



## *Your Voice for Public Health*

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### **An Act to Protect the Public Health and the Environment from Toxic Biological Agents (House Docket #4249)**

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The Massachusetts Public Health Association (MPHA) welcomes this opportunity to augment our oral testimony on An Act to Protect the Public Health and the Environment from Toxic Biological Agents. MPHA is a private, non-profit, non-partisan public health advocacy organization. We are a membership organization that includes public health professionals from across the state, including scientists, academics, community health workers, and public and private sector public health workers in a wide variety of specialties. MPHA is the state affiliate of the American Public Health Association and is wholly independent of the Massachusetts Department of Public Health.

MPHA strongly supports the intent of this legislation and believes that improved regulation of biosafety laboratories is necessary. It is crucial that we protect the public health of our communities and personal health of laboratory workers from the risks associated with biological research with pathogenic organisms.

We would like to thank Representative Gloria Fox for sponsoring this bill, and for raising this issue within the legislature. We would also like to thank our colleague organizations, Alternatives for Community & Environment and the Roxbury Safety Net, for calling attention to the need for more careful oversight of biological laboratories and public disclosure of high-risk organisms that will be present in these facilities. Their strong advocacy and organizing on behalf of their community has benefited all of us. MPHA shares their goal of developing a coherent, comprehensive policy to protect public health and safety.

MPHA is a science-based organization. We are convinced that protection of our communities and those individuals who work directly with potentially hazardous pathogens can be achieved in an effective manner, while maintaining the viability of an industry itself essential to protecting public health. We are working closely with Rep. Fox, Rep. Rushing, and others to offer technical recommendations that we believe will improve the proposed legislation. In that spirit, we hope these comments will facilitate the passage of strong and effective regulations – backed by sufficient resources to ensure proper implementation.

Oversight and regulation of biosafety laboratories can incorporate community concerns and recognize our right to know what potential risks have been brought into our communities. This can be accomplished by encouraging “best laboratory practice” standards and by citing and enforcing existing federal guidelines and references, as Cambridge has been doing for nearly thirty years. To be clear, it is the position of the MPHA that important research that includes the use of hazardous and life-threatening substances can be conducted in an urban area when, and only when, the proper behaviors, supervision, procedures, and reporting, are understood, in place, and ensured through a higher level of

compliance and transparency. Neither good intentions nor good faith can substitute for clear guidelines and effective monitoring.

MPHA recognizes and appreciates the urgency in adopting regulations for Biosafety Level 4 (BSL4) biological laboratories. The proposed BSL4 laboratory, to be built and operated in the Boston Medical Center area by Boston University, has raised reasonable and legitimate concerns about public health and safety. The public has a right to expect appropriate protection from the risks posed by biological research and a right to have the identity of specific high-risk pathogens shared with public health authorities in order to monitor and protect the health of the community. At the same time, the biomedical research community has an obligation to continue its work in order to limit, reverse, or prevent human suffering.

MPHA completely supports the intent of this bill and believes that improved regulation is necessary. However, we believe that this bill can and should be strengthened, most notably by aligning specific biosafety provisions with existing federal standards and guidelines and by separately considering the most appropriate approach to the regulation of BSL2 and BSL3 laboratories through a separate legislative effort. With this in mind, MPHA offers the following principles and specific comments:

1. **BIOMEDICAL RESEARCH IS CRITICAL FOR PUBLIC HEALTH:** Biological laboratories play a vital and essential role in conducting research for the purposes of protecting public health, from providing tests to developing vaccines. The proper notification of public health authorities regarding the presence of specific pathogens will only enhance the protection of the health of the community.
2. **RISKS ARE REGIONAL AND VARIABLE, AS WELL AS LOCAL:**  
Employees of BSL4 laboratories face the greatest risk of exposure, and efforts to establish the strongest possible occupational health and medical surveillance programs are essential for protecting these employees and the communities in which they live and through which they pass. Focus on the potential threats of a BSL4 lab to a relatively small geographic area around the lab facility may misdirect public concern from the need to protect the wider area potentially affected through travel and contact of lab employees. Individuals and communities in close geographic proximity to a BSL4 lab may or may not be those most at risk from a potential lab accident, though certain risks posed by the creation of an attractive target for terrorist activity must be taken seriously.
3. **WORKING GROUP PROCESS NEEDED TO FINE-TUNE LEGISLATION:** MPHA urges the committee to endorse the intent of this bill and to convene a legislative commission to improve the bill by addressing specific logistical and technical elements noted in this comment. This commission should have representation from multiple stakeholders, including community advocates and residents, biosafety professionals, regulators, state and municipal elected officials, local public health professionals, and public and private sector scientists, to consider the role that the state should play in assuring the highest standards of safety in these laboratories. This would temporarily extend the time necessary to enact such legislation, but would result in regulations that are more measured and balanced in scope and intent.
4. **SITING CRITERIA DO NOT CORRESPOND WELL TO THE IMPACTS OF BSL4 LAB:**  
This language does not add important assurances that directly address concerns that might be associated with high-risk bio-containment labs. This language appears to be taken from environmental impact regulations intended to mitigate the negative effect of disruptive industrial or utility facilities or, perhaps, brown fields (urban sites with a history of

contamination). Furthermore it reinforces the notion that proximal risk should be the primary concern of the community (as opposed to measures to address Lab-Acquired Infections and medical surveillance protocols and reporting requirements to local or state public health of any illnesses or work absences). These are not fact-based concerns, objectively, which shift focus from greater risks.

5. **SITE APPROVAL SHOULD NOT BE THE BURDEN OF LOCAL BOARDS OF HEALTH:**  
The process of selecting an acceptable site for a BSL4 laboratory should factor in the concerns and knowledge of all affected parties: community residents, public health professionals, biosafety professionals, scientists, regulators, and the general public. The approval of such a site should be informed by well-defined criteria developed to maximize the protection of public health and the environment. The people of Massachusetts have long maintained that a healthy and open democratic culture requires vigilance and strong expressions of public will in order to defend against arrogance and secrecy in our public endeavors. At the same time, the contributions of the Commonwealth of Massachusetts to the fields of science and medicine, recognized around the world as remarkable and distinguished, were only possible because of the shared values that favor progress and intellectual discovery. Indeed this tradition of progress even now distinguishes this state in the field of stem-cell research and sets a standard for other states. We believe that it is appropriate and necessary for legislation to authorize the Department of Public Health and/or the Department of Environmental Protection to establish such a process. It is not realistic or fair to expect local boards of health to have the expertise or resources to make such a determination using evidence-based arguments in an environment that is likely to be highly politically charged.
6. **THE RESPONSIBILITY TO APPROVE SPECIFIC RESEARCH PROTOCOLS SHOULD NOT BE PLACED WITH LOCAL OVERSIGHT BOARDS:**  
It is reasonable for local residents to expect that assurances of public health and safety will be established and maintained through reporting and inspection mechanisms, whether these are enforced by the state or by the local municipality. The decision to conduct certain experiments in a given facility should be driven by the ability of that laboratory to safely host that work by virtue of the containment measures and laboratory protocols in place. The best practices for safe operation of a laboratory at a given containment level (BSL1, BSL2, BSL3, BSL4) can be established through federal regulatory documents and industry protocol publications. Decisions regarding the necessary precautions for a specific experiment need to be produced by an internal, but independent, safety committee familiar with the hazards associated with the proposed work. Such a system can allow regulators to hold institutions responsible for safe operation and good judgment in assigning these containment levels. Local regulators should not become involved in the business of determining which work will be allowed when the proposed work would be conducted responsibly and at the appropriate containment level. At very least, the authority of the Community Advisory Board in previewing specific experiments should be clearly limited to judgments about the assignment of the appropriate containment level and not ethical judgments about the nature of the work itself. The final uses of basic research cannot be forecast by any oversight board and represent much broader public policy concerns.
7. **ENFORCEMENT AND COMMUNITY REPORTING REQUIREMENTS:** Proper enforcement of internal biosafety policies and inspection of containment facilities should be the responsibility of the state or local public health regulator. Accountability for the reasoning behind the use of a given containment level should be forthcoming from the laboratory safety committee. An annual report containing a summary of the approvals granted by the institutional biosafety committee (IBC) for the BSL4 facility should be provided to the appropriate local

public health authority. Neither fear nor misunderstandings should make it impossible for leading institutions to participate in the critical research contemplated. Better communication and a willingness to share information are required to ensure that such research is conducted in a safe and productive way and the community as a whole is protected.

8. STATE OVERSIGHT CAN ONLY WORK WITH NEEDED RESOURCES: Resources are crucial to ensuring that any laws and regulations are properly implemented. Insufficient funding for DPH and DEP will, inevitably, lead to insufficient monitoring and oversight of biological laboratories, regardless of the final form that this responsibility takes. The resources needed to operate an effective, well informed, and respected enforcement program is a small price to pay for protecting public health and safety and responsibly encouraging the growth of the biotech sector in Massachusetts.
9. USAGE OF TERM "TOXIC BIOLOGICAL AGENTS" AND RULES FOR SHARING INFORMATION ON SELECT AGENTS: Organisms that produce toxins are only one class of pathogens that might be present in this or any high-level containment lab. Other pathogenic organisms can represent a significant public health threat without being "toxic" (or capable of pathogenicity via release of toxins). By and large, the agents that produce toxins are used in BSL3 or BSL4 labs, and many are also Select Agents. There are restrictive rules from the USA PATRIOT Act that restrict institutions from sharing the identities of Select Agents if that information might then become public record. A mechanism for abiding by federal law and the provisions of this draft while enabling oversight authorities to receive the necessary details of research being proposed need to be established. These can be consistent with USA PATRIOT Act restrictions, but they need to be clarified in final regulations.
10. STRONGER MEDICAL SURVEILLANCE STANDARDS NEEDED:  
No special medical surveillance or occupational health requirements are included in the draft legislation. These may be the most important measures that can be taken to protect public health. There are repeated references to the NIH Guidelines without mentioning companion protocol "best practice" documents such as the Biosafety in Microbiological and Biomedical Laboratories (BMBL) that apply to non-recombinant labs, as well as recombinant ones. This section needs careful consideration of existing best practice guidelines that apply to all BL4 labs (rDNA and non-rDNA).
11. SECURITY PLANNING WITH ENFORCEMENT AGENCIES NEEDED: Security provisions appear as a laundry list of scenarios of greater and lesser threat or likelihood. Some appropriate language or jurisdiction should be assigned without overly specifying how the evaluation of security must be carried out. We understand that the language pertaining to security planning was taken from scenario planning for nuclear power plants and are not inherently unreasonable. Nevertheless, this provision should be forwarded to a Facilities Working Group with participation of local and federal law enforcement in order to rationalize the security requirements for BSL4 facilities.
12. RULES ON TRANSPORT OF HIGH-RISK AGENTS ARE NOT STRINGENT:  
Terminology: BSL 4 reflects a containment level, not a class of agents or pathogens. *Many laboratory professionals believe that the transportation requirements for highly pathogenic material are one of the weakest links in assuring that there will be no release of these materials.* Federal Department of Transportation standards are arguably quite lax, and *attention paid to strengthening these requirements would result in improved public safety.* We do recognize that there may be limitations on the establishment of state rules on transportation when federal

standards already exist, however insufficient they may be. Every effort to find a means to strengthen transport standards at the state level should be pursued.

13. AUTHORITY FOR ADDITIONAL LOCAL REGULATION NOT NEEDED:

Section 13 specifies that local governments can establish their own rules regulating or prohibiting biological activity within their community. We understand that this is intended to allow local control to exist even after this legislation is passed and that without this section local ordinances may be disallowed. We believe that local restriction should continue to be allowed. The reference to regulating or prohibiting rDNA, however, makes a confusing distinction between rDNA work and other biological work. This section should simply state that local restrictions over biological work should be allowed, whether they refer to rDNA work or all biological work.

14. REGULATION OF BSL2 AND BSL3 LABS NEED SEPARATE CONSIDERATION FROM

BSL4: BSL2 and, particularly, BSL3 laboratories also have risks associated with their operations that merit effective oversight and regulation. This bill legitimately raises the question of how this should be accomplished, but considerable additional effort is required to craft effective legislation for regulation of these lower risk facilities. The task of regulating BSL 2 and BSL 3 facilities, which number in the thousands across the Commonwealth, would overwhelm current state and local capacities and resources. The potential impacts of new regulation on a wide range of current scientific projects in a wide array of settings should be carefully considered. Different regulatory mechanisms and requirements may be advisable for different levels of biosafety labs. The provision in Section 14 authorizing the state Department of Public Health and the Department of Environmental Protection to promulgate regulations pertaining to BSL2 and BSL 3 laboratories should be retained. This process should engage all primary stakeholders and should be certain to include biosafety professionals and representatives from their local member organization, the New England Chapter of the American Biosafety Association (NE-ABSA). Representatives from the private biotech sector, the academic research sector, and state and local public health officials, and concerned residents should also be invited to join this process.

Thank you very much for this opportunity to help shape such important legislation for the residents of the Commonwealth. Please do not hesitate to call on us if the Massachusetts Public Health Association can be of further assistance to the committee in this effort. You may reach Geoff Wilkinson, MPHA executive director, at (617) 524-6696 x100 or MPHA Board member and Environmental Health Section co-chair, Sam Lipson, at (617) 665-3838 for assistance.

