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EDITORIAL

Bioprotection: the search for national regulation, integration of areas and construction of an institutional culture

Bioprotección: la búsqueda de regulación nacional, integración de áreas y construcción de una cultura institucional

Bioproteção: a busca pela regulação nacional, integração de áreas e construção de uma cultura institucional

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The concepts of biosafety and biosecurity go hand in hand but have different connotations and objectives. Understanding these concepts is essential for a risk assessment of biological agents to be applied more effectively in other contexts. It can be summarized that while biosafety focuses on accidents, escapes, or unintentional releases of biological agents, bioprotection, according to the recent publication Laboratory Biosecurity Guidance, by the World Health Organization (WHO), addresses:

> *"[...] policies, principles, technologies, and practices implemented for the protection, control, and accountability of biological materials, technology, and information, or of equipment, methods, skills, and data related to their handling. Biosecurity aims to prevent intentional or accidental unauthorized access and the loss, theft, misuse, diversion, release or even weaponization of these resources"*[1].

In general, the main objective of bioprotection is to ensure the safety of processes and research involving pathogenic biological agents and toxins, as well as valuable biological assets in biosafety. Biological defense or biodefense includes measures to control and mitigate the consequences of a biological attack that could affect the health of people, animals, and the environment.

There is an urgent need for a national policy on biosafety and bioprotection that brings together and organizes the existing regulatory framework and contextualizes the specificities of each area of interest. The integration of the areas of health, agriculture, science and technology, environment, defense, and institutional security must be contextualized in this context, filling the gaps in biosafety but, above all, building a regulatory framework for bioprotection. This editorial examines the importance of a coordinated national approach, the interface between multiple ministries, and the necessary transformation in institutional culture to ensure the effectiveness of bioprotection practices. The idea of a national authority to build and strengthen this process has been discussed by experts and institutions and could be an appropriate model for the advancement and institutionalization of the topic in Brazil.

Brazil, with its vast biodiversity and prominent role on the global stage, faces significant challenges related to biosafety in several areas of interest. The topic is well defined, but still little understood in the daily practice of researchers and institutions and has already occupied a strategic space on the government agenda, also being present in the scientific production of researchers in the area. The publication of the Ministry of Health, "Building the Biosafety and Bioprotection Policy"[2], can be considered an important milestone in which memories of events held and meetings between experts from different areas were gathered to address the issue in an integrated manner. Recent publications[3,4] point to important reflections and paths to be traced for the construction of a national biosafety and bioprotection policy.

Ordinance MD No. 2,312, of April 24, 2023, approves the Biosafety, Bioprotection, and Biological Defense Guidelines of the Ministry of Defense, being in this case, already an update of Ordinance No. 585/MD of 2013[5]. Likewise, the Ministry of Agriculture and Livestock updated the structure of the Permanent Commission for Biological Risk Management, Biosafety and Bioprotection (COMBioLAB), through Ordinance SDA/MAPA No. 1,004, of February 7, 2024, imposing greater emphasis on bioprotection concerning the previous ordinance[6]. In turn, high biological containment laboratories and facilities that handle and biocustody highly pathogenic agents are

considered critical infrastructures in the field of biosafety and bioprotection, which are included as objects of attention of the National Critical Infrastructure Security Plan, according to Decree No. 11,200, of September 15, 2022[7]. The biocustody of valuable biological assets by these facilities requires strict regulation to prevent security incidents, such as the escape of high-consequence pathogens with pandemic potential or even targets of interest for bioterrorism actions.

However, despite the efforts and advances mentioned, Brazil still lacks uniform national regulations that cover all aspects of bioprotection in its interdisciplinary nature. The urgency to harmonize national practices with international standards is also accompanied by the concern to internalize robust biological risk management systems, highlighting the need for rigorous controls based on systematic risk assessments, inventory of biological materials, specialized training, and inspection. The lack of a cohesive regulatory framework contributes to gaps in the protection of valuable biological assets and emergency response.

National regulation on biosafety should be based on a joint effort involving close collaboration between several ministries, such as Health, Agriculture, Defense, Science, and Technology. Each of these ministries plays a crucial role in managing biological risks and protecting valuable biological assets. The Institutional Security Office of the Presidency of the Republic, through Resolution GSI/PR No. 7, of August 20, 2020, established an interdisciplinary technical group (GT) tasked with preparing the National Biosafety and Bioprotection Policy. However, the product of this work was not sufficient for its effective implementation[8].

There is a need for effective governance and compliance that coordinates biosecurity policies across sectors, ensuring that all relevant ministries share information, standards, and responsibilities. This should be fundamentally based on technical guidelines. And, to this end, as mentioned previously, the idea of a national authority on Biosafety and Biosecurity could be a solution, since the topic is so transversal. Strengthening national biosafety and biosecurity is a strategic and intersectoral area that depends on technical teams trained to carry out assessments and inspections in services of interest, such as high-containment laboratories. The study[9], for example, describes the importance of technical committees directing the implementation of biosafety and bioprotection requirements and recommendations, as well as the challenge of their incorporation by institutions.

On the other hand, the transformation of individual and collective culture concerning bioprotection is a fundamental step for the success of policies and regulations and should be seen as an institutional commitment. Selected biological agents, dual-use agents - Dual Use Research of Concern (DURC), synthetic biology, gain-of-function studies, cyberbiosecurity, seem to be concepts that are still distant and imply little or no concern. In Brazil, this requires a paradigm shift at all levels, from laboratory managers to technicians and researchers. Promoting education and awareness about biosecurity, fostering collaboration between sectors, and encouraging a proactive and preventive approach are essential to transforming the institutional culture. This transformation must be based on the principle of Accountability, which, although difficult to translate directly into Portuguese, can be understood as ‘responsibility in the provision of accounts’. Furthermore, it is necessary to implement a continuous surveillance process structured in a biological risk management system. It is impossible to think about bioprotection without experiencing bioprotection everyday processes.

It is therefore understood that national regulation of laboratory biosafety in Brazil is urgent and imperative. We are dealing here with biosafety, but it does not proceed separately from biosafety. The creation of an integrated and coordinated structure, involving different ministries, universities, funding agencies and the scientific community, are predictive variables for the improvement and maturation for a significant cultural transition, where the process must constitute sustainability in a consolidated manner to guarantee the effective protection of biological assets, the safety of people, animals and the environment. Aligning national practices with international guidelines, such as those established by the WHO in 2024, will not only strengthen Brazil's capacity to face current and future biological challenges, but will also contribute to the construction of a more robust and resilient public health and national security system.

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