

## Chapter 198. Biotechnology Regulations

[HISTORY: Adopted by the Board of Health of the Town of Franklin 11-19-1993;<sup>[1]</sup> amended in its entirety 6-9-2010 by Bylaw Amendment No. 2010-1. Subsequent amendments noted where applicable.]

### GENERAL REFERENCES

Fees — See Ch. 82.

Licenses — See Ch. 110.

Zoning restrictions for biotechnology uses — See Ch. 185, § 185-42.

[1]: *Editor's Note: This regulation supersedes former Ch. 198, Biotechnology Regulations, adopted 5-5-1993 as Regulation 93-1.*

### § 198-1. Scope and purpose.

- A. This chapter shall apply to all institutions in the Town of Franklin engaged in biotechnology activities, including but not limited to the experiment with or use of rDNA technology.
- B. This chapter concerns the manner of use for uses otherwise permitted under the zoning bylaws of the Town of Franklin, and sets forth procedures and performance standards for the regulation of biotechnology in the Town of Franklin.
- C. This regulation is intended to protect the public health, safety and welfare from risks and potential risks posed by biotechnology activities, including but not limited to experimentation with or use of rDNA technology. This chapter shall be interpreted to supplement other local, state and federal laws and regulations.

### § 198-2. Permit requirements.

- A. No institution may be engaged in biotechnology activities in the Town of Franklin without first obtaining a biotechnology operating protocol permit issued by the Franklin Board of Health.
- B. A biotechnology operating protocol permit shall be issued to an applicant institution upon the Board of Health making a finding that the proposed biotechnology use has been described in sufficient detail to allow the Board of Health to conclude:
  - (1) That the institution is in compliance with the provisions of this chapter and any applicable National Institutes of Health guidelines.
  - (2) That the application is complete and adequate in provisions made for medical surveillance and environmental monitoring at the site of the proposed activity.

### § 198-3. Definitions.

As used in this chapter, the following terms shall have the meanings indicated:

## **BIOTECHNOLOGY**

The experimentation with or use of biological processes to research or develop or produce commercial products for human and animal health care, food consumption, agricultural applications and environmental protection by the application of scientific data and the techniques of engineering and technology to alter the genetic code of cells or organisms through physical, chemical or biochemical manipulation. For the purpose of this chapter, "biotechnology" shall not mean the propagation of, experimentation with or use of plant tissue cultures for horticultural or agricultural purposes nor shall it include conventional food or alcohol production activities.

## **BIOTECHNOLOGY MATERIALS**

Biotechnology products, biotechnology waste products and those materials used at the process of experimenting with or developing such products, excluding the hardware or instrumentation used in such processes.

## **BOARD**

The Franklin Board of Health.

## **INSTITUTION**

Any single individual, group of individuals, partnership, association, organization, corporation, educational institution or medical facility engaged or applying to engage in biotechnology activities within the Town of Franklin.

## **INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)**

A committee established by each institution and representing the interests of the community with respect to the public health and protection of the environment. Each IBC shall contain at least two members not affiliated with and not remunerated by the institution and at least one member from the institution's biotechnician staff.

## **NIH GUIDELINES**

Guidelines for Research Involving DNA Molecules as promulgated by the National Institutes of Health (NIH) of the United States Department of Health and Human Services and published in the Federal Register on May 7, 1986, and any subsequent federal amendment thereto.

## **RECOMBINANT DNA (rDNA) or RECOMBINANT DNA MOLECULES**

Either:

- A. Molecules constructed outside living cells by joining natural or synthetic nucleic acid segments (including but not limited to DNA and RNA) to other nucleic acid molecules that can replicate in a living cell.
- B. Nucleic acid molecules resulting from the replication of a molecule described in Subsection **A** of this definition above.

## **§ 198-4. Restrictions.**

- A. Experimentation with, or use of, recombinant DNA technology, classified by NIH guidelines as requiring BSL-4 (BioSafety Level 4) level of containment, shall not be permitted in the Town of Franklin.
- B. Biotechnology activities shall only be permitted in Biotechnology Use Overlay Districts zoned and established by the Franklin Town Council.<sup>[1]</sup>  
[1]: *Editor's Note: See Ch. 185, Zoning.*
- C. Any person having knowledge of an unlawful release into the environment of biotechnology materials within the Town shall immediately report the release, by the quickest available means and in no case

later than 24 hours, to the Town of Franklin Board of Health, Fire Department and Police Department.

- D. Provisions shall be made to protect against the discharge or loss of biotechnology materials through corrosion, accidental damage, spillage or vandalism, through such measures as secure storage areas, indoor storage protocols including container inspections, and devices and measures for spill control in laboratory and manufacturing areas and in the vicinity of delivery points.
- E. Biomedical waste products or by-products shall not be discharged through the municipal sewer system unless all viable microorganisms have been rendered noninfectious in accordance with 105 CMR 480.
- F. There shall be no changes in the types of organisms, containment levels or decontamination procedures used by a permittee without advance notice to the Franklin Board of Health. Changes that result in exceeding any limitations established in the institution's biotechnology operating protocol permit will require a new or amended permit.

## § 198-5. Administrative requirements.

- A. Each institution in the Town of Franklin engaging in biotechnology activities shall conform to applicable federal, state and local-health regulations which exist or may be promulgated. In addition, each institution experimenting-with or using rDNA technology shall comply with the administrative requirements set forth in the NIH guidelines, or any amendments thereof, established from time to time by the NIH, by other federal agencies or by act of Congress. No change in Franklin Board of Health regulations shall apply to work in progress or previously contracted for by an institution unless the Franklin Board of Health shall first hold a public hearing on such change after giving written notice to institutions in Franklin engaged in biotechnology activities.
- B. Institutional biosafety committees.
  - (1) The nonaffiliated representatives on each IBC shall be appointed by the institution with approval by the Chairman of the Franklin Board of Health. These members shall be officials of local public health or environmental protection agencies or Franklin residents whose educational and/or professional backgrounds are appropriate to the IBC's function, e.g., persons with background in the legal, medical, occupational health or environmental fields.
  - (2) The nonaffiliated representatives on each IBC shall be bound to the same provisions as to nondisclosure and nonuse of proprietary information and trade secrets as all other members of the institutional biosafety committee, except to the extent necessary to alleviate any public health hazard.
  - (3) Each IBC shall meet no less than twice a year. Each IBC shall record minutes of each of its meetings, and a copy of all minutes of IBC meetings shall be forwarded to the Franklin Board of Health within 14 days of the meeting after first removing any proprietary information and trade secrets therefrom. The full text shall remain on file in the records of the institution for inspection at all reasonable times by any member of the IBC.
  - (4) Every six months, the IBC shall provide its certification that the institution remains in compliance with this regulation and any applicable NIH guidelines.
- C. If the institution is engaged in rDNA research at the BSL-3 (BioSafety Level 3) containment level (as defined in the NIH guidelines), the institution shall appoint a biological safety officer (BSO) who shall be an additional member of the IBC.
- D. If the institution is engaged in rDNA research on a large scale (as defined by the NIH), the institution shall comply with all additional administrative requirements contained in the NIH Large Scale

Recommendations.

## § 198-6. Application and review process.

- A. Biotechnology operating protocol permit.
- (1) An applicant for a biotechnology operating protocol permit shall submit an application and an application review fee to the Board of Health, and shall file a copy thereof with the Town Clerk, Building Commissioner and Planning Board.
  - (2) The Board shall hold a public hearing within 45 calendar days of receiving a completed application and act upon the application within 30 calendar days of closure of the public hearing.
  - (3) The Board of Health may at any time reject as incomplete or inadequate any permit application which fails to provide the information required by this regulation.
  - (4) The applicant for a biotechnology operating protocol permit shall have the burden of convincing the Board that the activities proposed in the application meet or exceed the permit criteria herein. Failure to provide adequate evidence to the Board supporting this burden shall be sufficient cause for the Board to deny a permit. The Board may impose permit conditions which the Board deems necessary or desirable to protect human-health, safety-and-welfare.
  - (5) The Board shall render a written decision setting forth its findings and the reasons therefore. Such decision shall be filed in the office of the Town Clerk and copies mailed to the applicant, Building Commissioner and Planning Board.
  - (6) Institutions seeking such a biotechnology operating protocol permit from the Board of Health shall prepare and submit the following application materials:
    - (a) A plot plan showing the proposed location of the facility, the zoning classification of the site, building footprint, points of egress onto public ways, and available utilities.
    - (b) A detailed floor plan showing the following: internal layout of the facility; containment structures and equipment; and all points of egress, such as but not limited to:
      - [1] Sanitary disposal lines for sewage and wastewater.
      - [2] Laboratory or process waste lines.
      - [3] Building ventilation (natural and mechanical) exhausts and their respective quantity values of volumes/time and exit velocities.
      - [4] Solid, hazardous, biological and radiological wastes storage facilities.
    - (c) A listing of all organisms, containment levels and decontamination procedures to be employed.
    - (d) A plan, consistent with NIH guidelines, for a screening process for organisms used in experiments and for testing organisms resulting from such experiments.
    - (e) A plan, consistent with NIH guidelines, for a medical surveillance program for all employees engaged in the use of rDNA, together with the institution's health and safety manual. The health and safety manual shall include procedures required under NIH guidelines for the use of rDNA at all levels of containment in use at the facility, proper employee training and health surveillance programs, procedures for monitoring and minimizing potential environmental and personal exposure and a program for waste disposal in compliance with all applicable federal, state and local laws.

- (f) A plan, consistent with NIH guidelines, for an environmental monitoring program. These shall include but not be limited to the following:
- [1] A plan for the systematic monitoring of waste and waste processing.
  - [2] A plan to orient representatives of the institution's designated local hospital and the Franklin Board of Health, Fire Department and Police Department in the procedures to be used in the event of an emergency.
  - [3] A plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in the same building.
  - [4] A plan for systematic security of the premises.
- B. Fees. Any institution applying for a biotechnology operating protocol permit shall pay an application review fee while submitting its application to the Board of Health. Annually thereafter, a permit renewal fee shall be paid for each biotechnology operating protocol permit. Fee amounts are outlined in Chapter **82**, Attachment 1, of Franklin's Town Code.
- C. The Board of Health may select, retain and contract with a professionally competent person or agency to perform a review of any biotechnology operating protocol permit application. The payment for these services will be the responsibility of the applicant institution. Copies of documents resulting from such evaluations shall be submitted to the Franklin Planning Board as a party of interest, and for consideration during site plan review and, if applicable, the special permit approval process.
- D. Confidentiality of proprietary documents. The Board of Health, its employees and any party contracted to conduct a permit application review shall maintain the confidentiality of any proprietary information released to them while performing their duties, and the institution may require a nondisclosure agreement to protect such proprietary information.

## § 198-7. Inspections.

The Board of Health shall cause an inspection, at least annually, of each institution holding such permit to ensure compliance with the provisions of this regulation and the NIH guidelines. The Board of Health reserves the right to select, retain and contract with a professionally competent person or agency to perform inspections and reviews. The payment for these services will be the responsibility of the institution.

## § 198-8. Enforcement; violations and penalties.

- A. The Franklin Board of Health shall have the powers and responsibilities for enforcement of this chapter.
- B. Failure of an institution to comply with one or more of the provisions of this chapter shall subject the violator to the following:
- (1) A fine of \$500 per day. Each day's failure to comply shall constitute a separate and distinct offense.
  - (2) All costs and/or damages incurred against the land and costs incurred by the Town to mitigate and/or remedy conditions, including spills, resulting from the permittee's actions or from actions occurring on the permittee's site. Any such costs incurred by the Town shall constitute a debt due to the Town upon the completion of the mitigation and/or remedial work and the rendering of an account thereof to the owner of the land, his authorized agent or the occupant, and shall be recoverable from such owner or occupant in an action on contract. The provisions of MGL c. 139,

§3A, Paragraph 2, relative to liens for debt, and the collection of the claims for such debt, shall apply to any debt referred to in this section, except that the Board of Health shall act hereunder in place of the Mayor or Selectmen.

- (3) An enforcement order which may include without limitation a cease and desist order, provided that such order provides notice of an opportunity for a hearing with the Board of Health within seven business days of receipt of the order.
- C. Once a permit has been issued it may be revoked only after three days' advance written notice, a hearing and determination by the Board of Health that the institution involved has materially failed to comply with these regulations, the permit conditions or the NIH guidelines, including but not limited to a failure to report a release as required in **§198-4C** of this chapter.