

## Forum

### How legislations affect new taxonomic descriptions

Manuela da Silva,<sup>1,\*</sup> Philippe Desmeth,<sup>2</sup> Stephanus N. Venter,<sup>3</sup> Yogesh Shouche,<sup>4</sup> and  
Andrey Yurkov<sup>5</sup>

<sup>1</sup>Fundação Oswaldo Cruz (Fiocruz), Fiocruz COVID-19 Biobank, Rio de Janeiro, Brazil

<sup>2</sup>Belgian Science Policy Office, Brussels, Belgium

<sup>3</sup>Department of Biochemistry, Genetics and Microbiology and Forestry and Agricultural Biotechnology Institute (FABI), University of Pretoria, Pretoria, South Africa

<sup>4</sup>National Center for Microbial Resource, National Center for Cell Science, Pune, India

<sup>5</sup>Leibniz Institute DSMZ – German Collection of Microorganisms and Cell Cultures, Braunschweig, Germany

\* Correspondence email: [manuela.dasilva@fiocruz.br](mailto:manuela.dasilva@fiocruz.br)

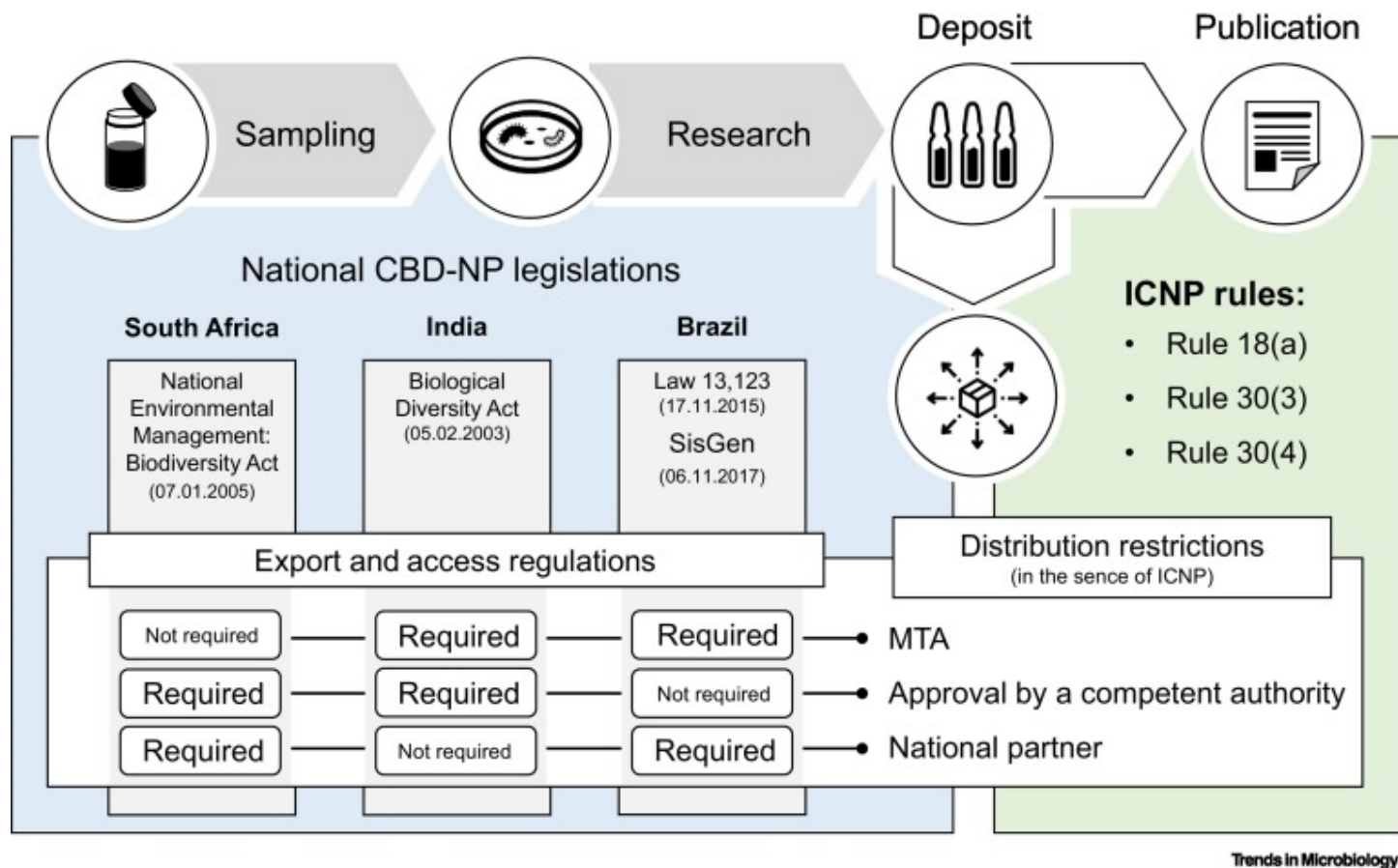
### Abstract

Restrictions placed on the distribution of biological material by the legislation of countries such as India, South Africa, or Brazil exclude strains that could serve as type material for the validation or valid publication of prokaryotic species names. This problem goes beyond prokaryotic taxonomy and is also relevant for other areas of biological research.

**Keywords** : access and benefit sharing ; new species ; prokaryotes ; culture collections ; genetic resources ; International Code of Nomenclature of Prokaryotes

### Impact of Access and Benefit Sharing legislation

In 2020, the *International Journal of Systematic and Evolutionary Microbiology* (IJSEM) informed authors that, according to the requirements of the International Code of Nomenclature of Prokaryotes (ICNP, aka the Code), the journal could no longer accept proof of deposit of type strains originating from countries such as India, South Africa, or Brazil, or from the Polar and Alpine Microbial Collection (Republic of South Korea) [1., 2., 3.]. These rejections were based on the requirements by the national Access and Benefit Sharing (ABS) legislations related to the sharing of biological material from these countries. This decision of the IJSEM, the ICSP's (International Committee on Systematics of Prokaryotes) official journal of record for prokaryotic names, has shaken the affected community of researchers working with prokaryotic organisms and highlighted the far-reaching problem of disagreement between national laws governing access to countries' genetic resources and the rules of the ICNP.



**Figure 1.** Summary of the impact of Brazilian, Indian, and South African legislations on the access and distribution of material from these countries in the light of the relevant International Code of Nomenclature of Prokaryotes (ICNP) rules.

The legislations affect all aspects of research, including sampling, isolation, deposition, and distribution of countries' genetic resources. The control over the deposition and distribution, restrictions of access in the sense of the ICNP, excludes strains that could serve as type material for the validation or valid publication of prokaryotic species names. Abbreviations: CBD-NP, Convention on Biological Diversity – Nagoya Protocol; MTA, Material Transfer Agreement.

## The requirements of the ICNP

The ICSP regulates the validation of all new prokaryotic species names by means of the ICNP (Figure 1). According to the ICNP, Rule 30(3b) <sup>[4]</sup>, one of the main requirements, is to deposit strains that serve as nomenclatural types in at least two collections in two different countries. This is to facilitate access to type strains which serve as reference material for future identification and taxonomic studies <sup>[5]</sup>. In this regard, culture collections play a major role in safeguarding type material and significantly contribute to the implementation of FAIR principles – the Findability, Accessibility, Interoperability, and Reusability of Genetic Resources and related data <sup>[6]</sup>. The Convention on Biological Diversity (CBD), its Nagoya Protocol (NP), and the subsequent national legislations determining the rules of access to countries' genetic resources are legally binding. Culture collections must strictly adhere to them.

Moreover, to avoid any restriction of access, ICNP Rule 30(4) states that organisms deposited in a way that could limit access may not serve as type strains. This provision has been interpreted to include a wide range of situations such as strains deposited as safe deposit or for patent purposes as well as those where prior consent or collaborations are required for sharing, accessing, and using the cultures <sup>[2,7]</sup> based on restrictive national ABS legislation. Such strains can be disqualified from becoming a proposed type strain of a new species under the ICNP because collections would not be able to distribute this strain without restrictions <sup>[1]</sup>. Strains from India and South Africa require prior consent for their distribution from national authorities and are not viewed as available without restrictions but rather as safe deposits <sup>[2]</sup>.

Similarly, some conditions of Material Transfer Agreements (MTAs) require that foreign institution must partner with a national institution before publishing any results or just communicating any basic research with the Brazilian genetic resource <sup>[3]</sup>. This may also hinder the implementation of ICNP rules, making it impossible to validly publish a taxonomic novelty, name, based on the material from Brazil.

## CBD and the NP

Restrictions on the distribution of biological material can be linked to how different countries responded to the CBD and the NP. The CBD, a multilateral international treaty, focusses on three main objectives: 'the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising out of the utilization of genetic resources' (United Nations, 1992). In 2014, the NP on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Secretariat of the CBD, 2014) entered into force to advance its third objective. Several countries have subsequently established or updated their national ABS legislation and regulations to control the use of genetic resources (including microorganisms) and associated traditional knowledge under their jurisdiction.

**Table 1.** Summary of the ABS legislation of Brazil, India, and South Africa

	Brazil	India	South Africa
Party to CBD and NP	05.1994 and 06.2021	02.1994 and 10.2012	11.1995 and 10.2014
Legislation	Provisional Act 2186-16 of 2001 Law 13,123 of 2015 Decree No. 8,772 of 2016	Biological Diversity Act of 2002	National Environmental Management: Biodiversity Act, Number 10 of 2004 Regulations on Bioprospecting, Access and Benefit-Sharing (Notice R 138 of 2008) Amendments to the Regulations on Bioprospecting, Access and Benefit-Sharing (Notice 447 of 2015)
Authority	Genetic Heritage Management Council (CGen) chaired by the Ministry of Environment	The National Biodiversity Authority (NBA)	Department of Forestry, Fisheries and the Environment (DFFE)
Register of users	National System for the Genetic Heritage and Associated Traditional Knowledge Management (SisGen)		Issuing authorities must keep a register of all applications and decisions.
Regulation of access	The term 'access' means 'utilization', that is, any Research and Development involving these resources.	The deposition of any microbial culture in a culture collection outside India by an Indian researcher, or the access to a culture by any non-Indian researcher either from an Indian or non-Indian culture collection requires prior approval from the NBA.	The regulations distinguish between export permits for 'Bioprospecting' and 'Research other than Bioprospecting' as well as the issuing authorities for such permits.
Temporal scope	Retroactive. The date of access is the date when the research material starts, not when it has been sampled or obtained. Therefore, when a researcher uses a given Brazilian genetic resource (GR) for research that is deposited in a biological collection, even before NP (2014).	Though not explicitly said, the regulation is retrospective, i.e., the culture deposited before the act came into existence are also under the purview of the Act.	These regulations are not applicable to any indigenous biological resources collected before April 2008.

<p>Export of genetic resources (GR), for example, to deposit a strain</p>	<p>The shipment must be recorded in the SisGen system. Only Brazilian citizens or permanent residents can conduct the recording and get the shipment receipt that is required together with the MTA. The Law authorizes the transfer of GR to third parties, provided that the accompanying MTA contains the same provisions of the original MTA for this transfer as well as any subsequent transfers.</p>	<p>Researchers need to complete 'Form C' with all relevant details including the name of the culture collection where the culture is deposited and submit it to the NBA. They do not have to wait for approval before sending the culture to a collection outside India.</p>	<p>Only South African citizens or permanent residents can apply directly for export permits required for the export of indigenous biological resources. Any foreign national needs to apply jointly with a South African person.</p>
<p>Access to genetic resources (GR)</p>	<p>Activities related to the use of GRs require a prior registration. In addition to shipment (see above), the activities include the application of any intellectual property right, or the commercialization of the intermediate product, or publication of results, partial or final, in scientific or communication media, or the notification of a finished product or reproductive material developed as result of the access.</p> <p>Foreigners cannot register their activities on their own because the process of the prior registration is presently open only to Brazilian scientific and technological research institutions. Therefore, a partnership with a Brazilian institution is required to carry out access to GR.</p> <p>This requirement also applies to access to Brazilian GR deposited in national and international <i>ex situ</i> collections.</p>	<p>Access to a culture by any non-Indian researcher either from an Indian or non-Indian culture collection requires prior approval from the NBA.</p>	<p>Indigenous biological resources may not be sold, donated or transferred to a third party without written consent by the issuing authority.</p>

Several developing biodiversity-rich countries have opted for tight control over their biological resources, such as requirement of prior permission and/or association with a national institution, to avoid uncontrolled access and exploitation as in the past <sup>[3]</sup>. These legislative measures often interfere with biodiversity and taxonomic research, as shown above.

To illustrate the complexity of the problem, the legislation in Brazil, India, and South Africa was reviewed (see the supplemental information online) to demonstrate the impact of the legislation on various aspects on the species description (Figure 1 and Table 1).

Also, this situation impedes regular flow of scientific data and monitored exchanges of biological material. You can protect only what you know, and hampering the increase in knowledge on biodiversity goes against the objectives of the CBD <sup>[8]</sup>.

### **Growing concern amongst taxonomists**

By mid-2022, 136 countries were parties of the NP, and the number is still growing. So is the diversity of national regulations implementing the NP. The number of intricacies and nuances is astonishing considering the fact that the access to genetic resources was thought to be utilized by a broad range of people <sup>[9]</sup>. The three examples of national laws (India, South Africa, or Brazil) referred to above are probably only the tip of the iceberg, since the list of countries implementing ABS regulations is not limited to the three examples above.

The sovereignty of countries to determine how they want to regulate access to genetic resources, also termed as biological resources and genetic heritage, cannot be called into question. However, there are different requirements by which access to genetic resources is regulated by different countries. Currently, some of them (India, South Africa, and Brazil) have one thing in common, namely, they effectively impact on the ‘unrestricted distribution’ envisaged under Rule 30 of the ICNP. This makes the task of prokaryotic taxonomists in these countries very difficult as, according to the present interpretation of what constitutes a restriction <sup>[2]</sup>, many countries will not be in a position to validate the new taxa identified from their genetic resources. Any solution to this problem should honor the spirit of the rule, namely, that type material should be available with no restriction for taxonomic purposes.

### **Future perspectives**

The implementation of national CBD and NP legislation showed the utmost importance of clarification of terms and definitions such as ‘access’ and ‘utilization’. Brazilian legislation is complex, and policy makers have struggled to resolve some specific issues. A solution, which was proposed with the help of the academy, has not yet been implemented, but is expected to come <sup>[10]</sup>.



Recently, changes to Rule 30(4) have been proposed in order to clarify restrictions under the Code such as third-party access permissions from national authorities. The problem of taxonomically invalid names based on the material from countries with restrictive ABS policies will persist as the IJSEM will still require the 'evidence' of availability to accompany the manuscripts <sup>[11,12]</sup>. If the evidence is to come from culture collections, the situation will create additional burden for collections' staff and require regular legal advisory.

An alternative might be to move from a system that requires prior authorization to a declaration system in which the various stakeholders who have collected administrative data on access and distribution of genetic resources upload this validated information into an open access database. This would allow countries of origin to monitor the flow and distribution of their genetic resources and ultimately benefit from the use of their biological assets. Such a move goes also towards a more multilateral approach of the ABS international system.

The problem presented here goes beyond prokaryotic taxonomy and is highly relevant for all other living organisms, data policies, health security, and conservation activities. This problem can be addressed only if all the stakeholders are involved in the development of a solution. We believe that discussions between scientific communities, taxonomists and culture collections, and the government agencies are essential to arrive at a workable solution.

## Declaration of interests

No interests are declared.

## References

1. Rahi, P. (2021) Regulating access can restrict participation in reporting new species and taxa. *Nat. Microbiol.* 6, 1469–1470
2. Tindall, B.J. (2020) Clarification of access regulations to genetic resources that are subject to the sovereign rights of sovereign states and the deposit of nomenclatural types under the International Code of Nomenclature of Prokaryotes. *Int. J. Syst. Evol. Microbiol.* 70, 317–320
3. Williams, C. et al. (2020) Conservation policy: helping or hindering science to unlock properties of plants and fungi. *Plants People Planet* 2, 535–545
4. Parker, C.T. et al. (2019) International Code of Nomenclature of Prokaryotes: Prokaryotic Code (2008 revision). *Int. J. Syst. Evol. Microbiol.* 69, S1–11
5. De Vos, P. and Truper, H.G. (2000) Judicial Commission of the International Committee on Systematic Bacteriology IXth International (IUMS) Congress of Bacteriology and Applied Microbiology. Minutes of the meetings, 14, 15 and 18 August 1999, Sydney, Australia. *Int. J. Syst. Evol. Microbiol.* 50, 2239–2244
6. Becker, P. et al. (2019) Public microbial resource centers: key hubs for findable, accessible, interoperable, and reusable (FAIR) microorganisms and genetic materials. *Appl. Environ. Microbiol.* 85, e01444–19

7. Euzéby, J.P. and Tindall, B.J. (2004) Status of strains that contravene Rules 27(3) and 30 of the Bacteriological Code. Request for an opinion. *Int. J. Syst. Evol. Microbiol.* 54, 293–301
8. Sirakaya, A. (2022) Is the Nagoya Protocol designed to conserve biodiversity? *Plants People Planet* 4, 68–75
9. Yurkov, A. et al. (2019) DSMZ: the European Union’s first registered collection under the Nagoya Protocol. *Microbiol. Aust.* 40, 108–113
10. da Silva, M. et al. (2021) Como problemas na Lei da Biodiversidade (Lei 13.123/2015) estão impedindo o registro de novas bactérias encontradas no Brasil. *J. Ciencia* 6823, 18
11. Oren, A. et al. (2022) ICSP response to ‘Regulating access can restrict participation in reporting new species and taxa’. *Nat. Microbiol.* 7, 1711–1712
12. Oren, A. et al. (2022) Proposals to emend Rules 8, 15, 22, 25a, 30(3)(b), 30(4), 34a, and Appendix 7 of the International Code of Nomenclature of Prokaryotes. *Int. J. Syst. Evol. Microbiol.* (in press)