

## **Forschungsstelle für Europäisches Umweltrecht (FEU)**



Universität Bremen



Research Center  
for European  
Environmental Law

## **Forschungsstelle für Europäisches Umweltrecht (FEU)**

### **FINAL REPORT**

### **Access to genetic resources for basic biological research and benefit sharing (“Facilitated access”)**

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# **Forschungsstelle für Europäisches Umweltrecht (FEU)**

## **1. Subject**

Access to genetic resources for basic biological research and benefit sharing

## **2. Keyword**

Access to genetic resources for basic research

## **3. Discipline**

International law, biology, biochemistry

## **4. Work and results report**

The Nagoya Protocol establishes a rather tight regime on the access to and the utilization of genetic resources. This may in practice become an obstacle for free basic research. While the Protocol does provide for simplified procedures for non-commercial research it is not yet clear how this clause must be understood and how it will be transformed into national laws and practices.

The initial project application was submitted in partnership with the University of Göttingen and the University of Bremen and foresaw two main tasks. The first task aimed to bring researchers and administrators of provider and user countries and scientists together in a workshop in order to discuss possible models of regulation and contracting. The overall target was to produce a summary of the proceedings of the workshop and based thereon revise the DFG guidelines for research in ABS and the model agreement on access to genetic resources produced in an earlier project by the Bremen team. The second task aimed to compile a commentary of the provisions of the Nagoya Protocol in order to help providers and users to understand the Protocol and how it should be implemented. The second task was not approved for funding.

The first application for renewal of the research project was done exclusively by the University of Bremen based on the need to enrich the initial one. The main tasks proposed for the project were three: First, editing and publication of a collection of papers on experiences with and solutions for access to genetic resources for basic research under the ABS regime; Second, adaptation and annotation of the already produced model agreements for access for basic research and benefit sharing; and Third, elaboration of a model ABS law for African states in the framework of the ongoing process of the African Union towards an implementation of the Nagoya Protocol. The third task was not approved for funding.

The third application for renewal was done corporately by the Universities of Bremen and Göttingen. It proposed to pursue research activities undertaken earlier under the theme on facilitated access to genetic resources for basic biodiversity research purposes by the University of Bremen and the University of Göttingen. The tasks foreseen were two: 1) Development of model access clauses based on the access agreements developed earlier as well as recommendations of the ABS working group (of the DFG Senate Commission for Biodiversity Research, SKBF) and feedback from experts, and 2) Revision of the DFG research guidelines on ABS. Besides reacting to feedback and comments from experts further work was needed on existing documents to update them to new realities and experiences following the adoption of the Nagoya Protocol.

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## 4.1 Output

### 4.1.1 Work packages

#### a) Organisation and hosting of an international conference

The aim of the conference was to bring researchers and administrative officials from provider and user countries together, inform them about the new state of international law and first national legislation implementing it, collect experiences with access and benefit sharing practices, initiate a discussion on new frameworks for research collaboration, and generate ideas about amicable solutions enabling free research while at the same time ensuring PIC and benefit sharing. The conference was also an important tool in effecting one of the two approaches of the project, i.e. “bottom up” approach aimed at collecting experiences made by researchers and administrative officials with ABS with a view to generate ideas about best practices that could inform national legislators when developing ABS regulation.<sup>1</sup>

The concrete exercises for this task included: identification of relevant themes; identification, contacting and invitation of conference speakers from national focal points and German research community; drafting of conference programme; logistical planning; and the actual hosting of the conference.

#### b) Revision of the DFG ABS guidelines

The DFG ABS Guidelines were drafted on the basis of the CBD and the Bonn Guidelines. The event of the adoption of the Nagoya Protocol in October 2010 rendered these Guidelines outdated. The concrete exercise in this regard therefore involved the drafting of a revised version of the Guidelines based on the edited and published proceedings of the conference<sup>2</sup> and to the new realities following the entry into force of the Nagoya Protocol (October 2014) as well as based on the recommendation of the DFG WG ABS and feedback and comments from other experts.

#### c) Publication of the conference proceedings

The findings of engagements between focal points and researchers have the potential to replicate achieved results in similar interactions. The project hence considered the publication and dissemination of the conference proceedings as one of its major tasks. The concrete exercise involved: review and editing of conference papers and incoming commentaries by authors; correspondence with authors; organisation of language check; formatting of papers; drafting of publication structure; identification of publisher; and initiation of publication process. The conference speakers committed themselves to provide written papers of their presentations at the conference. In total, fourteen (15) papers were anticipated. In order to enrich the results, the Bremen team invited four (4) papers after the conference: from experts engaged in basic scientific research (DSMZ and ICIPE) and lawyers engaged in ABS issues (IUCN and MICROB3 project).

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<sup>1</sup> The second approach was a “top down” aiming to interpret the content of the Nagoya Protocol with a view to develop more precise recommendations for national law making both on the provider and user state side.

<sup>2</sup> Project application No. WI 427/25-1.

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### **d) Revision and annotation of the model agreement on ABS**

In a minor project conducted earlier by the Bremen team, a model access agreement had been designed and proposed for use by researchers funded by the DFG as a blue print to assist them to assess one presented by the provider for signature, or a fallback text in cases of inertia. Like the DFG ABS Guidelines, that draft had been overtaken by events. The concrete exercise therefore involved its revision to reflect the requirements of the Nagoya Protocol as well as adaption to lessons learned from earlier ABS projects and undertakings. In order to make it more user-friendly, additional exercise involved its annotation.

### **e) Development of model access clauses**

Following several consultations by the ABS WG of the DFG Senate Commission on Biodiversity Research (SKBF) it was recommended that annotated model clauses should be produced from the already developed drafts of model agreements. In addition, it was advised that the clauses are tailored to the needs of those categories of research that are fundable by the DFG. Further, the language and style were to be tailored to facilitate easier understanding by biodiversity researchers who are often not (very) conversant with legal language. Likewise, following the 14<sup>th</sup> meeting of the WG on 7<sup>th</sup> March 2016 and a round of stakeholder consultations at a Berlin workshop on 2-3 March 2016, a lot of comments and feedback to the draft guidelines and model agreement were provided which needed careful analysis and integration in existing versions. This applied likewise to the guidelines.

#### **4.1.2 Results**

The summaries of work results below only relate to the tasks carried out exclusively by the University of Bremen and those shared by the project partners.

### **a) Organisation and hosting of an international conference**

An international conference was held on 19/21 January 2012 in Göttingen. The conference was hosted by the University of Göttingen. The preliminary proceedings of the conference with the main conclusions were submitted to the DFG shortly after the conference. These tasks were fully realised within the lifetime of the initial application grant.

### **b) Publication of the conference proceedings**

Most of the work was achieved within the lifetime of the initial application grant. There was still much work related to review and editing though which prompted the Bremen team to apply for renewal of the project. Most papers needed to be revised twice or thrice. By the end of the initial application grant, three papers had not been submitted. All papers needed a final and thorough language check prior to formatting. The editors relied on the availability of all papers to author the introductory chapter and prepare the final manuscript for publication.

The process proved more difficult than expected due to the following reasons:

- 1) The project involved a big number of contributors from developing countries who needed not only close supervision but also guidance. Often first drafts had to be restructured and at times new content input was proposed. Some had to be partially re-written as a result of incomprehensiveness. Such an

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input was necessary in order to achieve publishable results but it increased the volume of work by far.

- 2) The volume of work involved was not only exaggerated by the reasons mentioned under point 1) but also as a result of invited papers. The guidance, review and editing work involved was not been accounted for during the conception stage of the project.

In the lifetime of the renewed application grant this task was fully completed. The results of the project were published in an edited volume with **20 chapters** in June 2015 by Earthscan/Routledge, London. A copy of the front matter of the publication (including the table of contents) is annexed to this project report.

### **c) Revision and annotation of the model agreement on ABS**

The model access agreement was revised severally to reflect new developments and adapt it to new lessons and experiences. This process though was tightly intertwined with the comprehensive completion of the publication of the conference proceedings as the project aimed to ideally consummate the MAA on the basis of the published results.<sup>3</sup> In addition, the Bremen team found it more useful to undertake new revision based on new findings from other ABS projects. For example, new thinking was needed on how to address the issue of further uses of public domain information. Is such use to be considered as a change of intent? How should it be addressed? New findings showed that a simple “change of intent clause” was not sufficient to address all the concerns that discredit the ABS process. Another consideration is concerned with the fact that even “basic” researchers may at times wish to be allowed to utilise research results from the outset for purposes such as patenting and applications which are regarded as “commercial” in the sense of the Nagoya Protocol.

These and other considerations necessitated the introduction of pertinent optional clauses into the model agreement. It was hence necessary to complete this work in the lifetime of the renewed application grant. The revised and annotated version of the model agreement on access to genetic resources and benefit sharing was discussed severally in the meetings of the WG and revised accordingly.

### **d) Development of annotated model clauses and revision of the guidelines**

Model clauses were developed following recommendations provided (see 2.1.1 (e) above). Likewise, the guidelines were revised following the recommendations and concerns mentioned under 2.1.1 (b) above. The final versions of the clauses and the guidelines have been submitted to the ABS WG of the DFG.

#### ***4.1.3 Practical output***

The mid-term and final findings of the research project were instrumental in transferring knowledge into practice as follows:

#### **a) Outreach and consultancy**

The extension of the research project enabled the Bremen team to continue and strengthen its outreach and consultancy activities in the ongoing process of creating model ABS legislation in Latin America, the Caribbean and Africa. Dr. Kamau was invited to contribute and share his expertise in a science-policy workshop on Access

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<sup>3</sup> See project application No. WI 427/25-1.

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and Benefit-Sharing that focused on non-commercial, academic research in the Latin America and Caribbean region. The workshop took place on 20-22 November 2013 in Lima, Peru and was co-organised *inter alia* by DFG and was part of a DFG funded project of the University of Bonn. He was also invited to provide ABS expertise in the “Soda lakes of Kenya workshop” that was co-organised *inter alia* by KWS and took place in Naivasha, Kenya on 4-6 December 2013. The participants were mainly from the scientific community and industry. Dr. Kamau was also invited by GIZ to provide ABS expertise for the African Union (AU) process of establishing coordinated approach in the implementation of the Nagoya Protocol by AU Member States. He was involved in two meetings at the AU Head Quarters in Addis Ababa, Ethiopia, in February 2014 and in Cotonou, Benin, in March 2014. Gerd Winter is as a member of the Swiss expert group *sanu durabilitas* involved in the development of a comprehensive approach to biotechnology, including ABS issues. He was also invited to participate in the ongoing discussion within FAO regarding the opening up of the Multilateral System of the International Treaty on Plant Genetic Resources for ABS requirements.

### b) Links with other projects

The DFG funded research projects described above were linked with a research project funded by the EU Commission on marine microorganisms called MicroB3 (<http://www.microb3.eu/>). Within this basically scientific project one workpackage was mandated to develop an ABS agreement and other papers for marine microbial research. G. Winter together with C. v. Kries wrote a paper on the definition of non-commercial research in different legal contexts. Under his guidance another paper was written on ABS requirements under the Nagoya Protocol and the UN Convention on the Law of the Sea, and a model ABS for marine microbial research was drafted. These papers were also included in the edited volume mentioned above under subpara. 2.1.2 b).

#### 4.1.4 Relevant publications

Kamau/Winter (2016) Model clauses for mutually agreed terms on access to genetic resources and benefit sharing, 12/1 *Law, Environment and Development Journal*, pp. 1-17. Available online at [http://www.lead-journal.org/current\\_issue.htm](http://www.lead-journal.org/current_issue.htm)

Winter (2016) In Search for a Legal Framework for Synthetic Biology, in: Engelhard, Margret, *Synthetic Biology Analysed. Tools for Discussion and Evaluation*, Zürich: Springer, pp. 171 -211

Kamau/Winter/Stoll (Eds) (2015) *Research and development on genetic resources. Public domain approaches in implementing the Nagoya Protocol*, Earthscan-Routledge, London, 370pp

Winter/Fricke/Knoepfel (2015) Die biotechnische Nutzung genetischer Ressourcen und ihre Regulierung – Ein integrierender Vorschlag, *ZUR* 5, pp259-270

Kamau (2014) Valorisation of genetic resources, benefit sharing and conservation of biological diversity: What role for the ABS regime? in: Olaf Dilling/Till Markus (Eds), *Ex Rerum Natura Ius? – Sachzwang und Problemwahrnehmung im Umweltrecht*, Nomos, Baden Baden, pp143-173

Kamau/Winter (2013) An introduction to the international ABS regime and a comment on its transposition by the EU, 9/2 *Law, Environment and Development Journal*, pp106-126. Available online at <http://www.lead-journal.org/content/13106.pdf>

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### 5. Researchers with whom we cooperated

The project on facilitated access for basic biodiversity research managed to bring together 23 experts (see table 1). The experts come from different backgrounds/disciplines, including law and biology, and are engaged in varying professional activities, viz. scientific (biodiversity) research, legal academic research, legal practice, administrative functions e.g. access regulation as national focal points etc. Their affiliations include universities, botanical gardens, culture collections, conservation agencies, scientific organisations and environmental ministries and departments.

**Table 1:** *Collaborating researchers\**

	<b>Names</b>	<b>Background</b>	<b>Country</b>
1	Monica R. Sarmiento	Law	EC
2	Dr. Fabian Haas	Biology	DE/KE
3	Dr. Juliana Santilli	Law	BR
4	Thomas Greiber	Law	DE
5	Caroline v. Kries	Law	DE
6	David C. Oren	Biology	BR
7	Dr. Eliana Fontes	Biology	BR
8	Carlos A. Joly	Biology	BR
9	Maria Victoria Cabrera	Law	EC
10	Dr. Arief Yuwono	Agriculture	ID
11	Dr. Teguh Triono	Biology	ID
12	Veronica Kimutai	Law	KE
13	Dr. Edwardina O. Ndhine	Biology	KE
14	Kavaka Mukonyi Watai	Biology	KE
15	Prof. Dr. Erwin Beck	Biology	DE
16	Dr. Gemedo Dalle	Biology	ET
17	Dr. Susette Biber-Klemm	Law	CH
18	Sylvia I. Martinez	Biology/Chemistry	CH
19	Dr. Christoph Häuser	Biology	DE
20	Dr. Romano Mwirichia	Biology	KE
21	Dr. Dagmar Fritze	Biology	DE
22	André Oumard	Biology	DE

\* Prof. Gerd Winter, Prof. Peter-Tobias Stoll and Dr. Evanson Chege Kamau co-headed as well as coordinated the research project. Their background is law.

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23	Wolfram Lorenz	Biology	DE/ID
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The project also benefited from interviews with German basic scientific researchers with projects in different countries (Kenya, Brazil, Namibia, South Africa, China, Indonesia, Bolivia, Peru, Ecuador, Columbia, Mexico, Chile) and sponsored by different funding organisations. These include researchers affiliated to igb-Berlin, Institut für Geobotanik und Botanischer Garten-Halle-Wittenberg, Technische Universität Dresden, Leipzig-Zentrum für Marine Tropenökologie (ZMT)-Bremen and Universität Halle. Most of their projects are funded by DFG, DAAD and BMBF.

### 6. Summary, synthesis and major findings

The results of the research project take the perspective of research and development (R&D) on genetic resources and associated traditional knowledge and ask how this chain of utilization of resources is affected by the international and national ABS regimes. The ABS regime can be understood as framing the utilization chain by both enabling and restricting it through the establishment of property and use rights. The utilization process starts with the sampling of genetic resources (GR) or associated traditional knowledge (ATK), proceeds with R&D and may end in the public domain (collections, public media) or generate marketable products and information. The access phase is subject to the jurisdiction of the provider state while the utilization and commercialization stages escape the jurisdiction of the provider if the GR or TK is transferred to and utilized in another state.

The provider state can only use the access situation as a lever for controlling these processes. However, it would still have difficulties monitoring the utilization chain thus there is a tendency to severely restrict the allowed utilization.

Whether this is true in fact and what can be done to alleviate the burden for R&D without neglecting legitimate expectations of benefit-sharing is the subject of the collection of contributions in the book titled "Research and development on genetic resources. Public domain approaches in implementing the Nagoya Protocol" edited by Kamau/Winter/Stoll and published in June 2015 by Earthscan/Routledge (370pp). Summing them up and adding to them some more considerations the following observations can be highlighted:

- There is evidence from our case studies that access to genetic resources has in various countries been hampered by national ABS requirements.
- Following the demands of the Nagoya Protocol (NP), in particular those pertaining to legal certainty and simplification, some states have introduced new rules to this effect. They treat non-commercial research in privileged ways. Some shortcomings remain, however, e.g. unequal treatment between domestic and foreign researchers.
- One effective means of reducing the burden of obtaining PIC, MAT and MTA is the cooperation of provider states with trusted institutions.
- As in many respects the distinction between non-commercial and commercial research is of consequence. A definition of the term is suggested in the book.
- An issue that has widely escaped the attention of stakeholders and that seems to be producing new challenges is data management in the utilization process. The question arises therefore whether databases should also develop their rules on input clearance, tracking, and output conditions like the material collections to help tracking.

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- Another way to assist provider states in tracking their GR and/or ATK through the utilization chain is reinforcing the obligations of user states to monitor and enforce compliance with provider state requirements.
- As a general conclusion, the book shows that it is difficult but feasible to implement the bilateral approach proposed by the CBD/NP regime. A better alternative would, however, be to strive for common pool solutions such as those we make reference to.<sup>4</sup>

We hope the results of our research project will provide useful information and assistance in resolving issues addressed.

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<sup>4</sup> See Kamau, EC, Winter, G (eds.) *Common pools of genetic resources. Equity and innovation in international biodiversity law*, Earthscan/ Routledge 2013.