



The ABS Agreement

Key Elements and Commentary

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About the multi donor ABS Capacity Development Initiative

The ABS Capacity Development Initiative aims to contribute to poverty reduction, food security, technology transfer, social development including equity and rights, and biodiversity conservation through implementing the Nagoya Protocol (NP) on ABS and the third objective of the Convention on Biological Diversity (CBD) in its entirety. Established in 2006, the ABS Capacity Development Initiative is hosted by the German Federal Ministry for Economic Cooperation and Development, implemented by Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH and funded by the governments of Germany, Norway and Denmark, the Institut de la Francophonie pour le développement durable and the European Union.



What is an ABS Agreement?

An ABS agreement is essentially an agreement between parties regarding the terms of access and utilisation of genetic resources and associated traditional knowledge, including the sharing of benefits arising from utilization, subsequent applications and commercialization. An ABS agreement while unique to ABS shares some characteristics with ordinary contracts.

An ABS Agreement: Its Distinct Nature

It is important to keep in mind that each access situation has its specificities. Different types of users and sectors use genetic resources and associated traditional knowledge in different ways and for different purposes. While some elements of an ABS agreement may be standardized, others need to be handled flexibly on a case by case basis, in light of the legal and factual context.

The following list aims to highlight and explain the key elements of an ABS agreement. While some of the elements listed below are basic elements generally addressed in a contract or in a legally binding agreement between two Parties, others are unique to ABS agreements and will deserve special consideration in the process of negotiations between a provider and a user of genetic resources. Finally, it is important to note that these key ABS elements are not meant to answer all questions and challenges in ABS contracts but rather to provide a broad overview of legal issues to be aware of when negotiating an ABS Agreement.

A. The Preamble

Most agreements have a preamble at the beginning that precedes the provisions that detail the terms of a contract. A preamble introduces the parties to the agreement, the subject and nature of the agreement and its broad objectives. There are no rules about what a preamble should contain, except that it should be a simple and straightforward introduction to an agreement and should not be overloaded with details. Where applicable, however, the preamble may outline in a chronological way relevant past events, existing relevant regulations (for example export and research rules), and memorandum of understandings or invoke prior or on-going developments that are relevant to the agreement. In many jurisdictions the preamble is not considered binding as it only provides mere background and premise of the agreement.

B. Terms and Definitions

A good agreement needs to have a section that defines key terms that are used in the body of the agreement. If parties to the agreement do not share a common understanding of the applications of the essential terms of the agreement, they could have different views on what they have agreed to, leading to costly misunderstandings and conflicts that could even cause a break down in the agreement.

It is therefore critical to include a section in the ABS agreement, usually following the preamble, which lists the key terms of the agreement and defines them in a manner that is acceptable to all parties. This section should offer a sufficient level of precision to ensure it can be understood and enforced by the parties' national courts or an arbitrator in the event of a dispute.



However, not every term used in the ABS agreement needs to be defined. Parties could reasonably be assumed to share a common understanding of terms such as disputes, monetary, patent, trade mark, etc. However, other terms such as genetic resources, traditional knowledge, utilization, third party transfer etc., which have a specific meaning in relation to ABS, could be understood in different ways and would hence need to be defined.

C. Details of parties to the agreement, including representation authority of signatories, legal and financial ability to undertake contract, authority to determine access to GR and TK etc.

The preamble generally introduces the parties to the agreement. The parties to the agreement on both the provider and user side need to be clearly identified (including relevant contact information). Parties as entities need to have legal authority to sign the agreement (e.g. as representative of a company with authority to bind it, a legitimate representative of an indigenous and local community or national authority).

The provider of the genetic resources and/ or associated traditional knowledge must be the one vested with the legal authority to do so. For example, depending on the specific national legal situation of the country providing the genetic resources, the rights over the genetic resources may be vested with the national government, a landowner or indigenous and local communities or their trustee. In other words, depending on the national ABS legal framework, the ABS agreement can be negotiated with the competent national authority of the provider country or directly with the provider of the resources, which may be a private landowner or a community.

It should be noted that, although it is current practice in many countries, private persons should generally not sign ABS agreements. For example, researchers should not access the genetic resource and/or associated traditional knowledge as private individuals, but as authorized representatives on behalf of their institution. This is important in ensuring that the agreement entered into holds the desired degree of accountability and credibility. Furthermore, issuing research permits to individuals may render an ABS agreement ineffective, especially its provisions on IPR and benefit sharing, as usually any rights over the results of the research and the intellectual property developed rest with the institution.

It is also important that the agreement pre-empts and accommodates future changes in the composition of the parties by including the successors-in-title of the parties to the contract. Corporations, for example may be acquired or may merge and change their names under a new ownership.

Where agreements anticipate this kind of situation, it forecloses the possibility of a non-interested resulting entity from reneging on a pre-existing commitment on the basis of contractual technicalities. Further, involving successive entities as party to an ABS agreement imposes a burden on the Recipient to fully disclose its obligation under the present agreement to stakeholders in future corporate re-arrangements. The same argument can also be made in regard to sovereign states and ILCs.

Finally, a good understanding of the company-structure is important. For example, the benefit-sharing obligations should be placed in the entity where the actual profit is going to be earned.



D. Details regarding the genetic resources, i.e. collected material

While the section on definitions will define what the parties to the agreement mean by the term genetic resources and their utilization in general, this does not preclude the need to provide more information on the genetic resource in question in the terms of the agreement. The genetic resources that are being accessed for utilization need to be clearly identified. It is recommended that the Parties list each type of genetic resource, specifying its taxonomical determination and common name, the quantity of the material and the parts of the organism, if applicable, to be collected. A collection schedule should also be provided.

E. Details Regarding Traditional Knowledge Associated with the Genetic Resource (as applicable)

As there is no generally accepted definition of “traditional knowledge”, the common understanding of traditional knowledge may vary, as well as its permitted and prohibited uses in light of national circumstances. While the ABS laws of the country from where the traditional knowledge associated with genetic resources is accessed may have a definition or a description of what it means, it is still important to provide details regarding the concrete traditional knowledge being utilized in the definition of terms section of the agreement. This would not only prevent potential misunderstandings between the parties to the agreement, but also allow courts in user countries (when the user belongs or is domiciled) to have a better understanding of the subject matter for compliance and contractual enforcement issues.

F. Purpose and Scope of Utilization

ABS agreements should, to the extent possible, contain a detailed description of the exact purpose and scope of utilization of the genetic resources and associated traditional knowledge. Where an exhaustive list of activities that would constitute utilization of the resource or knowledge is not possible, it should be substituted by a non-exhaustive description of the type of activities that would constitute utilization for the purposes of the agreement.

Generally, a comprehensive and detailed project description includes all the necessary information and should be an integral part of the agreement (e.g. objective and scope, possible restrictions or exclusions from scope of the exact utilization of the material, as well as milestones and timeline). This information is critical as it describes in what form and for which purpose the genetic resource/ associated traditional knowledge can be utilized. Any other form and purpose of utilization would therefore not be within the scope of the agreement and would hence be prohibited.

In the event of a change in utilization, the agreement should create an obligation on the recipient /user of the genetic resource to disclose any “utilization” that was not anticipated in the initial agreement. It should also establish an obligation to negotiate a new agreement or to review/ renegotiate the agreement or relevant sections of the initial agreement, as the case may be, to take into account the new situation (As indicated in Section J)

In addition, to make the agreement more robust, it is also recommended to include in agreement concrete clauses outlining consequences/penalties that would be applicable in case of a breach of any of the terms of the agreement. (See section S on Breach of Agreement).



G. Material transfer conditions if part of an ABS Agreement (e.g. export purpose and information needed according to national export provisions)

Many countries already have standard material transfer agreements and conditions for research permits elaborated as part of an integral part of their national export policy, regulations or other related legislation. Conditions of material transfer may be integrated into the agreement or may remain as a standalone separate agreement. However, the standard material transfer agreements that are currently prevailing could have preceded the ABS legal framework in the country and may not elaborate in an ideal manner the ABS objective stipulated in the national law and the ABS agreement. Therefore it will be important to ensure that any standard agreements that are being used are in line with the ABS laws and regulations of the country.

H. Access rights granted (rights retained, exclusivity or non-exclusivity, further re-supply etc.)

The agreement must clearly identify the access rights and any rights retained (e.g. the provider retains ownership of the material). It may also address the issue of exclusivity/non-exclusivity, i.e. whether the accessing Party may have exclusive rights to access and utilize the genetic resource and/or associated traditional knowledge for a specific purpose or whether the providing Party may give similar rights to other potential users and on what terms or circumstances. Another issue may be further re-supply. Depending on the kind of research and development taking place, a continuous supply of the genetic resources may be required. In this context, it is advisable to identify the providing Party e.g. as the first source of supply, as well as agree on other specific requirements of the supply chain (e.g. sustainable collection methods, quality, time frames etc.).

I. Benefit sharing arrangements

The benefit-sharing arrangements deserve particular attention, as they represent a key component of each ABS agreement. They should address the following elements:

1. Non-monetary benefits

Non-monetary benefits generally arise in the research and development phase of a project in the form of sharing samples, research participation, training and transfer of technology etc. In most cases non-monetary benefits are easy to implement and can help to build in-country capacity in the medium to long term. Non-monetary benefits can play therefore a key role in a country's overall development strategy, building its national capacity in the bio-discovery sector.

2. Monetary benefits

Monetary benefits are generally linked to the commercialization of products based on the utilization of genetic resources and/or associated traditional knowledge, for example, through royalties, upfront payments, etc. In this context, parties to an agreement need to be aware of the fact that the likelihood of such monetary benefits is generally unknown at the time of access or at the beginning of a research and development project. While it is possible to negotiate monetary benefits at the time of access, it may be advisable to postpone agreement on monetary benefits at the time of commercialization in order to have a more realistic idea of what to negotiate (see also section 3 below).



3. Timeline or phases of benefit sharing scheme

Parties to the agreement should also agree on the timing of the different benefits and identify, for example, different phases of a benefit-sharing scheme. Whereas, for example, during the research phase of a project the focus will be on non-monetary benefits, such as training and sharing research results, the focus will shift as soon as commercialization of those results starts. For example, parties could agree to milestones payments, which are linked to specific accomplishments or identified milestones in the research and development process until commercialization.

4. Distribution and use of benefits: contribution to conservation and sustainable use

While the provider should be free to decide on the distribution and use of benefits according to its national regulatory system, as well as in light of national circumstances and the specific case at hand, the ABS agreement should endeavour to include some commitment on the part of both the provider and recipient to directly deploy parts of the benefits to conservation of biological diversity and the sustainable use of its components (e.g. payments to trust fund supporting biodiversity research, like taxonomy, or to community funds which helps preserving traditional livelihoods etc.).

J. Change of intent of utilization and new utilization

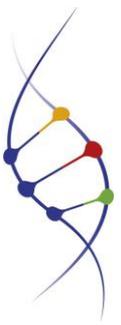
It is important to include a clear requirement to apply for a new permit, i.e. a new prior informed consent (PIC) and renegotiate the present agreement or enter into a new separate agreement, when a change of utilization or intent, which had not been foreseen at the time of access, takes place.

This can include a change from non-commercial to commercial intent, but also present a change in utilization (i.e. new and different kind of utilization which had not been agreed on at the time of access). Indications of a change of intent from non-commercial to commercial are, for example, the application for IPR or the transfer of the material to a commercial partner. A change of utilization could be a new and different commercial use of a genetic resource based on the discovery of unexpected properties.

K. Third party transfer (including transfer of rights)

The agreement must include provisions regarding whether the genetic resources, its derivatives and/or associated traditional knowledge may be transferred to third parties and if so, what conditions should apply. Users will often transfer the resource or sometimes derivatives thereof to other individuals or partners for further research/commercialisation. In this situation, the conditions and terms of the agreement with the initial user are to be transferred to this new user or third party.

The typical situation in ABS is that the party or body accessing the GR or TK *in situ* for research purposes is rarely the same as the one who will eventually commercialise a product based on that resource and/or associated TK. From the time of access until the time of commercialisation (if a product is developed and commercialised), a number of actors may be involved which will be in turn providers and users of genetic resources. Also as research is carried out, the genetic resource may change its form and derivatives of the initial genetic resource accessed may be developed and be passed on to a new user. It is therefore important for the initial ABS contract to cover derivatives in



order to avoid that the genetic resource or its derivatives are transferred to a third party without transferring obligations to this third party to obtain a new PIC and MAT from the provider for new utilizations that were not foreseen at the time of access.

L. Intellectual Property Rights (IPRs)

An ABS agreement for the utilization of genetic resources for non-commercial purposes normally excludes the use of IPRs over any genetic resources or derivatives thereof and should provide for the opportunity to renegotiate commercial use, including IPRs at a later stage (refer to section J on Change of Intent). In the case of utilization of genetic resources for commercial purposes, a more comprehensive ABS agreement will be needed, which should then address IPRs in more detail.

Among others, the kind of intellectual property rights sought, ownership as well as the distribution of the value derived from the IPRs will need to be addressed. The specific circumstances of the case in question (i.e. kind of utilization, sector specific subsequent application and commercialization) will need to be taken into consideration, as well as other aspects (general IP strategy of the user etc.). Issues that need to be considered in more detail as well as possible options to address these include the following:

- What IPRs could result from the ongoing research and development on the genetic resources that have been accessed?

The type of IPRs sought will depend, on a case-by-case basis, on the nature of the research carried out and on the type of protection sought for a particular product or process developed on the basis of a genetic resource. Potential IPRs may include patents or plant variety rights or other suitable IPRs, including trademarks and origin-based intellectual property such as geographical indications, depending on the type of protection sought and the subject matter of the protection.

- Who should own those IP rights? How should they be exercised, maintained, licensed or transferred?

The parties to an agreement must clarify who will have ownership of those IP rights. Joint ownership is one option, but it needs to be carefully considered, as it does not necessarily represent an ideal benefit-sharing mechanism. Rather, it also comes with costs and responsibilities of maintaining, securing and enforcing the rights in question. In addition, an IP right in itself does not guarantee concrete economic benefit. It needs to be commercially exploited in order to lead to benefits. In light of this, many users of genetic resources often choose not to commercialize IP rights themselves, but elect between a number of different options to manage those rights so as to get the commercial benefits of their research. A licensing agreement, which allows the IP owner to license an IP right to others to develop or use a product or process commercially, is a common way to do so. The ownership and control of the IP itself remains with the initial IP owner and benefits, e.g. royalties from the commercial development and use, are shared. Therefore, a provider's interests may be better served through sharing of the license fees of the invention in the contract rather than seeking to own a patent or other IPRs.



- How can you achieve the best outcome for the parties and an equitable sharing of benefits?

As mentioned in the previous paragraph, it is important that the provider of the genetic resource retains rights arising from this agreement with respect to the sharing of monetary benefits through, for example, a licensing agreement. At the same time, the provider may also be interested in more immediate benefits, which include broader, non-monetary benefits, such as infrastructural development, provision of incentives, transfer of technologies, training, capacity building, employment guarantee, etc. and which should also be taken into account when negotiating the IP provisions of the agreement.

IPRs issues are complex and this section only gives a first short introduction to some basic questions and issues to be considered when negotiating ABS agreements. Effort must be made to seek specialized legal advice/support given the asymmetry in IPRs competence between users and providers of genetic resources. Well-negotiated IPRs related provisions constitute crucial aspect of the success the ABS agreement. If not formulated in an appropriate manner, ill-considered IPRs clauses may be counterproductive to the ABS process. It may be necessary to provide for periodic review of IPRs in the light of developments and unforeseen aspects of the research and development or utilizations of genetic resources.

M. Confidential information

Confidential information includes privileged commercially valuable information, which may be in the nature of trade secret or restricted information, but is incidental to the information exchange between parties to the ABS agreement. Parties may therefore need to agree on the level of confidentiality needed in a particular case in light of the privileged information, which is being shared. Such a confidentiality obligation may apply to the ABS agreement as a whole or to specific terms thereof, in particular terms dealing with the genetic resources and the associated traditional knowledge, research results, the intended utilization or any other technical matters. However, provisions on confidential information should not be designed to undermine the requirement of prior informed consent of the provider party or other reporting requirements that may be mandated pursuant to applicable laws and regulations.

Parties to the agreement should clearly state in the agreement what should be treated as confidential. This can be in the interest of both the provider and the user party. For example, research results may be of great importance for the researcher itself, but also for the provider country if the research results are the basis for a potential commercialization in the long run or if the research results can contribute to building the national capacity of the provider country to utilize its own genetic resources based on an improved understanding of the value of its resources.

N. Publications and ownership of research results

The right to publish is closely linked to the issue of confidentiality of research results. Publishing information on the utilization of genetic and/or biochemical composition of genetic resources etc., thereby making it publicly available, may influence the market value of that information and may prevent the provider country from future benefits arising from the utilization of that information. The agreement should therefore include provisions that clarify in detail the extent, timing, and nature of any limits imposed on publishing any information on the genetic resources, traditional



knowledge or relevant research results. In this context, also the obligation to acknowledge the provider party as the source country of the material, as well as any other contribution or attributions to the research (e.g. joint authorship or application of IPRs) should be addressed in the agreement.

O. Reporting requirements

Detailed provisions on reporting requirements, including procedures of data-sharing and regular reports regarding activities to be carried out under the contract are of major importance. Reporting requirements represent the basis for monitoring and compliance control for the agreement, as well as an integral aspect of accountability. They are the basis for a transparent and long term relationship based on trust between the provider and the user. It should be noted that translation of reports and interpretation in the case of consultations may be necessary, so that everyone concerned can easily understand the content of the reports or follow the discussions etc. If necessary, the agreement should include clear instructions in this regard (e.g. provide for translation of relevant documents in a native language, the availability of interpretation).

P. Meetings

In some cases there may also be a need to organize periodic face-to-face meetings and consultations amongst the Parties on a regular basis. This could facilitate direct exchange of experiences and, where necessary, also resolve any controversial issues and further build confidence. The agreement should then specify the timing and location, frequency, as well as who should bear what costs for such meetings.

Q. Duration and termination of the Agreement

Any contract agreement includes duration and termination clauses (i.e. termination, expiration, cancellation and impossibility or frustration clauses). In the context of ABS, the agreement, for example, may be effective for the duration of a given research project or an initial testing period. However, the issue of termination is challenging as an ABS agreement may not be easily cancelled, as for example e.g. the genetic resource and the associated traditional knowledge and related information has already been transferred. In this context, an agreement on provisions that survive termination may prove to be useful (see section R below).

R. Survival clause

Parties to the agreement should also agree that certain provisions of the agreement, i.e. certain rights and responsibilities of the Parties will survive beyond termination. This should, for example, include the provisions on confidentiality, as well as those on publications and ownership over research results and other benefit-sharing. In addition, the agreement should give clarity on what happens to the material transferred e.g. whether any unused samples should be destroyed or returned to the provider, if at all possible.

S. Breach of the Agreement

To be more effective, the agreement should also include provisions specifying the consequences of a breach of the agreement. The agreement could, for example, include a provision that obliges the user to pay a penalty for any material breach of the Agreement. It could also be included, that the



provider may terminate the agreement and revoke the relevant permit by a written notice if the user defaults in the performance of any obligations under the agreement. The user should then, however, be notified in writing of such defaults by the provider and have the chance to seek remedy within a certain period of time after the date of notice.

T. Dispute resolution and settlement

Parties to the agreement should finally also agree on how to solve disputes related to the contract. It is recommended to first try to solve any dispute through informal negotiations. Parties may also opt for alternative dispute resolution (ADR) mechanisms, such as mediation and arbitration. ADR has the potential to provide quicker, cheaper and more effective solutions to disagreements among contracting parties than litigation in the courts. In transboundary situations, litigation, including issues related to access to justice and the recognition of foreign judgments can be challenging and costly. For example, when bringing an action before a foreign court, the plaintiff will have to deal with different rules relating to procedural matters etc. If the plaintiff institutes proceedings in his own country, it may be difficult to enforce the judgment against the user in a foreign jurisdiction.

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