SOCIEDADE BRASILEIRA DE BIOSSEGURANÇA E BIOPROTEÇÃO

SB3 Technical Note 04/2026

Beyond Scientific Merit – The Need for Biosafety and Biosecurity Assessment in Research Funding in Brazil

Executive Summary

The advancement of life sciences, including synthetic biology, genetic engineering, and artificial intelligence, has significantly expanded both the potential for innovation and the risks associated with scientific activities. In Brazil, the research funding system still does not structurally incorporate biosafety and biosecurity assessment as an independent and mandatory step, remaining largely restricted to the regulatory scope of genetically modified organisms. This gap may result in the funding of projects whose safe execution is not compatible with the available institutional capacity, generating weaknesses in infrastructure, technical qualification, governance, traceability, and risk mitigation. As a consequence, the risks of laboratory accidents, misuse of sensitive technologies, institutional compromise, and systemic impacts increase, especially in a context where biological risk management involves institutional, informational, digital, and strategic dimensions that are not yet fully integrated into the funding cycle.

In light of this scenario, the Brazilian Society for Biosafety and Biosecurity (SB3) proposes the creation of a formal, independent, and mandatory stage of biosafety and biosecurity assessment in research funding, structured in two phases: initial screening (risk identification) and detailed technical evaluation conducted by specialists. This approach should consider not only biological and dual-use risks (including DURC), but also the adequacy of infrastructure, team capacity, governance mechanisms, traceability of materials, and compatibility between resources and the complexity of activities. It is also recommended that these criteria be incorporated into funding calls, that Institutional Biosafety Committees (CIBios) be strengthened, that standardized assessment instruments be developed, and that integration with structures for the protection of strategic assets be promoted. SB3 emphasizes that such measures do not represent a restriction on research, but rather an essential condition for its sustainability, credibility, and international alignment, ensuring that scientific advancement occurs in a safe, responsible manner and in accordance with the risks involved.

1. Introduction

The accelerated advancement of the life sciences — including synthetic biology, advanced genetic engineering, high-consequence virology, metagenomics, experimentation with hazardous materials, and new technologies enabled by artificial intelligence — has significantly expanded both scientific capabilities and the risks associated with biomedical and biotechnological research. These advances present great potential for social and economic benefits, although they may also entail substantial risks, especially when

involving high-risk or high-consequence pathogens, dual-use agents, sensitive information, and methodologies with a high potential for risk amplification, including experimental approaches that may result in the enhancement of biological agent characteristics (often discussed internationally in the context of gain-of-function research – GOF).

In Brazil, the current regulatory framework is insufficient to keep pace with this scenario. Law No. 11.105/2005, which regulates risks related to genetically modified organisms, focuses on preventing environmental and health damage arising from GMOs, but does not cover risks associated with non-modified biological agents, dual use, sensitive research, containment infrastructure, or critical information management, including the assessment of risks associated with high-risk or high-consequence pathogens, even when manipulated using methodologies related to GMOs. This regulatory gap is directly reflected in funding practices, which do not include specific stages of independent technical assessment in biosafety and biosecurity within research funding and support processes, nor the compatibility between available resources and the technical requirements necessary for their safe implementation.

In this context, there is an urgent need to propose an integrated and contemporary risk assessment model capable of guiding researchers, institutions, and funding agencies in the qualified analysis of hazards associated with sensitive research. The absence of independent technical assessment creates vulnerabilities in the research system, potentially resulting in unsafe project execution, inadequate exposure to hazardous agents, institutional weaknesses, and reputational risks.

Therefore, this document presents the foundations, guidelines, and recommendations of SB3 for structuring a formal stage of biosafety and biosecurity assessment in research funding processes in Brazil involving high-risk or high-consequence pathogens, as well as zoonotic agents and emerging agents associated with outbreaks, especially when inserted in contexts of greater uncertainty or rapid spread.

It is also noteworthy that zoonotic agents and emerging agents associated with outbreaks, although not always initially classified as high-risk, may assume critical relevance due to their epidemiological dynamics, requiring equivalent attention from a biosafety and biosecurity perspective.

1.1. Current Context and Opportunity for Structural Advancement

The current moment unequivocally reinforces the relevance and urgency of the topic. Recent episodes involving the management, movement, and control of biological materials in high-containment research environments have brought public visibility to weaknesses that had already been identified from a technical perspective. As highlighted in previous Technical Notes by the Brazilian Society for Biosafety and Biosecurity (SB3), such situations should not be interpreted as isolated events, but rather as manifestations of structural gaps in the governance of biological materials, in the definition of institutional responsibilities, and in the integration between biosafety and biosecurity.

Thus, more than punctual or reactive responses, there is a need for structuring mechanisms capable of incorporating risk assessment from the conception and funding stages of research activities. In this process, research, development, and innovation funding agencies occupy a strategic position, as they possess a unique capacity to induce standards, practices, and institutional requirements.

2. Objective of the Technical Note

This Technical Note aims to propose the creation of a specialized, mandatory, and independent stage of biosafety and biosecurity assessment within the research funding cycle. This stage should be carried out by technically qualified specialists and operate separately from the evaluation of scientific merit. The objective is to ensure that projects involving high-risk or high-consequence pathogens, sensitive technologies, risk-related methodologies, or dual-use potential, including, when applicable, Dual Use Research of Concern (DURC), are adequately assessed with regard to biological risks, proliferation risks, informational risks, operational risks, and institutional risks. The Note also seeks to promote a culture of scientific responsibility, align national practices with international best practices, and consolidate mitigation mechanisms appropriate to Brazilian institutional capacities.

Additionally, the importance of traceability of materials and information associated with biological risk is highlighted, including their management throughout the life cycle, as well as the existence of institutional mechanisms for communication and coordination with entities responsible for the prevention, monitoring, and mitigation of these risks.

Furthermore, the Note aims to provide a basis for guiding researchers and managers regarding the minimum requirements for the safe execution of sensitive projects, contributing to scientific excellence, operational integrity, and the strengthening of the biosafety and biosecurity governance system in the country.

3. Diagnosis of the National Scenario

3.1. Regulatory and Operational Limitations

The current Brazilian regulatory framework presents significant limitations when compared to the contemporary needs of biological research. Although Law No. 11.105/2005 provides essential guidelines for work with genetically modified organisms, it does not address risks involving natural pathogens, high-risk or high-consequence agents, converging technologies, or sensitive research activities. The scope of CTNBio remains restricted and does not encompass the full range of risks associated with dual-use and biosecurity, nor does it provide adequate support for the technical assessment of these risks in research projects funded by public agencies. This gap is reflected in the absence of structured processes for prior biosafety and biosecurity assessment in the calls for proposals of major funding agencies, which rely heavily on researchers' self-declaration regarding infrastructure, training, and containment conditions, without independent validation.

The lack of formal mechanisms also contributes to the underestimation of operational and institutional risks, particularly in projects requiring containment levels above NB2, manipulation of dual-use agents, advanced genetic engineering, or integration of artificial intelligence tools into biological pipelines. The increasing technological sophistication, without a corresponding improvement in risk assessment mechanisms, amplifies vulnerabilities and reduces the ability of institutions to operate safely and sustainably.

Additionally, the absence of mechanisms to assess the sufficiency of financial resources in relation to the technical requirements of the proposed activities contributes to the implementation of operational and structural solutions that may not be fully aligned with international best practices.

3.2. Risks Associated with the Absence of Technical Assessment

The lack of a specialized technical stage for biosafety and biosecurity assessment may lead to the funding of projects whose safe execution is not supported by adequate institutional capacities, including limitations in infrastructure, team qualification, governance, and risk mitigation measures.

This misalignment between project approval and actual institutional capacity increases the likelihood of accidents, containment failures, misuse of sensitive technologies, and negative impacts on institutional integrity and national scientific governance.

4. Strategic Role of Funding Agencies in Inducing Biosafety and Biosecurity Governance

Research, development, and innovation funding agencies play a central role in defining scientific priorities, allocating resources, and inducing institutional practices. Traditionally, their evaluation processes focus on scientific merit, technical feasibility, and expected impact of proposals. However, in light of the increasing complexity of life sciences research, it becomes necessary to expand this scope by structurally incorporating the assessment of risks associated with biosafety, biosecurity, and dual use.

The absence of this dimension in funding processes contributes to the approval of projects whose execution depends on institutional capacities that are not always present or adequately structured. This includes, among other aspects, the lack of robust inventory and traceability systems, weaknesses in chain-of-custody mechanisms, absence of institutional biosecurity policies, and limitations in the governance of high-containment environments, as widely discussed in previous SB3 technical notes.

In this sense, funding agencies should be understood not only as financial supporters but as governance-inducing actors, positioned within the broader context of responsible governance of science, capable of establishing minimum requirements, promoting good practices, and fostering institutional convergence around consistent technical standards. In this context, it becomes essential for funding agencies to incorporate mechanisms that allow the assessment of the sufficiency and adequacy of proposed resources in relation

to biosafety and biosecurity requirements, avoiding the funding of activities whose safe execution depends on institutional conditions that are not fully established.

The incorporation of these dimensions into funding processes should be understood as a structuring component of public policies in science, technology, and innovation in sensitive areas.

4.1. Funding as an Instrument for Inducing Institutional Standards

The incorporation of biosafety and biosecurity criteria into funding processes represents one of the most effective ways to induce structural changes in the scientific system. By conditioning funding on the demonstration of institutional capacity for the safe management of biological risks, a mechanism is created to align scientific ambition with operational responsibility.

This movement is particularly relevant in projects involving high-risk or high-consequence pathogens, advanced recombinant technologies, manipulation of large volumes of biological material, or integration with sensitive digital systems. In such cases, prior assessment of risks and capacities should not be understood as an ancillary step, but as a central element of project feasibility.

In this model, institutional responsibility shifts from being predominantly reactive — associated with the occurrence of events or non-compliances — to assuming a structural and prospective character, being required already at the proposal submission stage. This implies that proposing institutions must demonstrate, in a verifiable manner, installed capacity, governance, and operational mechanisms compatible with the risks inherent to the proposed activities.

4.2. Integration with National Governance and Protection of Strategic Assets

The management of biological risks is not limited to the laboratory environment, extending to institutional, informational, digital, and strategic dimensions. In this context, aspects related to confidentiality, integrity, and availability of information become central, especially in light of the increasing digitalization of scientific activities. The protection of sensitive data, experimental protocols, genetic sequences, and other critical information falls within the field of cyberbiosecurity and must be considered an inseparable component of biosafety and biosecurity.

In Brazil, initiatives aimed at protecting strategic assets and monitoring sensitive risks, such as those conducted within the scope of the State, including the National Articulation Program between Government, Companies, and Academic Institutions for the Prevention and Mitigation of the Risk of Selected Chemical, Biological, Radiological, and Nuclear

Events[1] (PANGEIA) and the National Program for the Protection of Sensitive Knowledge[2] (PNPC), coordinated by the Brazilian Intelligence Agency (ABIN); the Interministerial Commission for the Control of Sensitive Goods Exports[3] (CIBES) and the National Program for State-Enterprise Integration in the Area of Sensitive Goods[4] (PRONABENS), conceived and implemented jointly by CGBS/MCTI and the Brazilian Intelligence Agency (ABIN).

These initiatives demonstrate the growing attention to the protection of scientific and technological assets of strategic relevance. However, this approach has not yet been fully integrated into research funding processes, nor into the prevailing institutional practices in the academic environment, resulting in gaps in the systematic consideration of risks associated with biosafety, biosecurity, and dual use.

This articulation between biosafety, biosecurity, and the protection of sensitive knowledge reinforces the need for integrated approaches, in which research funding is aligned not only with scientific objectives, but also with the mitigation of risks associated with national security, institutional integrity, and the responsible use of knowledge.

Tools and initiatives aimed at analyzing laboratory capacities and mapping risks, such as those associated with the national context (e.g., analytical platforms and intelligence initiatives applied to laboratory monitoring), may contribute to this process, provided they are integrated transparently and guided by technical and institutional principles.

Additionally, the management of these risks requires institutional coordination that respects the division of competencies among different levels of governance — federal, state, and municipal — particularly with regard to national security, health surveillance, and the regulation of sensitive activities. The absence of clear mechanisms for

[1] Established by Ordinance No. 112/GSI/PR, of December 17, 2018, it was implemented in voluntary partnership with public and private institutions, with the purpose of anticipating facts and situations related to the dissemination of selected chemical, biological, radiological, and nuclear (CBRN) agents, in order to support the decision-making process, considering as selected agents any CBRN agent or material whose dissemination has the potential to result in high impact on society, agriculture, and Brazilian natural resources; requires prevention, preparedness, and response with interministerial coordination; and results in a critical event for the country.

[2] Created in 1997, the PNPC promotes a culture of protection of sensitive knowledge within national entities, whether public or private. The National Program for the Protection of Sensitive Knowledge (PNPC) is a security consultancy focused on preventing espionage, sabotage, and information leakage, promoting the protection of sensitive knowledge in national institutions, both public and private. The PNPC works to raise awareness among individuals, identify threats and vulnerabilities in institutional protection systems, and provide recommendations to reduce the risk of incidents.

[3] Created by Law No. 9.112, of October 10, 1995, it is responsible for controlling the export of sensitive and dual-use goods, and services directly related to these goods, in the nuclear, chemical, biological, and missile areas.

[4] Its main focus is to carry out outreach activities for industries, research centers, universities, and public institutions whose activities are, in some way, related to sensitive goods or dual-use goods.

coordination among these levels may generate gaps, overlaps, or weaknesses in the implementation of biosafety and biosecurity measures.

4.3. Institutional Capacity, Funding, and Sustainability of High-Risk Environments

The safe execution of projects involving high-risk or high-consequence biological agents presupposes not only scientific qualification, but also the existence of infrastructure, governance, and resources compatible with the complexity of the proposed activities.

In the Brazilian context, there is, in some cases, a misalignment between the level of risk of funded activities and the resources effectively available for their safe implementation. This misalignment may manifest both in the establishment of new facilities and in the maintenance, updating, and renovation of existing structures, including high-containment biological environments.

Limited resources may directly impact institutional capacity to ensure adequate biosafety and biosecurity conditions, for example through the adoption of engineering solutions not fully aligned with international best practices, difficulty in hiring specialized professionals, limitations in validation and certification processes, and weaknesses in control, access, and traceability systems.

This scenario reinforces the need for funding processes to explicitly consider not only the scientific merit of proposals, but also the compatibility between available resources, existing infrastructure, and the technical requirements necessary for the safe execution of the proposed activities throughout their entire lifecycle.

When not identified in advance, this misalignment tends to be transferred to the project execution phase, manifesting in the form of operational adaptations, improvised solutions, and increased institutional risk.

5. Proposal for Formal Biosafety and Biosecurity Assessment Stages

5.1. Stage 1: Initial Screening (Rapid Screening)

The initial screening consists of a rapid and objective evaluation aimed at identifying proposals that involve risks from a biosafety and biosecurity perspective. This screening should consider criteria such as the nature of the biological agents handled, including high-risk or high-consequence pathogens, as well as emerging or zoonotic agents associated with outbreak events or epidemic potential; the type of experimental methodology; the required containment level; the use of technologies capable of amplifying risks, such as digital platforms and artificial intelligence tools; dual-use potential; the handling of sensitive information; and the institutional track record in biosafety and biosecurity. Proposals classified as low risk should proceed directly to scientific merit evaluation, while those identified as high or uncertain risk should be referred for in-depth technical assessment, including analysis of the compatibility between the proposed financial resources and the technical requirements necessary for the safe implementation of the activities.

5.2. Stage 2: Detailed Technical Assessment (Detailed Assessment)

The detailed assessment should be conducted by specialists with proven training in biosafety, biosecurity, containment engineering, dual-use risk analysis, and institutional governance. This stage should examine the probability of adverse events, the magnitude of damages associated with failures or accidents, the adequacy of containment infrastructure, the training of the involved team, institutional control and protection mechanisms, the capacity to manage sensitive information, and compliance with national and international standards, including the identification of activities potentially falling under Dual Use Research of Concern (DURC). The outcome of this assessment may include approval conditioned on specific mitigation measures, a request for proposal revision, or non-recommendation when there is incompatibility between risk and institutional capacity.

6. Structuring of the Specialized Technical Body

The implementation of this process requires the establishment of an independent technical body composed of experienced professionals certified in biosafety and biosecurity. These specialists must operate without ties to the proponents, be selected based on clear technical criteria, and possess practical experience in high-containment facilities, biological risk assessment, dual-use risk, protection systems, and the management of sensitive information, not replacing ethical or regulatory bodies, but adding an indispensable layer of safety, reinforcing the commitment to responsible practices in life sciences research.

7. Expected Benefits

The adoption of formal biosafety and biosecurity assessment stages will provide greater safety in the execution of sensitive projects, reduce the risks of laboratory accidents, and mitigate potential misuse of technologies. In addition, it will strengthen institutional scientific governance, increase the confidence of international partners, ensure better use of public resources, and enhance the quality of biosafety and biosecurity practices in the country. By allowing funding agencies to support only projects compatible with real technical capacities, the model will also contribute to consolidating a culture of responsibility and compliance within Brazilian research institutions.

8. International References and Emerging Trends

International experience has demonstrated a growing trend toward incorporating biosafety, biosecurity, and dual-use risk assessment criteria into research funding processes. Recent initiatives have structured models based on two complementary stages: an initial screening to identify potential risks and a detailed assessment conducted by specialists, focusing on the probability and magnitude of harm, as well as the adequacy of mitigation measures.

These models reflect the understanding that biological risk governance should begin at the research conception stage, being an integral part of the project lifecycle, rather than merely a subsequent operational requirement. By distinguishing low-risk projects from

those requiring in-depth evaluation, these systems enable the optimization of resources and the targeting of specialized technical attention to more complex situations.

The progressive adoption of such approaches in Brazil represents a strategic opportunity to align with international practices and strengthen the credibility of the national scientific system, including international discussions on the governance of sensitive research, such as DURC and Gain-of-Function (GOF).

9. Structural Recommendations

The incorporation of biosafety and biosecurity criteria into funding processes should not be understood as an ancillary measure, but as a structuring component of public policies in science, technology, and innovation in sensitive areas.

To effectively implement this proposal, it is recommended that funding agencies include clear biosafety and biosecurity guidelines in their calls for proposals, adopt standardized risk assessment forms, create registries of specialized risk assessors, require proof of infrastructure and training prior to project execution, establish binding mitigation plans, promote continuous capacity building, and incorporate tools for managing sensitive information. Periodic audits should be implemented for monitoring and verification of compliance, especially in higher-risk projects. The consolidation of these mechanisms will strengthen the national innovation system and position Brazil in a safer and more competitive manner in the international landscape.

Additionally, it is recommended that funding agencies establish formal mechanisms for coordination with institutions responsible for biosafety, biosecurity, and the protection of strategic assets, promoting an integrated approach that considers not only the operational risks of research, but also its institutional, informational, and strategic implications. This integration should occur in a transparent manner, based on technical criteria, and aligned with international commitments assumed by Brazil in the field of non-proliferation and the responsible use of science.

In this context, Institutional Biosafety Committees (CIBios) should evolve from structures predominantly focused on meeting specific regulatory requirements — particularly those associated with genetically modified organisms — to institutional bodies with an expanded scope, incorporating biosafety, biosecurity, dual-use risk assessment, and governance of biological materials in an integrated manner throughout the entire lifecycle of activities.

Additionally, it is recommended to assess the relevance of developing national reference frameworks for identifying and categorizing biological agents and materials of higher risk or high consequence, based on consolidated international experiences. Such frameworks may support the prioritization of assessments, the definition of differentiated biosafety and biosecurity requirements, and the direction of risk oversight and mitigation mechanisms, particularly in the context of research funding, in line with international initiatives such as select agents and toxins control programs.

10. Final Considerations

The Brazilian scientific system has advanced significantly but still lacks normative and operational mechanisms capable of keeping pace with the contemporary complexity of life sciences research.

The creation of formal biosafety and biosecurity assessment stages within the funding cycle represents an urgent and strategic measure to ensure that scientific advancement occurs in a safe, responsible manner aligned with international best practices.

The current moment clearly demonstrates that scientific advancement in sensitive areas cannot do without robust governance structures. The absence of formal biosafety and biosecurity assessment mechanisms within the funding cycle represents a critical gap, with direct implications for institutional security, scientific credibility, and the protection of society.

The incorporation of these dimensions into funding processes should not be understood as a restriction on research, but as a structuring condition for its sustainability, legitimacy, and alignment with international standards. In a scenario of increasing technological complexity and sensitivity of materials and knowledge involved, the absence of such mechanisms becomes not only a technical gap, but also a source of institutional and systemic risk.

Additionally, ensuring adequate biosafety and biosecurity conditions cannot be dissociated from the availability of resources compatible with the complexity of the activities carried out. The absence of such alignment may compromise not only the safe execution of projects, but also the institutional integrity of the organizations involved and the trust in the scientific system as a whole.

The Brazilian Society for Biosafety and Biosecurity (SB3) reaffirms its commitment to contributing technically to the strengthening of biosafety and biosecurity in Brazil, recognizing them as essential elements for the sustainability, credibility, and responsibility of the national scientific system. In this context, it stands ready to collaborate with funding agencies, research institutions, and other strategic actors in the development of guidelines, protocols, and instruments that promote scientific excellence in a safe, responsible manner aligned with international best practices.

11. Technical References and Recommended Readings

The structuring of biosafety and biosecurity assessment mechanisms within the research funding cycle should be aligned with internationally consolidated technical references that guide biological risk management, institutional governance, and the responsible conduct of scientific research.

Among the main references, the following stand out:

WHO Laboratory Biosafety Manual – 4th Edition (2020)

Core document from the World Health Organization that establishes a risk-based approach to laboratory biosafety, including principles applicable to the lifecycle of facilities and activities.

WHO Laboratory Biosecurity Guidance – 2nd Edition (2022)

International reference for the implementation of laboratory biosecurity measures, with a focus on access control, inventory, traceability, and institutional governance.

ISO 35001:2019 – Biorisk Management Systems

International standard that defines requirements for biorisk management systems, integrating biosafety and biosecurity in a systematic risk-based approach.

ISO 31000:2018 – Risk Management Guidelines

General guidelines for risk management applicable to institutional governance and decision-making in complex environments.

Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists (2021)

International reference focused on scientific responsibility, ethics, and the prevention of misuse of research.

Biological Weapons Convention (BWC / CPAB)

International treaty to which Brazil is a signatory, establishing commitments related to the prevention of misuse of biological agents.

HHS and USDA Select Agents and Toxins Regulations (42 CFR Part 73; 7 CFR Part 331; 9 CFR Part 121)

United States regulations that establish criteria for the control, possession, use, transfer, and registration of select agents and toxins, with a focus on biosafety, biosecurity, and traceability.

Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition (CDC/NIH, 2020)

Manual developed by the CDC and NIH as guidance for biomedical laboratories in the United States, widely adopted as an international reference for biosafety practices, including risk classification, containment levels, mitigation measures, and operational requirements.

National Science Advisory Board for Biosecurity (NSABB) – Recommendations for Oversight of Dual Use Research of Concern (DURC) and Gain-of-Function Research (USA)

International guidelines for the identification, assessment, and oversight of sensitive research, including DURC and studies with potential for amplification of biological risk.

WHO Global Guidance Framework for the Responsible Use of the Life Sciences (2022)

Global guidance for the responsible use of life sciences, including risk governance, dual-use considerations, and scientific responsibility.

National Initiatives (Brazil)

Programs such as PANGEIA, PNPC, and instruments associated with the control of sensitive goods (CIBES, PRONABENS) represent advances in the integration between science, security, and the protection of strategic assets.

These references reinforce the need for structured, integrated, and risk-based approaches, in which biosafety, biosecurity, and institutional governance are treated as inseparable components of contemporary scientific practice.

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