



City of Cambridge

In the Year One Thousand, Nine Hundred Eighty-One

AN ORDINANCE

In amendment to an Ordinance formerly entitled "The General Ordinances of the City of Cambridge" as revised in 1972 and now designated as "The Code of the City of Cambridge".

Be it ordained by the City Council of the City of Cambridge as follows:

Chapter Eleven entitled: "Health and Housing" is hereby amended by striking out the present Article II and substituting in place thereof a new Article II entitled Ordinance for the Use of Recombinant DNA Technology in the City of Cambridge which reads as follows:

ARTICLE II.

ORDINANCE FOR THE USE OF RECOMBINANT DNA TECHNOLOGY IN THE CITY OF CAMBRIDGE

Section 11-7. GUIDELINES FOR THE REGULATION OF RECOMBINANT DNA USE

I. DEFINITIONS

In the context of this ordinance the following definitions are adopted:

- a) Recombinant DNA molecules (RDNA) and organisms and viruses containing RDNA are those defined in the National Institutes of Health Guidelines promulgated in the Federal Register on November 21, 1980, and such amendments thereto as may be approved by the Cambridge Biohazards Committee.
- b) An institution is any single individual, group of individuals or organization.
- c) "Guidelines" are defined as:
 - 1) National Institutes of Health Guidelines for Research involving Recombinant DNA Molecules published in the Federal Register of November 21, 1980.

- 2) National Institutes of Health Physical Containment Recommendations for large scale use of organisms containing Recombinant DNA molecules as published in the Federal Register of April 11, 1980.
- 3) Administrative Practices Supplement to the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules as issued by the Office of Recombinant DNA Activities, November, 1980.
- 4) Such amendments to 1, 2, and 3 above adopted by the National Institutes of Health as may be approved by the Cambridge Biohazards Committee. In the event that the National Institutes of Health shall discontinue or abolish their guidelines, those guidelines in effect at the time of such discontinuance shall remain in effect in the City of Cambridge.

II. PURPOSE

All use of RDNA by institutions in the City of Cambridge shall be undertaken only in strict conformity with the "Guidelines", as defined above, and in conformity also with such other health regulations as the Commissioner of Health and Hospitals may from time to time promulgate.

III. CAMBRIDGE BIOHAZARDS COMMITTEE.

- a) A Cambridge Biohazards Committee (CBC) shall be established for the purpose of overseeing all use of RDNA in the City of Cambridge and of advising the Commissioner of Health and Hospitals and the Health Policy Board.
- b) The CBC shall be composed of the Commissioner of Health and Hospitals or his/her designee, the Chairperson of the Health Policy Board or a board member designated by the Chairperson and a minimum of three other members to be appointed by the City Manager. The City Manager is authorized to provide for the adequate staffing of the CBC.
- c) The CBC and the Commissioner of Health and Hospitals are empowered to retain competent professional assistance in carrying out their duties under this ordinance.
- d) The salaries and expenses of the staff and consultants of the CBC under this ordinance shall be apportioned to the institutions holding permits under this ordinance.

IV. PERMIT REQUIREMENT.

- a) All institutions proposing to use RDNA must obtain a permit from the Commissioner of Health and Hospitals with the approval of the CBC. Permit requirements include written agreement to:
 - 1) Follow the "Guidelines".
 - 2) Follow other conditions set forth in this ordinance.
 - 3) Allow inspection of facilities and pertinent records by the Cambridge Biohazards Committee.
 - 4) Prepare a Health and Safety manual which contains all procedures relevant to the use of RDNA at all levels of containment in use at the institution. Said manual shall be submitted to the Cambridge Biohazards Committee for review.
 - 5) Establish a training program of safeguards and procedures for personnel using RDNA.
- V. The Institutional Biosafety Committee (IBC) required by the National Institutes of Health Guidelines shall have at least one member who is a nondoctoral person from a laboratory technical staff and one representative approved by the Health Policy Board. The IBC shall be the final arbiter within an institution, with regard to the implementation of this Ordinance and the "Guidelines".
- VI. All minutes of the IBC meetings must be forwarded to the Commissioner of Health and Hospitals and the CBC. It shall also be the responsibility of the institution to file regular reports with the Cambridge Biohazards Committee, in a manner to be determined by the CBC.
- VII. Institutions using RDNA shall perform adequate screening to insure the purity of the strain of host organisms used in the experiments and shall test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics.
- VIII. All institutions are to provide an appropriate medical surveillance program as determined by the Institutional Biosafety Committee for all persons engaged in the use of RDNA. Such programs must be approved by the CBC.
- IX. The institution shall report within thirty (30) days to the CBC and the Commissioner of Health and Hospitals any significant problems with or violations of the "Guidelines" and any significant RDNA related accidents or illnesses.
- X. The premises in which RDNA is used must be totally and completely free of rodent and insect infestation.

Section 11-8. LARGE SCALE

All institutions using RDNA on a "Large Scale" (as defined in the "Guidelines") must adhere to the following requirements in addition to those stated in Section 11-7.

I. SPECIAL PERMIT.

All institutions must obtain a special Large Scale Permit (LS Permit) from the Commissioner of Health and Hospitals with the approval of the CBC, after the Commissioner and the CBC have conducted an appropriate public hearing. LS Permit requirements include written agreement to:

- a) Identify clearly all large scale RDNA use in the IBC minutes.
- b) Development procedures through the IBC for monitoring of large scale operations, for compliance with this ordinance and the "Guidelines". These procedures shall be approved by the CBC and the Commissioner of Health and Hospitals.
- c)
 - 1) Allow an annual inspection and review of the procedures and practices of Large Scale RDNA use for compliance with this ordinance. The scope of this inspection and review shall be mutually agreed upon by the institution and the CBC.
 - 2) The CBC shall retain a professionally competent person, persons, agency or institution to perform this inspection and review. The results shall be reported to the CBC, the Commissioner of Health and Hospitals and the institution involved.
 - 3) The institution shall reimburse the City for the expense of this inspection and review including an apportionment of the salaries of the staff of the CBC under Section 11-7, III subsections (b) and (c).
- d) Establish a Health-Safety Program for appropriate employees. Such a program is to include safety training, periodic re-training and periodic health surveillance. Details and procedures are to be established by each institution and approved by the CBC and the Commissioner of Health and Hospitals.
- e) Advance approval must be given by the CBC for Large Scale uses of RDNA requiring P2 or P3 physical containment.

Section 11-9. CAMBRIDGE BIOHAZARDS COMMITTEE (CBC).

I. Specific responsibilities of the CBC shall include:

- a) Establishing policies, procedures and criteria to aid in the implementation of this ordinance.
- b) Approving all amendment to the "Guidelines" before their implementation in Cambridge. In the event that the National Institutes of Health shall discontinue or abolish their guidelines, those guidelines in effect at the time of such discontinuance shall remain in effect in the City of Cambridge.

- c) Reviewing all proposals for RDNA use in the City of Cambridge for compliance with the "Guidelines" and conformity with such other regulations as the Commissioner of Health and Hospitals may from time to time promulgate.
- d) Reviewing manuals and worker training programs and approving health-safety programs and monitoring procedures required by Sections 11-7 and 11-8.
- e) Determining the manner in which institutions make reports or applications to the CBC, and the type of information required in such reports or applications. Reviewing reports, applications and recommendations by IBC and approving where appropriate. Carrying out site visits to institutional facilities.
- f) Developing a procedure for members of institutions where RDNA is used to report to the CBC violations of this ordinance, the "Guidelines", or any other health regulations as the Commissioner of Health & Hospitals may promulgate.

Section 11-10. RESTRICTIONS.

- I. RDNA use classified by the "Guidelines" as requiring P3 physical containment and biological containment greater than HV2 shall not be permitted without prior approval of the CBC. RDNA use requiring P4 containment shall not be permitted in the City of Cambridge.
- II. There shall be no deliberate release into the environment, that is, the sewers, drains or the air, of any organism containing recombinant DNA and further that any accidental release shall be reported to the Commissioner of Health and Hospitals within five days.

Section 11-11. PENALTIES.

- I. Violation of the conditions of this ordinance shall subject the violator to a fine of Two Hundred Dollars (\$200.00) per day and in addition the facility in which the violation occurs may be closed by the Commissioner of Health and Hospitals. Each day of violation shall constitute a separate and distinct offense.
- II. Once a permit has been issued it may be revoked by the Commissioner of Health and Hospitals only upon a determination (subject to judicial review) by the CBC and the Commissioner of Health and Hospitals after due notice and hearing, that the institution involved has materially failed to comply with the City Ordinance, the permit agreements or the "Guidelines" (notwithstanding reasonable notice and an opportunity to correct such failures to comply with the provisions of this ordinance).

Section 11-12. SEVERABILITY OF SECTIONS.

If any section, sub-section, sentence, clause, phrase or portion of this ordinance is for any reason held invalid or unconstitutional by any court of competent jurisdiction such portion shall be deemed a separate, distinct and independent provision, and such holding shall not affect the validity of the remaining portions thereof.

In City Council April 27, 1981.

Passed to be ordained as amended by a yeas and nays vote: Yeas 8; Nays 1; Absent 0.

James L. Sullivan, City Manager.

ATTEST:- Paul E. Healy, City Clerk.

1