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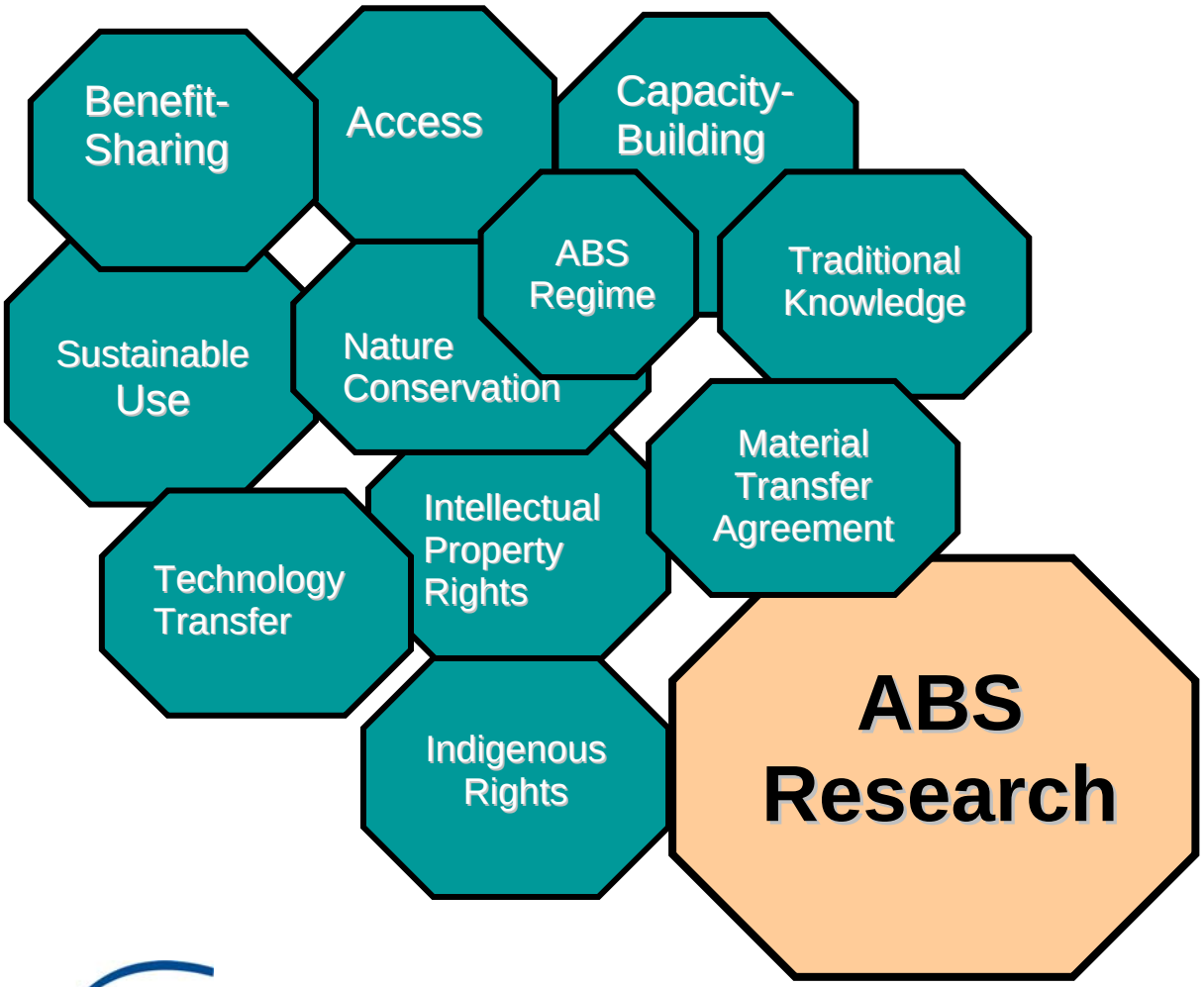
Interim Report



Federal Agency for Nature Conservation

BfN – Skripten 244

2009

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Research project of the Federal Agency for Nature Conservation

Federal Agency for Nature Conservation
Bonn – Bad Godesberg 2009

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BfN-Skripten are not available in book trade but can be obtained from the publisher (RothertB @Bfn.de).
Publisher: Bundesamt für Naturschutz (BfN)
Federal Agency for Nature Conservation
Konstantinstrasse 110
53179 Bonn, Germany
Tel.: +49 228/ 8491-0
Fax: +49 228/ 8491-200
URL: http://www.bfn.de

Printed by the printing office of the Federal Ministry of Environment, Nature Conservation and Nuclear Safety.

Printed on 100% recycled paper.

Bonn, Germany 2009

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Abbreviations

ABS	Access and benefit-sharing
ATCC	American Type Culture Collection
BCCM	Belgian Coordinated Collections of Microorganisms
BDP	Federal Association of German Plant Breeders
BfN	German Federal Agency for Nature Conservation
CBD	Convention on Biological Diversity
CHM	Clearing-house mechanism
CIOPORA	International community of breeders of asexually reproduced ornamental and fruit varieties.
COP 9	Ninth meeting of the Conference of the Parties
FAO	International Food and Agriculture Organisation
GR	Genetic Resources
IPEN	International Plant Exchange Network
IPR	Intellectual property rights
IR	International regime on access and benefit-sharing
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
LOC	Letter of Collection
MAT	Mutually agreed terms
MGR	Microbial Genetic Resources
MLS	Multilateral System
MOSAICC	Micro-organisms Sustainable Use and Access Regulation International Code of Conduct
MOU	Memorandum of Understanding
MTA	Material Transfer Agreement
NFP	National Focal Point
NCI	National Cancer Institut (USA)
NIE	New institutional economics
NIH	US National Institute of Health
NITIT	New institutional theory of international transactions
PGRFA	Plant Genetic Resources for Food and Agriculture
PIC	Prior informed consent
PPR	Plant Protection Right
SC	Science commons
SCO	Source Country Organization
SLA	Simple Letter Agreement
SMTA	Standard material transfer agreement
UBMTA	Uniform Biological Material Transfer Agreement
UNU	United Nations University
UPOV	International Union for the Protection of New Varieties of Plants

1 Background and purpose of the research project

The implementation of access and benefit-sharing (ABS) in the Convention on Biological Diversity (CBD) is not yet satisfactory. Therefore an international ABS regime (IR) that should contain a set of ABS instruments and measures under more equitable participation from all contracting parties is currently under negotiation.

In the beginning of 2007 the German Federal Agency for Nature Conservation (BfN) initiated a research project to analyse standardisation options for Material Transfer Agreements (MTAs) from an economic perspective as a potential element of the international ABS regime. The overall background for the investigation of this type of instrument is the assumption that high transaction costs and uncertainty, caused by information and transparency deficiencies, comprise the main barriers to the accomplishment of ABS contracts. The standardisation of contracts is known from both theory and practise as a classical countermeasure to combat this type of problem. The example of standardisation closest to ABS under the CBD is the recently adopted Standard Material Transfer Agreement (SMTA) under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

In the research project we intend to analyse whether model clauses are an appropriate instrument to reduce transaction costs, as well as how they should be designed to fit different kinds of transactions with genetic resources under the CBD. Furthermore, we discuss the question of the acceptance of this instrument among different user groups and providers. We chose sectoral *model clauses* to focus on as concrete option for contract standardisation for different reasons. From literature and preliminary interviews within the project we learned that ABS agreements vary in different aspects, even within what is typically described as a distinct user group (such as pharmaceuticals). A standard contract can hardly reflect these differences. Moreover, based on discussions with different stakeholders (users and providers), we can assume that there would be very little acceptance for real standardised contracts, even if they were differentiated by sector. Finally, COP 9 (Ninth meeting of the Conference of the Parties) put sectoral model clauses of MTAs on the official agenda for negotiations involving the International ABS Regime.

Due to limited capacities we focus on three main user groups: researchers from public institutions, pharmaceutical and biotechnological companies and plant breeders. We find these groups to best represent the heterogeneity in types of users, utilization forms and outcomes. Moreover, they are traditionally viewed as key user groups.

This report is a compilation of findings from previously conducted reports while providing an

overview of the procedures and results of the empirical investigations conducted thus far under the framework of this project. Chapter two summarizes some general considerations based on the Bonn Guidelines regarding the steps that should be taken to conclude an ABS agreement. In addition, this chapter highlights some contrasts to the literature on the heterogeneity of ABS agreements. The second section of chapter two provides a short compilation of user problems concluding and conducting ABS agreements found in the literature. In chapter three existing ABS model contracts developed by various entities concerned with ABS (for instance Biotechnology industry associations, ministries of member countries of the CBD, and others) are reviewed. This compilation allowed us to identify and understand potential differences in characteristics of contracts for transactions with genetic resources. Moreover, the compilation was used as input for the group discussions on model clauses for MTAs with two user groups. Chapter four presents findings from empirical surveys conducted thus far over the course of the project. This chapter is also divided in two sections. The first section elaborates on the in-depth discussions with users about problems experienced when concluding ABS agreements. The second section analyzes the interviews and group discussion with respect to potential model clauses for MTAs. Chapter five concludes this report with some closing remarks and an outlook on the next steps to be taken in the project.

2 ABS agreements

This chapter gives an introductory overview of ABS agreements as they are outlined in the Bonn Guidelines, while also summarizing information found in the literature on problems faced by users engaging in the process of negotiating ABS agreements. Both sections will assist in understanding the review of existing model contracts for ABS agreements in chapter 3, and the discussion of findings from the user survey in chapter 4.

2.1 Steps in ABS procedures

As a basis for discussing and analysing contents of ABS contracts and options for model contract elements, we attempt to understand the general nature of ABS agreements as they are suggested in the CBD. Table 1 compiles steps considered necessary for users to conclude and conduct an ABS agreement in compliance with the recommendations in the Bonn Guidelines. The Bonn Guidelines (2002) provide points of reference regarding how some of the procedural steps ought to be realized by users and providers to comply with the ABS provisions in the CBD. The instructions, however, are quite theoretical, and user studies indicate that in practice the realization is rather problematic.

Table 1: The Chain of conducting ABS according to the Bonn Guidelines of the CBD

Process stage	Measures
1) Market research	- Identification of the potential providers or users
	- Identification of supply/demand (what exactly does the provider/target group offer/request)
	- Screening for reliability (providers/users)
2) Negotiation of the contract	- Identification of contact points, stakeholders, etc. - Evaluation of offer/request (assessment of resource/information quality, possible benefits) - Negotiation of contract (Prior informed consent (PIC), Mutually agreed terms (MAT) (scope of access rights, timeframe), benefit-sharing obligations & mechanisms, (intellectual) property rights) - Setting up the contract (terminology, design)
3) Contract enforcement	- Legal verification of the contract - Monitoring/verification of misconduct of the other contracting party (user: acquisition, utilization, transfer, commercialization; provider: agreed upon items of supply such as quality, knowledge, exclusiveness of supply) - Dispute settlements - Sanctioning/remedies

Source: authors, based on Secretariat of the Convention on Biological Diversity (Bonn Guidelines), 2002.

Literature and initial interviews within the project show that in reality, transactions with genetic resources are heterogeneous. They differ in the characteristics of their attributes and in the institutional setting in which they are carried out. This is important for the discussion of model clauses as instruments to simplify the process of agreeing upon ABS contracts. The real nature of transactions with genetic resources has to be considered in such an instrument.

The literature review indicated a multitude of characteristics for different attributes affiliated with transactions involving genetic resources (table 2). The list in table 2, however, is not yet comprehensive, but should give an idea of the heterogeneity of the cases. It will be expanded on the basis of the survey within the project.

Table 2: Characteristics of attributes describing genetic resource transactions

Attributes	Characteristics	
Source of supply	Ex-situ	Non commercial (botanical gardens, gene banks…)
		Commercial (broker companies)
	In-situ	One source country
		Several source countries
Purpose of usage	Commercial	Development of end products
		Development of intermediate products
	Non-com.	Basic non-commercial research, option to transfer material to commercial users
		Basic research, Conservation
Relationship between genetic resource and product	Closely related	Chemical molecule found in the plant serves as prototype for an active compound in the product (pharmaceutical utilisation)
		Extracts (raw material) of the plant are substance of the content in the product (natural medicine, natural cosmetics, dietary supplement) (no genetic resources according to CBD definition; diff. views in other ABS laws)
	Not closely related	Molecule found in the plant needs to be modified in many steps to be included in the product (derivative in pharmaceutical utilisation)
		The function of an organism or its parts serve as a model (e.g. mimics in materials research, biotechnology)
	Not related	Genetic resource serves as tool in research and development (e.g. as catalyser)
Characteristics of material identifiable before utilization	Identifiable	Material obtained from ex-situ collections, further information included
	Partly ident.	Material acquired by bioprospection activities, type of related knowledge
	Not at all identifiable	Material obtained by wide scale, random bioprospection, no further information available / acquisition of sample of completely unidentified resources

Source: authors, based on a compilation of findings in Gehl Sampath, 2005, p. 26; Holm-Mueller, Richerzhagen and Taeuber, 2005; OECD, 2003, pp. 16f and 41f.

The aspect of characteristics of transactions with genetic resources was a core item of the survey within the project. Chapter 3.2 presents the findings revealed so far from group discussions and interviews.

The institutional settings under which transactions with genetic resources take place are found to vary enormously as well. Several factors were identified on the basis of the literature review and the findings from the survey in the first stage (see table 3).

Table 3: Institutional factors in provider countries with potential effects on transactions from the users' perspective

Factors	**Characteristics of institutional factors**
Allocation of property rights over genetic resources & authorisation to negotiate ABS	- Centrally managed - Split between many local communities/private entities/NGOs - No legislation/official regulation
Clarity and communication of property rights & access authorisation	Clearly defined and well communicated versus not defined, and poorly/not communicated
Market perception/ performance of transaction partners	Governmental support (e.g. central national Biodiversity Institute with strong external communication, well known in the branch, versus provider countries without national communication)
Signals of reliability	National information strategy can include reputation building measures, e.g. governmental support of ABS projects, institutional/legal environment certainty regarding contract enforcement, support of external communication
National ABS systems affect the negotiation of ABS contracts	- Complexity and restrictiveness of national regulations - Transparency and communication of regulations - Reliability of compliance - Capacity for and experience in negotiations
Setting up the contract	- Capacity, experience, ability in contract law/international contract law

Source: authors, based on expert interviews; stakeholder interviews; Gehl Sampath, 2005, p. 26; Holm-Mueller et al., 2005; OECD, 2003, pp. 16f, 41f; Richerzhagen, 2007.

Both aspects of ABS agreements, the attributes of transactions and institutional settings, have been discussed with users in the survey, with the interim findings presented in chapter 3.

2.2 User problems in ABS procedures – compilation of findings in literature

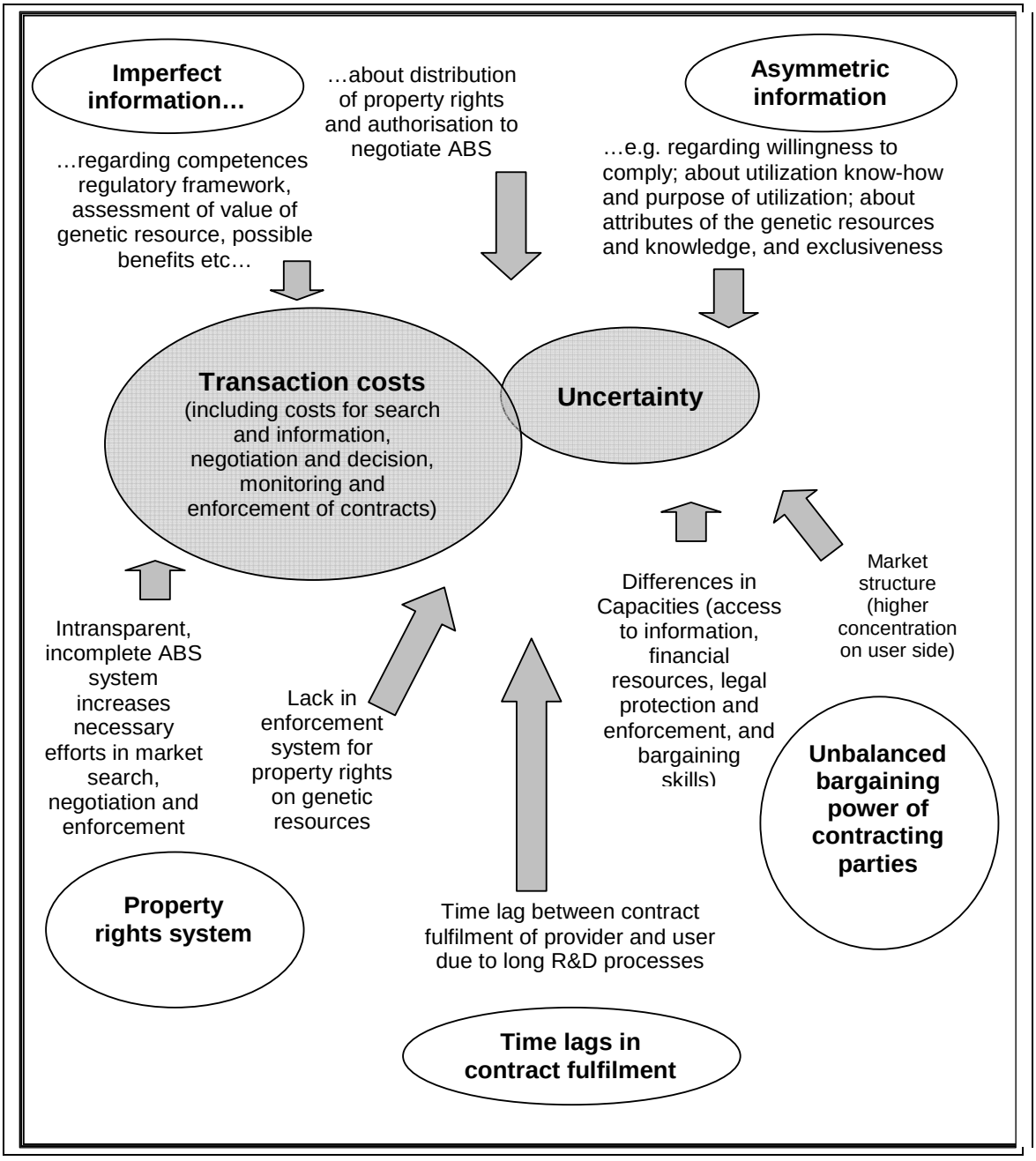
In the discussion of potential elements for the international ABS regime, user compliance with existing regulations is a major concern. It has been understood, that it is not primarily users unwillingness to comply that impedes successful benefit-sharing from genetic resources utilization. A multitude of other causes has been identified in ABS literature and in informal expert discussions, for example at the official CBD conferences.

The identification of actual problems born by concerned groups which shall be tackled by measures potentially to be implemented in the ABS regime seemed to us as a vital precondition for the discussion of such elements. This aspect raises the project's chance to significantly contribute to the ABS debate.

The information we had access to before we conducted interviews and group discussions in the frame of the project indicated problems such as imperfect or asymmetric information for users and providers as well as unbalanced market power of the contracting partners. Other relevant problems indicated as inhibiting successful ABS agreements included imperfect property rights systems for genetic resources and for products resulting from R&D with genetic resources, as well as large time lapses between the contract negotiation and fulfilment of the obligations of both parties (Holm-Müller et al., 2005, pp. 47; OECD, 2003, pp. 15; Richerzhagen, 2007, pp108-128). To demonstrate these problems, overview 1 provides some specifications of problems occurring in the ABS chain.

We found that work so far dealing with this issue has been insufficient in that it has not fulfilled the requirements of a systematic, in-depth analysis of the particular issue. Former studies on users of genetic resources were more focused on aspects like the utilization procedure, sources of supply for genetic resources, awareness of the CBD, and similar topics. Problems involving reaching and carrying out ABS agreements have only been dealt with as a side aspect in the investigations, but they merit more in-depth consideration. Nevertheless, what we have learned from existing studies serves us as basis for interviews and group discussions focussing on this issue in the framework of the project. Interim findings on this item are presented in chapter 3.1.

Overview 1: Problems occurring in the chain of access and benefit-sharing with genetic resources under the CBD coverage



Source: authors, basing on OECD, 2003, pp. 15-42; Richerzhagen, 2008, pp. 108-128; Richter and Furubotn, 1996.

3 Existing standardisation initiatives for ABS contracts

The idea of standardising Access and Benefit Sharing (ABS) contracts has been applied by various stakeholder groups in their ABS regimes for many years. The range of measures span the Bonn Guidelines, a set of non-binding, rather general guidelines for elements of the

Material Transfer Agreements (Secretariat of the Convention on Biological Diversity, 2002), to full fledged standardised contracts like the SMTA of the International Treaty ABS regime (International Treaty on Plant Genetic Resources for Food and Agriculture, 2006). Besides these multilateral measures, several other initiatives on different levels have evolved.

3.1 Guidelines for Material Transfer Agreements for ABS

The Bonn Guidelines recommend elements to be included in MTAs to cover the transaction of genetic resources under the CBD. Moreover they give an overview of possible forms of monetary and non-monetary benefit-sharing (Secretariat of the Convention on Biological Diversity, 2002, pp. 17-20) (see table 4).

Table 4: Suggestions for Elements of MTAs in the Bonn Guidelines

Introductory provisions
- Legal status of provider and user of genetic resources - General objectives of provider and user of genetic resources
ABS provisions
- Description of material covered by the agreement, other definitions - Permitted uses (under consideration of potential uses, products, derivatives (e.g. research, commercialization) - New Prior Informed Consent required in case of change of use - Regulation of intellectual property rights - Terms and forms of benefit-sharing (various suggestions for monetary and non-monetary benefit-sharing) - No warranties guaranteed by provider on identity and/or quality of the provided material - Regulation of the transfer of genetic resources and/or accompanying information to third parties - Duty to minimize environmental impacts of collecting activities
Legal provisions
- Obligation to comply with the MTA, - Termination and duration of agreement, - Dispute settlement arrangements, choice of law, guarantees, etc.

Source: Secretariat of the Convention on Biological Diversity (Bonn Guidelines) (2002), pp. 17-20.

As previously mentioned, the suggestions of the Bonn Guidelines are of a general nature. They do not differentiate between different kinds of genetic resources, procurement or utilisation forms.

The Swiss “ABS management tool”, developed by ABS experts under the direction of the International Institute for Sustainable Development, is more detailed and comprehensive. One feature of the tool is an extensive list of issues and suggestions for their solutions that might be of relevance to be included in MTAs (International Institute for Sustainable Development and State Secretariat for Economic Affairs, 2007, p. 20). The tool gives plenty of options but they are not classified on the basis of applications with regard to different user sectors. The user has to choose which items he considers necessary and how to formulate them as a contract clause.

3.2 Model and standard ABS contracts

Seven initiatives of standard or model contracts for transactions involving genetic resources are discussed in this passage. They go beyond the Bonn Guidelines and the Swiss ABS Management Tool in terms of the standardisation level, as they are complete model or standard contracts. The documents vary in length, amount of items covered and thereby concreteness of their contents. Table 5 gives an overview of the measures, their respective responsible institutions, target groups, main characteristics, and the intentions behind the approaches.

Table 5: Main characteristics of standardisation initiatives for ABS contracts

Name, Institution	Instrument, system	Target group	Intention/purpose
[1] Standard Material Transfer Agreement (SMTA, 12 pages) ITPGRFA, 2007	Completely standardised, private, bilateral material transfer contract (SMTA) between user and the multilateral system	Commercial & non-commercial users, although restricted to research, breeding and training for food & agriculture	Simplifying access to and exchange of genetic resources for food and agriculture (supporting food security & quality), lowering transaction costs
[2] Two model contracts for ABS, (both 31 pages) Government of Australia (Department of the Environment, Water, Heritage and the Arts), December 2005	- Two optional model MTAs for commercial use (Commonwealth land; Aboriginal or Trust land) - Recommendations for monetary benefit-sharing, timeframes for access approval, max. number of permits applicants may request - Penalty for non-compliance	Developed by government institution in its function as a provider of genetic resources. Guidance tool in ABS negotiations with commercial users.	- Meeting CBD obligations for ABS - Minimising transaction costs - Encouraging R&D - Avoiding decision-making delays - Facilitating flexible access arrangements for lengthy or even unlimited periods
[3] Model-MTA of BIO, Biotechnology Industry Organization (Model MTA: 11 pages)	- Model MTA in combination with voluntary Guidelines for members - […] no legal obligation that attaches from membership in BIO to adhere to the Guidelines."	Members of BIO, mainly Biotech-Companies for Bioprospecting activities	- Educating & supporting Bioprospecting activities - "[…] providing a useful "roadmap" for a BIO company […] in bioprospecting activities."
[4] Letter of Collection (LOC, 5 pages), Memorandum of Understanding (MOU, 6 pages) National Cancer Institut, NCI (USA), 1988	- Standardised contract form - No quantified benefit-sharing provisions - Only MOU: Source-country collaborator is solely responsible for abiding by all necessary access policies & PIC	Cancer fighting and prevention research, commercial and non-commercial utilization	- Providing a legal mechanism and fundamental framework for international cooperation - Balancing interests - Transcending national barriers, clearly defined common understanding of transactions

[5] Simple Letter Agreement (SLA), Uniform Biological Material Transfer Agreement (UBMTA), US National Institute of Health (NIH), 1995	Both are standard contracts based on the principles for research material transfers between not-for profit research of the National Health Institute. SLA: 1p. UBMTA: 8 p.	Restricted to academic research and domestic transactions with genetic resources	- Standardising biological material transfer within the United States - Minimising administrative impediments to academic research
[6] Science commons (sc) MTAs, Science commons project, since 2005, still under development. Approaches based on existing NIH Principles and Guidelines for the Sharing of Biomedical research Resources (see previous row)	- Sc MTA: modular MTAs for transfer of material & data between non-profit entities to for-profit entities (user of the tool chooses from a menu according the transaction characteristics). - For intra-academic exchange the utilisation of UBMTA and SLA is supported by new organisational tools that simplify contracting, searching etc.	Target group: not-for profit researchers from all scientific fields utilising genetic resources. For profit entities are affected indirectly when involved in genetic resource transactions with the target group.	- Lowering transaction costs, simplifying negotiations for material transfers between institutions (academia & for-profit) - Providing infrastructure for web-based transactions - Avoiding impediments - Improving accessibility and exchange of data, material, and metadata on genetic resource utilisation in research
[7] Model MTA (3 pages) and MTA check list in (MOSAICC) framework of Belgian Coordinated Collections of Microorganisms (BCCM), 2004 but revised and still under further development	Two voluntary instruments, differentiated by the complexity of the transaction structure: - MTA model form for usual transfers (e.g. delivery of test strains and exchanges between scientists), containing definitions - MTA check-list for more custom-made agreements	Ex-situ collections for microbial genetic resources; collections are providers and intermediaries (who obtain microbial genetic resources (MGRs) to extend their collections)	- Facilitating access - Helping collections to make appropriate agreements - Increasing uniformity in MTA contents & defining a minimum set of information - Electronic handling of digitalized MTAs (fast, cost-effective, reliable management of MGRs

Source: authors, based on (Footnotes stand for the entire corresponding row):

[1] International Treaty on Plant Genetic Resources for Food and Agriculture, 2006.; [2] http://www.environment.gov.au; personal communication with Department of the Environment, Water, Heritage, the Arts.; [3] BIO Industry Association, 2008 (http://www.bio.org/ip/international/200507memo.asp); [4] http://ttb.nci.nih.gov; Gupta, R, Gabrielsen, B. and M. Ferguson (2005), pp. 203-219; Rosenthal, J. P., 1996.; [5] http://ott.od.nih.gov; Rodriguez, V., 2005, pp. 489-491.; [6] http://sciencecommons.org; http://mta.sciencecommons.org/, Nguyen, T., 2007, pp. 139-141; Wilbanks, J., J. Boyle, 2006.; [7] http://bccm.belspo.be/projects/; Belgian Co-ordinated Collections of Micro-organisms, 2000; personal communication with Philip Desmeth

In the following section we take a closer look at the kind of transactions the model contracts are intended for, what is understood to be the object of transaction and the monetary benefit-sharing regulations in the respective systems.

1. The SMTA of the ITPGRFA

The SMTA is mainly thought to be applied to plant genetic resources held in ex-situ collections participating in the multilateral system (MLS) within the ABS regime of the ITPGRFA or in the public domain of member countries of the Treaty. Therefore, the SMTA is mainly applied to so-called “spot market” transactions. Such transactions are limited in complexity and extent. The resources transferred are inventoried in ex-situ collections and not completely new, but described to a certain extent. The benefit-sharing provisions for transactions with materials under the SMTA are standardised (International Treaty on Plant Genetic Resources for Food and Agriculture, 2006, p. 10-11). The money paid in the course of benefit-sharing flows into a multilateral fund from which it will be redistributed according to the priorities defined in a Global Plan of Action.

2. The Model MTA of the Australian Government

The model MTA of the Australian Government is intended to be applied to transactions with “[…] all kinds of biological resources including genetic resources, organisms and parts of organisms, populations, and any other biotic component of an ecosystem with actual or potential use” (Australian model ABS agreements, p. 3). In principle, its design is to fit all kinds of commercial transactions with biological resources, but the responsible authorities think it will be most useful for the procurement of in-situ resources, because most ex-situ collections in Australia have their own ABS regimes in place. This means it shall be applied to rather complex transactions with a high level of uncertainty.

The model contract provides numeric recommendations for monetary benefit sharing in the form of thresholds, which differ by sector and gross revenue of the product concerned. The percentages vary between 0 and 5% (Australian Government, Department of Environment and Heritage, 2005a and 2005b, both p. 26). It is recommended to adjust the amount and form of benefits depending on market conditions, the characteristics of the specific access agreement, and the circumstances of the contracting parties (Australian Government, Department of Environment and Heritage, 2004 p. 9).

3. BIO Model MTA and Guidelines for Bioprospecting activities

The Industry Organization BIO provides its members with a model MTA, which is in line with the Guidelines of the Association. Both documents shall serve users as best practice meth-

ods for negotiating and formulating contracts for bioprospecting agreements. They can be used as contractual elements of a Bioprospecting Agreement, as the basis for a transfer agreement entered into after the completion of collection activities undertaken following a Bioprospecting Agreement; as a Bioprospecting Agreement with an ex situ holding of genetic resources (BIO Model MTA, p. 1).

The model contract contains recommendations on how and when to negotiate and define appropriate benefit sharing, while it refers to the Bonn Guidelines. It states that benefits can vary widely, depending on the needs of the providers, "[…] including indigenous or local communities, the commercial value of the transferred physical samples, the intended use of the samples, and the likelihood of using the samples to create a commercially viable product, and other factors." According to the Guidelines a single definition or model formulation of benefit-sharing is not appropriate to reflect the variety of circumstances under which ABS agreements are reached and carried out (BIO, Modal MTA, p. 8).

4. The Letter of Collection (LOC) and the Memorandum of Understanding (MOU) from the US National Cancer Institute

LOC and MOU can be employed for transactions with Plants, micro-organisms, and marine macro-organisms as potential sources of novel anti-cancer drugs. The transactions differ in complexity and intensity of collaboration between user and source country organization (SCO). The LOC is applied for the acquisition of genetic resources from contracting region-specific collectors. The MOU is applied in research collaborations between user and source country institutions. In this case, the acquisition of material and the very initial research steps are carried out by the SCO. The improved material is transferred to the user country where further research and development is done (National Cancer Institute, 1988b, p. 1).

Both contracts contain clauses about appropriate compensation (e.g. in the form of royalties), which the SCO shall receive in case of commercialization (National Cancer Institute, 1988b, p. 3; National Cancer Institute, 1988b, p. 4). Concerning royalty rates it is suggested to take the contribution of both parties as a basis for assessment (Rosenthal 1997, p. 4). Furthermore, the relationship between the originally isolated product and the marketed drug should play a role (National Cancer Institute, 1988b, p. 3; National Cancer Institute, 1988b, p. 4).

5. Simple Letter Agreement (SLA) and Unified Biological Material Agreement (UBMTA) of the National Institutes of Health

SLA and UBMTA can cover all kinds of biological materials but are restricted to intra-academic material and the transfer of information. As the transfer to commercial entities is

prohibited, they do not contain any benefit-sharing regulations (National Institute of Health, 1995a and 1995b).

6. *The science commons model*

The science commons approach is based on the National Institute of Health "Principles and Guidelines for the Sharing of Biomedical research Resources". For the non-commercial transfer of material and information among academics they apply the original SLA and UBMTA. As part of the science commons project, special tools to disperse the utilization of SLA and UBMTA among academics are being developed. For transactions between academic and commercial entities, the science commons modular MTAs have been developed. Both measures are designed for pure material and information transactions rather than for complex research collaborations. The application of the science commons MTA is not restricted to a specific, more closely defined type of genetic resource. The definition of material transferred under SLA and UBMTA is given in the following paragraph. The science commons model contract does not contain benefit-sharing regulations (Wilbanks, J. and J. Boyle, 2006).

7. *The* Micro-organisms Sustainable Use and Access Regulation International Code of Conduct *(MOSAICC) MTA and check list for MTAs*

Both the model MTA and the checklist are to be used for transactions with microorganism genetic resources (MGRs) whereby the ex-situ collection acts as the provider (intermediary) or recipient of MGRs. Two instruments are designed to suit different types of transactions in terms of specificity and complexity. The checklist is utilised to support rather complex, customised transactions, whereas the model MTA is applicable to simple, more routine transactions (http://bccm.belspo.be/services/bccm_mta.php, and personal communication with Philip Desmeth, April 2008).

The Code of Conduct contains a comprehensive list of various benefit-sharing options with recommendations indicating when and how to apply which form. The model MTA provides a much shorter list and no concrete provisions or standards. The payment of royalties should fully depend on the successful commercial utilization of the MGRs and a part of the monetary compensation should be dedicated to technical and scientific cooperation programs (BCCM, 2000, II.2-II.4). It is recommended to negotiate a preliminary agreement on financial benefit sharing before starting R&D that could lead to commercialization (BCCM, 2000, I.8).

Table 6 elaborates the terms of some core elements of three of the presented model agreements in a comparative, in-depth way.

Table 6: Core Elements of three model MTAs for transactions with genetic resources under the scope of ABS regimes

	Model-MTA of Biotechnology Association BIO	FAO ITPGRFA SMTA	Australian model MTA for genetic resources
Definitions of genetic resources / applicability of the model contract	Physical samples of "regulated genetic resources" in situ or ex situ, essentially materials of (non-human) animal, plant or microbial origin that contain functional units of heredity and that are subject to the requirements of prior informed consent, etc. under the Convention on Biological Diversity. Explicitly excluded are materials obtained from humans or of human origin; not regulated Genetic Resources (GRs) (within the meaning of the BIO Guidelines); GRs in ex situ collections that were obtained from a Contracting Party prior to the date the CBD took effect for that Contracting Party; GRs that are made available to the public on an unrestricted basis […]; publicly available information (e.g. in scientific literature, disclosed in a patent or published patent application, or disseminated in an unrestricted fashion (Bio Guidelines, Art. I.B2).	Genetic material is any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity. Plant Genetic Resources for Food and Agriculture (PGRFA) means any genetic material of plant origin of actual or potential value for food and agriculture. PGRFA under Development means material derived from the material, and hence distinct from it, that is not yet ready for commercialization and which shall be further developed. "Product" means PGRFA that incorporate the material or any of its genetic parts or components that are ready for commercialization, excluding commodities and other products used for food, feed and processing." (Art. 2).	Access to Biological resources: "[…] the taking of biological resources of native species for research and development on any genetic resources, or biochemical compounds, comprising or contained in the biological resources […]". "Biological resources: "[…] includes genetic resources, organisms, parts of organisms, populations and any other biotic component of an ecosystem with actual or potential use or value for humanity;" Genetic resources: "[…] means any material of plant, animal, microbial or other origin that contains functional units of heredity and that has actual or potential value for humanity;"
Specifications regarding forms of utilization	Possible utilization forms: screening for biological properties, growth and study, extraction and isolation of chemical compounds, genomic analysis; fields: "pharmaceutical, agricultural, industrial processing, environmental remediation".	Plant Genetic Resources for Food and Agriculture specified in Annex 1 to the Standard Agreement and the available related information. These are plant genetic resources with particular relevance for food security. The SMTA is only valid for specified utilization purposes: research, breeding and training for food and	The Model MTA is designed for transactions with the intent of commercial or potential commercial utilization. No further limitations or specifications of the scope for application.

Continuation of table 6

	Model-MTA of Biotechnology Association BIO	FAO ITPGRFA SMTA	Australian model MTA for genetic resources
		agriculture. Purposes explicitly not included are chemical, pharmaceutical and/or other non-food/feed industrial uses (Art. 6.1).	
Handling of material after termination of the contract	The recipient and subsequent users have to destroy or return the material and genetic resources or other materials made from those samples to the provider, except if necessary to fulfil disclosure requirements for intellectual property rights (IPR) applications (Art. 4.2).	The material remains with the user, but he is encouraged to place results from his utilization process in the public domain (the MLS, Multilateral System of the ITPGRFA). No time-limitation is suggested	In case of termination for default: "the Access Party will deliver to the Commonwealth or destroy, at the Commonwealth's discretion, all Samples and Products that are the subject of this Agreement" (Art. 13.2)
Exclusivity rights for access	No suggestions	"The Recipient shall not claim any IPRs or other rights that limit the facilitated access to the Material provided under this Agreement, or its genetic parts or components, in the form received from the MLS" (Art. 6.2)	"The Access Party has the exclusive rights to all Samples and Products [transferred under the agreements]." (Art. 5.1)
Material transfer to third parties	The recipient is allowed to transfer the material without renegotiations to successors for whom he is acting as an agent, or to third parties who are authorized in writing to receive samples by, and to successors who are bound by the Agreement. (Art. 3.3). The recipient may transfer material to other third parties only after prior written permission by the provider (Commentary to Art. 4).	If a recipient obtains IPRs on products developed from the material or its components, obtained from the MLS, and assigns such IPRs to a third party, he shall transfer the benefit-sharing obligations of this Agreement to that third party" (Art. 6.10). Material received from the MLS and material under development based on material received from the MLS shall be transferred to subsequent users under new MTAs, and in compliance with the SMTA. The initial accessor shall notify the Governing Body of the ITPGRFA. If the recipient complies with these responsibilities he has no further obligations regarding the actions of any subsequent recipient.	The recipient may only provide access to samples or products or transfer or assign rights (including IPRs) to third parties applying agreements with proper terms and consistent with the MTA (including benefit-sharing obligations to the Commonwealth). Alternatively the third party can enter in a new agreement with the Commonwealth. If the third party only intends non-commercial use the contract has to include an undertaking not to carry out/allow others to use the material for commercial purposes unless a benefit-sharing agreement has been reached with the Access Party. The recipient has the obligation to report material transfers to the Commonwealth, including the details of the contract terms.

Benefit sharing	Does not contain model formulations or suggestions on concrete figures for benefit sharing, but references to define benefit sharing: needs of the beneficiaries, commercial value of the resource, intended utilisation form, likelihood that commercial benefits will be generated Recommendation to define the certain point in the future for benefit-sharing negotiations in the contract (e.g. a date, a certain step in the utilization process, the finalization of product development…).(Art. 5.1) Potential forms of benefit-sharing are listed in the Annex of the BIO Guidelines	Monetary Benefit Sharing is obligatory if the recipient develops a marketable product (e.g. a new plant variety) and does not provide unrestricted access to this product for other users via the MLS (0.77% of the turnaround with the product (Annex I); This step is voluntary if the product is accessible without restriction via the MLS (Art. 6.8); Or the recipient commits himself for ten years to pay 0.5% of his turnaround with all products based on material received from the MLS (Art. 6.11) Non-Monetary benefit-sharing: "The Recipient shall make available to the Multilateral System […] all non-confidential information that results from R&D carried out on the material, and is encouraged to share through the MLS non-monetary benefits expressly identified in Article 13.2 of the Treaty that result from such R&D. After the expiry or abandonment of the protection period of an IPR on a Product that incorporates the Material, the Recipient is encouraged to place a sample of this Product into a collection that is part of the MLS, for research and breeding."	The model contract contains recommendations and reference points for monetary benefit sharing (Threshold Payments). The shares are distinguished by product groups and gross Exploitation revenue. The payments are to be paid annually within 30 days after receipt of a correctly tendered tax invoice (Schedule 3; see also Annex to this document). The model contract also contains recommendations for non-monetary benefit sharing (schedule 4) Additionally the recipient has to provide taxonomic duplicates of all collected material to the provider, and the recipient has to acknowledge the provider in dealings with third parties.
Intellectual Property Rights (IPRs)	The recipient is not allowed to seek patents or plant variety protection rights for the provided Material as such, but may apply for the grant of patents claiming inventions developed using samples of the Material,	The recipient has the right to apply for the granting of IPRs on products developed using material from the MLS. He can decide (within national laws) how far he wants to restrict access to his PGRFA under development (Art. 5).	"Intellectual property as between the Commonwealth and the Access Party (but without affecting the position between the Access Party and a third party) Intellectual Property arising from R & D Activity is vested or will vest in the Access Party." (Art. 5.2)

Continuation of table 6			
	Model-MTA of Biotechnology Association BIO	**FAO ITPGRFA SMTA**	**Australian model MTA for genetic resources**
	including inventions embodied in modified forms of the materials, or for the grant of plant variety protection claiming varieties developed using samples of the Material (Art. 4.3).	After termination of the development period the recipient is encouraged to insert a sample of his product in the MLS and thereby make it available for further use without restrictions. If he/she chooses not to do so, monetary benefit-sharing requirements are binding.	
Specifications on time frames and terms of termination	Suggested term of contract is ten years. Suggested terms of termination: "[…] if any of the Parties provides notice in writing to the others of its intent to terminate the Agreement on a date no less than six-months from the date of the notice." (Art. 7.1) The obligations and rights regarding Intellectual Property Rights (see previous cell) shall survive the expiration or other termination of the Agreement. (Art. 7.2)	The contract remains effective as long as the SMTA is in place. The Provider undertakes that the Material is transferred in accordance with the following provisions of the Treaty: "Access shall be accorded expeditiously, without the need to track individual accessions and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved;" (Art. 5)	Termination by Agreement at any time by mutual agreement in writing. Termination for default: immediately, if a remedy is not possible or failed after a second written notice by the provider. In that case the recipient is thereafter not allowed to use or to grant permission to be used: any Samples or Products; IPRs arising from R&D; and the rights in all subsequent third party agreements are assigned to the provider. The recipient's right to sell Products or material containing a Product, by way of retail sale under commercial arrangements existing at the date of termination, as well as benefit-sharing obligations, will not be affected. (Art. 13)
Contribution to the conservation of the Biodiversity	The User should transfer information regarding the conservation of biodiversity to the provider	Simplified exchange, incorporation of developed or new material into the MLS, and benefit sharing are contributions towards the conservation of Biodiversity	Transfer of knowledge that is useful for the conservation of biodiversity to an Australian research establishment or indigenous groups

Source: authors.

Comparison of the different approaches - summarizing key points:

The instruments are designed to fulfil different needs of target groups, whereby the simplification of ABS procedures and the reduction of transaction costs are key intentions in all cases. In some cases the target group indicates a specific user sector.

Except for the ITPGRFA SMTA (SMTA) all systems differentiate requirements in ABS procedures for commercial and non-commercial utilisation of genetic resources. As a general rule the requirements are higher for commercial access purposes.

Except for the SMTA, all presented approaches tend to be model contracts and voluntary rather than “real” standard contracts.

The types of transactions and genetic resources covered by the different instruments vary in complexity, among other dimensions. The SMTA of the ITPGRFA and the SMTA of the Australian Government are both complete contracts, but the first one is a standard contract, while the second one is a model. The ITPGR SMTA is mainly applied to spot market transactions, in which users and providers do not cooperate in further research and development. The resources are obtained from an ex-situ collection and the products and benefits are redistributed to that “anonymous” system. The Australian governments` model contract, on the other hand, is designed to support more complex transactions with own collection of materials involved. It is explicitly meant to be used as a starting point and a guide in negotiating more case-adopted contracts.

Another aspect of application differences involves the kind of resources the measures are applied to; while the measures created by the Australian Government, the National Cancer Institutes, science commons and the National Health Institutes cover many different kinds of material under the term genetic resources, the SMTA and the MOSAICC model are restricted to specific types of genetic resources.

An additional important aspect is that several systems consider the varying level of complexity in user-provider relations in different ABS cases. The NCI system, for instance, provides different model contracts for different transaction types with respect to the intensity of cooperation between user and provider. The MOSAICC system recommends two different measures with regard to the complexity of the transactions: a model MTA for “simple” transactions and a checklist for customised transactions

Regarding monetary benefit sharing, we only find concrete numeric provisions in the SMTA of the Treaty. The Australian model contract nevertheless provides quantitative recommen-

dations for monetary benefit sharing (Australian Government, Department of Environment and Heritage, 2005a and 2005b, both p. 28). All other measures provide rather general recommendations for the assessment of forms and values of benefit sharing. These recommendations are mainly based on the economic value of the genetic resource in the R&D process of the user. The perspective of the Provider is generally neglected.

Table 7 provides the Internet links to the documents and the websites of the responsible institutions where relevant documents and related information can be found. Additionally, some experiences regarding the application of these instruments is provided by the concerned parties. One hardly finds valid information about experiences regarding the efficiency and acceptance of the different model and standard contracts. Involved parties and experts assume that they do reduce transaction costs. In the case of the Treaty SMTA, experts recognize that the demand for genetic resources from collections of the MLS has re-stabilised after it decreased significantly before the SMTA was implemented. They assume that this is partly due to the simplified procedure of which the SMTA is a major part, but independent evaluations of experiences with the existing approaches in particular would be helpful for further assessment.

The examples considered give an insight into the diversity of the approaches that already exist. They convey first-hand ideas for discussions with stakeholders, but they should not limit the range of options to be analyzed for new instruments in particular, since so little about their success is known.

Table 7: Internet links on Model MTAs and experiences reported by responsible institutions

Name & Link	Experiences with the instrument
SMTA of ITPGR http://www.planttreaty.org/smta_en.htm	- So far limited experiences since the SMTA was only recently implemented - The new, simplified instruments for accepting the contract seem essential for routine transactions. (Governing Body report page 4) - During the period from 1 January to 1 August 2007, approximately 100,000 samples were distributed under the SMTA (not including internal exchange within member centres of the MLS) - Only few centres experienced acceptance problems - Main issues for reconsideration reported by institutions applying the SMTA: • The complexity and length of the SMTA (high weight) • Bureaucratic requirements in case of obligatory payments • Duration of benefit-sharing obligations when restricted availability of material • Application of SMTA for transfer of improved material (under development) [1]

Continuation of table 7	
Name and Link	**Experiences with the instrument**
Model contract for ABS of the Australian Government http://www.environment.gov.au/biodiversity/science/access/model-agreements/index.html	Since the implementation of the model contract (December 2005), four ABS contracts for commercial utilization have been signed based on the model contract. Representatives assume that a reduction of time (and therewith transaction costs) in the process was occurring due to the model contract. The model contract will be further developed over time with the aim of streamlining the process and considering experiences and feedback by stakeholders. [2]
BIO Guidelines & BIO Model contract for Bioprospecting activities	No information http://www.bio.org/ip/international/200507memo.asp
LOC & MOU (US National Cancer Institute; http://ttc.nci.nih.gov/forms/	The relevance of the LOC in application is decreasing against the application of the MOU (collaborative research projects increasing and procurement through contract collectors is decreasing). [3]
SLA, UBMTA	SLA: http://www.nhlbi.nih.gov/tt/docs/sla_mta.pdf UBMTA: http://www.nhlbi.nih.gov/tt/docs/ubmta.pdf
Science commons http://mta.sciencecommons.org/	The science commons modular MTA is ready for utilisation and available on the science commons website. So far no academic institution has adopted it as a standard tool for material transfers to commercial entities. [4]
MOSAICC, Model MTA and Checklist: http://bccm.belspo.be/services/bccm_mta.php	All transactions with MGRs taking place with the members of the consortium that agreed upon utilising the MTA. Positive acceptance by customers. After initial confirmation by the customer this remains valid for following orders made by the same customer. [5]
Source: authors, basing on: [1] International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), 2006; ITPGRFA, 2007; [2] Personal communications (P.c.) with Belinda Brown, Department of the Environment, Water, Heritage and the Arts, Government of Australia; [4] P.C. with Thinh Nguyen, Counsel for Science Commons; P.c. with Philip Desmeth, BCCM *links most recently checked on 22 December 2008	

4 The user survey

The first section of this chapter deals with the concept of the survey within the framework of the project. The following sections provide an overview of the findings derived from the survey stages conducted so far.

4.1 Frame of the survey

Genetic resources serve as an input for various uses and purposes in a multitude of fields (see overview 2). Three important fields were selected as research groups for the project, namely researchers from public institutions, pharmaceutical and industrial biotechnology companies and plant breeding companies (limited thus far to crops).

Overview 2: Users of Genetic Resources – Survey Groups in the Research Project

Biotechnology in the Private Sector (Other than plant breeding)	**Plant Breeding** (Traditional breeding techniques and biotechnology applications)
• Red biotechnology: Pharmaceuticals • Industrial/white biotechnology: personal care, • Plant protection, fertilizers, bioenergy, food	• Crops • Ornamentals plants, fruit • Vegetables • Energy Plants • Spices and medicinal plants
Public Research Institutions Ex-situ collections	**Others**
• Researchers at universities and other institutions (pharmaceutical biology, plant breeding, chemistry, taxonomy, materials, animal breeding, etc.) • Botanical gardens, Zoos, Herbariums, Museums • Gene banks, microorganism collections	• Pets • Botanical Medicine

Source: authors.

The main task within the research project is to discuss opportunities, limitations and implementation issues of model clauses for Material Transfer Agreements with users of genetic resources which are concerned with ABS. From the initial stages we could not assume that all survey participants would have a clear understanding of model clauses, moreover their opinions based on different levels of understanding might differ greatly. Therefore we approached the overall question in three steps during the interview process.

First we asked users to report problems that occurred in the chain of acquisition and utilization of genetic resources. This served to better understand potential sources for the failure of ABS agreements or impediments to their successful completion.

In the next step we discussed a list of potential contract elements, such as the terms of benefit sharing, material transfer to third parties, IPRs and others. We asked the users whether they viewed these items as having a general relevance to ABS contracts in their fields. Subsequently we conducted a group discussion to determine whether a common understanding exists as to how such elements could be completed in terms of content.

Finally we asked the users whether they thought that model clauses for MTAs or ABS con-

tracts in general could assist in the process of negotiating with providers.

The main method for data collection was initially thought to be group discussions, but a review of existing literature and initial contacts with users and user representatives showed that individual, exploratory interviews with single users were necessary as preparation for group discussions. The understanding of ABS agreements and contracts was to limited to directly start with group discussions. This first step of the survey has been finalized. In all three target groups we have conducted exploratory one-on-one interviews with at least four users. Additionally, representatives of industry associations were interviewed and we gathered information from side events during ABS Working Group (WG) 5 and 6 as well as COP 9 (see interim report no. 3).

Within the first two investigative groups we were able to hold group discussions after initial contact was made and a certain level of trust was established. In the plant breeding sector however, we approached two associations for support in contacting potential survey participants. Thus far we have succeeded in conducting individual interviews with users from this group, but the willingness to participate in a group discussion seems to be low for this sector. Branch representatives see several possible reasons for this. First, German plant breeding companies are (with a few exceptions) rather small companies, particularly compared with the pharmaceutical and industrial biotechnology industry. Most of the plant-breeding companies do not have their own legal departments. They might lack the capacity to deal with ABS issues on an in-depth level themselves and prefer to leave this to their branch association, the Federal German Association of Plant Breeders (BDP), and the International community of breeders of asexually reproduced ornamental and fruit varieties CIOPORA. Furthermore, the awareness of legal implications for their day-to-day work by an international Access and Benefit-sharing regime and the ABS regime under the ITPGRFA is small in this group. Another factor is that companies might be reluctant to discuss individual experiences and views in a group for fear of divulging sensitive competitive information. However, now that we have established personal contacts to plant breeding companies we will organize a group discussion in this investigative group and discuss the results in our final report.

4.2 Interim findings of the survey

The ways in which information was gathered in interviews and group discussions were to a large extent exploratory and the level of preliminary information of the participants varied among the groups. As a result, the outcomes of the survey differ among the groups in terms

of the concreteness and in the overall amount of information revealed.

The first section of this chapter on survey outcomes resumes the experiences of the participants regarding problems occurring in concluding ABS agreements. The second section deals with considerations of different elements of MTAs. In the third section the views stated by participants regarding chances and limitations of model clauses as measures to support ABS agreements are summarized. In each thematic section the findings are presented separately for each of the investigational groups, followed by a summary of major differences as well as points for which consensus could be reached.

4.2.1 User problems with ABS

Researchers from publicly funded institutions

Problems in ABS processes reported by researchers from public institutions can be classified under three main issues: provider-centred problems (table 8), user-centred problems, (table 9) and problems of a higher institutional level.

“Provider-centred problems” are issues users felt were shortcomings related to the governance system, transparency of the regulatory system, legal capabilities or the general position taken by providers towards ABS (see table 8).

Table 8: Provider-Centred Problems; Survey Group: Researchers From Public Institutions

Negotiation with Providers

- Lack of competent contact person
- Lack of expertise on provider side to assess access requests (often complex research approaches)
- Unclear hierarchy of responsibility regarding ABS issues on provider side
- Unclear regulations about other groups, e.g. indigenous people, that have to be consulted (PIC)
- Providers lack knowledge of legal situation

Benefit-sharing

- Mistrust of users
- Fear of exploitation
- Exorbitant claims for benefit-sharing

National ABS Laws

- Lack of transparency
- Legal systems / procedural requirements vary among different provider countries
- Intransparent distribution of benefits increases risk of corruption accusations for user

Source: Authors, based on survey.

Table 9: User-Centred Problems in ABS; Investigational Group: Researchers from Public Institutions

General lack of information and awareness of researchers, contact persons at research institutions and granting institutions regarding

- Concern for ABS regulations
- Current political and legal situation
- Limited capacity to achieve & process information on ABS regulations (legal issues are not core competencies of natural scientists)
- Very limited legal competencies of research institutions regarding ABS

Specific case-related problems

- Identification of appropriate procedure
- Finding the authorised partner in the provider country to negotiate ABS
- Identification of other groups that need to be consulted according to national ABS laws
- Adapted communication (language, complexity of research intention)
- Definition of fair benefit-sharing offer
- Adequate formulation of agreement in contract

Integration of ABS in research project planning

- Anticipation of research process regarding relevant issues for ABS contract
- Consideration of policies of research institutions when defining the utilisation intention and other MTA elements (e.g. benefit-sharing and IPRs)
- Communication of ABS issues between researchers and universities, granting institutions and industry partners in terms of integration of benefit sharing in financial planning of the project
- Bridging finances for the initialisation & negotiation time before the start of a project
- Back-up plan to safeguard the research project (risk that ABS negotiations lack)

Source: authors, based on survey.

Of special interest, and we assume these are typical problems for this group, are issues centred on the integration of ABS principles in research planning (see shaded box in table 9). This has much to do with the researchers' intermediary position. They are the party engaged in direct interaction with providers, but their institution (e.g. the university) and external financing bodies decide on research policies, the distribution of research grants and in fact often are the contracting authorities in ABS agreements. This means the researchers often

are the ones initiating ABS agreements, but have a limited say in negotiations.

Users from this target group demand a superordinate entity (e.g. at the CBD level, with representatives of providers and users) to check best practise initiatives like codes of conduct, guidelines, etc. for ABS regarding their consistency with general ABS provisions in the CBD. Such an entity could also provide Guidelines for Memorandums of Understanding (MOUs). MOUs seem to be a useful tool to communicate complex research projects to providers of genetic resources. From the researchers' perspective, the clear communication of what they intend to do with the genetic resources is extremely important. Misunderstandings and mistrust are perceived as sources of impediments in research projects or even the breakdown of cooperation between users and providers.

Pharmacy and Industrial Biotechnology

A main reason why many former users in the field of pharmaceuticals have ceased engagement in natural product research in recent years are new technologies allowing the substitution of genetic resources as input for R&D, for instance the field of combinatorial chemistry. Most survey participants in this group do not see transaction costs as a main reason not to engage in ABS agreements or even to cease natural product research. In relation to other cost items accruing in the chain of R&D using genetic resources, the costs for acquiring the resources are assessed as being rather moderate. However, although the overall opinion in this group was that transaction costs are not a main reason to cease engagement in ABS agreements so far, high bureaucratic hurdles are seen as potential impediments for the demand of genetic resources.

At first glance these two statements may seem contradictory. However, most survey participants are active in natural product research and by the time they have established individual strategies of efficient means of procurement. In these cases transaction costs might be low. Often intermediaries in source countries, may it be research institutions or broker companies, are involved in the chain. One of their major responsibilities is to deal with the national administrative access requirements or at least support the company in this. These arrangements might be for efficiency reasons; the intermediaries in source countries better understand the rules of the game in their own country (for instance the language, culture, business practices) and they might face a higher level of trust from the providing entity. Furthermore, the company seeks to distribute a part of the legal uncertainty and image risk inherent in intransparent ABS regimes by establishing in a private contract with the intermediary that the latter will retain resources and transfer them to the company only in accordance with national access legislation. Another strategy is to choose, if possible, a

provider country that has unbureaucratic and transparent access requirements in place.

This means that users currently participating in the survey assess their transaction costs as tolerable, but they can imagine that they could be significantly higher; particularly if national ABS regimes are supplemented by compliance measures in the frame of an international regime. Such measures might imply additional bureaucratic efforts which cannot be distributed to intermediaries in the existing arrangements.

A problem of a rather general nature stated by users in this survey group is that ABS is a strongly politicised issue and the expectations for benefit sharing are excessive from their perspective. This leads to a difficult atmosphere for ABS negotiations between users and providers.

In general, image risks resulting from engaging with providers of genetic resources are seen as a significant threat to companies conducting natural product research. Users see themselves as potential victims of biopirating accusations. The greatest risks are seen under circumstances in which concerned minorities, for instance a local groups or indigenous peoples in a provider country, do not feel or are assumed to be not well represented by the governmental entities who take decisions in ABS negotiations.

Based on these problems the participants of the group discussion saw a potential benefit from the standardization or harmonization of ABS requirements in provider countries as a means to increase legal certainty for users and circumvent a race to the bottom of ABS standards.

Plant Breeding Companies

Interview partners from this group reported various ways of procuring material for plant breeding: commercial varieties which are the result of a breeding process can simply be purchased on the market and used for further breeding under the “breeders’ exemption” (based on the International Union for the Protection of New Varieties of Plants, UPOV), although not all material on the market is protected by plant protection rights. Breeders might also exchange material under development among each other using bilateral licensing agreements, and breeders have their own collections of material from former breeding programs. “Raw” genetic material is acquired from gene banks or botanical gardens, as well as via individual expeditions and collecting activities.

Materials that are acquired from gene banks or botanical gardens are usually (even before the SMTA of the ITPGRFA was in place) transferred under standard MTAs, without extensive efforts for administrative requirements. Improved varieties which are available on the market fall under the “Breeders Exemption” (UPOV) and can therefore be used for

further breeding purposes without additional requirements. In the case of material under development or raw material among breeders, informal conventions on licensing terms are applied (at least in some areas).

With one exception our interview partners did not report severe problems or impediments in materials / genetic resource acquisitions. One breeding company reported the failure of an ABS project within which the provision of certain land species of a crop was demanded in exchange for an exchange of scientific staff and breeding cooperation. The project failed because the providing entity was insecure regarding the national access regulations and finally (two years after the request was posed by the company) decided not to grant access.

In other cases personal contacts and trust established during long-term relationships with entities in the provider countries helped to set up arrangements for material transfers and exchanges without bigger problems in terms of negotiations and administrative requirements. Another participant reported that they conducted regular collection expeditions in different target countries in cooperation with a German gene bank and a gene bank in the target country. Here, as described before, a private company cooperates with public entities in the source country to delegate the management of administrative access requirements.

A significant impediment to demand of raw material from Ex-Situ Collections is that such material is often described and evaluated only at a very low level. For most plant breeders the costs to carry out these pre-breeding steps are too expensive and they do not match the commercial expectations of including the material in the breeding programs.

4.2.2 Discussion about characteristic elements of ABS agreements

Based on a review of existing standardisation initiatives for ABS contracts (see chapter 2) and ABS literature, we identified a set of items of potential relevance for ABS contracts. We raised these items in the group discussions to learn about the users` views and discuss whether a common practice or consensus regarding the individual issues exists within the group. Within the plant breeders group we have not yet conducted a group discussion, but some items were discussed in one-on-one interviews and in expert interviews. These findings are summarized in this chapter as well.

For preparation of the group discussion we provided the participants with an overview of model contracts (see table six, chapter 2.2). The model contracts served in some cases as a starting point for the discussion. In addition we asked the participants about further characteristic contract elements which should also be taken into consideration.

Taking into consideration all aspects that were discussed with the survey participants, six seemed most important with respect to model clauses for ABS contracts. Those six are

gathered in this report:

1. Utilisation intention (description, classification of the purpose of acquisition)
2. Material transfer to third parties
3. Benefit sharing
4. Intellectual Property Rights
5. Publications
6. Exclusivity Rights for Access and Utilization

The following sections give an overview and interpretation of the statements and discussions of the different target groups within the survey.

1. Utilisation Intention

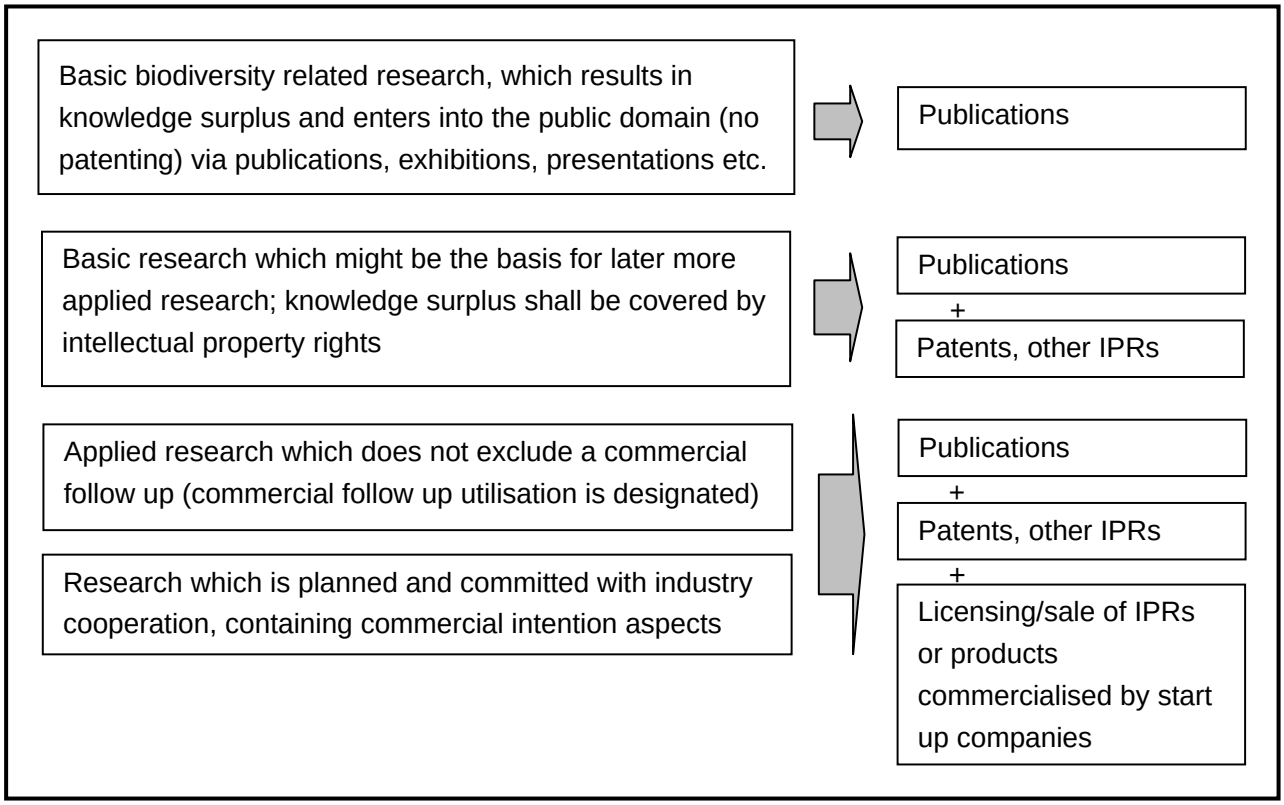
Users from public research institutions

In our survey this group covers users that are not commercial companies but researchers from institutions in some way financed by public funding, e.g. universities, research institutions, botanical gardens, museums etc. The entities differ regarding their legal forms, organisational structures and research policies. Moreover, a considerable part of public research in natural science is committed to external funding and/or industry cooperation.

We learned that the applicability and the dedication of research to some kind of “economically useful” outcome are of increasing relevance in publicly funded research institutions, particularly if they want to receive external funding. One example is the directive of many universities for researchers to apply for patents whenever possible. This of course has implications for ABS negotiations between researchers and potential providers of genetic resources. Researchers are bound by their institutional grant regulations when defining their position on the issue of “utilisation intention”. For a considerable part of research taking place at public institutions, utilisation permits limited to publications are not sufficient, even if the researcher himself has no commercial intention.

We can distinguish three main utilisation types found in ABS agreements involving researchers from public institutions. These should be reflected in a range of model clauses on utilisation intention/permission for MTAs for this user group (see overview 4).

Overview 3: Options for MTA clauses with respect to utilisation forms



Source: authors, based on survey.

It is unclear to what extent the research institutions and granting bodies are aware of the impacts of their policies on ABS negotiations and the conflict between an increasing demand for applicability in research and the safeguarding of IPRs resulting from research on the one hand and the demand for simplified access procedures for basic research on the other hand. We recommend involvement of entities in research institutions and granting bodies that are responsible for research policies (law department, strategic management) in the discussion of sectoral specificities of ABS agreements.

Pharmacy and Industrial Biotechnology

Users in this investigatory group also report different utilization purposes for genetic resources, though all of them are characterized by commercial interest. The resources are used as input in different stages of the research, development, and mass production of a good. Application fields range from testing genetic resources for active leads that can be used as patterns for synthesized molecules or the use of biocatalysts in an industrial production process, to the utilization of genetic resources as active compounds in drugs.

The chain can roughly be divided into three stages:

1st Stage: Efficiency Analysis

2nd Stage: Potential Evaluation

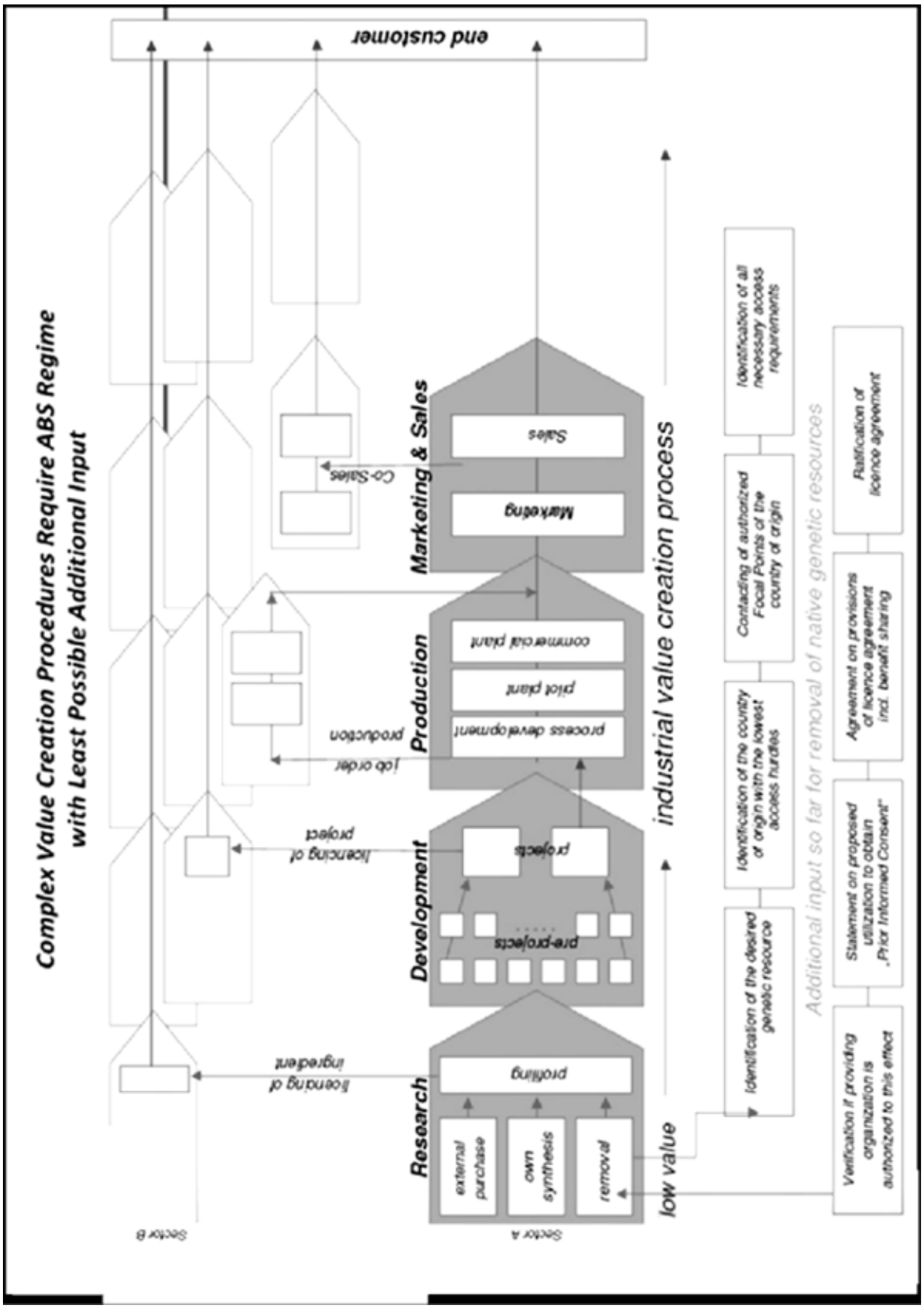
3rd Stage: Project Development (in Pharmacy: evaluating clinical trials)

The different steps within this chain are often not captured by one single company. A company might outsource certain activities or buy and/or sell certain intermediate products. Overview 4 shows the complexity of the value creation chain in this industry sector (overview 4, see next page). Often several stakeholders contribute to research, development and production of a product in the chain and are therefore affected by an ABS agreement.

The different activities within the chain lead to various intermediate products with different values. Therefore the willingness to invest in acquisition costs and options for benefit sharing vary. The closeness between the genetic resource (as input) and the product could be one cost-determining factor. This could differ among the various fields in industrial biotechnology and pharmacy as well as within one field.

Regarding potential model clauses on utilization forms for this target group, the discussion yielded that utilization purposes for genetic resources within the field of pharmaceuticals and industrial biotechnology vary, but they can be subsumed to a limited number of categories. This might be a starting point to design model clauses on utilization intentions/scopes allowed under a certain MTA.

Overview 4: The chain of utilizing genetic resources in the biotechnology industry



Source: Deutsche Industrievereinigung Biotechnologie (German Biotech Industry Association), 2008.

Plant Breeding Companies

In this investigatory group the acquisition of genetic resources is usually dedicated to innovation in the breeding process. A typical purpose for using genetic resources in the breeding process is to search for and integrate tolerances against diseases and develop improved plant varieties. Another goal can be to transfer plant characteristics connected to a certain habitat (water, daylight, and temperature requirements).

The technical procedure of breeding can be distinguished in classical breeding methods (e.g. selection breeding) and marker supported methods (application of biotechnology). This differentiation is important because the types of outcomes of the utilization process differ in terms of applicable IPRs. Classical breeding results in a successful case maximal in a new plant variety, which (in Europe) can only be protected with plant protection rights. This IPR includes the breeders' exemption and therefore leaves room for further use. In the latter case products of the utilization process can be protected with patents, which implies significant differences regarding further use of the product of utilization (Herrlinger et al. 2003). This is definitely an issue to consider for model clauses on utilization intentions in an ABS contract, which might also be reflected in benefit-sharing obligations.

The intention of breeding activities in this survey group is to develop a marketable product, as the participants were working as breeders for private companies. However, some interview partners also stressed explicitly their aim of supporting the source countries in their breeding activities.

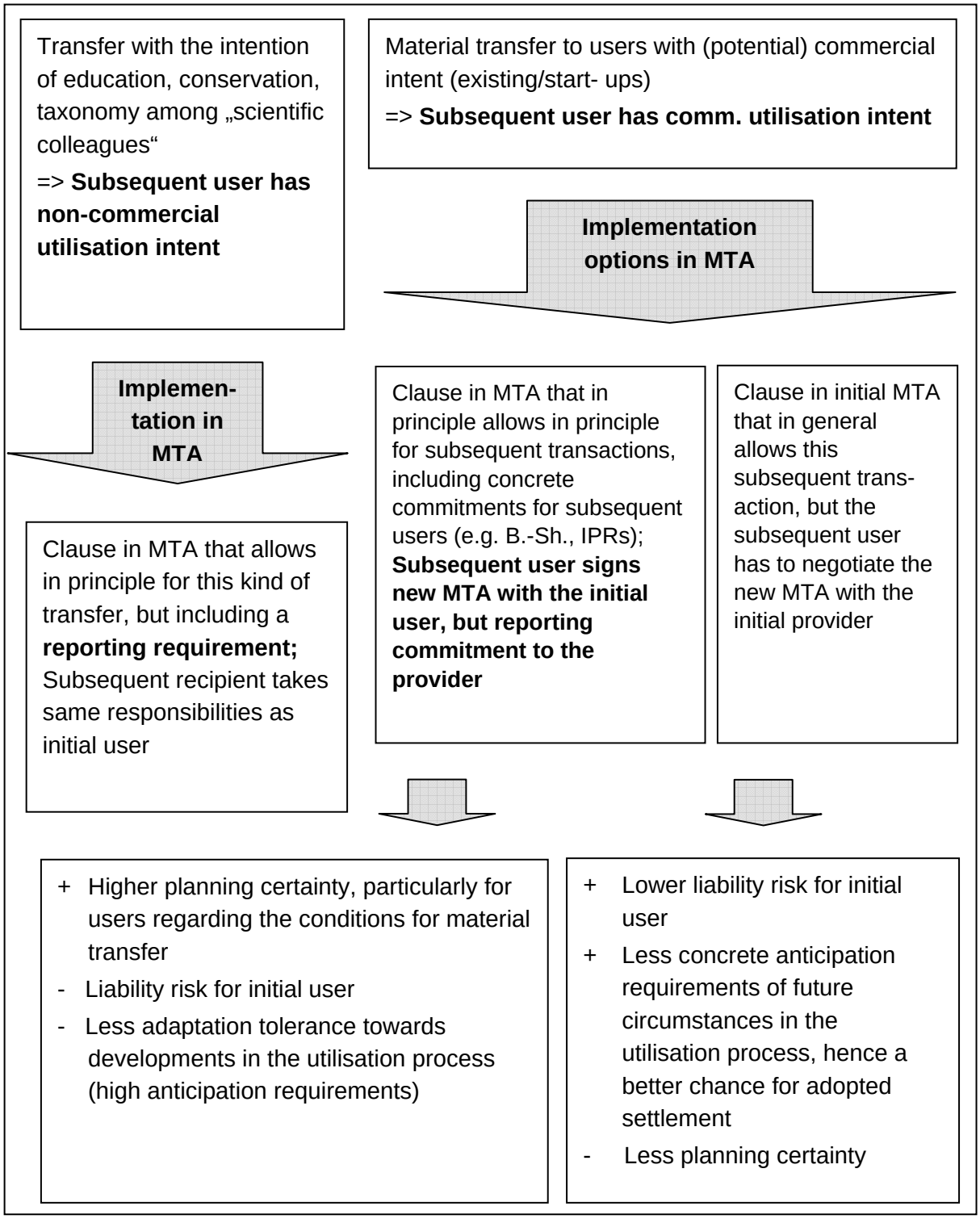
⇨ **Transfer of material or information to third parties (subsequent users)**

Users from public research institutions

Users from this survey group reported two main types of material transfer to third parties, differing in the utilisation intention of the subsequent user. In overview 6 these types are described, supplemented by considerations of respective contract clauses for MTAs.

The regulation of material transfers to subsequent users in ABS contracts is very important for researchers from public institutions because shared material and information among colleagues is a vital key for research progress. Moreover, individual researchers or research groups are often a link in a whole chain of research and development with genetic resources, for instance in cooperation projects with industry partners or with other public research institutions.

Overview 5: Options for regulation material transfer to third parties in MTA clauses for publicly-funded research



Source: authors, based on user survey.

With whom subsequent users shall be required to negotiate MTAs is a core question of liability in ABS. Both options are elaborated with their pros and cons in overview 4. The legal implications of the different options need to be discussed more extensively with experts from fields other than economics, e.g. lawyers.

Pharmacy and Industrial Biotechnology

As mentioned in the previous section on utilization intention, material transfers among different stakeholders in the chain of research, development and production of pharmaceuticals and industrial biotechnology products is common practice. Materials and related information are transferred among different entities in the commercial sector, but public research institutions like universities can also be involved in the framework of a research cooperation or contract research.

We can distinguish three main forms of material transfers reported by users of this survey group:

1. Outsourcing of certain activities which are part of the R&D program, which means that intermediate products flow back into the chain of the outsourcing user;

2. Sales of intermediate products based on genetic resources, whereby these products serve as input in the production process of a different company without further research on the product being conducted (for instance fine chemicals);

3. Transfer of genetic resources and/or related information to other users who wish to conduct their own R&D with them, detached from R&D activities of the transferring company.

Users stated that an MTA between the provider and user should contain a clause with the terms of material transfers to third parties. This would determine the value of the resources transferred. The more freely the user can work with the resource, the higher the potential value for the user.

Liability regarding third-party activities was also an issue raised in the discussion. According to the participants, it is a common business practice and in line with international private law that the transferring party (the company which first received material from a provider) is not accountable for actions of subsequent recipients, as long as the transferring party acts in compliance with the contract with the initial provider.

Plant Breeding Companies

Breeders from the private sector exchange “raw” genetic resources and breed material with other breeders from both the private and public sectors. This happens mainly via multistake-

holder breeding programs under breeders associations (for instance the Gesellschaft für Pflanzenzüchtung, GPZ). The exchange of material and information is a key driver of progress in the sector, as the breeding process is lengthy, costly and often information is generated which is of general interest for the sector but not necessarily confidential. There seem to be strong links (at least in the European crop breeding sector) between the private and the public sectors. Many breeders call for an increase in evaluating material held in ex-situ collections, which would be publicly available information.

According to the statements of interview partners, material is usually transferred with standard or model MTAs which have been provided, for instance, by ex-situ collections in the past. Mutual trust has been mentioned as an important prerequisite for the exchange of material and information among breeders in Germany and also with breeders in source countries of genetic resources.

- **Benefit-sharing**

Users from public research institutions

Among the survey participants of this group we found a general consensus to support sharing of benefits resulting from research with genetic resources and related knowledge. Most of the researchers are aware that benefit-sharing is an essential component of MTAs or general ABS agreements. However, based on outcomes of former user studies, we can assume that this does not hold for all researchers from public institutions, and that there are differences among the scientific fields (Holm-Müller et. al., 2005).

Different forms of benefit sharing (monetary, non-monetary) are present in ABS agreements for this user group. Capacity building and technology transfers (the latter in larger, well-staffed and financially well-equipped projects) are buzzwords in projects with the involvement of public institutions, which are often also requirements for the acquisition of external research funding. However, it seems that not all institutions and granting bodies necessarily connect this requirement with the ABS principle of the CBD.

If results-oriented payments are parts of the agreement, they are most likely linked to patent disposal or licensing. Some users reported that upfront payments are also performed, e.g. as a payment in return for sample provisions or in terms of infrastructure investments (e.g. a car that becomes the provider’s property after a cooperation project ends) (table 10).

Table 10: Suggestions for Monetary Benefit Sharing in ABS agreements, research group: researchers from public institutions

Results-oriented payments (or equivalent material benefits)	**Upfront payments (independent of outcomes)**
Suggestions: ⇨ Equal participation of all entities in the ABS agreement. This option seems most favourable if all stakeholders actively contribute to the research process. (Approach is applied in other fields of joint research, e.g. cooperation among public institutions and industry). ⇨ Definition of shares according to criteria such as contributed efforts in reaching the research goals (financial, time, etc.), state of the material provided, related information provided	**Suggestions:** ⇨ Basic payments could be a percentage of the overall research fund for the particular project, e.g. as overhead costs of the project accruing in the provider country for administration ⇨ Further adjustment of the percentage according to the "service" of the provider (samples versus collection permits; state of the material and related information)

Source: Authors, based on stakeholder interview and group discussion.

Guidelines, particularly for monetary and non-monetary benefit sharing in research projects could be a useful tool for communication between researchers and their institutions for the financial planning of research projects and for negotiations between users and providers.

Pharmacy and Industrial Biotechnology

The group discussion revealed that within this survey group the concept of benefit sharing was still unclear although all participants had experiences with transactions with genetic resources under the scope of the CBD. Confusion existed regarding which entities should be the beneficiary in benefit-sharing agreements according to the ABS principle in the CBD. For example, should benefit sharing always include transfers dedicated to a determined governmental entity in the provider country, even if the transaction takes place without governmental participation? Also the jurisdiction of ABS for certain transactions and not others was an unclear concept. Views of the survey participants and means of addressing these issues vary.

In particular, users from industrial biotechnology reported that they acquired genetic resources mostly via “simple” buying transactions with commercial intermediaries (broker companies in provider countries). Ex-situ culture collections like the Belgian Co-Ordinated Collections of Micro-Organisms (BCCM) and the American Type Culture Collection (ATCC)[1] are further intermediaries. In both cases benefit-sharing payments for genetic resources takes the form of fees per acquisition/sample. The users did not explicitly label this as benefit sharing in the sense of the CBD, particularly not if the source is an Institution conducting ex-situ conservation and material provisions. In both types of transactions (1. material is collected and transferred to the user by an intermediary company; 2. material is acquired from an ex-situ conservation institution) the users usually do not have direct contact with governmental entities in the “providing country“ to negotiate the terms of the transfer.

Participants reported on more complex benefit-sharing models tend to engage in more complex in transactions with a higher level of collaboration and integration of the R&D chain between user and provider entities, as well as where bioprospecting activities (here meant as the acquisition of new genetic resources from in-situ sources) are included. The terms of benefit-sharing are individual and a matter of negotiation. They depend for instance on the specific needs of the provider (what works best differs on a case-by-case basis: short-term technology and capacity transfers versus long-term, insecure money transfers) and the capabilities of the company (not all companies can engage in technology transfers). Views about royalties as an element of benefit sharing differed among the interviewees, but they are common practice in some ABS agreements.

As reference points for equitable benefit sharing, the participants of the group discussion indicated the overall effort required in the process of R&D for developing a commercial product, as well as the relationship between the genetic resources as input factors and the product (as a measure for the contribution of the resource). The characteristics of both criteria vary among utilization cases in the target group. although it might be possible to define rough categories.

The overall tendency in the discussion was that users from this group are generally willing to carry out benefit-sharing activities, but they see certain contradictions. They see a benefit-sharing principle, which obliges companies to conduct benefit-sharing with (governmental)

[1]ATCC is a private, non-profit institution dedicated to the collection, preservation and distribution of authentic cultures of living microorganisms, viruses, DNA probes, plants, and human and animal cells. (http://www.lgcstandards-atcc.org/Home/tabid/477/Default.aspx).

entities not actively contributing to the underlying transaction (like a tax). On the one hand ABS is discussed as a measure to define commercial values for genetic resources. In that sense thethe principles of business in international private law would apply, and there payments are thought to be related to the provision of a certain good or a service between two transacting parties. This is a matter of framing and understanding benefit sharing, which should be communicated to concerned groups ni a consistent way.

The discussion showed that benefit sharing would require a whole range of model clauses to cover the variety of cases appropriately. Establishing guidelines could support the process of choosing the compatible clause from a menu of clauses for an individual case. However, designing model clauses with more concrete terms on the core issues of benefit sharing then existing examples presented in chapter three could add more in-depth information on the value chain and costs for R&D when genetic resources are needed.

Plant Breeding Companies

The overall view on benefit sharing in the plant-breeding sector stated by associations and large companies is that the system of free access to and exchange of improved varieties and information is a major act of benefit sharing as such. However, the plant breeders interviewed in our survey reported different additional forms of bilateral benefit sharing: bilateral exchanges of raw material or material under development, exchanges and training of scientific staff, financing of expeditions in which source country gene banks participated, cooperation in evaluating material, and collaboration in scientific publications.

The breeders state that usually the contribution of a single resource to the development of a new marketable variety is extremely small. However, this might vary among plant types, as does the breeding effort required to develop a new variety. In the sense of model clauses it might be interesting to elaborate on defining groups of plants with similar characteristics regarding the closeness of the genetic resource and product. The same holds true for costs and efforts for the entire breeding process.

Summarizing remarks on benefit sharing over all three groups

An important issue of monetary benefit sharing is the timing for negotiations on concrete figures. Some suggestions on this issue are summarized in table 11.

Attempts to estimate the value of non-monetary benefit-sharing measures from the providers' perspective could help negotiations, including such aspects as capacity building, infra-

structure building, and knowledge expansion, which can be performed in the frame of ABS agreements. In general model clauses on benefit sharing should reflect the variety of settings in provider countries. Knowledge transfer, capacity building, and technology transfer measures need to be adapted to the provider country's capacity of assimilation, taking into consideration such factors as the infrastructure, for example.

Table 11: Options for monetary benefit sharing in ABS agreements, user group: public research institutions

Concrete percentages / numbers formulated and fixed in MTA	**Definition of a range of payment options in the MTA => choice at a more advanced stage of the project (Criteria including progress, results, and decision-making stages need to be defined in the MTA)**	**Formulation in MTA that monetary benefit sharing will be negotiated in case of commercialisation.**
+ Theoretically no deferment at later stages in the project due to renegotiations **-** Requires proper anticipation of the development of the utilisation process	**+** Assists decisions for later negotiations, contains possible solutions in the contract **+** Flexibility regarding actual developments in the utilisation process **-** High level of requirements regarding transparency, communication and trust between user and provider **-** Negotiation problem remains existent and can cause impediments at later, core stages in the utilisation process	**+** Minimal impediments to initiating research, favourable for researcher in terms of financing project outlines **+** Reduces the risk that research remains undone and hence increases the total chance of creating benefits **+** Problem of negotiating benefit sharing is reduced in complexity because uncertainty regarding further use is no longer existent **-** High requirements in fairness from user's side (possible if users are researchers from pubic institutions because commercial benefits are not their core interest), as well as provider trust.

Source: authors, based on survey.

- **Intellectual Property Rights**

Users from public research institutions

As mentioned before, IPRs show an increasing relevance in the public research sector. Moreover, IPRs are a tool with which public research entities can generate commercial benefits from engagement in research involving genetic resources. Therefore, depending on the concrete research field, IPRs can be a key issue in ABS contracts for this survey group.

Some researchers reported actual projects in which joint patents are integral parts of the ABS contracts. Researchers are used to the principal of joint patents with industry partners from cooperation projects in other fields than genetic resources. The participants in the group discussion stated that they see a possibility of applying the same principle to providers of genetic resources as they contribute to the research by providing a significant input factor (the legal requirements of patent sharing were not discussed in this group).

Some further considerations on IPR model clauses raised in this group discussion are:

- Joint patents between users and providers could be a means of monetary benefit sharing, particularly if the provider contributes to the research process beyond the mere provision of raw samples.

- The option of joint patents could increase the self-interest of providers to ease the negotiation process and the administrative requirements. It might also be a tool to demonstrate fair participation and reduce mistrust.

- Joint patents are a challenging that if it comes to commercialising a joint patent to a subsequent user, both patent holders have to agree on the terms of the transaction (both the price and with whom to conduct business). It could be useful to decide on certain criteria for this procedure in the MTA to circumvent problems at a later stage.

Pharmacy and Industrial Biotechnology

The survey participants from this group are familiar with the principle of joint patents. However, in the context of ABS they see problems applying this concept. Joint patents would require that providers in fact contribute to the invention for which a patent is sought. This is a precondition stated in the patent law.

One participant elaborated on a case in which such a joint patent would be manageable: If a provider contributes to the concept of the patent by providing the traditional knowledge about

certain healing powers of a plant, and based on this knowledge the company extracts an active component from a plant and develops a drug, benefit sharing in terms of patent law should then be based on the national ABS regulations, and could be similar to allowance directives like the German Employee`s Invention Law (Arbeitnehmererfindungsgesetz).

Among the survey participants we did not identify a common condition regarding IPRs of genetic resources transferred under an MTA. The tendency seems that when resources are acquired via commercial intermediaries, more rights are transferred to the user, while in cases where contracts are concluded with entities determined by provider countries with governments as official representatives, more rights remain with the provider.

Plant Breeding Companies

Under European regulations, plant breeders can apply for plant protection rights (PPR) for a new variety. Such an IPR is applicable for traditional breeding techniques (selection breeding, crossing, cloning).

PPRs are granted if a variety fulfils certain criteria (Herrlinger et al., 2003; p. 246). The process of achieving such a right is lengthy and costly and a breeder will only engage in it if the new variety has sufficient commercial potential. Only select plant breeding products on the market are protected by a PPR. Despite this plant varieties under protection can be purchased and used for further breeding activities by any plant breeder without explicit consent of the holder of the PPR (Breeders Exemption in German law[2] in accordance with the UPOV convention).

Since the 1980s biotechnology has been applied as new technique in plant breeding, one example being marker-assisted selection. Since the European Biopatenting Directive (1998), products from biotechnological plant breeding can be protected with Biopatents if they fulfil the patenting criteria (they are novel, non-obvious, and useful). Plants or parts of plants can be part of so-called Biopatents if they are part of the invention, for instance a certain technique to locate, extract and transfer a gene of a certain plant (Herrlinger, 2003, p. 251f). Biopatents provide a stronger, more exclusive protection right compared with PPRs.

2 http://transpatent.com/gesetze/sortschg

- **Publications**

This is an issue that was discussed in depth only with users from the public research sector.

Through publications, “new“ information about genetic resources and related knowledge moves to the public domain. Moreover, potential subsequent access to information is less controllable for the initial providers. In this sense publications are definitely a form of utilisation intention and they contain the risk of a loss of control. A mechanism to prevent or limit the risk of information acquisition by third parties without affirmation of the providers can be viewed as a prerequisite for facilitated access procedures for users only intending to publish in scientific publications. We had the impression that a substantial part of researchers are not aware of these interrelations and the resulting problems. The main findings from the discussion on this issue are:

- Model clauses on publications should classify kinds of information and related procedures for publication permits.

- The publication of information without explicit permission in an ABS contract should be regarded as a breach of contract.

- Researchers reported from experiences in other fields than ABS that publications resulting from research cooperation with industry partners are carried out under contractually formulated principles like reporting requirements, prior consultations and veto rights. These principles, adapted to the relationship between users and providers, might also be applicable in ABS agreements to reduce the risk of a loss of control.

- Users should refer to the providers in publications.

It should be stated in publications that subsequent users are requested to negotiate a new MTA (with the initial user or directly with the provider depending on the system chosen in the initial MTA).

- **Exclusivity rights for access to genetic resources**

Exclusivity rights regarding the access to genetic resources in ABS contracts can take different forms ranging from full exclusion of other potential users from access to the genetic resource(s) for a certain time frame to limited exclusivity only for specific utilisation forms or research questions. The later form allows the provider to engage with several users for the same resource but for different utilisation forms.

Users from public research institutions

Group discussions among users from public institutions found the group divided on this aspect. Most participants preferred a general open access approach for genetic resources, which would prohibit exclusivity rights. However, individual researchers see exclusivity rights for specific forms of utilisation as an instrument to secure research investments. This potential MTA element seems to be of relevance only in fields with a high level of applicability, e.g. in pharmaceutical biotechnology. A potential benefit for providers resulting from better planning for researchers is that the researcher might increase investments in research and therewith the chance to generate benefits.

Finally, participants in the group discussion found that MTA model clauses on exclusivity applicable to this group should be limited to certain forms of utilisation or research questions and with a limited timeframe. An option could be the expiration of the exclusivity right for access/utilization granted by the provider if the user manages to apply for a patent within the defined timeframe . If the user does not succeed within an agreed timeframe, the provider can reconsider engagement with other users or renegotiation and renewal of the arrangement with the first user.

Users from pharmacy and Industrial Biotechnology

In this research group, two forms of exclusivity are also known, namely exclusivity of access and exclusivity of a certain utilization form. Both are viewed as options for the user to gain competitive advantages in the sense of a head start to conduct certain research steps exclusively, for instance efficiency analyses.

Access exclusivity would increase incentives for users to invest in broad trials of the resource, which would increase the likelihood of commercial success. The users thought that the level of exclusivity that is finally agreed upon would be a matter of negotiation. Users' willingness to pay would depend on many criteria, including anticipation of success, uniqueness of the resources, and the level of information available on the resources. It would be comparably low for random samples.

4.2.3 Users deliberations and appraisals on model clauses

Users from public research institutions

Users from this group are usually not trained lawyers and they only have limited access to legal assistance. In that sense the capacities and training of natural scientists are wasted if those working with genetic resources need to engage in lengthy administrative procedures

and contract negotiations including finite legal details as a prerequisite to conducting research, their core task. Therefore, users from this target group view each measure to simplify such procedures as an enhancement. Model clauses could be an option to increase legal certainty and to speed up administrative procedures, particularly if several entities are involved in the decision-making process on the user side. Moreover, users stated that they would very much appreciate a central contact for support in administrative and legal issues on ABS. Saving time, specifically reducing lead times for research activities is an important issue in the public research sector, as researchers and financing are often bound by certain projects with fixed time constraints. However, the discussion and interviews showed that this user group is particularly characterized by extremely heterogeneous ABS cases. This would need to be reflected in selecting model clauses.

Pharmacy and Industrial Biotechnology

In this survey group model clauses for ABS contracts were viewed more controversially than in the previous group. The overall attitude was one of scepticism. The concept and the goals of the instrument, as introduced in the debate on an international ABS regime by the EU, are still unclear to survey participants in this group (although these individuals try to stay current on the overall regime debate). Reluctance to support this measure also seems to stem from a rejection of additional restrictions and a fear of interference with competencies to negotiate bilateral contracts. Confidentiality and competitive aspects are further reasons. An argument raised by participants was that they doubted model clauses could appropriately reflect the heterogeneity of transactions with genetic resources (among others the needs of providers). However, after a lively discussion users tended to find the idea of supportive checklists and guidelines for contracts feasible.

Plant breeding companies

The official representatives of the European seed industry ESA (European Seed Association) call for an extension of the scope of the ITPGRFA SMTA on all crops. The standard contract is supposed to be workable and could be applied for all ABS-relevant transactions of plant breeders with crops (ESA, 2008, p. 4). However, in our interviews plant-breeding companies revealed diverging opinions regarding the applicability and feasibility of model contracts for all transactions with genetic resources. Based on their experiences in transactions with gene banks and botanical gardens, some users find this a practical means to keep administrative efforts/costs low, particularly as most small and medium-sized plant breeding companies in Germany have no individual legal department. On the other hand,

users engaging in transactions directly with entities in provider countries more strongly stress the individuality of cases, for instance the specific needs of providers and the administrative systems and infrastructure in provider countries. Such agreements would depend more on mutual trust and understanding, what could hardly be reflected in standard contracts like the SMTA. Here model cases would allow for more flexibility.

5 Conclusions

Through the survey of the project we revealed and systematized problems users experienced when they engaged in ABS agreements. This provides the basis for debating and finally developing supportive measures for the implementation of ABS. We distinguished three main problem categories based on the survey findings:

- User-centric problems consisted primarily of a lack of awareness, insufficient information, legal incapacity and communication problems among different stakeholders on the user side. Depending on the decision-making structures within a user entity, more than one actor is involved in the process of contract negotiations. Particularly at public research institutions, unawareness and uncertainty about the implications and how to handle ABS in administrative and legal departments can be problematic.

- Provider-centric problems included similar shortcomings on the provider side as elaborated on the user side as well as a lack of trust and the tendency towards exorbitant expectations regarding benefit sharing among providers (according to some participants).

- The third problem category is linked to the imprecise provisions on ABS in the CBD and resulting heterogeneous transformation on the national level and confusion among users, specifically the intended beneficiaries who are directly affected by these transactions, about the actual concept of ABS.

Certainly some, but not all of these problems can be tackled by workable model clauses for ABS agreements. This instrument can for instance help to overcome the lack of legal capacities in user entities and probably also in provider entities and thereby speed up negotiation procedures. Besides model clauses, users especially from the public sector would appreciate a national advisory body that can provide a variety of support regarding ABS issues, for instance legal advice, help identifying administrative requirements, and information on general questions.

Problems linked to the heterogeneity of ABS regulations in member countries and the lack of communication of contact partners and national ABS regulations can hardly be tackled by model clauses. These issues have to be approached by different measures.

As core content elements of ABS agreements we identified:

- Utilisation intention (description, classification of the purpose of acquisition)
- Material transfer to third parties
- Benefit sharing
- Intellectual Property Rights
- Publications
- Exclusivity Rights for Access and Utilization

Discussing these issues with the survey participants revealed a multitude of possible combinations, even within what is often called a “user group”. This holds particularly true for researchers from public institutions. However, we derived several findings of relevance for the development of core model clauses for ABS agreements.

The utilization intention is quite possibly the item with the widest variety of options among and within the groups. We recommend the overall distinction of three classes of utilization intention, differentiated by the product that users attempt to generate: scientific publications; patents or other IPRs; the commercialization of a product or an IPR. To develop more concrete model clauses, the chain of utilization in different industry fields and science fields could be subdivided into distinguishable types of utilization or intermediary products. Analogies can be found for some types of utilization among the groups. The overall perception of users was that the clear definition of utilization rights in the ABS contract is vital to secure investments in research and development.

Material transfer and the exchange of information with third parties (subsequent users) are important in all three groups, and therefore the options and terms have to be defined in the initial contract. This was accepted as common knowledge among the users in all groups. Altogether we found strong linkages for the exchange of materials between the private and

the public sectors. Researchers from public institutions also frequently exchange material and information with each other. Exchange with commercial entities is especially important as public researchers often depend on the private sector for project funding and vice-versa, meaning that companies outsource parts of their research programs to the public sector. In drug research and development, companies and public institutions collaborate even at the stage of acquiring genetic resources. In the plant breeding sector the linkages between private and public sector are also very strong, both in joint research projects where several companies and public institutions collaborate in basic research, as well as in bilateral collaborations between a plant breeding company and for instance a working group at a university institute. Menus of model clauses should contain clauses on material transfer and should reflect the strong interlinkages between the two sectors.

A tricky question involves liability regarding potential inappropriate actions of third parties. Particularly the users from pharmacy and industrial biotechnology expressed a strong resistance to a model in which the initial user is liable for subsequent recipients' actions.

Benefit sharing is maybe the most controversial issue in the whole ABS debate. The overall consensus among participants was that they accept in some way "paying" for access to genetic resources. For some users this meant conducting a whole range of benefit-sharing measures, for others it meant paying a fixed fee to a certain intermediary. The huge differences mainly reflect the type of relationship between the user and the provider, and whether the provider is an intermediary (a gene bank or a broker company) or a provider country authority. In the first case benefit sharing is often reduced to payments of standard fees and many users would not understand this kind of transaction as ABS. A very interesting aspect raised by the participants in the survey was that monetary benefit sharing is applied in some cases, even in the public research sector,.

The overall recommendation for model clauses derived from the discussions is that they need to be flexible enough to reflect the users' options and the needs of the providers. A full standardization of monetary benefit sharing, particularly for complex transactions, is seen as impossible and would not be feasible for both sides. However, model clauses with formulation suggestions for monetary benefit sharing and guidelines for choosing the appropriate option could be useful.

To develop such model clauses and guidelines we recommend working on the identification of the value chain and cost components in typical utilization fields for genetic resources to have a more objective basis for generating suggestions on monetary benefit sharing (or

equally valuable non-monetary benefit-sharing measures). Secondly we recommend considering “the real value of non-monetary benefit-sharing” in a more in-depth way, for instance the creation of new working places, improvement of scientific infrastructure, etc. If the value of such measures for the beneficiary party could be outlined, the discussion on monetary benefit sharing could be relieved to a certain extent.

Intellectual Property Rights can be viewed as a component of benefit sharing. In all three groups IPRs are a vital aspect of products developed with the utilization of genetic resources. Even in the public research sector, IPRs are playing an increasingly important role because research institutions have to compete with each other in the acquisition of external grants. Moreover, selling and licensing of IPRs is a source of income generation.

All user groups reflected in the survey are in some way familiar with the concept of joint IPRs (patents), although experience of joint patents with providers of genetic resources is not widespread. Although this is viewed as a potential option for benefit sharing, particularly companies stressed the requirements for joint patents contained in the patent law. According to this, providers of genetic resources could only participate directly in a patent application if they contribute to the invention to be patented.

Publications have been identified as matter of relevance for ABS agreements. Scientists rely on publications; however they should be handled carefully in the sense that they have the potential to reveal confidential information to potential subsequent users. Providers have very limited possibilities to restrict access to information on “their” resources once this information has been published. It has to be considered that information published in a scientific journal or at scientific conferences is not necessarily received only by researchers with non-commercial interests.

It is necessary to raise the awareness of this potential conflict among scientists. Even within the group of participants in our survey, the linkages between ABS and publications were not fully known. One prerequisite in MTAs should be that the user at least informs the provider about intended publications and that he mentions in the publication the source and provider of the genetic resources concerned. Publications could potentially even contain a paragraph that urges third parties to contact the provider if they want to use the material or information on the material for further research or other purposes.

Exclusivity of access has been raised as matter of importance in all three user groups. The level to which it is approved differs by timeframe and scope. For instance, exclusivity can be divided into access for certain research questions or utilization purposes or for full exclusive

access to a resource. In general exclusivity is a tool to generate competitive time advantages in research. Which scope a provider and a user agree upon depends mainly on the user's willingness to pay and the price demanded by the provider. In general we would recommend a model in which exclusivity is limited to a certain timeframe and contains the option of renegotiation. This leaves the option for the provider and the user to decide after a certain time whether investments in prolonged exclusivity seem promising.

In the discussion of the concreteness of model clauses for ABS agreements, we see a general trade-off between concreteness of model contracts/clauses and therewith the simplification of transactions achievable on the one hand and the degree of freedom left to the transactors and therewith the adaptation to the specificity of the individual case. This trade-off should be kept in mind in the discussion on concreteness of model clauses. Concreteness best achieves the aim of reducing transaction costs at the start of a project and increases trust among contracting parties. However, it is true that concreteness can be an impediment or simply not applicable if the transactions targeted are too heterogeneous. If model contracts are concrete, but do not fit to the individual case, renegotiations will be necessary at later stages in projects, which might increase transaction costs and the risk of losing investments.

Therefore, different types of transactions (ABS agreements) should be categorized, for instance according to the criteria raised in table 2, page 7 and the type of relationship between the user and provider (long term research collaborations versus spot market-transactions). The categories can demonstrate different levels of complexity of the transaction (the ABS agreement). For rather complex transactions entire sets of model clauses for each core contract item should be provided. The terminology should be left rather open. Guidelines (more precise than the Bonn Guidelines) could help to define the terms in the individual case. For less complex ABS cases even complete model contracts, probably with more concrete clauses, could be achievable. This could be a helpful option particularly for public researchers who would restrict their utilization to publications and otherwise negotiate a new contract.

One aim of the project was to elaborate on the feasibility and acceptance of menus of model clauses as elements within the international ABS regime. The overview of existing ABS model contracts developed by some stakeholder entities involved in genetic resources transactions (for instance the biotechnology industry association BIO, the Belgian Co-Ordinated Collections of Microorganisms, and others) show that at least some parties see a benefit in this instrument. The responsible entities stated that model contracts should simplify transactions and reduce uncertainty for their target group (BIO, NCI, Science Com-

mons). Moreover, they can function as a signal about the framework terms of contracting towards potential transaction partners (Australian example, BCCM).

The examples described vary in concreteness of terminology in the model contract, for instance regarding benefit sharing. A common form is that the model contract contains a clause determining that benefit sharing should generally occur, but it leaves open the form and amounts to individual negotiations. The model contracts are then supplemented by guidelines that provide support and reference points on how to define concrete terms for benefit sharing. This model should reflect the heterogeneity of cases and leave room for the parties to bring their specific needs into the agreement via bilateral negotiations. In contrast, the SMTA of the ITPGRFA contains standardized, concrete terms on monetary benefit sharing (but not for non-monetary benefit sharing). Plant breeders industry associations, for instance the German Plant Breeders Association and the European Seed Association, have participated in developing the SMTA and support it in official statements (for instance at Side Events of COP 9). The Australian model contract is also much more concrete on benefit sharing provisions. It has a list attached with concrete threshold payments (% of revenues) for certain user groups and certain levels of gross exploitation. In this way they allow for differentiation by different user types or product groups, but still are quite concrete on requirements for monetary benefit sharing.

Within the survey of the research project we discussed with participating users their appraisal of model clauses for MTAs as supportive instruments within the framework of the International ABS regime. The reactions were heterogeneous. Particularly, researchers from public institutions and plant breeders were receptive and thought model clauses might be a measure to reduce their transaction costs and risk from uncertainty. However, some raised the problem of heterogeneity of ABS cases even within their groups. Other participants, particularly from the pharmaceutical and industrial biotechnology sector were more reluctant and sceptical. In this group we particularly encountered the rejection of regulative measures for ABS. Refusal or reluctance of MTA model clauses are likely to stem, at least to some extent, from unclear communication and misunderstanding of the concept pursued by model clauses. Users from this group fear additional restrictions and fixed standards for benefit sharing, the distribution of IPRs for products, and related items. They argue that the heterogeneity of cases does not allow for the development of appropriate standards. Standards (if they are too high) would impede the demand for genetic resources. Nevertheless, within the discussions it turned out that if model clauses were voluntary, and if they reflected the variety of cases, users from this group might also find them supportive.

This shows that there is still some confusion about the distinction between standards and model clauses. If model clauses are to be developed by a bottom up approach or with the participation of users, the concrete concept of model clauses that is intended by the actors on the political level needs to be communicated to the target groups in a better way.

Regarding the overall acceptance and applicability of model clauses for ABS contracts we assume it would also be very helpful to integrate the providers' side in the process. First of all, provider entities would rather trust in the fairness of model clauses if "their representatives" contributed to designing the instrument as well. Mutual trust among providers and users could be better supported by such model clauses. Secondly, contracts for transactions with genetic resources reflect the interests of both contracting parties; otherwise one would not agree to the contract. If terminologies for model clauses are developed only on the basis of users' perceptions, the information on how contracts should/could look like will be biased. Such model clauses bear the risk of not being achievable in practice.

The research project is ongoing until February 2010. In the next working steps more research will be done on model clauses for ABS agreements. Additionally the principle of multilateral environmental funds will be investigated regarding the applicability and feasibility for ABS. The final project report will be compiled by the end of the project, and presumably published shortly after.

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- http://ott.od.nih.gov
- http://www.planttreaty.org/smta_en.htm
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