements of the rule.

The requirements for release of GEOs are based on considerations of unreasonable adverse effects on human health or the environment. The size of a company will have no effect on the determination; thus, it is not appropriate to exempt any company from the rules. Since the requirements set by these rules are reasonable to prevent unreasonable adverse effects to human health or the environment, any alternative method to further reduce the impact would be contrary to Minnesota Statutes chapters 18 B, 18C, 18F, and 116C.

Elton R. Redalen

Elton R. Redalen
Commissioner

9-1-94

Date