

November 2, 2021

TO: SOMERVILLE MAYOR AND CITY COUNCIL

FROM: LEE AUSPITZ, [REDACTED] [REDACTED]

RE: UPDATING SOMERVILLE'S 1994 BIOTECHNOLOGY ORDINANCE (Chapter VI, Article 4)

### *Summary*

High rental rates for biotechnology laboratory space are fueling a spillover of biotech real estate investment from Cambridge and Boston into Somerville. To prepare for leasing, the City's 1994 regulatory framework for biotech tenants needs to be updated, activated, broadened and refined to cover the full variety of biotech laboratory activity. The experience of Cambridge suggests that a rigorous regulatory regime can serve to promote vigorous biotech growth while protecting public health. As developers have already announced plans for over three million square feet of lab/office space in Somerville, the City should act promptly to upgrade its 1994 biotechnology ordinance (*Chapter VI, Article 4*). As matters now stand the Somerville ordinance has the effect of discouraging harmless research while leaving potentially toxic, "Level 3" labs unregulated.

### *Background*

Since the early 1980s both the World Health Organization (WHO) and the US Centers for Disease Control and Prevention (CDC) have worked continuously on detailed manuals setting out safety guidelines for biotechnology laboratories. The CDC and WHO manuals now in their 6<sup>th</sup> and 5<sup>th</sup> editions respectively, employ a four-tiered approach to BioSafety Levels (BSLs 1-4). The aim is to reduce the well-documented potential for the spread of lab-associated infections (LAIs). At highest risk is Bio Safety Level 4, which deals with potentially lethal materials in self-sequestered facilities. There are only about a dozen such labs in the US, one of which is under the aegis of Boston University. Level 4 labs are currently banned in Cambridge and Somerville. Labs in the BSL 3 to 4 range also pose toxic risks. They are therefore closely monitored in Cambridge, a "world capital" of biotech, with annually renewable public health permits, fines for violations levied daily, and provision for closure on short notice for compliance failures.

Somerville is no stranger to such issues. In January 1981 the City received a pioneering application for a commercial recombinant DNA lab in an industrial building on the Somerville side of Beacon Street. The Mayor and Board of Alderman were initially receptive to the lab, but after a stormy public meeting the City deferred action, pending a report from a broadly based committee of residents and experts. Though the applicant withdrew, the committee completed its report, which led to the City's adoption later in 1981 of an ordinance focused on recombinant DNA (rDNA).

The City's determination to regulate what then seemed to be a potentially hazardous activity was strengthened by an unrelated event. In April 1981 Somerville fell victim to the worst chemical spill in the history of Massachusetts: the leakage of hazardous fumes from a supposedly sealed tank car in a city-based freight yard. The spill, which required the temporary evacuation of thousands of Somerville residents, served as a reminder that mishaps happen.

In 1994 the City updated its biotech ordinance with a few general phrases to include biotechnology research beyond recombinant DNA. However, the enforcement provisions, though rigorous, remained limited to recombinant DNA. There has been no change in the ordinance since 1994, no record of its enforcement body after 2001, and indeed, no minutes to suggest that it has ever met.

Meanwhile, at the federal and international levels forty years of continuous upgrading of CDC/WHO lab safety guidelines have greatly allayed public concerns about lab-associated infections. At BSL levels 1 and 2, experts now consider the risks to be negligible when CDC /WHO guidelines are followed. At BSL 3 and 4, more regulations are considered appropriate, including regular inspections by municipal boards of health and outright banning of highest risk labs in densely populated areas.

#### *Areas of deficiency*

1. **Somerville's 1994 Biotechnology Ordinance** (*Chapter 6, Article IV, link attached*) is seriously out of date. Though intended to broaden the focus of the 1981 ordinance, its enforcement provisions retain the City's original preoccupation with recombinant DNA research. The ordinance cites NIH guidelines on rDNA but fails to cite what has become the more inclusive and controlling standard: CDC's lab safety manual: the so-called "BMBL" ---*Biosafety in Microbiological and Biomedical Laboratories*, now in its sixth edition (*link attached below*). The BMBL addresses the full range of lab activity and lays out minimum practices for the four biosafety risk levels. Though not a regulatory document as such, the BMBL manual is given the force of law in Cambridge and Boston, where it is incorporated by reference into the governing Biosafety Regulations (*links attached*). The Somerville ordinance of 1994 is lacking in comparable coverage and specificity. It does not mention the BMBL and retains what is now an outdated focus on rDNA research (as detailed in point #3 below).

2. **The Somerville Biotech Safety Committee**, which is charged by City Ordinance with public health enforcement of labs, appears to have been defunct for at least twenty years. A public records search revealed no minutes and no activity after 2001, presumably because no rDNA lab applications have been submitted. Even if the Committee were active, its rigorously detailed enforcement authority under the 1994 ordinance extends only to recombinant DNA research, omitting the category of pathogens. Somerville, like Cambridge, prohibits the very highest risk labs (BSL 4) but, unlike Cambridge, Somerville is silent on high risk labs in the BSL 3 to 4 range.

3. **The outdated Somerville focus on rDNA** can be read to cover harmless activity in the Level 1-2 range while ignoring research on pathogens that may pose lab-associated infection risks. In correspondence with this writer, the director of a world class academic virology lab writes: "There are certainly rDNA experiments (we do them all the time) that do NOT require Biosafety Level 3 measures. Most of them are in fact Biosafety Level 1. What matters is not so much the rDNA as the cells or organisms they are being used with. I think that the Somerville ordinance may be so outdated that it doesn't even distinguish between rDNA and pathogens. We've come to think of rDNA as a regular laboratory reagent for many purposes, to be used to cause a cell (either bacterial or mammalian) to express a protein. All gene editing, most of which is done in cells in culture for lab experiments, not in animals or plants that can reproduce, involves rDNA."

**These deficiencies are all easy to correct. With the first high-rise lab building nearing completion in Boynton Yards, prompt attention is advisable before leasing begins.**

#### *Measures to Consider*

A. Update the Somerville Biotech Ordinance of 1994, using the Cambridge template as a time-tested, lab-friendly starting point. The main improvements to be found in the Cambridge ordinances are

-- using a risk-level approach to replace an outdated focus on rDNA

- a scientifically grounded definition of biotech that includes the whole range of lab activity
- incorporation by reference of comprehensive federal safety guidelines as found in the most recent BMBL edition and elsewhere
- stipulation that in cases of conflict BMBL safety standards supersede NIH rDNA standards
- requirement for annual re-permitting of BSL-3 labs whether self-standing or in lab incubators, with license fees to cover the administrative costs

#### B. Administrative considerations

- share administrative burdens by requiring landlords to write into leases specific reference to BMBL and other relevant guidelines
- require a safety report from an institutional point of contact in leased BSL-3 labs as part of annual re-permitting
- consider outsourcing inspections until the volume of work justifies adding full-time staff

#### *Conclusion*

In recent years Somerville has been at the forefront of many health and tech issues. It would be in keeping with its innovative spirit to have a regulatory framework in place in anticipation of the coming wave of biotech leasing. This memo is submitted as a public-spirited alert, in the expectation that City leaders will improve upon its analysis and suggestions.

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#### *Links*

CDC's most recent "BMBL" (*Biosafety in Microbiological and Biomedical Laboratories, 6th edition, 2020*):  
<https://www.cdc.gov/labs/BMBL.html>

Somerville 1994 Biotechnology Ordinance

[https://library.municode.com/ma/somerville/codes/code\\_of\\_ordinances?nodeId=PTIICOOR\\_CH6HE\\_ARTIVBIRE](https://library.municode.com/ma/somerville/codes/code_of_ordinances?nodeId=PTIICOOR_CH6HE_ARTIVBIRE)

Cambridge 2009 Biosafety Regulation

[https://www.cambridgepublichealth.org/Cambridge\\_Biosafety\\_Regulation\\_2009.pdf](https://www.cambridgepublichealth.org/Cambridge_Biosafety_Regulation_2009.pdf)

Boston 2006/2019 Biosafety Regulation (not yet included here is a 2021 amendment striking rDNA focus)

<https://bphc.org/boardofhealth/regulations/Documents/Biological%20Laboratory%20Regulation%20As%20Amended%20January%2016%202019.pdf>