

SURVEY OF INTERNATIONAL AND NATIONAL STANDARDS RELATED TO THE AMAZON BIOBUSINESS CENTER (CBA)



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ABSTRACT

The article aims to survey and map the international and national standards that impact or are related to the activities of the Amazon Biobusiness Center (CBA), dividing them into four thematic axes, for a more didactic presentation: Environmental, Business, Administrative and Tax/Financial/Economic. This is an exploratory, bibliographic, documental study with a qualitative approach. The methodology is structured in the collection, analysis and organization of standards related to the themes of biotechnology, biobusiness, bioeconomy, innovation, ST&I aimed at the CBA. It is concluded that the integration of international and national standards, although fraught with challenges, also offers significant opportunities for CBA. Compliance with international treaties and Brazilian standards can open doors to research partnerships, funding and access to global markets, in addition to strengthening CBA's position as a reference center in biotechnology and bioeconomy. However, the complexity of the regulations, the lack of harmonization between them, and the need for constant adaptation to changes in legislation can be significant obstacles to the efficient execution of CBA projects.

Keywords: Amazon Biobusiness Center. International Standards. National Standards. Science, Technology & Innovation.

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INTRODUCTION

The Amazon Biobusiness Center (CBA) is an institution dedicated to the development and implementation of innovative and sustainable solutions for the Amazon region. Its main objective is to promote the bioeconomy and biobusiness based on practices that connect local biodiversity with cutting-edge technologies, generating economic and environmental value. Through its activities, CBA seeks to enhance the responsible use of the Amazon's natural resources, fostering the development of biotechnologies applied in various areas, such as agriculture, health, and industry (CBAmazonia, 2023).

Among the main activities of the CBA, the proposal to use sludge from the Sewage Treatment Plant for the production of organic fertilizer stands out, a project that contributes to sustainability and the improvement of waste management. Another important project is the obtaining and characterization of clarified bacaba and açai beverages, with clinical studies focused on the control of diseases such as atherosclerosis and obesity. In addition, CBA develops innovative solutions for agriculture, such as the use of microorganisms in the biological control of pests and diseases and the production of regional biofertilizers. The Center is also dedicated to structuring the curauá production chain and creating sustainable packaging based on agro-industrial waste (CBAmazonia, 2023).

CBA plays a crucial role in boosting technological projects that meet local and global demands, such as the use of Amazonian microalgae for the production of natural pigments and inputs for plant-based products. Another relevant project is the CBA Analytical Center, which aims to monitor the quality of the copaiba oil production chain, which is essential for the preservation and sustainable use of Amazonian natural resources. These initiatives reflect CBA's commitment to research, innovation, and the creation of solutions that bring benefits to both society and the environment (CBAmazonia, 2023).

Once this information is presented, the following question arises: what are the international and national standards related to the existence and activity of the Amazon Biobusiness Center? Knowing, reflecting and understanding the scope of such standards is fundamental for the implementation and functioning of this Center. It is crucial to identify legal barriers and opportunities for improvement in the regulatory environment, ensuring that CBA can operate efficiently, in line with current regulations, and contribute more effectively to sustainable development and innovation in the region.

In addition, the work is aligned with the United Nations (UN) 2030 Agenda, which establishes the 17 goals and 169 goals of sustainable development (UN, 2025). This article aims to carry out a survey of international and national standards related to CBA's activities, with emphasis on environmental, business, administrative and tax legislation. From this analysis, it will be possible to understand the main legal challenges faced by the center and propose suggestions to optimize its operation.

METHODOLOGY

It is an exploratory, bibliographic, documentary study with a qualitative approach, according to the teachings of Lakatos and Marconi (2003). The methodology is structured in stages that cover the collection, analysis and organization of standards related to the themes of biotechnology, biobusiness, bioeconomy, innovation, ST&I, focusing on four thematic axes of standards, for a more didactic presentation: Environmental, Business, Administrative and Tax/Financial/Economic. Its general objective is to survey and map the standards (international and national) that impact or are related to the activities of the Amazon Biobusiness Center (CBA), dividing them into four thematic axes.

As a primary source, a survey of treaties, conventions, protocols and international agreements pertinent to the CBA was made, considering conventions of the United Nations (UN), the World Trade Organization (WTO), the World Health Organization (WHO), among others. Also as a primary source, federal legislation related to the thematic axes was identified and selected. This includes laws, decrees, ordinances, regulations, and resolutions. As a secondary source, legal databases, academic articles, government publications, and other documents that may indicate relevant norms were consulted.

THEMATIC AXES

- **Environmental Standards:** These comprise the standards that regulate environmental protection and sustainability in biotechnology and biobusiness activities, including regulations on the use of Amazonian biodiversity, environmental licensing, and preservation of ecosystems.
- **Business Standards:** These comprise the rules that deal with business regulations applicable to companies and organizations operating in the biotechnology and biobusiness sector, including the creation and management of companies, rules on intellectual property, public-private partnerships, and innovations in the sector.

- **Administrative Rules:** Comprise the rules that regulate the organization, operation and governance of the CBA, focusing on administrative processes, decision structures, requirements for research and development programs, and partnerships with universities and companies.
- **Tax, Financial and Economic Rules:** Comprise the rules that affect the financing, taxation and economic viability of projects and businesses related to the CBA, such as tax incentives, innovation investment policies, startup financing and regulations on international trade in biotechnological products.

COLLECTION AND ANALYSIS PROCEDURE

- **Data Collection:** Data collection was carried out in legal databases and official publications, such as the websites of the UN, the Planalto and the Brazilian Federal Government. The survey of the standards will be done from documents and institutional sources.
- **Classification and Organization:** The standards were classified within the four thematic axes, creating a normative matrix that facilitates the understanding of the connection of each standard with the activities of the CBA.
- **Qualitative Analysis:** The analysis comprises a qualitative approach after reading and interpreting the selected standards, seeking to understand the impact and applicability on the activities of the CBA.

PRESENTATION OF THE RESULTS

The results are presented by Thematic Axis, Interview Results, Proposals for Normative Change, Conclusion and Suggestions for Future Research.

Discussion: The discussion involves a critical analysis of the identified norms and their impacts on the activities of the CBA, correlating them with the existing literature and the practice observed in the interviews.

This methodology aims to provide a preliminary survey of the rules applicable to the CBA, creating a basis for future research and legal improvements in the operation of the Center.

RESULTS

This chapter presents and discusses the international treaties and national standards that affect the existence and operation of the Amazon Biobusiness Center (CBA).

INTERNATIONAL TREATIES AFFECTING THE CBA

Increasingly, treaties are becoming important sources of international law and as a means of developing peaceful cooperation between nations, whatever their constitutional and social systems. This is stated in the preamble of the Vienna Convention on the Law of Treaties (Brasil, 2009). It also states that "treaty" means an international agreement concluded in writing between States and governed by international law, whether it consists of a single instrument or of two or more related instruments, whatever their specific denomination (art. 3, 1., a).

The International Treaty is a genus, which contains the following species: Convention, Agreement, Protocol, Exchange of Banknotes, Charter, Constitution and Statute. Chart 1 summarizes the concept of each of the types of international treaties, as explained in the Legal Encyclopedia of PUCSP (2022):

Table 1 – Types of International Treaties

Category	Description	Observations / Examples
Convention	The term "Convention" is used for treaties concluded with a high level of formality and by several States simultaneously – that is, they are multilateral acts. This term refers to the idea of an assembly meeting, where several states meet to discuss and establish general rules of common interest. The purpose is to regulate the behavior of States in various sectors, establishing rules for topics of great relevance and scope.	E.g.: Vienna Conventions on diplomatic relations, consular relations and treaty law; Conventions on civil aviation, safety at sea and labor issues.
Agreement	The "Agreement" is used to designate international treaties that involve a smaller number of States and have less relative importance than a convention. In the case of Brazil, the term is widely used in bilateral negotiations involving commercial, political, economic, cultural, scientific or technical matters. It can be considered as an instrument of reciprocal cooperation and, when even simpler and more temporary, it can also be called an arrangement or adjustment, especially to complement or improve a negotiation already concluded.	E.g.: Operational agreements for the execution of cooperation programs; bilateral agreements signed between a country and an International Organization (e.g., headquarters agreements).
Protocol	The "Protocol" is an instrument that can be used interchangeably to designate both bilateral and	E.g.: Kyoto Protocol – a multilateral environmental treaty that

Category	Description	Observations / Examples
Exchange of Notes	<p>multilateral treaties. It may indicate the final act of an international meeting or conference, or represent a complementary step to an existing treaty, either to detail, modify or establish specific conditions for its execution.</p> <p>"Exchange of banknotes" refers to the exchange of diplomatic notes that complements or modifies aspects of a treaty already concluded. This modality is less formal, serving to resolve administrative or bureaucratic issues or even to interpret clauses of a previously concluded agreement, without the need to draft a new complete treaty.</p>	<p>complements the United Nations Framework Convention on Climate Change; Additional protocols to the Geneva Conventions, which expand the protection of victims of armed conflict.</p> <p>E.g.: Used to adjust or interpret clauses of an existing international agreement, facilitating administrative compliance and the intensification of diplomatic relations between States.</p>
Charter, Constitution, Statute	<p>These terms are used to designate the constitutive treaty of international entities or organizations. When a treaty establishes the creation and rules of operation of an organization, its name can vary: it can be called a "Charter" when it comes to the founding document (such as that of the UN); "Constitution" when referring to the act of creating an international entity focused on education, culture and science; or "Statute" when the instrument, in addition to creating the entity, also regulates the operational and operating rules (for example, of international courts).</p>	<p>E.g.: Charter of the United Nations (constitutive of the UN); Constitution of UNESCO; Statute of the International Court of Justice (ICJ) and the International Atomic Energy Agency (IAEA).</p>

(Source: the authors, 2025).

Chart 1 presents the characteristics and observations regarding each type of international treaty, to facilitate the understanding of each one. Having presented the concepts of each type of International Treaty, it is appropriate to present some international treaties that consider biotechnology, biobusiness, bioeconomy and innovation, which are subjects related to the CBA (Chart 2).

Table 2 – International Treaties that affect the CBA

Treaty Name	Species	Number of the Ratification Standard in Brazil	Subject	Summary of the Main Points Impacting the CBA
Convention on Biological Diversity (CBD)	Convention	Legislative Decree No. 2/1994, and Decree No. 2,519/1998	Biodiversity conservation, sustainable use and benefit sharing	They establish the sovereignty of countries over their genetic resources and define conditions for access and benefit sharing, influencing the sustainable exploitation of Amazonian resources by the CBA.
Nagoya Protocol on Access to Genetic Resources and	Protocol/ Agreement	Decree No. 11,865/2023	Access to genetic resources and benefit sharing	They define the requirements for access to genetic resources and prior informed consent, directly impacting CBA's

Treaty Name	Species	Number of the Ratification Standard in Brazil	Subject	Summary of the Main Points Impacting the CBA
Fair and Equitable Sharing of Benefits				bioprospecting and biotechnology activities.
United Nations Framework Convention on Climate Change (UNFCCC)	Convention	Decree No. 2,652/1998	Climate change mitigation and adaptation	It establishes guidelines for reducing emissions and adapting to climate change, encouraging the development of sustainable technologies and bioeconomy practices in CBA activities.
Cartagena Protocol on Biosafety	Protocol	Decree No. 5,705/2006	Biosafety and transboundary movement of living modified organisms (LMOs)	Art. 5 and 7: Establish standards for the safe management of LMOs, impacting the use of biotechnology and ensuring safety in the technical processes of the CBA.
United Nations Declaration on the Rights of Indigenous Peoples	Statement	It has no formal ratification; adopted by the UN in 2007 and supported by Brazil	Indigenous peoples' rights over natural resources and traditional knowledge	It emphasizes the right of indigenous peoples over their natural resources and traditional knowledge, influencing the exploitation of biological resources in the Amazon by the CBA.
United Nations Global Compact	Pact	Voluntary adherence; does not require formal ratification	Corporate sustainability, human rights, environment and business ethics	It encourages responsible business practices, affecting biobusiness and bioeconomy initiatives that involve responsible business practices, aligning CBA's operations with global principles of sustainability and ethics.
Paris Agreement on Climate Change	Agreement	Decree No. 9,073/2017	Limiting global warming and promoting sustainable practices	Art. 2 and 4: Involve commitments by countries to limit global warming and promote sustainable practices, directly impacting the bioeconomy, biotechnology and environmental management sectors related to CBA activities.
Amazon Cooperation Treaty (ATT)	Treaty/Agreement	Decree No. 85,050/1980	Regional cooperation for conservation and sustainable development	It establishes cooperation between the countries of the Amazon basin for the preservation of biodiversity and sustainable development, affecting preservation and sustainable development initiatives that impact the activities of the CBA.
International Convention for the Protection of New	Convention	Decree No. 3,109/1999	Intellectual property and	Regulates intellectual property rights over new varieties of plants, affecting biobusinesses

Treaty Name	Species	Number of the Ratification Standard in Brazil	Subject	Summary of the Main Points Impacting the CBA
Varieties of Plants (UPOV)			protection of new plant varieties	related to agricultural biotechnology and bioprospecting of genetic resources, areas of interest to the CBA.

Source: the authors, 2025.

The international treaties that regulate biodiversity, bioeconomy and biotechnological innovation have a direct impact on the activities of the Amazon Biobusiness Center (CBA), determining normative guidelines that influence everything from research and bioprospecting to the commercialization of products and the formation of international partnerships. The Convention on Biological Diversity (CBD), ratified by Brazil (1998), establishes national sovereignty over genetic resources and imposes rules on access and benefit sharing, which can both guarantee legal certainty to the CBA's activities and increase the complexity of bioprospecting processes. The Nagoya Protocol (Brazil, 2023), which complements the CBD, reinforces the need for prior informed consent and fair agreements, ensuring greater protection for local communities and their traditional knowledge, but at the same time imposing bureaucratic requirements that can slow down the development of research and technological innovations.

The United Nations Framework Convention on Climate Change (Brazil, 1998) and the Paris Agreement (Brazil, 2017) establish commitments to reduce carbon emissions and encourage sustainable practices, which favors the development of technologies with low environmental impact and the attraction of international investments aimed at projects aligned with the green economy. The Cartagena Protocol on Biosafety (Brasil, 2006), in turn, regulates the transboundary movement of living modified organisms, imposing strict requirements for the use of biotechnology in the Amazon. This ensures greater environmental safety, but it can also restrict CBA's adoption of new technologies, making it difficult for it to compete in global markets. The United Nations Declaration on the Rights of Indigenous Peoples (UN, 2008) emphasizes the need for recognition and respect for the rights of local communities over their knowledge and natural resources, a determining factor for the sustainable exploitation of Amazonian biodiversity, while imposing additional restrictions on scientific research and the development of products based on traditional knowledge.

The United Nations Global Compact (UN, 2000), which is voluntary, establishes guidelines for corporate sustainability and business ethics, aligning CBA's operations with global principles and facilitating the achievement of certifications and partnerships with international institutions. The Amazon Cooperation Treaty (Brazil, 1980) encourages collaboration between the countries of the Amazon basin for sustainable development and the preservation of biodiversity, promoting a more favorable environment for the exchange of knowledge and technologies among the countries of the region. The International Convention for the Protection of New Varieties of Plants (UPOV) (Brazil, 1999) ensures intellectual property rights over innovations in agricultural biotechnology, which can stimulate investments in genetic improvement of Amazonian species, but also limit access to genetic material in common use.

In view of this legal framework, it is necessary to question how international treaties facilitate or hinder the activities of the Amazon Biobusiness Center, considering their economic, social and environmental implications. In the economic aspect, treaties such as the Paris Agreement (Brazil, 2017) and the United Nations Global Compact (UN, 2000) create a favorable environment for attracting investments for sustainable projects, allowing CBA to expand its initiatives in bioeconomy and technological innovation. However, the Convention on Biological Diversity (Brazil, 1998) and the Nagoya Protocol (Brazil, 2023) establish restrictions on the exploitation of genetic resources, which can hinder the import of new technologies and delay the commercialization of bioproducts, increasing the time and costs associated with complying with regulatory requirements. In addition, the Cartagena Protocol (Brazil, 2006), by imposing strict standards on genetically modified organisms, may limit the insertion of CBA in advanced biotechnology markets, restricting its global competitiveness.

From a social point of view, the United Nations Declaration on the Rights of Indigenous Peoples (UN, 2007) imposes the need to respect and integrate traditional communities into the bioeconomy, ensuring that their knowledge is protected and properly remunerated. This factor promotes greater equity in the distribution of the benefits of biodiversity exploitation, but it can also generate bureaucratic obstacles that delay the execution of projects and research. In the environmental aspect, treaties such as the United Nations Framework Convention on Climate Change (Brazil, 1998) encourage the development of sustainable production practices, which strengthens CBA's performance in accordance with international standards and favors the development of new business

models based on sustainability. However, the need to meet multiple environmental commitments can increase CBA's operating costs, making it difficult to adopt innovations and implement efficient industrial processes.

In this context, the influence of international treaties on the CBA is not one-dimensional, but rather a dynamic relationship between opportunities and challenges. While some standards create a safe regulatory environment for investments and sustainable innovation, others impose barriers that can hinder access to new technologies, the commercialization of products, and the development of scientific research. CBA's success will therefore depend on its ability to adapt to this complex regulatory landscape, ensuring compliance with international standards without compromising its competitiveness and capacity for innovation. The harmonization between regulation, innovation and sustainability will be the key for CBA to reach its potential as a strategic center of bioeconomy and technological development for the Amazon and the world.

NATIONAL RULES RELATED TO THE CBA

In the legal sphere, the concept of legal norm is widely accepted as a rule of conduct established by a competent authority, intended to regulate the behavior of individuals within a society. These rules have an imperative, bilateral and coercive character, meaning that they are mandatory, involve rights and duties between the parties and can be imposed through sanctions applied by the government in case of non-compliance.

Norm is a genus, of which Constitutional, Infra-constitutional, Legal and Infra-legal norms are species. Chart 3 presents the main types of rules existing in Brazil (CNJ, 2018):

Table 3 – Main types of Norms in Brazil

Kind of Norm	Description
Constitutional Norms	Norms established by the Federal Constitution, which is the supreme law of the country and the basis of validity of all other norms.
Complementary Laws	Norms that complement the Constitution, dealing with specific matters and requiring approval by an absolute majority in the National Congress.
Ordinary Laws	Norms that regulate general matters not reserved to complementary laws, approved by a simple majority in the National Congress.
Delegated Laws	Rules drawn up by the President of the Republic after delegation from the National Congress, with the force of ordinary law.
Provisional Measures	Rules with the force of law issued by the President in cases of urgency and relevance, which must be approved by Congress to become definitive law.
Legislative Decrees	Normative acts intended to regulate matters of exclusive competence of the National Congress, such as the approval of international treaties.
Resolutions	Normative acts intended to regulate matters of exclusive competence of each of the Legislative Houses, without the need for presidential sanction.
Decrees	Normative acts issued by the Executive Branch to regulate laws, detailing their application.
Ordinances and Normative Instructions	Internal administrative acts that establish specific procedures within public agencies.

Source: the authors, 2025.

A preliminary survey of the rules related to the CBA was carried out. For didactic purposes, the legislation was divided into 4 (four) axes: Environmental Standards; Business Standards; Administrative Rules and Tax, Financial and Economic Rules, as summarized in the Tables structured below:

Table 4 – Main National Environmental Standards related to the CBA

THEME	NUMBER
Constitution of the Federative Republic of Brazil	s/nº, granted on October 5, 1988
National Environmental Policy	Law No. 6,938/1981
Pesticides	Law No. 14,785/2023
Plant Variety Protection	Law No. 9,456/1997 and Decree No. 2,366/1997
National System of Nature Conservation Units	Law No. 9,985/2000 and Decree No. 5,591/2005
Biosafety	Law No. 11,105/2005, Decree No. 5,591/2005, CNS Resolution No. 196/96, 251/97 and 292/99
Biodiversity	Law No. 13,123/2015 and Decree No. 4,339/2002
Plant Health Defense	Decree No. 24114/1934
Biotechnology	Decree No. 6,041/2007

THEME	NUMBER
Ecological-Economic Macrozonning of the Legal Amazon - MacroZEE of the Legal Amazon	Decree No. 4,212/2002 and Decree No. 7,378/2010

Source: the authors, 2025.

Brazilian environmental legislation, especially the Constitution of the Federative Republic of Brazil (Brasil, 1988), contains three articles more directly related to the CBA and its activities. Article 218 allocates public resources for the promotion of science and technology. Article 225 of the Federal Constitution deals with the right to an ecologically balanced environment and the responsibility of everyone to defend and preserve it for present and future generations. This implies that the CBA must conduct its activities in a way that minimizes environmental impact, promoting the sustainable use of the Amazon's natural resources. In turn, Article 231 recognizes the rights of indigenous peoples to their social organization, customs, languages, beliefs and traditions, and the original rights over the lands they traditionally occupy, which has implications for bioprospecting and the use of traditional knowledge associated with biodiversity.

Law No. 6,938/81, which establishes the National Environmental Policy (Brasil, 1981), establishes the principles and guidelines for environmental protection, which must be observed by the CBA in all its activities. The Center should therefore seek the development of projects that promote sustainability and the conservation of Amazonian biodiversity, in line with the principles of sustainable development. Law No. 9,456/97 (Brasil, 1997) and Decree No. 2,366/97 (Brasil, 1997) deal with the protection of plant varieties and establish rules on the protection of rights related to the genetic improvement of plants, which may interfere with the research, development and commercialization practices of bioproducts, biotechnologies and cultivars developed by these institutions.

In turn, Law No. 9,985/00 (Brasil, 2000) and Decree No. 5,591/05 (Brasil, 2005) deal with the National System of Nature Conservation Units (SNUC). These areas can directly influence the development of economic activities, such as biobusiness, in the Amazon ecosystem. Law No. 11,105/05 (Brasil, 2005), Decree No. 5,591/05 (Brasil, 2005) and the Resolutions of the National Health Council (CNS) No. 196/96, No. 251/97 and No. 292/99 (Brasil, 1996, 1997, 1999) deal with Biosafety. The Amazon Biobusiness Center, when engaging in biotechnology research and development, must observe the requirements of these standards especially in relation to conducting experiments with genetically modified

organisms, to ensure that it complies with safety requirements and that environmental and health impacts are controlled.

On the subject of Plant Health Defense, there is Decree No. 24,114/34 (Brasil, 1934), which establishes guidelines for combating these threats, including inspections, quarantines, phytosanitary certifications and other preventive measures to protect Brazilian agriculture. Such guidelines must be observed by the CBA, especially when its activities involve the cultivation, collection or manipulation of plant species. Regarding Biotechnology, there is Decree No. 6.041/07 (Brasil, 2007), which establishes the biotechnological guidelines in Brazil, taking into account aspects such as safety, biosafety, and the promotion of technological innovation. The decree points to the creation of mechanisms for the promotion of biotechnology businesses, which could facilitate the CBA's work in search of new ventures in the area. However, the center would need to adapt to the requirements established by the Decree, such as the integration of biotechnology with public policies.

Law No. 14,785/23 (Brasil, 2023) establishes guidelines for research and experimentation with pesticides, affecting the development of bioinputs and sustainable agricultural products that the Center may be developing. Law No. 13,123/15 (Brasil, 2015), regulated by Decree No. 8,772/16 (Brasil, 2016), regulates access to genetic heritage and associated traditional knowledge, imposing rules for research and economic exploitation of Amazonian biodiversity resources, essential for the Center's activities. In addition, Decree No. 4,339/02 (Brasil, 2022) establishes principles for the implementation of the National Biodiversity Policy, guiding conservation and sustainable use practices that must be incorporated into the Center's operations. Therefore, these legislations establish the regulatory framework that the CBA must follow to ensure legal compliance and promote sustainability in its initiatives.

Finally, Decree No. 4,212/02 (Brasil, 2002) and Decree No. 7,378/10 (Brasil, 2010) provide for the Ecological-Economic Macro zoning of the Legal Amazon (MacroZEE). The MacroZEE is an instrument that seeks to promote the socioeconomic development of the region in an environmentally balanced way, taking into account the conservation of ecosystems and the promotion of economic activities compatible with sustainability. On the other hand, restricted use or full protection zones can hinder the viability of commercial activities involving biotechnology and biodiversity.

Table 5 presents the main national Administrative rules, which belong to the branch of Public Law and govern the State's performance in the administration of collective interests:

Table 5 – Main National Administrative Rules related to the CBA

THEME	NUMBER
Constitution of the Federative Republic of Brazil - highlight articles applicable to public administration and social organization	s/nº, granted on October 5, 1988
Manaus Free Trade Zone (ZFM) and Superintendence of the Manaus Free Trade Zone (SUFRAMA)	Decree-Law No. 288/196, Law No. 8,389/1991, Decree No. 61,444/1967, MDIC Ordinance No. 1,753-SEI, 10/16/2018
Organization of the Federal Administration	Decree-Law No. 200/67
Social Organizations	Law No. 9,637/1998, Law No. 9,790/1999, Decree No. 9,190/2017, Law No. 8,958/1994 and Decree No. 7,423/2010
Brazilian Program of Molecular Ecology for the Sustainable Use of Amazon Biodiversity (PROBEM)	Decree No. 4,284/2002
Amazon Biobusiness Center (CBA)	Decree No. 11,516/2023 and ME Ordinance No. 2,287/2022
Amazon System of Satellite Laboratories Project	Ordinance – MCTIC No. 4,046/2020
Brazil-Biotec Initiative	Ordinance – MCTIC No. 4,488/2021
Bidding and Contracts	Law 8,666/1993, art. 24, XXIV and Law No. 14,133/2021
National Policy for Regional Development	Decree No. 11,962/2024
Committee on Research and Development Activities in the Amazon (CAPDA)	CAPDA Resolution No. 9/2019, LC No. 177/2021, Law No. 8,387/91 (2nd, P. 18, i OR ii).
Monitoring and Evaluation Committee (CAA)	SE/MDIC Ordinance No. 82/2024

Source: the authors, 2025

The Federal Constitution (Brasil, 1988) contains several provisions that directly impact public administration and social organization in Brazil, and which, therefore, have an influence on the existence and activities of the Amazon Biobusiness Center. Article 170 highlights the importance of reconciling economic activities, such as those in the biotechnology sector, with the sustainability and social development of the Amazon region. The basic principles that should govern the public administration, set forth in article 37,

apply both to SUFRAMA and to the social organization that manages it, directly impacting the way the Center is managed.

The Manaus Free Trade Zone (ZFM) and the Superintendence of the Manaus Free Trade Zone (SUFRAMA) are regulated by the following rules: Decree-Law No. 288/67, (Brazil, 1967), Law No. 8,389/91 (Brazil, 1991), Decree No. 61,444/67 (Brazil, 1967), MDIC Ordinance No. 1,753-SEI, 10/16/18 (Brazil, 2018). The tax benefits and incentives provided for industries in the ZFM can benefit the CBA by allowing it to use incentives for the development of technologies and businesses focused on biotechnology in the region, within the economic model of the ZFM, since the ZFM tax regime has as one of its objectives to support innovative and sustainable economic sectors, as is the case with biotechnology.

Decree-Law No. 200/67 (Brasil, 1967), which deals with the organization of the Federal Administration, establishes the bases of the administrative structure of the federal government, with general rules on the management and functioning of direct and indirect public administration bodies. The rules on social organization in the context of the aforementioned Decree may impact the existence and activities of the CBA, both due to the need for alignment with the efficiency and coordination guidelines of the federal administration. Law No. 9,637/98 (Brazil, 1998), Law No. 9,790/99 (Brazil, 1999), Decree No. 9,190/17 (Brazil, 2017), Law No. 8,958/94 (Brazil, 1994) and Decree No. 7,423/10 (Brazil, 2010) deal with Social Organizations and establish the legal bases for their operation under the responsibility of an OS, ensuring efficiency in the implementation of public policies aimed at sustainable development and innovation in the Amazon.

Decree No. 4,284/02 (Brasil, 2002) instituted the Brazilian Program of Molecular Ecology for the Sustainable Use of the Biodiversity of the Amazon (PROBEM). It establishes criteria for the management and operation of private non-profit entities that work in the management of public policies, which implies the need to adapt the CBA's activities to the legal requirements for the recognition and financing of its actions within the program.

The CBA was once called the Amazon Biotechnology Center, a period in which it was governed by the Decree of 04/01/08 (Brasil, 2008). Currently, Decree No. 11,516/23 (Brasil, 2023) qualifies the *Universitas Foundation* for Amazonian Studies as a social organization, for the execution of scientific research, technological development, and innovation activities in the area of bioeconomy, through the management, operation, and

maintenance of the CBA, under the supervision of the Ministry of Development, Industry, Commerce, and Services.

Ordinance ME No. 2,287/22 (Brazil, 2022) authorizes the publication of research, technological development, and innovation activities aimed at businesses in the bioeconomy area of the Amazon Biotechnology Center. Ordinance – MCTIC No. 4,046/20 (Brazil, 2020) provides for the Amazon System of Satellite Laboratories Project of which CBA is part, since SALAS MCTI is a project that aims to install infrastructures to support scientific research in the Amazon territory. In turn, Ordinance – MCTIC No. 4,488/21 (Brazil, 2021) provides for the Brazil-Biotec Initiative. As this ordinance establishes guidelines to foster biotechnology and innovation through partnerships with social organizations, it can influence the management of the CBA, including governance requirements, financing, and strategic alignment with federal public policies.

The Bidding Law (Law No. 8,666/93 and Law No. 14,133/21) (Brasil, 1993, 2021) allows the direct contracting of qualified social organizations, streamlining their relationship with the government. Decree No. 11,962/24 (Brasil, 2024), by establishing guidelines for the National Regional Development Policy, encourages bioeconomy projects in the Amazon, favoring the center in terms of funding and strategic priorities. The rules related to CAPDA (CAPDA-Resolution No. 9/19, LC No. 177/21 and Law No. 8,387/91) (Brazil, 2019, 2021, 1991) guide the use of tax incentives and R&D resources for the Manaus Free Trade Zone, which can expand investment and collaboration opportunities for the center, strengthening its role in innovation and sustainable development in the region.

Finally, Ordinance SE/MDIC No. 82/24 (Brazil, 2024) instituted the omission of Monitoring and Evaluation (CAA), as a technical advisory body to the processes of guidance, monitoring and evaluation of the Management Contract signed between the Union, through the MDIC, and FUEA, with Suframa as an intervening party, with the objective of subsidizing the processes related to the ministerial supervision of the CBA.

Chart 6 presents a summary of rules aimed at the production, circulation and protection of goods and services.

Table 6 – Main National Business Standards related to the CBA

THEME	NUMBER
Constitution of the Federative Republic of Brazil	s/nº, granted on October 5, 1988
Consumer Protection	Law No. 8,078/1990

Industrial Property	Law No. 9,279/1996
Copyright	Law No. 9,610/1998
Information Protection	Law No. 10,603/2002
Innovation	Law No. 10,973/2004 and Decrees No. 9283/2018, No. 4,946/2003, No. 8,772/2016, No. 9,283/2018, No. 11,474/2023
Legal Framework for Science, Technology and Innovation	Law No. 13,243/2016
Partner Network	Decree No. 10,496/2020, Decree No. 11,271/2022 and SEGES/MGI Ordinance No. 4,890/2023
PROTECSUS	ME/Suframa Joint Ordinance No. 268/2020

Source: the authors, 2025

The Constitution of the Federative Republic of Brazil (Brasil, 1988), in its article 170, VI deals with entrepreneurship and the defense of the environment, strengthens the role of the center in the bioeconomy, issues transversal to the CBA. Article 219 determines that the domestic market must be encouraged as a national asset, promoting economic and social development. This can benefit the center by integrating its activities with policies to encourage bioindustry and technological innovation in the region. Law No. 8,078/90 (Brazil, 1990) created the Consumer Protection Code, which establishes that products and services offered must meet minimum standards of quality and safety. This may impact CBA in its functions of supporting and facilitating the commercialization of products and technologies, especially those from biotechnology, innovation or production processes in the Amazon.

Law No. 9,279/96 (Industrial Property Law) (Brazil, 1996) and Law No. 9,610/98 (Copyright Law) (Brazil, 1998) regulate the protection of innovations and intellectual creations generated by the center, ensuring rights over patents and works resulting from research, while Law No. 10,603/02 (Brazil, 2002) deals with the protection of test data and other knowledge relevant to the development of bioproducts.

With regard to the incentive to research, development and innovation, Law No. 10.973/04 (Innovation Law) (Brasil, 2004) and its regulatory decrees establish guidelines for the partnership between the center and public or private institutions, allowing the transfer of technology and the use of public resources for the promotion of research. Law No. 13,243/16 (Legal Framework for Science, Technology, and Innovation) (Brazil, 2016) expands these mechanisms, relaxing rules for interaction between the public and private

sectors and facilitating the capture of investments for sustainable innovation projects in the Amazon. In addition, decrees related to access to genetic heritage and benefit sharing , such as Decree No. 8,772/16, regulate the sustainable use of Amazonian biodiversity, which is essential for the Center's activities.

'Decrees No. 10,496/20 (Brazil, 2020) and No. 11,271/22 (Brazil, 2022), respectively, deal with the Integrated Registry of Investment Projects (Cipi) for the centralized registration of information on infrastructure investment projects, funded with resources from the Fiscal and Social Security Budgets, within the scope of the bodies and entities of the Federal Executive Branch that are part of the Fiscal and Social Security Budgets; and the Federal Partnership Management System (Sigpar), with a view to organizing the activities of planning, coordination, guidance and management of partnerships for the implementation of public policies in a decentralized manner. The standards contribute to efficiency in the execution of public policies, optimizing the impact of the CBA and on the sustainable development of the Amazon.

SEGES/MGI Ordinance No. 4,890/23 (Brazil, 2023), Partnership Network within the scope of Sigpar, which aims to foster collaborative governance, reinforcing principles of efficiency, transparency, and control, indispensable elements to ensure the compliance of the center's operations with the strategic objectives of the innovation and sustainable development policy in the Amazon.

Finally, the ME/SUFRAMA Joint Ordinance No. 268/20 (Brazil, 2020) regulates investment in research, development, and innovation activities, resulting from Technological Projects with the Objective of Environmental Sustainability (PROTECSUS), in the area of the Western Amazon and the State of Amapá. It directly impacts CBA's activities by enabling access to financial resources for research, development and innovation (RD&I) projects.

Chart 7 deals with the rules that regulate essential aspects of collection, management of public resources and state intervention in the economy:

Table 7 – Main National Tax, Financial and Economic Norms related to the CBA

THEME	NUMBER
Constitution of the Federative Republic of Brazil	s/nº, granted on October 5, 1988
National Bioeconomy Strategy	Decree No. 12,044/2024
Import (tax exemption/reduction)	Law No. 8,032/1990

Federal Fiscal Budget: Suframa and CBA	Law No. 10,161/2000 and Law No. 10,044/2000
Suframa	Suframa Ordinances No. 347/2020, 745/2023, No. 1,703/2024, No. 1398/2024
CAS - Board of Directors of Suframa	CAS Resolution No. 02/2021, 205/2021
Fiscal Responsibility	Complementary Law No. 101/2000
Tax benefit for companies	Decree No. 10,521/2020
Tax incentive for technology companies	Law No. 8,248/1991, Law No. 8,387/1991 and Decrees No. 5,906/2006, No. 10,356/2020, No. 10,521/2020
Tax incentives for technological innovation	Law No. 11,196/2005, No. 11,484/2007
Customs activities and foreign trade	Decree No. 6,759/2009
Basic Production Process (PPB)	Law No. 11,484/2007, Decree No. 6,008/2006
Interministerial Ordinances on PPB	PI MDIC/MCTI No. 177/2002, No. 685/2007, PI ME/MCTI No. 4,546/2021
Access of social organizations (OSs) to RD&I resources generated by companies installed in the ZFM	MDIC/Suframa Joint Ordinances No. 11/2023 and No. 12/2023 Ordinance GM-MDIC No. 378/2023

Source: the authors, 2025.

The Constitution of the Federative Republic of Brazil, in its article 150, item VI, "a" and "c" establishes limitations on the power to tax, providing for tax immunity for non-profit entities and for assets, income or services of public entities, which can benefit the Center by reducing its tax burden and increasing its capacity to invest in innovation and sustainable development. Article 174, paragraph 2, on the other hand, determines that the State can encourage the organization of economic activity in the form of cooperativism and other associative forms, in addition to acting as a normative and regulatory agent of economic activity, which can favor the Center by ensuring government support, financial incentives and strategic partnerships within the regional development and bioeconomy policy.

The National Bioeconomy Strategy (Brazil, 2024) establishes guidelines for the sustainable development of the bioeconomy in Brazil, which can directly impact the CBA by guiding public policies, incentives, and regulations aimed at research, innovation, and commercialization of biotechnological products in the region. The Center's activities may be influenced by the strategic priorities established in the Decree, such as the valorization of Amazonian biodiversity and the promotion of sustainable production chains.

Law No. 8,032/10 (Brasil, 2010), by providing for tax exemption or reduction on the import of specific equipment and inputs, can benefit the center by reducing operating costs for research and innovation, facilitating the acquisition of cutting-edge technologies and promoting greater competitiveness in the bioeconomy sector. Laws No. 10,161/00 and No. 10,044/00 (Brasil, 2000) guarantee the allocation of resources from the Federal Fiscal Budget to Suframa and CBA, ensuring their maintenance and development. Suframa's Ordinances (No. 347/20, 745/23, 1,703/24, and 1,398/24) (Brazil 2020, 2023, 2024) establish operational guidelines, criteria for the transfer of resources, project execution, and accountability, influencing CBA's autonomy and its ability to foster innovation and sustainable development in the Amazon bioeconomy.

CAS Resolutions No. 02/21 and No. 205/21 (Brazil, 2021), of Suframa's Board of Directors, establish guidelines for the granting and maintenance of tax incentives in the Manaus Free Trade Zone, which may affect fundraising and the feasibility of CBA projects. The Fiscal Responsibility Law (LC nº 101/00) (Brasil, 2000) imposes limits and rules for the management of public resources, restricting spending and requiring transparency in the budget execution of the CBA. Decree No. 10,521/20 (Brasil, 2020) regulates the granting of tax benefits to companies in the Western Amazon, which can attract private investments to the CBA, stimulating strategic partnerships and expanding the economic and technological impact of its activities on the regional bioeconomy.

Complementary Law No. 101/00 (Brasil, 2000), known as the Fiscal Responsibility Law (LRF), can directly impact the activities of the Amazon Biobusiness Center, as it establishes rules for responsible fiscal management, restricting the use of public resources and imposing limits on the execution of expenses. The Center, being a public social organization, may face budget constraints and challenges related to the financial management and sustainability of its projects, if the responsible public entity is unable to comply with the fiscal parameters established by the LRF. Decree No. 10,521/20 (Brasil, 2020), which deals with tax benefits for companies, can have an indirect impact by encouraging the installation of biotechnology and innovation companies in the region, creating an environment conducive to the development of businesses related to the Center. However, the effectiveness of this tax benefit will depend on the Center's articulation with the private sector and compliance with tax requirements so that companies can take advantage of such incentives.

Law No. 8,248/91 and Law No. 8,387/91 (Brazil, 1991), along with subsequent decrees, such as Decrees No. 5,906/06 (Brazil, 2006), No. 10,356/20 (Brazil, 2020), and No. 10,521/20 (Brazil, 2020), encourage investments in technology and innovation in strategic areas, including the Amazon region. The CBA can benefit from these rules by attracting companies and startups that seek these tax incentives, stimulating research and development of sustainable and innovative solutions. In addition, Law No. 11,196/05 (Brazil, 2005) and Law No. 11,484/07 (Brazil, 2007), aimed at technological innovation, can enable the development of new products and processes that meet the needs of the Amazon biome, favoring both environmental sustainability and the local economy. These tax incentives can facilitate partnerships, technical cooperation, and the expansion of projects in the CBA, positively impacting its mission to promote the development of technologies aimed at the preservation and sustainable use of the Amazon.

Decree No. 6,759/09 (Brasil, 2009), which regulates customs activities and foreign trade, may influence the movement of inputs and products to and from the CBA, facilitating or hindering the international trade of biotechnology and related products. Law No. 8,248/91 and its modifications, together with Decrees No. 5,906/06 (Brazil, 2006) and No. 6,405/08 (Brazil, 2008), when dealing with the Basic Production Process (PPB), directly impact the manufacture and qualification of local products, which may be relevant for companies operating in the CBA, encouraging research and development of technologies in the biotechnology sector. In addition, the Interministerial Ordinances on the PPB (such as PI MDIC/MCTI No. 177/02 and PI ME/MCTI No. 4,546/21) (Brasil, 2002, 2021) may provide guidance for complying with specific requirements for the production and commercialization of biotechnological products, which may affect the way companies in the CBA are inserted in the domestic and foreign markets. In general, these rules regulate tax incentives and benefits, impacting both the economic viability and the competitiveness of the activities developed in the CBA.

On the other hand, MDIC/Suframa Joint Ordinances No. 11/23 and No. 12/23 (Brazil, 2023), together with GM-MDIC Ordinance No. 378/23 (Brazil, 2023), expand OS's access to RD&I resources generated by companies in the Manaus Free Trade Zone, creating a more favorable environment for CBA to seek partnerships and financial resources aimed at the development of biotechnology. Indirectly, these regulations can strengthen CBA's performance by allowing greater capillarity for innovative projects, in

addition to contributing to its financial sustainability and relevance within the innovation ecosystem in the Amazon.

DISCUSSION

The Amazon Biobusiness Center (CBA) emerged as an alternative to the industrialization of electronics in the Amazon region (Almeida, 2024). It is inserted in a context of high socio-environmental and scientific relevance, and its performance is directly influenced by several (inter)national regulations. Research projects related to industrial biotechnology in the state of Amazonas are mostly developed by CBA (Oliveira, 2023). From the survey of standards related to the CBA, it is observed that legal regulations and development policies, both national and international, play a crucial role in the sustainability and effectiveness of the initiatives promoted by the center.

As an example of the relevance of CBA in the Amazon scenario, one of the goals listed in Mission 5 of the New Industry Brazil (NIB) is to increase the technological and sustainable use of biodiversity by the industry. To achieve this goal, different actions were proposed, such as, for example, the training of agents in the innovation ecosystem of the Amazon region in terms of intellectual property; creation of the "Green Seal" and "Amazon Seal", in addition to the structuring of the Amazon Biobusiness Center (CBA):

The CBA will now have a business center operating on two fronts: 1) search for research, beyond its own laboratories, that will result in "off-the-shelf" products that are part of the Center's portfolio and that will be offered to potential investors; 2) from partnerships with the private sector, ensure the supply of raw materials regularly at competitive prices, providing minimum conditions for the industry to establish itself and there is sustainability in the work of the communities directly involved, such as riverside dwellers and native peoples. (MDIC, 2025)

Another example of the importance of the Center for the region is contained in the Action Plan for the Prevention and Control of Deforestation in the Legal Amazon (PPCDAm), phase V. In its Annex 1, it is possible to see in the Summary Table Axis I – Sustainable Productive Activities, that among the Strategic Objectives of the Plan is: Stimulate sustainable productive activities, where one of the expected results, related to the expanded and strengthened bioeconomy, sociobiodiversity, agroecology and agroecological transition in the Amazon is: to encourage the bioeconomy and biodiversity economies in the Amazon through the Amazon Biobusiness Center (CBA) (MDIC/MMA/ Censipam – MD) (Brazil, 2023).

Regarding the standards presented, it should be noted that the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources are fundamental international standards for the CBA, especially considering the context of Amazonian biodiversity. The CBD commits signatory countries to protect biological diversity and promote the sustainable use of natural resources, essential elements for the work of the CBA, focused on the research and development of bioproducts. The CBD faces difficulties in implementation because it is a framework convention that, although it establishes principles and commitments for the protection of biodiversity, lacks multilateral resources to enable conservation and sustainable use. Instead, its contractualist approach limits collaboration between the Parties, especially between the countries of the South (Godinho; da Mota, 2013).

The Nagoya Protocol, in turn, regulates access to genetic resources and the fair and equitable sharing of benefits arising from this access. At the CBA, these treaties are applied by ensuring that research involving biological resources in the Amazon follows the precepts of justice and equity, providing benefits to local communities and ensuring regularity in the use of the region's genetic resources. In addition, Law No. 13,123/15 and Decree No. 5,591/05, which regulate access to genetic resources and the protection of associated traditional knowledge, are national rules that directly impact the CBA. Despite normative advances, the chapter exposes significant gaps, such as the difficulty in ensuring prior informed consent and fair sharing of benefits (Ferreira; Tupiassu, Gros-Désormeaux; 2024).

Law No. 13,123/15 establishes procedures for access to genetic resources and the sharing of benefits, in line with the Nagoya Protocol, and, therefore, regulates how the CBA must act to ensure the legal and ethical use of Amazonian biological resources. Decree No. 5,591/05 complements this legislation by regulating the exploitation of traditional knowledge of indigenous and local communities, areas of activity of the CBA in the development of bioproducts. These regulations require the CBA to have a robust structure to ensure the legal and ethical compliance of its activities.

In a more local scenario, MDIC/Suframa Joint Ordinance No. 11/23 and GM-MDIC Ordinance No. 378/23 are directly connected to the possibility of CBA's access to tax incentives and support for the development of innovative technologies. These ordinances facilitate the integration of the CBA with companies installed in the Manaus Free Trade Zone, allowing the use of tax incentives and the stimulus to the development of Research,

Development and Innovation (RD&I) projects in the Amazon region. Such devices offer CBA the opportunity to establish strategic partnerships with the private sector, enhancing its research and development activities, which are fundamental for the growth of biotrade and sustainable technologies.

However, the complexity of legal regulations, both at the national and international levels, represents a significant challenge for the CBA. The need to adapt to regulatory requirements, often with divergent criteria, can make it difficult to implement projects and collaborate with international partners. The constant updating of legislation and bureaucratic challenges, such as the need to prove benefits and compliance with legislation on access and distribution of resources, require a robust and well-informed administrative structure.

On the other hand, regulations can create a favorable environment for international collaboration, promoting access to new resources, partnerships, and markets. Adherence to treaties such as the CBD and the Nagoya Protocol can open doors for CBA on the global stage, allowing partnerships with foreign institutions and companies focused on research and innovation in biotechnology and sustainability. However, regulations can also be an obstacle if there is a lack of harmonization between local and international requirements, which can discourage foreign investment and hinder the internationalization process of the innovations developed at the Center.

When analyzing the trajectory of the CBA, it is worth highlighting a latent evolution: the legal nature (management by a Social Organization), which was recommended in scientific research (Cabral, et. al, 2023) became a reality through Decree No. 11,516/23. Another advance for the Center was Decree No. 12,044/24, which instituted the National Bioeconomy Strategy (Brasil, 2024). Such content was also suggested in a previous work (Cabral; Lasmar; Mafra, 2022). These are two steps towards taking full advantage of the potential of the CBA.

In conclusion, the CBA, by inserting itself in the legal-normative scenario that regulates biodiversity, biotechnology and sustainable innovations, must navigate between opportunities and challenges. Critical analysis of the standards reveals that, although there is great potential for development and collaboration, continuous adaptation to complex legal requirements is a fundamental requirement to ensure the effectiveness and sustainability of their projects.

CONCLUSION

The Amazon Biobusiness Center (CBA) plays a key role in the sustainable development of the region, with a focus on the bioeconomy and the responsible use of the Amazon's natural resources through innovative biotechnologies. Its performance is directly related to a wide range of legal regulations that regulate its activities. In this study, international treaties and national legislation that impact the CBA were analyzed, revealing both challenges and opportunities. This conclusion is organised by themes, starting with international treaties and then analysing the relevant national legislation.

International treaties are extremely important for the CBA's performance, as they establish rules that regulate the use of natural resources and promote global collaboration for environmental preservation. Among the main international treaties that directly impact the activities of the CBA, the Convention on Biological Diversity (CBD) **and the** Nagoya Protocol stand out, which deal, respectively, with the preservation of biodiversity and access to genetic resources and the fair sharing of benefits arising from their use. These treaties are key to ensuring that CBA acts ethically and responsibly when accessing Amazonian biodiversity, aligning with international standards and contributing to global environmental protection.

Brazil's accession to the CBD and the Nagoya Protocol creates a context that favors international collaboration, allowing the CBA to integrate into global research and development networks. Such standards provide the possibility of establishing partnerships with international institutions and companies, obtaining financing and participating in joint projects focused on biotechnology and sustainability. However, these conventions impose strict requirements on the use of genetic resources, which requires the CBA to implement mechanisms to ensure compliance with legal obligations, such as detailed documentation of access to resources and fair sharing of the benefits generated.

In addition, the United Nations Framework Convention on Climate Change (UNFCCC) **and the** Paris Agreement also influence CBA's operations, as they deal with mitigating the impacts of climate change and promoting sustainable practices in all sectors of the economy. The CBA's alignment with these treaties not only strengthens its international position, but also opens doors for new projects involving green technologies and solutions for climate change adaptation.

On the other hand, the main difficulty in relation to international treaties lies in the implementation of regulatory requirements, which often require an adaptation of local

regulations. The lack of harmonization between international requirements and national legislation can generate administrative and procedural challenges, impacting efficiency in the execution of projects and international partnerships. The implementation of such standards requires careful administrative management and clear processes that ensure compliance, which can represent a challenge for CBA, especially considering the diversity of regulations that involve different areas of law, such as environmental, commercial, and scientific.

In the national scenario, the CBA is inserted in a multifaceted regulatory framework, which covers everything from environmental protection to issues of technological innovation and corporate governance. Brazilian legislation provides a robust set of regulations, with the aim of ensuring that CBA's activities comply with State guidelines, as well as promoting sustainable development and innovation.

An important example is Law No. 6,938/81, which establishes the National Environmental Policy, creating instruments for environmental protection and preservation, which includes regulations on the use of natural resources. This legislation is fundamental to CBA's activities, as it defines the environmental parameters that must be followed, ensuring that its operations do not harm the biodiversity and ecosystems of the Amazon. Together with Law No. 9,985/00, which creates the National System of Nature Conservation Units, these rules provide the necessary legal framework for the preservation of the Amazon, ensuring that the projects carried out by CBA are aligned with environmental requirements.

Law No. 11,105/05 and Decree No. 5,591/05 deal with safety in biotechnology, regulating the use of genetically modified organisms (GMOs). These laws are especially relevant to the CBA, since they regulate the research and application of biotechnologies that use Amazonian biodiversity. While these standards are essential to ensure the safety of biotech innovations, they also pose significant challenges, as they require the CBA to follow detailed and rigorous procedures for approving projects involving GMOs, which can delay the development of new technologies.

Law No. 13,123/15, in turn, deals with access to Brazilian genetic heritage and the sharing of benefits generated from the use of genetic resources. This legislation, together with Decree No. 9,073/17, establishes the procedures for licensing and documenting the use of genetic resources, which makes the CBA responsible for ensuring that all access and benefits are properly reported to the competent authorities. While this standard is

crucial to ensure compliance with international obligations, it also requires a high level of organization and administrative *compliance*, which can pose operational challenges.

In addition, Law No. 9,456/97 and Decree No. 2,366/97 regulate intellectual property on biotechnological inventions, including patents for inventions involving genetic resources. The CBA needs to ensure that its innovations are properly registered and protected, which can lead to legal challenges, especially when it comes to resources that are shared internationally, as required by the Nagoya Protocol. Intellectual property protection also extends to other areas, such as applied research in biotechnology, requiring constant vigilance over patent rights and licensing agreements.

Decree No. 11,962/24 and Law No. 14,133/21, which regulate bids and administrative contracts, also directly affect the CBA, especially when it comes to partnerships with public agencies or private companies. These legislations impose specific rules for the contracting of services and acquisition of products, which requires the CBA to have a rigorous bidding process and compliance with the principles of legality, impersonality, morality, publicity and efficiency. The management of these contracts and partnerships must be done in a transparent and efficient manner, ensuring that all legal requirements are met.

Finally, tax and financial legislation also plays a crucial role in CBA operations. Law No. 9,279/96, which deals with industrial property, and Law No. 8,666/93, which regulates bids and administrative contracts, are fundamental to the operation of the CBA, as they define how it can obtain financial resources, how to apply the funds received and how it can benefit from tax incentives. Such laws, together with more specific rules for innovation incentives, such as Law No. 10,973/04, offer a legal framework that can facilitate access to tax incentives and public resources, promoting innovation and sustainable economic development in the Amazon region.

The integration of international and national standards, while fraught with challenges, also offers significant opportunities for CBA. Compliance with international treaties and Brazilian legislation can open doors for research partnerships, funding, and access to global markets, in addition to strengthening CBA's position as a reference center in biotechnology and bioeconomy. However, the complexity of the regulations, the lack of harmonization between them, and the need for constant adaptation to changes in legislation can be significant obstacles to the efficient execution of CBA projects.

To overcome these challenges, the CBA will need a robust administrative structure, capable of dealing with the complexity of the rules and ensuring compliance with legal requirements efficiently and strategically. The integration of effective governance and the promotion of partnerships with research institutions and international companies will be essential to maximize opportunities and minimize the obstacles imposed by regulations.

The success of the CBA will depend on its ability to adapt and integrate legal requirements into its development strategy. Alignment with international and national standards will be essential to ensure the continuity of its activities, the development of new products and the expansion of its operations. If CBA manages to balance compliance with legal requirements with the need for innovation and adaptation to the global market, it can play a crucial role in the sustainable development of the Amazon, promoting the bioeconomy and biodiversity preservation in an innovative and efficient way.

As a recommendation for future research, it is suggested that a survey of state (Amazonas) and municipal (Manaus) standards related to the CBA be carried out. It is also suggested that interviews be conducted with CBA employees and former employees, as well as experts in the legal area, to assess how the rules identified in this work impact the existence and activities of the CBA. The interviews should be analyzed in order to identify the main regulatory obstacles faced and suggestions for improvements to optimize the CBA's activities. Based on the analysis of the rules and the interviews carried out, suggestions for legislative changes, creation or suppression of rules should be prepared, aiming to mitigate the administrative and operational obstacles of the CBA. These proposals will be directed to an improvement of the legislation, aiming at greater efficiency and effectiveness in the activities of the Amazon Biobusiness Center.

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