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FINAL REPORT

THEME:

Design of a Model Agreement for Access to Genetic Resources and Benefit Sharing

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Contents

1. Subject
Model Access Agreement

2 Keywords
Access to genetic resources and benefit sharing (ABS), model access agreement, basic (non-commercial) research

3. Discipline
Environmental law; economic law

4. Team composition
The team was composed of Prof. Dr. Gerd Winter (project supervisor) and Dr. Evanson C. Kamau (senior researcher).

5. Problem situation and background

5.1 Problem situation

The DFG Guidelines for funding proposals concerning research projects within the scope of the CBD alert researchers to their obligations under the CBD and national regimes on access to genetic resources and benefit sharing. While the guidelines do well in transposing the legal obligations into points to consider and steps to take in the planning and implementing of research projects, they are quite complicated and demanding for the individual researcher. While the thrust is on ensuring compliance with the provider state requirements the researcher will often find a situation where the law and institutions of provider states are either underdeveloped, thus leaving the researcher with a high degree of uncertainty, or overambitious, thus costing the researcher immense time and money to overcome all hurdles. The unsatisfactory result could be that researchers are deterred from planning projects involving access to genetic resources.

In such a situation, well designed access agreements (AA) are core. Only very few provider countries have model agreements to offer, and in those countries which do apply such agreements the text is often either very short, and incomplete, or over-extensive and therefore legally risky for the access seeker. In such a situation it would be helpful for the researcher to have a model at hand which he or she may produce when no model agreement is operated by a provider country, or which he or she may take as a blueprint when assessing one which was presented for signature. If the model AA is framed in a balanced way respecting both the provider and user interests the provider state institutions may more easily be convinced that access should be granted. This can help both in the situation of under-developed and over-ambitious national legislation and institutions. An advanced example is the model

agreement operated by Australia,[1] which served as a source of inspiration for our project.

In any case, the use of model AAs should not be made compulsory by the DFG. The researcher should be free to negotiate an individual and specific agreement on his or her own terms, if in a position to do so. The model agreement shall be usable as a fall-back text that may help in situations of inertia.

5.2 Background

The background of this project was based on an already concluded project sponsored by the DFG (2006–2009) with the theme: 'Law and Practice in Access to Genetic Resources and Benefit Sharing with the Example of Kenya, Brazil and Germany.' The project aimed to analyse the legal frameworks and the actual practices in ABS in three exemplary countries – two megadiverse provider countries, Kenya and Brazil, and one user country, Germany. Paying attention to specific aspects of ABS, namely, the proportion or extent of administrative impediments on research and development (R&D) activities, the possibility of securing benefits from utilized resources, and the linking of access and compensation systems of resource States with the rules of the user States, the goal was to develop suggestions for improvement of existing regimes.

The main findings of the research as related to model AA were the following:

- Many provider measures possess overbureacratic hurdles, which are destined to control commercial research but unintentionally impede basic research
- Scarcely is any differentiation made between access requirements for basic research and commercial research
- Many provider measures use a vague legal language
- Many provider regimes suffer from legislative gaps and inconsistencies
- Major gaps remain with respect to the interface between ABS legal frameworks and intellectual property rights
- Prior consultation and capacity building are very decisive to a successful access process
- Public law measures must be complemented by precise agreements in order to ensure fair and equitable benefit-sharing
- A claim for benefit sharing can be raised in a user country on the basis of a contract or tort
- Most user countries have done little to implement the Art. 15.7 CBD obligation

Based on these findings the question arising was: In which possible ways could this situation be reformed?

Two solutions were identified: either taking a radical turn towards common pool solutions or improving the current bilateral exchange between providers and users through better agreements. This project explores the second option as it is more

[1] Reprinted in Evanson Chege Kamau, Gerd Winter (Eds.) Genetic Resources, Traditional Knowledge and the Law: Solutions for Access and Benefit Sharing, London: Earthscan, 2009. See also Geoff Burton, Australian ABS Law and Administration – A Model Law and Approach? In: Kamau/Winter, op. cit.

pragmatic and requires less effort. The first option would be examined in a more extensive project thereafter.

6. Methodology

National and international legal texts were analysed respecting the usual methods of interpretation. Interviews were conducted with researchers in order to learn about practical problems of access for research. Methods of designing contracts were applied in the development of the model AA.

7. Work progress

7.1 Definitions (Phase I)

Due to the different meanings given by the CBD and national laws to such terms as PIC (prior informed consent), MTA (material transfer agreement) and MAT (mutually agreed terms), authorisation, access agreement etc., we deemed it important to start with clarification of terminology.

As many varying definitions as possible were collected and synchronised with the help of square brackets. As the scope to be regulated by the AA became more clear and specific, the useful terminologies were isolated and refined by elimination of the square brackets.

7.2 Selected ABS regulations (Phase II)

In order to find out the most important requirements from the provider countries' point of view, we selected three countries with fairly successful ABS regulations from three different continents:

1) Australia:
- EPBC Regulations 2000
- EPBC Amendment Regulations 2005 (No. 2)

2) Africa (South Africa):
- Bioprospecting, Access and Benefit Sharing Regulations, 2008
- Biodiversity Act 2004

3) South America (Costa Rica):
- General Rules for the Access to the Genetic and Bio-chemical Elements and Resources of the Biodiversity, 2003

Save comparing the key ABS elements of these regulations with one another, the elements were also compared with the corresponding Bonn Guidelines.

7.3 Selected Material Transfer Agreements and Guidelines (Phase III)

In order to find out the most important requirements from the provider's point of view, we studied the following model and specific MTAs and ABS guidelines:

7.3.1 Model MTAs

1) Biotechnology Industry Organization (BIO), USA
2) Central Science Laboratory (CSL), UK
3) Kyusu University, Japan
4) India Council of Agricultural Research, New Delhi
5) CABI, UK – Governmental Non-Profit Organization
6) Agriculture and Agri-Food Canada (AAFC) (for Germplasm and unregistered lines)
7) National Institute of Agrobiological Sciences (Genebank), Japan
8) The Royal Botanic Gardens, Kew, UK (for DNA)
9) Biological Innovation for Open Society (BiOS) of CAMBIA (International non-profit organization), Canberra, Australia

7.3.2 Specific MTAs

1) J. Craig Venter Institute, USA & Commonwealth of Australia, 2004
2) Institut Pertanian Bogor/Universitas Tadulako, Indonesia and Georg-August University of Goettingen, 2003

7.3.3 Guidelines

1) Bonn Guidelines
2) DFG Guidelines for funding proposals concerning research projects within the scope of the CBD
3) Common policy guidelines for (participating) botanic gardens, Cartagena, November 2000

7.3.4 Model MTAs under the ITPGR

1) Genebank Gatersleben of the Leibniz Institute of Plant Genetics and Crop Plant Research (IPK), Germany
2) The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT)
3) WARDA -The Africa Rice Center
4) The International Rice Research Institute (IRRI), Metro Manila, Philippines

7.4 Interviews (Phase IV)

7.4.1 With researchers and DFG personnel

Initially only a few interviews with DFG funded researchers and DFG personnel with experience in access regulations and agreements were envisaged. However, we latter imagined that consulting more widely, including with non-DFG funded researchers was more likely to deliver better results because: 1) The problem being examined is general for basic research, and 2) Some DFG funded researchers might feel monitored and attempt to give obscured information. So it was vital to have views from non-DFG sponsored researchers for comparison sake as well as ensuring that

the conclusions are near accurate. Below is a table showing the number of researchers interviewed, their areas of research or brief descriptions of their projects, and their sponsors or affiliations.

	Projects / Area of Research	Sponsor / Affiliation
1.	Paraphyletischer Ursprung, Diversität und geographische Verbreitung des Dictyosphaerium-Morphotypes der Grünalgen	DFG
2.	Reconstruction of the refuge theory in tropical Africa in the Marantaceae	DFG
3.	Umsetzung der CBD / ABS in Indonesien	DFG
4.	Fischereibiologie	ZMT / DAAD
5.	Mangrovenökologie	ZMT / DAAD
6.	Marine Botanik	UoB, Faculty: Biology & Chemistry
7.	Evolution of growth and life forms in Piperales Country and continent relation	DFG
8.	Regeneration tropischer Bergwaldarten	DFG
9.	Pflanzenphysiologie	DFG
10.	Evolution der Vielfalt	- - -

DAAD Deutscher Akademischer Austausch Dienst, DFG Deutsche Forschungsgemeinschaft, UoB University of Bremen, ZMT Zentrum für Marine Tropenökologie

7.4.2 Major views/observations and suggestions

7.4.2.1 Major views/observations

1) The access procedures and requirements vary from country to country.
2) Export of specimens from particular countries is extremely difficult and at times impossible. Brazil was mentioned by most researchers as one of the strictest countries.
3) The timeline between application and approval is in some cases too long occasionally forcing researchers to withdraw their projects. Bolivia and Peru were mentioned as extremely slow in granting permits. Although some researchers submit their applications one year before the project is scheduled to begin, permits are often not ready by the end of that period. Brazil was mentioned again in this regard concerning permits for export of materials.
4) Collaboration with local partners is the most preferred mode of carrying basic research and is more often than not an initiative of the (foreign) researcher. Researchers with local collaborators have more ease in obtaining permits first, because there is less suspicion and second, often local collaborators secure the permits all alone.
5) Co-authoring of research results with local collaborators is the most common form of sharing non-commercial benefits. Others are capacity building and technology transfer.

6) Researchers with steadily long-running projects or who have had multiple projects over a long period of time in the same countries encounter fewer problems in obtaining permits for access and transfer of materials. Most researchers understand (and agree) that dishonest activities (biopiracy) by fellow researchers have brought mistrust and animosity in provider countries and plead for fair dealing with providers by all basic researchers. This shows that trust-building is a vital element towards easing of access for basic research.

7) It is important for the researcher to publish the results as swift as possible once the research has been concluded. PIC requirement before publication that might cause delay in publishing as well as endanger the researcher's results is undesirable to all interviewed researchers and would be a reason to withdraw/abandon the project for some.

8) Basic researchers cannot ensure that those who commercialize research results which are already in the public domain share benefits with the providers: it is impossible to track the downstream movement of the results. However, most researchers said that the results of basic research cannot be readily commercialized.

9) Specimens can be passed to third parties through agreements but it is barely possible to ensure that they are not abused downstream.

10) The practicality of PIC by the provider before materials are passed to third parties would depend on the form and scope of the activities of the researcher. For collections of botanic gardens (bG), for example, the costs, time and work involved in securing such a PIC would be so enormous to bear both for the bG and the provider.

11) Most basic researchers said that it is not possible to precisely describe the genetic qualities in biological materials at the onset of access as a means of differentiating non-commercial and commercial research. Almost all said that their projects have nothing to do with genetic resources but rather with biological resources which are describable. They were also of the opinion that the description/proposal of the project should be sufficient in indicating whether it is non-commercial or commercial. However, most agreed that some non-commercial researches can change to commercial if the researcher so desired.

12) Most researchers think that a model AA – that standardizes access requirements – would ease things, if acceptable to providers. A few, however, thought that providers might see it as a means of control or manipulation from outside.

7.4.2.2 Suggestions

1) The researcher should find out in advance the access requirements of the provider on an individual basis.

2) The researcher should find out in advance which laws come into play and which agents must give consent.

3) The application for access should be submitted well in advance of the project schedule.

4) It is strongly recommended that projects are carried out in collaboration with local partners.
5) If possible local partners should be involved in all the stages of the research. This likewise solves the problem of likely delay in the publication phase as the local partner is also an interested party.
6) The project description and proposal should be as thorough as possible.
7) For new projects it is important to be transparent as much as possible in order to quash any suspicion and to help in trust-building.

7.5 Designing of the MAA (Phase V)

Based on our proposal, the examined ABS regulations, MTAs, guidelines and interviews conducted with researchers, a list of the main topics that require attention in ABS were listed. Then the main elements of an ABS contractual agreement were considered and listed down. The latter consisted of the structure of the contract and comprised of the following, among others: parties to the contract, definitions, rights and obligations of the parties pertaining to access, export and use of the materials, transfer to third parties, reporting and sharing of information, benefit sharing, publications, and conservation and sustainable use of biodiversity. The topics were then sorted out according to the elements under which they fell and, constructed into legal formulations that made up the paragraphs. Using this procedure the first draft of the AA was produced.

Production of the second draft entailed elimination as well as reformulation of contradicting and over-stretched rights and obligations, restructuring and controlling to ensure that the paragraphs were positioned under the right elements.

Production of the third draft entailed reduction of the contents as much as necessary in order to achieve a simplified AA the best we could. At this stage we considered it necessary to produce three different versions due to the evidently distinguishable rights and obligations of the state, landowners and indigenous and local traditional communities. This brought about the production of a refined and shortened fourth draft in three versions.

7.6 Presentation of the drafts at the DFG ABS-Group Meeting (Bonn, 5 February 2010) (Phase VI)

The three versions of draft four were presented in Bonn before the DFG ABS-Group. The group critically went through all the provisions of the draft. The exercise profited a lot from the presence and practical experience of researchers, DFG personnel and academicians. The critique, comments and suggestions of the group were taken note of and made use of in the revision phase.

7.7 Revision, integration of concerns from latter interviews, DFG ABS-Group and production of the final copies (Phase VII)

The seventh and final phase entailed further revision of draft four and integration of new concerns and considerations, which resulted into draft five.

8. Deliverables

The final product of this project consists of three varying versions of the model AA attached to this document. The first version, which is to be concluded with the state, is the main and full agreement, i.e. containing all relevant provisions, and is structured as follows: (1) preamble, (2) definitions, and further, provisions on (3) access and transfer of materials (the required permits/consents, what the user is allowed to access, from which geographical area and in which quantities, compensation), (4) use of the materials (permitted uses, change of purpose, storage of accessed materials), (5) transfer to third parties (under which conditions and for what purpose), (6) reporting and sharing information (which information the user should submit to the provider and in which timelines), (7) sharing other benefits (forms of benefits to be shared with the provider save information), (8) publications (conditions for disclosure and publication, acknowledgement, co-authorship and submission of final (published) results to the provider), (9) conservation and sustainable use of biodiversity (obligations of the user vis-á-vis the environment), (10) confidentiality (restriction on disclosure of confidential information and materials to third parties, duration of restrictions), (11) liability and indemnity, (12) termination of agreement (notices, obligations and restrictions surviving termination), (13) dispute resolution (notices and forms), and finally, (14) other provisions including duration, expiry and renewal of agreement and choice of law.

The second and third model AA, which are to be concluded with indigenous or traditional local communities and private landowners, follow the same structure as the first, but they either deviate from the provisions of the first due to restricted rights, varied rights and obligations, or because their execution is referred to the first, or they are not included at all. These include provisions on export of materials (partly referred and restricted), their uses and transfer to third parties (partly referred and restricted), reporting (varied and partly referred), benefit sharing (varied), publication (restricted), liability and indemnity (not included) and dispute settlement (not included). They also deviate slightly from one another due to the distinct features of the rights at stake.

This variation between the first and the other two is largely a result of the assumption that most countries consider genetic resources as a property of the state. Likewise, the CBD states that "…the authority to determine access to genetic resources rests with the national governments and is subject to national legislation" (Art. 15.1). Therefore, whilst the owner or custodian of the land upon which the biological resource is found has the right to grant or deny access, as well as receive compensation for the biological material, the genetic properties of that material belong to the state. Consequently, the state has the sovereign right to determine their uses and handling and to receive benefits derived from their utilization. Thus the rights and obligations that accrue once the biological resource leaves the domain of the private owner or community are to be pursued by the state and the recipient.

The model AA presents the researcher with the following options:

1) To use the model AA (as the main agreement) if the provider does not possess any, either as is or with variations.
2) To use the model AA as a reference in bargaining better terms and conditions in agreements presented to him/her by the provider.
3) To conclude only the first AA with the state if none is required with private landowners or indigenous or traditional local communities.
4) To use all if for each stakeholder an agreement is required.

9. Main challenges

1) The concerns of both basic researchers and providers are so broad to contain in the model AA considering also that a very detailed and long document is undesirable to most researchers.
2) Balancing providers' and users' interests in the AA, especially trying to accommodate the interests of basic researchers without damaging providers' trust was quite challenging.