CHAPTER 4410
ENVIRONMENTAL QUALITY BOARD
ENVIRONMENTAL REVIEW; CRITICAL AREAS

4410.0200 DEFINITIONS AND ABBREVIATIONS.

[For text of subps 1 to 35, see M.R.]

Subp. 35a. **Genetically engineered organism.** "Genetically engineered organism" has the meaning given in part 4420.0010, subpart 14.

Subp. 35b. **Genetic engineering.** "Genetic engineering" has the meaning given in part 4420.0010, subpart 15.

[For text of subps 36 to 55, see M.R.]

Subp. 55a. **Organism.** "Organism" has the meaning given in part 4420.0010, subpart 18.

[For text of subps 56 to 71a, see M.R.]

Subp. 71b. **Release.** "Release" has the meaning given in part 4420.0010, subpart 19.

[For text of subps 73 to 96, see M.R.]

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4410.4300 MANDATORY EAW CATEGORIES.

[For text of subps 1 to 34, see M.R.]

Subp. 35. **Release of genetically engineered organisms.** For the release of a genetically engineered organism that requires a release permit from the EQB under chapter 4420, the EQB is the RGU. For all other releases of genetically engineered organisms, the RGU is the permitting state agency. This subpart does not apply to the direct medical application of genetically engineered organisms to humans or animals.

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

4410.8000 SPECIAL RULES FOR RELEASE OF GENETICALLY ENGINEERED ORGANISMS.

Subpart 1. **Generally.** Environmental review for the release of genetically engineered organisms shall be conducted according to the procedures in parts 4410.1200 to 4410.3000 except as provided in items A to C.

A. In part 4410.1400 when the EQB is the RGU, it shall have 45 days to add supplementary material, if necessary, and to approve the EAW for distribution.

B. In part 4410.1700 when the EQB is the RGU, part 4410.1700, subpart 2a, does not apply.

C. In deciding whether a project has the potential for significant environmental effects, the criteria in part 4410.1700, subpart 7, shall be replaced by the following factors:

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

(2) the history of any previous environmental uses of the genetically engineered organism;

(3) the potential for the genetically engineered organisms to cause adverse environmental effects including, but not limited to:

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

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

(c) the extent to which the genetically engineered organism's competitiveness and survivability under environmental stress including, but not limited to, dormancy, temperature tolerance, fire resistance, drought resistance, or ability to disperse in the environment have 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;

(d) 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;

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

(f) 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;

(4) the adequacy and appropriateness of proposed measures, if any, for confinement of the genetically engineered organism;

(5) any previous risk assessments for the same or similar organisms prepared by federal or state agencies and their adequacy and relevance to the current proposal including, but not limited to, consideration of the following:

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

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

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

(6) the conclusions reached and conditions imposed by federal agencies with jurisdiction over the proposed release;

(7) 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;

(8) the type, extent, and reversibility of environmental effects;

(9) the cumulative potential effects of related or anticipated future projects; and

(10) the extent to which the environmental effects are subject to mitigation by ongoing public regulatory authority.

Subp. 2. **EAW and EIS preparation.**

A. The EAW shall be prepared, using an interdisciplinary approach that will ensure the integrated use of the natural and environmental sciences. The review should include involvement of the following disciplines, as appropriate: microbiology, ecology, public health, biological safety, agronomy, plant biology, risk assessment, molecular biology, biochemistry, entomology, vertebrate biology, physical and biological containment, and other appropriate disciplines.

B. The EAW shall be written in plain and objective language and include clear presentation of the proposed release and of the issues of concern.

C. When the EQB is the RGU, the EQB chair may direct the EQB genetic engineering advisory committee to provide advice and comment on the EAW or EIS. The chair may appoint special members to the advisory committee to assist with specific EAWs or EISs.

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*