

**4420.0035 BASIS FOR DECISION.**

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

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

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

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

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

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

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

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

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

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

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

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

(3) the extent to which the genetically engineered organism's competitiveness, survivability under environmental stress including, but not limited to,

dormancy, temperature tolerance, fire resistance, and drought resistance, or ability to disperse in the environment has been changed or potentially changed as a result of the genetic engineering. The determination of potential changes must be based minimally on the natural history of the recipient organism and the potential effects of natural selection on the genetically engineered organism;

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

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

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

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

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

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

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

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

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

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

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

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

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

**Statutory Authority:** *MS s 116C.94*

**History:** *17 SR 139*

**Published Electronically:** *August 21, 2007*