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New Legislation and Practice and their Compliance with Nagoya Protocol

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University of Bremen

New ABS Legislations and Practice and their Compliance with the Nagoya Protocol

Results of an international conference held in Bremen, Germany 19/20 September 2018,* Overseas Museum

*This document has been compiled and edited by the author based on presentations made during the conference and discussions of the project team following the conference. All speakers are hereby acknowledged. Any error or misinterpretation of the presentations is the sole responsibility of the author.

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1. Introduction

1.1 Subject of research

Our research focuses on access to genetic resources, traditional knowledge and benefit-sharing under the Convention on Biological Diversity (CBD) of 1992. The Convention protects the diversity of species and habitats, as well as genetic diversity within animal and plant species. The Convention came into force in 1993 and has a membership of 196 states and the EU.[1] It has three objectives: conservation of biodiversity; sustainable use of its components; and the fair and equitable sharing of benefits arising from the utilisation of genetic resources. The purpose of the third objective (benefit-sharing in short) is, in particular, to ensure that the countries that have genetic resources - typically the developing countries - have a share in the resulting uses. Thus, the CBD pursues not only an ecological approach but also a socio-economic objective. The latter is substantiated by the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*. This additional protocol to the CBD was adopted in 2010. It came into force in 2014 and now has a membership of 112 parties including the EU.[2] The focus of the research is on the new regulations and practice on ABS.

The Nagoya Protocol (NP) abrogated public domain access to genetic resources under international law. This has fundamentally changed the legal framework for research and development (R&D) with genetic resources. Obligations were introduced to identify genetic resources (GR) in the field as well as in the laboratory based on cooperation with the countries of origin. These obligations must be transposed into national law by all parties to the Protocol. The European Union (EU) has transposed the NP with Regulation (EU) No 511/2014[3] by introducing compliance standards applicable across the EU, but with the due diligence, a non-NP concept, as its core concept for compliance. A number of EU Member States (MS) have already implemented the EU Regulation implementing the obligations of the NP domestically, including Germany, France and Spain. Similarly, implementation activities continue in many CBD member states, although some states still lack practical solutions for implementation. Many issues remain either controversial or unresolved. Examples include questions about Digital Sequence Information (DSI); scope of provider rights; the role of databases; inadequate definitions of central CBD terminology such as genetic resources, utilization; or incomplete regulations on the necessary proof of compliance with the CBD, e.g. for non-commercial users of GR, as well as the related verification of compliance with international legal requirements.

1.2 Research project[4]

Launched in February 2017 at the University of Bremen, the project titled "*New ABS legislation and practice and their compliance with the Nagoya Protocol*" is dedicated to the implementation of the access and benefit-sharing rules of the Nagoya Protocol in view of selected newly arisen and unresolved issues.

There is still a lack of studies that examine the implementation of the Nagoya Protocol in member states of the CBD, not just descriptively, but also analytically and in a problem-oriented

[1] www.cbd.int.
[2] Ibid, as at 25 January 2019.
[3] Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.
[4] For research questions, objectives, methodology and results of the inception workshop see Kamau, EC et al. (March 2018) New and arising issues in implementing the Nagoya Protocol. Workshop presentations and discussions, Forschungsstelle fuer Europaesches Umweltrecht (FEU), University of Bremen, https://www.jura.uni-bremen.de/uploads/Kamau_ABS/Kamau_et_al._New_and_arising_issues_in_implementing_the_Nagoya_Protocol_Workshop_presentations_and_discussions-1.pdf.

approach. This is partly due to the recent entry into force of the NP in 2014 and partly due to the highly specialized nature of the subject. Although existing work on the interpretation of the CBD and/or the NP can be used as starting research basis, the issues mentioned above, among others, have hardly been dealt with so far. The research project attempts to close this gap. It examines the national legislation in force after the entry into force of the NP and how it is put into practice in terms of what solutions it finds for certain salient issues and whether the solutions are compatible with the standardizations of the NP. The project also examines the extent to which available country experience can provide solutions to similar issues in other countries.

The project is organised in deliverables of 9 workpackages (Annex I) and has set timelines (Annex II). There are 17 country case studies being examined and the EU and 9 general themes by a team of 20 persons (Annex III). This report only covers the results of WP 5, the international conference.

2. International conference

In line with WP 5 an international conference was held at the Overseas Museum in Bremen City on 19/20 September 2018 in order to present the preliminary findings of the ongoing research. The Dean of the Law Faculty of the University of Bremen, Prof. Lorenz Kähler, welcomed the participants and the Senator for Environment, Housing and Transport of the Hanseatic State of Bremen, Dr. Joachim Lohse, officially opened the conference. Conference participants came from 18 different countries (see list of participants, Annex IV and photo gallery at the end).

Photo 1: *Welcoming conference participants, Prof. Dr. Lorenz Kähler*

Photo 2: *Opening the conference, Dr. Joachim Lohse*

Picture 3: *Conference participants outside the Overseas Museum*

Centre (in green tie): *Senator for Environment, Housing and Transport of the Hanseatic State of Bremen*

The presentations were centred on the focus of the project in particular based on the selected case studies and general themes. However, a number of speakers were invited to speak on other themes of relevance to the focus of the project. This report gives detailed results of

presentations on country case studies and only briefly mentions other presentations. However, results of preceding discussions on some of the other themes are accessible online.[5]

Pictures: *Participants in the conference hall*

[5] Ibid.

2.1 Country case studies

Two case studies under the project (Malaysia and Algeria) were not presented and two (India and Norway) have been removed from the list of case studies being examined. Germany is now been examined under the question on ABS approaches of EU and Member States as all questions of relevance for MS that adopt only user measures are covered thereunder.

2.1.1 ABS Approaches of the EU and Member States

The presentation was made by Prof. Dr. Gerd Winter. He highlighted the ABS legal Acts of the EU, discussed the architecture of the provider and user regime in the EU and made an evaluation of the regime established by the *EU Regulation 511/2014*.

The EU is party to the CBD (1994) and the NP (2014). The ABS legal Acts of the EU are *Regulation of EP/Council 511/2014* establishing compliance regime. It focuses on user

obligations and leaves MS free to establish access measures. In addition there are two Commission documents, i.e. Implementing *Regulation of EU Commission 2015/1866* specifying due diligence declaration and the Guidance Document of the EU Commission specifying the scope and core obligations of *Regulation 511/2014*. The latter is not binding upon MS. More Commission Guidance is under elaboration by *Ad Hoc* Working Group focusing on the scope of compliance regime in relation to different sectors (biocontrol, biotechnologies, cosmetics, food and feed, pharmaceuticals, plant and animal breeding, research institutions).

EU Member States that have established provider regime at the moment are France (CBD 1994, NP 2016, IT 2005), Spain (CBD 1994, NP 2014, IT 2004), Bulgaria (CBD 1996, NP 2016, IT 2004) and Malta (CBD 2001, NP 2017, IT 2016). However, only France and Spain have elaborate measures in their new (i.e. post-NP) ABS legislations. In France, the new ABS regime was introduced through insertion of section 3 of Chapter II of Title I of the 4th book of the *Code de l' Environnement*. The law was adopted by the Assemblée Nationale on 20 July 2016. It was followed by the decree on the Access to Genetic Resources and Benefit-sharing (ABS) of 1st July 2017 that specifies the ABS rules. In Spain, the regime on ABS is laid down in the *Natural Heritage and Biodiversity Law (Ley No. 42 de 2007, Patrimonio Natural y la Biodiversidad)*. Law No. 42 de 2007 provides a general article enabling Spain to further develop detailed ABS regulations to implement the CBD and the FAO International Treaty (Article 68). Accordingly, the government can regulate access to GR through a regulation. To comply with the NP, the EU Regulation 511/2014 and to regulate access to Spanish GR, Law 42/2007 was amended through Law 33/2015 (B.O.E 22/09/2015). These amendments are in force since 7 October 2015. Both countries establish access measures that can be summarised in a generalised way as follows: They establish obligations on prior informed consent (PIC) and mutually agreed terms (MAT) but differentiate requirements depending on the purpose of access of GR, i.e. whether for commercial or non-commercial research purposes. It follows that commercial and non-commercial researches are differentiated. Authorisation of access to associated traditional knowledge (ATK) is granted only after consultation with communities and consent of designated local authorities is obtained. Allowed utilisation and benefit sharing are determined and established by authorisation. The current measures do not address the issue of DSI.

In discussing the user regime of the EU Member States Prof. Winter looked at its objectives, competences of the MS, scope and the content of the regulatory regime. The user regime hopes to achieve adherence with ABS requirements of provider states. Implementation is basically left to the MS but the Commission retains some competences, *viz*. in regard to due diligence declarations, approval of collections and best practices. Its material and personal scope covers R&D in EU on GR accessed in countries with access regime, being NP contracting parties. The temporal scope covers GR accessed after the entry into force of the Nagoya Protocol for the Union (12 Oct. 2014). The regulatory content of the regime consists mainly of four components which are meant to ensure compliance: Basic obligations of users, due diligence declaration at research and premarketing stages ("monitoring"), administrative supervision ("checks") and facilitation of compliance monitoring and checks.

A number of critical comments were made concerning the basic orientation of monitoring and checking (i.e. whether it's formal or substantial); in regard to access; allowed utilisation; transfer and reporting and benefit sharing; interaction with provider state authorities; definition of some terms e.g. "access" in relation to bulk commodities; issues concerning DSI; chemical derivatives and large screening.

2.1.2 New legislation and practice in Asia

Two presentations were made covering South Korea and Vietnam by Prof. Jae-Hyup Lee (over video skype) and Dr. Thi Huong Trang Tran, respectively. Both countries have post-NP ABS legislations.

South Korea

South Korea (also referred to as Republic of Korea) is party to the CBD (1995) and its NP (2017) and also to the IT (2009). The *Act on Access and Utilization of Genetic Resources and Sharing of Benefits* (the "Act on Genetic Resources") entered into force in August 2017, the same month she became party to the NP. It implements the obligations of the NP in S. Korea concerning PIC, MAT and benefit-sharing (BS) in regard to terrestrial GR. The Act is based on the bill of 2013 except minor changes and supplementation with provisions on improving national life and promoting international cooperation, as well as an emphasis on processes and procedures related to the NP. The management and regulation of issues concerning marine biological resources were organised around different statues because they fell under jurisdictions of different government institutes. To step-up efficiency in management and effectively deal with policies on marine organisms, the relevant laws,[6] which had been enacted under the Ministry of Land, Transport, and Maritime Affairs, and the Ministry for Food, Agriculture, Forestry, and Fisheries, were re-enacted under one Ministry, the Ministry of Oceans and Fisheries as the Act on Marine Bio-Resources and the Act on the Conservation, Management, and Use of Agricultural Bio-resources in 2016. In addition, the Act on Marine Bio-Resources was amended in December 2016 to include additional articles providing a legal basis for the benefit-sharing and the conservation and management of traditional knowledge related to marine bio-resources. The speaker noted that the ABS obligations of these statutes are only addressed to foreign users.

A number of positive developments have been achieved through these legislations. Apart from establishing PIC, MAT, BS and compliance obligations in an attempt to comply with the NP, the Act on Genetic Resources has, for example, defined the term "utilisation" in Article 2 and established simplified procedures for "non-commercial research purposes" and provided waivers under Article 10-2. However, there are still evident weak points. For example, no concrete activities are identified as utilisation and hence it is hard to use the definition to establish when utilisation commences and when it terminates; the use of the terms "access" and "acquisition" is confusing; and it is not clear how providers' rights and duties relate to GR. In the same vein there is no definition of the terms "commercial" and "non-commercial" and hence no clear parameters of differentiating these types of research. The fragmentation of implementation mandates between different institutions also was identified as a weakening factor. Issues of ATK were likewise mentioned as challenging to deal with because it is difficult for any community in Korea to be recognised as an ILC.

Viet Nam

Viet Nam is party to the CBD (1995) and became party to the NP on 12 October 2014. She is not party to the IT. In 2017 the government issued *Decree No. 59/2017/ND-CP* to implement the ABS provisions of the Biodiversity Law 2008 (Sect. 1, Ch. V) in line with the obligations of the NP. The scope of the legislation extends to all biological resources situated in Viet Nam whether native or exotic used for R&D activities and to derivatives. It also covers GR for food and agriculture including those under Annex I as Viet Nam is not party to the IT. It includes important definition, *viz*. "genetic resources", "access to genetic resources", "traditional knowledge on genetic resources", "provider", "user"/"accessor" and "utilization". The definition of "utilization" is adopted from the NP but Decree 59 does not provide a list of activities that are considered utilisation. The CNA provides a list under a document of guiding implementation of the Decree 59 which will be published soon. A NFP has been established and two CNAs each responsible for different types of GR. Access requirements for foreigners and nationals are provided as well as procedures for the grant of an access licence. Once the access licence is obtained, the licence holder has a right to transfer and export GR abroad. Both monetary and non-monetary benefits

[6] Act on Securing, Management, and Use of Marine Biological Resources and the Act on Conservation, Management, and Use of Agricultural and Fisheries Biological Resources.

may be shared depending on how the GR are used and a formula for sharing has been developed. Checkpoints have been established to enforce compliance.

Decree 59 establishes temporal scope: it does not apply to GR accessed pre 2009, thus for such GR no registration is required. For GR accessed and used after 2009 until 2017 without a licence registration to obtain ABS License is required. Any access to GR post 2017 must be done subject to registration and request for an ABS license. Since the new law was adopted, over 20 requests for access to GR for both commercial and non-commercial purposes have been made. Negotiations are also ongoing for the use of different types of GR: plants, insects, microorganisms.

2.2.3 New legislation and practice in Australia

Australia is party to the CBD (1993) and ITPGRFA (2005) but not to NP. By 1999 *The Environment Protection and Biodiversity Conservation Act* (EPBC Act), a national law including ABS, was established. Australia's goal for the utilisation of its genetic resources was identified in The 1996 *National Strategy for the Conservation of Australia's Biological Diversity*. I.e. to ensure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia. In order to achieve this goal a national enquiry dubbed Voumard Enquiry was held in 1999 which consulted with the environment, indigenous, biotechnology governments and scientific research sector. It also held public hearings and took submissions and included a member of the SCBD on its Advisory Committee along with sectoral expertise. The Voumard Enquiry came up with 71 recommendations to establish a model, best practice, least cost and legally certain ABS system in law. Many of the principles and constructive ideas found in the Voumard Report were included in the Bonn Guidelines of 2002. Following the adoption of the latter in 2002 the Australian national government, upon negotiation with its states and territories through the Council of Australian Governments (COAG), adopted the 2002 *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources*.

Australia's ABS implementation strategy aimed to make Australia a welcome place to undertake R&D on the utilisation of its genetic resources through the drafting of a national ABS law reflecting Voumard's principles, being engaged internationally to influence ABS policy development in the UN system (e.g. by arguing forcefully for the inclusion of the ideas of the Voumard Report in the development of the Bonn Guidelines) and supporting national and international taxonomic institutions.

The innovations of the Australian ABS system includes:

1. **Strengthening legal certainty, reducing transaction and compliance costs**. Australia addressed this by trialing secure 'Electronic Verification' i.e. publication of ABS permits and research reports on the internet, all held behind a secure firewall.

2. **Distinguishing between commercial and non-commercial use of genetic resources** following which a free, simple, one page contractual document for non-commercial research with only 4 conditions was established.

3. **Establishing model contacts** which were published on the internet.

4. **Protecting indigenous land rights & traditional knowledge** over the biological, genetic and biochemical material found on their land and benefits accruing from their use through ABS regulations.

5. **Trialing the concept of 'Trusted Collections'** through which A.I.M.S. (Australian Institute of Marine Science) was granted an ABS exemption as its processes and

procedure already met the objectives of the EPBC's ABS Regulations. This idea was taken up by the EU as registered collections provisions.

Among the 8 states and territory governments Queensland and Northern Territory have ABS regulations in place: *Biodiscovery Act of 2004* and *Biological Resources Act of 2006*, respectively. The former establishes a dual contracting and permitting system but suffers operational failure due to few or no applicants. Queensland has drafted a new ABS Act which was scheduled for release in 2018. The latter is modelled on the national law. It allows for retrospective grant of ABS and respects benefit-sharing rights of indigenous and other private landowners.

Western Australia, South Australia, Victoria, New South Wales and Tasmania have no ABS law in place but rely on a patchwork of land use, environmental and fishing laws. Whilst many of them have stated they have draft laws in varying stages of preparation, all jurisdictions are waiting on the ratification of the Nagoya Protocol by the national government. This process has been slowed down by the impact of resources boom, neoliberal economics and the recent radical conservative politics leading to policy failure.

2.2.4 New legislation and practice in Africa

Three presentations were made covering four African countries: Ethiopia by Ashenafi Ayenew Hailu, South Africa and Kenya in a comparative way by Dr. Evanson Chege Kamau, and Cameroon by Dr. Marcelin Tonye Mahop.

Ethiopia

Ethiopia is party to the CBD (1994), NP (2012) and the IT (2003). Access to GR and ATK and BS is regulated in Ethiopia by the *Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006* and the *Access to Genetic Resources and Community Knowledge, And Community Rights Council of Ministers Regulation 169/2009* thereto. These are pre-NP statutes which Ethiopia to a great extent considers compliant with the NP, but according to the speaker, review is undergoing to achieve harmonisation with the NP. The legislation defines a number of definitions *viz*. "access", "genetic resources" and "derivative" and covers access to *in-situ* and *ex-situ* GR and ATK. PGRFA under Annex I of the IT are not expressly exempted but a facilitated procedure of access for such GR is created using the SMTA of the IT. It is interesting to note that the definition of GR extends the scope of the legislation to genetic information of any genetic material of biological resource having actual or potential value and derivatives of such GR. Access and export of GR and ATK are allowed only subject to PIC of the Ethiopian Biodiversity Institute (EBI) and concerned local community, respectively, and possession of an access permit from EBI. Local state organs that are empowered to conserve GR, however, do not need any permit to access GR or ATK but they are forbidden from sharing the same with third parties and exporting out of Ethiopia without a permit. Foreign users must present a letter from the competent authority of their countries assuring that they will uphold and enforce the access obligations. In spite of this condition, foreigners will only be permitted to carry out research on accessed GR and/or ATK abroad if such research cannot be undertaken in Ethiopia. If this is the case, the institution hosting the research must issue an assurance letter that it shall enforce and observe the obligations related to the access and use. R&D activities planned in the country benefit from a facilitated access procedure. Access procedures for access with commercial and non-commercial purposes are established. The formats of material transfer agreement (MTA) and benefit sharing agreement (BSA) that should be concluded are also available and downloadable. A list of reasons why access may be denied is available. Permit holders must comply with certain obligations which include non-transfer to third parties and change of intent without prior authorisation from EBI, or acquiring intellectual property rights (IPRs) over GR or parts thereof without negotiation of a new agreement with EBI and its conclusion based on the relevant Ethiopian laws. The legislation has sanctions against violations

and the EBI has established a number of measures to enforce compliance with national ABS obligations.

One of the most interesting observations made about the Ethiopian regime is its benefit distribution approach which probably is based on the principle that the ownership of GR shall be vested in the state and the Ethiopian people. Accordingly, 50% of all benefits obtained from GRs go to the communities and 50% to conservation of biodiversity whereas 100% of the benefits from ATK go to the communities. It is also important to mention that even non-registered ATK is still considered as protected by community rights.

South Africa and Kenya

South Africa is party to the CBD (1996) and NP (2014) but not to the IT. Kenya on the other hand is party to all three treaties (1994, 2014 and 2003, resp.). Both countries operate pre-NP legislations the key ones for regulating ABS in S. Africa being the *National Environmental Management: Biodiversity Act, No. 10 of 2004* and *Bioprospecting, Access and Benefit-Sharing Regulations, 2008* and in Kenya *The Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006* in Kenya. Unlike Kenya, however, S. Africa has revised its statutes severally in an effort to comply with the NP through the Act amendments of 2009 and 2013 and new Regulations of 2015. As a result there is more clarity concerning ABS requirements for access and use of S. African GR and ATK. For example, the terms "bioprospecting", is defined and used as an important determinant of the application of ABS legislation, its geographical, material and personal scope as well as the trigger for sharing benefits. The material scope would include both genetic and biological resources as long as bioprospecting is intended. Of course it is difficult to establish how "bioprospecting" differs from the NP definition of "utilisation" and creates confusion in particular because the term "utilisation" is also used in the regime. Activities that would include bioprospecting are also provided. The term "genetic resources" is also defined and was expanded in the revisions of 2013 to include information on GR. Types of R&D are also differentiated and consequently different requirements for ABS and procedures established. Facilitation of some types of research and the possibility of integration of permits for access and export for bioprospecting are also provided. The regime, however, still suffers from a number of weaknesses. For instance, there are so many scattered bits of statutes which make it burdensome for an applicant to easily understand the regime, or initiate his/her undertaking with certainty of having full knowledge of its operation. The appeal sections of the Act were also appealed and it is not clear which complaint channels now exist for an aggrieved applicant.

De jure situation in Kenya has not changed. How existing laws describe the requirements and procedures as well as suggestions for improving the regime can be read in Kamau/Winter 2009 (London: Earthscan). Theoretically, therefore, the regime still suffers from unclarity and uncertainty caused by overlapping mandates of the state agencies having jurisdiction to regulate ABS and complex procedures. The good news for users is that the *de facto* functioning of the regime at the moment is more conducive as a number of practical measures have been initiated by the relevant agencies to combat weaknesses that ensue from the legal architecture. That includes the establishment of an *ad hoc* ABS permitting committee (ABSpc) of the different stakeholders which has helped cut the application duration tremendously and the publication of an ABS tool-kit. The weakness of the ABSpc approach lies in the fact that it is not supported by law and thus creates a new ground for legal uncertainty. These and other weaknesses are being proactively confronted currently and there is even hope of creation of a one-stop shop.

Cameroon

Cameroon is party to the CBD (1995), NP (2017) and the IT (2005). There is no stand-alone law for regulation of ABS and a number of instruments are applied, mainly the *Forestry Law, 1994*, the *National ABS Strategy, 2012*, and the *National ABS Action Plan of 2016*. As ABS cases are

addressed on a case by case basis, a number of other sectoral instruments may apply in practice, *viz*. the *Environmental Framework Law, 1996* and the *Guidelines of the Ministry of Research* for the acquisition of research permits. There is an ongoing process to implement the Nagoya Protocol and a draft stand-alone law– *Loi Relative à l'Accès aux Ressources Génétiques et aux Connaissances Traditionnelles Associées et au Partage Juste et Equitable des Avantages Découlant de leur Utilisation* – a draft implementing decree, draft PIC, MAT and model ABS permit have been produced. The draft ABS law defines some important terms such as utilisation, genetic material, genetic resources, customary right, valorisation of research results and vulgarisation of research results. The draft raises a number of questions concerning compliance with the NP e.g. in respect to legal certainty, clarity and transparency in line with Article 6 (3) (a). The law will apply to access to GR and ATK and BS and deals with such issues as new uses (i.e. establishes temporal scope), transfer to third parties and transboundary cooperation. Interestingly, the draft ABS law and the draft implementing regulations address the application of intellectual rights tools to the products or processes derived from the utilisation of Cameroon's biological and GR and ATK. The prospective regime addresses the role of the state in ensuring that the application of either existing IPRs tools or a future *sui generis* system (as another implementing regulation) ensure the protection of the rights of local communities. The draft also defines access procedures and the roles of relevant national authorities. Where access involves ATK the applicant will be required to comply with the local communities PIC process and their biocultural protocols, but the PIC is issued by the competent authority. A facilitated access procedure for non-commercial research is established with exemptions. Access to Annex I PGRFA is exempt with a simple declaration to the competent authority and following consultation between the authority and the Ministry of Agriculture. Compliance measures focus on ensuring adherence by users to own measures.

2.2.5 New legislation and practice in South America

Four presentations covering Costa Rica, Ecuador and Peru, Argentina and Brazil were made by Prof. Jorge Cabrera, Dr. Maria Victoria Cabrera Ormaza, Dr. Luciana Carla Silvestri and Lilian Massini Mozini, resp.

Costa Rica

Costa Rica is party to CBD (1994) and IT (2006) but not to NP. She is one of the first countries to regulate ABS when few examples and no lessons were available from the implementation of the regime. *The Biodiversity Law* (BL) was enacted in 1998 and dedicated several provisions and chapters to what form the ABS regime together with *Regulations for Access to In-situ Genetic Resources of 2003* and *Regulations on Access to Ex-situ Genetic Resources of 2007*. Of relevance as well are the post-NP Memorandum of Understanding with the IT Focal Points of 2015 towards a synergistic implementation of both ABS systems, addressing concerns and grey areas, and Regulations on the procedures for imposing sanctions for the violation of the BL of 2016, albeit the latter focuses on a pre-NP provision. The scope of the regime extends to all GR biochemical resources of both exotic and native species but excludes human GR. The law provides special access regime for public universities but only Costa Rica University made use of it in 1999 before the deadline for the offer expired. Access for research by such research is granted by the Biodiversity Commission. The issue of DSI and utilisation of bulk resources is not explicitly mentioned, but permits and PIC/MAT may address them on a case by case basis. A number of key definitions are provided *viz*. access, bioprospecting, PIC and TK. Non-commercial research is considered as a different category of activity but in practice requirements and procedures are not different. No particular requirements are imposed for access under this category except the obligation to come back and renegotiate in case of change of intent. In such cases further R&D must stop first although it is not clear what triggers a change of intent. Commercial (bioprospecting access) is defined as "direct intention" to commercialize but there are no criteria of what constitutes "direct intention". The rights of provider State are extended to future uses of materials derived from the samples (extracts, fractions) after the permit expires through

the public domain concept. For such use a new permit, PIC and MAT are necessary. The regime provides procedures for access and leaves negotiations for BS mainly to providers and users – except for a few minimum conditions. Regulations on procedures for imposing sanctions have improved compliance with national law albeit there are no cases to confirm this assumption. There are no measures to enforce compliance with laws of other provider countries. Checkpoints have been established but their functioning is not free of flaws. There are still challenges with the ratification of the NP and incorporation of some of its innovative provisions, including on non-commercial research and scope. Costa Rica has issued about 550 permits mostly for basic research but also for bioprospecting (commercial research) and, for the first time in 2017, for economic development.

Ecuador and Peru

Ecuador and Peru are party to the CBD (1993), NP (2017, 2014) and the IT (2004, 2003), resp. and operate pre-NP regimes with different sets of complementary regulations (of an administrative and legislative nature). They have also ratified the ILO Convention 169 as indigenous issues are crucial in both countries. In addition, they are members of a sub-regional ABS regime, *Common Regime on Access to Genetic Resources of the Andean Community of Nations, Decision 391 of 1996*. Ecuador did not have its own regulation until 2011 when *Executive Decree No. 905* was adopted. The Decree reaffirms the spirit and concepts contained in Decision 391, adds definitions e.g. "bioprospecting", establishes the CNA and other relevant institutions, further elaborates procedure for obtaining access to GR and intangible components thereto and sets conditions for negotiation of an access agreement. Through the Ministerial Agreement 034 of 2015 rules were adopted for the conclusion of the so-called frame access agreements exclusively for research purposes by natural or legal persons with mandatory participation of a national support institution. The permit for such research is valid for 3-5 years. There is no definition of non-commercial research but a contract MAE-DNB-2016-0045 has been developed to authorise scientific research. Access for scientific research and for commercial purposes is dealt with by different bodies.

The regime regulating ABS in Peru was adopted in 2002 and is titled *Statute No. 27811 (2002): Regime for the Protection of Collective Knowledge of Indigenous Communities derived from Biological Resources* and makes reference to Decision 391. It provides for license agreements for the use of collective knowledge and requires a contribution of at least 10% of benefits from commercial use of ATK to be deposited in a fund for the Development of indigenous peoples. In addition *Resolution No. 087-2008 of the Ministry of the Environment: Regulation on Access to Genetic Resources* establishes mandates of the bodies with jurisdiction to regulate access with different agencies for different resources. The Ministry is the CNA and makes regulations. Besides, *Resolution 060-2016-SERFOR (2016)* has been issued under Statute No. 27811 (2002) with guidelines for issuing authorisations for scientific research on wild flora and fauna (SERFOR). Instituto Nacional de Innovación Agraria is the CNA. Peru has issued an IRCC.

As a general conclusion for Ecuador and Peru, it is notable that the inconsistencies between Decision 391 and the NP are reflected in relevant national laws of member countries. Decision 391 being the main legal basis for these laws mirrors its approach e.g. of absolute state ownership and control over GR and power to impose requirements, including on BS, instead of equity and fairness on them. Until now there is no experience on granting access to GR for commercial purposes and rules for the distribution of benefits are contested.

Argentina

Argentina is party to the CBD (1995), NP (2017) and the IT (2016). She is a federal State of 23 Provinces and 1 Federal district. According to the Constitution, provinces have the original ownership over natural resources including GR. Whilst the federal government has the power to set minimum environmental protection standards, provinces have mandate to set standards to

complement the government standards. Provinces grant PIC and negotiate MAT. There is no ABS law and relevant issues, e.g. on export of GR and scientific research, are regulated at the national and provincial levels through different pre- and post-NP administrative decisions. Only eight provinces though have ABS relevant legislations. These legislation do not use a harmonised approach: some, for instance, include biological resources to the scope and others not; derivatives are not always included. Legal frameworks do not include useful definitions or mention DSI, take a provider side perspective, apply same procedures for commercial and non-commercial research and generally have no measures for TK protection. There are also no checkpoints. The development of ABS law setting minimum standards have been mandated but little has happened in this area causing a setback in implementation of ABS in Argentina. The development of a national legislation under a GEF/UNDP project is ongoing but the current draft already shows numerous weaknesses.

Brazil

Brazil is party to the CBD (1994), IT (2006) but not to the NP. Brazil has a post-NP legislation, the *Brazilian Biodiversity Law, Federal Law No. 13,123/2015 of 20 May 2015* (BL). It entered into force on 17 November 2015 thus repealing the old law, *Provisional Measure No. 2,186/2001 of 23 August 2003*. It is regulated by *DECREE Nº 8.772, of 11 May 2016*. The Biodiversity Law provides for access to genetic heritage components, protection and access to ATK and the fair and equitable sharing of benefits for conservation and sustainable use of biodiversity. The term "genetic heritage" means information of genetic origin from plants, animals, microorganisms or species of other nature, including substances derived from the metabolism of these living beings. Hence it covers a broad spectrum of research activities and also reaches to utilisation of information from genetic sequences based on Brazilian genetic heritage published in public databases. Exempted from its scope are human genetic material, microorganisms which are not considered national genetic heritage and plant and animal species introduced in the country that do not form spontaneous populations and that have not acquired own distinctive features in the country. It covers land and marine territory under the jurisdiction of Brazil including its continental shelf and exclusive economic zone. Some important definitions are considered. For example, access to the genetic patrimony is defined as research or technological development applied to specimen of the genetic patrimony which would be understood as covering R&D on bulk resources. Competent authorities are established. The Genetic Heritage Management Council (CGEN) is the ABS competent national authority responsible for, among others, the elaboration of sublegal rules, the establishment of a database on registrations, authorisations and notifications, decisions on appeals against decision of competent authorities, receiving registrations, provision of authorisations and receiving the prior notification and agreement concerning the commercial exploitation of final products and reproductive material. CGEN is the only authority with mandate to give consent for "access" (R&D). The authorisation to collect samples is competence of environmental institutions or private owners. Other entities that participate in ABS are the National Council for Scientific and Technological Development (CNPq) of the Science, Technology, Innovation and Communication Ministry (MCTIC); Chico Mendes Institute for Biodiversity Conservation (ICMBio); ILCs and private land owners. The legislation establishes requirements and procedures for access to genetic patrimony and ATK with a supervisory structure which is considered by the Brazilian law as in principle simplified for access for any R&D. Only at the stage of commercial exploitation of final products or reproductive material tighter control is established. Foreign researchers cannot access alone and must cooperate with local natural or legal persons. For non-commercial or commercial R&D purposes registration prior to access to the genetic patrimony must be done. An electronic database called SisGen has been created through which registration must be done. Activities subject to registration are listed and include shipment of GR for purposes of access. In addition, a MTA must be concluded between the national and foreign natural or legal persons with clauses *inter alia* to allow or disallow further transfer. The PIC and consent of ILCs and private persons must be obtained; for the former entity if the GR is traditional and local. For purposes of

economic exploitation, notification is required. For access involving collection of genetic heritage in certain territories e.g. in national security or maritime areas prior authorisation is required. Other permits may be required in addition e.g. under CITES (issued by IBAMA, Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis). Benefits can be monetary or non-monetary. A benefit-sharing obligation is only triggered by economic exploitation of finished product(s) or reproductive material (sale of final products or materials derived from the exploitation of national genetic heritage or ATK). Benefits are paid into a benefit fund, National Fund for Sharing Benefit ("FNRB"), created under the jurisdiction of the Brazilian Ministry of the Environment in order to support GR, ATK and promote the sustainable use of GR. A formula of sharing benefits has been established depending on whether the provider is the State, ILCs or collections. Small companies and suppliers (with an annual gross income of US$ 111,000 to US$ 1,11 million / year) are exempted from sharing benefits.

3. General project themes

3.1 Experiences of researchers with new requirements

Following the adoption and entry into force of the NP it is expedient to examine how users of GR, in particular for non-commercial research, are coping up with the regulations of access from provider countries and how these regulations impact on foreign collaboration. Dr. Romano Mwirichia Kachiuru and Prof. Erwin Beck presented on their experiences in Kenya and Ecuador and Peru, respectively. As already mentioned, both countries operate pre-NP legislations, but some reorganisation in varying ways has taken place in an attempt to line up the regimes with the NP. As reported by the speakers, users of GR continue to experience many challenges while requesting for access even with post-NP applications. More information on challenges in Ecuador and Peru can be obtained online from the inception workshop report document.[7] The legal situation in Kenya is described in Kamau/Winter (eds.), *Genetic Resources, Traditional Knowledge and the Law* (Earthscan: 2009) and Kamau/Winter/Stoll (eds.), *Research and Development on Genetic Resources* (Routledge: 2015).[8]

3.2 Experiences and challenges with monitoring value chain

China Williams presented on ways of monitoring value chain in connection to access to and transfer of GR and the experiences gained by RBG Kew as well as challenges faced. The key messages of this report can be obtained online from the inception workshop report document.[9]

3.3 Due diligence obligation and compliance

Thomas Greiber presented on the experiences of the German CNA with the implementation of due diligence obligation whilst Prof. Dr. Christine Godt and Markus Buchardi looked at what this concept can learn from the due diligence clause as used in other policy areas. The reports preceding the conference can also be obtained online from the inception workshop report document.[10]

3.4 Rights over digital sequence information

Dr. Chris Lyal presented on the current debate concerning the rights over genetic resources and digital sequence information (DSI). Technological development and sophistication has raised concerns about the possibility of circumventing ABS requirements and procedures and thus promoting a new form of biopiracy, "digital biopiracy". These concerns were brought before the

[7] Supra note 4.
[8] Reports of projets preceding these publications can be obtained online from the FEU website at https://www.jura.uni-bremen.de/institutes/research-centre-for-european-environmental-law/new-abs-legislation/ (navigate under "ABS").
[9] Supra note 4.
[10] Ibid.

CBD COP 13 and MOP 2 following which a number of processes have been initiated including fact-finding and discussions in different technical groups (AHTEG, SBSTTA). In addition, parallel discussions were initiated by and in various relevant international organisations and bodies, *viz*. ITPGRFA, WHO (PIP), UNCLOS and WIPO. The outcomes up to date were discussed in the recent COP-MOP meetings in Sharm El-Sheikh, Egypt (17-29 November 2018). The presentation was centred on a number of key questions: What is DSI? Does DSI fall under the sovereign rights of the provider country of the GR? Can the use of DSI fall under CBD/NP? Can DSI be incorporated into current ABS model? If DSI did fall under the NP, how would it be implemented? These questions are being interrogated further and, in addition, a synthesis of the outcome of the discussions during COP-14 is being prepared.

3.5 Temporal and material scopes of genetic resources

Marie Schloen presented on the rights over GR and their temporal and material scopes. The discussion centred on the challenges ABS obligations cause when applied to the innovation process in agricultural breeding. This is aggravated by the fact that contractual obligations persist throughout the breeding process. The ongoing research upon which the presentation was based tries to examine how cut-off points can be established for such obligations, and hence for provider rights, in breeding sector as an antidote. Following a number of considerations, including the current architecture of ABS and the impacts on and consequences for the breeding sector, a number of possible cut-off points were suggested. These are available in the online inception workshop report document.[11]

3.6 Contracts and ABS

Morten Walløe Tvedt presented on "Essential shifts in thinking about ABS contracts". The gist of the presentation was how to make ABS contracts work. In a nutshell, preliminary planning of the necessary steps from access to consequences and antidotes for contractual violation, avoidance or minimisation of ambiguity, use of enforceable legal language *inter alia* are key issues to consider. Details of the proposed solutions can be read in Tomme Rosanne Young and M. W. Tvedt, "*Drafting Successful Access and Benefit-sharing Contracts*" (Brill: 2017).

4. Other themes of relevance

4.1 Registration of collections under Regulation (EU) 511/2014: Experience of DSMZ

Dr. Amber Hartmann Scholz, in a presentation prepared together with her colleague Dr. Hilke Püschner, presented on the experiences of DSMZ with the registration process of collections under the EU Regulation 511/2014. According to Article 5 of the Regulation, "The Commission shall establish and maintain a register of collections within the Union …" which "shall include the references of the collections of genetic resources, or of parts of those collections, identified as meeting the criteria set out in paragraph 3". Accordingly, "… a collection shall demonstrate its capacity to:

(a) apply standardised procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third persons for their utilisation in line with the Convention and the Nagoya Protocol;

(b) supply genetic resources and related information to third persons for their utilisation only with documentation providing evidence that the genetic resources and the related information

[11] Ibid.

were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and, where relevant, with mutually agreed terms;

(c) keep records of all samples of genetic resources and related information supplied to third persons for their utilisation;

(d) establish or use unique identifiers, where possible, for samples of genetic resources supplied to third persons; and

(e) use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.

Member States are obliged to carry out regular verification to ascertain that these criteria are maintained.

Having fulfilled the requirements of the EU Regulation, DSMZ recently became the first collection in the EU to be included in the register of collections and was officially approved by the BfN in mid-April 2018. Dr. Scholz explained how DSMZ fulfils EU users' due diligence requirements (Article 4) through the collection and, conversely, how the institute works with more than 50 provider countries to verify their Nagoya-related documentation, and the lessons learned from these efforts.

4.2 Report of the SCBD on status of implementation of the Nagoya Protocol

Beatriz Gomez of the SCBD made a presentation by video skype on the implementation process of the NP by Parties and non-Parties and what progress has been made this far. The report upon which the presentation was based is annexed to this document (Annex V).

4.3 Status of implementation of the Nagoya Protocol at the ITPGRFA

Francisco López presented on the status of implementation of the Nagoya Protocol (NP) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The ITPGRFA has the same objectives as the CBD but it regulates all plant genetic resources for food and agriculture (PGRFA). Both instruments are at the same legal level, but the ITPGRFA is a specialised instrument. Indeed, Art. 4 of the NP leaves the door open for the ITPGRFA and other specialised agreements to be recognized also in the future. The ABS system of the ITPGRFA is regulated in Section IV as the Multilateral System of Access and Benefit-sharing (MLS). It comprehends in a mandatory way a list of crop and forages (listed as genera and species) included in its Annex I, which are in the public domain and under the direct control of the Contracting Party. In this case, the NP does not apply to ABS in regard to the said PGRFA. However, the NP and the ITPGRFA must be implemented in a mutually supportive manner (Art. 4.3 NP) at global and national levels. The Governing Body (GB) of the ITPGRFA emphasises the necessity for close cooperation and coordination between both instruments and underlines the need to promote coherence and mutual supportiveness between them. In that spirit a new Memorandum of Cooperation with the CBD was adopted in 2018 that foresees institutional cooperation through numerous undertakings, including workshops and other events, exchange of information etc. The first workshop on the harmonious and mutually supportive implementation of these instruments at the national level was held in June 2014 in Rome and was jointly organized by the Secretariats in partnership with the ABS Capacity Development Initiative and Biodiversity International. It was attended by IT and NP focal points from each of the participating countries. The workshop made a number of recommendations e.g. the need to repeat the workshop with expanded participation; continued support of national implementation efforts by the Secretariats and partner institutions; develop information and training materials from the process to support similar future initiatives; and consider similar model for regional meetings.

The national reports sent to the ITPGRFA give a positive assessment of the implementation of ABS for PGRFA with the 2015 – 2018 statistics indicating a high membership to the ITPGRFA and number of permits issued as well as Standard Material Transfer Agreements (SMTAs) concluded. The number of genetic resources available for exchange through the MLS of the ITPGRFA is impressive standing at 2.3 million PGRFA. The Treaty's Benefit-sharing Fund (BSF) has done three project cycles since 2010, with the fourth one launched in 2018. The BSF has supported projects in over 55 developing countries so far. However, the ITPGRFA is working on further improving the system. At the request of the Fifth Governing Body, opinions and advice generated by the *Ad Hoc* Technical Advisory Committee on the MLS and the SMTA were made available by the Secretariat in a booklet downloadable at http://www.fao.org/3/a-i4578e.pdf. In addition, a new tool to assist national-level policy actors to identify appropriate measures to implement the MLS within their country has been published online. It deals with questions such as how to deal with requests for purposes that are (or may be) beyond the scope of the MLS and how to ensure legal space for the implementation of the MLS.

The current critical challenges for the ITPGRFA are: to continue supporting smallholder farmers; establishing a strong financial and operational footing; supporting the implementation at the national level in collaboration with other partners; and working towards achieving universal membership. In this context, it is important to highlight the following processes: the policy review of the MLS of ABS in order to enhance it; get stable and predictable funding including through review of its Funding Strategy; the implementation of the Global Information System (GLIS); the identification of options for the implementation of Farmers' Rights; and the consideration of new and emerging issues like Digital Sequence Information (DSI) / Genomic Sequence Data (GSD).

4.4 Implementation of the NP in ACP countries, progress and challenges

Dr. Andreas Drews presented on the implementation of the NP in ACP countries and progress made as well as challenges faced. The ABS Capacity Development Initiative of the GIZ has been active in building the capacity of ACP countries to implement the CBD and subsequently the NP since 2007. The presentation focused on the status of implementation of the 10 African partner countries of the Initiative. According to the current status 8 of them have ratified the NP while the bill of ratification of 1 of the countries has been approved. Debate on ratification is ongoing in 1 of the countries. Almost all of them have institutional frameworks in place with all having designated national focal points, 9 having an ABS Committee although 1 is *ad hoc* and 1 research-oriented. Concerning CNAs 6 countries have established them, 1 is under development and 3 have none. Lastly, in 9 countries there are either new laws/regulations in place or old ones in the review process, or new ones are being developed. In 1 country there is no regulatory framework on ABS. Among the challenges experienced are the following:

- The countries are different in their governance / tenure structures and require custom-fit support to achieve effective ABS implementation- one-size-fits-all approach cannot apply
- Insufficient capacities and experiences e.g. in negotiation of ABS agreements, understanding R&D/IP/business models and value chains in sectors and developing valorization strategies for GR, biological resources and ATK
- Top down mindset due to lack of support schemes for applied R&D and SME product development causing dependence on outside bioprospectors
- Institutional deficiencies caused by overcharged officers, fluctuation of personnel and barely any cooperation between public and private sector

5. Reflections and cross-cutting issues

Based on case study presentations some positive as well as negative observations can be made. There are considerable efforts being made by countries to comply with the obligations of the Nagoya Protocol. They include putting in place institutional frameworks with clear mandates. Vietnam, for instance, has designated two CNAs for different types of GR and Ecuador different institutions for different types of research. The duration for research permits which used to have a validity of maximum 1 year in Ecuador can now have a duration of 3-5 years. In several countries attempts have been made to come up with clear definitions, differentiate between commercial and non-commercial research mainly through establishment of criteria for the non-commercial research and utilising activities, facilitating non-commercial research by establishing a separate access procedure and streamlining procedures. Some countries establish a clear formula for sharing benefits e.g. Brazil, SA and Ethiopia. The latter's formula e.g. is very pro conservation and pro communities and a good example of how countries can implement Articles 9 and 5.5 NP even though it is pre-NP.

There is much nevertheless still in need of being fixed. It was even observed that some of the flaws in the new legislations and practice have arisen in the attempt to comply. Several observations concerning the implications of implementation were made by Prof. Dr. Gerd Winter, Thomas Greiber, Dr. Maria Victoria Cabrera Ormaza and Prof. Jorge Cabrera Medaglia during the conference on 19/20 September 2018 and by the project team members during their meeting on 21 September 2018. The key ones are listed below in bullet points:

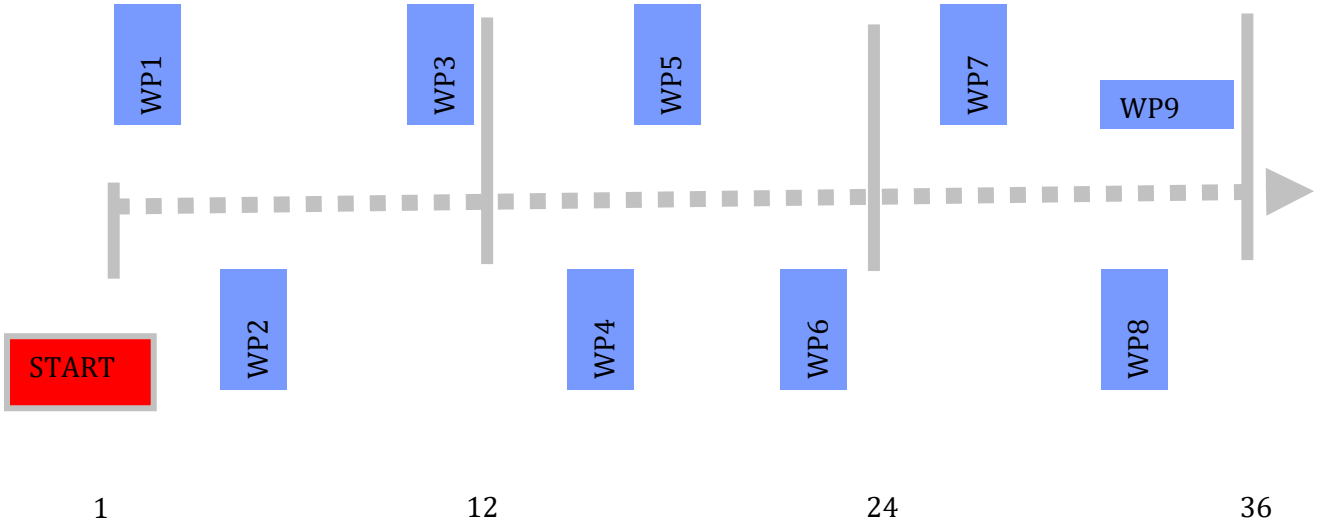
- General observation: access seems to have become more complicated, e.g. Ecuador
- Legislations:
  - Multiple procedures, e.g. Kenya
  - Fragmented provisions through revisions, e.g. S. Africa
- Scope: unclarity cause legal uncertainty for all sides
  - E.g. material scope and temporal scopes of already accessed materials
  - E.g. how far provider rights extend – answers found at times in definitions, MTAs
- No clear facilitation for non-commercial research
  - No consensus on criteria
  - Trend to facilitate, but there are still concerns about the grey areas
- Difference in understanding of terms: e.g. legal certainty; transparency; checkpoints (e.g. in line with Art.17 NP *vs*. national checkpoints); DSI (data, information, knowledge); commercial, non-commercial research, access
- Transparency
  - Unconventional allocation/claim of rights, no clear articulation in national legislation of user obligations *vis-à-vis* such rights, e.g. Ethiopia
  - Claim of rights in vacuum, e.g. administrative practice without supporting law, e.g. Kenya
  - Practice *vs.* law: at times conflicting, e.g. Kenya
  - What's the motivation of legislations?: block/hinder?; protect? (e.g. Ethiopia)
- Procedures
  - Multiple agencies, e.g. S. Korea, Kenya
  - Bureaucratic monsters, e.g. Kenya, Argentina

  - Described by law, but non-existent in practice, e.g. S. Africa
- Development of legislations
  - At times no focus on compliance
  - Outside influence (e.g. of scientists in other countries) in disregard of internal realities, e.g. movement of western scientists copied in Brazil; movement of scientists in Brazil copied in Argentina; or by donor requirements, e.g. Viet Nam
- Compliance
  - No user measures in legislations of traditional provider countries

Annex I: Deliverables (WPs)

	2017			2018				2019			2020
WP	FEB-APR 3	MAY 1	JUN-DEC 7	JAN 1	FEB-APR 3	MAY-JUN 2	JUL-DEC 6	JAN 1	FEB-JUN 5	JUL-DEC 6	**JAN 1**
I. QAs + Lit. review,	X										
II. Incept. Workshop		X									
III. Case studies examination			X	X							
IV. Data org., evaluation					X						
V. Int. conference.						X					
VI. Drafting							X				
VII. Review workshop								X			
VIII. Revision, submission									X		
IX. Publication										X	**X**
36 Contdown !	**33**	**32**	**25**	**24**	**21**	**19**	**13**	**12**	**7**	**1**	**0**

Annex II: Timelines



Annex III: Project team and case studies and general themes under examination

Head of project *Dr. Evanson Chege Kamau*

Table 1: *Experts undertaking case studies*

	Names	**Case studies**
1.	Prof. Jorge Cabrera Medaglia	Costa Rica
2.	Dr. Marcelin Tonye Mahop	Cameroon, Algeria, France
3.	Ba Tu Nguyen; Dr. Tran Thi Huong Trang	Vietnam
4.	Prof. Jae-Hyup Lee	South Korea
5.	Prof. Maria Victoria Cabrera Ormaza	Ecuador, Peru
6.	Dr. Luciana Carla Silvestri	Argentina, Spain
7.	Lilian Massini Mozini	Brazil
8.	Geoffrey Burton	Australia
9.	Ashenafi Ayenew Hailu	Ethiopia
10.	Dr. Evanson Chege Kamau	Kenya, South Africa, Malaysia

Table 2: *Experts investigating general themes*

	Names	**Theme**
1.	Prof. Gerd Winter and Dr. Evanson Chege Kamau	ABS approaches of EU and Member States
2.	China Williams	Rights over genetic resources and ways of monitoring value chain
3.	Prof. Christine Godt	The due diligence clause interpreted against the background of its use in other policy areas
4.	Dr. Chris Lyal	Rights over genetic resources and digital sequence information: Current debate
5.	Prof. Erwin Beck	Post Nagoya Protocol experiences for basic research in Ecuador, Peru
6.	Marie Schloen	Rights over genetic resources and their temporal and material scopes: Possible cut-off points
7.	Thomas Greiber	Experience of BfN with implementation of due diligence obligation in Germany
8.	Dr. Romano M. Kachiuru	Cooperation with foreign scientists under new ABS regulations – Case of Kenya
9.	Morten Walløe Tvedt	Essential shifts in thinking about ABS contracts

Annex IV: List of conference participants

ABS CONFERENCE of THE UNIVERSITY OF BREMEN

19/20 September 2018

Venue: Überseemuseum, Bahnhofplatz 13, Bremen

Surname	First name	Title	E-Mail	Biodata / Affiliation	Country
Bartholomé	Sarah	Ms.	bartholome@uni-bremen.de	PhD Candidate, International Research Training Group "INTERCOAST", University of Bremen	Germany
Beck	Erwin	Prof.	Erwin.Beck@uni-bayreuth.de	Professor Emeritus, University of Bayreuth; Chair, ABS WG of the Senate Commission on Biodiversity Research of the DFG	Germany
Behrens	Lüder	Dr.	mailto:behrens@boehmert.de	Patent lawyer, European Patent and Trademark Attorney	Germany
Biber-Klemm	Susette	Dr.	susette.biber-klemm@syntrans.ch	MAE Syntrans - Synthesis by Transfer, Manager; Former coordinator of the program ABS of the Swiss Academy of Science, Basel	Switzerland
Boensch	Alexandra	Ms.	Alexandra.boensch@bdp-online.de	Staff lawyer, German Plant Breeders' Association	Germany
Burchardi	Markus	Mr.	markus.burchardi@uni-oldenburg.de	Research assistant/PhD candidate, Department of International and European Economic Law, Carl von Ossietzky University of Oldenburg	Germany
Burton	Geoff	Mr.	geoff@jeanshannon.com	Principal Consultant, Genetic Resources Management, Jean Shannon and Associates. Visiting Senior Research Fellow, UNU-IAS, Tokyo, Japan	Australia
Cabrera Ormaza	Maria Victoria	Prof.	marvic.co@gmail.com	Law Professor, Universidad Espiritu Santo-Ecuador	Ecuador
Drews	Andreas	Dr.	andreas.drews@giz.de	Manager, ABS Capacity Development Initiative,	Germany

				Division Climate, Environment & Infrastructure, Department GloBe (Sector and Global Programmes), GIZ	
Engelmoer	Daniel	Dr.	Daniel.Engelmoer@bayer.com	Patent Scientist, Bayer - Crop Science, Monsanto Holland BV, Bergschenhoek	The Netherlands
Galbiatti Silveira	Paula	Ms.	galbiatt@uni-bremen.de	PhD Candidate, FEU, University of Bremen	Germany/Brazil
Godt	Christine	Prof.	Christine.godt@uni-oldenburg.de	Professor of law; Jean-Monnet Chair of International and European Economic Law, Carl von Ossietzky University of Oldenburg	Germany
Gomez	Beatriz	Ms.	beatriz.gomez@cbd.int	Associate Programme Officer, Scientific and Policy Support, Secretariat of the Convention on Biological Diversity	Canada
Greiber	Thomas	Mr.	Thomas.Greiber@BfN.de	Legal Officer, Federal Agency for Nature Conservation, Bonn – "Competent National Authority for the Nagoya Protocol"	Germany
Hailu	Ashenafi Ayenew	Mr.	ayenewashenafi2007@gmail.com	Director, Genetic Resources Access and Benefit Sharing Directorate of the Ethiopian Biodiversity Institute, Addis Ababa. National Focal Point	Ethiopia
Hartman Scholz	Amber	Dr.	amber.h.scholz@dsmz.de	Scientific Deputy Director, Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures	Germany
Hein	Christian Daniel	Mr.	christian.daniel.hein@uni-oldenburg.de	Student, University of Oldenburg, Faculty of Law and Economics	Germany
Hoernschemeyer	Thomas	PD Dr.	thomas.hoernschemeyer@senckenberg.de	Coordinator, Biodiversity Informatics, Senckenberg Society for Nature Research (SGN), Frankfurt/Main	Germany
Jabs	Thorsten	Dr.	thorsten.jabs@basf.com	Senior Counsel, Global Intellectual Property – European Patent Attorney, Patentassessor	Germany
Kachiuru	Romano Mwirichia	Dr.	rkachiuru2000@yahoo.com	Senior lecturer of microbiology, University of Embu, Kenya	Kenya

Kamau	Evanson Chege	Dr.	echege@uni-bremen.de	Senior research fellow (in law), University of Bremen	Germany/Kenya
Körner	Talline	Ms.	koerner.talline@gmail.com	Law student, University of Bremen; Student Research Assistant, Research Center for European Environmental Law (FEU)	Germany
Laugs	Karin	Ms.	k.laugs@rijkzwaan.nl	Company lawyer, Rijk Zwaan Zaadteelt en Zaadhandel B.V.	The Netherlands
Lee	Jae-Hyup	Prof.	jhyup@snu.ac.kr	Law Professor, Seoul National University	South Korea
Lopez	Francisco	Mr.	Francisco.Lopez@fao.org	Technical Officer, International Treaty on Plant Genetic Resources for Food and Agriculture	Italy (FAO, Rome)
Lyal	Chris	Dr.	C.lyal@nhm.ac.uk	Scientific Associate, Department of Life Sciences, The Natural History Museum, London	United Kingdom
Tonye Mahop	Marcelin	Dr.	tonye2169@gmail.com	Research Fellow, University of Leeds, UK; Legal consultant on ABS, IPR	Cameroon / United Kingdom
Martinez	Sylvia	Ms.	sylvia.martinez@unibas.ch	University of Basel, Department of Environmental Sciences – Botany, Swiss Plant Science Web, Executive Secretary	Switzerland
Medaglia	Jorge Cabrera	Prof.	jorgecmedaglia@hotmail.com	Professor of Environmental Law, University of Costa; Legal adviser, National Biodiversity Institute	Costa Rica
Mozini	Lilian Massini	Ms.	lmozini@ambiente-global.com	Environmental lawyer, legal consultant	Brazil
Neumann	Dirk	Mr.	neumann@snsb.de	Bavarian Natural History Collections, Bavarian State Collection of Zoology, Section Ichthyology / DNA-Storage	Germany
Ngwerume	Charlene	Ms.	cngwerume@googlemail.com	Student, University of Oldenburg, Faculty of Law and Economics	Germany
Oelschlägel	Birgit	Dr.	birgit.oelschlaegel@tu-dresden.de	Research Associate at Technical University Dresden, Faculty of Biology, Institute for Botany.	Germany
Palmetshofer	Alois	PD Dr.	a.palmetshofer@uni-wuerzburg.de	Coordinator BioCareers, Faculty of Biology; Chair Conference of Biological Departments; Vice Chair COIMBRA Group Life	Germany

				Sciences, Biocenter University of Wuerzburg	
Püschner	Hilke	Dr.	Hilke.pueschner@dsmz.de	Corporate Counsel, Leibniz Institute DSMZ – German Collection of Microorganisms and Cell Cultures	Germany
Schloen	Marie	Ms.	mschloen@yahoo.com	PhD Candidate, University of Bremen	Germany
Siems	Karsten	Dr.	k.siems@ac-discovery.com	VP Research & Development, AnalytiCon Discovery GmbH	Germany
Silvestri	Luciana Carla	Dr.	silvestriluciana@yahoo.com.ar	Research Fellow (in law), National Council for Scientific and Technological Research (CONICET). Legal Consultant.	Argentina
Sirakaya	Aysegul	Ms.	ays.sirakaya@abs-int.eu	Legal Advisor, ABS-int, Belgium; PhD researcher on ABS models at Ghent University Faculty of Law	Belgium
Tran	Thi Huong Trang	Dr.	tranglpsd@gmail.com	Legal consultant, Biodiversity, Natural Resources, Environmental Law; Independent consultant for Biodiversity Conservation Agency, Vietnam	Vietnam/France
Tvedt	Morten Walløe	Mr.	mwtvedt@fni.no	Senior research fellow (in law), Fridtjof Nansen Institute in Lysaker, Norway	Norway
Williams	China	Ms.	C.Williams@kew.org	Lawyer, The Royal Botanic Gardens, Kew, Conventions and Policy Section	United Kingdom
Winter	Gerd	Prof.	gwinter@uni-bremen.de	Research Professor of public law and sociology of law, University of Bremen	Germany

Annex V: Progress in implementation of NP as reported by the SCBD

First Assessment and Review of the effectiveness of the Protocol: Short Summary and Findings

by the Secretariat of the Convention on Biological Diversity

Introduction

The Nagoya Protocol on ABS was adopted on 29 October 2010 in Nagoya, Japan and entered into force on 12 October 2014. As of 6 of September 2018, 111 Parties to the CBD have ratified this instrument

In accordance with Article 31 of the Nagoya Protocol, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) shall undertake, four years after the entry into force of the Protocol, an evaluation of the effectiveness of the Protocol.

As the Protocol entered into force on 12 October 2014, the first assessment and review of the effectiveness of the Protocol is to be undertaken by the Parties at its third meeting which will be convened from 17 to 29 November 2018 in Sharm El-Sheikh, Egypt. In decision NP-2/4, the meeting of the Parties decided on a process and a methodology for conducting the first assessment and review of the effectiveness of the Protocol.

Article 29 of the Protocol requires each Party to monitor the implementation of its obligations under the Nagoya Protocol and to report to the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) on measures that it has taken to implement the Protocol.

The first meeting of COP-MOP, in decision NP-1/3, agreed on the format and guidelines for submission of an interim national report on the implementation of the Nagoya Protocol, and requested Parties to the Protocol to submit the report twelve months prior to the third meeting of COP-MOP. The decision also welcomed submissions of relevant information by non-Parties. Interim national reports were due to be submitted by 1 November 2017.

As of 6 September August 2018, 81 Parties to the Nagoya Protocol and 6 non-Parties had submitted a report. All interim national reports received are available online on the ABS Clearing-House at the following link (https://absch.cbd.int/reports), with the exception of three reports that were submitted offline. The ABS Clearing-House also hosts a report analyser tool that enables the analysis of information contained in the interim national report by question, country/ies or region.

In preparation for COP-MOP 3, the Subsidiary Body on Implementation (SBI) at its second meeting in July 2018 reviewed the analysis and synthesis of information prepared by the Executive Secretary (document CBD/SBI/2/3) and submitted its findings and recommendations for consideration by the COP-MOP at its third meeting (recommendation SBI-2/2).[12]

The Executive Secretary also prepared a number of information documents to support the analysis of information by SBI:

[12]All documents are available in the website of the meeting of the Subsidiary Body on Implementation. https://www.cbd.int/meetings/SBI-02

- Documents CBD/SBI/2/INF/313 and CBD/SBI/2/INF/414 provide an analysis of information contained in the interim national reports and the ABS Clearing-House as of 22 February 201815.

- Document CBD/SBI/2/INF/8 takes stock of the use of model contractual clauses, codes of conduct, guidelines, best practices and standards as well as indigenous peoples and local communities' customary laws, community protocols and procedures; and

- Document CBD/SBI/2/INF/7 reviews the implementation and operation of the Access and Benefit-sharing Clearing-House.

The following provides information on progress made by Parties in implementing the Protocol according to the analysis prepared for the first assessment and review of the effectiveness of the Protocol.

Progress made by Parties and non-Parties in implementing the Protocol16

In order to make the Protocol operational, Parties need, as a first step, to put the necessary access and benefit-sharing legislative, administrative and policy measures in place, and to establish institutional arrangements to implement them (i.e. a national focal point, one or more competent national authorities and one or more checkpoints). The publication of mandatory information in the ABS Clearing-House (including information on the permits or their equivalent issued at the time of access) is also essential for the implementation of the Protocol.

The following provides a short summary of progress made by Parties and non-Parties according to information available to the Secretariat.

A. Legislative, administrative or policy measures on ABS

With respect to the legislative, administrative or policy measures on ABS, and as of 22 February 2018, 75 Parties (71%) have some ABS measures in place. The measures reported vary in the degree of specificity and comprehensiveness and many were adopted prior to the adoption of the Nagoya Protocol. Some Parties reported having general legislation which relates to ABS (for example, general environmental legislation, or measures dealing with animal husbandry, forests), while others have adopted specific ABS measures to implement the Protocol.

Of the 75 Parties that have ABS measures in place, 44 indicated that they are currently revising existing or developing new ABS measures to implement the Protocol, and 10 Parties are planning to develop additional ABS measures. Based on information available, it is unclear how many Parties have adopted all measures necessary to implement the Protocol. Thirty non-Parties reported having ABS measures in place.

A number of provisions of the Protocol require Parties to adopt legislative, administrative or policy measures on ABS. The format of the interim national report endeavours to collect

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13 Document CBD/SBI/2/INF/3 analyses the information contained in the interim national reports and the ABS Clearing-House. The analysis provides: (a) quantitative information with a view to establishing reference points for each of the questions of the interim national report; and (b) a qualitative analysis based on the information provided in the text entries. With regard to the quantitative analysis, the document provides disaggregated data of the "yes"/"no" responses provided by Parties and by non-Parties.

14 Document CBD/SBI/2/INF/4 provides additional statistical details by disaggregating information by CBD regional groups on the yes/no responses provided by Parties and non-Parties to the questions contained in the interim national report.

15As of 22 February 2018, 69 Parties and 6 Parties to the Nagoya Protocol had submitted an interim national report.

16 More details are available in document CBD/SBI/2/INF/3.

information on the progress Parties are making towards fulfilment of these obligations through a number of questions on access, benefit-sharing, compliance with domestic legislation or regulatory requirements on ABS, monitoring the utilization of genetic resources, and compliance with mutually agreed terms, special considerations, as well as the questions on the provisions related to indigenous peoples and local communities. [17]

B. Institutional arrangements

As of 22 February 2018, 103 Parties and 67 non-Parties have established a national focal point on ABS, 57 Parties and 8 non-Parties have established one or more competent national authorities, and 29 Parties and 1 non-Party had designated one or more checkpoints.

C. Publication of information in the ABS Clearing-House

The following table summarizes national information made available to the ABS Clearing-House as of 6 September 2018.

Type of information	***Number of records published***	***Number of Parties***	***Number of non-Parties***
Competent national authorities	77	50	9
ABS measures	220	51	5
Checkpoints	52	24	1
Permits or their equivalent constituting an internationally recognized certificate of compliance	219	12	0
Checkpoint communiqués	3	3	0
National websites or databases	43	27	4

[17] Information on the responses provided to all questions of the interim national report is available in document CBD/SBI/2/INF/3.

Photo gallery

Dr. Joachim Lohse, Senator for Envi-ronment, Bremen (left), and Prof. Dr. Lorenz Kähler, Dean Law, University of Bremen (right)

Group photograph outside the Overseas Museum

Photographs show different speakers making presentations and participants both attentive but also actively making interventions, contributions or asking questions

Prof. Jay-Hyup Lee via video Skype from Hawaii


Introduction & History
Australia Ratified the CBD on 18 June 1993.
By1994. Australia – well positioned to take advantage of CBD Article 15 (&) or ABS.
•It had:
– Mega biodiversity – 10% of the world's species present - often not yet explored
– An innovative biotech industry (now worth AU$100 billion or EU65 billion)
– Established scientific research institutions
– A history of investment and scientific collaboration
– Broad community support for the environment, &
– The Environment Protection And Biodiversity Conservation Act 1999 (EPBC Act). A national law including ABS


What are the Treaty's objectives?


Beatriz Gomez, SCBD, over video Skype from Montreal, Canada


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o
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contract·because It is bio1091ca\
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uncertain; because sc1ence 1s dynam1c and e
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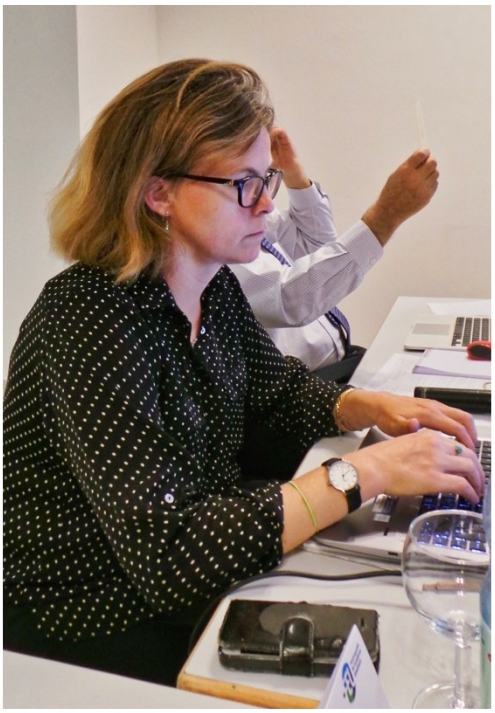
Reduce flexibili and remove doubt
FRIDTJOF NANSENS INSTITUTT
Concrete and s ecific, but not narrow


Dr. Romano Mwirichia Kachluru


Key element of the content of contracts:


Overview: Due Diligence
I. Spring board (19.4.2017): DD as import and export tool for regulation
II. Summary of Expertise on Liability of Registered Collections BIN
III. Today (19.9.2018): Art. 4.5 Reg. 511/2014 : Identify the Standard of Care




Rights over genetic resources and digital sequence information: Current debate
Chris Lyal


Dr. Thorsten Jabs
Germany


Possible to take sequence from online digital
and re-create it
Concern over 'digital biopiracy' / avoiding ABS
Scientific and philosophical discussions equating genes with information

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ssinica) and coffee (Coffea

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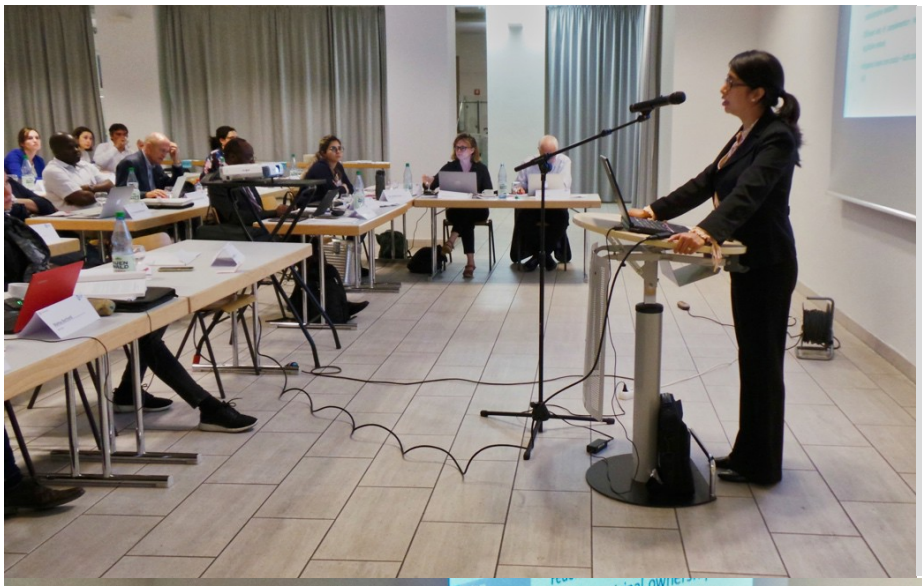
Thomas Greibe


Universität Bremen
1 LITER


Jorge Cabrera Medaglia


lenovo


AUEN
WALD
Medium

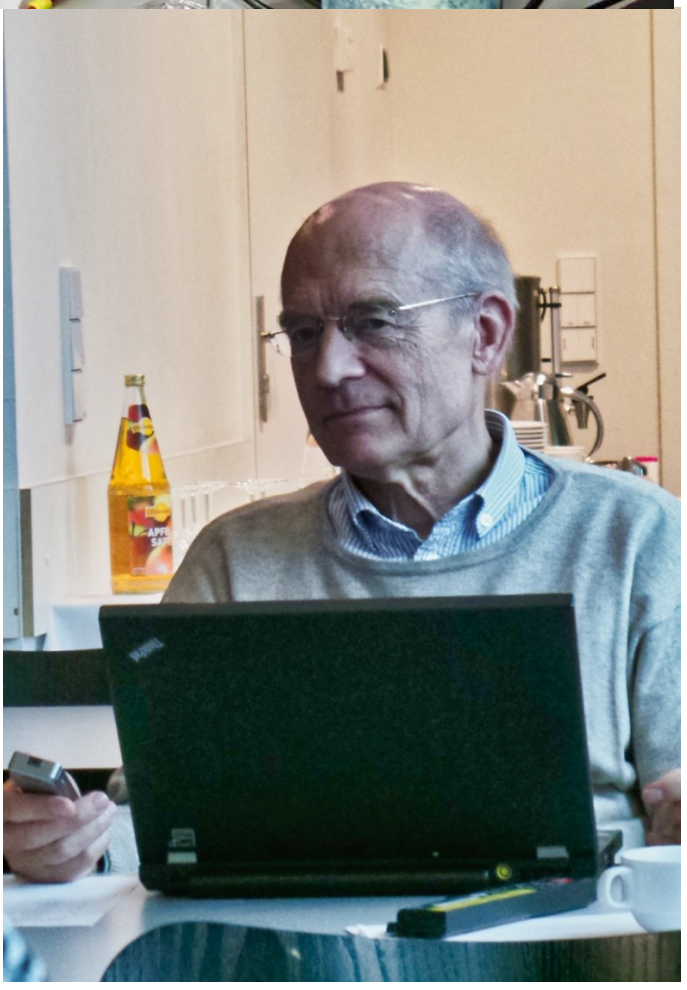


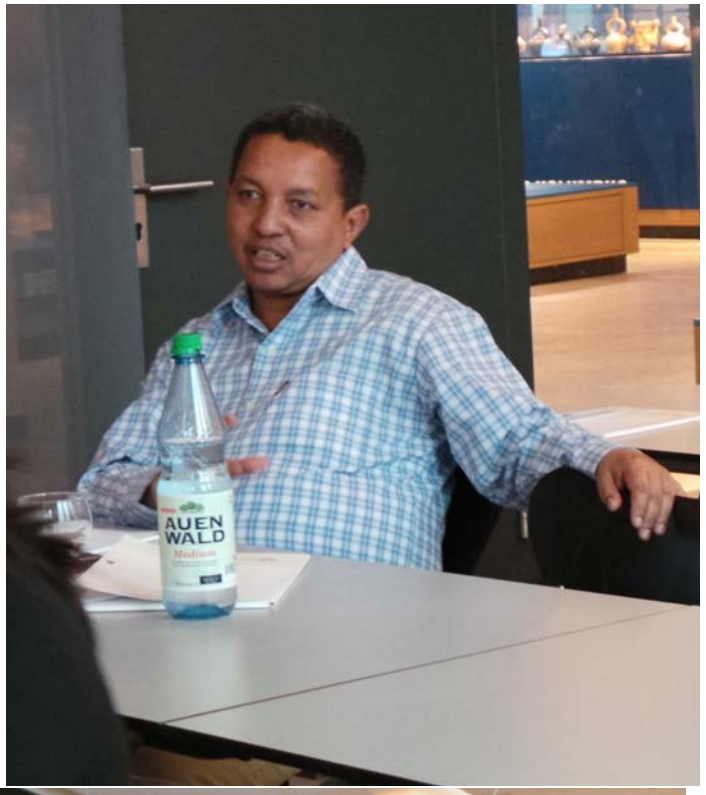

Provinces original owners
NNRR, including GGRR (art. 124)
Federal Gov. sets minimum
environmental protection
standards, Provi those
necessary to com
(art. 124)

Below: Guided tour, Bremen City, 19.9.2018


stein-zeit

Team meeting, 21.9.2018




AUEN
WALD

Below: Team guided tour, Overseas Museum, Bremen, 21.9.2018


Education –
Awareness of the Future
503
Bildung –
Bewusstsein für die Zukunft


To whom does nature belong?