REPORT OF THE ABS BONN WORKSHOP

A workshop on Access and Benefit Sharing:

BENEFIT SHARING FROM ACADEMIC RESEARCH

Bonn, 2-3 July, 2015

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DFG Deutsche Forschungsgemeinschaft

A workshop organized by the Institute of Food and Resource Economics, University of Bonn (ILR, Uni-Bonn), at the Zoological Research Museum Alexander Koenig (ZFMK), Bonn. Funded by the German Research Foundation (DFG)

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On 2-3 July 2015, a group of 38 participants got together at the Zoological Research Museum Alexander Koenig (ZFMK), Bonn, Germany, to generate a dialogue on access and benefit sharing of non-commercial research, based on the findings of two surveys conducted in Germany and worldwide. The participants came from a variety of research institutions, international organizations and public administration offices from several countries, including users and provider countries of genetic resources. the results and recommendations of the meeting are presented here. The workshop was ably facilitated by Mrs. Katrin Benninghoff and the organizers greatly acknowledge the German Research Foundation for funding the project and the meeting, as well as the kind contributions made by the participants, especially the CBD Secretariat and the ABS Initiative.

LIST OF ACRONYMS

ABS	Access and benefit sharing
ABS-CH	Access and benefit sharing Clearing House
CGEN	Genetic Heritage Management Council (Brazil)
DFG	German Research Foundation
DNA	Deoxyribonucleic acid
EU	European Union
GR	Genetic resources
ILR	Institute for Food and Resource Economics (University of Bonn)
IRCC	International Recognized Certificate of Compliance
IUBS	International Union of Biological Sciences
LIPI	Indonesian Institute of Science
MAT	Mutually agreed terms
MTA	Material transfer agreement
NP	Nagoya Protocol
PIC	Prior informed consent
R&D	Research and development
SSC-IUCN	Species Survival Commission – International Union for Conservation of Nature
SERFOR	National Forestry Service, Peru
SERNANP	National Protected Areas Service, Peru
TK	Traditional knowledge

1. Background

Since the adoption in 2010 of the Nagoya Protocol (NP), the legally binding mechanism to implement access and benefit sharing (ABS) under the Convention on Biological Diversity (CBD), questions regarding the implementation of ABS and the NP have raised great attention. A switch between discussion of conceptual issues and their application is still continuing as many countries and regions prepare themselves to implement the NP. Article 8a of the NP calls for Parties to create conditions to promote and encourage research that contributes to the conservation and sustainable use of biological diversity, including through *simplified measures on access for non-commercial research*.

The German Research Foundation (DFG), dedicated to basic research, is one of the few funding agencies around the world that has implemented (since 2008) voluntary guidelines to promote the application of the principles and procedures of ABS among its applicants.

Since mid-2012 the Institute for Food and Resource Economics (ILR) from the University of Bonn has been working on "Benefits from and constraints to ABS-relevant basic research", a project funded by DFG. The study has been gathering information on direct and collateral benefits derived from research activities as well as assessing most relevant barriers encountered when requesting access to biological/genetic material.

Two online surveys were undertaken to collect data, one among German scientists and the other international, through members of the International Union of Biological Sciences (IUBS) and the Species Survival Commission of the International Union for Conservation of Nature (SSC-IUCN) communities.

Contextualizing these data and sharing the results will provide users and provider countries with an opportunity to discuss how research is done, how commercial and non-commercial research might be differentiated, or when change of intent can take place. This, in turn, can provide information on the basis of which appropriate rules and procedures for access and benefit sharing, regarding the academic sector, can be designed.

2. Presentations summary

Results of online surveys in Germany and globally, on benefit sharing and Annex 1 of the Nagoya Protocol

- ✓ Two surveys were made; one in Germany among academic researchers working on biodiversity related fields and the other internationally, among those working mostly towards conservation and sustainable use of species (species survival commission of IUCN) and other researchers in biology (International Union of Biological Sciences).

- ✓ The research showed that it is not straightforward to characterize non-commercial research from either the *methods* used for research, the *domain* of research or the *field* of research. For example, using molecular techniques is highly related to non-commercial research and does not necessarily imply future commercial uses.
- ✓ Most researchers work in collaboration with peers from universities in providing countries, although participation of governmental (non-scientists) representatives is now occurring in at least 40% of the cases.
- ✓ To select the study site, scientists prefer sites with long-standing information and established partnerships.
- ✓ Benefits arising from research ranged from capacity building and technology transfer, which are expected benefits under CBD and Annex 1 of the Nagoya Protocol, to infrastructure and other socio-economic benefits. Clear and direct inputs to conservation and sustainable use occurred in at least 49% of the cases in the German survey, and in at least 79% of cases in the international survey. Below is a summary of the range of benefits identified in the studies.

Capacity-building	Collaborations: Contributions	Technology transfer	Socio-economic benefits	Contribution to conservation & sustainable use
Training of local workers in new skills	In designing the research project	Biology Labs, new equipment	Social recognition for the people	Raising environmental awareness
Training of graduate students in user's university	In doing field work	Databases	Adding monetary value to biodiversity	Improving species-specific management
Joint research projects	In analyzing data	Collections	Increasing agricultural yield	Developing sustainable land-use directives
Long-term university cooperation programs	In writing joint publications	IT-infrastructure (computers, software)	Enabling ecotourism	Initiation of environmental conservation measures
Establishment of post-graduate programs in providing country	Others	Training on use of new technology/know-how transfer	Establishing or developing new public/private partnership< 5%)	Development of new science related policies (publications, data management)
Staff exchange		Technical support	Product development (< 10%)	Others

The presentation about benefits, according to Annex 1 of the Nagoya Protocol, proposed two additional non-exclusive ways of grouping benefits: either being individual, institutional or social, according to who gets the benefits or, depending in the types of benefits such as capacity-building,

collaborations, technology transfer and socio-economic benefits. It also proposed the inclusion of some new benefits to the list; namely, conservation and sustainable use of natural resources, increase of environmental awareness, contribution to the creation of policies aiming to the conservation and sustainable use of biodiversity, and encouragement to the private sector to invest in conservation projects.

Participants discussed in different groups the outputs of the surveys and made the following comments:

- ✓ The Annex of the NP presents two lists with examples for kinds of monetary and non-monetary benefits that may arise out of the utilization of genetic resources and which may be shared. The participants agreed that all examples in the list (and there are certainly more) of monetary and non-monetary benefits have their value and significance and cannot be weighed in importance against each other but rather must be taken into context with the proposed research project.
- ✓ The participants were encouraged to see that the length of the list for non-monetary benefits is twice as long as the one for monetary benefits, which suggests that participation in research, as well as institutional and human capacity building, has high priority. This is particularly important for basic, non-commercial research where the purpose of the research is to serve basic science and answer fundamental questions. For example, in the field of microbiology, fewer than 1% of microbial species have been cultivated in the laboratory and the vast majority of bacteria are only known through partial DNA fragments or not known at all. Thus, there is a large up-front amount of basic research and analysis that must be done before long-term commercialization potential can be explored.
- ✓ It is also important that scientific techniques themselves do not trigger specific benefit expectations, without an understanding of the intended purpose of a technique. For example, whole genome sequencing of a bacterial genome is often necessary for basic biological research to answer questions about metabolism and physiology.
- ✓ One provider country indicated that DNA sequencing, no matter what the purpose, could trigger commercialization intent and the resulting commercial benefit expectations. This is scientifically inaccurate and would undoubtedly create a false expectation. Instead, ABS could be used to trigger joint ventures and promote other means to share (monetary) benefits.
- ✓ There were also comments related to some issues for provider countries. For instance, it was recognized that penalties for non-compliance should be in place, in a proportionate manner, and that control should not be a problem if conditions are clear in the MAT. It was highlighted that the benefit sharing could be both ways; i.e., the user should be able to get a contract with clarity. Users should when necessary get advice from their own institution about the terms.
- ✓ It was advised not to use CBD language in contracts, but more appropriate to write legally binding contracts, with legal language.
- ✓ When discussing the several options currently offered to scientist when agreeing on PIC and MAT, it was recommended, for instance, not to sign a letter saying that the genetic resource will never be used by a third party, or for commercial uses, as this might be an institutional decission.
- ✓ In general, institutional projects will be better off in getting access to genetic resources, than projects carried out by individual researchers, for which transaction costs might become too high. Thus, it appears that in the coming years, projects undertaken by individual researcher will become more and more difficult to undertake.
- ✓ The workshop members also emphasized the importance of considering the context of the proposed research project before selecting benefits from the list. There is a clear decision point by e.g. assessing the funding source. For non-commercial public research the ultimate funding

objective is to serve the greater public good. For commercial or for-profit enterprises, the objective is to ultimately create value (and profit) for shareholders. Thus in the former case benefits such as capacity building, training in research laboratories, attendance of conferences and workshops, transfer of knowledge, etc. are common, expected and valuable benefits that can accrue at relatively early time points. At later stages, co-authoring scientific publications, sharing of results with the research community and getting into dialogue with them, are medium-term benefits.

- ✓ It was also suggested, although not thoroughly discussed, that states should regulate expectations on benefits for the provider country, as in general benefits will match the funder intention.
- ✓ In the same way, it was also suggested that it might be worth helping countries to convert current permits, where they are used, to explicitly state PIC and MAT by identifying key parts of what is required in Art. 17.4 in the NP. Model contracts and MTAs will certainly help to decrease administration costs, and facilitate exchange of material.
- ✓ The group also discussed the varying time scales and statistical probabilities of benefit accruals, which should inform expectations and hopes for benefits of both parties. Normally only at later stages and after significant investment costs and process development can potential commercially products be put onto the market. While from this point in time on monetary benefits might accrue, non-monetary benefits such as participation in the production and marketing processes (which again lead to capacity building) might also be of importance.
- ✓ Finally, it was also noted that for benefit sharing to work, it is important to know who should recognize the benefits, and with whom you negotiate them, as these entities should be highly aligned, if not the same.

Nagoya Protocol on Access to Genetic Resources and Benefit-Sharing: Recent Developments and the ABS Clearing House

Valérie Normand from the CBD Secretariat informed the participants about the main activities developed by the Secretariat to support the operationalization of the NP, and adoption by countries to the NP: 62 ratifications and 92 signatures, at the moment of the workshop. In relation to the ABS-CH she explained that its goal is to facilitate the implementation of the NP and the exchange of relevant information on access, benefit-sharing and compliance. It is an online resource registering two types of information, national records and reference records. Thus there is the possibility for all to contribute. Furthermore, it will be the place where the International Recognized Certificate of Compliance (IRCC) is published; a tool that will help to monitor the utilization of GR. Also, the ABS-CH will also publish non-confidential information on utilization produced by national Checkpoints.

New developments in technology: the role of Information

The afternoon session of day 1 ended with a presentation by Prof. Dr. Gabriele M. König from the Institute from Pharmaceutical Biology, University of Bonn. She showed that two thirds of new drugs are still derived from natural products. Through some practical examples from the literature, she explained how genetic engineering, using biotechnology, is used to produce drug precursors, but can take many years (nearly 10 years in the example presented). She showed how bio-synthetic compounds derived from plants or terrestrial micro-organisms can be produced, through very

intensive and complex research work, always needing some biological precursors or bio-platforms, and entailing several steps before any drug development can take place. Another almost unexplored realm is the ocean and its micro-organisms, very few of which can be cultivated with existent techniques.

As for the developments in the next 20 years or more, it is expected that bio-informatics tools may help to manage big data that will be produced by new generation sequencing, which will probably allow global access to genetic resources. Positive outputs of these developments will be, for instance, gene therapy. In her talk she also made a strong point about how she enjoyed sourcing genetic resources from other countries, working in partnership, and had many students working in her labs (capacity building), but that increasingly for her science research she didn't need to do that, and if provider countries access legislation became too complex this would stop (and so would the capacity building). Finally she concluded by saying that we are still far from being able to synthesize large DNA molecules, let alone large organisms.

A panel, composed of P. Desmeth, M. Weigend, K.Holm-Müller, M. da Silva and G. König, commented as follows:

- ✓ Science goes faster that regulations. As an example, prices for sequencing have gone from 5 thousand to 5 cents, making the use of molecular techniques much more accessible. Another example is data provision (mega-data), where it will be difficult to decide for instance who will be the provider.
- ✓ The Nagoya Protocol, legally covering only genetic resources and traditional knowledge associated with genetic resources, will be therefore be outdated, as some technologies such as biosynthesis are not sufficiently covered. Furthermore, although some traditional knowledge can be still kept secret, a large amount of TK is already in the public domain. Some provider country national legislation may deal with access to information.
- ✓ If the scientific community could come up with solutions,
  - It will be key to consider aspects of benefit sharing,
  - Capacity building should be responsibility of the research community
  - And should be aligned with the conservation and sustainable use included in national plans.
  - It will be key to building trust with provider countries, to ensure that national legislation or terms in permits relating to information access, use and supply, is workable.
- ✓ Another angle to consider will be a multilateral system so that potential monetary benefits of all these new developments that have not been covered by the NP could be directed to a fund to be used in research, capacity building and other types of benefit sharing. (This is a concept that is raised in Article 10 of NP and needs to be explored further by the Parties)

3. Case analysis

The participants broke into four groups to analyse four possible research scenarios, , each set in the context of a workshop participant's country. The aim was to work through the details of an realistic scenario to better understand procedures and regulations for access and uses of genetic resources, associated traditional knowledge and output information, in provider and user countries, and identify issues.

CASE 1 Provider: a local market. Country: Brazil

- Professor Morgan from the Berliner University studies plant-animal interactions (chemo-ecology).
- He went to Brazil and bought at the market plants with alkaloids attracting butterflies. These plants were sold as a traditional medicine to cure angina.
- He brought the plants back to his lab in Germany in his suitcase, and discovered that the alkaloid contains a toxic substance (a pyrrolizidine alkaloid), not yet regulated in the market, that can harm human beings.
- He published his results in the *Journal of Chemical Ecology*. One of his co-authors is a student from Brazil.
- He sent samples of the plants to the botanical garden and to the Herbarium in Germany.

Questions:

(1) What should have been done to ensure access was legal? Please describe the complete process, including timeframe, authorities, permits needed, according to ABS and other regulations.

For any research conducted by a foreign scientist in Brazil, the first thing to do is to get associated to a Brazilian Institution, which will be responsible for the project and legally responsible for the access, and will apply for the Authorization's Request for Collecting and Research by Foreigners (Scientific Expedition) granted by the Ministry of Science, Technology and Innovation (MCTI) through an electronic system administered by the National Council for Scientific and Technological Development (CNPq).

If TK is involved, there are 2 options:

a) <u>If to be collected from the field</u>. In this case the Brazilian Institution to which the scientist is associated should consult the official Indigenous ? affairs body (National Indigenous? Foundation - FUNAI), when the access occurs in indigenous lands. Then it should apply for PIC for TK from the legitimate leader of the indigenous group; or from a representing/organizing association (must be acknowledged by the indigenous group). There is a subsequent Anthropologist Evaluation. Additionally the applicant will need an MTA for transport, which is a Brazilian form signed by legal representatives of both project partners. Then with these three documents (PIC, Anthropologist Evaluation, MTA),

as well as the joint project, the Brazilian Institution can request the access to GR and TKA to the ABS National Competent Authority (Genetic Heritage Management Council, CGEN).

b) If the GR is obtained from a market (could be compared to an "ex-situ" collection)[1]. The Brazilian Institute to which the scientist is associated should apply for a PIC to the CNPq (electronically) within the framework of a joint project. When applying for the PIC an MTA (for transporting samples) must be attached. CNPq will issue the PIC and transporting sample permit.

In both cases (a and b) the Brazilian Institution has to indicate a *Trusted Depository Collection* previously accredited by CGEN for the deposit of a sample of the genetic resource, even when coming from a market. The deposit must occur *before* shipment abroad.

After the Brazilian Institution sends the documents for the permit application, CGEN evaluates and if everything is all right, the council votes (majority) and authorizes it. Then the authorization is published in the official gazette (PIC).

Once in Europe, the EU regulation (plus Implementing Act) will apply. In the case of a German user, the German law on implementing the EU regulation will also be applicable.

In case of external funding supporting the project, a "due diligence declaration" should be made to the user country Checkpoint (in this case in Germany), once the GR and TK has been accessed. This demonstrates the users' capability of complying with obligations under Europe and national laws.

In case of institutional funding, there may be internal checks for ABS on compliance (be prepared for compliance checks by BfN). This demonstrate the user's capability of reporting/documenting obligations under Europe and national laws.

Below how the group had developed the case:

- Scope of usage:
  - Buy plant GR+TK in Brazil
  - Export plant + GR to Europe
  - Performing analysis in Brazil + Germany
  - Publishing results in journals
  - Deposit GR in German botanical garden and herbaria.

- Applicable laws:
  - Transporting toxic substances back home (other relevant legal fields that need to be considered outside ABS/NP).
  - ICAO/IATA regulations on classified dangerous goods
  - Phytosanitary regulations (veterinary regulations)
  - Customs law, biosafety, working security

- Documents/steps:

1 - Joint project between German scientist and Brazilian research institute

2- Source of TK A: sourcing “from the field”

B: sourcing “market” (comp. “ex-situ collection”)

- *Sub-case A*: GR +TK from the field
  - 3. Apply for PIC for TK
    - From legitimate leader of indigenous group
    - From representing/organizing association (must be acknowledged by indigenous group)
  - 4. Anthropologist evaluation
  - 5. MTA for transport (Brazilian form signed by legal representatives of both project partners).
- *Sub case B:* GR +TK from market
  - 3. Apply for PIC at CNPQ (electronically)
  - 4. Join project (for access)
  - 5. MTA (for transport)

6. Apply for permit at CGEN:
   - Joint project
   - PIC
   - Anthropological Evaluation
   - MTA

   = Evaluation, vote by majority and authorization by CGEN

   = Permit published in Official Gazette
7. Deposit GR sample in Brazilian Accredited collection.
8. Export GR (+TK) outside Brazil
9. Import GR (+TK) into EU
10. Research and publishing “GR + TK”
11. Deposit GR sample in German Botanical Garden and herbaria.

- Application of the EU Regulation 511/2014: (including Implementation Act)

  For the <u>user</u>: applicable national law of Germany on implementing EU ABS Regulation

  1) In case of external funding: „due diligence“ declaration (prior to actively start the project and access the GR and TK[2]). This is to demonstrate capacity of reporting/documenting obligations under European and national laws
  2) In case of institutional funding: internal checks for ABS compliance (e.g. “compliance checks” to be prepared for BfN). Also to demonstrate capacity of reporting/documenting obligations under European and national laws.
  3) For deposition
     - Follow access conditions given in legal documents from Country of Origin (PIC, MAT, others).-
     - Follow accession policy of collection
     - Provide proof of legal ownership (e.g. via own MTA).
- Authorities (Brazil):

[2] Under the EU Regulation the declaration does not have to be made until both the funding and the GR / TKaGR have been accessed.

- CGEN
- CNPq
- Traditional community authorities/representatives

- Authorities (EU/Germany):
  - Funding agency i.a. (what is i.a. ?)
  - BfN
- *Permits :*
  - PIC
  - MTA
  - Permit i.a.

Documents:
- Anthropol. evaluation
- Project
- Accession form (deposit)
- Due diligence declaration i.A.
- MTA (deposit) i.A.

- Legal partner:
  - Brazilian research institute
  - Legitimate representative of traditional community
- Type of research: non-commercial
- Benefit sharing: Officially no benefit sharing (because it is research)
- If there is a change of intent:
  - Notify the Brazilian authority
  - Meet the requirements and process for commercial research

(2) Who would have been the legal partner?

A Brazilian research institute. If the sample was taken from the field, a legitimate representative of the traditional community holding the TK.

(3) What benefits can be shared? How could that be arranged?

Officially, Brazil makes no demand for benefit sharing from non-commercial research (but such requirements may be set out in MAT between the institutions involved)

(4) How will the group qualify this research? non-commercial or commercial?

The group qualified it as non-commercial research.

Recommendations: Regularization

- ✓ Joint research project with Brazilian research institution, which will apply for the Authorization's Request for Collecting and Research by Foreigners (Scientific Expedition).
- ✓ Deposit of genetic resource (plant) in a Brazilian collection accredited as Trusted Depository Collection.
- ✓ Regularization of the process in CGEN required by the Brazilian institution for access and transport abroad.
  - Requires: project, MTA
- ✓ CGEN analyses the case and votes (majority)
- ✓ Authorization is published in the official gazette (PIC).

Open unsolved question*:* change of intent. If there is a change of intent, the Brazilian Institution has to go back to CGEN and require an authorization for bioprospecting and/or technological development. For this MAT are necessary, besides the project.

Editor´s note. In summary, it will not be allowed in Brazil to acquire material in the market and use it for research activities, even if the purpose is not commercial. However, regularization is possible. It is worth noting than in this particular case, there was no change of intent. Also, please note that Brazil is in the process of changing its regulation. The information given above, follows the current framework (procedures according to the Provisional Act 2.186/2001), in force until it is replaced in November 2015.

An additional open question: the scenario for the TK to be accessed; the fact that it is in the market, does it mean that it is already in the public domain?

CASE 2 A typical non-commercial research project. Country: Indonesia

- A researcher from an EU museum that implements an approved Best Practice is contacted by a conservation organization in Indonesia to develop and implement an inventory to establish a terrestrial protected area.
- The inventory will include, e.g., plants, butterflies, venomous animals
- A consortium is put together from UK, Germany, France and Indonesia; all members will conduct fieldwork, and identify specimens; some specimens will be sent to other experts in various countries for (identification) study.
- An inventory is produced, together with scientific papers. Sequence data are placed on GenBank, and thus are publicly available.

Questions:

(1) What should the team of researcher do to ensure the project can take place?

The research team shall make sure that the Indonesian Government acknowledges the contacting conservation organization as a suitable research partner for the planned development of a protected terrestrial area (this can be done by consulting consular representatives / the Ministry for Research, Technology and Higher education). Then members of the team should apply for the required permits. As a first step a partnership agreement will be needed, for which a template is available (see below).

(2) Do all members of the team have to apply independently in Indonesia?

Yes, a *research permit* is obligatory and based on individuals, not on institution. Application is possible online (http://frp.ristek.go.id/). Permit process includes a research visa. Below some of the information required for the *research permit*:

a) A formal letter of request to do research in Indonesia, including the address of the Indonesian consulate from which the researcher will obtain the visa.
b) A detailed research proposal.
c) The researcher's curriculum vitae (CV) including 2 letters of recommendation.
d) A letter of acceptance from Indonesian Counterpart (an Indonesian academic institution and/or a Research Centre).

e) Letter guaranteeing sufficient funds to cover research and living expenses in Indonesia and fees for the Indonesian Counterpart(s).

Additionally, a *collection permit* (for which no official guidelines exist), will be required. To request it, the counterpart institution should send a letter to the Directorate General of the Nature Conservation Department of the Ministry for Forestry (in Bahasa Indonesia) containing details of the team, where the sampling will take place, the methodology, a list of species to be collected and the number of specimens (as far as possible). A full proposal and detailed explanation of what is planned with the samples, and further processes should be attached – along with a copy of the research permit(s) of the foreign researcher(s) involved. The species list is necessary for administrators to differentiate between protected and non-protected species since different procedures apply.

The Ministry for Forestry then sends a letter to LIPI asking for a recommendation (to speed up the process the research team should request such a letter of recommendation from LIPI first and get in direct communication to minimize misunderstandings and possible rejections).

I. Non-protected species: The Ministry issues a recommendation and hands over final decision to local sub-branch of Ministry (Like Nature Conservation Department on Province level, and / or National Park authorities). They issue the final collection permit.
II. Protected species: The legal department of the Directorate General issues a decree allowing the collection (time consuming procedure).
III. If working in protected areas: the authorities will register all samples taken and issue an? documents with a detailed list. But, this is not the case.

(3) What conditions are necessary for sending specimens to third parties in other countries? Who owns the genetic resources at the museums in Europe?

The Indonesian State owns the samples. Transferring samples from Indonesia to another country can be done:

a) as a loan between collections, if it is an official collaboration with a collection. This provides the opportunity of export for exchange of samples between collections.
or
b) based on an MTA and *an export permit* from the Ministry for Forestry and Environment. If non-nationals of Indonesia are involved in the collection of the samples, beside the research permit, a collection permit is needed (see above). Depositing copies of samples is normally required as part of the conditions of an export permit. If this is not possible, a statement is needed, guaranteeing the return of samples / specimens.
c) In any case, for protected species (under CITES) an additional permit from the Minister of the Ministry for Forestry and Environment (National Authority) is required.
d) Transferring samples to a third party, in another country (or in the same country where the sample has been deposited), requires the authorization of the Indonesian counterpart institution.
e) Export permit from LIPI (Indonesian Institute of Science).

(4) What should happen to the scientific papers and inventory? Where are they published? Who are the authors? Is there any need to put in details of the permits?

a) All research results shall be made available to the partners. Copies of publications are stored at the institution issuing the research permit (FRP-MENRISTEK).
b) For reasons of knowledge transfer and capacity building, it is desired by the Indonesian Government that publications are developed jointly between the partners; co-authorship- depending on scientific involvement in the research.
c) As part of Best Practice research, publication policy, Intellectual Property Rights and equal benefit sharing should be stipulated in a *technical agreement (MoA),* acknowledged by the Indonesian State Secretary before the research collaboration starts.
d) As for where to publish the results, there are no restrictions
e) To mention permit details in publications is not required by Indonesian law. However, Indonesian authorities randomly check international publications to verify whether research was done with proper permits.

(5) Are there any issues about publishing the sequence data on GenBank? Which?

Not certainly. However, there are often questions about "the juridical status" of a GenBank.

(6) Recommendations for researchers

- ✓ Most important is to get the right information first. Regulations are complex and not available via the single source of the clearing house mechanism.
- ✓ Find appropriate partner(s) (person or institution in Indonesia) who have the necessary understanding and are able to assist the research team on all administrative matters. Consult reliable institutions such as Indonesian Embassies, FRP MENRISTEk and National Focal Points.
- ✓ Develop a detailed collaboration agreement acknowledged by the Indonesian State Secretary, covering issues like IPR and data policy, ABS, Publication Policy, sample handling, ownership of specimens.
- ✓ Develop a MTA in line with NP and national legislation; acknowledgement from State Secretary recommended.
- ✓ Get the necessary permits (research permit, collection and export permits; in addition a permit to work in protected areas and working with endangered species, in those specific cases).
- ✓ Although not obliged, mention permit number in publications (e.g. listed in the acknowledgement part of the paper).
- ✓ Bear in mind that transfer to third party for non-commercial use (for taxonomic identification for example) will require approval of Indonesian authorities:
    - Directorate General of the Nature Conservation Department of the Ministry for Forestry
    - National reference collection at LIPI
- ✓ Benefit sharing from basic research may include: involving Indonesian partners in publications and capacity building (i.e. abroad identification of spp), and sharing results and data with partners and stakeholders.
- ✓ Further, the research team shall consult the National Focal Point for Global Taxonomy Initiative (NFP TI) and contact and involve the National Reference Centre for Biodiversity Conservation (Research Centre for Biology, LIPI, with its national Herbarium and Zoological Museum).

Editor´s Note: In the case of the **Philippines**, it would have been required to involve a Philippine institution as a research collaborator or counterpart for a non-commercial scientific research on wildlife, just like it is the case in Indonesia. Furthermore, prior to obtaining a Memorandum of Agreement (MOA), researchers must have to seek PIC from the local communities where the research for the proposed new terrestrial protected area will take place. The office issuing the MOA is either the Department of Environment and Natural Resources or the Palawan Council for Sustainable Development, depending on the location of the collection. An additional research permit (gratuitous) may be issued whenever necessary. To export the samples, an export permit shall be required together with local transport permit. Export of samples shall be specified in the MOA and/or supplemental document (research proposal) that such export of sample is part of the research activity; an agreement to exchange samples shall be also specified in the MOA, further specific activities to be done with the samples, like DNA sequencing, shall be specified in the MOA. Logically and practically, the move to push a new terrestrial protected area would require local Philippine government initiative or implementation. As such, required non-commercial scientific research on wildlife collaboration with non-Philippine institutions would be facilitated if deemed essential.

CASE 3 From basic to commercial research? Country: Peru

- An EU university has been working in Peru for many years, with local counterparts, studying Carbon decay and sampling soil micro-organisms.
- They have published in journals in both countries, and sequence information has been put on GenBank.
- Based on a publication on a bacteria, including collections from 2015, but also earlier specimens deposited in a public collection, the EU lead researcher is approached by a company who wish to investigate possibilities to patent it, for its capability to decompose polymers (plastic material), as this is implicit from the Gene sequence.

Questions:

(1) What agreements are the EU researchers likely to have? What benefit-sharing agreements might be in place?

The researchers must have a permit to do research, to collect specimens and an access contract, to have been able to export the samples. Below is the process they must have followed:

A. Get a Peruvian partner (with an MOU, letter of intent or similar).
B. Get a Research Permit. This requires the
    a. project details, including location and list of species;
    b. a letter of introduction by the researcher´s institution, for the researcher and for each of the partners and participants in the project;
    c. The researcher CV.
    d. Note that for molecular studies, the researcher will need to apply for an Access Contract, issued by the competent authority (*) once the material has been collected and before leaving the country.

This permit must be issued by the appropriate authorities

a. Terrestrial not protected areas: SERFOR (M. Agriculture)*
b. Protected area: SERNANP (Min. Environment)
c. Marine: Min. Of Production*
d. Cultivated and domesticated plants & animals: (Min of Agriculture)*

Only (*) are also competent authority re. ABS.

C. If in an *indigenous community or territory*: need permission from community to be in land. If the research involves TK, need permission from Ministry of Culture.
D. Export permits. Requirements.
    a. Proof that 50% of the collection has been left in a Peruvian institution;
    b. List of material collected (no specific legislation in Peru to cover microorganisms)
    c. Research permit
    d. No sequencing allowed without separate ABS contract from relevant competent authority (see 2 a-d above)
E. Contract requirements (no timeline associated):
    a. National institute for support and supervision (as well as a partner)
    b. To cover sequencing and publication, to do the necessary analysis
    c. Benefit sharing: capacity building, joint research, etc.

There is no timeline defined for these procedures.

(2) When approached by the commercial body, what should the researcher do?

If the researcher is going to be involved in the development of a product, he should go back to Peru and renegotiate a contract with the relevant ministry (SERFOR in this case).

If he is not involved, then the university and the company should go together to Peru to negotiate a contract. If the university is not going to be involved, then the company should do it. The procedures to do this were not discussed.

(3) *How will the group qualify this research? Non-commercial or commercial?*

The research project itself was not commercial, but when the company approaches the researcher, there is a change of intent.

Recommendations and open questions:

- ✓ Peru to upload ABS and related information into ABSCH, including legislation and flow chart/decision tree with procedures.
- ✓ Consider biology of organisms: i.e. cDNA sequencing for basic microbial research
- ✓ Timelines: Peruvian authorities should aim to regulate permit timelines to give some clarity to researchers as to how long the process will take
- ✓ To the scientists: If there is a change of intent, tell the commercial company to go back to Peru.
- ✓ Write to Peruvian authorities to explain difficulties and open a *Dialogue*.

Editor´s note. The group analysed the procedures in place in Peru for research purposes (there is no difference between commercial and non-commercial so far), which follow Decision 391 of the Andean Community. Nevertheless, it was noted that, so far, there has not been any contract in Peru for commercial purpose; therefore, the authorities have no experience with that type of cases or with establishing the benefits.

The participant from China commented that in China there is currently no ABS legislation. Collaborations happen between researchers and institutions without intervention of authorities.

CASE 4 Information Country: Australia

- An EU researcher has collected plants from Australia and at the same time villagers where he was working volunteered information about traditional uses of the plants
- The researcher made a note of the information, and when back in his institution added it to his institution's database and put a reference on the specimen labels
- The researcher's institution has an open access policy, so their database is freely available externally; they have also digitized the specimen data (TK associated) and images
- A third party non-profit organization develops a medicine from the published information, and disseminates it in the EU

Questions:

(1)If the researcher's permit did not mention traditional knowledge, what should he do / have done?

- The legal requirements for the collector will vary according to where the collector is working.
- There are different requirements for Commonwealth (Federally owned or managed areas) and State lands, and for indigenously owned land.
- Commonwealth land (e.g. Kakadu National Park) is indigenous land leased to the Commonwealth. Outside the boundaries of the Federally managed land the law of the relevant State or Territory would apply. The Northern Territory has similar ABS Laws to the Commonwealth, in Queensland the ABS law has no mention of TK and does not apply to privately owned lands, while Western Australia has no ABS law but relies on elements of other acts. Federal (Commonwealth law) generally applies to Australia's marine jurisdiction (14 million square kilometers), designated Commonwealth areas, offshore Islands and some other small terrestrial areas.
- Assuming the Collector is on indigenously owned land leased to the Commonwealth as a National Park, the permit is national not state. However, for the permit to be issued there has to be agreement with the Indigenous Community; the Community owns the resources.
- Generally (in a national park) one would indicate to the permitting authority that one was talking to the community before applying for a permit. The process depends very much on where the work is to be done, and an aim is to make it simple to determine who the actors are and what process tree they should follow.
- There must be a benefit-sharing agreement <u>for the access to the plant</u> because there will not be a permit without such an agreement. The National Competent Authority must be satisfied that the benefit-sharing agreement is fairly made. Fairness is measured against explicit criteria.
- Under Australian law, if there is any intention of using TK, the researcher has to tell the owners of the TK and get their permission. If he does not tell them the permit is void. [The Community will assume that disclosure to a third party though a database is use, and would expect to have the right to give or withhold permission.] An amendment to PIC and MAT must be in writing. This may be from the individual or the appropriate body from the community.
- The researcher (collector) has to go to the Community and ask their permission to record the TK information if this is to go into the database (and thus become public information).

- If the researcher picked up the TK outside the Community area (e.g. in a bar in a town in Queensland) then there is no obligation to the Community under Queensland ABS law.
- However, the researcher's duty when subsequently accessing the physical material is to make it clear to the Community that he is going to use the TK he has acquired elsewhere. The Community will then decide to give permission to collect and access the material.
- The permit (if a Commonwealth permit) may require the permit holder not to allow others to carry out R&D for commercial purposes if the stated intended use is for non-commercial purposes. This may limit open access. The obligation to put results into the public realm means that the information is a public good and therefore is open to any and all sorts of uses of that information.
- If the permit is for commercial purposes then the benefits will be shared according to the terms of the benefit-sharing agreement between the provider of the material and the user.

➢ *Recommendations*

✓ Obtain information of requirements by country
  - NFP, ABSCH, colleague's experience

✓ Researcher should get PIC before recording any TK when offered
  - Should explain that the data may be used by third parties.
  - If TK is already in his possession should inform the Community when accessing the GR that he plans to use the TK

(2) If the researcher did not seek additional PIC and MAT, should the TK be included in the database and on the specimens? What should happen to it? What should the home institution do?

- Do not include TK on the database.
  - A disclaimer on database is legally binding but may not be enforceable
- If the institution wishes to (or has) published the TK on the database the researcher should go back to the Community because if the TK is published all of the permit is voided
- First step if issue is discovered is that the institution should remove the information from the database.
- If the community does not agree to the disclosure of the TK then permit remains void
  - Institution now holding the material illegally and should return it.

➢ *Recommendations*
- ✓ Institution should have policies and processes to manage situation
- ✓ Do not publish TK without clarity on PIC and MAT
- ✓ In the data flow between data capture and data publication there should be a filter for ABS compliance
- ✓ Put disclaimer on database
- ✓ Remove from database as soon as discovered
- ✓ Return to the community to seek new PIC and renegotiate MAT (publication without 3rd party use discovered)
- ✓ If the third party has developed the product the institution engages with the third party to work together with them to approach the community.

(4) + (3) What should the third party do?

- Australia is not a Party to the Nagoya Protocol so there is no liability under the EU Regulation
- Information is not on the ABS-CH so again there are no obligations under the EU Regulation.

- If one assumes for the sake of argument that Australia is a Party, and information on legal requirements is posted then:
    - If the development is only from information and GR have not been involved:
        - Assumed in EU Regulation that this does not fall under due diligence obligations
    - If the relevant plant has been obtained by the 3rd party from another research organization (botanic garden) where it has been grown for decades the original link between TK and GR is broken, and there is no liability under the EU Regulation.
- Leaves Reputational damage and ethical issues
    - Should go back to the ILC
    - If a disclaimer had been put on the research institution database prohibiting commercial use there may be a case to be answered there.

(5) How will the group describe this research? non-commercial or commercial?

Original research is non-commercial. Third party is commercial? Not enough information to be sure.

Final remarks, by the editor. During the different sessions and in the corridors, several other ideas were raised during the meeting.

- ✓ For instance, one proposal emphasized the need to establish an internationally recognized MTA, consistent with the terms of the NP, to protect and facilitate non-commercial and basic research.
- ✓ EU to work with scientific collections and bodies to agree best-practice guidelines to enable international recognition of national and international collections as NP compliant.
- ✓ Agreed Guidelines should reduce transaction costs and delays, and their use should demonstrate NP compliance and legal certainty.
- ✓ Develop a system in the ABSCH, to register users who are compliant to policies operating in research circles (mostly collections, such as those under IPEN and CETAF). This should help provider countries to identify the affiliation of stakeholders. This may also trigger a demand to use the ABSCH website.

Develop clear guidance on what to do in the case of change of use/intent both in the case of change of use by the researcher (or institution), and also in the case of passing material to a third party that may use the material commercially. In this case where does the responsibility lie to inform the provider country of a change of use? With the researcher?

4. Recommendations

By way of conclusion, the participants agreed on putting together a group of recommendations to somehow summarize the analysis made during the two days and to foster further discussions around the subject of access and benefit sharing within academia.

a) To scientists and the scientific community

- ✓ Increase focus on non-monetary benefits (e.g. share knowledge), particularly in alignment with provider country NBSAPs and other relevant policy priorities.
- ✓ Inform yourself on laws and procedures on obtaining, using and transferring material.
- ✓ Seek information on national contacts, laws and regulations on the ABS CH.
- ✓ Contact your legal or technology transfer department or ensure your institution has access to relevant expert legal advice.

- ✓ Develop consistent MTA and, where appropriate, seek active involvement of the Association of University Technology Managers[3].
- ✓ Negotiate framework agreements (with clear use statements).
- ✓ Obtain legal certainty over permitted use of material to conduct research
- ✓ Go to countries with clear ABS procedures
- ✓ Take note that access legislation of the provider country and laws in the user country may differ in scope and may trigger different (reporting) obligations for the user.
- ✓ Disclose source of origin of genetic resources and associated TK when publishing articles and if submitting an application for patent.
- ✓ Communicate to peers to share and raise awareness on ABS regulations
- ✓ Share codes of conduct with peers.
- ✓ Participate in policy development with government agencies and with scientific associations
- ✓ Develop model contractual clauses and share those clauses; there is a need for standardized contractual clauses.
- ✓ International collections open to showcase developing countries genetic resources provided under ABS agreements to benefit science and developing countries.

b) Overall recommendations to others

i. For policy-makers/provider and user countries:

- ✓ Establish clear timelines for issuing permits for research, after application submission.
- ✓ Simpler and quicker permit processes makes countries more attractive to foreign researchers.
- ✓ Consider biology of all living organisms including those invisible, known to science only by DNA.
- ✓ Whenever possible, clarify definitions or discuss the concrete application of terms such as "research and development", and "utilization".
- ✓ Clarify procedures for change of intent, use and the need to renegotiate PIC with provider (especially need to establish who has the responsibility to notify change of intent).
- ✓ To include key players (such as researchers and their representative bodies) in the process of policy development.
- ✓ To agree on standardized approaches, on a sectoral or categorical basis, for implementation of Article 8a of the Nagoya Protocol. Encourage this at next COP-MOP.
- ✓ Clear harmonization between user and provider countries to respect ABS, is highly needed for compliance and due diligence.

ii. For NP Parties desiring to submit information to ABS-CH

- ✓ Countries are encouraged to provide information to ABS-CH, if possible, on a decision-tree describing the process to follow to obtain PIC and MAT for access to GR (work flow)
- ✓ Countries are encouraged to provide information to the ABS-CH on whether access to GR (and related traditional knowledge) is restricted/controlled or not under any law or regulation in the country, even if not designed to manage Access under the Nagoya Protocol.
- ✓ Countries that do not require any ABS permit or PIC ought to post a statement on the ABSCH to this effect or provide written confirmation on request
- ✓ Include when ABS legislation was made available to ABSCH, including when legislation subsequently superseded was added, amended or removed.[4]

[3] see https://www.autm.net/Home.htm

iii. For EU funding agencies

- ✓ Implementation of EU regulation is not free – there is a need to take into account transaction costs and provide specific funding.
- ✓ EU to establish a help desk for researchers

c) Overall unresolved /open issues that require clarification

- ✓ How to deal with DNA sequencing in non-commercial research. DNA sequences for non-commercial research, are subject to access permits?
- ✓ How to deal (in practice) with third party restrictions in the common scientific practice of specimen exchange?
- ✓ Where is the boundary between non-commercial/basic research and commercial applications?
- ✓ Clarify the meaning of "research and development".
- ✓ How to cope with the fact that science is developing faster than legal systems can respond.
- ✓ *Liability* is multi-layered: individuals, institutions, third parties?
- ✓ How to deal with user/provider country legislations if they do not match in scope?
- ✓ ABS systems should also take into account the specific uses/utilization/dealing with micro-organisms (animal or plant GR focused uses may not always be relevant)
- ✓ Create certainty: help users (scientists) to *understand EU regulations or any other national and regional regulations*.
- ✓ What to do with and how to protect TK part "wrongly" already in the public domain?
- ✓ How to assess the adequacy of country measures against NP obligations (compliance with NP)?
- ✓ What is the legal status of collections?
- ✓ EU regulations: how complete are they regarding non-commercial research? Is it adequately covered?

[4] Article 14(2)(a) of the Nagoya Protocol requires the posting of up-to-date ABS legislation. This suggestion does not contradict it; it means that the ABSCH should state the history and changes in legislation, so as to provide certainty related to time.

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Annex 2. Program of the workshop

2nd July: Introduction and inputs

9:00 – 9:30	• Welcome remarks by Prof. Dr. Wolfgang Wägele (Director, ZFMK) • Background, objective and expected outcomes of the meeting (Prof. Dr. Karin Holm-Müller, ILR, Uni-Bonn)
9:30 – 10:30	• Results of two online surveys on benefit sharing in academic research, in Germany and worldwide (L. Rodríguez, ILR, Uni-Bonn) • Questions and answers; Comments
10:30 – 11:00	• **Coffee**
11.00 – 12:30	• A review of benefits: Annex 1 of the NP & surveys (L. Rodríguez) • Questions and answers; Discussion (buzz groups and plenary)
12:30 – 14:00	• **Lunch**
14:00 – 15:00	• The Clearing House Mechanism for the Nagoya Protocol Valerie Normand, CBD secretariat
15:00 - 15:30	• **Coffee**
15:30 - 18:00	• "New developments in biotechnology: the role of information" Gabriele M. **König, Institute of Pharmaceutical Biology, Uni-Bonn** Panel and open discussion Panel: Maximilian Weigend, Director of the Bonn Botanical Garden; Philippe Desmeth, President, World Federation for Culture Collections, Karin Holm-Müller, chair of Resource and Environmental Economics ILR, Uni-Bonn; Manuela da Silva, Oswaldo Cruz Foundation, Brazil.
19:00-22:00	• **Joint dinner** -Restaurant Dacapo, Theaterstraße 1, 53111 Bonn

Friday 3th July: Inputs from participants about current practices

9:00 – 9:30	• Introduction to group work
9:30 – 10:30	• ***Group work:*** case analyses to review access procedures, common practices, challenges and bottlenecks, from access to benefit sharing (Cases related to academic research will be fictitious; legal framework and actual procedures will be as real as possible, covering all continents, and taking into consideration the stage of development of different countries) • ***Countries:*** Australia, Brazil, China, Costa Rica, Indonesia, the Philippines, Peru, and European countries.
10:30 – 11:00	• **Coffee**
11:00 – 12:30	• Group work (continued)
12:30 – 14:00	• **Lunch**

14:00 – 15:30	• Presentation and discussion of group results • Conclusions
15:30 – 16:00	• **Coffee and goodbyes**