FORSCHUNGSTELLE FÜR EUROPÄISCHES UMWELTRECHT (FEU)

ABS Project funded by the German Research Foundation (DFG), 2017 - 2020

New Legislation and Practice and Compliance with Nagoya Protocol

2018

University of Bremen

An ABS Project funded by the German Research Foundation (DFG), 2017 - 2020

THEME:

New Legislation and Practice and Compliance with Nagoya Protocol

Universität Bremen

Forschungsstelle für Europäisches Umweltrecht

The project is hosted by the Research Center for European Environmental Law (FEU), University of Bremen, Germany

New and arising issues in implementing the Nagoya Protocol

- Workshop presentations and discussions -

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Recommended citation: 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/NEWAND1.PDF

Abbreviations / Acronyms

ABS CH	ABS Clearing-House
ABS	Access Benefit-Sharing
ABSA	Access and Benefit Sharing Agreements
BBNJ	Biodiversity Beyond National Jurisdictions
Bfn	Bundesamt Für Naturschutz (Federal Agency for Nature Conservation)
CAN	Community of Andean Nations
CAN	Competent National Authority
CBD	Convention on Biological Diversity
EU	European Union
EUTR	European Union Timber Regulation
GR	Genetic Resources
INSDC	International Nucleotide Sequence Database Collaboration
IRCC	Internationally Recognized Certificate of Compliance
MAT	Mutually Agreed Terms
MS	Member States
MTA(S)	Material Transfer Agreement(s)
NFP	National Focal Point
NHM	National History Museum London
PIC	Prior Informed Consent
R&D	Research and Development
RBG	Royal Botanic Gardens, Kew
SENESCYT	Secretaria Nacional De Educación, Ciencia, Tecnología E Innovación
UNCLOS	United Nations Convention on the Law Of The Sea
WHO	World Health Organization

Figures

Diagrams

Tables

Map

Acknowledgements

The additional effort of Gerd Winter, Christine Godt, Marie Schloen, China Williams, Maria Victoria Cabrera Ormaza, Erwin Beck and Chris Lyal who carried out a thorough revision of selected parts of the first draft as well as a review of the final version is greatly appreciated.

I also acknowledge my student assistant, Christin Reinke, for undertaking the first transcription of the workshop presentations and discussions.

Lily Rodriguez is also hereby acknowledged for providing some input on Peru as well as clarifications during the revision stage of this report.

Finally, the German Research Foundation (DFG) is highly appreciated for granting the financial support needed to host the kick-off workshop as well as to execute the project as a whole.

Evanson Chege Kamau

Contents

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 benefit-sharing. The purpose of this third objective 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 has now been ratified by 104 states and the EU.[2] The focus of the research is on the new regulations on ABS of the Protocol.

The Nagoya Protocol 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 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 Nagoya Protocol with Regulation (EU) No 511/2014[3] by introducing compliance standards applicable across the Union, but with the due diligence, a non-Nagoya Protocol concept, as its core concept for compliance. A number of EU member states have already implemented the EU Regulation implementing the obligations of the Nagoya Protocol 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 CBD central 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 genetic resources, as well as the related verification of compliance with international legal requirements, etc.

1.2 Research project

Launched in February 2017 at the University of Bremen, the project titled "*New ABS legislation and practice and compliance with the Nagoya Protocol*" is dedicated to the

[1] www.cbd.int.
[2] Ibid.
[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.

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 analytically and problem-oriented. This is partly due to the recent entry into force of the Nagoya Protocol 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 Nagoya Protocol can be used as starting research basis, the issues mentioned above, among others, have hardly been dealt with so far. The research project will attempt to close this gap. It examines the national legislation in force after the entry into force of the Nagoya Protocol 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 Nagoya Protocol. The project also examines the extent to which available country experience can provide solutions to similar issues in other countries.

1.3 Summary of project research questions, objectives and methods

1.3.1 Research questions

A selected number of issues have been identified and are been examined *inter alia*:

- Definition of "genetic resources" and the ensuing challenges of regulating downstream results of R&D.
- Definition of "utilization" and the question of what it really consists of, which uses are considered as utilization, when utilization should be considered as having started or ended.
- Compliance in regard to non-commercial research.
- Compliance in regard to further R&D on research results (data and information) in public domain.
- Compliance in regard to materials supplied by intermediaries (especially informal entities). This question touches on the issue of bulk commodities (i.e. biological resources initially acquired for non R&D purposes when used in R&D).
- Checking compliance (How should it be organised? Who shall be checked? What shall be checked?).
- Due diligence in the EU and checking compliance following/repeating the same questions as in checking compliance above.

The research is based on case studies. The project team comprises an international mixed group of 19 lawyers and scientists (see tables 1, 2). Currently, legislation and practice of 18 selected countries from 5 continents (S. America, Asia, Africa, Europe and Australia) are being examined. The project is projected to last 36 months. The team will endeavour to offer

solutions to the new challenges. It is also anticipated that results generated in the course of the project will be fed into the implementation process.

1.3.2 Objectives

The main objective of the project is to conduct a post Nagoya Protocol implementation study of ABS legislation and practice. The specific objective is to find out how the new ABS legislation and practice are coping with selected salient questions/issues that have arisen in the implementation stage. To achieve this, the selected issues will be discussed with the aim to expose the challenges they pose to implementation, as a first step. As a second step, it shall be examined how obligations related to those selected questions/issues have been integrated as well as addressed in the new ABS laws. This will help in checking *de jure* compliance of the new laws with the Protocol. Finally, since *de facto* compliance can only be gauged by their performance, current practice will also be scrutinised limiting the study as much as possible to the new questions/issues that have been selected. Examination of current practice will not be limited to state administrative practices alone but will also make a survey covering a number of sectors that use GR and ATK to establish how they are coping with the new situation. The study will be based on country case studies, as already mentioned. It aims to produce results which will be used to first, make a general assessment of the future impact of the NP for R&D on genetic resources and ATK; second, assess the success of national approaches in achieving efficiency and effectiveness in ABS; third, to suggest points of horizontal cross-fertilisation of national ABS laws and practice; and fourth, to generate solutions for open, unresolved and emerging questions to be fed into the implementation process.

1.3.3 Research methods

The legal examination uses the usual methods of legal-scientific analysis and legal-dogmatic structuring of complex legal provisions. Attention is paid to stratifications of different legal levels starting from international law through regional law to national and sub-national law. The social procedure stretches from the designing of (legal) rules to questions of compliance, efficiency and governance. The empirical study is based on analytical document and literature analysis and evaluation as well as qualitative, partly structured, interviews. Document and literature analysis and evaluation will focus on texts of ABS laws, permits, MAT templates and newly concluded contract texts, any post-NP surveys looking at new laws that may become available in the course of the research, and existing grey-market literature. Empirical study will also embrace experiences with the new national legal frameworks on one hand, and activities of concrete cases of access and benefit sharing on the other hand. Interviews are planned in a number of organisations/institutions, and also with a number of administrative officials and experts as well as with other relevant personalities (e.g. actors in the field), where possible.

1.4 Project team

Head of project *Dr. Evanson Chege Kamau*

Table 1: *Experts undertaking case studies*

	Names	**Case studies**
1.	Prof. Jorge Cabrera Medaglia	Costa Rica, Brazil
2.	Dr. Marcelin Tonye Mahop	Cameroon, Algeria, France
3.	Ba Tu Nguyen	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	Ethiopia
10.	Morten Walløe Tvedt	Norway
11.	Dr. Evanson Chege Kamau	Kenya, South Africa, Germany, Malaysia

Table 2: *Experts investigating general themes*

	Names	**Theme**
1.	Prof. Gerd Winter	Authentication and regularisation of material supplied by informal "intermediaries"
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.	Romano M. Kachiuru	Cooperation with foreign scientists under new ABS regulations – Case of Kenya
9.	Morten Walløe Tvedt	Making ABS work through contracts

1.5 Milestones

The project has three milestones. The first is an inaugural meeting (kick-off workshop), which took place at the premises of the University of Bremen on 19 April 2017 and was attended by twelve participants (picture below). The second big event will be an international conference that will be taking place on 19 - 20 September 2018 at the Overseas Museum in Bremen City. The third event will be a review workshop that is provisionally planned in May/June 2019 at the University conference room in Teerhof.

2. Inception Workshop

2.1 Objectives of workshop

The inception workshop had the following objectives:

- To create an opportunity and atmosphere for introduction of project partners;
- To introduce the project, its objectives, methodologies, workpackages, timelines;
- To discuss the workload and expected results;
- To test the relevance of the theme; and
- To optimize the objectives and research questions.

Six questions were planned for discussions during the inception workshop with each group from three dealing with two questions each in concurrent group work. Each group was also allocated two specific issues to be presented by selected experts (see Annex I, II). The results of the group work were later presented in a plenary for discussion by all participants. The results are presented in three parts each encompassing two questions and a special report.

2.2 Participants of the workshop

Outside GW[4] 1 (picture 1) and in front of the main door to the Research Center for European Environmental Law (picture 2)

Picture 1 (from left): C. Godt, B.T. Nguyen, C. Lyal, C. Williams, T. Greiber, M.V. Cabrera Ormaza, E.C. Kamau, M.T. Mahop, J.C. Medaglia, G. Winter. M. Schloen, L.C. Silvestri

[4] Geisteswissenschaft (en: Hummanities).

Picture 2

The following report is an output of the kick-off workshop stemming from the results of group work discussions, presentations on specific selected themes (see Annex I, II) and round-table discussions. Attempt has been made to maintain the results, including views expressed, in their original form. Only harmonization of round-table discussions, structuring and updating of outdated information, e.g. in regard to the ratification of the Nagoya Protocol, has been made.

Part A: Access to and rights over genetic resources and monitoring and tracking their use

The first group dealt with the questions on intermediaries and monitoring and tracking the use of genetic resources. It also presented two special reports on tracking and scientists' experiences with ABS regimes.

3. Intermediaries

It was reported that three main questions can be raised concerning intermediaries: 1) What kinds of intermediaries are there, or can be considered? 2) What are their roles and functions? 3) Do they deserve a special legal status, special privileges maybe within provider and user state legislations?

3.1 What kinds of intermediaries can be identified?

A number of entities can be considered as intermediaries. These include public collections, e.g. the UK Royal Botanic Gardens (RBG), Kew and The Natural History Museum (NHM)

London; private collections of companies; smaller collections of universities and research institutions from provider and user states; gene banks and "brokers."[5]

According to the group, brokers are expected to come up more frequently than before in order to facilitate access to users. Such brokers usually do not understand their function in the ABS process and would need to be educated. There are other entities, whose activities involve a brokerage function, and they are easier to educate, but they do not perceive ABS as any of their roles. These include the supermarkets e.g. in regard to the purchase of an orange by a researcher who decides to conduct R&D activities on it. Those brokers that just collect and sell material are the critical ones in terms of the material being bought on local markets, e.g. a bag full of seeds, and compliance in user states, but such might not be interested in being educated. They do not even care about any requirements and do not know to whom they will sell. This shows the multiple issues that need to be addressed in order to more correctly classify intermediaries. This includes a clarification of what access means, e.g. access being *ex post* access occurring after the orange was bought for consumption uses and eventually going through the R&D chain. It was concluded, therefore, that the discussion in this issue should rather focus on the definition of access than whether this is a brokerage function or not. The starting point should be whether this is covered by ABS.

The case of collections can be taken as a learning point in this regard. Some countries e.g. France and Brazil would consider access to have happened at the moment the genetic resources are taken from the collection regardless of when they were collected from the wild. For instance, if one would wish to utilise a specimen of a sample collected way back in 1920 and lying in a Paris museum, this event will still fall under ABS regulation. This is because the specimen is still located in the country where the sample was first collected. Hence, this should be seen as a new event, new access for R&D. That means the specimen from that country held in an *ex situ* collection should be seen as a special concept of intermediary. There is a place between the wild and the user where the specimens are held that still falls specifically under international regulation.

But other than e.g. the example of old French material in a French collection, it was questioned whether this would equally apply in a hypothetical case of old material from the now Democratic Republic of Congo in a Belgian collection. How would this question be solved if the material is being accessed there and Belgium also extends its access legislation to *in situ* material? This question was not further discussed but an opinion was expressed that this event might be different and probably involving more of an ethical question.

The question of intermediary functions in the agriculture sector was also raised in the round of discussions. Unlike cases where material may be exchanged only between the first receiver and the one who ultimately releases the first product in the market, the agriculture sector value chain tends to involve different actors. In such a scenario, the material would change hands as various actors perform their tasks thereon as well as further develop it until, at one point, someone releases the product in the market. This kind of passing-on may

[5] The term "brokers" here was used to refer to entities that collect genetic resources for sale to users without the aim of preserving them.

involve, for example, up to five different institutions. Originally this would happen without ABS. In line with the ABS requirements, the contract at the first access would have to be passed on downstream, in this case five times, before the product is released. Would the "in-between actors" also be referred to as intermediaries that do not define themselves as such? Normally, they would define themselves as biotechnology laboratory or breeding company etc. Do they become intermediaries in the ABS process?

According to a quick opinion, such actors cannot be termed intermediaries, but are (all) users. The mere fact that they pass on the material does not make them intermediaries. It would depend on the specific activity they perform. Accordingly, intermediaries acquire material (possibly access it, according to national law) and may or may not do research on it, but they do not utilise. Usually they pass on to someone else to do utilisation. Intermediaries are crucial to implementation of the ABS regime, but because of the way it has been constructed they are often not caught by it. Therefore it is important to examine what their role is and what their obligations are.

It was noted that it would be very difficult to draw a distinction between a gene bank, which also does some initial research, and any other research association that is in the middle of the chain and carries out some activities. It would therefore be critical also for the project to examine whether such initial research activities qualify as R&D or not.

In particular categorising collections might be a difficult task because they are very often involved in activities across both sides of the line. Their work involves someone doing collection in the field, and then sampling a block of green things from a larger resource on some basis, the plants, the pretty flower etc., identifying the species, maybe different ones, putting a name on them. Thereby it is established in which condition the sample is, which species this and the other are, or where which species can be sent. The next person down the chain will be probably sampling again. The question is, would this be termed as utilisation?

From the EU perspective, fulfilling the sole function of a collection; sampling, storing, transferring, would not qualify as utilisation. But as the case often is, "they basically do everything; from sequencing etc." The colleague next door, the curator, or another department might be undertaking such activities. "And such people are doing utilisation, but the curator who just puts the stuff in the collection and passes it on …" cannot be said to be utilising." Therefore, it would depend on how the identification is conducted before the conclusion is reached whether this or that material can be passed on. There could be different ways of doing that. Looking simply at the material with the (naked) eyes or a microscope and deciding that it is fresh and still green hence good for transferring, but the other is brown and not. That would not be termed as utilisation. On the other hand, if the decision is based on genetic analysis of the material that would lean towards R&D on biochemical composition and might already fall under utilisation. According to one of the discussants, the practice of the competent national authority of Costa Rica, for example, would not consider looking at a sample with the (naked) eyes as utilisation, but using molecular technique falls under the ABS regime. The Costa Rican ABS legislation does not use the term "utilisation" though, but the term "access" is used with the same implication.

These are the practical problems in the reality that need to be addressed, for example, by taking examples of definitions of access and utilisation by national legislations and showing all the differences. In regard to what consists R&D on biochemical component and hence utilisation, the project should try to draw a clear line of activities that are excluded because it does not make sense to regulate these kind of issues. Columbia and Peru take such an approach.

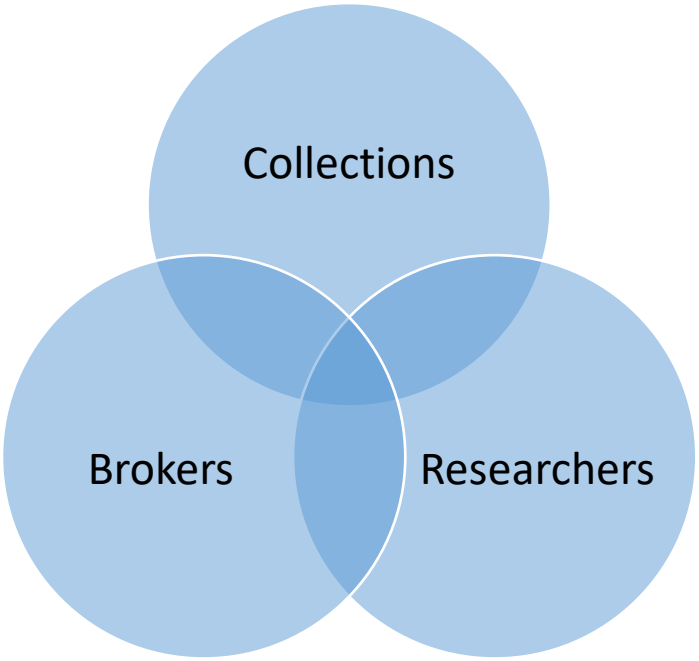
For the workshop it was recommended that the participants first look at the functions of "intermediaries" instead of trying to define the terms. This could be done by thinking of three circles that partially overlap (see diagram 1). Each circle would represent the functions that are undertaken by the actors. The first circle represents collections, the second, research mainly of a taxonomic nature, and the third pure collectors (that do nothing else) and pure brokers. All these can, however, overlap at one point: collections can do research but can also have a brokering function. The non-overlapping part would then be the full function, e.g. of a collection. It was noted that by starting with definition of the terms the participants lost the sense of the function.

Several recommendations were made concerning additional issues that the project would need to examine in view of the question on intermediaries:

a) Explore and elaborate the concept of intermediaries. This idea is presently not clear even at the low level. It is not dealt with in legislations, at least not under that term. The actor may be regulated in different ways but not based on categorisation as an intermediary. It is critical hence to qualify what an intermediary is and what (functions) it possesses. For that purpose it would be useful to explore the terms used by national legislation to refer to those performing intermediary functions.
b) Elaborate the concept of utilisation. What is the practical meaning of utilisation? When does it begin, when does it end? What exactly is research and development on biochemical components? A study of the EU Commission sectoral guidance documents on identification of utilisation and the Frascati Manual (see diagram 3) on definition of R&D was recommended in this regard. According to the latter identification is not considered as utilisation,[6] but discovery of new knowledge.

[6] According to the manual R&D comprises "... creative and systematic work undertaken in order to increase the stock of knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge."

Diagram 1: *Illustration of functions of intermediaries*



Source: *Proposed by Gerd Winter*

3.2 What roles and functions do intermediaries have?

In the group's view, the term "intermediaries" makes it clear what roles and functions such actors have. However, this term is not very often used in law, as already mentioned – at least not in the EU regulation. Rather, the term "collection" is probably used although this term (collection) makes the function unclear if the activities of the collection go beyond just collecting and preserving resources.

The major role the collections could play is, of course, to facilitate access to users of genetic resources. If users can receive genetic material from a collection, they do not need to spend money to go to the spot in order to collect it there. Equally important maybe is that they do not need to deal with bureaucracy; they can trust that the genetic resource contained has been collected in conformity with the access legislation and that the costs thereof (as well as other costs that are involved) are reasonable. In this regard it is important that users are able to prove that access was made legally. To that effect intermediaries should be in a position to provide the user with such information. This would require them (intermediaries) to collect and maintain such information, which will become good practice.

Depending on the collection, another function is probably to produce knowledge; to do research on the material, mostly taxonomic. Collections as well as receptionist practices produce enormous taxonomic information, which is a major benefit. Collections may, however, go beyond this by engaging in learning about the functions of genetic resources and maybe even of the genetic makeup in general.

Considering the work of gene banks in the microbial area an additional function of intermediaries was named, i.e. authentication. At times the researchers need the collection for their normal research work whereby they pay for the service of the collection to have their material authenticated so that they can proceed with their research. So it is like a task, a function in the research process that can only be fulfilled by the collection. Consequently the microbial community has a completely different view concerning what a collection is actually doing and for what. It is not so much for conserving the material like one would see it from a plant perspective, but conserving them in an authenticated, unified version because otherwise microbes continuously change. Hence such collections have a different mind-set; they are like service providers.

Intermediaries are not just part of a sealed pipeline, but are results-built. So like many other institutions, collections are a place where people from a provider country come to do research, to build a casting. They are a source where information spread around. Opinion was aired that this function might be more important than getting stuck on considering collections as part of a supply chain. Some parts of a supply chain are much more problematic and often involve numerous agents. Such chains may be carrying out anonymous business, making their activities anonymous. So the issue of transferring the information would consequently be the challenging thing to look at. One may, however, have a single agent which is working in a country and certainly doing business.

As an add-on it was underlined that the functions of intermediaries listed above depict the enormous benefits they produce. Based on this it was suggested that the research project elaborates as well as seeks solutions for some of the critical issues that inconvenience their activities. These include the definition of utilisation and in particular "research and development" in regard to taxonomic research. Some of the participants considered taxonomic research as a non-utilising activity. It was reported that RBG Kew, for instance, does not consider taxonomic research as utilisation. In addition, considering that many obligations are addressed to users, it is important to conduct a thorough examination of who actually is a user.

3.3 Do intermediaries deserve special status, special privileges maybe within provider and user state legislations?

Looking at the functions and structures of intermediaries, it was recommended that collections should be awarded a special legal status in the ABS process. The EU-regulation, for example, has a category of registered collections which requires *inter alia* that collections included in such a register exhibit good practices concerning access, concerning adherence to the requirements of provider states. Is it thinkable that provider states in a way give such collections facilitated access to genetic resources? That would allow a collection to obtain samples and just to notify what they have collected. In this case, prior informed consent (PIC) would be implied in this special status of the collection (for non-commercial research purposes). Australia, for example, has established a facilitated online procedure for non-commercial purposes. One of the criteria to determine whether an applicant fits into the facilitating access in Australia is if such an applicant has signed up to the Principles and Common Policy Guidelines on Access to Genetic Resources and Benefit Sharing

(https://www.bgci.org/policy/abs_principles/). The group was of the opinion that this discussion could even be elaborated further to contemplate whether provider states should not open up a special facilitated procedure for foreign collections that are registered and considered as "trusted". This could likewise be one more incentive for collections to apply for the status of "trusted registered collections." The provider state legislation could relate to the EU or other user state legislation on trusted collections. According to the group's views, provider states should also have regulations for collections located in their own jurisdictions.

In addition, it was added that the provider country legislation should likewise regulate to some extent small extract companies that act as intermediaries. Currently there are many in-country suppliers of genetic resources that are unregulated in national legislation. The normal ABS procedure dictates that if one wishes to collect plants or extracts, for example in Madagascar or Thailand, s/he should go through the access legislation. However, at the moment one could buy extracts or plants online from companies and nurseries in both those countries, which is easier and simpler for a company in Europe than going to collect. The suppliers, however, would probably not have heard about ABS or Nagoya Protocol and hence would not alert the acquirer of the need for ABS permits and other requirements. Such intermediaries play a big role in many sectors and need careful regulation in provider country legislation.

3.3.1 Registered collection *vs* trusted collection

A vigorous discussion ensued concerning the terms "registered collection" and "trusted collection". A note of caution was first and foremost sounded against using the terms as synonyms, the two being different concepts. It was explained that the registered collection is a business deal; it is a particular case where a collection fulfils certain conditions in order to supply to users. The fact that a collection has not registered any part of its collection is not because it does not meet the requirements, or it needs a business model, it is due to the costs involved. That is the reason why, although collections in the EU are subject to the regulation and must meet certain requirements, there are currently no registered collections or applications for registration. The NHM, for instance, is a very large collection and has considered this issue in some detail with the conclusion that there is no need to move into that business space. The Museum does not have any business case to do it: it is a cost with risk and no benefits that can be seen, it was reckoned. So the current plan for NHM is not to apply for registration for any part of the collection since such application would be inappropriate for the collection.

It was elaborated by a member of the working group that the idea contemplated though is that, a registered collection might stand to benefit from facilitated access to genetic resources if through such registration the provider could consider it as a trusted collection. Whereas it was reluctantly admitted that that could be possible, it was further argued that the case is different when talking about supporting biodiversity conservation, on the one hand, and supporting business, on the other hand. Therefore, it was argued, a registered collection in the European context is a greater risk for provider countries than a lesser risk because the material is almost explicitly going into business away from the control of the

collection that had accessed it. Consequently, a facilitated implied PIC procedure based on the concept of "trusted registered collection" must take into consideration that tracking of third party transfer activities become harder and riskier down the value chain. Thus, other controls of tracking the downstream movement and utilisation of the material) would be needed, but doubt was expressed that provider countries would opt for such an approach.

3.3.2 Problems of registering a collection

During the discussion a number of problems concerning registration of collections were mentioned:

a) If part of the collection is registered the collection would need to set up a separate administrative system to manage the rest of the registered collection.
b) The conditions under which a non-commercial collection has legally acquired the material (for the collection), hence prior informed consent (PIC) and mutually agreed terms (MAT), will not necessarily be appropriate for the business user. The user will still have to do a lot of assessment to ensure that s/he can utilise the material. This is assuming that the material is not supplied under the facilitated model of implied PIC proposed above, which perhaps is simpler to use.

However, the argument suggesting only private or commercial orientated collections would apply for registration was rebutted. It was noted that in the German case, for example, those most interested in registering supply material to both commercial and non-commercial users. But, of course, that requires an investment on their side, and hardly anyone so far sees it as a good investment. One needs to have a business case or some other interest in mind.

3.3.3 What is a business case?

A business case is an argument, or a model, which shows you how to recoup the costs of setting up and managing the collection. Registering and managing a registered collection has an actual cost in terms of money and staff time. If you are going to have it in that form you will need some sort of economic model, if you like, to help you support it. That means spending on managing a registered collection for other users as supposed to managing the collection for your own internal purposes. The cost involved has to be recouped from somewhere. The people you are likely to recoup it from, i.e. sell the material to, are people with money. Thus, if the original model is pinned on the Australian model, but the supply is made to all possible users, the non-commercial status would be ruined. Academic users can also provide substantial financial support to a collection without it changing its status into a registered collection, as the experience of the NHM London shows. A business model might be more interesting, but there is no evidence that there is enough money in it to make it actually worthwhile.

It was argued that the approach suggested earlier of offering facilitated access to collections in exchange of registration could also be regarded as an attempt to create a business model. This is because, according to the description of a business model provided, one of the aims is to recover costs. Hence the concepts of a business model were proposed: business one, i.e. recovering of the cost of the collection, and business two, i.e. making money out of the

genetic potential of the plant. With this understanding the approach "facilitated access for registration" would fall under business one. If the provider states could include a clause in their access legislations to that effect, that might serve as an incentive for collections to register. It would probably not solve the problem of cost recovering, but it could save some costs at another point, namely at the process of getting access. Another reason a collection might be interested in getting registered is for reputation reasons. This will give the collection the opportunity to be distinguished or outstanding as the first on the market.

The concept "business one" proposed above is not presently rooted in any reference evidence, it was noted, but it was agreed that it is a good and novel idea to examine for the future. Critical at the moment is finding responsible countries as practices and transparency go along well in dealing with the question of trust.

In the plenary discussion it was suggested that for purposes of the research project a working definition or criteria for identification of "intermediaries" should be sought before addressing the three main questions above (*kinds of intermediaries, roles and functions and whether they deserve special status*). Although the difficulties of defining terms were acknowledged, the development of at least certain criteria was deemed necessary for consistency sake. In addition, since the issue of possible special legal status of intermediaries seems to be a *lex ferenda* question, it was proposed that exploring the current state practice of any trend towards recognition of such a special status might be useful.

Concerning collections, which acquire the status of trusted registered collections, an opinion was expressed that from the point of view of provider, it seems reasonable that their activities should be subject to regular monitoring. This point would, however, need more elaboration.

4. Tracking genetic resources down the value chain

4.1 Rights over genetic resources and tracking

The second question concerned rights over genetic resources and tracking of such resources down the value chain. How can it be ensured that the chain is not broken such that the chances of the provider to share in benefits are increased? Is there any exemplary tracking practice and experience currently worth of emulation?

This is an issue that is well known. The international framework under the CBD and the Nagoya protocol recognises the sovereign rights of states over genetic material. Based thereon it establishes a regime for access to such material from the provider side for R&D. In the same vein, a regime for compliance is created on the user side, which is meant to limit the violation of the provider rights based on access to GR, and ensure benefit sharing. This includes monitoring of the utilisation of GR as foreseen by Article 17 of the Nagoya Protocol. The EU user regulation on compliance is based on the concept of due diligence.

The several rights of the provider may also extend to the information network, to the results of research, *via* clauses on MAT in the material transfer agreements (MTAs). The provider state would normally do that as a way of controlling the fate of any information on GR

produced downstream, in particular to ensure benefit sharing. Hence, if the provider state negotiates the agreement and succeeds in establishing a clause concerning whether and how the information shall be published and used for such purposes, including, for instance, the commercial uses, this is a possible use of the sovereign rights of the provider state. In practice, many of such clauses may probably be found in MTAs. This raises the problem of, first, how these conditions can be attached to the information which travels to various data bases until the final use in a product, and two, how the different users can be bound by such contractual clauses agreed between two parties. A viral clause may be attached, for example, requiring that the user must ensure that the second user complies with the conditions of the first contract. However, this, of course, is likely to be lost on the way through the downstream stages of value chain.

Therefore, there are mainly two identifiable problems. One, a more technical problem addressed to the informatics people namely, is it technically possible that the conditions established through a MAT travel through data banks? Two, a legal problem: How can it be ensured that the user feels himself or herself bound by certain conditions? Both questions could not be solved and were deemed difficult to answer and even maybe impossible to solve (in terms of bioinformatics and having subsequent users bound by contractual conditions). It was, nonetheless, agreed that this problematic remains interesting and relevant for the project. In that regard, provider state legislation and practice, in particular concerning MATs, should be examined. The following should be found out: 1) To what extent are clauses on the management of information included in MTAs? 2) To what extent are such clauses able to deliver expected results?

4.2 Contracts and third parties

Following this discussion a question was raised concerning binding of third parties in contracts. Why is it not proper to bind third parties in a contract? As an illustration of third party binding an example was given that if A lends his/her property to B, A can choose to include a clause saying B is allowed to lend it further to C under certain conditions. In order for that to work, A must oblige B to pass on to C (third party) the specific conditions, or generally, the conditions of the contract. This was considered a normal approach in mutual terms. One tries to oblige the other person to pass on the same duty. The problem in contract law is that once the chain is broken, i.e. once the duty is not passed on, it is lost. In that case it would be impossible to trace any violations occurring after the time the chain was broken. However, the person who violated by not passing on the duty is identifiable. But probably the most interesting question that arises is concerning the subsequent users who receive the material without the knowledge that it was attached to third party obligations. What is the fate of the third party if it is not known who violated the contract and hence when the chain was broken? In the plenary discussion, one of the discussants expressed the view that there could not be a single answer to this question. It would depend on civil/ public law regulation applicable to contracts with third parties, she said. Hence, she suggested that, without going that far, one could try to see to what extent the implementing regulation for the Protocol allows for transfer of rights and obligations derived from MAT in more general terms. This question will be examined in details looking at the basic principles of contract law and applicability of contract law norms in ABS situations.

Concerning enforcement of contractual clauses down the value chain, an idea was flagged that checkpoints could be identified and operationalised in user countries as required under Article 17 of the Nagoya Protocol as one of the ways of tracking. If someone is not playing by the rules, there is no chance for the provider country to know that the chain was broken, or that someone in the line did not pass on the duty, leave alone pursue or challenge the issue. Hence, the idea is that checkpoints could be used to trace back the points of violation. For example, if the checking is due at the point of putting the product on the market, it can be verified at that point how and from where the information or material used in the final product was received. The African countries are very keen on seeing IPR offices being identified as potential checkpoints for disclosure requirements. At the moment there is a big discrepancy concerning this issue between providers and users in developed countries. Developed countries do not want to allow that. The implication is, if a university researcher or a user wants to apply for a patent, s/he would not be obliged to disclose the origin of the information that was used for his/her business. This is an issue to be included in the discussion even though, as already mentioned, it is a difficult one to solve; it is difficult to track the origin of genetic material. How can checkpoints be employed in tracking genetic material? Would this imply turning a contractual bilateral duty into a public one?

Besides searching for ways of tracking, which was difficult to solve anyway, it was suggested that an examination be carried out to find out whether it is possible to put the relevant MAT clauses in law instead of placing them in MTAs. This was done, for example, in the Executive Decree 905 adopted in Ecuador to implement the Community of Andean Nations regime on genetic resources, according to one of the participants. This would make them a legal obligation by law to anyone who receives and uses GR or information thereof. The obligations will not have to be agreed in a contract and the user will not have to enter into a new contract with third parties reflecting the initial duties. Would it be possible to use such an approach? Whereas an opinion was raised that it would be possible to use such an approach, it was added that in such a case the language of IPRs must be avoided. This is because if used in law it will come close to claiming property rights over the information and yet, clearly, such right was not intended by contracting parties when designing Art. 15 CBD. Hence, it was proposed that the user should see to it that the agreed conditions travel with the R&D generated information about the GR through publication media, and that benefits arising *via* the use of that information are shared with the provider state. The group saw the necessity for a thorough discourse to discuss how these obligations should be framed/formulated in law.

4.3 Role of local and indigenous communities

The question of tracking cannot be considered without examining the role local and indigenous communities play in the access granting procedure. It was bemoaned that often such stakeholders are ignored or excluded; their inclusion is vital in such processes when access touches on genetic resources owned, or rather held by them. Some African countries, for example, have a monopolistic right of the state over resources approach and do not care much about such communities. This question should be looked at as a matter of provider state legislation. On the other hand, the role of such communities in the ABS process can only be fully strengthened if the user country legislation equally addresses the issue. It

should at least ensure that no use is given to traditional knowledge associated with genetic resources without compliance with the requirements of consent of such communities obtained through a participatory procedure that meets the requirements of international law on indigenous peoples.

5. Special reports on tracking and experiences of users

5.1 Ensuring that obligations in permits and access legislation are adhered to: An exemplary case of tracking by RBG Kew

This report was made by China Willians and is based on RBG Kew's relatively long and practical experience in monitoring the use of genetic resources (GR) and their transfer to third parties. According to her presentation, RBG Kew has a concrete strategy for ensuring that obligations in permits and access legislation are adhered to. Although it is not claimed that this strategy is perfect and suffers no challenges and/or limitations, it offers a number of useful lessons for tracking.

RBG Kew's scientific vision is to document and understand global plant and fungal diversity and its uses. Kew has a very large collection, a herbarium of nearly 8 million (see table 3). There are 40 open access science data bases, DNA banks. Hundreds of scientists visit the collection each year. Kew's scientists still make over 60 overseas plant collecting trips annually. The volume of annual exchange (involving coming in and going out) consists of over 60,000 herbarium specimens and 10,000 live plants and seeds.

Table 3: *Kew collections in numbers*

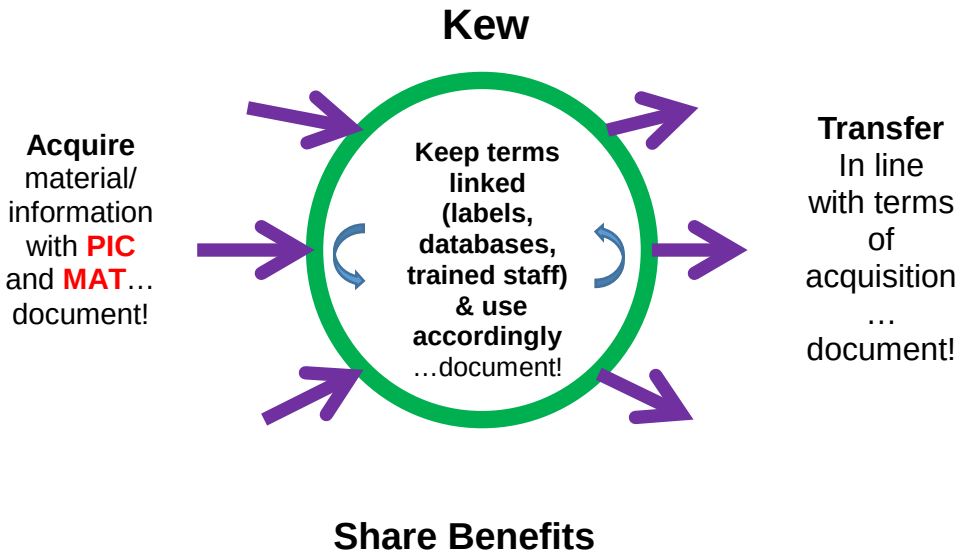
Herbarium (7.5 M) & Fungarium (1.25 M)
Living collections (+30,000 species)
Millennium Seed Bank (+30,000 species; c. 2 billion seeds)
Over 40 open access science databases
DNA and tissue bank (+42,000 accessions)
DNA C-value (+7,000 species)
Slide collections (+100,000 slides)
Library (> 750,000 volumes), archives (250,000), artwork (> 175,000) , paintings, prints and drawings

Source: *Powerpoint presentation by China Williams*

The basic principal of the herbarium is that material is obtained with PIC and MATs. The terms linked with the GR are recorded in relevant databases, and Kew ensures that those resources are used according to those terms. Transfer to third places only takes place in line with the terms of acquisition. That is a big challenge because Kew is a historic collection with lots of different collections which all have different databases and collection management

systems. Taking for example the millennium seed bank built in the year 2000, there is a data base designed specifically with fields for relevant information and restrictions. But in the wood anatomy department, a written logbook is still used and needs to be consulted before specimens are used. What this means is that staff training is essential to ensure that the correct procedures are followed, all terms and conditions are recorded, and that staff and visitors know where to find this information, and that procedures and policies on using the collections, both for staff and visitors, are clear and accessible. This is likewise important in guaranteeing the reputation of the collection. It is also vital to understand how the collections are used before ensuring that the right restrictions are put in place, and where these restrictions are recorded.

Diagram 2: *Basic principles of RBG Kew operations*



Source: *Powerpoint presention by China Williams*

Hence, Kew has what is called an ABS toolkit which includes and operationalises Kew's policy on ABS (www.cbd.int/abs/submissions/icnp-3/EU-Kew-letter.pdf).

This is set out guidelines for staff, which are on the intranet (internal website). There is an overseas field work policy and other policies and procedures relating to visitors, data collection etc. as well as regularly updated model agreements and clauses.

Under Kew's standard Memorandum of Collaboration Kew may loan or supply material transferred or any derivatives from the material and transfer data to other institutions for the purpose of scientific research or education *providing that such loan or supply is on terms which* ***prohibit commercialisation.*** Commercial application here is defined as "applying for, obtaining or transferring IPRs or other tangible or intangible rights by sale or license or in any other manner, commencement of product development, conducting market research,

seeking premarket approval and/or the sale of resulting product". Kew's standard ABSA (**A**ccess and **B**enefit **S**haring **A**greements) also states that Kew may loan or supply material to a third party for the purpose of scientific research or education, provided that such third party signs a written agreement with Kew prohibiting commercialisation of the material without permission and a further loan and supply for material and associated images or associated data by that third party. The exchange of material for identification and verification purposes, for taxonomic study, etc. is vital for the non-commercial conservation research necessary to achieve the objectives of the CBD.

Kew's donation agreement is used when material is donated to Kew and the donating individual or institution has no supply agreement of its own. It is used to set out how Kew may use the material, and if there are any restrictions on use. Standard terms are that material may be made available for scientific study, used for the common good, sent or further distributed to other scientific institutions on terms that allow scientific research and prohibit commercialisation without going back to the original provider to negotiate new PIC.

A third party who receives material from Kew under non-commercial restrictions and later wishes to use it for commercial purposes must go back to the country of origin, the country that provided the material, and negotiate with that country to get the necessary permissions for the change of use. Where this change of intent takes place after Kew transferred the material to a third party, the obligation to negotiate new PIC and MAT rests with the third party intending to utilise the material. The group discussed ethical issues around management of these situations – should there be an obligation on the intermediary, in this case Kew, to track and monitor use? Where should this burden lie?

The other key thing is what is known as management systems. Kew has data bases basically to keep track of the key information, i.e. the PIC and MAT documents, the agreements, the permits, the certificates of compliance. That is a big job which basically involves scanning those agreements and documents and filing them and connecting them with the material in order to keep everything up to date. The date of access of the material from the country of origin, the country that provided the material, is also kept. Each material will be having different terms of use, including any restriction, benefit-sharing requirements and any unique identify supplied with the material. The core information of all these must be linked to the future use of that material and outputs, including publications. This – linking initial terms to outputs – is one of the crucial data management issues all intermediaries face. Most importantly, the staff needs to be trained on how to use existing tools. Therefore, again, staff training is really important: the staff must know where to look, which bits to pay attention to and what to do when things go wrong. This again underlines the importance of searching for tracking mechanisms because if things go wrong with the bilateral contracts, which only bind the two parties, the ability to track is limited and the chances of establishing the point of violation are slim.

One result of this is stricter conditions being imposed by countries of origin, in order to retain control. In some cases providers prohibit further distribution of material for any purpose, even for non-commercial use. If anyone (a third party) wants the material, s/he

must go back and ask for it from the country that provided it. The group discussed how best to resolve these issues.

Kew, in addition, use and follow a number of best practices and codes of conduct. There are different codes of conduct that have been developed in the non-commercial research sector and give reassurance of best practice being followed in this ever changing arena. Examples include:

- ABS Clearing House provides access to Codes of Conduct and guidelines within the Reference Records, under the heading Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards https://absch.cbd.int/search/reference-records/
- Botanic Gardens Conservation International (BGCI), ABS Learning Modules for Botanic Gardens: https://www.bgci.org/policy/abs_learning/
- CBD Website provides links to a number of Codes of Conduct, guidelines and best practices at https://www.cbd.int/abs/instruments/default.shtml
- The Principles and Common Policy Guidelines on ABS for Botanic Gardens https://www.bgci.org/policy/abs_principles/
- Consortium of European Taxonomic Facilities (CETAF), 2015, CETAF Code Of Conduct & Best Practices For ABS (Access & Benefit-Sharing) http://cetaf.org/taxonomy/publications
- Global Genome Biodiversity Network (GGBN), 2015, Best Practice for Access and Benefit-Sharing. Also GGBN Code of Conduct http://wiki.ggbn.org/ggbn/Documents
- International Plant Exchange Network (IPEN) Code of Conduct https://www.bgci.org/files/ABS/IPEN/IPEN%20Code%20of%20Conduct.doc (more information about IPEN can be found at https://www.bgci.org/policy/ipen/
- Micro-Organisms Sustainable use and Access regulation International Code of Conduct (MOSAICC) - http://bccm.belspo.be/projects/mosaicc Includes: MOSAICC Code of Conduct, with annexes Model MTA, Model PIC application form http://bccm.belspo.be/documents/files/projects/mosaicc/code2011.pdf
- Swiss Academy of Sciences Best Practice Guide on ABS - http://www.naturalsciences.ch/organisations/biodiversity/abs/goodpractice
- BBSRC guidance for researchers on obligations relating to the Nagoya Protocol: http://www.bbsrc.ac.uk/about/policies-standards/good-scientific-practice/

5.2 Experiences of researchers with new conditions for access to genetic resources

The report is based on the experience of two scientists, Prof. Erwin Beck and Dr. Lily Rodriguez, with their research activities in Ecuador and Peru as presented by Dr. Maria Victoria Cabrera Ormaza. The presentation commenced with an explanation of the legal system of the two countries. Both countries belong to the Community of Andean Nations (CAN) and hence participate in the sub-regional common regime on access to genetic resources established in 1996 under the Andean Pact. Peru has ratified the Nagoya Protocol. By the time this presentation was being made Ecuador had only signed and the discussion of possible ratification was still ongoing. The government had sent the text of the Protocol to the constitutional court some years ago to examine its compatibility with the constitution. It

is not clear whether delay to ratify was to give the country time to first adapt to the requirements of the Protocol. This finally took place on 19 December 2017.[7]

Map 1: *Participation of CAN states in the sub-regional common regime on ABS*

- Venezuela
  neither ratified nor signed
- Colombia
  signed 2011
- Ecuador
  ratified 2017
- Peru
  ratified, member since October 2014
- Bolivia
  accessed, member since January 2017

Source of map: *http://u.osu.edu/peek.9/files/2014/04/somosCAN_mapa2-1tzbhmm.jpg (as acknowledged by Erwin Beck and Lily Rodriguez)*

Source of information on participation: *Powerpoint presentation by Erwin Beck & Lily Rodriguez*

Ecuador and Peru are bound by the common regime of the CAN. This regime is provider-centred under the principle of sovereignty of states over their natural resources. It distinguishes between commercial and non-commercial research and establishes different procedures, but under conditions that subject even the latter to the PIC of the country of

[7] www.cbd.int.

origin. In the end there is no *de facto* differentiation as the conditions are more or less similar.

A number of instruments that had been conceptualised in order to operationalise the sub-regional regime are unfortunately still dormant. The Regional Biodiversity Strategy[8] which was to enhance the implementation of the CAN regime remains unfulfilled. The implementation of these strategies proved problematic rendering them *quasi* inexistent. In 2005 the Andean countries resolved to develop interpretation guidelines to the common regime in accordance with the Regional Biodiversity Strategy, but this has not occurred until now. Also, the Andean Committee on Genetic Resources was created but is still inoperative. According to the speaker the implementation of this regime has proved ineffective. This situation is reflected in the existing lacuna in national legal frameworks.

5.2.1 Ecuador

Ecuador adopted a national regulation to implement the CAN legal framework in 2011. Following the adoption, a competent national authority was created and, in addition, "support institutions" that take part in the process of determination of access application. There was no clear designation of a national focal point (NFP), but with the existence of several institutions created under this regulation one could say several existed. Following the ratification of the Nagoya Protocol end of 2017 a NFP was designated and notified to the ABS CH beginning of 2018.[9]

Following a similar model, Ecuador establishes a different procedure for non-commercial research, albeit without elaborating how the term should be understood. A non-exhaustive list of activities that are considered as such, however, is provided. According to Prof. Beck's experience that does not create a clear or significant difference between requirements for research permits and authorizations for the use of genetic resources by different types of research. It was pointed out that a researcher has to visit a number of institutions in order to obtain different permissions before undertaking any research. This is aggravated by the fact that mandates and functions of some participating institutions overlap. In addition, to receive permission for non-commercial research researchers must obtain a research certificate from SENESCYT (Secretaria Nacional de Educación, Ciencia, Tecnología e Innovación), the institution in charge of supervising educational and research activities of universities and research institutes in Ecuador.[10]

Access procedures have become even more cumbersome for non-commercial research since 2014. Besides procedures mentioned above, researches must now also go to the national biodiversity institute where they have to explain the research project and plan and also ask for potential collaboration. By inference it implies that this institution has a right not only to

[8] The regional biodiversity strategies are changing and at the end all negotiations shall be done at the Central Ministerio del Ambiente, involving several other institutions or focal points. Local Universities have to apply for a research permit as well for their own projects, and negotiate details, if genetic resources are considered.

[9] https://absch.cbd.int/countries/EC, accessed 21 January 2018.

[10] In 2016, a new legislation on intellectual property was adopted, which is entitled Codigo Organico de la Economia Social de los Conocimientos, Creatividad e Innovación. According to this legislation, the national research institute (National Institute of Biodiversity) should act as the custodian of the genetic resources. In practice, this institution shall also take part in the decision-making process relating to permissions of access.

issue authorisations, but also to be involved in every research activity –i.e. to take part in it– which, from a researcher's perspective, is another problem. The procedure at the national biodiversity institute is deemed very important because the institute was created by the government to undertake overall supervision of all types of research on national biodiversity. According to Article 69 of the 2016 legislation, it is this institute that shall decide on access requests and coordinate the process of negotiation of benefits. As at now it is still not decided whether permits should be obtained from the federal Ministerio del Ambiente in Quito, or as usual from the Provincial Ministries. It is expected, however, that the decision will be made soon, including whether applicants for permits for basic scientific (non-commercial) research will be expected to establish a contract (MAT, contracto marco).

There is also lack of clarity concerning what the legislation considers as research permit and authorisation for access to genetic resources. According to the former national environmental legislation it was possible for researchers to obtain research permits from local agencies of the minister of environment. Later doubt was expressed as to whether such permits allow researchers to carry out research on genetic resources thus creating confusion. A new environmental code adopted recently clearly establishes that these research permits are not sufficient for undertaking non-commercial research on genetic resources.

Whether we will get the permits from the federal Ministerio del Ambiente in Quito, or as usual from the Provincial Ministries, is still not decided. But since we start working still this year, we expect the decision to come soon. They will also tell us whether we have to establish a contract (MAT, contracto marco) or not.

Other issues include:

1) Permits do not provide permissions for transportation (within Ecuador from the field to the lab) or export (to another country) of samples;

2) Validity of permits is limited in time: permits are always valid for a duration of 1 year. Nevertheless researchers must declare to the authorities the complete duration of the project and its funding (usually 3 years), but still subject to new application for the same in addition to submission of reports;

3) Researchers are obliged to report results in Spanish*;* and

4) Researchers are obliged to include national universities as contact partners.

In summary:

1) The authorities in charge of the genetic resources and the research permit are the Ministry of Environment; National Biodiversity Institute (INB); and the Secretaría Nacional de Educación superior, Ciencia, Tecnología e Innovación (SENESCYT).
2) As at now permits for research and export are obtained from the Environmental Ministries of the Provinces.
3) There about eight focal points.
4) It takes approximately six months to obtain a research permit.
5) It takes approximately six to twelve weeks to obtain an export permit.

6) An application costs USD 20.

5.2.2 Peru

The situation in Peru was reported based on the experience of Lily Rodriguez who has worked on biodiversity-related projects in Lima for many years. Accordingly, the state of affairs is basically the same as in Ecuador. The challenges affecting non-commercial research include:

1) There is no indication of what constitutes non-commercial research;
2) The fees are arbitrary imposed by the government;
3) The competent national authorities[11] have a big discretion and can literally conclude an agreement without any explanation why they do so. This can be observed in CAN in general;
4) To obtain a research permit a number of conditions must be fulfilled.

There is a new forest regulation of 2016[12] that allows the approval of scientific research activities without a commercial intent through scientific research authorisations. Such include the development of activities of basic taxonomic research, wildlife, related to molecular studies with taxonomic, systematics, phylogeographic, biogeographic, evolutives and of conservation genetics' purposes.[13] This might create more confusion because scientists could think this covers non-commercial research on genetic resources. The speaker expressed her opinion that from the reading of the regulation text this is not the case and hence there is need to fulfil the requirements of the CAN legislation. Until now there are no regulations for microorganisms.

The following conditions apply for research permits and access to genetic resources:

1) Description of the project: Field of research, list of Species, localization;
2) CV of private investigator;
3) Dossiers on co-workers;
4) Letter of recommendation from the home-institution;
5) Counterpart: MOU or another document („Letter of Intent" about cooperation of the institutions in the provider and the home country;
6) PIC (if requested by the authority);
7) If local communities involved: Document of agreement;
8) If utilization of TK in involved: Permit by Ministry of Education; and
9) No time limit for the duration of the licensing procedure.

[11] There are five competent national authorities notified to the ABS CH, see https://absch.cbd.int/countries/PE, accessed 21 January 2018.
[12] DS 018 and 19, MINAGRI-2016.
[13] Ibid.

For research without a commercial intention no contract is required and no fees for the research permit. An application for an export permit must be accompanied by the following documents:

1) Research permit;
2) Complete list of biological materials;
3) Documentation for deposit of duplicates of the collected materials in an authorized collection; and
4) For molecular work, a permit of access to the material by the respective authority.

5.2.3 General advanced assessment of post-Nagoya Protocol situation of non-commercial research

In conclusion the state of research on genetic resources in general was assessed. It was noted that a number of changes have occurred that could be judged as fair, which is an improvement. These include:

- Security of compensation of provider countries and indigenous communities for the use of GR & TK (Benefit Sharing between user and provider);
- Legal security of users, controlled by the state;
- Transparency of biodiversity research in the EU and later on in the CBD (ABS CH); and
- Biopiracy more complicated (monitoring of GR).

However, it was also reckoned that certain less appealing situations for academic research still persist. These include:

- Lack of a general procedure issued by the CBD which is obligatory for all members to the NP. There is no effort in that direction. Thus any project in any country is treated individually and the outcome depends on the cleverness of the applicants. This holds in particular, if indigenous communities are to be involved. There is no clear regulation what an indigenous community is. As long as a financial benefit is concerned, communities like to be considered as indigenous. However, if the state of social development counts, this attitude changes: they do not like to be considered as backward.
- No obligation of provider countries to grant access to GR. National laws have (still) priority;
- Art. 8a only asks for encouragement and no obligation to facilitate the procedure for basic/non-commercial research;
- Procedures for PIC, MAT, IRCC are time consuming, country-specific, not uniform;
- Arbitrary fees for research permits;
- High expectations by the providers for benefits; and

- Drastic fines, not only for biopiracy, but also for neglecting due diligence.

In the round-table discussion a comment was made concerning the problem of multiplicity of permits to be obtained prior to access. Reference was made, for instance, concerning the situation in Kenya where up to eight different permits could be needed initially to take a sample, depending on a number of considerations, whereas only one is concerned with ABS. Such permits include the research permit which was the norm of an old tradition that pre-exists ABS. Other concern access to nature protected areas etc. This kind of practice was seen as adverse to R&D on genetic resources, and by implication to benefit-sharing. The project was hence encouraged to come up with suggestions on how to improve provider state legislation. One way would be through simplification of procedures for which the project should come up with a concept of an integrated profile. This would mean all aspects *viz*. nature protection, research and ABS issues are integrated into one permit. The different agencies hence become participants in the permit, but not agencies in charge of providing their own permits. However, another opinion suggested that legal tradition or legal perspective of each country should be taken into consideration. The participation of different institutions in the ABS process in Ecuador, for example, is equated to efficiency according to interviews conducted by one of the participants with ministry officials. Their argument is based on the fact that if the minister of environment deals with all relevant issues then s/he is overloaded with work making the process slower. Hence, it was suggested that the project should take that perspective into consideration by examining what each country defines as efficient while looking at how ABS is expedited in the country.

It was mentioned that Kenya is currently designing an online permit application procedure which will offer an integrated system. Controversially, it also contemplates including indigenous communities. The system will have a so-called one or single entry point/agency and was expected to be launched in July 2017. Doubt was expressed, however, by one of the participants that the design of the Kenyan system comprises an integrated system. In his opinion it is simply a single portal to seek the permission, but various elements still under the authority of different departments. Consequently those departments still have the power to approve or disapprove since the authority to decide has not been taken away from them: if one rejects the application then it has failed. Full integration should give relevant agencies a say in the proceedings, but not power to reject.

Another participant also explained that Gabon and Equatorial Guinea are also pushing for an integrated system in ABS. According to an interview conducted with the officer in charge of ABS in Gabon the idea is to have one point of decision-making in spite of the existence of various agencies and bodies. However, in the course of the process those who have certain interests should be consulted. There are challenges nonetheless convincing other agencies e.g. those charged with coordination of protected areas to give up their current decision-making mandates.

It was suggested that such procedures that are struggling to come up with access simplification profiles should be examined to see what they offer and how they are meant to operate.

Part B: Utilisation and digital information

The second group examined the questions about utilisation and digital sequence information (DSI), and presented a report on possible cut-off points for provider rights.

6. Utilisation and digital sequence information

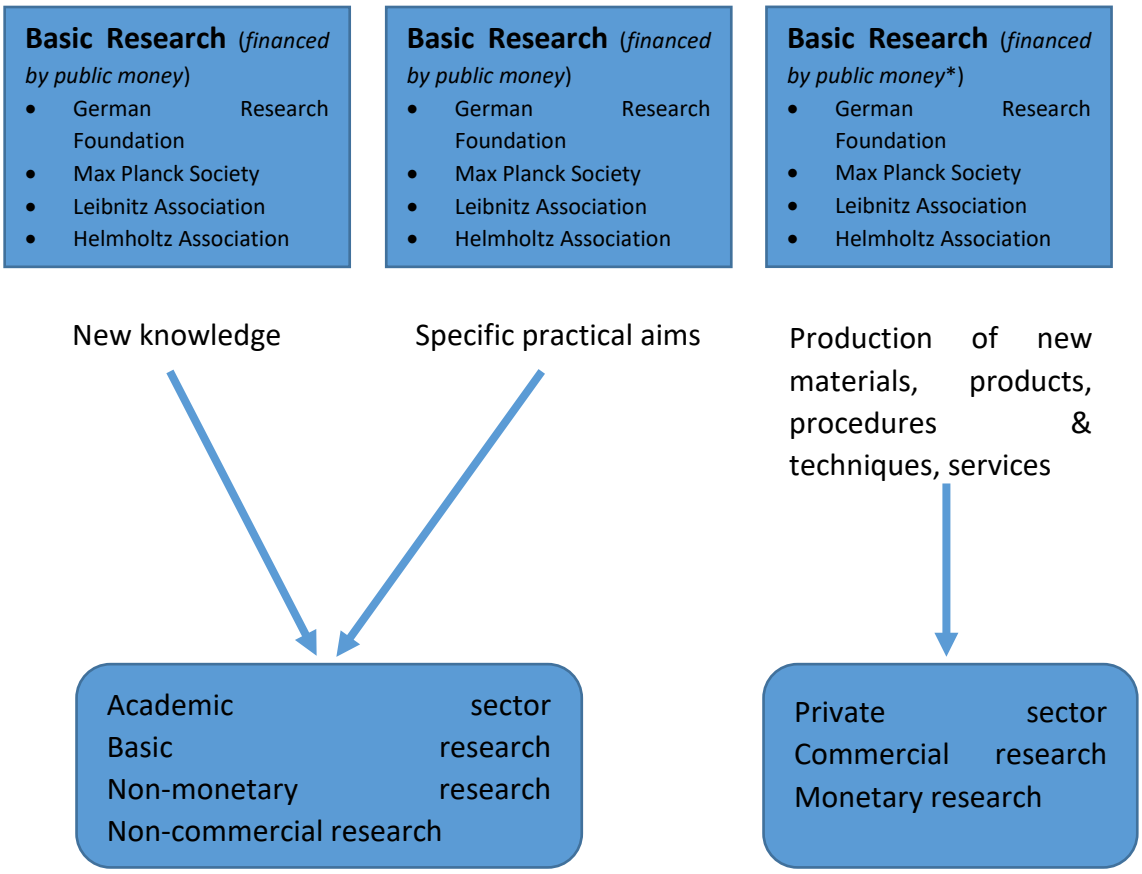
6.1 Utilisation

According to the group, although the term "utilization" has been defined in the Nagoya Protocol, within this definition the meaning of "research and development" remains an unresolved issue. Under the EU regulation (Guidance document 2016/C 313/01) there are two definitions of R&D for use in implementation, which deliver different practical outcomes for the scope of the Regulation. The first is the "litmus test" about the extent to which an activity is going to deliver value to the value chain. The second is taken from the Frascati Manual, and is far more rigorous and far more inclusive (see diagram 3). There are other definitions floating about elsewhere. Other countries are considering different definitions. But, at least, it is an issue with some results. There are still many open questions, however, and the group tried to point out at a number of them.

It was questioned whether utilisation is or should be defined in law, or in administrative implementation of laws (e.g. the EU Regulation compared to the European Guidance Document referred to above). In practical terms what actually is utilisation and how frequently does research undertake this activity? For instance, how many plant breeders are sequencing the DNA of their plants? Alternatively, how many are just implicitly making inferences about the properties of the plant's genes by looking at a phenotype? In that case, would plant breeding using phenotypic information only be judged as utilisation? Is screening (where large numbers of GR may be assessed with only a small proportion taken for further examination) utilisation? Is it pragmatic to consider it not as utilisation (or within scope of compliance legislation) just because of the high volume of items being treated? Is it feasible, helpful and/or legitimate to subject such activities to heavy documentation and due diligence requirements? The existence of many open questions was seen as an indication that resolution of what utilisation is, and how compliance legislation should be recognised is needed. This should happen in a manner provider countries find reassuring as well as users and regulators find possible to implement. It would also be helpful to investigate any system that provides clarity regarding the beginning and end of utilisation and how this is managed in legislation.

It is important to look for existing definitions of utilisation, e.g. examples of country legislations which have clearly stated what comprises and what does not comprise utilisation. An opinion was expressed that mismatch between provider and user countries' legislative reach and expectations might need early attention. For instance, the decision by a country like Peru or Columbia that basic research activities do not fall under utilisation would not affect EU MS implementation of the EU Regulation if EU considers such activities as utilisation.

Diagram 3: *Types of research as differentiated by the OECD Frascati manuel (2015) with examples of financiers in Germany*



***Patents**

Source: *Powerpoint presentation by Erwin Beck & Lily Rodriguez*

The group felt that information currently available to the project on the ways that genetic material is "utilised" by different stakeholder groups is probably insufficient to understand the potential range of activities that might be considered "utilisation". Further sources of information to address and which should be sought by the project include contributions made by stakeholder associations (e.g. biocontrol, plant breeding) during the development of the Nagoya Protocol; outputs of expert meetings in preparation for the Nagoya Protocol; submissions by stakeholders to the European Commission in the development of the EU Regulation; use cases developed in the EU sectoral guidance documents for the commission by various groups specifying what the scope should be based on varying real cases, e.g. breeding, biocontrol etc. The outcomes of such inquiries might give an indication where such definitions are best housed.

In relation to the term "utilisation" the term "access", which has never really been defined, should be investigated, the group said. Important questions in this regard include: What does it mean? Has there been a shift in the way it is understood under the CBD, the Nagoya Protocol, and under the different regulations in various countries? One reading of access might be to say that country A may reserve access rights over a genetic resource collection in country B because the genetic resource has been sitting in an *ex situ* in country A for decades or centuries. But that might not be feasible or permissible. The examination of the term is critical, it was concluded.

6.2 Digital information

It was first noted that when ABS discussions commenced an essentially simple model was envisioned: *access to genetic resources, their utilisation, and sharing of benefits from such use*. That simple linear model seems inapplicable to lots of stuff going on currently. The volumes, abilities to manipulate genes and other applications on genetic resources are constantly changing. Some of the issues arising, e.g. the question of digital information data and screening, are the result of this imperfect model. One has to question how much the original model can be patched with these issues to develop a feasible model, and whether it would really work as well as become applicable.

The issue of digital information is often confronted in ABS in regard to contracts and third party use of information. It is still unclear how this should work, what the legal implications are and what a legal model for transferring those obligations should look like. It is in particular complicated when data or information has been placed in public domain. Looking at public databases and their underlying axioms of free access, the set of rules of their operation (which were considered in the discussions as broader than even might be required under ABS) and the impacts restrictions might have, e.g. on non-commercial scientific research and its benefits, it is clear that the underlying issues cannot simply be resolved by establishing requirements in haste. The fundamental legal basis of the public databases comprising INSDC (International Nucleotide Sequence Database Collaboration) is public access without restriction. This cannot be changed with a quick patch. The entire base of this system and the high level requirement for open access for scientific results e.g. in the EU will have to be changed, which is not a straight forward thing.

Scientific research (unless carried out under conditions of commercial secrecy and not published) requires that sequence data are published as a condition of publishing the research results. The benefits produced by this information cannot be generated if the publication is not done; they will be lost. These benefits can be quantified by looking at the amount of information in the public domain. The big public databases, for instance, are hubs of genetic information, molecular information, names of species distributions, of ethology, morphology etc. There are numerous pipelines where people are publishing different information. If countries could build those pipelines of information into their domestic environmental management systems, then suddenly the value of benefits would be hugely magnified. That is a big capacity issue though, but the example is nonetheless a good demonstration of a simple, efficient and global model of ABS: *a scientist goes to a country and accesses genetic resources, comes back and utilises them and then sends back benefits*.

In addition to issues to examine in connection to digital information, synthetic biology and the relationship between ABS and IPR were recommended. The argument in support of this was that issues on digital information will have an impact on synthetic biology (as it is likely to have on other areas) and because moving into digital information leads into a potential for IPR issues.

6.3 Sources of material on digital information

The group suggested a number of sources, which could be a useful resource in dealing with the question of digital information. They include:

1) Information gathered by the CBD in 2017/18. This includes outputs of expert groups in preparation for the COP/MOP in Sharm El-Sheikh, Egypt (10-22 November 2018); submissions by countries; stakeholder organisations etc. Since the kick-off meeting took place, further resources have become available, particularly the submissions to the CBD's Ad-Hoc Technical Expert Group on DSI and the Commissioned Report to the CBD.[14]

2) Brazilian case and the African guidelines. These are examples of countries already exerting southern rights over their digital information and it is worthwhile to watch what they are doing and how they are trying to operationalize their legislations;

3) Similar work under the Plant Treaty and WHO; and

4) Discussions on digital information in regard to biodiversity beyond national jurisdictions (BBNJ) under the UNCLOS.

7. Special report on possible cut-off points for provider country rights

This presentation was made by Marie Schloen based on her ongoing research focusing on how to adapt the ABS approach to the innovation system in agricultural breeding, both for plants and animals. There are a lot of unclarities, questions and tough problems arising in the community that have been discussed for more than ten years now. One of the aspects raised by the industry is that ABS rights as they stand at the moment know no termination. In other words, there are no cut-off points either in terms of duration, or in terms of material. That is a tough problem for the agricultural community as will be explained below. In that context, it is important to explain what happens in the downstream process after a genetic resource is exchanged under an ABS contract for use in the field of agricultural breeding.

7.1 Value chain in agricultural breeding

The basic problem for the agriculture community is that the ABS system as currently constituted sees benefit sharing linked to the use, or the generation of benefit, through the use of a specific genetic resource. That means, however, according to the way the system is designed, a specific genetic resource and its parts and components need to be tracked. Even if the system waives the tracking obligation like the International Treaty on Plant Genetic

[14] Both can be accessed here: https://www.cbd.int/abs/dsi-gr/ahteg.shtml.

Resources for Food and Agriculture does, benefits arising from a specific resource must be shared and the user must know where the genetic resource and its components ended up.

That may seem a simple thing for a different industry where the genetic identity of the genetic resource remains stable. On the contrary, the innovation process in agricultural breeding can be likened to a river. It is a continuous flow of genetic information through the breeding population. The genetic resource would be integrated in this flow, split up in its components and mixed with other genetic information. In every generation, one innovative step is added onto another and the breeding gain is cumulative.

Furthermore, traditionally agricultural breeding is closely linked to agricultural production and the breeding population is overlapping or even identical to the production population.

Looking at the innovation process of breeding one would then ask: Where is the genetic resource and where is the product of its use? For example, the genetic resource would be a breeding bull or wheat seeds. The product generated from the use of these genetic resources would again be the next generation breeding animal or selected seeds to be sold. There has been a certain degree of specialisation between production and breeding during the last 150 years. Within developed countries this has taken place in regard to certain species and specialist industry (breeders) that provide breeding material in some geographical areas. In Germany, for instance, one can distinguish farmers who are mainly not engaged in breeding, and breeders who are mainly not producing. That works for example for wheat, ray, pigs (at least partly) and mainly chicken. It does not, for example, work for cows even in Germany where the same population producing milk is still also the breeding population (at least on the female side). Hence, the product of the use of the genetic resource would be the next generation of milking (and breeding) cows. On an abstract level that means in the traditional breeding process there is never a genetically stable or static point in the constant flow of genetic improvement. What specialized breeding industries actually do is to artificially create static points within this flow of genetic information. For example, when they create a commercial variety, it can be imagined as them taking out a certain genetic subset from the breeding pool which is then commercialized as a genetically stable variety over the next couple of years. In the meantime, the same genetic diversity represented in this variety will be continued to be genetically improved and integrated in the breeding pool. Thus, the flow of genetic information and the cumulative innovation will continue in the background.

7.2 Challenges of using genetic resources under ABS obligations

What happens then if a breeding company takes a genetic resource from outside, e.g. from a gene bank under an MTA?

Usually the new genetic resource would not be included in the breeding pool for legal concerns. However, if it is included, which would essentially be envisaged in ABS, then it would be integrated in the breeding process and population, split up into its components and mixed with other genetic information. That means, the legal obligations of the MTA would now apply to the whole breeding population for ever. This is because sequences from plants and animals are huge; they are not microbes. Even if some species have been fully

sequenced barely would a breeder – and rarely a farmer – have complete sequence of all their individuals. Hence, whenever a genetic resource with legal obligations attached to it is allowed to enter into a breeding pool, bits and pieces of its sequence could end up everywhere and thereby extend the same legal obligations to other genetic components they are now combined with. Therefore, the breeding pool becomes a kind of black box for the breeders. They would know that the genetic components of the genetic resource and the attached legal obligations are somewhere in it, but they would not know where exactly. Consequently, everything that comes out of the breeding pool, every new variety, every new product and artificial static moment of improvement that is sold, has to suddenly be sold under the legal requirements of the MTA and benefits would have to be shared with the provider of the genetic resource. As there is no end to the legal obligations in terms of timing and as some components of the genetic resource may potentially be present in the breeding pool forever, breeders would have to sell all future varieties developed from the breeding pool under those legal requirements. While there is no end to the legal obligations once taken on board, with every breeding cycle new genetic resources attached to new legal obligations and providers may be added to the breeding pool. Thus, the breeding pool as a whole keeps accumulating legal obligations. Any potential output of the breeding pool, i.e. a commercial variety, would carry all those legal obligations, because there is no limit to them in material terms and because the genetic identity of the different inputs to and outputs from the breeding pool remains at least partially unknown to the breeder. As there is no material limit to the ABS obligations, even small components of the original sequence of a genetic resource, regardless of whether their presence is intended and whether it is of any breeding value, would trigger those obligations. And while breeders may be able to confirm that no component of a certain genetic resource has intentionally been used in a certain variety, they will not be able to guarantee that no part of its sequence is included in the relevant genetic combination.

7.3 Current approach by breeders

Through legal departments of breeding companies genetic resources attached to contractual obligations are separated. Those provided under conditions, which breeders deem impossible to fulfil, e.g. involving a tracking process, are “genetically controlled,” i.e. isolated from the breeding population. This can only be done, however, by big plant breeding and probably big poultry and pig breeding companies. Small companies and farmer breeders alike are not able to do that. Hence, for the latter it implies avoiding the use of such material.

7.4 Lessons from IPRs as a remedy to ABS-related challenges

In an attempt to solve this conflict between the current ABS system and the innovation process of agricultural breeding, some suggest to simply exclude agricultural breeding from ABS. However, that may very well run counter to the original intention of ABS and Schloen’s research attempts to look for solutions within the ABS system. It looks at the functioning of intellectual property rights (IPRs) protection instruments and what can be learned from them for ABS *vis-à-vis* agricultural breeding. For example, in IPRs the level of requirements to be granted an exclusive use right is related to the width of the protection granted. Thus, while plant variety protection has for example rather low requirements for protection

(compared to patents), the width of the protection is also quite narrow. The exclusive use right granted under plant variety protection extends only to a specific combination of traits for twenty years. Anybody can take, for instance, part or parts of the combination of traits, assemble it differently with something else, and use it freely. Therefore, what is protected is only the combination of traits as such. Unlike this, patent protection for plant breeding is wider and hence somebody else cannot use the protected trait or sequence for further breeding or innovation without the licence of the breeder. On the other hand, the requirements for protection are higher and granted only for a specific trait or sequence. Even with this system of protecting specific sequences for a limited duration of 20 years, innovation can be inhibited because of what is known as patent thickets. This is caused by overlying patents on different traits from varying patent holders within one genetic resource or one organism. That is difficult for researchers who have to find out which patents have been granted on the material and who to obtain licences from prior to its further utilisation. Compared to this, ABS thickets would be worse because they involve the entire sequence and they continue accumulating over time.

One way forward may consequently be to limit ABS rights similarly to how IPRs are restricted. The EU has suggested some restrictions in terms of time, e.g. up to 20 years, and in terms of material, e.g. a threshold of 6.25 per cent of the original sequence. This is a first start probably, although the latter proposition is problematic because it would exclude the use of a specific identified gene (coding for example for a pest resistance or another valuable trait), as individual genes would make up much less than 6.25 per cent of the sequence of the genetic resource. It is therefore suggested that the system of restrictions should reflect on the value of the contribution of the original genetic resource, and the value of the innovation that was provided by the user.

7.5 Possible cut-off points

Three cut-off points have been suggested:

7.5.1 Screening phase

This is during screening processes intended to identify the samples of genetic resources that could be used, e.g. one out of thousands. The question is: What happens to the contracts entered into in regard to discarded genetic resources? It is suggested that benefit-sharing obligations connected to such resources end at the moment such material is discarded, but the knowledge generated through screening is shared also with their providers. That is because such genetic resources likewise have contributed in generating benefits of additional knowledge. Depending on the gene contribution of the genetic resource in breeding the genetic resource may contribute qualitative and/or quantitative traits.

7.5.2 Qualitative traits

In this case the genetic resource contributed a qualitative trait, coded for by one gene (or a very small number of genes). The sequence is known, its location is known and the trait is valuable, e.g. a pest resistance. In such a case there is no black box problem and the benefits should be shared with the provider. But what should happen after third party transfer to another breeder? Who takes the commercial variety containing the relevant trait for further breeding? For such a breeder it would be relatively easy to isolate the relevant gene and

integrate it in their own genetic background. Thus the benefit-sharing obligations should extent to such a third party. It is, however, suggested that ABS obligations for qualitative traits end for the first and all subsequent users 20 years after the first commercialisation. At that point the qualitative trait would enter the public domain and could be freely used.

7.5.3 Quantitative traits

Most cases of breeding with genetic resources actually involve the use of genes coding for quantitative traits. This would for example be the case when genetic resources are used for base broadening efforts. The breeder would normally combine them with their own genetic background to boost the variation and then select. For example, a breeder takes 800 samples from the gene bank and combines them with his own breeding pool to boost low input tolerance. As a result the black box challenge is triggered. During the course of a multiple years breeding programme, variation is created, crosses are performed and selection is applied continuously. While most of the resulting genetic setup may be originating from the breeders advanced genetic background, some of it will stem from the inserted genetic resources. And those components are now contributing to the performance of the breeding output, in this case the low input tolerance. The challenge is that it is mostly unknown which one of the 800 genetic resources contributed which part of the resulting product and what the individual contributions are worth. Such a trait would also not be so easily usable by a third party. It could not be easily isolated and integrated in another genetic background. In order to make use of it, a third party would have to invest in substantive breeding/innovation themselves. It is therefore suggested that in such cases the first user should share benefits for twenty years after the first commercialisation, while subsequent users should be freed from the ABS obligations.

7.6 Reactions on proposed cut-off points

The above cut-off points have been suggested as a way to ameliorate the ABS-related challenges in the breeding industry, but not as a panacea. During the round-table discussions a number of views were expressed which can be summarised as follows:

1) There is a need to seek tangible solutions to existing challenges e.g. the ones proposed above, which are easily, uniformly and practically applicable by national compliance authorities, even though such solutions might not be scientifically proved;

2) It is not easy for a national competent authority to explain to sectors, lobbyists, relevant ministries etc. why varying thresholds are used and therefore even political solutions which are simple and pragmatic are desirable as long as they are feasible in terms of applicability, time, staff etc.;

3) Such solutions might not be applicable, however, to all sectors. The 6.25 per cent maximum threshold (used in CITES context), for instance, would not be feasible for plant breeding as mentioned above. With this all the blockbuster genes, for example, would be lost as the percentage of the sequence in plants and animals is very tiny. In addition, if it is established and not realised, this would upset the provider countries;

4) In seeking solutions complication of the work of national compliance authorities should be avoided. It was mentioned, for example, that it would be an illusion to expect a national authority to check the intention (of the user), including its change, or numerous varying conditions;

5) The initial goal of respecting the rights of the provider and consequently sharing benefits should not be underprivileged, underestimated, hindered or lost. Therefore, what is pragmatic and feasible should not only serve the interests of the user or national competent authority of user country and its constituents;

6) Many developing countries are not aware of the developments in user countries, e.g. on the proposals for ABS regulation in some sectors, or modes of sharing or limiting benefits and should be kept in the loop;

7) Such developments and proposals are important for drafters and decision-makers because while developing legislation, for instance, the needs of plant or animal breeding sectors could only be reflected if their specific characteristics and practices are known to them; and

8) Being pro-active in implementation should be seen positively as it moves the process ahead even though the initial steps might not be perfect. Through such attempts the real issues and challenges, which are not perceived in negotiations, become evident. This applies likewise to the International Treaty.

Part C: Compliance and due diligence

The third group dealt with the topic about compliance in general and due diligence within the European Union (EU) and presented a special report on due diligence clause interpreted from other policy areas.

8. Compliance

8.1 Compliance in general

The group mentioned the importance of distinguishing the different compliance contexts or levels that apply to compliance in general and the need for the project to examine them concurrently. These contexts/levels are: compliance with the Nagoya protocol; compliance with the provider country legislation; and compliance with the EU due diligence obligation. Not all of them match as there are different scopes etc. Hence, a researcher being in compliance with the EU legislation, for example, does not mean that s/he is in compliance with the provider state legislation. In the same vein, being in compliance with the provider state legislation does not mean that the provider state has fulfilled its obligations under the Nagoya protocol and other international conventions like the ILO 169 and so on and so forth.

The group also questioned whether the “term” compliance enjoys the same meaning between the provider and the user. It was concluded forthwith that this needs to be considered as the understanding of the term might not necessarily be the same. The group

noted that providers, for instance, understand compliance in connection to users' compliance with their national legislations. It was therefore pointed out that there is a need to harmonise the understanding and hence of interaction between both sides – providers and users.

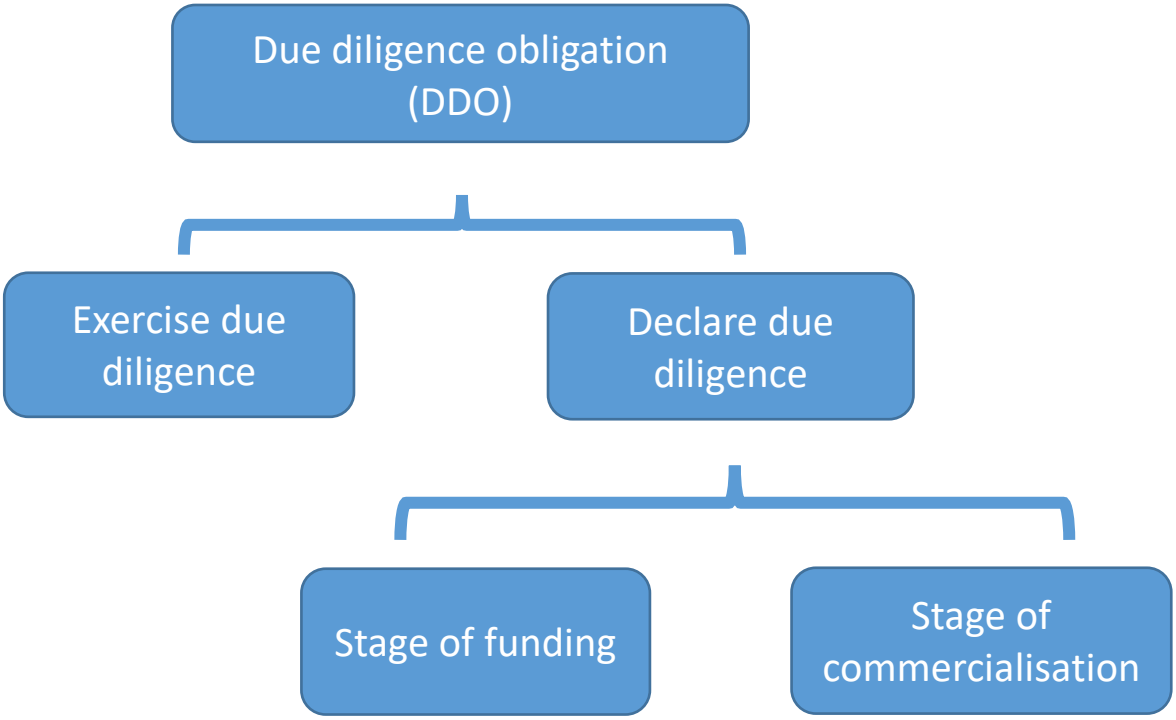
Concerning compliance of users with the national legislation of the provider a question arose as to what extent a user can ensure compliance with a foreign (i.e. not own) legislation. It was suggested that in addition to other instruments that can be implemented in user countries to effect compliance, a declaration of due diligence as required by the EU regulation could be considered as a general approach. Another critical element for compliance that was discussed in the context of Latin America is the importance of including consent of local communities. This obligation is established not only in an international treaty, but also by most of the constitutions of Latin American countries. As an important and interesting question for the research project an analysis of the possibility of user countries demanding that their researchers comply with obligations relating to local communities was recommended. The group also recommended that such issues should be discussed not only from an international but also a transnational law perspective.

8.2 Compliance under the EU concept of due diligence

With regard to due diligence obligation, there is also need to differentiate between the overall or general due diligence obligation in the Article 4 of the EU regulation, and the obligations to file due diligence declarations under Article 7 paragraph 1 and paragraph 2 (see diagram 4). The mere fact that one does not necessarily have an obligation to file a due diligence declaration does not mean that s/he does not have to follow or fulfil the overall due diligence obligation.

One interesting question asked during the discussions was what the due diligence obligation actually comprises in terms of whether due diligence is fulfilled by data documentation management only or the content of the documents shall also be checked. In other words, when can due diligence be said to have been diligently accomplished? What would the competent national authority (CNA) have to check to certify that indeed it was accomplished? Would the mere filling of a declaration of due diligence by the user be sufficient to convince or satisfy the CNA that it was, or would the latter also have to check the/other documents? In the same vein, with the obligation on users to keep documents up to twenty years, how far back can the CNA check if the checking is taking place after many years or at the end of the value chain? Would the CNA consult the archives to try and find out whether everything was done right? Would it be possible to trace what transpired many years ago? Would the CNA have the capacity to undertake such and other related tasks? What and how much can be expected from the CNA?

Diagram 4: *Due diligence obligation*



Source: *Kamau*

It was argued that by making the due diligence declaration the user does not even have to declare that s/he has met the conditions relating to access. All s/he has to declare under the EU regulation is that s/he has various pieces of paper or agreements – has PIC and MAT – without getting into details. The situation might, however, be different where a product has been developed as some commercial value is involved. Such might need a closer look. In general what the competent authority can check is whether filing has been done on time, whether it is correct from the outside, from a general supervision point of view. It will be up to the provider country to practically do the detailed checking. The user country competent authority does not have the detailed information to be able to make verification. According to the group, the CBD Secretariat very much understands the model to be that a checkpoint communique is delivered through the idea of Clearing-House that the utilisation of one type of genetic resources or the other of a certain quantity is taking place in a certain way, by a certain entity in country X. Or there is a provision for that if it is confidential to be sent direct to the competent authority of the provider country. It will be up to the provider country to check if that matches in the information that they have and if not then to take action under article 15 and 16 of the Protocol then the user country has an obligation to do something about it. That includes, for example, regarding a case of change of intent contractually agreed upon between the provider and the user. If the user is making a declaration of due

diligence under Article 7.2 (i.e. when the product comes to the European market), maybe by checking some boxes concerning the type of utilisation and the sort of product, that declaration will go through as a checkpoint communique and the information is available for notification to the provider country competent authority. Consequently, if the use has changed from non-commercial to commercial that information will be available to the provider country giving the latter the opportunity to take action. What that action is, is not very clearly defined and, as pointed in the project proposal, that needs to be addressed. What was stressed at this stage is the critical importance of communication between provider and user states in the different approaches in terms of checking compliance. That shapes the understanding concerning what to expect from one another and the internal processes. For example, what should the provider expect from the EU due diligence declaration? What follows after the checkpoint communique comes in? What does the provider state have to do? And what can the provider state expect then from the user state, again in terms of its enforcement activities?

Although it is likely that a person who has something to hide does not make due diligence declaration, an interesting question is how much it is going to be about pursuing criminal activity or something of the sort if lying is involved in the process. This question was not given attention based on the argument that the discussion focused more on how to manage what is believed should happen and hence on people who are trying to get it right rather than those who try to get it wrong.

Another reason that was mentioned why the competent authority of the user country cannot make the final verification is because article 17 of the protocol has provision allowing parties, i.e. the user and the competent authority of the provider country, to keep certain elements of the agreement confidential. Such elements are not put in the internationally recognized certificate of compliance (IRCC) and hence are also not available at the ABS-CH. Consequently, the competent authority of the user country not being a party to the agreement would not have any information concerning those terms. The checkpoint of competent authority in the European terminology would therefore not be in a position to check such terms.

Caution was raised against expecting much from what national competent authorities can do to ensure compliance. For example, if taxonomic sequencing is taken as utilisation, the NHM London would be making about 1.500 declarations of due diligence under article 7.1 or more per year. That means, from the due diligence obligation of Articles 7.1 and 7.2, the competent authorities are likely to be flooded with declarations. “That would imply 1.500 clicks for the competent authority (…) for documentation that will most likely have to be sent further as paper copies,” it was reckoned. This was found by some commentators as going against the original condition of the EU regulation and the rationale of simplifying matters for non-commercial research and hence the intent of the Nagoya Protocol. The question for the competent authority in circumstances involving such an amount of work would therefore probably be, how could compliance be verified without actually checking the documentation behind it? This makes some countries e.g. Germany prefer a paper-free procedure of declaration and further communication, which, however, might be challenging for developing countries, it was added.

It should be understood, however, that due diligence declaration has other purposes than checking. For instance, it is a channel through which the competent authority gets information concerning who is using genetic resources. Some users are not known and hence are not yet in the data base. That is an important prior information for the competent authority "(…) to find out who are our users and to decide whether we want to do a risk base check on such and such a user or not." Therefore, there is a potential positive side of getting the declarations in terms of management. Eventually such information would probably be simply transferred through the clearing-house mechanism as a checkpoint communique, and then to the provider state, which has the whole document with all terms and conditions, including the confidential ones.

The group noted that in comparison with other countries the EU is doing a good job by at least trying to look at how compliance could be organised, and how it could be made effective. It was suggested that instead of the competent authority trying to do too much, it should have a simple system of producing the check of the communique and then the provider country checking its correctness. That way even the amount of work involved would be less. According to individual views, the terms on checking are not even binding as some imagine. It was noted that if the focus is on putting too much load on the competent authorities of user countries with the hope that they handle all rising expectations on checking, nothing is going to happen. First, by doing so it is assumed that the competent authority has information that it does not necessarily have. Second, that might require the provider country to supply that information, which the provider country may not wish to do, or have the capacity to do. It was therefore advised that instead of discrediting the current process for example in the EU and thus causing further mistrust it should be seen as a process that is becoming an example to other countries, which to a certain extent could even probably be emulated. The focus should hence be on how it could be strengthened, for example, by suggesting ways it could grow and how existing gaps could be covered.

It was proposed that the ongoing project focus on how the different systems of provider and user states, or even EU system as one of the few compliance systems in user countries, can match together. Do they fit together or what conditions are necessary for them to do so? Even though certain pieces will be missing so that a perfect puzzle is not achieved, a step forward will have been made. That would be helpful for the ABS process thus for the implementation of the Nagoya protocol. At the moment it is still unclear how things fit together! As a general observation, it is also notable that compliance measures in regard to foreign legislations are still lacking in the implementation by traditional provider countries. For example if a Brazilian accesses genetic resources in Costa Rica, what are the measures Brazil is putting in place to ensure that Costa Rican ABS legislation is respected (in Brazil), assuming that both countries are party to the protocol? However, some of their measures may be seen in that light. For example, the Peruvian legislation provides for national supervisory mechanisms to ensure that the terms of access agreement are complied with. These mechanisms can collaborate with other mechanisms in other countries in the region.

8.3 What should be checked to ascertain compliance?

Based on personal views of one of the discussants, if the content should be checked, PIC would more likely be the one to be checked than MAT. This leads to the potential recommendation to the provider states to put more obligations or regulations in the PIC than in the MAT. That means parties have to decide to regulate everything in the PIC. Concerning compliance checks in general both in Germany (see report below) and the EU much is still under discussion with competent national authorities still struggling to get the head around what they actually want to check and how they are going to check it in terms of human financial resources as well as time and actually what is feasible in terms of change.

9. Special reports on experiences of national competent authority in checking due diligence and due diligence clause interpreted from other policy areas

9.1 Due diligence checks and experiences of the German competent national authority

The report by Thomas Greiber briefed on efforts by the German competent national authority, BfN (Federal Agency for Nature Conservation), to implement compliance obligations of the Nagoya Protocol and the EU Reg. 511/2014. He started by explaining that the BfN has not had a long experience in the implementation of the due diligence obligation. Most of the experience from other areas that can be borrowed is mainly from the timber trade context and is barely applicable. In addition, there is no indication as to what sector is higher in terms of risk of non-compliance than the other. All such information that can be useful in the ABS area is lacking and hence the BfN has started from a theoretical basis. Nevertheless, the authority possesses useful information concerning its understanding of the same as well as ideas on how its compliance checks could look like and how they can be organised.

9.1.1 Starting point

The first thing as already said above is to identify the general due diligence obligation and what measures are necessary in order to enforce it. The general due diligence obligation according to Article 4.3 EU Reg. 511/2014 is to seek, keep and transfer relevant documentation. For that it is important to engage/employ a risk assessment procedure obliging the user, if s/he finds out at some point of the R&D chain that some information puts in question the legality of the material being used, or s/he is uncertain concerning the same, to go back to the country that provided the material and get a PIC as well as establish MAT, or an equivalent of these. Alternatively, if that is not possible, the user should stop the utilisation. In addition an option of mitigating the risks of non-compliance is foreseen through the acquisition of genetic resources from registered collections. Currently there is no registered collection yet. The risk can also be mitigated by applying for recognition of best practices. So far there are no officially recognised best practices. There are several applications for such recognition but none has been successful.

The second is to identify the additional (to the general) due diligence obligation, which consists of two declarations: at the stage of research funding and at the stage of final product development. The Commission is currently working on an electronic system called

"DECLARE" to facilitate the submission of the due diligence declarations. The test (or beta) version is currently being tested including by EU member states and it is hoped that the system will be ready and running by mid 2018. The EU member states are free to decide whether they want to use this system or not. Some member states might opt to develop their own system. Germany has decided to go for the "DECLARE" system at least at the beginning with the freedom to withdraw and develop own system if there are substantial deficiencies.

9.1.2 Compliance checks

The genesis of checks is the obligation to undertake compliance checks under Article 9.1. For the competent authority there are important qualifiers which are mentioned in § 2. Accordingly, the checks must be effective, proportionate and dissuasive. Unfortunately, there is no explanation what that actually means or what criteria shall be used to establish whether the checks meet that standard. Also important is that there are two triggers of compliance checks comprising of the obligation to develop the so-called risk-based plans, or control plans based on risked-based approach (see diagram 5). The BfN supposes that this will potentially be the regular control and is currently focussing on how such checks could look like. However, there are situations where the authority might have substantiated concerns about non-compliance. In such circumstances the authority shall undertake compliance checks which might be referred to as exceptional controls. This may essentially result from "blackmailing" or "whistle blowing". Information on non-compliance can also be submitted by the provider states, NGO´s etc. In addition, backstopping may at times occur through accusations of companies reporting their competitors of being non-compliant. This seems to happen in the timber industry as reported by some UK experts. However, not all reports may be based on facts.

9.1.3 Risk-based assessments

The BfN is considering doing a risk-based assessment with regard to the danger of non-compliance with the due diligence requirements in regard to diligent behaviour (general obligation) and submission of due diligence declarations (additional obligation). The objective of such a risk-based approach is to undertake more frequent control of high risk users than low risk users rather than carrying out checks on a random basis. In order to identify higher or lower risk two types of assessments shall be undertaken: a sector specific and a user risk assessment.

In Germany there are different sectors such as are currently differentiated in the context of the EU sector guidance documents. To make an assessment of the risk with regard to the different sectors the BfN might look at or try to judge the ABS awareness in individual sectors.

Diagram 5: *Risk-based approach*

Source: *Powerpoint presentation by Thomas Greiber*

Later the performance of individual companies or institutions may be considered based on sectors. The aim is to combine these types of assessments: the sector specific with the more specific user assessment looking at individual dynamic factors which can be influenced by the users. For example, if there is a sustainability strategy in a company that might imply the risk assessment is lower. On the other hand, if a company has nothing to report in terms of compliance strategies the risk assessment might go up. However, to conduct such checks information on users and utilisations must be available.

9.1.4 Possible sources of information

Where to get information on users and utilisations is an important and practical aspect. Although due diligence declarations are an important source, other sources are being searched for. German law foresees a reporting obligation to the patent office. Consequently, patent applications based on genetic resource must be reported (to the patent office). If the BfN receives such reports it might be considered whether to undertake either high, medium or low risk assessment. Another idea is to undertake user surveys, reports from user controls, from past user controls, where it is found out whether the material in question has ever been transferred to third parties, IRCC statistics etc. There are college statistics, for instance, showing which material is being imported and used in research. Such statistics should help in giving information concerning which institutions are involved in research on

flora and fauna and who is using such material. However, it is important to acknowledge that access to such reports will not always be successful due to data protection reasons. In addition, notification by donor agencies would also be a vital source of information. The BfN has already consulted with the ministry concerning this approach although the latter is not convinced about the need to burden its researchers with such obligations.

9.1.5 Organisation of checks

In terms of the first user checks the BfN intends to organise itself in a stepwise approach.

Step 1: Identification of users

This is presently being done in order to develop a data base of potential users in Germany. These are referred as potential users because first, it is not yet fully clear what utilisation comprises. Some uses are (utilisation) while others are not. Second, it is difficult to find detailed information on users, companies, research institutions etc. Although lists exist but often they contain only addresses or websites and probably some basic information about the entity. With such limited information it is unlikely to understand what they actually do in particular in regard to high-tech activities. In spite of such challenges the BfN is working on such a data base and it is hoped that the preliminary data base will be ready soon.

Step 2: User surveys

This is planned and will involve sending out of questionnaires with questions on the Nagoya Protocol and the EU regulation to all the institutions that are listed in the BfN data base and thereby assess their knowledge as well as raise their conscious about the relevant issues. The questionnaires will be anonymous. This relates hence to the first approach mentioned above.

Step 3: Conduct user checks

The BfN is considering doing “checks of leaders,” an idea borrowed from UK colleges. During the first meeting of EU CNAs end of March 2017 UK experts working on timber trade issues mentioned that their approach is actually looking at companies or institutions with high standards. Accordingly, these are more likely to be compliant. The idea behind this approach is first of all to learn how institutions are doing it and likewise to develop a benchmark for conducting checks in other companies and institutions. This helps to indicate whether the latter are having the same standards. Save being a good idea it is also a more collaborative approach with the users. After the “checks on leaders” the BfN will do a first control cycle first, based on a random selection, and then an initial proper risk assessment maybe in 2018 hopefully based on some information from whatever sources.

9.1.6 Execution of checks

The BfN also plans to execute its checks using a step-by-step approach.

Step 1: Starting from the desk in a written manner

This will involve requesting users for specific information e.g. about their activities through written communication.

Step 2: Physical or on-the-spot checks

If the BfN gets any implicating information or indications that some irregular activity is likely being undertaken, then such a check will be done. In such circumstances samples may even be taken if it is necessary to make any clarifications. In case of violations compliance can be enforced again in a stepwise manner starting with regulatory fines ranging up to € 50.000 and ultimately criminal sanctions. Benefits generated by a purported violator can also be demanded and there is no limit on that.

9.1.7 Challenges faced by BfN

1) Reaching a conclusion as to what is feasible in terms of possible number of controls.
2) Understanding how long it will take to undertake one check.
3) Limited human resources. Albeit, compared to other EU member states, Germany is already well equipped. There are currently 4.2 positions and it is planned to hire 2 more. It was expected that by end of 2017 BfN will have 6.2 positions.
4) Lack of clear criteria of "effective," "proportionate" and "dissuasive" checks. Proportion means that BfN cannot entirely focus on one sector and forget about the others. At the same time checking, for instance, 10 users from each sector would also not be proportionate. For example, the bio-tech sector is huge whilst the bio-control sector will be very limited.
5) Information management through user data base. According to a user study conducted in Germany in 2005 a data base of 500 institutions of users and potential users of genetic resources was produced. In 2016 the BfN sent its Nagoya Protocol to all 500 addresses. Through this exercise it was found out that approximately 10 years down the line 50 % of the data was outdated because the institutions either did not exist anymore, they had moved or merged. Even if they just moved it would be difficult to trace them. Therefore, first, the study of 2005 gives an indication of the big number of users in Germany and hence the enormous work before the BfN. Second, the results of the first communication using the addresses in the old data base of 2005 shows the practical problem of keeping and updating data.
6) Understanding what utilisation really is. At the EU level the process of discussing unresolved issues is still ongoing. As a result BfN cannot simply say everything is out or within the scope of regulation, but rather try to find a balanced approach. For example, if one says the issue of human biome is out for some reasons, e.g. due to ethical reasons, then the question arises why human biome is treated differently from pathogens. One cannot apply one approach to pathogens and a completely different one to human biome. The same applies to commodities, plant breeding, animal breeding, bio-tech sector etc. Therefore, BfN is also trying to come up with practical or pragmatic answers and solutions to such issues.
7) Much time and energy invested in looking for appropriate approaches for implementing the compliance obligation and solutions to challenges, including striving to understand the relevant EU documents. Currently there are 6 sectoral guidance documents with two more expected soon. In addition, the BfN will have to develop the German position and contribute to the EU position on DSI for negotiations in the next COP/MOP.

9.2 The due diligence clause interpreted against the background of its use in other policy areas

This report was presented by Prof. Christine Godt. The comparison aims at putting the EU ABS regulation (2014) into a larger picture of five other compliance regimes. Mutatis mutandis, all are different and understand the due diligence standard differently. However, they are after the same intellectual legal problem. They all set up a transnational compliance regime where they knit together two different legislations: One from the provider country and one from a user country. The question is: how do we make these two legally separated legislations communicate? That is what all novel legislations do. That is essentially the object of the current comparison.

9.2.1 Which regulations are these?

Besides the EU timber regulation (2010), on which the ABS-Reg. (2014) is modelled, there is the save harbour agreement on personal data protection (now General Data Protection Reg. 2016), the European diamonds regulation (2002), which is an older regulation to the timber regulation, and the clinical trials regulation in the pharmaceutical sector (2014).

Though these regulations differ, they pretty much use the same mechanisms of compliance and self-regulation and declarations with regard to specific objectives to which corporations have to commit. This even applies to the clinical trials conducted abroad, when data is used for market authorisations in Europe. In such cases it has to be ensured that data produced e.g. in Argentina, South Africa or Thailand meets the European standards of functional testing.

Again, the problem at hand is the same: there are two legislations with differences to knit together. Probably the most significant difference is in ABS regulation where the aim is to import law. Before the European ABS regulation came into place the reflection was on how or whether at all to monitor compliance of a foreign country's regulation. The European regulation now sets up its own standard which conceives due diligence as a European standard of care. But the background is still the nexus with the compliance regime of the provider country. The speaker was of the opinion that this could non-technically and cautiously be referred to as a kind-of communication of importation of regimes. That implies respect in a certain way of the provider country's regime.

The clinical trials, carbon emission on ships, safe harbour agreements and timber and diamond regulations aim at an exportation of the European standard. So basically the idea is inverse. Looking at these compliance systems, that is the most important difference.

9.2.2 What are the mechanisms?

The regimes are built around three common features: First, they are all based on compliance, which is based on industrial self-evaluation. The common idea is that an external organisation organised by industry controls the compliance of a set standard, thus mitigating between the firm and the state. Most of the time, the idea of self-evaluation is linked to the idea of self-regulation. Second, most are risk-based, or at least the word "risk" is found in most regulations. What that means is not really clear. "Risk Management" as a legal duty alludes to an *a priori* non-fixed duty which is sector-wise different and changes

over time. Third, they are based on a document which shows declaration of compliance. The documents may be referred to as “document of due diligence” or “document of compliance”, but basically they mean the same thing. It is a document which, for example, states, “I declare that I do comply based on self-evaluation or on the evaluation of my auditor organisation”. Built on the documentation, they build and keep an enormous data base. Under the pharmaceutical regulation, for example, attempt is made to keep a track of all clinical trials around the whole world, which are of some importance to the authorisation system for Europe. That will essentially result into a gigantic database. It is thus to be assumed that in organising a database for ABS compliance purposes similar technical problems will be encountered.

The regimes differ as to voluntariness and to the degree to which they are connected to administrative enforcement. The ABS mechanism is not voluntary, but in comparison with the declaration of carbon emissions in the shipping sector it is lax. As the timber regulation, the ABS regulation is risk-based and thus establishes a dynamic standard of care. The resulting tendency is that users define their own obligation as long as possible with different non-compliance effects. The text of the EU regulation says, for example, if PIC and MAT are missing resp. the use is not in compliance with PIC/MAT anymore, the user must stop utilisation. It seems that the dynamic standard of care allows the regulation to retard the stop of utilisation in situations where a permit is not available and cannot be obtained (despite engagement in obtaining it). In contrast to the compliance regime in the carbon emission regulation for the shipping sector, the ABS-regime is comparably lax. When a ship owner/operator is repeatedly unable to produce the declaration on the carbon emission s/he is prohibited to enter not only any European port, but any European Economic Area port. This is a straight forward prohibition to enter all ports in Europe. It is a very strict standard which seemingly is a great difference.

9.2.3 Which lessons can be learned?

The ABS regulation is not isolated even though one may talk about it as an animal which is so strange, but which shares many features with other modern transnational regulations. They all build up a novel type of international administration. Hence, one may talk about focal points and check points, data bases which built up an international communication between international organisations, and which are fed by national authorities.

9.2.4 Remaining problems

Two problems remain. One, these declarations have a high risk of becoming paper tigers limiting the work of authorities into a paper task. Since the legal duty is dynamic there is the risk that the due diligence standards evolve – the objective reason being that the due diligence standard wants to respond to the specific situations of different sectors. Therefore, there is a need to be flexible with regard to the specific situations of the sectors and therefore due diligence is not fixed upfront. That is understandable but is also very risky in those terms. Two, a widespread misunderstanding is that competent authorities in user countries are obliged to enforce a foreign country’s law, which they usually reject. In the ABS regulation, there is no international consensus that there is a common goal like in the

climate change regime, where we talk about differentiated duties between countries with a common goal. That is not the standard in the ABS community.

9.2.5 What are the consequences?

There is still a high risk of failure for two different reasons. One, the regulatory capture on the side of national administration; and two, the due diligence duty which is put on individual companies is mainly a management duty which may end up in lack of enforcement.

9.2.6 Comments

Following the presentation a number of comments were made during the round-table discussions by different discussants, which can be summarised as follows:

1) The European Union Timber Regulation (EUTR) seems to be the mother of all current EU due diligence approaches. However, whereas common approaches between the EUTR and other due diligence regulations are noticeable, huge differences too have developed. For example, the purpose of the due diligence in the EUTR is clear but in the Nagoya Protocol it is not yet. Also concerning consequences for non-compliance the EUTR paints compliance in the context of a friendly business approach whilst compliance in the Nagoya Protocol foresees strict sanctions including prohibition of the utilisation of genetic material if deemed illegal. In addition, other sectors *viz*. ABS, carbon etc. seems to have a huge bureaucratic monster to deal with as a consequence, which does not seem to be the intention of the initial due diligence approach under the EUTR. It was questioned whether existing divergences in other regulations could be a result of their drafters being unaware of how the original due diligence approach was meant to function.
2) Concerning the thought that due diligence was initially understood as an obligation to be fulfilled in a business friendly atmosphere, it would mean that the business has to fulfil the declaration and hand it in. Since the cost of managing the entire mechanism lies on the government of the state, i.e. on the entire society that pays for it, that implies the transfer of individual responsibility into a public duty.
3) The comparison of the varying compliance regimes with the ABS regime is an interesting example of importation of law. Other examples always focus on exportation of legal standards (of developed) countries to other countries and checking whether they behave accordingly. There is also the issue of jurisdictions which raises the question of applicability of foreign standards based on the territorial principle. In a way they will not apply but now user countries have to apply such standards on their own users. This is a difference which may also lead to differences in practicing due diligence. In a way, it is easier because reference is made to foreign legal texts; there is no need to look at own practice. In timber trade one would have to look at foreign practice to ascertain whether it corresponds with own standards before applying it. Thus differences may arise in applying due diligence.
4) Probably the reason why one mechanism is enforced more strictly than the other is due to different interests. For example, in the climate change agreement there are common goals; common responsibilities but differentiated obligations. Thus, it is

easier to link these obligations with climate change mitigation whereas it is difficult to link the ABS mechanism with biodiversity conservation. Maybe that is the reason user countries, developed countries, do not see the common goals and consequently do not take the compliance obligation as serious as other obligations.

5) It would probably be different if we had a multinational system where it is clear that benefit-sharing raised resources for biodiversity conservation. If that was clear it would be easier to organize a multinational system and in that case maybe have a common goal. That is not clear in the Nagoya Protocol; Article 9 is very soft. The overall objective currently is to achieve fair and equitable benefit-sharing, but from a user country's view it is difficult to ascertain whether benefits shared are used for conservation. They can flow into every other channel save conservation.
6) That obligation (to direct the benefits arising from the utilization of genetic resources to conservation) was missing in the CBD and is missing in the Nagoya Protocol. If that duty had been stipulated clearly the implementation process would be easier because there would be more trust. It will not only be an issue of distribution of benefits but a conservation matter. Since that is so unclear the common goal got lost. It became provider countries pitched against user countries, which does not really make sense.
7) That is the fault. Looking at the carbon bilateral system, the amount of money directed to conservation is very low. That is a recipe for destroying the whole system with time if the funds are not put to conservation.

Annex I

Table 4: *Thematic discussions (themes and groups)*

Group	**Themes**	**Cooperating scientists**	**Partners charged with case studies**	**Room for group work** (*10:30 – 12:30*)	**Special reports** (*Reporting to be done in ZERP Room after lunch – 14:00 – 17:15*)
A	1. Intermediaries 2. Rights over GR and tracking	1. G. Winter 2. C. Williams 3. L. Krienitz	4. M.T. Mahop 5. Ba Tu Nguyen	FEU library (B 2245)	- Exemplary case of RBG Kew (C. Williams) (5 mins) - Experience with research on GR provided by provider country scientists (L. Krienitz) (5 mins)
B	1. Utilisation 2. Digital information	1. C. Lyal 2. E. Beck 3. M. Schloen	4. J. Cabrera 5. L. Silvestri	bigas boardroom (C 1140)	- Current discussion on Digital Sequence Information focusing on basic biodiversity research (E. Beck) (5 mins) - Ideas on "exhaustion" of rights (M. Schloen) (5 mins)
C	1. Compliance (general) 2. Due diligence (EU)	1. C. Godt 2. T. Greiber	3. M.V. Cabrera Ormaza 4. E.C. Kamau	Café Europa (C 2100)	- Declaration of Compliance in regard to CO2 emissions in large ship sector and lessons for Declaration of Due Diligence in ABS (C. Godt) (5 mins) - Brief report on the implementation of due diligence based on the experience of the BfN up to date (T. Greiber) (5 mins)

Annex II

Table 5: *Group work, reporting and discussions*

<table>
<tr><th colspan="3">Suggested approach</th></tr>
<tr><th colspan="2">Total allocated time for group work</th><th>Issues to check</th></tr>
<tr><td colspan="2">Each group has two themes to deal with within 2 hrs (10:30 – 12:30).</td><td>The group should try to discuss the questions raised in the proposal in regard to the themes allocated to the group checking the following issues, among others:
- what the real issues are in regard to themes allocated.
- whether the issues have been raised in the proposal.
- whether the issues raised in the proposal have already been resolved and how.
- whether the issues raised in the proposal are relevant. If not, why?
- whether the foreseen approach of dealing with them is apt. If not, how can this be optimized?
- are there maybe other more relevant issues in regard to the theme that we should rather be focused on? (not much different from the first point but can be different).
- how much information is available in regard to these issues according to the partners' QA-QA testing questionnaire? How are they being implemented by countries in law and practice? (the partners in the group will analyse feedbacks from all case studies (only) in regard to the group themes).
- other relevant issues, but focused to the objectives and limited to the core issues.</td></tr>
<tr><th colspan="3">Group work and feedback (reporting)</th></tr>
<tr><th colspan="2">Time slots</th><th>Special reports</th></tr>
<tr><td colspan="2">Each group will have 1 hr after lunch for presenting group work results and for "special reports". Discussions related to the group themes will also take place within the time allocated to the group.</td><td>I. Exemplary case of RBG Kew (C. Williams) (5 mins)
II. Experience with research on GR provided by provider country scientists (L. Krienitz) (5 mins)
III. Current discussion on Digital Sequence Information focusing on basic biodiversity research (E. Beck) (5 mins)
IV. Ideas on “exhaustion” of rights (cut-off points) (M. Schloen) (5 mins)
V. Declaration of Compliance in regard to CO2 emissions in large ship sector and lessons for Declaration of Due Diligence in ABS (C. Godt) (5 mins)
VI. Brief report on the implementation of due diligence based on the experience of the BfN up to date (T. Greiber) (5 mins)</td></tr>
<tr><th colspan="3">Groups and members</th></tr>
<tr><th>A</th><th>B</th><th>C</th></tr>
<tr><td>1. G. Winter (in charge)
2. C. Williams
3. L. Krienitz
4. M.T. Mahop (asst.)
5. Ba Tu Nguyen</td><td>1. C. Lyal (in charge)
2. E. Beck
3. M. Schloen
4. J. Cabrera (asst.)
5. L. Silvestri</td><td>1. C. Godt (in charge)
2. T. Greiber
3. M.V. Cabrera Ormaza (asst.)
4. E.C. Kamau</td></tr>
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