



March 7th, 2024

The Honorable Senator Brian J. Feldman
Chair, Education, Energy, and the Environment
2 West-Miller Senate Office Building
Annapolis, Maryland 21401

BIOQUAL Inc. urges an unfavorable report on SB 761 – Testing Facilities That Use Animals – Licensing and Regulation.

This bill would require facilities that use animals in research, education, or testing to be licensed by the State Department of Agriculture. The bill requires an inspection and payment of a licensing fee before the State may issue such a license. It creates a State Inspector of Animal Welfare, which is to inspect all licensed facilities each year, a responsibility it can delegate to animal welfare organizations. It requires researchers to justify the use of animals to the state inspector, addressing whether another suitable model is available, whether the research can be performed ethically on human subjects, and whether animals are necessary to accelerate responses to life-threatening or debilitating conditions. In addition, it includes provisions regarding the adoption of dogs and cats used for research and creates duplicative and onerous reporting requirements. There are significant criminal penalties associated with violations of the bill.

BIOQUAL Inc. (BIOQUAL), a Maryland based Contract Research Organization founded in 1981, has long been engaged in development of in-vivo testing programs and has been extensively involved in research efforts to develop vaccines and therapies against emerging diseases including AIDS, Hepatitis, Influenza, Zika, Chikungunya and many others. Most recently, the company has played a vital role in COVID-19 research and in the development of successful vaccines and therapies against the SARS-CoV-2 pandemic. The use of animals in this research was essential to the rapid development of the COVID-19 vaccines that are estimated to have saved millions of lives worldwide (ref. Lancet Infect Dis 2022; 22: 1293-302, June 23, 2022; [https://doi.org/10.1016/S1473-3099\(22\)00320-6](https://doi.org/10.1016/S1473-3099(22)00320-6)).

Animal models are a necessary component of BIOQUAL's mission to provide innovative research support for improved global health. BIOQUAL is a USDA Registered Class R Research Facility, holds an Assurance with the Office of Laboratory Animal Welfare (OLAW), and is an Accredited institution with the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Further, to ensure ethical and human treatment, BIOQUAL is committed to:

- Having a duly constituted Institutional Animal Care and Use Committee (IACUC) that is qualified through the experience and expertise of its members to ensure that all research and teaching protocols using live vertebrate animals are designed and performed in a humane manner that complies with all applicable laws, policies, and guidelines.
- Fostering a culture of recognition and appreciation for the role of animals in research for all staff.
- Incorporating the 3Rs of animal research (Replacement, Reduction, and Refinement) to constantly seek to improve our program of animal care, and
- Maintaining the highest standards of animal care and use through a collaborative approach involving veterinarians, scientists, and animal support staff.



The proposed bill places undue burden and bureaucracy on research operations, adding layers of administrative work and increases to operational costs that will hinder the development of such vaccines and treatments. The proposed structure duplicates existing federal oversight, undermines the institutional animal care and use committee's authority and responsibility for expert evaluation of proposed research, and generates onerous administrative burden.

SB761 duplicates existing federal oversight.

Research institutions are subject to the Animal Welfare Act and Regulations (AWAR) and compliance with the PHS Policy. Through the extensive requirements and guidance provided through these bodies, institutions communicate regularly with federal oversight representatives - including unannounced annual inspection by the USDA. Additionally, through accreditation with AAALAC, institutions must have robust policies in place to ensure animal health and welfare is prioritized and maintained. Further, through the internal IACUC, institutions must comply with the following responsibilities:

- Review, at least semiannually, the institution's program for the humane care and use of animals;
- Inspect, at least semiannually, the institution's animal facilities (including satellite facilities);
- Prepare reports to the Institutional Official (IO) of the IACUC evaluations;
- Review animal welfare concerns;
- Make recommendations to the IO on any aspect of the animal program, facilities, or personnel training;
- Review and approve activities related to the care and use of animals;
- Review and approve, proposed significant changes to the use of animals in ongoing activities; and
- Be authorized to suspend an activity involving animals.

The proposed bill duplicates many of these processes, such as annual/bi-annual inspection by the State Department of Agriculture, and annual reporting of animal use. BIOQUAL takes the responsibilities of the 3Rs principles seriously and supports such measures, but this bill provides very little in the direction of creating meaningful improvements to the actual welfare of animals.

Undermining IACUC Authority and Responsibility

Furthermore, this proposed legislation undermines the authority and responsibility of Institutional Animal Care and Use Committees (IACUCs). This duplication of oversight not only adds to the bureaucratic burden but also dilutes the expertise and effectiveness of established IACUCs in evaluating and approving research protocols involving animal subjects. By requiring researchers to justify the use of animals directly to the state body, the bill diminishes the role of IACUCs, which are comprised of experienced professionals dedicated to ensuring the ethical treatment of animals in research. This erosion of IACUC authority undermines the rigorous evaluation process that has long been established to safeguard animal welfare and scientific integrity within research institutions. Consequently, SB761 poses a significant threat to the autonomy and effectiveness of IACUCs, jeopardizing the welfare of research animals and hindering scientific progress.



This bill generates onerous administrative burden.

The bill requires the type, number, and purpose of all test methods conducted by a testing facility to be reported annually to the State Secretary of Agriculture. This is a massive step up in administrative burden from the current regulatory reporting requirements. To elucidate, a given research study may include 10 or more test methods, each often conducted at multiple times over the duration of the study. The scale of this reporting would reach into the hundreds of pages and FTE-hours to account for the level of detail required.

Impact

In conclusion, SB761 will create negative impact on research operations, undue administrative burden, duplication of existing federal oversight, and lacks meaningful improvements to animal welfare. As a company committed to ethical research and the development of vaccines and therapies, we believe that this bill would hinder scientific progress and innovation rather than enhance animal welfare or regulatory oversight. For these reasons, we urge an unfavorable report on Senate bill 761.