

ARTICLE IV. ~~BIOTECHNOLOGY RESEARCH~~[4]

Footnotes:

~~(4) Editor's note — Art. IV, §§ 6-56—6-69, was repealed by Ord. No. 1994-4, adopted Feb. 24, 1994. The article related to recombinant deoxyribonucleic acid research and was derived from Ord. No. 1981-12, §§ 1—11, 14. Ord. No. 1994-4 also added new §§ 6-56—6-70.~~

CITY OF SOMERVILLE
ORDINANCE NO. 2022-
IN THE CITY COUNCIL: _____, 2022

AN ORDINANCE REPLACING THE PROVISIONS OF CHAPTER 6,
ARTICLE IV AND AMENDING SECTION 1-11(b) OF THE CODE OF
ORDINANCES OF THE CITY OF SOMERVILLE

Be it ordained by the City Council, in session assembled, that the provisions of Chapter 6, Article IV, "Biotechnology Research" are hereby stricken and replaced with the following provisions:

Sec. 6-56. - Biotechnology ordinance.

This article shall be known and may be cited as the "Somerville Biotechnology Ordinance."

~~(Ord. No. 1994-4, 2-24-94)~~

Sec. 6-57. - Biotechnology ordinance purpose.

It is the purpose of this article and the policy of the city to protect the public health, safety and general welfare of the ~~citizens~~residents of the city, and to promote the development of clean and pollution-free industry, through the regulation of ~~all~~the research and use of recombinant deoxyribonucleic acid (~~RDNA~~)research("rDNA") and ~~all biological material therapies or diagnostics use, within the city's borders and to promote the development of clean and pollution-free industry~~agents. The research and use of rDNA and biological agents in the city shall be undertaken only in strict conformity with the guidelines as herein defined, this article and the SBC policies and procedures authorized herein.

~~(Ord. No. 1994-4, 2-24-94)~~

Sec. 6-58. - Biotechnology ordinance applicable to ~~RDNA~~rDNA and/or biological agent research.

This article shall apply to all institutions in the city which use ~~rdna~~rDNA technology, ~~or biological agents as herein defined.~~ This article shall require that ~~all rdna~~rDNA and biological agent research and use be done only in strict conformity with the guidelines, ~~hereinafter defined, as well as with all such other health regulations as herein defined, this article and the director of the board of health may from time to time promulgate~~SBC policies and procedures authorized herein. However, should a conflict arise between this article and the guidelines, this article shall take precedence.

~~(Ord. No. 1994-4, 2-24-94)~~

Sec. 6-59. - Definitions.

The following words, terms and phrases, when used in this article shall have the meanings ascribed to them in this section, except where the context clearly indicates otherwise:

Biological Agents: any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia or protozoa) or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance that requires BSL-2 through BSL-4 containment as defined below.

Biosafety Level (BSL): the level of protective measures needed in a laboratory setting to protect workers, the environment and the public. The BSL of individual biological agents shall be that which is recommended in the most recent version of the Centers for Disease Control (CDC)/NIH Publication: "Biosafety in Microbiological and Biomedical Laboratories (BMBL)".

Brown-out: is an intentional or unintentional drop in voltage in an electrical power supply system. Intentional brownouts are used for load reduction in an emergency. A voltage reduction may be an effect of disruption of an electrical grid, or may occasionally be imposed in an effort to reduce load and prevent a power outage, known as a blackout.

Chair: the Chair of the Somerville Biosafety Committee, unless the context clearly indicates otherwise.

~~Guidelines are defined as shall mean:~~

~~1.~~ (1) *NIH Guidelines:* National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules as published in the Federal Register of May 7, 1986, as well as NIH's Design Requirements Manual as amended, March 5, 2020 for proposed BSL-3 laboratories.

~~Except (2)~~ *Biosafety in Microbiological and Biomedical Laboratories (BMBL):* unless otherwise specified, is defined as limited, published by paragraph the Centers for Disease Control and Prevention and National Institutes of Health, as amended.

~~2.—(3), below, any)~~ Any amendments, revisions, new editions or substitutions enacted subsequent to the above-referenced guidelines, including, but not limited to: Notices of Action under NIH Guidelines for Research Involving rDNA Molecules on August 24, 1987; July 29,

1988; October 26, 1988; March 13, 1989; March 1, 1990; September 12, 1990; July 18, 1991; October 15, 1991; November 21, 1991; January 28, 1992; and April 22, 1992.

Amendments to (1) and (2), above, or the BMBL which are adopted by the DHHS, Centers for Disease Control and Prevention ("CDC") and NIH and approved/accepted by the Somerville Biosafety Committee (hereinafter "SBC"). Amendments not acted upon by the SBC within 60/sixty days shall be deemed to be constructively approved/considered accepted. In the event that the NIH shall discontinue or abolish its guidelines/Guidelines or BMBL are discontinued or abolished, those guidelines/Guidelines in effect at the time of such discontinuance shall remain in effect in Somerville unless discontinued by.

3- In the event that there is a majority vote of the SBC conflict between the NIH Guidelines and the BMBL, the BMBL shall control.

Institution: A a single individual, group of individuals, association, organization, corporation, educational institution, or medical facility conducting rDNA/rDNA or biological agent research, rDNA or use, which may include, but is not limited to, development, rDNA production, or biological material therapies or diagnostics.

Institutional Biosafety Committee: a local institutional committee established by an institution in accordance with the guidelines, section 6-67 and the SBC policies and procedures to review and oversee biological research conducted by the institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment. (See section IV-B-2 of the NIH Guidelines.)

Low Risk Facility: any institution that creates, propagates, imports or uses rDNA in any form where: (1) the experiments are all exempt from the NIH Guidelines under Section III-F of the NIH Guidelines, or (2) users are not constructing rDNA organisms but are merely propagating them; or any institution conducting rDNA research or use that only requires BSL-1 containment.

Recombinant deoxyribonucleic acid (rDNA/rDNA) and molecules and organisms and viruses containing rDNA: As as defined in the NIH Guidelines promulgated in the Federal Register on May 7, 1986, and such amendments thereto unless otherwise disapproved/not accepted by the Somerville Biosafety Committee. Biological materials therapies or diagnostics include, but are not limited to, living cell therapy.

(Ord. No. 1994-4, 2-24-94)

Cross reference ~~—~~ Definitions and rules of construction, § 1-4.

Somerville Biosafety Committee or SBC: the committee established pursuant to section 6-60 to oversee the registration of low risk facilities and permitting of institutions conducting research or use of rDNA or biological agents.

SBC Policies and Procedures: the policies, procedures and criteria established by the SBC pursuant to section 6-60 to aid in the implementation of this article.

Sec. 6-60. - Biosafety committee.

~~a-~~ (a) Establishment: A There is hereby established a Somerville Biosafety Committee (hereinafter "SBC;") which shall be established for oversee the purpose registration of overseeing the establishment low risk facilities, and permitting of institutions conducting or proposing to conduct of all rDNA research or involving the use of and developments of rDNA or other biological material therapies or diagnostics, in the city agents that require BSL-2, BSL-2 (Enhanced) or BSL-3. The SBC shall address safety concerns associated with areas of biotechnology research and make recommendations to the board of health and the City of Somerville.

~~b-~~ (b) Composition; terms of members; vacancies:- The SBC shall be composed of the environmental protection officer, the director of the board of health or his/her sustainability and environment or their designee, the agent or director of the board of health pursuant to M.G.L. c. 111, s. 30 or their designee or if no such agent or director is appointed, the HHS director or their designee, the emergency management director or their designee, a representative from the fire department, a member the director of the planning department and the office of housing strategic planning and community development ("OHCD"), or their designee, the director of inspectional services or their designee; and three members to be appointed by the mayor and approved by the city council, which shall include an expert in the biotechnology field from the academic community, and two members representative of the citizenry community members of Somerville, all so appointed by the mayor and approved by the city council. The membership should be broad-based and as representative as possible. The members appointed by the mayor shall serve for a three-year term. Of the original appointees to the SBC, the expert from the academic community shall serve for two years and the two members representative of the citizenry of Somerville shall serve one for three years and one for four years as the mayor shall so decide. Any person appointed to fill a vacancy shall serve for the unexpired term of that vacancy.

~~(c)~~ (c) Appointment of the Chair: The Chair shall be designated by a majority vote of the SBC.

(d) Professional assistance authorized; costs: The SBC, environmental protection officer, and the director of the board of health are empowered to jointly The SBC may retain competent professional assistance in carrying out their duties under this article, in accordance with the regular city procedures for obtaining such assistance.

~~(d)~~ (e) Responsibilities: Specific responsibilities of the SBC shall include:

~~1-~~ (1) Establishing policies, procedures, and criteria to aid in the implementation of this article.

(2) Determining the manner in which permit holders, registered institutions, and low risk facilities and institutions applying for registration or a permit pursuant to this article make reports or applications to the SBC and the type of information required in such reports or applications.

~~2-~~ (3) Reviewing reports, registrations, applications, and recommendations by the institutional biosafety committees (IBC), and all other relevant documents.

~~3-~~ (4) Conducting site visits to proposed BSL-2 (Enhanced) and permitted BSL-3 facilities.

4. ~~(5)~~ Reviewing manuals and worker training programs, approving health-safety programs ~~and, waste removal processes and emergency response~~ contingency plans, and monitoring the procedures required by this article.
5. ~~(6)~~ Establishing procedures for individuals reporting violations of this article, the guidelines or any health regulations to the SBC.
6. ~~(7)~~ Providing assistance to institutions during the permitting process.
7. ~~Approving~~ (8) Accepting all amendments to the guidelines before implementation.

~~(Ord. No. 1994-4, 2-24-94)~~

(f) In addition to the duties listed above, the SBC may:

(1) Recommend to the Mayor and City Council amendments to this article to keep it abreast of the best scientific and industrial practice.

(2) Recommend to the Mayor and City Council amendments to other City ordinances bearing on biological and chemical laboratories.

(3) Share relevant documents with City departments and the board of health as needed to aid in the implementation of this article.

Sec. 6-61. ~~rDNA~~ Registration for low risk facilities

(a) Low risk facilities, as defined above, may conduct research and use of rDNA without a permit, provided, however, that such facilities shall register with the SBC and the City Clerk prior to conducting such research and use.

(b) The written application for registration shall be submitted to the SBC in writing on a form provided for such purpose, accompanied by the required fee, if any, and shall include:

(1) Name and curriculum vitae of a person in the organization familiar with the proposed rDNA research or use and the NIH Guidelines.

(2) A brief summary from the above-named person describing the proposed rDNA research or use and providing:

(A) A list of all of the institution's facilities within the City of Somerville, including the address and a description of the research or use of rDNA at each facility.

(B) Name and type of organisms (host/donor [foreign DNA]/vector) being used.

(C) Reference to the section of the NIH Guidelines where the rDNA research or use falls.

(D) If Recombinant DNA Molecules containing eukaryotic viruses are propagated in cells, give the approximate percentage of viral genome present.

(E) The scale (in liters) on which the organisms will be grown.

(F) An assurance that all rDNA research or use will be carried out following the NIH Guidelines, where applicable.

(G) Name of biological waste handler, if any, and written assurance that all waste will be disposed of according to all applicable federal, state, and local codes.

(H) Description of annual safety training and refresher training provided to laboratory staff.

(c) A registration application shall be approved by the SBC if all of the information in subsection (b) is provided and the registration application is deemed complete by the SBC. The SBC may require additional information to be submitted if the application is incomplete, and may require the applicant to submit a full permit application if the SBC determines that such permit is required under this article.

(d) The SBC shall make a final determination on a registration application within 30 days of the submission of the application. The SBC shall notify the City Clerk of such final determination, and, upon the acceptance of the City Clerk, the applicant shall be promptly notified, and registration shall be issued, if approved.

(e) A registration shall be valid for a period of one year and shall be renewed annually, unless sooner revoked in accordance with this article. Applications for registration renewal shall be submitted to the SBC. Registrations may be amended in accordance with the policies and procedures of the SBC.

(f) The SBC may set forth policies and procedures consistent with this article for the submission, review, and approval of registration applications and issuance, amendment, renewal and revocation of registrations. The SBC may establish fees for the processing of registrations as defined by SBC policies and procedures.

Sec. 6-62. - Biosafety permits.

~~All institutions~~(a) Any institution conducting or proposing to employ rDNA technology must conduct research or use of rDNA or biological agents that require BSL-2, BSL-2 (Enhanced) or BSL-3 shall obtain a permit from the SBC and shall comply with the Zoning Ordinance of the City of Somerville. The institution shall submit an application for a permit to the SBC containing the following information:

~~a-~~ (1) A statement by the institution that it shall comply with the provisions of this article, the ~~NIH~~ guidelines and all federal and state laws.

(2) A list of all of the institution's facilities within the City of Somerville, including the address and a description of the research or use of rDNA or biological agents at each facility.

~~b.~~ (3) A written agreement that reasonable inspections of facilities and pertinent records by the SBC shall be allowed.

~~c.~~ (4) A health and safety manual which ~~contains~~shall contain all procedures relevant to use of ~~RDNA~~RDNA and/or biological agents at all levels of containment in use at the particular facility.

~~d.~~ (5) A plan for waste disposal in compliance with all applicable federal, state and local laws.

~~e.~~ (6) A training program of safeguards and procedures for personnel using ~~RDNA~~RDNA and/or biological agents.

~~f.~~ (7) An emergency response contingency plan which addresses, ~~but is not limited to addressing~~ containment during fire or other emergencies, ~~and the education/~~ and safeguarding of first responders ~~such as fire fighters,~~ responses to inclement weather and power loss or brown-outs, and protection of employees and visitors in the building, responders, and the surrounding community.

~~g.~~ (8) An appropriate medical and environmental surveillance program in accordance with the guidelines.

~~A~~(9) A risk assessment of the activities to take place in the lab and possible impacts to employees, other building occupants, and the public.

(10) Proof of Liability Insurance in an amount deemed sufficient by the SBC and naming the City of Somerville as an additional insured.

(11) Effective rodent and insect control programs which shall be in place on premises where permitted research and use takes place in accordance with Article 2 section 11-38.

(12) A plot plan showing the proposed location of the facility and a floor plan showing the layout of the facility.

(13) A list of all containment levels and decontamination procedures to be employed.

(b) The applicant shall agree to release, indemnify, defend and hold the City of Somerville and its agents harmless as to any claims, assessments, damages or causes of action arising out of or related to the activities proposed or permitted.

(c) As part of the process of reviewing the permit ~~to employ RDNA technology~~application, the SBC may request additional information from the applicant.

(d) A permit shall be issued to the applicant if all of the above information is completed and complies with the guidelines, this article and current ~~technical~~industry standards. Permits shall be valid for one year from the date of issuance and shall be renewed on an annual basis, unless sooner revoked in accordance with this article. Applications for permit renewal shall be submitted to the SBC. In accordance with the policies and procedures of the SBC, permits

may be amended and may be issued with reasonable conditions or restrictions relative to the SBC's interest in protecting public health.

(e) The SBC may set forth policies and procedures consistent with this article for the submission, review, and approval of permit applications and issuance, amendment, renewal and revocation of permits. The SBC may establish fees for the issuance/processing of permits as defined by SBC policies and procedures.

Sec. 6-63. – BSL-4 containment not permitted

Institutions requiring containment defined by the guidelines as BSL-4 shall not be permitted in the City of Somerville.

Sec. 6-64. –Exemptions

Laboratories in educational institutions used exclusively for instruction and not research experiments, and medical or clinical facilities that collect patient samples for testing at offsite laboratories, shall be exempt from the registration and permitting requirements of this article; provided, however, that clinical laboratories that are developing new diagnostic testing using rDNA or biologic agents shall comply with said requirements. All such facilities shall operate in compliance with all other applicable laws and regulations of the City.

Sec. 6-65. - Permit procedure.

(a) Applications for a permit under this article shall be made to the SBC on a form provided for that purpose, accompanied by the required fee, if necessary to cover professional assistance or other costs incurred, any. When an application has been received in a completed form, as designated herein, a copy thereof shall be forwarded to the City Clerk, and the acceptance of the City Clerk shall designate the date of filing.

(Ord. No. 1994-4, 2-24-94)

(b) The SBC shall meet to discuss the completed application within 45 days after the date of filing with the City Clerk, and the SBC shall make a final determination on a completed application within 60 days after such date of filing. If no action is taken within the time permitted, the permit is deemed denied. The SBC shall notify the City Clerk of such final determination, and, upon the acceptance of the City Clerk, the applicant shall be promptly notified, and a permit shall be issued if so approved.

Sec. 6-66 Compliance with zoning ordinance

All institutions registered, permitted or applying for a registration or permit shall comply with the zoning ordinance of the City of Somerville.

Sec. 6-67. - Institutional biosafety committee.

~~The institutional biosafety committee ("An institution applying for a registration or permit pursuant to this article shall establish an IBC") shall be established in accordance with the guidelines. in accordance with the guidelines to review and oversee rDNA and biological research and use conducted by the institution, provided, however, that the IBC shall include two community representatives approved by the SBC, at least one of whom shall be a resident of the city. The IBC shall be the final arbiter within an institution with regard to regarding the implementation of this article and the guidelines.~~

~~(Ord. No. 1994-4, 2-24-94)~~

Sec. 6-~~63.~~ Institutional biosafety committee ~~68.~~ – IBC reports.

~~All Each registered or permitted institution shall file regular reports with the SBC and IBC, in a manner to be determined by the SBC. The IBC shall forward all meeting minutes of IBC meetings shall be forwarded to the director of the board of health and the SBC. Copies to the SBC, and shall submit to the SBC in a timely manner copies of all reports submitted to outside regulatory agencies, including but not limited to NIH, shall be submitted to the SBC in a timely manner.~~

~~(Ord. No. 1994-4, 2-24-94)~~

~~The IBC shall notify the SBC, in a written report, of any significant changes to the research or use, equipment, facilities or any other significant changes to the information submitted as part of the registration or permit application.~~

Sec. 6-~~64.~~ RDNA ~~69.~~ Emergency procedure: accident, illness and violation reports.

~~The (a) Any accidental release or exposure, or research or use related accident or illness, which represents a potential hazard to employees or the public, shall be reported by the permit holder or registered institution immediately to the fire department via 911, the agent or director of the board of health pursuant to M.G.L. c. 111, s. 30, the emergency management director, and the SBC no later than 24 hours after such release, exposure, accident or illness.~~

~~(b) The permit holder or registered institution shall report, within eight hours, to the SBC in writing any significant problems with or violations of the guidelines or this article and any significant RDNA-related accidents or illnesses no later than thirty days after such violation is known or should be known; unless the violation creates an emergency situation under subsection (a).~~

~~The permit holder shall demonstrate how emergency measures complied with the contingency plan. The permit (c) The permit holder or registered institution shall also provide the SBC, within 14 days, of any incidents pursuant to subsection (a), a written report describing how emergency measures complied with the emergency response contingency plan, and what actions shall be taken to correct the problem or violation and prevent the problem or violation from recurring.~~

~~(Ord. No. 1994-4, 2-24-94)~~

~~d) **Sec. 6-65. — Rodent and insect control.**~~

~~Effective rodent and insect control programs shall be in place on premises where RDNA use takes place.~~

~~(Ord. No. 1994-4, 2-24-94)~~

~~**Sec. 6-66. — BL4 containment.**~~

~~RDNA use requiring containment defined by the guidelines as "BL4" shall not be permitted in Somerville.~~

~~(Ord. No. 1994-4, 2-24-94)~~

~~**Sec. 6-67. — Emergency procedure.**~~

~~a. — Any accidental release which represents a potential hazard to employees or the public shall be reported to the SBC, board of health and the fire department immediately, and in no case more than 24 hours after the permit holder knew or should have known about any such release.~~

~~b. The mayor may, in his or her~~their~~ discretion, if satisfied that a dangerous condition exists relating to any RDNA~~RDNA and/or biological agent~~ research or use, declare an emergency and take action as ~~he or his or her designee deems~~ necessary to remedy the emergency.~~

~~(Ord. No. 1994-4, 2-24-94)~~

~~**Sec. 6-68**~~ **70 Confidentiality of documents.**

Proprietary documents as designated by the institution proposing to use biological agents shall be separated from the documents available to the public, subject to applicable public records law. The SBC shall develop policies and procedures to protect the confidentiality of any information including but not limited to that which, if released, could jeopardize the health and safety of the public, such as but not limited to lab locations and security measures.

~~**Sec. 6-71. - Enforcement.**~~

~~a. (a) Any institution which violates any provision of this article shall be subject to a fine in accordance with the provisions of section 1-11. Each day a violation continues shall constitute a separate and distinct offense.~~

~~b. (b) Once a registration or permit has been issued, it may be revoked, suspended, or modified by the SBC upon determination by the SBC, after due notice and hearing, that the permit holder~~registered or permitted institution~~ has materially failed to comply with this article, the terms of the registration or permit, or the guidelines.~~

~~c. (c) Notwithstanding ~~the above,~~subsection (b), the SBC, upon a determination that any violation constitutes an immediate and severe threat to the public health and safety, may order the immediate revocation of the registration or permit and preliminary closure of any premises~~low-risk facility, institution~~ or laboratory within a facility or institution engaging in or~~

contributing to such threat, without prior notice and hearing, but with subsequent timely notice and hearing.

(Ord. No. 1994-4, 2-24-94; Ord. No. 2006-09, § D, 4-11-2006)

Sec. 6-69. – Permit procedure.

~~a. Applications for a permit under this article shall~~ d) Final decisions of the SBC may be made appealed to the SBC on a form provided for that purpose, accompanied by the required fee, if any. When an application has been received in a completed form, as designated herein, a copy shall be forwarded to the city clerk by the SBC. The stamp of the city clerk shall designate the date of filing. Copies of the completed application shall be distributed to those boards and departments as determined by the SBC, which shall include, but not be limited to, the board of health, the environmental officer, OHCD, inspectional services division, the fire department and the planning board.

~~b. The SBC shall meet to discuss the application within 45 days after the filing of such application with the city clerk and shall take final action on a completed application within 60 days after such completed application has been submitted. If no action is taken within the time~~ extent permitted, the permit is deemed denied by law, in a court of competent jurisdiction.

(Ord. No. 1994-4, 2-24-94)

Sec. 6-70--72. – Severability.

If any section, subsection, sentence, clause, or portion of this article is for any reason held invalid 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.

(Ord. No. 1994-4, 2-24-94)

Sec. 6-73. – Effective date

This ordinance shall take effect 30 days after approval of the City Council and the Mayor.

Sec. 6-74. – Existing institutions

This article shall apply to all institutions applying for a permit or registration after the effective date. An institution that was permitted prior to the effective date shall not be required to submit a new permit application under section 6-62 until renewal of their permit, provided, however that said institutions shall otherwise comply with this article and the guidelines, and shall respond to SBC requests for updated documents or additional information prior to the permit renewal as needed for the protection of public health and safety.

An institution that has submitted a permit application prior to the effective date that is still under review by the SBC shall make a reasonable effort to comply with the SBC requests for

additional documentation and information to bring the institution into compliance with permit application requirements herein.

Be it further ordained by the City Council, that Section 1-11(b) of the Code of Ordinances of the City of Somerville is hereby amended as follows:

<u>Offense</u>	<u>Fine</u>	<u>Enforcing Personnel</u>
<u>Biotechnology Research (Chapter 6, Article IV).</u>	<u>\$300.00</u>	<u>Police, biosafety committee, inspectional services</u>

APPROVED:

President
City Council