

STATE OF MINNESOTA  
OFFICE OF ADMINISTRATIVE HEARINGS  
FOR THE MINNESOTA ENVIRONMENTAL QUALITY BOARD

In the Matter of the Proposed Adoption  
of Permanent Rules Relating to the Release  
of Genetically Engineered Organisms, Proposed  
Amendments to Minn. Rules Pts. 4410.0200,  
4410.4300, 4410.8000 and Proposed New Minn.  
Rules Pts. 4420.0010 to 4420.0070.

REPORT OF THE  
ADMINISTRATIVE LAW JUDGE

EDITOR'S NOTE: In the interest of brevity, some material  
has been omitted from this published version.

The above-entitled matter came on for hearing before Administrative Law Judge Allen E. Giles on January 27, 1992, at 1:00 p.m., in Room 301 of the Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155. This is the second rulemaking proceeding on the proposed rules. Hearings were also held at the same location on September 27 and October 25, 1991, as a part of the first rulemaking proceeding. This is explained more fully in Finding 8 below.

This Report is part of a rulemaking proceeding held pursuant to Minn. Stat. P 14.131 to 14.20, to hear public comment, to determine whether the Minnesota Environmental Quality Board has fulfilled all relevant, substantive and procedural requirements of law applicable to the adoption of the rules, whether the proposed rules are needed and reasonable and whether or not modifications to the rules proposed by the Minnesota Environmental Quality Board (hereinafter also referred to as "the Board" or EQB) after initial publication constitute impermissible, substantial changes.

Alan R. Mitchell, Special Assistant Attorney General, Second Floor Ford Building, 117 University Avenue, St. Paul, Minnesota 55155, and Eldon Kaul, Assistant Attorney General, Suite 200, 520 Lafayette Road, St. Paul, Minnesota 55155, appeared on behalf of the EQB. The Board's hearing panel consisted of John Hynes, Permit Compliance Manager, and Michael Sullivan, Executive Director.

Approximately 25 persons attended the hearing on January 27, 1992, and 16 persons signed the hearing register. Approximately 75 persons attended the previous hearings on September 27, and October 25, 1991; 55 persons signed the

hearing register at those hearings.

The record remained open for the submission of written comments for 10 calendar days following the January 27 hearing to February 6, 1992. Pursuant to Minn. Stat. P 14.15, Subd. 1 (1990), 3 business days were allowed for the filing of responsive comments. At the close of business on February 11, 1992, the rulemaking record closed for all purposes. The Administrative Law Judge received written comments from interested persons during the comment period. The MEQB submitted written comments responding to matters discussed at the hearings and proposed further amendments to the rules.

The EQB must wait at least five working days before taking any final action on the rules; during that period, this Report must be made available to all interested persons upon request.

Pursuant to the provisions of Minn. Stat. P 14.15, subd. 3 and 4, this Report has been submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings of this Report, he will advise the EQB of actions which will correct the defects and the Board may not adopt the rule until the Chief Administrative Law Judge determines that the defects have been corrected. However, in those instances where the Chief Administrative Law Judge identifies defects which relate to the issues of need or reasonableness, the EQB may either adopt the Chief Administrative Law Judge's suggested actions to cure the defects or, in the alternative, if the EQB does not elect to adopt the suggested actions, it must submit the proposed rule to the Legislative Commission to

If the EQB elects to adopt the suggested actions of the Chief Administrative Law Judge and makes no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, then the EQB may proceed to adopt the rule and submit it to the Revisor of Statutes for a review of the form. If the EQB makes changes in the rule other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, then it shall submit the rule, with the complete record, to the Chief Administrative Law Judge for a review of the changes before adopting it and submitting it to the Revisor of Statutes.

When the EQB files the rule with the Secretary of State, it shall give notice on the day of filing to all persons who requested that they be informed of the filing.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

#### FINDINGS OF FACT

##### Procedural\_Requirements

1. On December 23, 1991 the EQB filed the following documents with the

Administrative Law Judge:

- (a) A copy of the proposed rules certified by the Revisor of Statutes.
- (b) The Order for Hearing.
- (c) The Notice of Hearing proposed to be issued.
- (d) An Addendum to the Statement of Need and Reasonableness (hereinafter also referred to as "SONAR") that supplimented the SONAR by considering the impact of the proposed rule on small businesses.
- (e) A Statement of Additional Notice which indicated that notice was being mailed to all persons that registered at the September 27 and October 25, 1991 hearings in the first rulemaking proceeding and to the list of businesses provided by the Minnesota Biotechnology Association.

2. On Monday, December 23, 1991, a Notice of Hearing on the proposed rules were published at 16 State Register (S.R.) 1528. The Notice of Hearing indicated that the proposed rules were previously published at 16 S.R. 422-433, August 26, 1991. The Notice of Hearing also indicated that the EQB was required to hold another hearing because the agency failed to consider the impact of the proposed rules on small businesses. The Notice further indicated that the entire record of the previous rulemaking proceeding would be incorporated into this proceeding and that it was not necessary for anyone who submitted oral or written testimony at the previous proceeding to resubmit testimony, only new testimony needed to be submitted.

3. On December 23, 1991, the EQB mailed the Notice of Hearing to all persons and associations who had registered their names with the EQB for the purpose of receiving such notice.

4. The hearing was held on January 27, 1992, the period for submission of written comment and statements remained open for 10 days after the hearing date to February 6. The record closed on February 11, 1992, the third business day following the close of the comment period.

5. Minn. Rules Pt. 1400.0600 requires that the EQB file the following documents with the Administrative Law Judge at least 25 days before the hearing:

- (a) The Notice of Hearing as mailed.
- (b) The Agency's certification that its mailing list was accurate and complete.
- (c) The Affidavit of Mailing the Notice to all persons on the Agency's list.
- (d) An Affidavit of Additional Notice.
- (e) The names of EQB personnel who will represent the Agency at the hearing together with the names of any other witnesses solicited by the Agency to appear on its behalf.
- (f) A copy of the State Register containing the proposed rules.
- (g) The Petition requesting a rule hearing.

These documents were not filed at the Office of Administrative Hearings 25 days

before the hearing. Instead they were submitted at the hearing.

6. Failure to comply with Minn. Rules Pt. 1400.0600 constitutes a  
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7. In determining whether a procedural error is harmless, one must examine the extent to which the agency deviated from the requirements, whether the deviation was inadvertent, and the potential impact the procedural irregularity could have on public participation in the rulemaking process. Auerbach Administrative Rulemaking in Minnesota, 63 Minn. L. Rev. 151, 215 (1979); but see *Johnson\_Brothers\_Wholesale\_Liquor\_Co.\_v.\_Novak*, 295 N.W.2d 238, 241-42 (Minn. 1980). In this case the documents were available for inspection and copying at the Office of Administrative Hearings from after the date of the hearing to February 11, 1992, the date the record closed. At the hearing and in comments after the hearing no member of the public has complained of prejudice resulting from the Board's failure to comply strictly with Minn. Rules Pt. 1400.0600. Under these circumstances the Administrative Law Judge finds the error to be harmless, not affecting the ability of the EQB to adopt the proposed rules. See *City\_of\_Minneapolis\_v.\_Wurtele*, 291 N.W.2d 386, 391 (Minn. 1980); see also *Handle\_With\_Care\_v.\_Department\_of\_Human\_Services*, 406 N.W.2d 518 (Minn. 1987).

Second\_Rulemaking\_Proceeding.

8. As has been referenced earlier in this Report, this is the second rulemaking proceeding on the proposed rules. Hearings were held on September 25 and October 27, 1991, and the record initially closed on November 12, 1991, in the first rulemaking proceeding. After the close of the record on November 12, 1991, the Administrative Law Judge concluded that the EQB had failed to properly notice and discuss in its SONAR the impact of the proposed rules on small businesses as required by Minn. Stat. § 14.115, Subd. 2. The entire record from the first rulemaking proceeding, including the transcripts of the hearings on September 25, and October 27, 1991, as well as all the comments submitted up to the close of the record on November 12, 1991, were preserved and submitted as an exhibit in this rulemaking proceeding at the hearing on January 27, 1992.

Small\_Business\_Considerations\_in\_Rulemaking.

9. Minn. Stat. § 14.115, Subd. 2 (1990) requires state agencies proposing rules affecting small business to consider methods for reducing adverse impact on those businesses. As stated earlier, this is the second rulemaking proceeding on the proposed rules. In the first rulemaking proceeding the EQB stated in its Notice of Hearing that the proposed rules would not have a direct impact on small businesses. The EQB's SONAR contained no discussion or explanation of the impact that the proposed rules will have on small businesses as required by Minn. Stat. § 14.115, Subd. 2. The Minnesota Administrative Procedures Act prohibits approval of proposed state agency rules

that have failed to comply with this provision. As a result the EQB terminated the rulemaking proceedings and issued a Notice of Hearing for a second rulemaking proceeding on December 23, 1991. At that time the Administrative Law Judge was also supplied with an Addendum to the Statement of Need and Reasonableness. In the Addendum and its Notice of Hearing the EQB states that the proposed rules will have an impact on small businesses. Small business, like large businesses, engaged in production of biotechnology products may require experimentation or field testing of the genetically engineered organism. Therefore, small businesses, like large businesses, must be subject to these rules in order to accomplish the purposes of the enabling legislation.

10. The EQB explained in its SONAR that the same requirements for the use and release of genetically engineered organisms must apply regardless of the size of the business entity that is using or releasing the genetically engineered organism. The EQB further explained that "a threat to human health or the environment from a genetically engineered organism is the same regardless if a large business or a small business releases the organism." The EQB stated a

The agency believes that it would be inappropriate to allow small businesses to use and release genetically engineered organisms in ways that are not permitted by large businesses and that may jeopardize public health or the environment. The agency has been cognizant of the concerns of all business that the government not unduly hinder the development of this emerging industry, yet the agency must fulfill its mandate to protect public health and the environment. These rules provide a reasonable mechanism for providing the government and the public with the necessary information to ensure that health and environmental consequences are evaluated in advance of the release of genetically engineered organisms while not delaying industry in its endeavor to seek improvement in the agricultural, medical, and other fields, through the development of genetically engineered organisms.

11. The Administrative Law Judge finds that the EQB has considered all the factors for reducing the impact of the proposed rules on small businesses as required by Minn. Stat. § 14.115, Subd. 2. The Administrative Law Judge further finds that the EQB has also complied with all other requirements for evaluating the impact of the proposed rules on small businesses.

Fiscal\_Note.

12. Minn. Stat. § 14.11, Subd. 1, requires the preparation of a fiscal note when the adoption of a rule will result in an expenditure of public funds in excess of \$100,000.00 per year by local public bodies. The notice must include an estimate of the total cost to local public bodies for a two-year

period. In its Notice of Hearing the EQB stated that the proposed rules would not require the expenditure of public funds by local public bodies. The Administrative Law Judge finds that no fiscal note is required for these rules, since no expenditures of public money are required by the proposed rules.

#### Impact\_on\_Agricultural\_Land.

13. Minn. Stat. § 14.11, Subd. 2 (1990), imposes additional statutory requirements when the rules proposed have a "direct and substantial adverse impact on agricultural land in the state." The statutory requirements referred to are found in Minn. Stat. § 17.80 to 17.84. Under those statutory provisions, adverse impact includes the following: (a) Acquisition of farmland for a nonagricultural purpose; (b) Granting a permit for the nonagricultural use of farmland; and (c) using state-owned land for nonagricultural purposes, or granting or loaning state funds for uses incompatible with agriculture. Genetically engineered organisms that have commercial agricultural applications will have an impact on agriculture, but that impact does not fall within the statutory definition of "direct and substantial adverse impact on agricultural land." The Administrative Law Judge finds that the proposed rules will have no substantial adverse impact on agricultural land within the meaning of Minn. Stat. § 14.11, Subd. 2 (1990).

#### Advisory\_Committee\_on\_Genetically\_Engineered\_Organisms.

14. Minn. Stat. § 116C.93 requires that the EQB establish an advisory committee on genetically engineered organisms to provide the Board with advice "on general issues involving genetic engineering and on issues relating to specific proposals." The advisory committee provides technical expertise in areas in which the EQB is lacking. The EQB consulted with the committee on substantive scientific aspects of the proposed rules regarding the release of genetically engineered organisms. The committee made recommendations, some of which were incorporated into the proposed rules. SONAR at 3.

#### State\_Regulation\_of\_Genetic\_Engineering.

15. Minn. Stat. § 116C.91, Subd. 3 defines "Genetic Engineering" in part as "the introduction of new genetic material to an organism or the regrouping of an organism's genes using techniques or t

16. Genetic engineering or more specifically, the product of this biotechnology process, a genetically engineered organism or "GEO" offers substantial promise for providing a wide range of benefits to society, particularly in the areas of human health care, animal health care and development, plant agriculture, food production, and environmental management. Hoffman, "The Biotechnology Revolution and Its Regulatory Evolution," 38 Drake Law Review 471 (1988-1989). Entrepreneurs have quickly recognized the potential commercial applications of genetic engineering and have made substantial commercial investment in the development of GEOs. In general, to

be effective a genetically engineered organism must survive in the environment at least for the period of time necessary to accomplish a designated task. To measure the effectiveness of GEOs, biotechnicians must conduct field tests that involve the deliberate release of a genetically engineered organism into the environment.

17. Academies, scientists, and other scholars and experts in the field of genetic engineering have widely divergent views about the risks to human health and the environment that arises from the environmental release of genetically engineered organisms.

18. This rulemaking proceeding has emerged as the most recent forum in which these widely divergent views have collided.

19. There are those who assert that genetic engineering is really nothing new and poses no risk or risks no greater than those already existing in classical animal or plant breeding processes. The National Academy of Sciences has recently concluded that with respect to field testing of GEOs "There is no evidence that unique hazards exist in the use of recombinant DNA techniques or in the transfer of genes between unrelated organisms." National Academy of Sciences, Introduction of Recombinant DNA-Engineered Organisms Into the Environment: Key issues, 822 (1987).; Law of Environmental Protection Section 18.02(4)(d), (S. Novick, D. Stever, and M. Mellon BDS. 1987 -- "To date, ecologists have not identified any new adverse ecological consequences which flow directly from the method by which organisms were engineered . . . Some ecologists even refuse to distinguish among traditional and advanced methods of genetic engineering when discussing environmental risk.")

20. Many commentators, including the University Committees, the Minnesota Biotechnology Associations, Biotechnica International, Inc., D. Glass Associates, the FDA and the Molecular Biology Institute of UCLA, assert that genetic engineering is not inherently more risky than classical plant or animal breeding; that regulation should focus on risk instead of on the genetic engineering process and it is indefensible to assert that genetic engineering is more risky than classical animal or plant breeding; and that state regulation will duplicate regulation already in place at the federal level by the U.S. Department of Agriculture, FDA and the EPA. They argue that the additional layer of regulation will discourage research and development of biotechnologies in this state.

21. In contrast to these views, there are others who view the deliberate release of genetically engineered plants and animals into the environment through field trials or agriculture use as posing potential risks that are

unknown but capable of having extreme, irreversible consequences. Note, "The Monkey's Paw: Regulating the Deliberate Environmental Release of Genetically Engineered Organisms," 66 Washington Law Review 247, (1991). While there is a very low risk that GEOs will imperil human health or the environment there is a concern that if there is such exposure, the potential ecological impact could be catastrophic. Note, "The Rutabaga That Ate Pittsburg", 72 Virginia Law Review, 1529 (1986). Some have termed this as a "low probability/high consequence" risk and have likened it to the risk associated with nuclear power plants. Id. at 1560.

23. The debate regarding the potential impact of environmentally released GEOs on human health and the environment has come too late to affect the outcome of this proceeding. The Minnesota Legislature has already determined that all genetic engineering releases must be regulated. The Legislature has directed the EQB to establish procedures and standards for conducting environmental reviews and issuing permits for releases of genetically engineered organisms. The purpose of the proposed rules as stated in Minn. Rules Pt. 4420.0015, Subp. 3 is as follows:

1. Protect human health and the environment from any significant or material adverse impacts that could result from the release of genetically engineered organisms.
2. Allow for the orderly and safe development and use of released genetically engineered organism.
3. Provide information to the EQB and the public concerning proposed releases of genetically engineered organisms.
4. Provide an orderly and timely process for making decisions on permits for the release of genetically engineered organisms.

#### Statutory Authority for Proposed Rules.

24. In 1989 the Minnesota Legislature enacted Minn. Stat. § 116C.91 to 116C.95 (1990) authorizing the EQB to promulgate rules relating to the deliberate release into the environment of genetically engineered organisms within the state of Minnesota. Minn. Stat. § 116C.94 mandates that the Board's proposed rules require a permit and an environmental assessment worksheet for any release of genetically engineered organism not subject to a significant environmental permit from another state agency. In 1991, the Legislature amended the Board's rulemaking authority by defining "significant environmental permit" and carving out another exception for certain qualified federal agency permits. The Administrative Law Judge concludes that the EQB has general statutory authority to adopt these rules.

Public\_Concern\_for\_or\_Promotion\_of\_Genetic\_Engineering.

25. The Administrative Law Judge received approximately 200 comment letters regarding the proposed rule. Approximately 150 of those letters were from citizens commenting generally about the proposed rules. The general citizen letters support the proposed rule's requirement of a permit for release of a genetically engineered organism. In addition to the requirement of a permit, the general correspondence letters also support a requirement of full disclosure of the potential impact on human health and impact on the environment. In other words, every application for a permit would fully disclose the known impact on human health and impact on the environment of a potential proposed release. The positions and points of view taken by the following citizens are typical of the positions or points of view expressed in the general comment letters

26. The Administrative Law Judge also received letters from persons involved in agricultural production, principally farmers and food processors. These commentators expressed concern that the proposed rules will discourage agricultural achievements and place farmers at a competitive disadvantage compared to farmers in surrounding states. They further state that federal regulations of the U.S.D.A., F.D.A. and E.P.A. already regulate genetic engineering, and as other states are not considering such regulations, why should Minnesota farmers be burdened with the potential inability to use certain genetically engineered bio-insecticides or varieties of plants. The following letters are good summary of the comments made:

Reasonableness\_of\_the\_Proposed\_Rules

27. The question of whether a rule is reasonable focuses on whether it has a rational basis. The Minnesota Court of Appeals has held a rule to be reasonable if it is rationally related to the end sought to be achieved by the statute. Broen\_Memorial\_Home\_v.\_Minnesota\_Department\_of\_H of the proposed rules. The agency has also supplied comments following the hearing to supplement the testimony presented at the public hearings.

28. After careful review and consideration of the EQB's Statement of Need and Reasonableness and based upon the agency's oral presentation at the hearings, and comments submitted after those hearings, and after having considered testimony from the hearings and voluminous comments from the public regarding the proposed rules, the Administrative Law Judge finds that the EQB has affirmatively established the need and reasonableness of each part of the proposed rules except as otherwise qualified or determined by the findings and conclusions that follow.

Changes\_Made\_to\_the\_Proposed\_Rules.

29. The proposed rules generated much public interest. Comments and suggestions made in the course of the rulemaking proceedings have been voluminous. Certain parts of the rule are scientific in nature. Many academic, environmental and biotechnical industry groups submitted technical changes to the Administrative Law Judge.

30. The rule was initially published in the State Register on August 26, 1991. From the date of publication and continuing through the end of the final response period on February 11, 1992, the EQB, on its own initiative and in response to public comments, has made numerous changes to the proposed rules. The changes in the rules are EQB's response to the testimony at the hearings and comments of the public received after the hearings.

31. In the course of the two rulemaking proceedings, the EQB has made numerous modifications to accommodate various stated concerns and to improve the rules. The Administrative Procedures Act allows an agency such as the EQB during a rulemaking process to make modifications to the rules as proposed unless the modifications constitute substantial change. Minn. Stat. P 14.15, Subd. 3. According to Minn. Rule Pt. 1400.1100, Subp. 1, a modification is a substantial change if: (a) it affects classes of people who could not have been reasonably expected to comment on the proposed rules at the hearing; (b) the changes go to a new subject matter of significant substantive effect; or (c) the change results in a fundamentally different rule in effect. Applying these standards to the modifications to the proposed rules the Administrative Law Judge finds and concludes that the changes made by the EQB are reasonable and in response to public comments and do not constitute impermissible substantial changes.

32. The Administrative Law Judge will not go through a section-by-section analysis of the proposed rules addressing issues of need, reasonableness and statutory authority. Instead, the following analysis will focus only upon situations where the Administrative Law Judge believes that there is problem with the proposed rules or an issue which deserves explanation.

33. As previously indicated this Report will not discuss each rule part. A part not commented on in this Report is hereby found to be needed and reasonable and does not exceed the statutory authority of the EQB for the promulgation thereof.

Analysis\_of\_Rule\_Parts\_Generating\_Significant\_Public\_Commentary.

Containment\_Facility\_and\_Certifications\_-\_Minn.\_Rules\_Pt.\_4420.0020,\_Subp.\_5, Renumbered\_Minn.\_Rules\_Pt.\_4420.0070.

34. Because a release was defined as the placement or use of a genetically engineered organism outside a "containment facility" the EQB reasoned that it was necessary for it to define "containment facility" and require a certain level of biosafety at such a facility. The rule as originally proposed required that the owner or operator of a facility -- such as a research laboratory that engages in, for example, recombinant DNA experiments -- be required to file "supporting documents" establishing the level of biosafety maintained in the facility in order to obtain a certification. Thus all laboratories, greenhouses and other places where genetic engineeri

35. The University Committees opposed the requirement that the University

certify the biosafety of each lab engaged in the manipulation of genetic material or recombinant DNA research. The University Committees asserted that the EQB did not have statutory authority to certify and inspect containment facilities. In addition, the EQB did not have the employees or the expertise to evaluate and inspect the hundreds of labs at the University of Minnesota engaged in recombinant DNA experimentation. The University Committees further argued that the certification and inspection requirements are redundant and unnecessary, and the cost for establishing a certification and inspection system with appropriate expertise would be extremely costly for the state.

Professor Michael C. Flickinger, chairman of the University of Minnesota Institutional Biosafety Committee (IBC) explained that the University of Minnesota labs engaged in recombinant DNA research already complied with the NIH guidelines for recombinant DNA research, including assessment of the appropriate containment levels required by the Guidelines and assessment of the facilities, practices and training of investigators involved in recombinant DNA research. He concluded as follows:

Redundant certification and inspection would be extremely cumbersome and confusing, both for the University and the state of Minnesota, and is unnecessary as all laboratories are currently certified by the existing NIH - mandated University IBC. The overwhelming majority of investigations involving recombinant DNA molecules at the University of Minnesota do not involve deliberate release of organisms into the environment.

36. D. Glass Associates opposed proposed rule Pt. 4420.0020, Subp. 5 relating to certification of containment facilities:

The provisions of Pt. 4420.0020, Subp. 5 would create a requirement for every institution in the state conducting research in the broad fields of genetic manipulation to register their laboratory facilities with the EQB, to submit apparently significant documentation in support of chosen containment levels and to have the lab certified as adequately contained. D. Glass Associates strongly opposes this provision. Not only would it create a new regulatory program within the EQB far larger than EQB staff probably expect, but it would greatly inconvenience a very large number of institutions, especially academic institutions, by imposing new, unnecessary burdens for previously unregulated activities. . . . EQB may not be aware of the extent to which the rDNA have become routine both in scientific research and in teaching. Recombinant DNA is used in virtually every biology research laboratory in the world, and rDNA methods are routinely taught in high school classes all around the United States, no doubt including Minnesota. The proposed certification requirement in these regulations could easily encompass hundreds of facilities, many of which have never been

subject to an regulation at all, and where most haven't the slightest desire to conduct the outdoor experiments that are the real target of the 1989 legislation. In short, creation of this scheme would be a bureaucratic nightmare for EQB.

Biotechnica International, Inc., a/k/a Plant Science Research, Inc. of Minnetonka concurred with the comments of D. Glass Associates.

38. Responding to these comments, the EQB has proposed numerous changes to the containment facility certification requirements. The changes appear in new Pt. 4420.0070. As revised the proposed rules no longer require the filing of "supporting documents" demonstrating compliance with NIH guidelines. Th

39. The University Committees also asserted that the EQB did not have the statutory authority to certify and inspect containment facilities. The EQB indicates that its authority for inspecting and certifying containment facilities is implied from Minn. Stat. P 116C.91, Subd. 6. Minn. Stat. P 116C.91, subd. 6 defines "release" as follows:

"Release" means the placement or use of a genetically engineered organism outside a contained laboratory, greenhouse, building, structure, or other similar facility or under any other conditions not specifically determined by the Board to be adequately contained.

According to this language a release occurs when a genetically engineered organism is placed outside a contained facility or outside under conditions determined by the Board to not be contained. Because the EQB must determine whether a release permit is necessary it is reasonable for it to inspect and obtain information regarding the status of containment of various facilities from which releases might occur.

40. The Administrative Law Judge concludes that the EQB has the statutory authority to inspect and to require information regarding the status of containment in facilities where genetically engineered organisms are used or developed.

Significant\_Environmental\_Permit.\_\_Minn.\_Rules\_Pts.\_4420.0010,\_Subp.\_20; 4420.0020,\_Sup.\_3;\_\_Renumbered\_4420.0010,\_Subp.\_21;\_4420.0075.

41. Minn. Stat. P 116C.94(b) requires that these proposed rules 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. P 116C.91, Subd. 7 (Supp. 1991) defines a significant environmental permit (SEP) 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 Minn. Stat. P 116C.91 to 116C.96, Chapter 116D., and the rules adopted under them." Exemptions for significant environmental permits are necessary to avoid overlapping permit authority of various agencies, to avoid double-permitting requirements with

multiple reviews and competing agency jurisdictions. The EQB maintains that it has overall responsibility for a GEO release even when a SEP for the release has been issued by another agency.

42. The SEP exemption generated a large number of comments. Commentators were concerned with avoiding duplication and defining the jurisdictional role of the EQB with respect to other state agencies that were qualified to issue SEPs. For SEP exempted releases, what is the role and relationship between EQB and the permitting state agency?

43. The EQB asserts that based on Minn. Stat. § 116C.92, it has final and overall responsibility with respect to compliance with environmental review standards for GEO releases even when a SEP from another state agency has been issued for the release. Minn. Stat. § 116C.92 requires that the EQB be the state agency having governmental oversight for environmental review of the release of genetically engineered organisms. That provision states as follows:

The Environmental Quality Board is designated the state coordinating organization for state and federal regulatory activities relating to genetically engineered organisms.

Further support for EQB's claim that it is the chief state agency for GEO releases came from testimony of Representative Phyllis Kahn. State Representative Phyllis Kahn was an active cosponsor of the 1989 legislation establishing a regulatory framework for governmental oversight of the release of genetically engineered organisms. She was also the chief author of the 1991 amendments to Minn. Stat. §§ 116C.91 - 116C.95 (1990). Representative Kahn stated that the Legislature intended for the EQB to have primary responsibility for the regulation of environmental review of releases of gene

In 1989 the Legislature designed a regulatory framework governing genetically engineered organisms (GEOs). That places EQB in a dominant position. EQB was instructed to conduct environmental review of proposed releases and create a permit program governing releases. EQB was given discretionary authority to waive permit requirements when in the Board's judgment another state agency would be issuing a "significant environmental permit". . .

In 1991, the Minnesota Department of Agriculture brought to the Legislature a department bill requesting that MDA be given regulatory authority over GEOs in the area of pesticides, fertilizers and plants. The bill was necessary to allow MDA to qualify as a "significant environmental permit" issuer under then proposed EQB rules. I agreed to author the bill, provided it be amended so that it did not conflict with the 1989 legislation. As a result the original bill was amended to make MDA authority subject to oversight by EQB under the 1989 Act.

44. In 1991, the Minnesota Legislature authorized the Department of Agriculture (DOA) to issue permits for the release of genetically engineered agricultural products including pesticides, fertilizer, soil amendments and plant amendments. Minnesota Laws 1991 Chapter 250. As a result of this authority the DOA's genetic engineering permits will very likely qualify for SEP status. The role and relationship of the EQB in connection with the Department of Agriculture's performance of governmental oversight over genetically engineered agricultural products generated much discussion and comment throughout this rulemaking proceeding. The University Committees and Grand Metropolitan/Pillsbury argue that under the proposed rules the EQB has preempted all other regulatory authority by other state or federal agencies for genetically engineered organisms. Biotechnica International, Inc. asserted that the EQB had authority to regulate only those releases for which there were no adequate regulation by other agencies.

Northrup King and the University Committees argued that the definition of "release" in the EQB enabling legislation Minn. Stat. § 116C.91, subd. 6, defines "release" was in direct conflict with the definition provided in Minn. Stat. §§ 18B.021, subd. 22a., 18C.005, subd. 27a. and 18F.021, subd. 8, which each defined "release" as follows:

"Release" means the placement or use of a genetically engineered organism outside a contained laboratory, greenhouse, building, structure, or other similar facility or under other conditions not specifically determined by the Commissioner to be adequately contained. (Emphasis added).

Minn. Stat. § 116C.91, Subd. 6 provides as follows:

"Release" means the placement or use of a genetically engineered organism outside a contained laboratory . . . or under any other conditions not specifically determined by the Board to be adequately contained. (Emphasis added.)

45. Northrup King and the University Committees argue that under these definitions of "release" both the EQB and the Commissioner of Agriculture are given statutory authority to regulate the release of genetically engineered agricultural products outside a contained facility and to determine if facilities are adequately contained. These parties also argue that because the Commissioner of Agriculture's authority is more specific the Commissioner's decision regarding "release" must control.

46. In response to arguments like these regarding its relationship with state agencies that may qualify for SEPs, the EQB made substantial changes in the provisions relating to significant environmental permits. Most of the changes focused on avoiding the jurisdictional con

Limiting\_Requests\_for\_a\_SEP\_Findings\_to\_Requests\_Made\_by\_Agencies.

47. Minn. Rules at 4420.0075, Subp. 2, limits requests for a finding of a significant environmental permit to requests by an Agency. Subp. 2 provides as follows:

Subp. 2. Request for finding of a significant environmental permit. An agency may request the Board to find that a permit is a significant environmental permit for the release of certain genetically engineered organisms. (Emphasis added.)

The enabling legislation for this provision Minn. Stat. § 116C.94(b) (Supp. 1991) states that "a permit from the Board is not required if the proposer can demonstrate to the Board that a significant environmental permit is required."

The "proposer" of a release must also be authorized to request that a release permit be exempted on the basis that a significant environmental permit is required by another state agency. The EQB does not offer any explanation as to why requests for a significant environmental permit are limited to requests made by an "agency".

48. The Administrative Law Judge finds that limiting the request for a finding of significant environmental permit status to requests by an "agency" is contrary to the requirements of Minn. Stat. § 116C.94(b), the enabling legislation. To correct this defect the EQB should insert language that also authorizes a "proposer" to request significant environmental permits exemption for a release.

Exemption\_for\_Federal\_Permits.

49. Minn. Stat. § 116C.94(c) requires that the EQB authorize an exemption to Board permits for federally permitted projects that comply with environmental review standards comparable to those required by these proposed rules. Minn. Stat. § 116C.94(c) states in part as follows:

A person proposing a release for which a federal permit is required may apply to the Board for an exemption from the Board's permit or to an agency with a significant environmental permit for the proposed release for an exemption for the agency's permit. . . The Board or agency may grant the exemption if the Board or agency finds that the federal permit issued is in compliance with requirements of Chapter 116D. and rules adopted under it and any other requirement of the Board's or agency's authority regarding the release of genetically engineered organisms. . .

Thus the Board's rules must avoid duplicating environmental review where a federal permit has comparable environmental review standards. Minn. Rules Pt.

4420.0020, Subp. 1, states that "a release permit is required for all releases." Exemptions are made for SEPs and "other agency permits." Minn.

Rules Pt. 4420.0080 which authorizes an exemption for "other agency permits" would appear to apply to federal permits. However, at no place in the EQB's SONAR does it state that this proposed rule part is intended to avoid duplicating environmental review where federal permits provide comparable environmental review. Minn. Rule Pt. 4420.0080, Subp. 2, provides in part as follows:

The Board may exempt a release from a release permit if an agency permit is required . . . (Emphasis added.)

50. As the proposed rule now stands, federal permits would not qualify regardless of environmental review standards applied. The reason federal permitted releases would not qualify is that the definition of "agency" is limited to State of Minnesota departments, boards or agencies.

51. The proposed rules will conflict with Minn. Stat. § 116C.94(c) unless an exemption is also authorized for federal permit releases that have comparable environmental review requirements. The failure to include in the proposed rules an exemption for qualified federal permit releases constitutes a defect in the rule. To correct this defect it will be necessary for the EQB to amend the definition of "agency

Inspection\_of\_Releases\_Issued\_a\_Significant\_Environmental\_Permit.

52. The EQB retains authority to inspect any release that has been issued a significant environmental permit in proposed Minn. Rules 4420.0075, Subp. 6.

The Department of Agriculture opposes this proposed rule and asserts that it constitutes a substantial change from the originally noticed rule. The DOA argues that the language did not appear in the originally proposed rules; was not discussed by the EQB genetic engineering advisory committee; is not expressly authorized by statute; will lead to unnecessary confusion as to which agency is responsible for enforcing the permit and preempt the enforcement authority of the state agency responsible for issuing the permit.

53. The Board's response to the Department of Agriculture's claims is that the inspection authority is necessary because the Board's task is to ensure that the agencies permit given significant environmental permit status actually meets the statutory requirement of Minn. Stat. § 116C.91, subd. 7. The Board further stated in its SONAR that:

Once the permit is approved by the Board, the Board must be able to determine that the permits are being issued and carried out in accordance with the appropriate requirements.

54. The Administrative Law Judge agrees with DOA that the language authorizing Board inspection of releases authorized by other state agencies could be disruptive to the regulatory framework anticipated for these rules. For example, these rules anticipate that the Commissioner of Agriculture will exercise his statutory authority to determine whether, for example, genetically engineered pesticides are used or maintained adequately in a containment

facility.

55. The requirements for a significant environmental permit as specified in Minn. Stat. § 116C.91, subd. 7, are stated in that subdivision as follows:

"Significant environmental permit" means a permit issued by a state agency with the authority to deny, modify, revoke, or place conditions on the permit in compliance with the requirements of § 116C.91 to 116C.96, Chapter 116D, and the rules adopted under them.

According to this language, a state agency that has the authority to deny, modify, revoke or place conditions on a permit and conducts environmental review as required by the above-cited statutes and rules should receive significant environmental permit status. Because these are the standards that apply to the issuance of a significant environmental permit, it would appear that the Board could ascertain whether a particular state agency is complying or has complied with these requirements without a physical inspection of the use and containment of, for example, genetically engineered pesticides.

56. Although the Administrative Law Judge is doubtful of the need for the provision authorizing the Board to inspect significant environmental permits issued by other state agencies, the Administrative Law Judge agrees that the Board has the authority to conduct these inspections.

57. With respect to DOA's assertion of a substantial change, the administrative Law Judge finds that the proposed language does not constitute a substantial change from what was originally proposed. The proposed language does not affect a new class of people and does not raise a new subject matter. The proposed change does not result in a rule fundamentally different in effect from that contained in the notice of hearing.

Mandatory\_Environmental\_Assessment\_Worksheet\_(EAW)\_Categories\_Minn.\_Rules\_Pt. 4410.4300,\_Subp.\_35.

58. This proposed rule amends the environmental review rules, Minn. Rules Pt. 4410, to include a new mandatory EAW category for the release of genetically engineered organisms. This amendment carries out the statutory mandate of Minn. Stat. § 116C.94 that the Board adopt rules that require an EAW for the proposed release of

59. In response to comments made at the hearing regarding the application of genetically engineered organisms to human therapeutics, language was added to the proposed rule to eliminate or exclude human therapeutics. The EQB indicated that the Advisory Committee had not considered the impact of these rules on human therapeutics. The Board also indicated in its SONAR that it was

not clear if the Legislature intended that human therapy be included under the Board's permits. Testimony at the hearing indicated that extensive changes to the proposed rules would be necessary to appropriately address this issue. For this reason the EQB recommended that the proposed rules exclude releases of genetically engineered organisms used in human therapeutics.

60. The Administrative Law Judge finds that the proposed change to exclude GEOs involved in human therapeutics is reasonable and in response to public comments and does not constitute a substantial change.

#### Mandatory\_Environmental\_Impact\_Statement\_(EIS)\_for\_GEOs.

61. A number of the commentators recommended that the proposed rules be amended so as to include the environmental release of genetically engineered organisms as a mandatory environmental impact statement (EIS) category. The Minnesota Food Association, Dr. Kapuscinski, Minnesota Project, Minnesota Chapter of American Fisheries Society, and In Fisherman all believed that GEOs warranted a mandatory EIS category. James Payne, Chair of the EQB Advisory Committee, noted that the committee had discussed this issue and recognized that while the 1990 legislation mandated EAWs, it was silent on EISs. The 1991 amendments to Minnesota Statutes, Chapter 116C, did not include any specific requirement for EISs. The Minnesota Department of Natural Resources opposed the requirement of an EIS for genetic engineering releases. The DNR argued in its comments that since an EAW will be required for any release, the most appropriate mechanism to address the potential need for an EIS for a GEO release is through the EAW process specified in the EQB's Environmental Review Program rules. Through the EAW process, the agency responsible for governmental oversight can decide whether an EIS is required as a part of its decision regarding the potential for significant environmental effects of a particular release. See Minn. Rules pts. 4410.1700 and 4410.8000.

62. The Administrative Law Judge finds that the enabling legislation does not require that genetic engineering releases be identified as a mandatory environmental impact statement category. The EQB acted within the bounds of its statutory authority when it refused to include this requested amendment.

#### Factors\_to\_Consider\_When\_Deciding\_Whether\_a\_GEO\_Release\_Permit\_Will\_have\_Adverse\_Environmental\_Effects.

63. Minn. Rules pts. 4410.8000 Special Rules for Release of Genetically Engineered Organisms, and 4420.0035 - Basis for Decision, identified the standards and considerations that must be evaluated when making a decision regarding issuance of a permit for the release of a genetically engineered organism. These provisions contain scientific criteria to be used for review of environmental assessment worksheets and permit requests. Within these provisions, the Genetic Engineering Advisory Committee has proposed an exhaustive list of the potential impacts of proposed field tests of genetically

engineered organisms. Biotechnica International, Inc. commented that "every item on this list cannot possibly be applicable to each potential field test" and therefore recommended that some leeway or discretion be authorized to allow consideration of various factors as they are "applicable" or "appropriate". The Minnesota Biotechnology Association commented that several of these factors were not scientifically defensible and were an over-reaction to a biotechnology process that was not inherently more risky than classical plant or animal breeding.

64. The technical and scientific criteria co

Standards\_for\_Denying\_or\_Revoking\_a\_Permit,\_Minn.\_Rules\_pt.\_4420.0035,\_subp.\_  
2  
(C).

65. Minn. Rule pt. 4420.0035, subp. 2, identifies the circumstances that justify action by the Board to deny or revoke a release permit or to deny modification of a release permit. One of the standards identified as a basis for this decision is the following language:

C. That the release will\_result\_or\_has\_resulted\_in significant or material adverse effects on human health or the environment;  
(Emphasis added.)

The National Environmental Defense Fund, the National Audubon Society, and the Minnesota Audubon Council asserted that the language emphasized above would be virtually impossible to meet and therefore would not provide a means to protect the public and the environment from potential adverse effects of releases of genetically engineered organisms. The Environmental Defense Fund stated as follows:

EDF finds this standard, that a release will\_result or has resulted in adverse effects, unreasonable. The environment is highly complex and constantly changing. When an organism, chemical, or other entity is placed in the environment, it is often possible to predict scientifically that this new entity will likely have certain adverse effects, but impossible scientifically to say that it definitely "will result in" those effects. Moreover, scientists work by proving that hypotheses are not true. Scientists don't prove truths. Thus, even if there is convincing evidence that an organism is causing adverse effects after it is introduced to the environment, it may be extremely difficult to truly demonstrate it "has resulted in" these effects.

Similarly, the National Audubon Society and the Minnesota Audubon Council asserted that the particular regulation was useless because there "will always

be some uncertainty" as to the adverse effects. The EDF recommended alternative language stating that it would be far more reasonable and in line with other environmental standards for the rule to state that a permit can be denied or revoked if the release "can reasonably be anticipated to result in, or scientific evidence indicates has resulted in, significant or material adverse effects".

66. In essence, EDF argues that it is impossible for the EQB and its Advisory Committee to know with any certainty that a release "will result" in significant or material adverse effects. Before such a release is actually made, scientists can only make an educated guess as to whether the release will be dangerous to human health and the environment.

67. The EQB has not responded in its comments to these recommendations. However, The Administrative Law Judge finds that it is reasonable for the EQB not to include language along the lines of that recommended by EDF and the National Audubon Society. The Administrative Law Judge believes these recommendations are reasonable and consistent with the preventive nature of the proposed rules. The Administrative Law Judge recommends and encourages the EQB to consider the issue raised by the EDF. If the Board decides to revise this language so as to accommodate the concerns raised by the EDF and the National Audubon Society, the change would not constitute an impermissible substantial change.

#### Interdisciplinary Approach to Environmental Review and Evaluation of Applications for a Permit

68. Several commentators, including Dr. Kapuscinski, Ms. Margo Stark of the Minnesota Food Association, and the Minnesota Catholic Conference, asserted that an interdisciplinary approach that required face-to-face meetings regarding environmental review and applications for permits should be in the rules. The proposed rule does require an interdisciplinary team but does not require mandatory face-to-face meetings of the participants. The Board stated in its commen

69. The Administrative Law Judge finds that it is reasonable for the Board to pursue the flexible approach proposed in the rules. The present language does not prevent such meetings and encompasses a broader flexibility to do what is appropriate for particular applications without becoming burdensome.

#### Trade Secret Information - Minn. Rules Pt. 4420.0045, Subp. 2.

70. Minn. Rules Pt. 4420.0045, Subp. 2 as originally proposed by the EQB prohibited an applicant for a release permit from excluding from the application information identified as trade secret information that related a proposed project's effects on human health or the environment. This position was widely supported by persons or groups that commented during the rulemaking proceeding including the Minnesota Food Association, the National Wildlife Society, Minnesota Project, the Environmental Defense Fund, the National

Audubon Society and the Minnesota Audubon Council. Opposition to this required disclosure of trade secret information was opposed by University Committees, the Minnesota Biotechnology Association, Grand Metropolitan/Pillsbury, Biotechnica International, Inc. and D. Glass Associates, Inc. These organizations basically assert that the biotechnology industry is very competitive and having to disclose proprietary information could put them at a competitive disadvantage.

71. The trade secret issue has been essentially eliminated as a contested matter in this proceeding. The EQB was advised by its counsel that the Board could not determine in these rules the status and treatment to be accorded trade secret data. The Minnesota Government Data Practices Act, Minn. Stat. Ch. 13 has determined the treatment to be accorded government data that has been classified as trade secret. Under the Minnesota Government Data Practices Act, when certain data are identified as trade secret, they must be treated as confidential unless the responsible agency authority determines that the data should be classified in some other category. The Board has revised Subp. 2 so that it complies with the Minnesota Government Data Practices Act.

Based upon the foregoing Findings of Fact, the Administrative Law Judge makes the following:

#### CONCLUSIONS

1. That the EQB gave proper notice of the hearing in this matter.
2. That the EQB has fulfilled the procedural requirements of Minn. Stat. §§ 14.14, Subds. 1, 1a and 14.14, subd. 2, and all other procedural requirements of law or rule.
3. That the EQB has demonstrated its statutory authority to adopt the proposed rules and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3 and 14.50 (i)(ii), except as noted at Finding 48, 50 and 51.
4. That the EQB has documented the need for and reasonableness of its proposed rules with an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2 and 14.50 (iii).
5. That the amendments and additions to the proposed rules which were suggested by the EQB after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3, and Minn. Rule 1400.1000, Subp. 1 and 1400.1100.
6. That the Administrative Law Judge has suggested action to correct the defects cited in Conclusion 3 as noted at Finding 48 and 51.

7. That due to Conclusion 3, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. P 14.15, subd. 3.

8. That any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

9. That a finding or conclusion of need and reasonableness in regard to any particular rule subsection does not pr

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

It is hereby recommended that the proposed rules be adopted except where specifically otherwise noted above.

Dated this 11th day of March, 1991.

/s/ Allen E. Giles

ALLEN E. GILES

Administrative Law Judge