Supplementary material:

How legislations affect new taxonomic descriptions.

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Access to Genetic Resources

Short descriptions and summaries of the regulatory environment of genetic resources (also referred to as indigenous biological resources or genetic heritage) in Brazil, India and South Africa are provided to better understand specific differences in the national legislation and regulations of these countries. Figure 1 provides a summary of the main aspects impacting on various aspects on the description and validation of names of new bacterial and archaeal species.

Brazil

Brazil is party to the CBD since May 1994 and to the Nagoya Protocol, since June 2021. It has updated its national ABS legislation on 17 November 2015 when the Law 13,123 ^[i] came into force, replacing the previous legislation, Provisional Act 2186-16 of 2001 ^[ii]. The Law is regulated through Decree No. 8,772 of May 11, 2016. The Ministry of Environment has developed the National System for the Genetic Heritage and Associated Traditional Knowledge Management (SisGen), an online system to be used by researchers to register their research and development activities with the Brazilian

genetic heritage (GH) in compliance with the legislation. The current legislation has replaced the previous authorization by the self-declaratory register in SisGen [1].

Note that the term "access" has a particular meaning in the Brazilian legislation. Unlike the Nagoya Protocol and some national legislation in which the term access is understood as acquisition or collection, in the Brazil this term means "utilization", that is, Research and Development involving these resources. Therefore, according to Brazilian legislation, when a researcher uses a given Brazilian GH for research that is deposited in a biological collection, even before 2014 when the Nagoya Protocol came into force, the legislation must be complied with [1].

Under Brazilian laws GH are provided to foreign users with a Material Transfer Agreement (MTA), signed by the legal representatives of the providing and receiving institutions (e.g., culture collections), and the shipment must be recorded in the SisGen system. The Law authorizes the transfer of GH 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 [1].

Foreign researchers linked with a research institution based abroad can conduct research with Brazilian GH without any obligation. However, before publishing any results, applying for intellectual property rights and / or commercializing products, the foreign institution must partner with a public or private Brazilian scientific and technological research institution, which must take responsibility for registering the activity in SisGen. This requirement also applies to access to Brazilian GH deposited in national and international *ex situ* collections or to nucleotide sequences deposited in public databases, which were obtained from Brazilian GH, regardless of when and where they were deposited [1].

The legislation is in conflict with the long-existing practice of depositing of microorganisms in international culture collections for nomenclatural purposes, meaning that bacterial taxonomists have been unable to publish the description of new bacterial species using strains from Brazil [2]. From the point of view of ICNP wording, IJSEM policies, and operational procedures of many international culture collections the requirement that foreign researchers must get associated with a Brazilian scientific and technological research institution is a restriction of the access to the type strains. It has the unfortunate result that Brazilian microbial diversity, as unique as that of plants and animals, cannot be validly described.

India

India became party to CBD in February 1994 and signed the Nagoya Protocol in October 2012. The Indian legislation regulating the access to biological resources, named "Biological Diversity Act" [iii] came into force in 2002. The act states that approval from the National Biodiversity Authority is required before a person can obtain any biological resource occurring in India.

Thus, as per the Biodiversity Act 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 National Biodiversity Authority (NBA). This requirement poses serious problems for taxonomic research, especially prokaryotes under the ICNP, as prior permission is required before type strains could be deposited in collections or thereafter distributed to any third party.

The first issue was partially resolved with the development of a form called "Form C". Researchers simply need to complete this form 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. However, it did not solve the second issue of researchers from other countries accessing the cultures of Indian origin deposited in collections outside India. This is still considered as "restricted access" and does not conform with the ICSP Rule 30(4).

South Africa

South Africa became a party to the CBD in 1996, two years after Brazil and India, whereas it became a party to the NP on 12 October 2014, the day the protocol entered into force. As part of its commitment to the CBD, bioprospecting and export of "indigenous biological resources" were covered in the National Environmental Management: Biodiversity Act (NEMBA), Number 10 of 2004 [iv]. The act states that the export of such material without a permit is illegal.

The Bio-prospecting, Access and Benefit-Sharing Regulations were published nearly four years later and came into effect on 1 April 2008 [v]. These regulations have since been amended in 2015. These regulations are not applicable to any genetic resource collected before April 2008 when these regulations were implemented and precede the implementation of the NP on 12 October 2014 by nearly seven years.

The regulations make provision for a dual permit system. Bioprospecting permission and permits are dealt with by the National department, currently the Department of Forestry, Fisheries and the Environment. Export permits for material used for "research other than Bioprospecting", which includes taxonomic and diversity studies, are to be issued by one of the nine provincial departments for environmental affairs responsible for the area where the material was collected. This adds a layer of complexity as the primary responsibility of these departments is the conservation and

management of the wildlife and flora indigenous to the province. It was found that there is limited, if no capacity to deal with issues related to microorganisms.

As in the case of Brazil, only South African citizens or permanent residents can apply directly for export permits. Any foreign national needs to apply jointly with a South African person. The regulations also state that this material may not be sold, donated or transferred to a third party without written consent by the issuing authority. This stipulation is in conflict with the requirements of the ICNP Rule 30(4) and excludes all bacterial strains to be used as type strains for the description of new species, if it was collected after April 2008.

References

[1] da Silva, M. (2019) Brazil, example of a non-Nagoya Protocol country. *Microbiology Australia* 40, 106–108.

[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.

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[i] Anon (2015) Law N° 13, 123 dated May 20, 2015, Official Journal of the Federal Government of Brazil. (https://absch.cbd.int/database/record/ABSCH-MSR-BR-238963)

[ii] Anon (2001) Provisional Act N° 2, 186 -16 dated August 23, 2001, Official Journal of the Federal Government of Brazil. (https://absch.cbd.int/en/database/record/ABSCH-MSR-BR-202010)

[iii] Anon (2002) The Biological Diversity Act, 2002 No 18 of 2003, The Gazette of India. (https://absch.cbd.int/en/database/record/ABSCH-MSR-IN-208216)

[iv] Anon (2004) No. 10 of 2004: National Environmental Management: Biodiversity Act 2004, Government Gazette, Republic of South Africa.

(https://absch.cbd.int/en/database/record/ABSCH-MSR-ZA-202223)

[v] Anon (2008) No. R. 137 National Environmental Management: Biodiversity Act 2004 (Act 10 of 2004): Regulation on bio-prospecting, access and benefit-sharing, Government Gazette, Republic of South Africa.

(https://absch.cbd.int/en/database/record/ABSCH-MSR-ZA-202222)