

ORDINANCE NO. 5010 -N.S.

REGULATING THE USE OF HAZARDOUS BIOLOGICAL RESEARCH IN THE CITY OF BERKELEY.

BE IT ORDAINED by the Council of the City of Berkeley as follows:

Section 1. LEGISLATIVE FINDINGS.

The City Council of the City of Berkeley hereby finds and declares that:

a. Many types of biological research, such as research related to recombinant Deoxyribonucleic Acid (DNA), are of exceptional importance and may offer many potential benefits, but are also characterized by major uncertainties and possible significant hazards regarding effects on the human population, other organisms, and the general environment.

b. Some biological research is generally considered by the scientific community to be so dangerous that it has been completely banned.

c. The application of existing guidelines and controls on DNA research promulgated by the National Institute of Health are only applicable to NIH-funded research, while many non-NIH-funded private and public research projects continue to be unregulated.

d. Rapid scientific advances in the biological research area can reasonably be expected to produce further experimental circumstances which could be hazardous to the general public.

e. It is in the public interest that the health and welfare of the citizens of the City of Berkeley be protected by requiring all hazardous biological research to comply with strict safety standards.

Section 2. DEFINITIONS.

a. "City Council" means the City Council of the City of Berkeley.

- b. "City Manager" means the City Manager of the City of Berkeley.
- c. "Department of Public Health" means the Department of Public Health of the City of Berkeley.
- d. "DNA" means Deoxyribonucleic Acid.
- e. "Hazardous biological research" means any research, study, investigation or experiment which employs organisms or infectious agents which are capable, or can be rendered capable, of causing harm, directly or indirectly, to the health of the residents of the City of Berkeley and to the natural environment.
- f. "Permit" means a permit to engage in hazardous biological research, recombinant DNA research or use of DNA technology, issued by the City Council of the City of Berkeley.
- g. "Recombinant DNA" means molecules that consist of different segments of deoxyribonucleic acid which have been joined together in cell-free systems and which have the capacity to infect and replicate in some host cell, either autonomously or as an integrated part of the host's genome.
- h. "Research facility" means a facility which conducts hazardous biological research.

Section 3. REGISTRATION.

a. The City Council, upon recommendation of the City Manager, shall issue permits to all persons and institutions wishing to conduct hazardous biological research, recombinant DNA research or proposing to use recombinant DNA technology, which shall be valid for a period of one year, or for a shorter period as the City Council may establish for said research or project. The permit and permit renewal may be subject to such terms and conditions as the City Council finds are necessary to carry out the purposes of this ordinance. The permit fee shall be \$100.00.

b. Any person or institution planning to commence or engage in hazardous biological research, recombinant DNA research or proposing to use DNA technology in the City of Berkeley after the effective date of this ordinance shall apply in writing for a permit and shall not commence the research or use of said technology without having been issued a permit to do so from the City Council.

c. A permit shall not be issued by the City Council and an application therefor shall be denied unless:

(1) The application therefor contains or is accompanied by the following information:

(a) A specific description of all organisms, agents, and procedures to be employed in the research or use of DNA technology.

(b) A description of all hazards, including potential hazards, of the research or use of DNA technology being proposed.

(c) The name of all researchers and associated personnel and other persons who may be subject to hazards from the research or use of the DNA technology.

(d) A full description of proposed measures to be taken for the protection of the research personnel, the general public and the environment.

(2) The City Council finds that:

(a) All the recombinant DNA experiments shall be undertaken only in strict conformity with the "Guidelines" of the National Institute of Health (NIH), as set forth in the Federal Register dated September 9, 1976, or any amendment thereof, or as may be established from time to time by NIH, by other federal agencies, or by Act of Congress, and in conformity with such other regulations as the Director of the Department of Public Health may from time to time promulgate.

(b) All experiments undertaken at the P3 level of phy- ←

sical containment shall require an NIH certified host-vector system of at least an EK2 level of biological containment.

(c) Institutions or persons undertaking recombinant DNA experiments shall perform adequate screening and/or have certification from vendor or provider as to 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.

(d) As part of the institution's or person's health monitoring responsibilities it shall in good faith make every attempt, subject to the limitation of the available technology, to monitor the survival and escape of the host organisms, or any component thereof, in the laboratory worker. This should include whatever means are available to monitor the intestinal flora of the laboratory worker.

(e) All cases of unusual illnesses occurring in workers associated with all recombinant DNA research being carried out in the City of Berkeley shall be fully investigated and reported in detail to the Director of the Department of Public Health.

#### Section 4. ENFORCEMENT.

a. In order to enforce this ordinance, the City Manager shall seek the aid and expertise of the University of California Bio-Hazards Committee and is authorized to enter into such agreements as may be necessary to accomplish the purposes of this ordinance.

b. Officers, employees, agents or inspectors designated by the Director of the Department of Public Health are authorized, upon presenting appropriate credentials to the owner, operator, or agent in charge of a research facility engaged in hazardous biological research, recombinant DNA research or use of DNA technology to inspect, at reasonable times and in a reasonable manner,

such research facility and all equipment, materials, containers, records, files, papers, processes, controls, facilities, and other things therein, in order to determine whether such research facility is being operated in compliance with this ordinance, the guidelines established hereunder, and the terms of any permit that may have been issued with respect to such research facility.

c. Upon completion of any such inspection and prior to leaving the premises, the officer, employee, or agent making the inspection shall give the owner, operator, or agent in charge a report summarizing any conditions or practices observed by him or her which, in his or her judgment, indicate a violation of this ordinance or any guideline established or permit issued hereunder. The inspector shall also prepare a written report of his or her findings and send it to such owner, operator, or agent within a reasonable time.

d. A permit issued by the City Council may be revoked, suspended, or conditions imposed if the City Council finds, after reasonable notice and opportunity for a hearing, that such permittee:

(1) Misrepresents any material fact in obtaining a permit.

(2) Has engaged in or attempted to engage in or represented himself or herself as entitled to perform any hazardous biological research, recombinant DNA research or use DNA technology or procedure or category of procedures not authorized by the permit.

(3) Has failed to comply with guidelines with respect to research facilities or personnel prescribed by the Department of Public Health pursuant to this ordinance.

(4) Has failed to comply with reasonable requests of the Department of Public Health for any information or materials the Department of Public Health deems necessary to determine continued eligibility for its permit or continued compliance with the Department of Public Health's regulations.

(5) Has refused a reasonable request from the Department of Public Health or any officer or employee designated by the Department of Public Health for permission to inspect the research facility and its operations and pertinent records at any reasonable time.

Section 5. VIOLATION.

Every person violating or contributing in any way to the violation of any of the provisions of this ordinance shall be punishable as set forth in Chapter 1.20 of the Berkeley Municipal Code (Ordinance No. 4869-N.S.).

Section 6. SEVERABILITY.

If any provision of this ordinance or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of this ordinance which can be given effect without the invalid provisions or applications, and to this end the provisions of this ordinance are severable.

Section 7. POSTING.

Copies of this Bill are hereby ordered published by posting with the vote thereon for two (2) days at the ten (10) prominent places in the City of Berkeley as designated by Ordinance No. 2032-N.S.

At a regular meeting of the Council of the City of Berkeley, held on the thirteenth day of September, 1977, this Bill was passed to print and ordered published by posting by the following vote:

Ayes: Councilmembers Davis, Dean, Denton, Feller, Hancock, Hone, Rumford, Segesta and President Widener.

Noes: None.

Absent: None.

ATTEST: EDYTHE CAMPBELL  
City Clerk and Clerk of the Council

In effect: October 21, 1977