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MODEL CLAUSES FOR MUTUALLY AGREED TERMS ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING

Gerd Winter & Evanson Chege Kamau

SELECTED INSTRUMENTS

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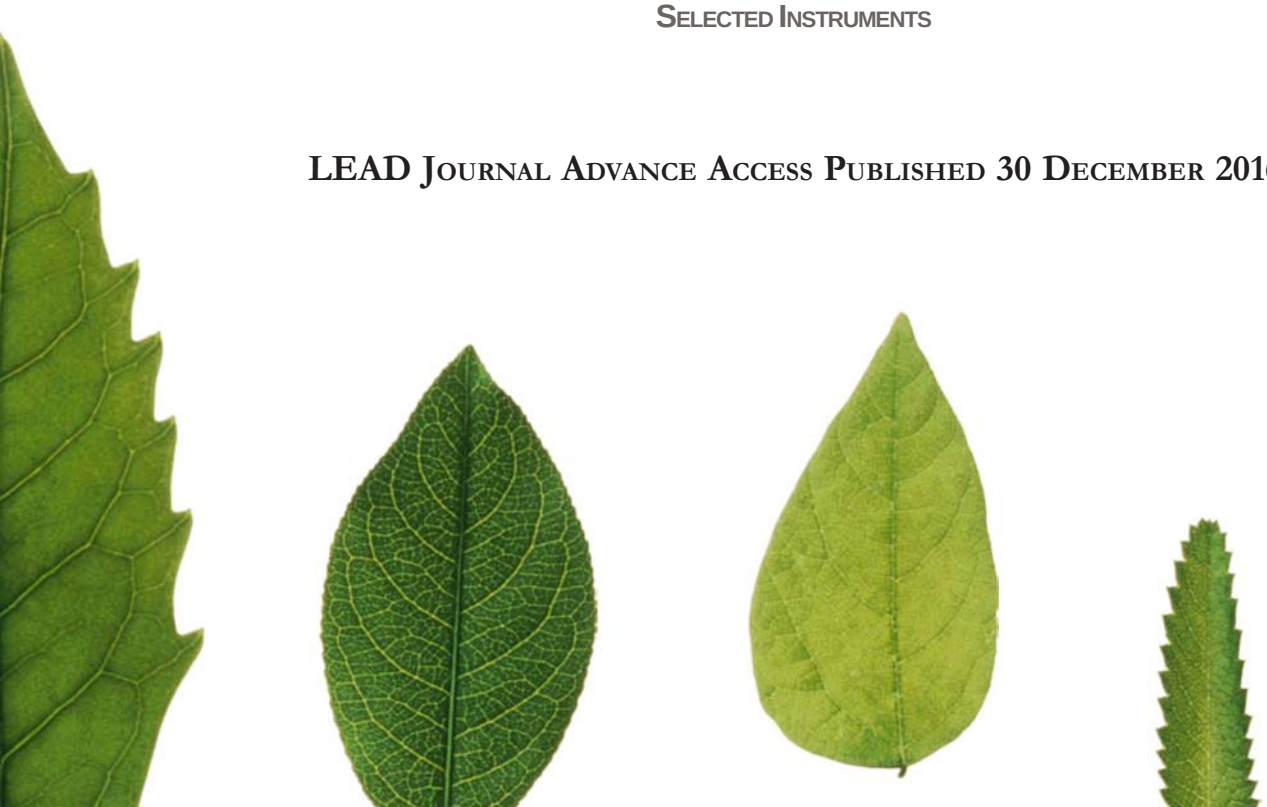

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Selected Instruments

MODEL CLAUSES FOR MUTUALLY AGREED TERMS ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING*

Gerd Winter & Evanson Chege Kamau**

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* The model clauses were elaborated for the German Research Foundation (DFG) and are being processed of the same to become recommended practice.

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INTRODUCTION

These model clauses are meant to serve researchers when negotiating an agreement on access to genetic resources with provider state authorities. At times provider states do not have their own model agreement, or the one they use appears to be over-restrictive or otherwise inappropriate from the user perspective. In such cases these model clauses and their explanations shall furnish the researcher with a tool for negotiating fair and equitable terms. They can also serve as reference if the provider state regulation requires that the partner to the access agreement must be a domestic researcher or research institution.

The model clauses may be used as a source from which some parts may be taken but can also serve as a blueprint for a full fledged agreement.

Although primarily addressed to applicants for funding the model clauses are not written from the perspective of researchers only. They do not take sides with the researcher's interest marking bargaining positions for further negotiation. Rather they are written with an attempt to take the interests of both the provider and user of genetic resources into account and propose fair and equitable solutions. This is done in a mood to build trust between the parties, trust being a most precious good on the way to understanding, conserving and sustainably using biodiversity. It is therefore hoped that the model clauses may even be adopted by provider states as valuable reference.

Of course, an agreement must only be concluded if this is required by the provider state. The researcher will therefore as a first step inquire it the provider state did establish legislation to that effect.

Provider states that have done so will normally require that both an access permit is obtained and an access agreement concluded. The access permit is, under national law, a unilateral administrative act containing the prior informed consent (PIC) (as it is called in the language of international law), whilst the access agreement is a contract containing the mutually agreed terms (MAT) (as called in international law).

PIC and MAT in legal terminology

	unilateral	*bilateral*
International terminology	*Prior informed consent (PIC)*	*Mutually agreed terms (MAT)*
National terminology	*Access permit*	*Access agreement*

In addition to the access permit often further permits are required such as permits for research in general, environmental impact, entrance to protected areas, export, sanitary and phytosanitary concerns etc.. The access agreement may refer to this with a view to integrate procedures, possibly as proposed in model clause 1.2/ 1.3.

If the researcher plans to export the accessed samples and utilize them in his/her home facilities it is most likely and legitimate for the provider state to include related clauses (also called material transfer agreement – MTA – in practice) in the access agreement. This is important because due to the territoriality principle in international law, administrative acts such as the access permit cannot be enforced in a foreign country where the material is used (called 'user country'). In contrast, due to internationally agreed rules on contract law, an access agreement can be brought to court and enforced in foreign jurisdictions.

If the applicant cooperates with a domestic individual or institution the parties will conclude a research cooperation agreement that contains the details of their collaboration. This agreement must not be confounded with the access agreement which is concluded between the researcher and the provider state authority (or an institution empowered to represent the same). The access agreement should only include the essentials of cooperation that the provider state authority finds important to be laid down in a contract of which it is a partner itself.

As an access agreement establishes rights and duties and may trigger enforcement by administrative authorities and courts the model clauses are unavoidably framed in legal language. They should however also be understandable for attentive and experienced scientists. It is nevertheless recommended that a lawyer who is familiar with ABS issues should be consulted before an agreement is signed. Research institutions will need to ensure that appropriate advice is made available.

OPENING CLAUSE

In an attempt to raise certainty the provider is likely to show preference in dealing with a person who is attached to an institution in the user country, or who acts as a representative of such an institution. The reason behind this is because it may become difficult for the provider to trace the whereabouts of an individual once s/he leaves the provider country.

It is advised that as far as possible the recipient affiliates him- or herself to an institution and, prior to

application of a permit of access, be in possession of proof that the institution will host the research and bear the responsibilities and liabilities foreseen in the agreement. Both the responsible researcher and the institution for which s/he works should become contract partners. The involvement of the institution is expected to facilitate the implementation of the contract obligations.

Vice versa, the recipient should ascertain the genuineness of the party acting as a provider in representation of the provider state.

THIS AGREEMENT *is made on this* _____ *[insert number of the day of the month] day of* _____ *[insert the month and the year]*

BETWEEN:

_____

[Insert the names of the provider country authority, the authorized representative and the full contact details]

("the ***Provider****")*

AND:

*(1)*_____

[Insert the name of the recipient institution and its representative and full contact details]

*(2)*_____

[Insert the name of the head researcher and full contact details]

("the ***Recipients****")*

hereinafter referred to as "the **Parties**", and constitutes a contract.

The opening clause contains the names and contacts of the parties to the agreement. In many ABS agreements and in the following the parties are referred to as "provider" and "recipient".

PREAMBULAR CLAUSE

A preamble (at times referred to as recitals) can be described as a statement of facts or assumptions upon which a contract is based. It introduces what the parties have agreed in the substantive part of the agreement. It puts the agreement into context and describes the goals of the agreement. On the other hand, it does not contain any promises. It does not contain any restrictions or commitments and possesses no independent vitality as a source of rights or obligations. Parties may add other recitals if they wish, including concerning themselves, their capacity and their activities. But the preamble could also be removed entirely without disrupting the specific terms of the agreement. However, the preamble can be a useful tool of construing and interpreting ambiguous language of the substantive provisions of the agreement. If included, the preamble should avoid general statements but rather concretely formulate the underlying concerns and motivations, identify the issues addressed in and the actual need for an agreement as well as explain the reasons for its main provisions.

Activities involving access to genetic resources should be consistent with the provisions of the Convention on Biological Diversity, its Nagoya Protocol and other international, regional, national and sub-national laws and policies concerning biodiversity;

States have sovereign rights over their own biological resources and the authority to determine access to genetic resources rests with national governments;

Access to genetic resources and benefit-sharing shall provide an incentive for the conservation and sustainable use of biodiversity;

The conditions of access and their utilization and their possible transfer should be specified;

The benefits arising from the use of genetic resources should be shared fairly and equitably with the country of origin that provided the genetic resources and with other stakeholders, as appropriate;

Access to genetic resources is subject to the prior informed consent of the party providing such genetic resources and to the establishment of mutually agreed terms;

The need to support research that enhances the general knowledge about biodiversity and thereby contributes to the conservation and sustainable use of biodiversity;

Therefore access to genetic resources for non-commercial research and development should be facilitated.

The recitals proposed here put the access agreement into its legal contexts, reiterate its fundamental substantial conditions and give guidance as to the content and common objectives of the agreement.

CLAUSE 1. OBJECTIVE AND REGULATORY CONTEXT OF THE AGREEMENT

1.1 This agreement sets out the terms and conditions that shall apply to the access and utilization of genetic resources in the project titled

_____

1.2 This agreement includes the access permit of the provider state.

Alternative:
1.2 This agreement shall become effective only upon the issuance by the competent provider state authority of the access permit.

(Delete non-applicable paragraph)

1.2. The recipient shall obtain additional permits as required by the law of the provider state. These are, in particular:

_____

1.3 The provider is satisfied that the consents and permits will be obtained in due course.

Alternative 1
1.3 The provider is satisfied that these consents and permits were obtained.

Alternative 2
1.3 The provider institution shall provide or obtain the following consents and permits for the recipient:

_____

Clause 1.1 sets out the general objective of the agreement.

Clause 1.2 clarifies the relationship between MAT and PIC, or the access agreement and the access permit in national terminology. The recipient should find out the practice of the provider state concerning the effect of access agreements. Some countries' law foresees that such an agreement only becomes effective upon the issuance of the access permit by the competent national authority. Whichever the case, the recipient should ensure that s/he has obtained the access permit (or its equivalent) because it is the one that serves as evidence of the decision of the provider to grant prior informed consent and of the establishment of mutually agreed terms (Article 6.3 (e) NP). If notified to the ABS Clearing-House, it shall constitute an internationally recognised certificate of compliance (Article 17.2) hence evidence that the genetic resource which it covers has been accessed in accordance with the prior informed consent and that mutually agreed terms have been established as required by the domestic legislation or regulatory requirements of the provider (Article 17.3 NP).

The further paragraphs place the agreement in context with other consents and permits the recipient may have to obtain. Such other consents and permits may concern nature and environmental protection, general research oversight, international trade, phytosanitary requirements, etc. The parties can agree that the recipient must obtain them before the agreement is signed, or that they shall be obtained later on. They can also agree that the provider is prepared to provide them or secure them for the recipient.

Of particular importance are consents and permits for access to genetic resources belonging to indigenous communities. In such cases, and of course depending on the procedure established by domestic law, a representative of such communities may have to be asked to sign.

CLAUSE 2. DEFINITIONS

It is strongly advised that access agreements adopt the terminology of the relevant international instruments, and in particular the Convention on Biological Diversity and the Nagoya Protocol. However, it is not always that internationally agreed definitions exist for certain terms, such as "access" and "non-commercial"/ "commercial". Even if they do, parties may want to give the term a different meaning for the specific purpose of their agreement. In such circumstances parties should be free to create or vary the definition for the term with the understanding, of course, that the validity of such a definition is limited to the parties' agreement. Differences between terms used in

international law (such as "PIC") and corresponding terms under domestic law (such as "permit") should also be taken into account.

As used in this agreement, the following terms shall have the meaning provided below.

"Access" *means collecting genetic resources from the location where they are found in situ or ex situ, or acquiring them at the market or other places.*

"Accessed genetic resources" *means the genetic resources accessed on the basis of this agreement.*

"Access permit" *means a written authorization issued by the authority of a provider country that allows a person to access genetic resources under certain conditions.*

"Genetic resources" *under Art ...means any material of plant, animal, microbial or other origin containing functional units of heredity and having actual or potential value.*

"Derivative" *means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.*

"Prior informed consent" *in the line of Art. 6 NP means consent given by a provider state authority (competent national authority) to access genetic resources based on advance information provided by the user.*

"Utilization of genetic resources" *means research and/or development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.*

"Biotechnology" *means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.*

"Utilization for commercial purposes" *for the purposes of this agreement means research and development that aims at producing marketable associated knowledge, including products and processes developed, and bringing it to the market, be it through intellectual property rights or sales or otherwise, at more than incremental cost for dissemination.*

"Utilization for non-commercial purposes" *means research and development that aims at enhancing the knowledge about the accessed genetic resource including products and processes developed therefrom, and making such knowledge publicly available and usable at no more than incremental cost for dissemination.*

"Third party" *means any person other than the recipient and the provider. Partners collaborating in a research project and employees of the provider or recipient are not regarded as third parties.*

"Trusted collection" *means a set of collected samples of genetic resources and related information accumulated and stored by public or private entities that is registered according to Article 5 Regulation (EU) 511/2014 and open for public use.*

The definition of "utilization of genetic resources" can only be well understood if its definition in Article 2 (c) NP and the definition of "biotechnology" in Article 2 (d) NP are read together. According to Article 2 (c) NP, utilization means research and development. In other words, applied research and development of products or processes is implied in the term utilization. This is also indicated by the definition of biotechnology which includes the making or modifying of products and processes. Not included in the term is, however, the commercialization of developed products (cf. Article 5 NP).

The distinction between commercial and non-commercial purposes and their definitions need further explanation. It is indispensable because different procedures and obligations can and should be attached to them, such as the simplification of access and the right and obligation to publish research results. One may use a substantive criterion that distinguishes between basic research and applied research/development of products. However, results from basic research (such as genes and their function) may at an early stage of research be patented or synthesized and/or traded on the market. Alternatively, an institutional criterion may be chosen by asking whether the research institution belongs to the public or private sector. But public research institutions are not necessarily confined to non-commercial research while private ones may sometimes work for the public domain.

For the present model clause it is suggested that the intention of the researcher and developer best distinguishes the two realms from each other: A

commercial intention would be that the knowledge and derived products and processes shall be marketable and be brought to the market. By contrast, a non-commercial intention would be that the knowledge, products and processes – be they marketable or not – shall be made publicly accessible and usable at not more than incremental costs thus feeding and enhancing the public domain. By incremental costs it is understood that the costs of publication of knowledge may be charged to the users, but not the market value of the knowledge.

CLAUSE 3. SCIENTIFIC COLLABORATION AND CAPACITY BUILDING

Scientific collaboration and capacity building is possibly the most seminal kind of sharing benefits from R&D on genetic resources. Some model agreements list them as one of many other kinds of shared benefits. This is perfectly in order. Alternatively, like in the present model clause, they can be introduced as a separate clause and be placed at a prominent place at the start of the substantial provisions. This is especially advisable if a provider state requires scientific cooperation and capacity building is a basic precondition, and not only as a corollary of access.

The clause can of course be deleted ort ignored if the provider state and the researcher agree that the genetic resource shall exclusively be utilized by the researcher.

3.1 The recipient shall collaborate with institutions and persons from the provider state when planning and implementing the project that is the subject of this agreement. Such collaboration shall basically take the following forms the details of which will be agreed on in a separate cooperation contract:

Involvement of local researchers in the projected R&D activities

_____

Education and training for R&D

_____

Provision of equipment for R&D and training of its use

_____

Research funding and other support for local research institution(s) to conduct research on species collected as samples or the ecosystem from which they were collected

_____

Others

_____

(Parts or all forms of collaboration and capacity building to be deleted if no specification is required)

Alternative:
3.1 The recipient shall collaborate with the provider state's institutions and experts when planning and implementing the project that is the subject of this agreement. The forms and details of the collaboration and/or capacity building shall be agreed upon by the parties in a separate cooperation agreement.

(The entire article 3 may be deleted if no collaboration and/or capacity building is foreseen)

Clause 3.1 determines the involvement of provider state researchers in the research and development activities, and other forms of collaboration and capacity building. Details of the collaboration are normally laid down in a separate research/collaboration agreement between the researchers on the provider and user state side. The basics may however also be included in the access agreement in order to enable the provider to enforce the provisions on a contractual basis.

If the project does not involve collaboration with provider state researchers the clause will be deleted.

CLAUSE 4. ACCESS TO GENETIC RESOURCES

When negotiating access conditions provider and user interests may differ at the outset. The provider state may aim at narrowing down the kinds, volume and location of genetic resources that shall be accessed but is at a risk that the researcher may try what is called forum shopping, i.e. to approach another state with more generous access conditions. Vice versa, the researcher will normally be interested in as free as possible a margin of acquisition but is at a risk to arouse mistrust on the provider side. The solution offered here is to leave the specification to the negotiations of the parties. It includes, as one important element of building compromise, to allow for stepwise specification.

4.1 The recipient is permitted to access genetic resources as follows:

(a) Kinds of samples, including the kind of genetic resources, if known:

_____
_____

(b) Number and quantity of samples:

_____
_____

(c) Geographical location of collection:

_____
_____

(d) Time period for collection:

_____
_____

(The details may be laid down in an annex to the agreement)

4.2 The recipient shall within …… [time period to be specified by the parties] after collection of the samples notify the provider the kinds of genetic resources which the recipient intends to utilize. The provider may within ……. weeks [to be specified] raise objections in which case the parties will seek agreement on the kinds of genetic resources that the recipient is allowed to utilize.

Alternative:
4.2 The recipient shall notify the provider within a reasonable time after collection of the samples the kinds of genetic resources which the recipient intends to utilize.

4.3 The costs for accessing the genetic resources shall be borne by the recipient.

The provider may consent to a rough description of the genetic resources but may require the recipient to give a precise definition of the kind and number of specimens to be accessed and utilized *ex ante*. Such a detailed description can be annexed to the agreement. If this is not possible (for instance because the sample must first be screened), it is advisable for the applicant to seek for the inclusion of a clause (such as paragraph 4.2) allowing for *ex post* submission of such information and, upon mutual agreement with the provider, defining a reasonable timeline to do that. To be on the safe side vis-à-vis timelines the applicant may preferably want to have the alternative formulation of paragraph 4.2 inserted to win more time than the provider may allow if this is specified.

The provider may be more willing to agree to a less broad description of the sample if internal researchers participate in the research project.

CLAUSE 5. MOVEMENT AND DEPOSIT OF THE ACCESSED GENETIC RESOURCES

While provider states sometimes prefer that the Genetic Resources are utilized within their territory it is normally in the interest of the researcher to be able to conduct R and/or D in his home facilities. When negotiating this issue parties should be guided by concerns how best R and/or D results can be achieved keeping in mind that local researchers may wish to be substantially be involved.

5.1 The recipient is permitted to move the accessed genetic resources abroad to his/her facilities and to the facilities of collaborators declared in accordance with Clause 7.2 of this agreement.

Alternative 1
5.1 The recipient is permitted to utilize the genetic resources accessed only in the provider state.

Alternative 2:
5.1 The recipient will perform the following R&D activities in the provider state:

_____

(delete what is not applicable)

5.2 The recipient shall deposit a sample of the accessed materials with a local collaborating institution.

5.3 The recipient shall deposit a sample of the accessed genetic resources with a local repository.

(to be deleted if the provider does not require the recipient to deposit samples)

Clause 5 opens up alternatives how to deal with the question of transfer of the accessed GR to the researcher's home country. If the transfer is agreed the relevant clause constitutes what is often termed the material transfer agreement (MTA). This MTA is only concerned with moving the sample geographically. It does not already allow for the transfer of the material to third parties (see further on this matter Clause 7).Clause 5 also addresses the question whether a sample of the accessed material shall be deposited with the collaborating institution – which will be the case if a research collaboration is foreseen – and/or with a local repository if such exists in the provider state. See further Clause 8 concerning the deposit in collections at a later stage of utilization.

CLAUSE 6. UTILIZATION OF THE ACCESSED GENETIC RESOURCES

The researcher will be interested to be entitled to unlimited R&D. This corresponds to the general interest of mankind, including also of the provider state, in increasing the general knowledge about biological diversity. On the other side, the provider state will wish to ensure that it receives a share of the benefits – non-commercial as well as commercial ones – possibly drawn from the genetic resources. One way to ensure this is to limit the kinds of allowed utilization of the accessed genetic resources. Although such control over the utilization is not mentioned in the NP it is implied in the powers of regulating access. Given this situation it is up to the parties to negotiate a mutually agreeable solution. It is submitted that the recipient should be given unlimited leeway for non-commercial R&D, but that conditions should be agreed concerning commercial intentions. However, the parties may also agree that R&D shall be unlimited including also commercial intentions. This can be of interest for the provider state in case of well designed R&D cooperation.

6.1 The recipient is permitted to conduct any kind of research and development on the accessed genetic resources, including also educational activities, notwithstanding a non-commercial or commercial intent.

Alternative 1:
6.1 The recipient is permitted to conduct any research and development on the accessed genetic resources, including educational activities, but for non-commercial purposes only.

Alternative 2:
6.1 The recipient is permitted to conduct the following R&D on the accessed genetic resources, including educational activities, for non-commercial purposes:

_____

(delete the non-applicable option)

6.2 The recipient shall without delay inform and in good faith renegotiate this agreement with the provider if the intent of the agreed purpose changes from non-commercial to commercial.

6.3 The recipient is permitted to conduct research and development of the accessed genetic resources for commercial purposes:

Specifications, if deemed necessary(e.g. application for patenting):

_____
(delete if not applicable)

The sovereign rights of provider states to regulate access to their genetic resources imply that the provider somehow determines the allowed research and development (or utilization in terms of the NP and this agreement). Of course it is a matter of negotiations to what extent the agreement leaves broad space or narrows it down. Following Article 8 (a) NP provider states shall facilitate the utilization by allowing for a broad margin of research and development activities if the research and development is aimed at non-commercial purposes. The parties may however also agree that the utilization shall enable commercial intentions, such as, for instance, the application for the patenting of some research or development results. A third option is that the original non-commercial intention later on changes into commercial, in which case the agreement must be renegotiated. Clause 6 opens these options up.

Clause 6 does not propose any timeline for the envisaged utilization. Given the unpredictability of strict timing of R and/or D any determination would be prone to frequent additional negotiation and adaptation of the agreement.

CLAUSE 7. TRANSFER OF MATERIAL AND KNOWLEDGE TO THIRD PARTIES AND COLLABORATORS

The transfer of material and related information to individual third persons and to the public at large should be distinguished. The first case is part of common exchange and interaction in the course of R&D activities, the latter is concerned with the publication of the research results. The first case is addressed in Clauses 7 and 9, the latter in Clause 10. The recipient will be interested to be free to transfer the material and the research results according to his/her intentions and need while the provider may wish to control this process in order to avoid that the material and knowledge is used for purposes for wish it did not give its consent. Clause 7 suggests a solution that concedes the recipient room to manoeuvre and sees to that the third person is nevertheless bound to the conditions of the provider's consent.

7.1 The recipient may transfer to a third party the accessed GR or parts thereof, provided that the third party shall be bound by the pertinent provisions of this agreement. The recipient shall notify such transfer to the provider.

Alternative:
7.1 The recipient shall not transfer the accessed genetic resources or parts thereof to any third party save with the written prior informed consent of the provider.

(delete the option not adopted)

7.2 The provider permits the recipient to transfer the accessed genetic resources or parts thereof to collaborating researchers for the purposes of joint research and/or development on the same.

List the collaborating researchers if required
_____

7.3 The recipient shall be held accountable for any actions of collaborating scientists in violation of the pertinent provisions of this agreement.

(delete if not applicable)

7.4 Paragraphs 7.1 to 7.3 apply accordingly to the transfer to third parties or collaborating researchers of results of R&D on the accessed genetic resources.

Clause 7 describes the conditions under which the recipient is allowed to transfer the accessed genetic resources to third parties. Paragraph 7.1 introduces the so called "viral licence clause" for such transfers. The viral licence concept means that the originally signed contract provisions between the provider and the recipient travel with the genetic material upon transfer to a third recipient and subsequent recipients: that is to say, the subsequent recipients are bound by the same obligations that were imposed on the (first) recipient. The provider is therefore reassured that the conditions which were agreed by the parties will be respected further down in the transfer chain. This is an important clause given that, usually, provider states' legislation tends not to facilitate access to genetic resources for research purposes due to legal uncertainty regarding the transfer to third parties and the treatment of materials and knowledge produced from them by researchers.

As an alternative the provider may insist that any transfer to third persons shall be subject to its explicit consent (alternative 1, Clause 7.1). Of course, such a clause complicates the research process and should be avoided if possible.

Partners to the research project can be treated differently from third parties thus facilitating the transfer of the accessed genetic resources among the project participants. In this case the recipient as lead researcher takes responsibility that the pertinent provisions of the agreement are respected by partners without them becoming formal parties to the agreement (Clause 7.2 and 7.3).

Clause 7.4 extends the viral clause and the responsibility of the recipient to the transfer of knowledge that has been generated in the course of the research and development process. This extension may raise controversy. An argument against would be that the Nagoya Protocol rejected claims of provider states in intellectual property of the information contained in their genetic resources. However, provider states may use their acknowledged rights to the genetic material to allow access only under the condition that they can

influence the flow of knowledge produced on their genetic resources. Clause 7.4 follows this line, as does Clause 11.2 concerning the publication of research results based on accessed genetic resources.

CLAUSE 8. RECORD KEEPING AND REPORTING

The provider will wish to be informed about the progress of utilization of the accessed GR whilst the recipient may regard this as an additional bureaucratic burden. It is up to the negotiations to find a viable compromise.

8.1 The recipient shall maintain records concerning the handling, storage and physical movement of the samples and be prepared to provide such records to the provider if requested.

Add time period for storage of records

_____

8.2 The recipient shall furnish the provider, or the authority or person designated by the same, with reports detailing the progress of the utilization and any occurring commercialization. The time of furnishing shall be every ___ (months, years) starting with _____ (date). The designated authority or person shall be

_____.

(delete paragraph if not pertinent or parts/sections that do not apply)

Clause 8 determines which records should be kept, how research progress should be documented and reports thereto submitted to the provider. Concerning the reporting duties claused 8.2 provides the possibility that the addressee of the reports shall be the domestic researcher or research institution rather than the state authority.

CLAUSE 9. BENEFIT SHARING THROUGH THE SHARING OF R&D RESULTS

The provider state may wish to have access to the results of R&D on the accessed genetic resources even if the R&D is not imbedded in a close R&D collaboration, and even if the R&D results shall be published later on. Privileged access of this kind may be searched for as one way of sharing non-commercial benefits, or as a means to check whether parts of the knowledge are suited to be commercialized. Access to the R&D results can be enabled by reporting duties of the recipient, as suggested in Clause 9.

9.1 The recipient shall furnish the provider, or the authority or person designated by the same, with the results of the R&D on the accessed genetic resources and provide assistance in their assessment or interpretation as reasonably requested.

9.2 The R&D results shall be furnished ___ (weeks, months) prior to publication. The provider shall ensure that the knowledge remains undisclosed to third parties until the recipient publishes them as allowed and required under Clause 12.

9.3 The recipient shall furnish the provider or the authority or person designated by the same with a copy, scan or freely accessible electronic link of any publication based on the utilization of the accessed genetic resources.

_____
(insert name and address of authority or person if applicable)

9.4 Clauses 9.1 to 9.2 shall apply to results from R&D agreed for non-commercial and commercial purposes.

Alternative:
9.3 Clauses 9.1 to 9.2 shall apply to results from R&D agreed for non-commercial purposes only.

Clause 9 grants the provider privileged access to the results and is offered further explanation. This can be promised to be done even before publication of the results. In that case the results must be kept confidential by the provider in order not to hinder their publication. Alternatively the provider may agree that the recipient only informs the provider once the results have been published.

Clause 9.4 determines whether R&D results shall be furnished if obtained from non-commercial and commercial, or only from non-commercial R&D.

CLAUSE 10. BENEFIT SHARING THROUGH INDICATION OF ORIGIN AND JOINT PUBLICATION OF R&D RESULTS

Clause 10 shall ensure that the origin of the genetic resource is made known and the contribution of scientists from the provider state is acknowledged.

10.1 The recipient shall indicate in any publication of R&D results the provider country as the source of the genetic resources, including, if existent, the date or registration number of the access permit and/or agreement.

10.2 The recipient shall acknowledge in any publication of R&D results the role of local scientists, and, where such scientists substantially contributed to the result, their (co)authorship.

The indication of origin and acknowledgment of collaboration is anyway frequent practice in R and/or D communities but is reinforced by being made a clause of the agreement.

CLAUSE 11. BENEFIT SHARING THROUGH STORAGE OF ACCESSED GENETIC RESOURCES

Towards the end of the R&D project the recipient may wish to store the genetic resources and related information in an appropriate collection. The provider state may, as any other state, have access to the collection and thus have a share in the benefit of storage in a publicly accessible collection. But it may wish to allow the storage only if the collection has practices in place that ensure that the information about the origin of the genetic resources as well as any conditions of the access agreement are respected. Clause 10 suggests a viable solution in that situation.

11.1 The recipient is entitled to deposit the genetic resources including taxonomic information in trusted collections.

11.2 The recipient is liable to inform the collection of the origin of the genetic resource and of any conditions of utilization laid down in this agreement.

Clause 11 allows to store material and related knowledge in collections but the collection must be trustworthy to abide by the access conditions of the provider state. This is ensured if the collection is registered and supervised according to Article 5 Regulation (EU) 511/2014.The recipient is liable to inform the collection accordingly.

CLAUSE 12. BENEFIT SHARING THROUGH PUBLICATION OF R&D RESULTS

The provider will, like any other institution or person, have access to the public domain of knowledge on genetic resources, including publicly accessible data bases and other publication media. By consenting that the R&D results are published the provider at the same time contributes to the enhancement of the public domain thereby providing a service for the global public. This is very much in line with the numerous provisions of the CBD that aim at the generation and exchange of information for the sake of the conservation and sustainable use of biodiversity, such as, e.g., Article 17 CBD. If the parties agree that insofar as the knowledge is commercializable or may be further utilized for commercial purposes the provider may want to prevent users of the knowledge from doing this without its prior consent. Clause 12 offers a solution taking also into account that publication media such as data bases may not (yet) provide the possibility of tracing knowledge to provider states and their access conditions. The clause also covers

12.1 Insofar as according to Clause 6.1 the utilization of the accessed genetic resources is not restricted in terms of non-commercial or commercial intention the recipient has discretion to decide whether, how and when to publish the results of R&D on the accessed genetic resources.

Alternative:
12.1 Insofar as according to Clause 6.1 Alternatives 1 or 2 the utilization is aimed at non-commercial purposes only the recipient is obliged to publish the R&D results.

12.2 In the case of Clause 12.1 Alternative the recipient shall use an appropriate earmark providing that the R&D results shall not be used for commercial purposes unless the

prior informed consent of the provider has been sought. The recipient shall make reasonable efforts to this effect if such earmarking is not offered by a public data base or other publication medium.

(to be deleted if parties agree not to restrict the use of public domain knowledge)

12.3 The provider shall not hold the recipient accountable for any actions committed by third parties who utilize any R&D results that have been published or disclosed according to paragraph 10.1 Alternative and 10.2.

12.4 The obligations under Clauses 12.1 -12.2 shall not prejudice any rights of the recipient resulting from renegotiation of this agreement permitting him/her to utilize accessed genetic resources for commercial purposes.

By this clause parties will fix terms on the publication of R&D results. The publication is up to the recipient's decision if no restriction as to non-commercial or commercial intent was agreed. If the parties agree on utilization for non-commercial purposes only this entails an obligation of the recipient to publish the results and of the provider to accept this.

However, the provider may wish to benefit from eventual commercial uses by third parties of the published knowledge. In that case the provider may wish to oblige the recipient to earmark the knowledge in its publication that any commercial utilization requires its prior consent.

Of course this comes with new challenges not only for the recipients, but also for databases. As some of them may not be willing to let the restriction travel with the data, the agreement opens up the possibility that either the recipient's burden is reduced to a due diligence duty (Clause 12.2, 2nd sentence).

Such somewhat limited duty entails that the recipient is freed from liability for unlawful utilization by their parties of the published R&D results (Clause 12.3).

Clause 12.4 maintains the recipient's right to come back to the provider for renegotiation of terms.

CLAUSE 13. PERMITTED COMMERCIALIZATION

Insofar as utilization for commercial purposes was agreed between the parties it is still to be determined what kinds of commercial gain shall be allowed. The provider may be interested to narrow down the range of commercialization while the latter will wish to have a margin of discretion. Clause 13 attempts to enable amicable solutions. The determination of what kinds of commercialization shall be allowed is also a precondition for an appropriate sharing of commercial benefits, which is addressed in Clause 14. As commercialisation normally requires that the knowledge is not previously publicly available provisions on confidentiality also need to be laid down.

13.1 Insofar as according to Clause 6.2 or 6.3 the recipient was agreed to utilize the accessed genetic resources for commercial purposes s/he is free to choose any kind of commercialization. The provider must be kept informed according to Clause 8.2.

Alternative 1:
13.1 The recipient may commercialize R&D results in the following ways:

_____

Specify as agreed, e.g. application for patenting, sales of bioparts, sales of bioinformation

Alternative2:
13.1 The recipient may commercialize R&D results only upon prior consent of the provider.

13.2 Insofar as according to Clause 6.2 or 6.3 the recipient was agreed to utilize the accessed genetic resources for commercial purposes the recipient is entitled to keep the R&D results confidential.

13.3 The recipient is at any time entitled to publish results from R&D that was agreed to be conducted for commercial purposes.

Alternative
13.3 The recipient is only with the consent of the provider entitled to publish results from R&D that was agreed to be conducted for commercial purposes.

13.4 The obligation of sharing benefits according to Clauses 9 and 10 remain applicable in any case of Clauses 13.1 to 13.3.

Clause 13.1 offers alternatives as to the range of commercialization the recipient may undertake.While it will be common practice that the recipient who aims at commercialization keeps R and/or D results secret Clause 13.2 stipulates this as his/her right.

However, the parties may also agree that R and/or D results can be published even in a context of commercialization. Clause 13.3 offers alternative in that regard.

Clause 13.4 ensures that agreed commercialization does not waive the obligations under Clauses 9 and 10 to share R and/or D results, indicate origins and acknowledge contributions of local scientists.

CLAUSE 14. SHARING OF COMMERCIAL BENEFITS

Clause 14 determines the sharing of benefits in cases of commercial utilization of the accessed genetic resources. It covers those forms of proprietary utilization that were agreed upon between the Parties according to Clauses 6.2 and 6.3, and also forms of proprietary utilization that were not agreed and undertaken in breach of Article 6.1.

14.1 Any application for obtaining intellectual property rights for R&D results shall be filed jointly with the provider or an institution or person named by the provider.

Alternative
14.1 The recipient is entitled to apply for obtaining any intellectual property right notwithstanding the obligation to share monetary revenue according to Clause 14.3.

14.2 The recipient agrees to pay an up-front compensation of ___ (amount to be specified) to the provider, if the recipient utilizes the accessed genetic resources for commercial purposes. The payment is due to the provider within — months (term to be specified) after consent on the kinds of genetic resources to be utilized has been reached under Article 6.2 or 6.3. The payment shall be transferred to the following account of the provider:

_____
(This clause is to be crossed out if not applicable)

14.3 The recipient shall share with the provider in a fair and equitable way any monetary benefits obtained from the utilization of the accessed genetic resources according to Article 6.2 or 6.3, or related R&D results, for commercial purposes.

14.4 The share shall be determined by further negotiations between the Parties to this agreement.

Alternative:
14.4 The share shall be _____ percent of the revenue from sales of the product or process based on the accessed genetic resources. It shall be paid on the basis of a financial report to be sent to the provider or an authority designated by the same at the end of any year of any revenue generation to the account designated by the same.

_____
(Insert authority and account details if applicable)

14.5 If the recipient utilizes the accessed genetic resources or utilizes the associated genetic knowledge for commercial purposes without being entitled according to Clauses 6.2 or 6.3, and therefore in breach of the conditions of this agreement, he or she must share with the provider any monetary benefit obtained from such utilization or use. The share shall be _____ per cent of the revenue from sales of the product or process based on the accessed genetic resources. It shall be paid on the basis of a financial report to be sent to the provider or an authority designated by the same in due time upon request by the same.

_____
(Insert authority and account details if applicable)

(This entire Clause or some of its paragraphs can be crossed out if not applicable)

In cases of utilization of the accessed GR for commercial purposes, the recipient has to share with the provider in a fair and equitable way any monetary

benefits obtained therefrom. Clause 14.2 foresees the possibility of an up-front payment. It is suggested that such payment shall preferably not be agreed because at the negotiation stage of the agreement, the economic value of the genetic resources is unknown.

While this clause may therefore be crossed out, it is compulsory to regulate an ex post compensation. The Parties may either decide to determine a posteriori the share of benefits by further negotiation (14.4) or to determine a priori the share (in percentage) of the revenue from the sales of the products or processes based on the accessed GR (14.4 Alternative). This clause thus establishes the possibility for an ex ante compensatory liability scheme.

Clause 14.5 goes further imposing on the recipient the share of monetary benefits in cases where proprietary utilization of the accessed GR has been undertaken with no prior informed consent of the provider (if this would be required according to the provider's legislation), in breach of the agreement. For such cases of breach the Parties are required to define a priori the percentage of the share.

CLAUSE 15. OTHER LAWS TO BE RESPECTED

The Article brings attention to the recipient about the fact that in the course of sampling, utilizing, and moving of the genetic resources s/he might be confronted with certain domestic legal requirements protecting different public interests such as human health, the environment, or fiscal concerns.

15.1 The recipient shall ensure that the collection, storage, transfer, utilization, and exportation of the genetic resources complies with all applicable laws of the provider State on the protection of human health and the environment, on taxes, on customs and on any other concern.

15.2 The recipient shall, if it has been established that the access caused or is likely to cause adverse impact on any species or population, or any ecosystem or ecological community, discontinue collection and removal of the materials and, at his or her cost, undertake measures to remedy, mitigate or hinder such impact in accordance as required by the pertinent provider state's legislation.

CLAUSE 16. LIABILITY TO PREVENT AND COMPENSATE DAMAGE

It may occur that damage is caused by the recipient to third persons while utilizing the accessed GR, such as, for instance, when applying biotechnology. In that case the recipient should be liable to compensate and free the provider from any own liability. Damage may however also be caused among the parties to the contract from violation of contracted duties, such as, for instance, if the provider delays the procedures or the recipient fails to report or share research results. The model clauses do not establish rules on damage compensation because this would be hard to negotiate and only create mistrust between the parties. Instead, Clause 16.2 ascertains that the two parties shall take their duties seriously. Anyway, Clause 17.2 provides the possibility of termination of the agreement. In addition, the national liability regimes of the provider and user state may be invoked in outstanding cases.

16.1 The recipient indemnifies the provider against all liability and damage to third persons resulting from taking, using and disposing of the materials by the recipient.

16.2 The provider and recipient oblige themselves to honour their obligations under this agreement and any other duty that is relevant for the realization of this agreement in such a manner that does not result to delay, loss or any other inconvenience for the other party.

Clause 16 establishes that the provider is indemnified against claims of third parties resulting from the utilization by the recipient of the accessed GR. In addition, the mutual obligation to act bona fide in implementing the agreement is established without however providing for a specific liability scheme.

CLAUSE 17. TIME AND TERMINATION OF AGREEMENT

As the access agreement is concerned with a R and/or D project a date of termination should be agreed allowing for flexibility according to the project progress. Provisions are also needed on the termination upon the violation of the agreement.

17.1 This agreement shall be in effect for a duration of _____ [insert the number of years of the agreement's validity] years from the date of its execution [and would be automatically renewable for a further _____ [insert the number of years of automatic renewal] years, unless otherwise agreed to by the parties.

17.2 This agreement may be terminated by either party at any time subject to a prior written notice of _____ [insert the duration] to the other party, for material breach of the agreement, or if either party, subject to a a similar prior notice, informs the other party of its intent to terminate the agreement.

17.3 The obligations and rights contained in Articles .....shall survive the expiration or other termination of this agreement.

17.4 The recipient shall not assign any of the recipient's rights under this agreement to any person upon termination of this agreement.

Termination provisions define how the contract may come to an end. The contract may expire naturally or through premature termination by either party. The provisions also determine what happens to the parties' rights after the contract has expired.

CLAUSE 18. DISPUTE RESOLUTION

Different views may arise between the parties concerning the interpretation and implementation of provisions of the access agreement. In such cases a dispute resolution mechanism should available to solve the issue. Clause 18 aims at a stepwise procedure ranging from informal to more formal procedures.

18.1 No party shall, in case of a dispute arising from this agreement, commence court or arbitration proceedings (except proceedings for urgent interlocutory relief) other than in full compliance of this Article.

18.2 A party to this agreement claiming that a dispute has arisen under or in relation to this agreement must serve the other party with a written notice specifying the nature of the dispute on receipt of which the dispute resolution shall forthwith begin.

18.3 Any dispute arising from this agreement shall be resolved expeditiously foremost by negotiation in good faith failure to which the parties shall engage informal dispute resolution techniques.

18.4 If the dispute is not resolved by negotiation within _____ [insert the duration] [days] from the day of receipt of the notice by the party therewith served, the parties shall choose dispute resolution by a neutral third party arbitrator, to be mutually agreed. If no agreement can be reached within 6 months the parties shall ask the ABS Clearing House under Article 14 NP to nominate a person. That person shall be regarded as agreed arbitrator.

18.5 The arbitrator shall determine the procedure for arbitration. The decision of the arbitrator shall be final and binding.

According to Clause 18 dispute resolution shall proceed in the following steps:

- Written notice
- Negotiation
- Arbitration
- Court proceedings

CLAUSE 19. LEGAL CLAUSES

Clause 19 contains formalities that shall be observed in order to ensure legal certainty. They range from how to serve a notice via a good faith clause to the determination of the applicable national legal order.

19.1 Any notice under this agreement may be served by hand delivery or by forwarding by prepaid post, return receipt requested, to the address of the party or to such other address as may be notified in writing by the party from time to time and in the case of service by post it shall be deemed to have been received upon receipt. Notices may be served by recognized overnight courier, facsimile transmission, fax or e-mail and are valid if in fact received, as demonstrated by a valid transmission report or notification of delivery.

19.2 This agreement constitutes the entire agreement between the parties relating to the subject matter. The parties do not make any representations or warranties except those contained in this agreement.

19.3 If any provision of this agreement, or any part thereof, is unenforceable or invalid for any reason, the relevant provision or part will be deemed to be modified to the extent necessary to remedy such unenforceability or invalidity or, if this is not

possible, then such provision or part will be deleted from this agreement, without affecting the enforceability or validity of any other provision of this agreement.

19.4 Any matters not stipulated in this agreement or/and clarifications in connection with the interpretation or execution thereof shall be discussed by the parties in good faith in search of a reasonable and amicable solution.

19.5 This agreement may not be extended, cancelled or amended otherwise other than by a written agreement signed by the parties.

19.6 This agreement shall be construed and enforced in accordance with and governed by the laws and regulations of _____ [insert the country having jurisdiction], without regard to its conflict of law principles.

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