



# Convention on Biological Diversity

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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION Second meeting Cancun, Mexico, 4–17 December 2016 Item 8 of the provisional agenda\*

## EXECUTIVE SUMMARY OF THE ABS BONN WORKSHOP "A WORKSHOP ON ACCESS AND BENEFIT SHARING: BENEFIT SHARING FROM ACADEMIC RESEARCH"

Note by the Executive Secretary

The Executive Secretary is circulating herewith, for the information of participants in the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, the report of the Bonn Workshop "A workshop on Access and Benefit Sharing: Benefit Sharing from Academic Research" organized by the Institute of Food and Resources Economics, University of Bonn, at the Zoological Research Museum Alexander Koening, Bonn, from 2 to 3 July 2015.

1. The document is being circulated in the form and language in which it was received by the Secretariat.

<sup>\*</sup> UNEP/CBD/NP/COP-MOP/2/1/Rev.1.

EXECUTIVE SUMMARY OF THE ABS BONN WORKSHOP

A workshop on Access and Benefit Sharing: BENEFIT SHARING FROM ACADEMIC RESEARCH

Bonn, 2-3 July, 2015





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) Report edited by: Lily O. Rodriguez 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 noncommercial 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 Heidbrink. 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.

## 1. 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)

## 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<sup>1</sup>.
- 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.

<sup>&</sup>lt;sup>1</sup> see <u>https://www.autm.net/Home.htm</u>

 International collections open to showcase developing countries genetic resources provided under ABS agreements to benefit science and developing countries.

## b) Overall recommendations

#### 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 Sa 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.<sup>2</sup>

#### 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

<sup>&</sup>lt;sup>3</sup> 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.

## c) Overall unresolved /open issues that require clarification

- How to deal with DNA sequencing in non-commercial research. DNA sequences for noncommercial 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 microorganisms (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?

The complete report can be found in the ABS Clearing House: https://absch.cbd.int/search/reference-records/VLR , ABSCH-VLR-SCBD-206689