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LAND USE LAWS AND POLICIES MODEL BIOGENETICS BYLAW

GRAFTON, MASSACHUSETTS

SPRING, 1991

Principal Investigator
John R. Mullin, Ph.D., AICP

The Center for Economic Development would like to thank the Technical Assistance Committee for their efforts

Zenia Kotval, Project Coordinator Celeste Comeau, Research Assistant Maureen Moriarty

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Section 1. Definitions

"DNA" - deoxyribonucleic acid

"Recombinant DNA" (RDNA) or "Recombinant DNA molecules "-

(1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell

or

(2) DNA molecules which result from the replication of a molecule described in (1) above.

"NIH Guidelines"

1. "Guidelines for Research Involving Recombinant DNA molecules" promulgated by the National Institute of Health (NIH) of the United States Department of Health and Human Services and published in 46 F.R. 34463-34487 on July 1, 1981, as may be amended by the NIH.

and

2. "Recombinant DNA Research; Physical Containment Recommendations for Large-Scale Uses of Organisms Containing Recombinant DNA Molecules" (NIH Large Scale Recommendations) promulgated by the National Institute of Health of the United States Department of Health and Human Services and published in 45 F.R. 24968-24971 on April 11, 1980, as may be amended by the NIH. A Copy is on file in the Town Planners Office.

Section 2. Scope

This Chapter shall apply to all organizations in the Town of Grafton which experiment with or use RDNA technology.

Section 3. Restrictions

RDNA use classified by NIH guidelines as requiring P4 level of containment shall be prohibited in the Town of Grafton

Section 4. Regulations

All uses of RDNA by institutions in the Town of Grafton shall be undertaken only in conformity with current and applicable NIH guidelines, as promulgated in the Federal Register and as may be amended from time to time by the NIH or by any successor agency.

Section 5. Administrative Requirements

Each organization in the Town of Grafton which experiments with or uses RDNA technology shall comply with the administrative practices set forth in the NIH guidelines, including but not limited to the following:

- 1. The establishment of an Institutional Biosafety Committee (IBC) which shall contain at least five members, of whom at least two (but no less than 20%) shall not be affiliated with the institution and shall represent the interest of the community with respect to health and the protection of the environment.
- (a) The IBC shall contain at least one representative from the from the organization's bio-tech staff
- (b) The non-affiliated representatives on the IBC shall be appointed by the organization with notice to the Town Planning Board.
- (c) The non-affiliated representatives on the IBC shall be persons active in medical, occupational health or environmental concerns in the community.
- (d) The non-affiliated representatives on the IBC shall be bound by the same rules prohibiting use and disclosure of proprietary information and trade secrets as other members of the IBC.
- (e) The IBC shall establish a set of rules and administrative procedures governing its operation in accordance with the NIH guidelines
- The provision of safety plans and manuals which shall be subject to the approval of the IBC
- 3. The provision of proper training and appropriate safeguards and procedures for minimizing potential environmental and personal exposure
- 4. If the organization is engaged in RDNA research at the P3 containment level(as defined in the NIH standards), the appointment of a Biological Safety Officer who shall be a member of the IBC.
- 5.If the organization is engaged in RDNA research on a "large scale" (as defined in the NIH Large Scale Recommendations), compliance with all additional administrative requirements contained in the NIH Large Scale Recommendationsis required.

Section 6. Permits and Inspections

No organization may employ RDNA technology in the Town of Grafton without a special permit issued by the Town Planning Board.

1. Such permit shall be issued only after a comprehensive review of the proposed project by a certified health expert selected by the IBC but paid by the organization and certification that the organization is in compliance with this ordinance and the NIH guidelines.

- Any institution aggrieved by a final decision to deny or to grant a permit may seek relief in any court of competent jurisdiction, as provided by the laws of this Commonwealth.
- 3. The Town Planning Board shall inspect at least annually each organization holding such a permit to ensure compliance with the provisions of this ordinance and the NIH guidelines.
- 4. The Planning Board may require from an organization such information and data as is necessary to ensure compliance with this ordinance.

Section 7. Environmental Surveillance Programs.

All organizations employing RDNA technology within the Town of Grafton shall provide appropriate medical and environmental surveillance programs in accordance with the NIH guidelines.

- 1. The environmental surveillance program shall include a plan for the systematic monitoring of waste to ensure that recombinant organisms will not be released into the environment.
- 2. The environmental surveillance program shall include a plan to train representatives or consultants of the Grafton Town Planning Board, the Grafton Fire Department, and the Grafton Police Department in the procedures to be used in the event of an emergency.
- 3. Any release into the environment of recombinant organisms posing a threat to public health shall be immediately reported to the Commissioner of the Department of Public Health or his/her designee.

Section 8. Penalties

Any person or organization who violates any provision of this ordinance shall be punished by a fine of up to \$300 for each separate violation.

Section 9. Enforcement

Enforcement of this ordinance shall be the duty of the Town Planning Board