



June 2013

USING MATERIAL TRANSFER AGREEMENTS TO PUT ACCESS AND BENEFIT SHARING (ABS) IN PRACTICE

Table of Contents

<u>ABOUT THIS NOTE</u>	<u>3</u>
<u>BACKGROUND</u>	<u>4</u>
What is a material transfer agreement?	4
Why use a material transfer agreement?	4
How do material transfer agreements relate to ABS?	4
Why should companies consider ABS in material transfer agreements?.....	4
<u>ADDRESSING ABS IN MATERIAL TRANSFER AGREEMENTS</u>	<u>5</u>
1. Parties	5
2. Object	7
3. Definitions	8
4. Description of the material.....	9
5. Permitted uses	11
6. Link with ABS legislation	12
7. Transfer to third parties	13
8. Change of use	14
9. Intellectual Property.....	15
10. Benefit sharing	17
11. Other common clauses	19
12. Final clauses	20

ABOUT THIS NOTE

- » This note was prepared by the Union for Ethical BioTrade (UEBT) to support the work of its members, partners and other organizations towards the ethical sourcing of biodiversity.
- » The objective of this note is to promote and facilitate respect for internationally recognized principles on how access to biodiversity for research and development should take place and how the benefits resulting from such activities should be shared in a fair and equitable manner. In particular, this note focuses on how material transfer agreements can be used by companies conveying or receiving plant, animal, or other biological material for use in research and development, in order to ensure compliance with principles on access and benefit sharing (ABS).
- » This note includes background information on material transfer agreements, as well as on their link with ABS principles. It then outlines the main elements in material transfer agreements – such as parties, definitions, rights and obligations and intellectual property – considering, in each case, specific issues that arise in relation to ABS. For example, how is ownership of the material defined for the purposes of ABS? How is ownership of the material different from the right to authorize research and development? How is it different from ownership of the intellectual property arising from the utilization of the material? What is the importance of listing the permitted uses? What is the link between material transfer agreements and compliance with ABS laws and regulations? Finally, it provides examples of the types of clauses that might be included in material transfer agreements to deal with these issues.
- » The information in this note is intended for management or technical staff within companies, rather than at specialized lawyers or legal consultants. It aims to provide an initial understanding of issues that could be addressed through material transfer agreements, in order to facilitate internal discussions and decisions on whether and how to use these contracts in the particular circumstances.
- » Please consider that the information on this note is provided for informational purposes only and does not constitute legal advice. The issues discussed and examples provided are intended, but not promised or guaranteed to be current or complete. They should in no way be understood as an indication or assurance of future results. UEBT strongly recommends seeking the advice of an attorney prior to preparing and using a material transfer agreement.

BACKGROUND

What is a material transfer agreement?

A material transfer agreement is a contract that regulates the transfer of tangible biological material (such as plant parts, extracts or compounds) for research and development. Companies, universities and other organizations use material transfer agreements when sending or receiving samples of biological material, in order to define the rights of the provider and the recipient to these samples, as well as to potentially commercially valuable information, methods, compounds, or products resulting from research and development.

Why use a material transfer agreement?

Material transfer agreements are a useful tool for both providers and recipients of biological material for research and development. For the provider, these agreements are a way to safeguard rights over the material and any associated information made available, as well as to receive appropriate compensation for contributions to new findings or products. For the recipient, material transfer agreements offer transparency and legal certainty for research and development activities and results.

How do material transfer agreements relate to ABS?

Sending samples or otherwise making available biological material for its use in research and development falls within internationally recognized principles on access and benefit sharing (ABS). The Convention on Biological Diversity (CBD), an international agreement between more than 190 countries, and its Nagoya Protocol, adopted in 2010, establish rules for biodiversity-based research and development. These rules are implemented through national laws and regulations, as well as standards and codes of conduct.

Companies and other organizations may use material transfer agreements to ensure compliance with national laws and regulations on ABS when sending or receiving biological material for research and development. For example, material transfer agreements may establish the mutually agreed terms on the basis of which research and development takes place and resulting benefits are shared.

Why should companies consider ABS in material transfer agreements?

For companies and other organizations sending or receiving samples of biological material for research and development, addressing ABS principles and requirements in material transfer agreements is a simple approach to:

- Facilitate discussions on purpose and conditions of transferring the material,
- Promote transparency and understanding along the supply chain,
- Clarify rights and responsibilities between provider and recipient,
- Ensure compliance with terms and conditions,
- Support compliance with legal requirements on ABS, and
- Avoid claims of biopiracy.

ADDRESSING ABS IN MATERIAL TRANSFER AGREEMENTS

Material transfer agreements are intrinsically suited to address ABS-related considerations. These agreements commonly include provisions to define the rights of the provider and the recipient with regards to the biological material, as well as to potentially valuable research and development results. As a result, they are a useful tool for companies and other organizations to advance compliance with ABS requirements when sending or receiving biological material for research and development.

Addressing ABS in material transfer agreements does raise some particular issues. There may be questions such as the appropriate parties to the agreement, the way in which various concepts should be understood, and the extent to which benefit sharing should be considered. The following sections provide an overview of these issues in relation to the main components of the material transfer agreements, as well as suggestions on possible ways to adapt these provisions.

1. Parties

Who are the 'parties' in a material transfer agreement?

In a material transfer agreement, parties are persons or organizations sending and receiving samples of biological material for research and development. As in other contracts, the parties must have the capacity and authority to assign or assume the specified rights and obligations. For example, the provider must be authorized to grant the right to use the biological material under certain terms and conditions. The recipient must be able to agree on the terms and conditions on how the sample will be utilized and who will own the results of research and development.

In an MTA, the recipient is acquiring biological material for research and development. If the plant material is not being acquired for this purpose, an MTA is not required, though other types of agreements may be needed to secure eventual compliance with ABS principle. For example, the UEBT Undertaking is a set of conditions that companies can agree to when purchasing plant material for use as ingredients.

What are particular considerations in the context of ABS?

Rights over biodiversity also do not imply rights over associated traditional knowledge. Unless expressly stated, the transfer of plant material implies or confers no rights to the use of traditional knowledge.

The challenge in the ABS context is that rights over biological resources – e.g. ownership of a plant or a plant extract – do not necessarily entail the right to research their genetic or biochemical composition or develop new products or processes on the basis of such information – e.g. identify properties in the biochemical compounds in the plant, develop a standardized extract for use as a moisturizing ingredient and include it in the formulation of a skin care product.

That is, individuals, groups or organizations may own biological resources – for example, plants that grow on their land – but it is countries that have the authority, based on their sovereign rights, to regulate access to these biological resources for their use in research and development. International, national and customary laws may also recognize the rights of indigenous and local communities with regards to the use of certain biological resources and associated traditional knowledge for research and development.

National laws and regulations on ABS determine the persons, agencies or communities with rights over biodiversity for the purposes of research and

National laws and regulations address access to biodiversity for research and development in different ways. For example, according to South African regulations, parties to a material transfer agreement are the person or organization requesting a permit for bioprospecting or export and the person giving access to indigenous biological resources to which the application relates. In Brazil, authorization for access to biodiversity is required from the landowner where the collection or harvest of plant material is taking place.

development. These rules must, therefore, be taken into account when sending samples of biological material and negotiating material transfer agreements.

In countries with no ABS laws or regulations, other national, local or customary laws dealing with ownership and control of natural resources determine rights over biodiversity. Other factors to be considered in determining ownership and control over biodiversity include ownership of the land; the jurisdiction of regional and local authorities in the collection or harvest area; and the laws and practices of indigenous and local communities. For example, some indigenous and local communities develop protocols that affirm their rights and establish decision-making procedures in cases of interest in their resources.

If prior informed consent is obtained from a person, organization or community with the right to provide access to the biological material for research and development, ABS principles do not require the recipient to seek further authorizations from any other persons, organizations or communities with similar rights. Nevertheless, ABS or other applicable legislation may require different levels of consultation, coordination and benefit sharing with other rights or stakeholders. Even with no such requirements, parties may choose to include other persons, organizations or communities in discussions towards prior informed consent, in order to understand and consider the broad range of concerns, claims and implications related to the use of biodiversity for research and development.

Possible clauses

Given that owning biological material does not necessarily entitle the person or organization to transfer such material for the purposes of research and development, material transfer agreements should include a clause establishing the right of the provider – the entity sending the sample of biological material – to grant access for research and development.

- *The PROVIDER formally represents and warrants to RECIPIENT that it has the right and authority to enter into and perform this Agreement.*
- *Each of the Parties represents and warrants for itself that it has the right and authority to enter into and perform this Agreement and to provide and utilize the PLANT MATERIAL for the PERMITTED USES.*

When a word or phrase is put in capitals letters in material transfer agreements, it is because there is a particular definition for that word or phrase that is set forth earlier in the document.

These clauses may also indicate the legal basis for such rights, including references to international, national, local or customary laws. Furthermore, they may include references to warranties of having obtained, or commitments to obtain, all other permits or authorizations required to perform the agreement and comply with applicable law.

Moreover, a material transfer agreement may include references to ‘third parties’ – that is, persons, organizations or communities interested in the agreement, but not directly bound by it – in order to:

- *Define the rights of intended beneficiaries.* For example, a material transfer agreement may foresee the establishment of a trust fund managed by the authorities of the local community to which the provider belongs.
- *Address other claims or rights over genetic resources.* For example, Parties may warrant that, to the best of their knowledge, the performance of the agreement will not constitute or result in any infringement of third-party rights.
- *Facilitate monitoring and evaluation.* For example, the agreement may refer to a government agency as a third-party beneficiary, in order to allow it to monitor activities undertaken and ensure compliance with established rights and obligations.

2. Object

What is the object of a material transfer agreement?

The object in a material transfer agreement is the transfer of the biological material – though not its ownership – between the parties for research and development activities. Material transfer agreements usually indicate that, although a material has been transferred from provider to recipient, the ownership of the material and unmodified derivatives remains with the provider (see table on ‘Ownership and other rights linked to material transfer agreements’). As a consequence, material transfer agreements commonly include clauses that, for example, restrict the activities that the recipient may conduct, forbid commingling and demand the return of the material and related information at the end of the material (see section on ‘Other common clauses in material transfer agreements’).

What are particular considerations in the context of ABS?

In the context of ABS, the main purpose of the material transfer agreement remains to define ownership over the biological material and associated information. Indeed, defining ownership becomes even more significant in relation to ABS requirements. This is because, although individuals, groups or organizations may own biological resources, it is countries that have the authority to regulate whether and how the genetic or biochemical composition of these resources may be looked at and utilized in research and development (see table on ‘Ownership and other rights linked to material transfer agreements’). Consequently, the material transfer agreement must consider the authority of parties to send and receive the biological material in the context of ABS principles and related laws and regulations.

Additionally, material transfer agreements may have additional purposes in relation to ABS. For example, a material transfer agreement may serve to document prior informed consent or mutually agreed terms, as required by ABS laws and regulations or established by other norms and guidelines. In these cases, the agreement should clearly state its purpose: providing consent and establishing conditions for access to biodiversity for research and development. The agreement should refer to the specific laws, regulations, or other norms that the parties understand require, authorize or direct their rights and obligations. The object may also include references to other permits or documents relevant to compliance with ABS requirements.

Ownership and other rights linked to material transfer agreements			
	Provider	Provider country	Recipient
Tangible property	Biological material (e.g. plants, plant parts or extracts, microbial cultures).	Right to regulate utilization of genetic resources (e.g. to define who may grant prior informed consent for research into biochemical composition of the material).	New substances, compounds and ingredients using the materials.
Intangible property	Knowledge and know-how on properties, uses and methodologies linked to biological material.	Right to take measures to ensure that traditional knowledge held by indigenous and local communities is accessed with prior and informed consent and mutually agreed terms.	Intellectual property rights on novel compositions, processes or uses.

Possible clauses

Clauses defining the object of material transfer agreements are often simple, straightforward statements. However, agreements may also list the main rights and obligations as part of their object – rather than in separate provisions – making this clause the core of the agreement. Examples of clauses on the object of material transfer agreements include:

- *The object of the present Agreement is the transfer of the MATERIAL. This transfer is authorized only for use in the RESEARCH PROJECT described in Annex I. The RECIPIENT cannot transfer the MATERIAL in whole or in part to any party not expressly named in the present Agreement, without prior written consent from the PROVIDER. Likewise, use of the MATERIAL for commercial purposes requires a commercial license from the PROVIDER.*
- *The plant parts or extracts specified in this Agreement and related information referred to in Article X are hereby transferred from the PROVIDER to the RECIPIENT subject to the terms and conditions set out in this Agreement.*

3. Definitions

What definitions are needed in a material transfer agreement?

Material transfer agreements often include definitions to clarify terminology used in the text. Issues that are commonly addressed through definitions include the scope of the transferred material and the activities foreseen. For instance, material transfer agreements outline the specific plant or other material being conveyed. In addition, these agreements usually include a definition of ‘material’ – an explanation of what elements of the plants or other organisms sent are considered included in the agreement. Similarly, terms such as ‘research,’ ‘commercial use’ or ‘commercialization’ are often defined to outline the activities allowed under the agreement and those that require further authorization.

What are particular considerations in the context of ABS?

Definitions play a fundamental role in addressing ABS issues in material transfer agreements. The meaning of basic terms such as ‘research and development’ and ‘genetic resources’ is still unclear in many international and national provisions. Moreover, it is important for the provider and the recipient to discuss and agree on the exact scope of their rights and obligations with regards to the following issues:

- » Ownership over material transferred. In the context of ABS, material transfer agreements need to clarify what is the ‘material’ over which the provider has and retains ownership (see also section on ‘Description of the Material’). It is usual in material transfer agreements to indicate that, although a material has been transferred from provider to recipient, its ownership remains with the provider. Material transfer agreements also define the material, in order to affirm ownership not only over the sample being conveyed, but also over all naturally occurring genetic material, biological molecules and biochemical compounds in that sample (sometimes referred to as ‘unmodified derivatives’).
- » Activities conducted. In material transfer agreements involving one or more companies, definitions of foreseen activities are important in setting out the permitted uses and in establishing the milestones in research, development and commercialization that trigger rights and obligations. For example, ‘development activities’ may be defined as the formulation of a characterized extract for specific uses. ‘Commercialization’ may be defined to include the activities that will prompt negotiations on monetary benefits.

Finally, in addressing ABS, material transfer agreements may define basic principles like prior informed consent and mutually agreed terms. These definitions provide clarity and

transparency as to the rights over biodiversity claimed and transferred, the extent to which the agreement constitutes consent or conditions for access or utilization of genetic resources, and the link with applicable legal requirements on ABS.

Possible clauses

Definitions should make the text of the material transfer agreement easier to read and understand. It is preferable to put definitions in an annex to the agreement, though a specific clause within the text is also possible – particularly if definitions are not too numerous. The provider and the recipient should discuss, agree and incorporate definitions for all terms that may have particular meaning in the context of the agreement. Terms that are either unclear in ABS rules or practices or central to establishing ABS-related rights and obligations should also be defined. Examples of terms and definitions include:

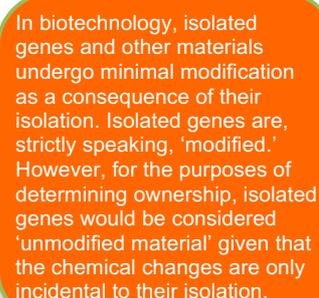
- *‘Plant material’ covers the plant parts and/or plant extracts listed in clause X; other plant parts that may have been transferred, even inadvertently, along with them; and any genetic material, biological molecules and biochemical compounds, whether isolated or not, naturally occurring in these plant parts and/or plant extracts.*
- *‘Material’ refers to the original material specified in clause X, as well as progeny and all unmodified derivatives.*
- *‘Unmodified derivatives’ are substances that constitute a functional or genetic subunit or product expressed by the original material, including purified sub-fractions of the original material and which may have been chemically or biochemically modified as an incident of, but not after, their isolation.*
- *‘Mutually agreed terms’ is the agreement reached between the providers of genetic resources, as defined by relevant national laws and regulations, and the organizations seeking the utilization of genetic resources, on the conditions of access and use of the resources and the benefits to be shared between both parties.*
- *‘Prior informed consent’ is the permission given by the competent authorities of the country providing the plant material or the delegated agencies, groups or individuals, for the utilization of genetic resources, as defined by relevant national laws or regulations.*
- *‘Research and development’ is the series of analyses, tests and other investigative activities conducted on the MATERIAL with the intention of identifying novel and useful properties to enable development of new products, processes, or services. Research and development is not deemed to include analyses and tests offered or used for commercial purposes, as for example using the MATERIAL in a diagnostic assay or screening assay for new products.*
- *“Product” means any natural ingredient or product that is a result of research and development activities, incorporates the PLANT MATERIAL and is ready for commercialization.*
- *‘Product development’ is the process of bringing new products or products with new characteristics to market. It includes product formulation, in which plant parts or derivatives are combined in specific proportions according to the desired quality and characteristics for the final product.*
- *‘Commercialization’ refers to activities to place on the market any ingredients or products or processes derived from the PLANT MATERIAL or otherwise retain monetary benefits from the sale, lease, or licensing of research results, whether patented or not.*

4. Description of the material

How are materials described in a material transfer agreement?

In their description of the material being conveyed, material transfer agreements consider two distinct aspects. First, material transfer agreements include a simple description of the sample being requested and sent. The material is usually identified in type, quantity and quality. For example, a determinate amount dried leaves, essential oils or other parts or extracts from a particular plant species.

Second, material transfer agreements – either alongside the above-mentioned description or in the section on definitions – also establish the extent to which their provisions cover known or potential elements or substances in this material. For example, the provider may assert rights not only over the plant extract being sent, but also clarify that the agreement covers any substance that is fractioned or purified from this extract, without further modification. In general, providers aim to secure broad ownership rights over the biological material being transferred. Recipients, in turn, aim to have legal certainty on their use of the material, as well as to safeguard ownership over their own research, innovation or inventions. For example, in its guidance on the use of material transfer agreements, the US National Institutes of Health recommends that the description of material exclude substances or inventions created by the recipient.



In biotechnology, isolated genes and other materials undergo minimal modification as a consequence of their isolation. Isolated genes are, strictly speaking, 'modified.' However, for the purposes of determining ownership, isolated genes would be considered 'unmodified material' given that the chemical changes are only incidental to their isolation.

What are particular considerations in the context of ABS?

Similarly, describing the extent to which a material transfer agreement covers the components of the biological material – as well as its derivatives, products and related information – is fundamental to ensuring compliance with ABS principles. Material transfer agreements should address questions such as:

- » What rights over the material is the provider willing and able to transfer to the recipient? International and national legislation establish particular rights, obligations and procedural requirements for access to biological material for its use in research and development (see table on 'Ownership and other rights linked to material transfer agreements in the section on 'Object'). Material transfer agreements should identify the material sent and the specific rights granted over such material. For example, the provider should retain ownership, or prevent the recipient from claiming any rights over unmodified derivatives of the material.
- » How do prior informed consent and mutually agreed terms consider elements and characteristics of the material that are known, foreseen or still undiscovered? It is important to note that the material transfer agreement – or related legislation – may establish obligations beyond the material covered. For example, a recipient may have the ownership of the tangible and intangible results of innovation on the sample provided. However, on the basis of the conditions established in the material transfer agreement or relevant legislation, the recipient may have obligations in relation to these results, including disclosing the origin of the material in patent applications or sharing monetary or non-monetary benefits with the provider or third parties (see section on 'Parties').

Possible clauses

For the description of the actual materials being transferred, a clause should be drafted that describes the type, quantity and specifications of the material sent. This clause may be complemented with a reference to other, inadvertent material or substances sent along with the sample – for example, parts of the plant roots that may be found to have valuable properties – and naturally-occurring genetic and biochemical information and substances.

- *'Plant material' covers the plant parts and/or plant extracts listed in clause X; other plant parts that may have been transferred, even inadvertently, along with them; and any*

genetic material, biological molecules and biochemical compounds, whether isolated or not, naturally occurring in these plants, plant parts and plant extracts.

For the description of other known or potential elements and substances that is or not considered as part of the transferred material and thus covered or not by the agreement, see section on 'Definitions.'

5. Permitted uses

What are the types of uses foreseen in a material transfer agreement?

Material transfer agreements specify how the recipient can and cannot use the material. Generally, these agreements cover the transfer of plant or other biological material for research activities, which are described in detail in one of the clauses or annexes. Material transfer agreements will also include limitations on the use of the material, prohibiting the recipient for using the materials in any manner other than the specifically defined research activities. Moreover, many agreements include conditions or restrictions for the material to be used for commercial purposes.

What are particular considerations in the context of ABS?

A clear description of the permitted uses is fundamental to ensure compliance with ABS principles. Prior informed consent is based and granted in relation to specific activities. As a result, material transfer agreements conveying or reflecting such consent would need to describe the permitted uses that are covered. This description would also seek to ensure that the scope of prior informed consent is respected along the research and development process. Material transfer agreements will often include a provision that expressly states that any change of use would require a new or updated prior informed consent.

Material transfer agreements should strive to consider and respect any ethical concerns of stakeholders as to the utilization of plant or other biological resources, particularly indigenous and local communities with social, cultural and historical links with these resources.

Describing permitted uses of the plant or other biological material is also important in terms of equitable benefit sharing. During the research phase, there may be limited sharing of benefits or a focus on non-monetary benefits such as training and information exchange. Nevertheless, once an active ingredient is extracted, characterized, purified or otherwise developed for commercial use, the sharing of additional benefits or the need to negotiate such sharing is likely to be triggered. It is thus useful to clarify which activities require further negotiation.

The listing of permitted uses should consider – to the extent possible – the potential uses of the material, as well as its possible derivatives and products. It should also be linked to the definition of 'commercial use' or 'commercialization' in the agreement.

Possible clauses

The specific activities that are foreseen and agreed upon in relation to the material will depend on the circumstances. In all cases, the permitted uses should be described in detail, however, either within the text of the agreement or in one of the annexes. Additionally, certain ABS laws or regulations may require applicants to present a research project or plan that describes details of the research, development or commercialization that the company proposes to undertake, as well as a proposed timetable for these activities. Material transfer agreements can refer back to such projects or plans and incorporate them as an integral part of their text. There are also more general clauses that may complement – rather than replace – a detailed description of permitted uses, including the following examples:

- *The RECIPIENT shall only use the MATERIAL for research purposes. The MATERIAL shall not be used for commercial purposes, including for the avoidance of doubt for the production or sale of any products or processes without prior written authorization by the PROVIDER and compliance with applicable legal requirements.*

- *The MATERIAL shall only be used for test, reference, bioassay and control purposes; for the avoidance of doubt, a bioassay does not include using the material in any assay offered or used for commercial purposes, such as drug screening or diagnostic testing. This AGREEMENT does not grant RECIPIENT the right to use the MATERIAL for any commercial purpose, which includes but is not limited to activities such as patenting, product development, licensing, and seeking pre-market approval.*
- *RECIPIENT will screen samples of the MATERIAL for commercial potential. In order to ensure compliance with benefit sharing provisions of this Agreement, the RECIPIENT shall immediately notify PROVIDER of positive results and, upon an intended commercial use of the MATERIAL, negotiate equitable sharing of resulting benefits, within the parameters foreseen in Annex I.*
- *RECIPIENT shall perform screening of the PLANT MATERIAL for the following types of activity, selected at the discretion of the RECIPIENT: moisturizing, anti-aging, UV protection and skin lightening.*
- *RECIPIENT shall notify the PROVIDER whenever it decides to proceed with the development of any compound derived from PLANT MATERIAL supplied pursuant to this AGREEMENT.*

6. Link with ABS legislation

Do material transfer agreements include references to legislation?

Beyond provisions on governing law, most material transfer agreement do not include references to legislation. Their use may be subject to compliance with various internal protocols and sanitary and phytosanitary regulations, but such issues are generally mentioned or addressed beyond the text of the agreements. Material transfer agreements may mention that the plant or other biological material cannot be tested on humans or used in plants and animals consumed as food. However, these restrictions are more linked to liability concerns than legal compliance. For example, it is not uncommon in material transfer agreements to shift liability associated with possible toxicity of plant materials to the recipient.

How should material transfer agreements deal with ABS legislation?

A growing number of countries have laws or policies in place to implement ABS principles established in the CBD and the Nagoya Protocol. These laws and regulations establish specific procedures or requirements for companies accessing or using biodiversity for research and development. As a result, these rules may be relevant for the negotiation and content of material transfer agreements addressing biodiversity-based research and development.

According to the CBD, over 55 countries have laws or policies on ABS. These measures may address issues such as rights over biodiversity or associated traditional knowledge, procedures for access for research and development, and guidelines on prior informed consent or sharing of benefits. In practice, however, these measures may not be in operation. For example, some countries have not identified the competent authorities or steps to obtain permits.

If national rules on ABS apply to activities covered by the material transfer agreements, two possible situations arise:

- » National laws or regulations expressly address the use of material transfer agreements. These agreements may be considered as possible tools to establish or document ABS requirements such as prior informed consent or mutually agreed terms. In this case, material transfer agreements may need to include specific requirements relating to permits, consent or negotiation processes, as established in the applicable legal provisions. They may also need to be approved or endorsed by competent authorities.

- » National laws or regulations do not expressly consider material transfer agreements. In this case, a material transfer agreement may nevertheless fulfill or refer to ABS requirements such as negotiations or agreements on prior informed consent, mutually agreed terms or benefit sharing.

Possible clauses

The need and type of provisions addressing ABS legislation will depend on the existence of relevant legal requirements and the link between these requirements and the material transfer agreement at issue. References to applicable ABS requirements may be made in various provisions, from the preliminary considerations to the clauses identifying the Parties and their obligations. These references may also be made through a separate clause, such as the following examples:

- *Prior to initiating any research activities, the RECIPIENT shall obtain and present to the PROVIDER the authorization to conduct such activities, issued by the competent authorities pursuant to national law.*
- *PROVIDER shall ensure that the MATERIAL has been obtained in accordance with applicable legal requirements, including PRIOR INFORMED CONSENT from any persons or groups with relevant rights over the MATERIAL.*
- *PARTIES agree that any access, transfer and use of the PLANT MATERIAL for research and development will be conducted with the authorization of competent national authorities and in a manner that ensures the equitable sharing of resulting benefits.*
- *The PROVIDER undertakes to help RECIPIENT to secure the prior informed consent of any competent national and local authorities and of any other appropriate stakeholders to enable research and development activities described in Annex 1.*

7. Transfer to third parties

Why do material transfer agreements limit transfer to third parties?

In describing how the recipient can and cannot use the plant or other biological material, material transfer agreements often include restrictions on transferring samples, unmodified derivatives or related information to third parties. This is because third parties are not necessarily bound by the terms and conditions established in the material transfer agreement. The transfer of the material to third parties would thus risk the circumvention of terms and conditions and the inadequate recognition of the rights and contributions of the provider and other stakeholders.

The transfer of material should be distinguished from the assignment of the material transfer agreement. Assignment is the transfer of rights to another person or organization not originally part of the agreement. In this case, the assignee would have, unless stated otherwise, all the rights and duties under the agreement. Nevertheless, many material transfer agreements consider the characteristics of the person or entity involved, thus also prohibiting or restricting assignment.

What are particular considerations in the context of ABS?

Addressing the possible transfer to third parties of the material covered by the agreement, as well as the genetic or biochemical information linked to this material, is an important consideration in ensuring compliance with ABS principles along the research and development process. The Bonn Guidelines suggest that material transfer agreements address whether genetic resources or related information can be transferred and, if so, what conditions should apply. For example, the material transfer agreement may require prior notice to the provider or an agreement or assignment between the recipient and third party that safeguards some or all the rights of the provider and other stakeholders, such as on permitted uses, use of intellectual property protection and sharing of resulting benefits. Additionally, the material transfer agreement may notify the recipient that the transfer of the

material to third parties may trigger new or additional requirements under applicable ABS legislation, such a new application for prior informed consent.

Possible clauses

Possible clauses addressing the transfer to third parties of plant or other biological material covered by the agreement, as well as ensuring the continued validity of ABS-related terms and conditions, include:

- *RECIPIENT shall not transfer any part of the original material to third parties, nor undertake or allow duplication of the material for or by such parties, except with prior written authorization of PROVIDER.*
- *Transfer to third parties is allowed with prior authorization of the PROVIDER and a new benefit-sharing agreement.*
- *The RECIPIENT will not transfer or provide access to the tangible MATERIAL or any of the tangible or intangible findings of the research conducted under this Agreement to a third party, unless it does so under an agreement on terms consistent with this Agreement. The RECIPIENT shall furnish the PROVIDER with the name of each third party that an agreement is made with and details of the terms of the agreement.*

8. Change of use

Why anticipate 'change of use' in material transfer agreements?

The exchange of biological material underlies research and development in a number of different sectors, including food, agriculture and health. The narrowing of the gap between fundamental research and commercial development has meant that organizations providing samples to other entities increasingly want to secure their rights and interests in potentially valuable outcomes. These organizations employ material transfer agreements in order to send biological material with explanation of permitted uses and stipulations either prohibiting or establishing certain conditions for change of use. For example, many material transfer agreements require the negotiation of a revised agreement or a commercial license prior to any commercial use.

What are particular considerations in the context of ABS?



The issue of change of use is particularly relevant if the material transfer agreement covers non-commercial research. The Nagoya Protocol encourages countries to establish simplified procedures for access to biodiversity in cases of research for non-commercial purposes. It also highlights the need to address a change of intent for such research towards commercial use.

Anticipating a possible 'change of use' is important to ensure compliance with ABS principles and agreed upon terms and conditions along the supply chain. For example, if an indigenous community provided access to biological material from its land for the purposes of taxonomic research, any other use would require a new process towards prior informed consent. A clause on 'change of use' also advances the equitable sharing of benefits resulting from subsequent applications and commercialization of the results of research and development, as required by the Nagoya Protocol on ABS.

Clauses on 'change of use' should consider that both foreseen and unforeseen findings in the research and development process might lead to new uses. For example, tests conducted on plant extracts to determine their possible value as active ingredients for cosmetics may yield results interesting for other applications or other types of products.

Change of use should only take place after compliance with steps established in the terms and conditions of the material transfer agreement. Such steps may involve requirements for notification, renegotiation of certain elements of the agreement or a new process to obtain prior informed consent and establish mutually agreed terms. In particular, a change of use

may require new benefit-sharing provisions to reflect the range of possible benefits not considered or included in the initial terms of the material transfer agreement.

Possible clauses

Some examples of clauses on change of use include:

- *In the case that the RECIPIENT intends to use the biological material for purposes other than research and development activities described in Annex I, the RECIPIENT shall notify the PROVIDER prior to any such change of use in order to negotiate modifications to the material transfer agreement.*
- *The material cannot be used for any objective or purpose other than the one described in this paragraph, unless the RECIPIENT first receives authorization from the PROVIDER.*
- *The RECIPIENT shall only utilize the MATERIAL for purposes other than those established in clause X if there is prior, express and written permission from the PROVIDER and compliance with any applicable legislative or regulatory requirements in the country or countries in which plants are collected or harvested and plant parts and/or plant extracts utilized.*
- *If at any time the RECIPIENT determines that the research data dictates a substantial change in the direction of the work, the PARTIES shall make a good faith effort to agree on any necessary changes to the scope of the APPROVED RESEARCH, only after consultation with and approval of the THIRD-PARTY BENEFICIARIES.*

9. Intellectual Property

Why do material transfer agreements address intellectual property?

Intellectual property is a central element in material transfer agreements, given that their main objective is defining ownership rights. Material transfer agreements seek to secure the tangible and intangible property that is or could be held by both the provider and the recipient in relation to the material (see table on 'Ownership and other rights linked to material transfer agreements' in section on 'Object'). The provider will maintain ownership over the sample conveyed. It may also have related intellectual property rights, such as know-how on the use of the plant for certain medicinal uses. The recipient may have intellectual property rights over novel compositions, uses or processes, including patents and trade secrets. It may also have rights over tangible property linked to the biological material, such as novel substances and compounds. Material transfer agreements often include provisions dealing with such ownership issues, and they also may include other issues such as the rights or limitations for the recipient to seek intellectual property rights, its duty to disclose inventions and arrangements on the granting of licenses.



Material transfer agreements may grant rights to the provider over intellectual property resulting from research and development. However, such rights should be based on actual contributions and not undermine recipient's ability to develop or commercialize results.

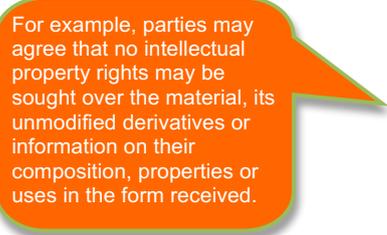
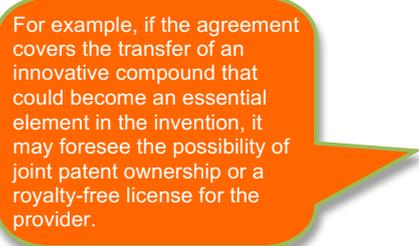
What are particular considerations in the context of ABS?

The CBD recognizes that intellectual property rights may influence putting in practice ABS principles, and calls for such rights to be supportive of its objectives. Patents, for example, can be useful tools to harness biodiversity-based innovation, generating benefits to be shared along the supply chain. At the same time, there are concerns that certain patent practices can undermine the rights of countries and communities over their biodiversity and traditional knowledge.

The Bonn Guidelines suggest that material transfer agreements address whether intellectual property rights may be sought and, if so, under what conditions. These guidelines also

consider possible approaches to addressing intellectual property rights, including provisions on joint research, obligations to secure rights on inventions and to provide licenses by common consent, and the possibility of joint ownership of rights, according to the degree of contribution.

Consequently, in dealing with activities falling under the scope of ABS principles, material transfer agreements should include provisions addressing two main sets of issues:

- » The extent to which Parties are entitled to claim intellectual property rights over the biological material, as well as its modified and unmodified derivatives and information on their genetic and biochemical composition, properties and uses. Here it is important to consider that making available or receiving certain material – regardless of who owns the material – does not necessarily entail intellectual property rights over the material, its known or potential applications or resulting inventions. Intellectual property rights should reflect rights and contributions in relation to the material and the knowledge.
- » Recognition of Parties' contributions to inventions or innovations resulting from the research and development, including through measures such as joint ownership, licenses, royalties and other mechanisms for benefit sharing. Such recognition should consider established rights over material and information, as well as contributions to research, development and commercialization processes made by both the provider and the recipient should be taken into account.

Possible clauses

Some of the possible clauses and approaches to deal with ownership and the sharing of benefits derived from intellectual property rights include:

- *The RECIPIENT agrees not to claim ownership over the MATERIAL, nor to seek intellectual property rights over the MATERIAL and/or its related information.*
- *The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS. The RECIPIENT shall have exclusive ownership of MODIFICATIONS (except for ownership rights to the MATERIAL included therein). If the MODIFICATIONS result from the collaborative efforts of the PROVIDER and the RECIPIENT, joint ownership shall be negotiated.*
- *In the event that RECIPIENT develops and patents any invention based on the RESEARCH conducted and using the MATERIAL provided under this Agreement, RECIPIENT and PROVIDER shall engage in good faith negotiations on mechanisms to make appropriate recognition of the contribution of the Parties, such as payment of certain royalties, a license under preferential terms or the selection of the PROVIDER as the preferential source of supply of the raw material.*
- *If inventions consist in products and processes that are patentable (i.e., novel, inventive and with practical utility) over the MATERIAL provided under this Agreement, the RECIPIENT will own any resulting patents or other intellectual property rights thereon.*
- *The RECIPIENT shall only claim patents or other intellectual property rights connected or referring to the MATERIAL, new forms or uses of the MATERIAL, or new processes for preparing, producing or manufacturing the MATERIAL, if:*
 - a. *There is prior, express and written permission from the PROVIDER; and*

- b. *There is compliance with any applicable legislative or regulatory requirements in the country or countries in which plants are collected or harvested.*
- *In the case of a patentable invention resulting from the activities undertaken as a result of this Agreement, the RECIPIENT is free to apply for patents with regard to such invention in its name and at its expense. Any such applications for patent should be promptly notified to the PROVIDER and include references to the country of origin of the MATERIAL, as well as any information on traditional uses considered in the research and development process. Inventorship of such patent applications will be determined according to the laws of the country where patents are sought.*
 - *If the RECIPIENT wishes to protect the results of its investigations based on the material received, by means of some system of intellectual property protection, he will provide prior notice to the PROVIDER. Any intellectual property rights sought with regard to results of investigations must conform to national and international legislation on access and benefit sharing, as well as to the terms of this Agreement.*

10. Benefit sharing

Do material transfer agreements include provisions on benefit sharing?

The use of material transfer agreements follows growing interest among academic and commercial entities in capturing the value of plant and other biological material shared with other institutions. Provisions on ownership of the material, as well as the results of research and development, often constitute *de facto* approaches to benefit sharing. For example, some material transfer agreements include arrangements on licenses and royalties. Others, while expressly disclaiming generating a license, may contemplate that the parties may enter into a license in the future. In relation to such licenses, material transfer agreements may also include a clause that states that, if and when a license is entered, it will contain provisions for milestones, minimum yearly payments, and royalty provisions. Such clauses may even include specific floors (or ceilings) below which (or above which) the milestones, minimum yearly or royalty payments will not fall (or exceed). Ultimately, the aim of such provisions is ensuring equitable sharing of benefits, taking into account the role and contributions of the different institutions.

What benefit sharing?

According to the Nagoya Protocol, there should be equitable sharing of benefits arising from biodiversity-based research and development, as well as subsequent applications and commercialization. For example, benefits considered should include those arising from the characterization of the medicinal properties of a type of berry, the development of a cosmetic ingredient based on such research, and the commercialization of the ingredient.

Benefits may be monetary and non-monetary. Monetary benefits may be linked to payments for access to the materials or revenues or intellectual property resulting from research and development, or include other types of financial support for conservation of biodiversity or local development. Non-monetary benefits may include sharing research and development results; information or technologies for the conservation, management and valorization of biodiversity; and other capacities linked to the objectives of the CBD.

There is no single definition of what is "fair and equitable." In each case, Parties must define the appropriate benefits and approaches to benefit sharing through mutually agreed terms, which could be established in the material transfer or other agreements. Moreover, as stated by the Bonn Guidelines, what is regarded as fair and equitable in the types of benefits and the benefit-sharing obligations and procedures varies "in light of the circumstances."

What are particular considerations in the context of ABS?

If activities facilitated or covered constitute biodiversity-based research and development, material transfer agreement should expressly consider the fair and equitable sharing of resulting benefits. Provisions may be included to establish a commitment to share benefits if certain milestones are reached in the research, development or commercialization process.

Additionally, the material transfer agreement may establish and define certain benefits to be shared, such as payment for the samples and the sharing of information, along with the timeline and approach for benefit sharing. National legislation may provide guidance or mandatory parameters for the negotiation or agreement on benefit sharing.

Who should share in the benefits?

According to the Bonn Guidelines, benefits should reach all those individuals, groups or entities that contributed to the resource management, research, development or commercialization processes. This may include governmental, non-governmental or academic institutions and indigenous and local communities.

When should benefits be shared?

Benefits can only be shared as they are generated – research conducted, interesting properties identified, potential applications developed and commercialized. As a result, it is often necessary to establish different phases of benefit sharing, considering the short, medium and long-term benefits that may arise. The appropriate balance would need to be considered on a case-by-case basis.

Possible clauses

Some of the possible clauses and approaches to deal with ownership and the sharing of benefits derived from intellectual property rights include:

- *RECIPIENT agrees to compensate PROVIDER for transfer of [quantity] of MATERIAL in the amount of [price], payable upon receipt. This compensation will not be considered a payment for transfer of ownership of the MATERIAL but only for costs covered with the collection and processing. Ownership in the MATERIAL will remain with the PROVIDER notwithstanding any payments made by the RECIPIENT.*
- *RECIPIENT shall compensate PROVIDER in advance for equipment, supplies and other expenses required for the collection, preparation and delivery of the MATERIAL, (although not for the transfer of ownership of the MATERIAL) as detailed in Clause X or agreed to in writing.*
- *RECIPIENT shall provide immediate notice to the PROVIDER if activities conducted by RECIPIENT result in a substance based on or incorporating the MATERIAL considered, selected or included in industrialization processes and shall negotiate in good faith with the PROVIDER terms for equitable sharing of resulting benefits, including an agreement to establish the PROVIDER as its first source of supply of the raw material for elaborating the invention.*
- *In the event that RECIPIENT derives income from the use, sale, or licensing of MATERIAL or MODIFICATIONS, RECIPIENT shall share [a percentage] of such income, with the PROVIDER.*
- *The PROVIDER shall share any income resulting from the use, sale, transfer or license of MATERIAL or MODIFICATIONS with individuals, organizations, or communities in the country of origin, as mandated by national regulations.*
- *The RECIPIENT shall share with the PROVIDER the results of activities detailed in Annex I, assessment of data, samples as reasonably requested, and provide reasonable assistance in their assessment or interpretation.*
- *In the event that research and development foreseen or unforeseen in Annex I ultimately leads to a PRODUCT, RECIPIENT shall deposit [amount or % of specific revenues] into a trust fund for local sustainable development to be established and maintained by mutual agreement between PROVIDER and RECIPIENT.*

11. Other common clauses

Through material transfer agreements, the provider transfers biological material to the recipient while maintaining ownership over the material and its unmodified derivatives. Material transfer agreements also safeguard rights over the intangible aspects of the biological material, including knowledge and innovation on related properties, uses and methodologies. As a consequence, it is common to include, at the end of the agreement additional clauses aimed at securing these rights. These clauses are equally relevant, and may have some particular aspects, in the context of ABS.

Issues	Possible clauses
<p>Confidentiality. Parties to a material transfer agreement agree to maintain certain information confidential in order to safeguard their respective rights over existing knowledge, planned research, or innovative findings on properties, uses and methodologies linked to the material. Confidentiality requirements are limited by specific exclusions of information – for example, information that was already known before accessing it under the material transfer agreement – and by permitted disclosures. Permitted disclosures usually include disclosure pursuant to legal obligations. This is particularly relevant in the context of ABS because laws and regulations may require certain information in order to provide necessary authorizations or agreements or to monitor compliance with prior informed consent and mutually agreed terms.</p>	<p>The RECIPIENT agrees to hold confidential all information and related know-how disclosed by PROVIDER concerning the MATERIAL that is marked as “Confidential” (“Confidential Information”).</p> <p>The PROVIDER agrees to hold confidential all information and related know-how disclosed by the RECIPIENT, as per reporting obligations in this Agreement, concerning research activities, research results or new compositions, uses and methodologies based on, containing, or relating to the MATERIAL or its MODIFIED DERIVATIVES.</p> <p>For the avoidance of doubt, it is not a breach of confidentiality obligations for one of the Parties to disclose Confidential Information when required by a legally-enforceable external demand — such as, for example, requests for information made in the course of procedures established in ABS laws and regulations, by a competent authority – if the following prerequisites are met: (1) notice is provided to the other Party immediately upon learning of the demand; and (2) If requested by the other Party, reasonable cooperation is provided with its efforts to limit the disclosure.</p>
<p>No commingling. The aim of this clause is to avoid compromising rights and obligations over the material through the combination of the sample at issue with other material possibly subject to different rules and conditions. For example, compliance with reporting requirements may be difficult if the research involves material that is subject to strict confidentiality requirements, or viceversa.</p>	<p><i>The MATERIAL shall not be utilized in, or commingled with, any other research project or program ongoing now or in the future in the laboratories or any project or program of the RECIPIENT, funded by any other private or public party.</i></p>
<p>Return of materials and associated information. The recipient does not gain ownership over the biological material or associated information. As a result, upon termination of material transfer agreement through which it had gained access to a sample, it is usually required to return or destroy any remaining material and related documents.</p>	<p><i>Upon termination of this Agreement, RECIPIENT shall, at PROVIDER’S request, return to the PROVIDER any remaining MATERIAL and any INFORMATION received from the PROVIDER.</i></p>
<p>No warranties. Given the purpose of a material transfer agreement, the material is generally considered to be experimental in nature and provided ‘as is’, with no warranties, express or implied. The clause is usually drafted in capital letters.</p>	<p><i>PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, WITH RESPECT TO THE MATERIALS, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT, COPYRIGHT, OR OTHER PROPRIETARY RIGHT OF ANY THIRD PARTY.</i></p>
<p>Liability. Material transfer agreements usually stipulates that the recipient assumes all liability for damages that may arise from the use, modification, storage and disposal of the material. The shift in</p>	<p><i>The MATERIAL may have biological and/or chemical properties that are unpredictable and unknown at the time of transfer. RECIPIENT shall assume all responsibility, financial and otherwise, for the</i></p>

liability to the recipient is linked to its generally greater ability to take related measures and obtain necessary insurance.

consequences either to RECIPIENT or to any third party of utilizing the Materials. RECIPIENT shall indemnify PROVIDER and hold PROVIDER harmless for any claim of liability made against Provider in conjunction with or related to the use by RECIPIENT of the MATERIAL.

12. Final clauses

Contracts, including material transfer agreements, incorporate clauses dealing with termination, choice of law and dispute resolutions. These clauses – though in many cases standard wording – are important, particularly in the context of ABS.

Issues	Possible clauses
<p>Termination. Material transfer agreements usually specify an expiration date for the agreement, as well as provide for earlier termination through advance, written notice. Nevertheless, certain clauses may retain validity even after the material transfer agreement is terminated, including obligations related to confidentiality. In the context of ABS, obligations linked to the benefit sharing may also extend beyond the period of the material transfer agreement.</p>	<p><i>This Agreement will terminate on [DATE]. The Agreement may be terminated on X months written notice by either Party to the other.</i></p> <p><i>The provisions of clauses Y and Z, together with any relevant definitions, will survive termination or expiration of this agreement.</i></p>
<p>Choice of law. Material transfer agreements often specify the laws of a particular jurisdiction as those governing formation, validity, and performance of the contract. This is particularly important in cases in which the provider and the recipient are in different countries. Moreover, in the context of ABS, care should be taken to ensure that the choice of law allows all actors and stakeholders, including the government and third-parties, to exercise their rights.</p>	<p><i>This agreement is governed by the laws of [COUNTRY].</i></p>
<p>Dispute resolution. Oftentimes, material transfer agreements include a clause that provides for any disagreement to be resolved under the mediation or arbitration, rather than going directly through a judicial process. According to the Nagoya Protocol, countries should encourage providers and users of genetic resources to consider options for such alternative dispute resolution approaches. This is important given that ABS issues tend to be complex and involve a range of stakeholders with differing perspectives and capacities.</p>	<p><i>Before the Parties resort to litigation to solve any dispute, the Parties agree to schedule a mandatory meeting in [CITY , COUNTRY] which meeting will be attended by a senior official of the respective organization. At that meeting, each side will present its dispute and the senior officials agree to enter into good faith negotiations in an attempt to resolve the dispute. In the event the matter is not resolved, the parties retain all applicable remedies available in law or equity, including arbitration or litigation.</i></p>
<p>Signatures. Authorized officials of the provider and the recipient organizations are usually the ones who sign material transfer agreements. This is also the case in the context of ABS. However, it is important to consider that the acceptability of the material transfer agreement for the purposes of ABS laws and regulations may depend on compliance with other requirements, including consulting stakeholders, securing prior informed consent, or obtaining approval by the competent national authorities (see section on ‘Parties.’)</p>	<p>--</p>