

Micro B3 Model Agreement on Access to Marine Microorganisms and Benefit-Sharing

Commentary

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Objectives and Legal Background of the Model Agreement

The Micro B3 Project, together with the Ocean Sampling Day Initiative, aims at studying marine microorganisms in different seas (their genetic diversity, their functions and their ecosystems), at producing genomics sequencing to be shared in an open source and open access database, and at fostering commercial product development. More specifically, Micro B3 offers improved tools to achieve facilitated access to the research results, including genomic and environmental data, and to integrate data of different marine scientific projects, through an innovative and interactive informatics system. Further, the project offers tools for specific capacity building to the research community.

As planned research is based on the taking of samples within internal waters, the territorial sea and the exclusive economic zone of coastal states, the Convention on Biological Diversity (CBD) applies. According to the CBD the coastal state may, by its national legislation, require its prior consent to the taking and utilization of its genetic resources and ask for the sharing of benefits drawn from the genetic resources. These requirements have been specified by the Nagoya Protocol (NP) that however is not yet in force. The conditions of access and benefit-sharing (ABS) are normally determined through a contract concluded between a research institution and the coastal state. This Micro B3 Model Agreement on ABS (hereinafter: Model Agreement) shall be a template for such contract. It is recommended that Micro B3 partners use this Model Agreement, unless the coastal state insists in the use of its own template. However, neither prior consent nor benefit-sharing is required if the Provider State does not make use of its sovereign rights under the CBD and the NP. The Provider State is free to decide not to establish an ABS regime and thus allowing for free research and development activities concerning its genetic resources. In this case the Model Agreement does not apply.

Whether a Provider State has established an ABS regime or not, can only be determined by examining its domestic legislation and practices. According to upcoming rules of user states a due diligence obligation applies in such cases. This means that the researcher has to take due care to find out the domestic procedure of the Provider State, if any exists. He/she is not required to carry out an in-depth legal analysis. Rather, it is sufficient diligence if he/she seeks advice at the National Focal Point on ABS of the Provider State. The latter is bound to notify to the CBD Secretariat under Article 4 NP. A list of National Focal Points is available at the CBD website (www.cbd.int).

Through minor changes in the text the Model Agreement can also be used for other projects such as projects on genetic resources other than marine microorganisms. The aim of the Model Agreement is thus to serve as model contractual clauses for mutually agreed terms according to Article 19 of the Nagoya Protocol. In this way it hopefully assists in a worldwide harmonization of procedures for access and benefit-sharing in international collaboration frameworks for genomics research.

Non-Commercial and Commercial Options within the Model Agreement

The Model Agreement applies to full commercial, hybrid and full non-commercial use at the point of access. This agreement can cover three situations:

- (A) PUBLIC DOMAIN: only public domain uses of genetic resources are envisioned when the resource is accessed. Therefore, only conditions for public domain uses are negotiated at the moment of first access (Article 4.2.). If desired, commercial uses can be envisioned at a later stage of the research process. Such commercial uses are permitted, but the conditions of this should be negotiated at the point of change of intent (consent clause under Article 4.4).
- (B) HYBRID: public domain uses of some genetic resources/some use of genetic resources are envisioned at the time of access together with some potential commercial uses for other genetic resources/other uses of the accessed genetic resource.
- (C) PROPRIETARY: commercial uses for all the accessed genetic resources are envisioned. Benefit-sharing conditions for commercial uses are to be negotiated upon the access to the genetic resources. In this case only Article 4.3 applies (Articles 4.2, 4.4 are to be deleted).

Mutual Benefits for the Provider and User from the Model Agreement

By signing the agreement, the Provider State gives the research consortium the permit to sample in its seas and enters into a partnership. In such a partnership some mutual benefits are automatically included; others can be decided upon negotiation of the agreement. These benefits are summarized below:

Automatic benefits from the agreement (for the Provider State)

- Access to scientific results and data through open access integrated databases
- Additional monetary benefits in case of proprietary use
- Benefits from the legal certainty provided by the agreement
- Partnership in a major international scientific bio-informatics network

Additional specific benefit-sharing items which can be agreed upon accessing the sample

Related to the sampling

- Mentoring of Provider State scientists by Micro B3 project scientists that provide information and training on sampling and sampling processing
- Participation of Provider State scientists in all the scientific research activities on the boat and on land related to the sampling activity and its analysis
- Archiving of the sampling for a certain period of time
- Possible support for finding sequencing partners/preferred long-term archive partners

Related to the processing

- Possible collaboration with Argonne National Laboratory (US) or other
- Support in fund raising from national funding agencies for sequencing (as an option, for a limited number of samples, additional support from the Micro B3 consortium can be envisioned when there are major capacity gaps)

Related to data management and integration and access

- Possible participation in training for capacity building on bioinformatics, data management and data analysis (Micro B3 summary schools and workshops)

Head Section of the Agreement and Article 1: Objective of the Agreement

1.1 The agreement sets out the terms for the access to genetic resources found in/on the Provider State's marine internal waters, territorial sea, exclusive economic zone or continental shelf, for the utilization and transfer to third parties of the accessed genetic resources, for the management and transfer to third parties of associated knowledge and for the sharing of benefits drawn from the same.

1.2 The agreement is part of the Micro B3 Consortium Agreement¹. Its rights and obligations extend to all Micro B3 partners.

1.3 The Parties agree to release a copy of the agreement to the registered users of the web portal built by the Micro B3 project.

1. Overview of the Article

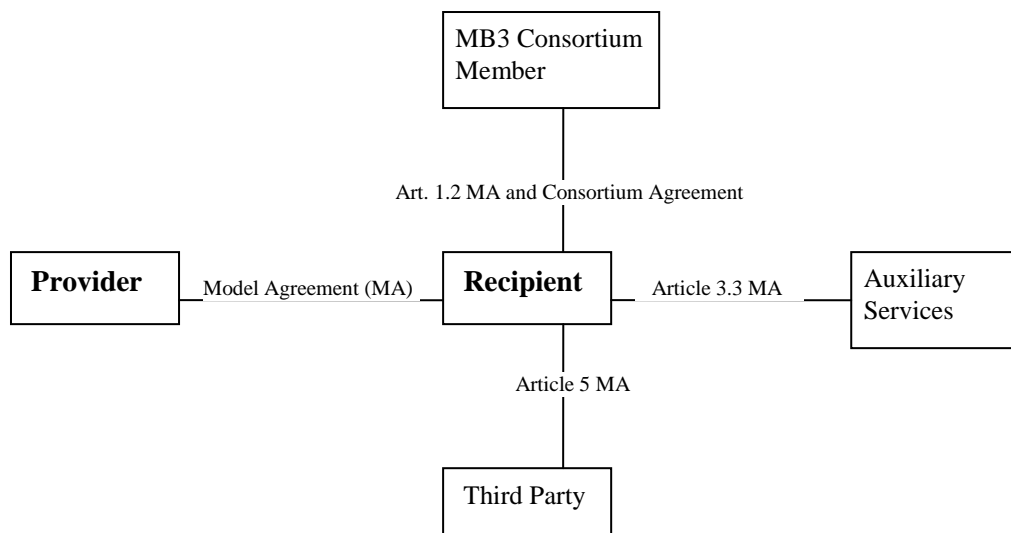
The Parties have to fill in their full names, addresses and contact persons in the head section of the Model Agreement. This initial requirement is necessary for their identification and their definition throughout the agreement (“Provider” and “Recipient”).

Article 1.1 introduces to the principal issues addressed by the Model Agreement. These are:

- the access to genetic resources found in/on the Provider State's internal waters, territorial sea, exclusive economic zone and continental shelf,
- the utilization and the transfer to third parties of the accessed genetic resources,
- the management and the transfer to third parties of associated knowledge and
- the sharing of benefits drawn from the utilization

In Article 1.2 it is set out that the Model Agreement is embedded in the Micro B3 Consortium Agreement. This implies that the Micro B3 Consortium Agreement will be amended by a clause obliging all Micro B3 partners to agree to the terms of the present Model Agreement. In particular, if Micro B3 partners receive genetic resources (GR) from the Recipient researcher they are bound to the pertinent provisions of this Model Agreement when utilizing the GR, reporting on results and generating benefits.

¹ The Consortium Agreement is publicly accessible at the Micro B3 website www.microb3.eu



Article 1.3 is a formal publication requirement: the Parties shall provide a copy of the agreement to the web portal of the Micro B3 project. This requirement helps tracking back the obligations of the initial agreement, if needed.

2. Legal Background

The Model Agreement is based on Article 15 of the Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP)² which has been ratified by 26 states³, but is not yet in force⁴. While Article 15 of the CBD contains the principles of access to genetic resources (GR) and the sharing of benefits drawn from the utilization of the resources (ABS), the NP elaborates the details of the transactions. The NP assumes that negotiations about access and benefit-sharing principally take place bilaterally between the “Party providing such (*genetic*) resources” and the “Party that has acquired the genetic resources”, e.g. Article 6.1 NP. In the Model Agreement they are referred to as “Provider” and “Recipient”.

Articles 5 and 6 NP are the core provisions of the Protocol since they regulate the principal mutual rights and obligations between the Parties: Article 6.1 requires that the Provider State shall be asked to give prior informed consent to user states seeking access to and utilization of genetic resources; Article 5.1 requires that the benefits arising out of the utilization of genetic resources shall be shared in a fair and equitable way according to mutually agreed terms. In addition, according to Article 6.3 (g) (iii) NP the Provider State may also require that the provisions of the agreement shall extend to third parties to whom genetic resources are transferred for further use.

The maritime zones are mentioned in Article 1 of the Model Agreement in order to identify those parts of the waters over which the coastal state is entitled to exercise sovereign rights concerning genetic resources. The different zones and their sovereign rights regimes are determined by the United Nations Convention on the Law of the Sea (UNCLOS). In relation

² Secretariat of the Convention on Biological Diversity, *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*. Montreal: CBD Secretariat, 2011

³ Up to the 3th of December 2013.

⁴ It will enter into force only after ratification by 50 states, which is expected to happen in 2014.

to research and development (R&D) on genetic resources these determinations largely coincide with those of the CBD and the NP (Articles 4 (a), 22.1 CBD).

Internal waters are subject to the full sovereignty of the coastal state (Article 2.1 UNCLOS), which includes the regulation of R&D activities on genetic resources. With certain exceptions, full sovereignty applies also within the territorial sea which covers a breadth of 12 nm measured from the baseline, i.e. the low water line. This includes exclusive rights on and the regulation of R&D on genetic resources (Articles 2.1, 3, 245 UNCLOS). Within the exclusive economic zone which forms a belt of 200 nm from the baseline, limited sovereign rights of the coastal states are acknowledged, once again including exclusive rights and the regulation of R&D on genetic resources (Articles 56, 246 UNCLOS). On the continental shelf beyond the 200 nm-baseline, reaching a maximum of 350 nm, sovereign rights may also be exercised in the subsoil and on the seabed, but only for the exploration and exploitation of natural resources, i.e. only for commercial R&D (Article 246.6 UNCLOS).

The remaining ocean is made up of the so-called areas beyond national jurisdiction (ABNJ) (Article 86 UNCLOS) which break down into the Area and the High Seas. States do not have sovereign rights in these zones. Therefore, the access to and the utilization of genetic resources taken from the ABNJ is free (Articles 87, 256 UNCLOS), but limited by the respect of the conditions laid down by UNCLOS regarding the protection of the environment, the interests of other States; and the right under the Convention with respect to activities in the Area (Article 87). No access agreement needs to be, nor can be concluded. Therefore the Model Agreement does not address the taking of samples in the ABNJ.

3. Explanation of the Article in Detail

The components of the agreement's head section clarify who shall be the Parties to the agreement. They are called the "Provider" and the "Recipient" and are the institutions competent to regulate the subject-matter of the agreement. They are the legal persons that bear the rights and duties of the agreement.

The signatory on the Provider side will normally be a governmental authority. The competence may however be delegated to a research institution. This depends on the domestic law of the Provider State. In order to identify who is the competent authority to sign an ABS agreement, the researcher should consult the national focal point on ABS of the Provider State. Further clarity can be obtained from the international ABS Clearing-House which shall be established according to Article 14 NP (not operational as of now). Its mission is to provide information on the national focal point and/or the national authority competent for access and benefit-sharing decisions. At the time of the composition of this Commentary (December 2013), the Clearing-House is entering the pilot phase. Meanwhile, however, researchers may directly consult the website of the CBD (www.cbd.int) which provides links to relevant national websites on ABS.

On the Recipient side the signatory will normally be a legal (public or private) entity such as a research organization or an industrial enterprise. The Recipient shall not be the individual researcher but the institution that employs the researcher. This ensures that the agreement survives changes of personnel and that its implementation is monitored.

The principal content of the agreement is the regulation of access to genetic resources (Article 3); their utilization (Article 4); their transfer to third parties (Article 5.1); the management (Article 6 – dissemination of knowledge) and transfer to third parties of associated knowledge

(Article 5.2); and the sharing of benefits drawn from the utilization. Benefits are regulated in Article 7 (acknowledgement of the role of scientists), Article 8 (recording and reporting), Article 9 (sharing of information), Article 10 (scientific collaboration with the Provider State and capacity-building) and Article 11 (monetary benefits). A detailed analysis follows under the respective Articles.

It is also necessary to define the geographical scope for the Recipient's collection of genetic resources: the Provider State's internal waters, territorial sea, its exclusive economic zone (EEZ) and its continental shelf. It is thus clear that the ABNJ is outside the scope of the agreement.

The geographical scope helps fencing the realm where the Recipient has to seek PIC before accessing and taking samples from the marine waters. It is not relevant for the other rights and obligations under the Model Agreement. This is due to the fact that the utilization and the benefit-sharing activities usually do not take place on the sea (*in situ*) unless, for example, the genetic material is analyzed in research laboratories on the research vessel directly after taking the sample (utilization) or the user state collaborates with scientists of the Provider State on the expedition boat (benefit-sharing). Relevant activities mostly take place outside the Provider State's sovereign realm (*ex situ*, e.g. in the user state).

Article 2: Definition of Terms

1. Overview of the Article

Article 2 contains the definitions of the key terms used throughout the agreement. The definitions help the contracting Parties to understand the content of the contractual clauses.

2. Legal Background

The terms and their definitions partially reflect those of the relevant international treaties, especially CBD, NP and UNCLOS, also including informal texts such as recommendations by the CBD Secretariat. In drafting the Model Agreement many of the authoritative and widely accepted terms and definitions have been adopted (such as, for example, the definition of genetic resources drawn from the CBD); however, more terms and definitions had to be introduced, taking into account the context and the objectives of the Micro B3 project.

3. Explanation of the Article in Detail

a) *Access means collecting genetic resources from the location where they are found.*

The definition of access focuses on the core activity of sampling. It is clear from the term "collecting" that this may consist of various activities such as surveying and using equipment to search for genetic resources.

b) *Accessed genetic resources means the genetic resources collected on the basis of this agreement.*

The term "accessed genetic resources" guarantees the identification of those genetic resources which are subject to the agreement (see Articles 3.1 and 3.2) and thus produces legal certainty for both Provider and Recipient about what shall be the exact objective of utilization, transfer and – in case of breach of contract (Article 16.4) – destruction.

c) **Associated genetic knowledge** means any experimental or observational data, information and other findings on the composition, life conditions and functions of the accessed genetic resources.

This is a newly introduced term that is crucial for distinguishing between:

- the knowledge which is directly linked to the accessed genetic resource - then the Provider may claim control of its use, ask for PIC before its transfer, or solicit benefit-sharing; and
- the knowledge which is not directly related to the accessed GR but may have been generated with its help (p.ex. by comparing genes and functions or by developing a new theory on sleeping genes won at the occasion of research with an accessed GR) - then the Provider is neither entitled to control its use nor to claim benefit-sharing.

The latter shall not be the object of the agreement since the Recipient may freely decide on its use.

It is recommended not to list and define “data” and “information” as extra categories but to introduce the umbrella term “knowledge” which is supposed to cover data and information as well as results and other findings.

Scientists normally understand “data” to be the characterization of the genetic resource and its life conditions (which are also called meta-data) referring to the immediate technical description, and “information” as a reference to research results on data. The term knowledge is introduced as a generic term covering both data and information.

d) **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.

The definition is taken from Article 2 (e) of the NP. Derivatives are objects of technological applications (“biotechnology”) and as such, they are objects of “utilization” as defined in paragraph l) of the present Article.

e) **Genetic resources** means any material of plant, animal, microbial or other origin containing functional units of heredity which is of actual or potential value.

This definition of genetic resources is a compilation of the definitions of “genetic material” and “genetic resources” in Article 2 CBD. It thus simplifies the use of the term “genetic resource”.

f) **Micro B3 partner** means an institution that is a Party to the Micro B3 Consortium Agreement.

Micro B3 partners shall have a special status vis-à-vis the Parties to the agreement. They are not third parties (see definition i)).

As they are Parties to the Micro B3 Consortium Agreement they are bound by the rights and obligations of the Model Agreement as provided in Article 1.2. They may receive genetic

resources and associated knowledge from the Recipient without the requirement of PIC from the Provider.

g) ***Ocean Sampling Days*** are simultaneous sampling campaigns in the world's oceans, as part of the Micro B3 project, aiming at providing insights about the microbial diversity and the identification of novel ocean derived biotechnologies.

The Model Agreement is principally addressed to the participants and drafted for the objectives of the Ocean Sampling Days that are organized by the Micro B3 project. The Ocean Sampling Days are aimed to be a worldwide endeavour to take samples of marine microorganisms at various locations, analyze them and feed the knowledge primarily into the public domain.

h) ***Provider State*** means the coastal state from whose marine internal waters, territorial sea, exclusive economic zone or continental shelf genetic resources are collected in situ.

The Model Agreement sometimes addresses the "Provider" and sometimes the "Provider State". When the term "Provider" is used it is meant the Provider as a Party to the agreement ("the authority", see head section of the agreement), being a representative of the Provider State and, according to the Provider State's national law, vested with the power to sign the agreement. By contrast, the term "Provider State" is used

- a) when the territory is described (Article 1);
- b) when the contribution is acknowledged because there may be more contributing institutions than the authority subscribing to the agreement (Article 7.2);
- c) where training, capacity-building shall be agreed (Article 10); and
- d) in the clause on the applicable law (Article 14).

i) ***Third party*** means any institution other than Micro B3 partners.

Third parties are relevant in the context of transfer of genetic resources and associated knowledge. They must be distinguished from Micro B3 partners (see Article 1.2). Institutions or individuals that are "contractually bound with the Recipient to provide specified assistance concerning the utilization of the accessed genetic resources" (see Article 3.3) are also not third parties, because they are commissioned to provide specified auxiliary services, but are not entitled to conduct their own R&D activities on the accessed GR.

j) ***Utilization for proprietary purposes*** means research and development that aims at protecting the associated knowledge, including products and processes developed, by patent rights, keeping the resulting knowledge secret, making the resulting knowledge accessible at more than incremental costs for dissemination and/or bringing the products and processes developed from the accessed genetic resources on the market.

This definition will be explained in conjunction with paragraph k) of this Article.

k) ***Utilization for the Public Domain*** means research and development that aims at making the associated knowledge, including products and processes developed, publicly available at no more than incremental costs for dissemination, and without being protected by patent rights or further restricted by other intellectual property rights.

It is a difficult task to define criteria for the distinction of the two forms of utilization but it is indispensable because different obligations are attached to them. 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 already be patented and thus “commercialized”. Alternatively, an institutional criterion may be chosen by asking whether the research institution and financial background belong 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 public benefit.

For the objective of this Model Agreement it is suggested that the question of functionality of the utilization – meaning the dimension of public availability of the associated knowledge – best distinguishes the two realms from each other. If the Recipient intends to make the knowledge publicly available without property protection or further restriction by other intellectual property rights, then the Recipient asks for access to the GR for the purpose of utilizing them for the public domain. If the Recipient’s intention is to protect the knowledge by patent rights or trade secrets and to limit or make costly public availability, it asks for access to the GR with the purpose of utilising them for proprietary purposes.

1) *Utilization of genetic resources means research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology which is any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.*

This is a compilation of the definitions of the terms “utilization of genetic resources” in Article 2 (c) NP and “biotechnology” in Article 2 (d) NP. 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. The application and commercialization of developed products is however not included in term (cf. Article 5 NP). R&D can however aim at application and commercialization. This would imply the privatization of R&D results and thus be, in the terminology of this Model Agreement, a case of utilization for proprietary uses.

Article 3: Access to Genetic Resources

3.1 The Recipient shall be entitled to collect samples as follows:

- a) **Kinds of samples⁵, including the kind of genetic resources⁶, if known:** _____
- b) **Number and quantity of samples:** _____
- c) **Geographical location of collection⁷:** _____
- d) **Time period for collection:** _____

**3.2 The Recipient shall within ... [time period to be specified by the Parties] after collection of the samples notify to the Provider the kinds of genetic resources 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 allowed to be utilized.
(This clause is to be crossed out if not applicable)⁸**

⁵ E.g. seawater, sediment.

⁶ The kind of genetic resources to be extracted from the sample, e.g. virus, bacteria, funghi, microorganism.

⁷ E.g. GPS coordinates.

⁸ Not applicable if kind of genetic resources included is known *ex ante* under Article 3.1.a)

3.3 The Recipient shall be entitled to move the accessed genetic resources to its premises and, subject to Article 1.2 of this agreement, to the premises of other Micro B3 partners, as well as to an institution or individual which is contractually bound with the Recipient to provide specified assistance concerning the utilization of the accessed genetic resources⁹.

3.4 The Recipient shall deliver a portion of the accessed genetic resources to the Provider or an institution designated by the same: _____

The samples shall be delivered in the following form: _____

(This clause or part of it is to be crossed out if not applicable)

3.5 The Recipient shall bear all the costs incurred in accessing and delivering the genetic resources.

1. Overview of the Article

The objective of Article 3 is the regulation of access to marine genetic resources as agreed by the Provider and the Recipient; it regulates the conditions of access and the rights and obligations of the Parties directly connected with the access.

These rights and obligations may be divided into principal performance obligations (obligation of the Provider to grant access; obligation of the Recipient to access the maritime zones under the agreed parameters: the agreed kind of sample, the agreed number and quantity of the samples, within the agreed geographical area, within the agreed time period) and secondary performance obligations (right of the Recipient to move the genetic resources to the premises of his own and to individuals and institutions offering auxiliary services; obligation of the Recipient to send a sample to the Provider State).

2. Legal Background

The rights of the Provider State in relation to give access to its genetic resources are regulated in Article 6 NP. Article 6.1 NP acknowledges the sovereign rights of the Provider States to require prior consent and, by implication, to set conditions for the access, such as conditions concerning the sampling and the moving of the sample. If a Provider State has made use of these rights the Model Agreement serves to specify such conditions in the individual case. Article 6.3 NP strives for legal clarity by requiring State Parties to take the necessary legislative, administrative and policy measures to “provide for information on how to apply for prior informed consent” (c) and to “set out criteria [...] for obtaining prior informed consent” (e). Normally Provider States ask for both the issuance of an access permit and the conclusion of an access contract. They may however also simplify procedures by providing the access permit as part of the access contract. This solution is suggested in the Model Agreement. If the Provider signs an agreement, including Article 3 as it is, it thereby grants access together with the prior consent. The Model Agreement does not however preclude the Provider State to require a permit in addition to it.

⁹ All other transfers are considered transfers to third parties and bound by the conditions under Article 5.

Considering the law of the seas, Articles 245, 246 and 248 UNCLOS acknowledge about the same sovereign rights for coastal states as Article 6 NP.

3. Explanation of the Article in Detail

In Article 3.1 the Parties to the agreement may define, through negotiation, the kinds of samples to be accessed (including the kind of genetic resources if known), the number and quantity of samples, the geographical location of sampling and the time period for sampling.

See as examples:

- a) Kind of sample: *Sediment*
- b) Number and quantity of sample: *a minimum of 50 samples of sediment of 50 mL*
- c) Geographical location of collection: *GPS coordinates*
- d) Time period for collection: *22th June – 29th June 2014*

Submitting this information to the Provider serves the interest of both parties; it provides legal certainty about the limits of the operation regarding the object, the amount of collection, the location and the time period.

The second paragraph (3.2) was inserted because at the time of conclusion of the agreement the Recipient will not necessarily know which kinds of genetic resource it will actually be able to extract from the sample. In that case it is sufficient to generally describe the sample (water, sediment, macroorganisms (sponges, algae, etc)) in Article 3.1; and, as a second step, to specify what kinds of genetic resources (virus, bacteria, prokaryotes, other microbial eukaryotes) shall be utilized as soon as this becomes clear from a screening of the sample. The Provider may in that case raise objections to subsequent utilization.

The third paragraph (3.3) regulates where the samples may be moved: to the premises of the Recipient, to the premises of Micro B3 partners and to the premises of institutions or individuals that provide auxiliary services such as sequencing etc. These latter transfers do not need a prior informed consent of the Provider for the following reasons: first Micro B3 Partners are bound by the Consortium Agreement and therefore also bound by the Model Agreement; second the institutions or individuals are engaged by the Recipient to provide specific technical assistance in the research and development process. This engagement shall not be burdened with too heavy administrative requirements (e.g. PIC of the Provider) in order not to hamper the research process.

The fourth paragraph (3.4) regulates the obligation of the Recipient to share the collected samples with the Provider. This requirement enables the Provider to supervise the R&D process by tracing the resulting knowledge to the genetic resource. It also enables the Provider to develop its own research activities.

The fifth paragraph (3.5) declares the Recipient responsible for all the costs incurred from accessing and delivering the samples.

Article 4 Utilization of Genetic Resources

4.1. The Recipient shall be entitled to the utilization of the accessed genetic resources.

Specifications, if deemed necessary: _____

4.2 The utilization of the accessed genetic resources shall be for the public domain.

Specifications, if deemed necessary: _____

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

4.3 The Recipient shall be entitled to utilize part/all (please cross out) of the accessed genetic resources for proprietary purposes:

Specifications, if deemed necessary: _____

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

4.4 Should the Recipient, after the conclusion of this agreement, intend to utilize the accessed genetic resources and/or use the associated genetic knowledge for proprietary purposes the Recipient shall seek the consent of the Provider.

Specifications of the consent procedure, if deemed necessary:

4.5 Should the Provider, after the conclusion of this agreement, intend to utilize the accessed genetic resources and/or use the associated genetic knowledge for proprietary purposes the Provider shall enter into amicable negotiations with the Recipient on the modification or termination of this agreement.

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

1. Overview of the Article

Article 4 focuses on the steps following access in the chain of valorizing the genetic resources. The Parties may here define the scope of utilization permitted to the Recipient. Basically, the Parties should regulate what kinds of research and development are to be allowed, and whether the utilization shall be exclusively for the public domain or if part or all of it may be carried out for proprietary purposes.

2. Legal Background

Article 4 of the Model Agreement is based on Articles 5.1 and 6.1, 6.3 (g) NP which acknowledge the sovereign rights of the Provider States to set conditions for access and benefit-sharing and thereby prepare the ground for access permits and mutually agreed terms. These conditions may imply some limits for the utilization of the accessed genetic resources. Similar consequences follow from Articles 245, 246 and 248 UNCLOS.

3. Explanation of the Article in Detail

The Article provides the opportunity to set mutually agreed terms concerning the utilization of the accessed genetic resources. This allows the Parties to individually balance their interests in negotiating special conditions of utilization.

In Article 4.1 the Parties may specify what kinds of research and development activities will exactly be carried out, which research methods may be used, etc. They may however also agree that any R&D shall be allowed and thus leave the space for specifications unfilled.

In Articles 4.2 and 4.3 the Parties shall agree on the functional objective of the utilization activities. Does the Recipient intend to submit the associated knowledge resulting from the

utilization of the GR exclusively to the public domain or is its intention to keep (part/all of) the knowledge for proprietary purposes?

The decision *pro or contra* public domain utilization necessarily entails respective follow-up obligations: the conditions of dissemination of associated knowledge, of reporting and sharing of information and of benefit-sharing may be different in the two cases.

Article 4.4 contains a clause regarding the change of intent by the Recipient. If the Recipient, after the conclusion of an agreement that limits all or part of the utilization of the resources to the public domain, decides to utilize the GR (or part of it) or use the associated knowledge for proprietary purposes, it must seek the prior consent of the Provider. Under “specifications” it may be agreed if, in that case, a simple notification is sufficient or if a formal authorization is needed. Other specifications such as benefit-sharing arrangements are regulated under Articles 11.3, 11.4.

A “change of intent” clause for the Provider is introduced by Article 4.5. It might happen that, after the Recipient has shared the sample and the knowledge with the Provider (Articles 3.3, 9.1), the Provider discovers a potential commercial application of the genetic resource or the associated knowledge, and would like to prevent the same from being submitted to the public domain. In that case, the Model Agreement does not give the Provider a one-sided right to withdraw its consent but rather enables it to renegotiate the contract. This solution is mirrored in the case of change of intent for the Recipient where mutual consent must equally be obtained.

As an alternative the Provider may waive its intention to renegotiate from the outset, for instance in exchange for an upfront payment. In that case Article 4.5 should be disregarded.

The Provider has another possibility to reserve *ex ante* a share in the commercialization activities by using the renegotiation clause of Article 4.4 and therefore by reaching an agreement on different conditions for benefit-sharing.

Article 5 Transfer of Genetic Resources to Third Parties

5.1 The Recipient may transfer to a third party the accessed genetic resources, or parts of them, provided that the third party agrees with the Recipient, to apply to the transferred genetic resources Articles 4 to 16 of this agreement.

5.2 If the Recipient intends to transfer to a third party the associated genetic knowledge which is not yet or shall not be submitted to the public domain according to Article 6, the third party shall agree with the Recipient, to apply to the transferred knowledge Articles 4 to 16 of this agreement.

5.3 In case of transfer to a third party, the Recipient needs the prior informed consent of the Provider, under one of the following modalities:¹⁰

¹⁰ NOTE OF CAUTION: The Parties should be aware that too heavy PIC requirements could significantly complicate the research and development process during the non-commercial stage considered in this contract (defined as public domain). A facilitated PIC procedure for non-commercial use (public domain use) as proposed here would also be to the advantage of the Provider State because this allows the Recipient to transfer GR or knowledge during the non-commercial stages more easily and thus might lead to increased commercial product development in later stages, in which a new negotiation with the Provider State is initiated according to the renegotiation clause in article 4.4.

- a notification of the transfer to the Provider or an institution designated by the same, along with the sending of a copy of the transfer agreement, will be considered as proof of prior informed consent. The institution shall be the following [if applicable]:_____
- other [specification of the modality]:_____

[This clause is to be crossed out upon agreement that the consent is not required]

1. Overview of the Article

Article 5 describes the conditions under which the Recipient is allowed to transfer the accessed genetic resources and/or the associated genetic knowledge to third parties. The Article introduces the so called “viral licence clause” for such transfers. The viral licence concept means that the originally signed contract between the Provider and the Recipient travels with the resource and the associated genetic knowledge upon transfer to a second and a third Recipient: that is so say that the subsequent recipients are bound by the same obligations that were imposed on the (first) Recipient in the contract concluded with the Provider. The Provider is therefore reassured that the conditions he had negotiated will be respected further down in the transfer chain. This is an important clause given that, usually, Provider States’ legislations 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 out of it by them.

2. Legal background

Article 6.3 (g) (iii) NP acknowledges that the Provider has sovereign rights to establish the conditions for transfer of the GR to third parties. This is commonly implemented by domestic legislation requiring prior consent of the Provider to material transfers to third parties.

The inclusion of the viral licence clause into the Model Agreement was inspired by the experience made with the Material Transfer Agreement used by the European Culture Collections (ECCO MTA). Under this MTA the transfer of the material

- a.) between scientists working in the same laboratory,
- b.) between partners in different institutions collaborating on a defined joint project for non-commercial purposes, or
- c.) between public service culture collections for accession purposes

is allowed provided that the MTA conditions for further distribution are equivalent to those that were agreed upon for the initial transfer of material. Article 5 of the Model Agreement however somewhat differs from the ECCO MTA: Scientists working in the same laboratory (above (a)) are bound by internal rules of the institution that signs the contract on the Recipient side. And collaborating partners (above (b)) are already bound by Article 2.1 of the Model Agreement, because they are Micro B3 partners. Article 5 therefore focuses on transfers to genuine third parties (which may also include culture collections (above (c))).

3. Explanation of the Article in Detail

The Model Agreement offers a viral licence clause in Article 5.

This clause guarantees that all obligations of the initial ABS agreement (Articles 4 – 16) will be imposed on any third party receiving the material and/or the knowledge associated with the GR (Article 5.1). The Recipient is allowed to transfer the material and/or the knowledge to a third party only under the condition that the third party agrees to respect the conditions of the initial ABS agreement (Article 5.2). This can be implemented by the third party signing an MTA stating that the initial ABS agreement shall be binding on it.

Article 5.3 provides two modalities of procedures, one of which the parties may choose:

- The Recipient notifies the Provider of any transfer to third parties. In this case the general prior consent the Provider grants by signing the Model Agreement is completed by targeting a specific transfer.
- The Parties introduce additional modalities: they define a period within which the Provider may raise objections or they introduce a requirement that the Provider must give its explicit consent.

It is recommended that the first option shall be chosen for public domain uses in order to avoid too heavy administrative burdens (see also footnote to Article 5).

A third option which is even less burdensome would be to disregard Article 5.3. In this case the general prior consent would be regarded as sufficient.

Article 6 Dissemination of Knowledge

6.1 The Recipient shall make the associated genetic knowledge publicly available at no more than incremental costs of dissemination. The dissemination can be through online media, print media or delivery upon request. The recommended forums for online dissemination are the Micro B3 Information System (www.microb3.eu) and existing data-bases and information networks such as the Global Biodiversity Information Facility (GBIF), SeaDataNet, Pangaea and the International Nucleotide Sequence Database Collaboration (INSDC).

6.2 Such knowledge shall be made available as soon as possible after its generation unless otherwise specified. No embargo period is allowed for the raw sequence data and the oceanographic data associated to the samples collected upon the Ocean Sampling Day.

Specifications if deemed necessary: _____

6.3 The Recipient shall make reasonable efforts to ensure that the release of associated genetic knowledge through online media, print media or delivery upon request will be organized such that users are bound not to use the associated genetic knowledge taken from the portals for proprietary purposes unless they have obtained prior informed consent of the Provider.

6.4 Paragraphs 1-3 of this Article do not apply to associated genetic knowledge used for proprietary purposes specified under Articles 4.3 and 4.4.

6.5 The Recipient shall make reasonable efforts to ensure that the users of knowledge accessed from the Micro B3 Information System provide to the System the

knowledge from their own research in such form and format as the System will reasonably require in order to promote the objectives of the utilization for the public domain.

1. Overview of the Article

The objective of Article 6 is to illustrate the different options for the dissemination policy concerning the associated genetic knowledge, and consequently the obligations of the Recipient in that regard. The dissemination policy differs according to the objectives of utilization of the accessed GR that have been agreed upon by the Parties under Article 4. If the utilization is exclusively for the public domain, the Recipient has to make the accessed genetic knowledge available in the public domain as soon as it has been generated. If the utilization is for proprietary purposes, the Recipient is not bound by dissemination obligations under Article 6.

2. Legal Background

The legal grounds for establishing such obligations for the Recipient is the principle of mutually agreed terms re-affirmed by Article 6.3 (e) of the NP.

Article 6 addresses issues of data management that have not yet been discussed in-depth in the ABS context. Neither the CBD nor the NP nor UNCLOS have specific provisions addressing the way the sovereign rights of Provider States entitle them to monitor and codetermine the processing of knowledge derived from R&D on accessed genetic resources. One important provision framing such rights is Article 5 NP which ensures that any “benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization” shall be shared with the Provider State. “Arising” also includes processes of knowledge generation from the R&D on the “original” material and for “new” material (such as products). If the phase of knowledge generation involves the submission of results to the public domain this entails the risk that the Provider State loses track of subsequent steps towards commercialization. It is therefore in the interest of the Provider to control the process to some extent. On the other hand, the Provider State is, according to Article 8 (a) NP, under the duty to facilitate non-commercial research, which is hereby understood as research for the public domain. Article 6 attempts to strike a balance between the freedom of public domain research and the legitimate rights of provider states to control the valorization chain.

3. Explanation of the Article in Detail

Article 6 illustrates the dissemination obligations of the Recipient in the cases where the genetic resources (or part of them) are accessed for utilization for the public domain as stated in Article 4.2 (or in Article 4.3). In these cases the Recipient commits itself to make the accessed genetic knowledge publicly available at no more than incremental costs for dissemination, and as soon as possible after its generation. The delivery of such knowledge upon request is also considered to be a variant of publication. A fee for access may be included, but this shall not exceed “incremental” costs. This is to be understood as costs for the storage and the technical means of transfer of knowledge.

Several forums for the online dissemination are recommended: the Micro B3 Information System (once it is in place and running) and some existing databases and information networks that have a strong reputation among scientists working on genomics.

Article 6.2 introduces an embargo period for dissemination: The Recipient shall publish the knowledge “as soon as possible” after its generation, but the Parties are free to further specify the embargo period.

No embargo period is allowed for the raw sequence data and oceanographic data associated with the samples collected within the Ocean Sampling Day (OSD) initiative. This aims at ensuring that the pools of data collected through the initiative will be publicly available immediately, as this is one of the main objectives of the initiative. It is also an important step to identify the participants to the OSD initiative and to ensure that the participants respect the OSD data policy.

In Article 6.3 the Model Agreement confers on the Recipient the responsibility to observe third party use of the knowledge. Users should not take knowledge from the public portal and use it for proprietary purposes unless they have obtained prior informed consent from the Provider. *De facto*, the monitoring of such requirements will however be difficult since the Recipient who has submitted knowledge to a database has no stakes in taking legal action against commercial uses. Nor is it feasible for the database operators to ensure that PIC has been obtained. For this reason databases normally ask users to agree with a disclaimer which frees the database from any liability *vis-à-vis* a right holder. These disclaimers need to be reconsidered in relation to Provider rights on genetic resources, but this will require more discussion and a longer learning process that cannot be predetermined by strict clauses in the present Model Agreement. Therefore, a goodwill clause rather than an obligation for the Recipient has been drafted using the softer formulation “shall make reasonable efforts to ensure”.

However, since the Model Agreement aims at serving as a template also beyond the Micro B3 project and the Ocean Sampling Days, the proprietary utilization of the GR allowed by Articles 4.3 and 4.4 needs to be granted legal protection by the agreement as well. Therefore, if the a respective clause negotiated with the Provider allows for the utilization of part or all of the accessed GR for proprietary purposes, according to Articles 4.3 and 4.4, these public domain dissemination obligations will cover only the associated genetic knowledge produced from the part of GR accessed for the public domain, if any. Otherwise no dissemination obligations bind the Recipient, and Article 6.1-6.3 do not apply.

The intention of Article 6.5 is that the users of knowledge from the Micro B3 Information System (once in place and running) give knowledge from their own research back to the System in order to promote the objectives of the utilization for the public domain. The Micro B3 Information System will set the forms and formats under which the knowledge is to be provided. Of course, such an obligation is difficult to enforce, both by the data base operators and by the Recipient. For this reason the related obligation of the Recipient is framed in soft language.

Article 7 Acknowledging the Contribution of the Provider State

7.1 When making associated genetic knowledge publicly available the Recipient shall indicate the country of origin of the utilized genetic resource.

7.2 When making associated genetic knowledge publicly available the Recipient shall acknowledge the role of scientists from the Provider State, and, where any work, significant advice or recommendations have been provided by such scientists, their (co-)authorship.

1. Overview of the Article

The objective of Article 7 is to acknowledge the contribution of the Provider State when the knowledge is made publicly available. First, it obliges the Recipient to indicate the origin of the accessed genetic resource and thus helps tracking the origin of the associated knowledge. Second, it requires the Recipient to acknowledge the role of scientists especially in the case of significant contribution to the research results.

These obligations bind the Recipient only in those cases in which the Provider has granted access to its GR allowing their utilization for the public domain.

2. Legal Background

The Bonn Guidelines require the users of genetic resources “to maintain all relevant data regarding the genetic resources, especially documentary evidence of the prior informed consent and information concerning the origin and the use of genetic resources and the benefits arising from such use” (paragraph 16 (b) (vi)). Moreover, paragraph 16 (d) (ii) requires the users of GR “to encourage the disclosure of origin of the GR and of traditional knowledge (TK)”.

In addition, the list of non-monetary benefits (appearing first as Annex II to the Bonn Guidelines and then repeated in the NP) includes the following benefits to be possibly shared:

- “Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the provider country”
- “Social recognition”
- “Joint ownership of intellectual property rights”.

2. Explanation of the Article in Detail

Article 7 is applicable when knowledge generated from the utilization of accessed genetic resources is published. Whether the publication is made as part of a public domain or proprietary track is of no concern. Moreover, publications concerning patented information are subject to the obligation to indicate the country of origin and acknowledge the collaboration of scientists, including co-authorship.

Article 8 Recording and Reporting

8.1 The Recipient shall maintain records concerning the storage and transfer of the accessed genetic resources and allow access to such records to the Provider or the authority designated by the same.

_____ (insert name and address of authority if applicable)

8.2 The Recipient shall report in writing to the Provider or the authority designated by the same every _____ [insert duration] months, beginning _____ and ending _____, providing details of the progress of utilization.

_____ (insert name and address of authority if applicable)

8.3 With relation to associated genetic knowledge used for proprietary purposes specified under Articles 4.3 and 4.4, the Recipient shall, when reporting according to paragraph 2 of this Article, also report on any steps taken towards obtaining or

implementing intellectual property protection and the selling of products or processes based on this knowledge¹¹.

1. Overview of the Article

The objective of Article 8 is to keep track of the accessed GR and their utilization, and to share this information with the Provider. This obligation helps monitoring the compliance with the mutually agreed terms concluded within the agreement.

2. Legal Background

Article 17 of the NP, on “monitoring the utilization of GR”, requires each Party to take appropriate measures to monitor and to enhance transparency about the utilization of genetic resources, in order to support compliance. Among these measures each Party shall encourage “users and providers of GR to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements” (Article 17.1 (b) NP).

In addition, the obligation to report on the progress of utilization is a possible non-monetary benefit listed in the annex of the Nagoya Protocol that reads as: “sharing of research and development results”.

3. Explanation of the Article in Detail

The Recipient must keep track of the storage and the transfer of the accessed GR and allow access to this information to the Provider upon demand. The Provider can designate the authority competent to ask for access to these records.

Moreover, the Recipient must report in writing to the Provider the details of progress of utilization of the accessed GR. The Recipient and the Provider have to agree on the time frame for these reporting activities and the Provider can designate the authority competent to receive the reports.

Finally, in the cases of associated genetic knowledge used for proprietary purposes (see Articles 4.3 and 4.4), the Recipient shall also report on any steps taken towards obtaining or implementing intellectual property protection and the selling of products or processes based on this knowledge.

These duties pursue a twofold objective: First, the Provider benefits from the reports related to the content since they may include new scientific findings. Second, the information enables it to regularly monitor if the Recipient complies with the contractual obligations vis-à-vis the utilization of the accessed GR.

Article 9 Sharing of Knowledge

9.1 The Recipient shall provide the Provider, or the authority designated by the same, with the associated genetic knowledge and provide assistance in their assessment or interpretation as reasonably requested.

_____ (insert name and address of authority if applicable)

¹¹ Subject to negotiation of the Parties it could be agreed that the consent of the Provider is required for certain steps of commercialization such as the bringing on the market of the product.

9.2 Such knowledge shall, at the latest, be provided once it has been made publicly available.

Specifications if deemed necessary¹²: _____

9.3 The obligation under paragraph 1 of this Article extends to associated genetic knowledge used for proprietary purposes specified under Articles 4.3 and 4.4. When using the knowledge the Provider shall not prejudice any use for proprietary purposes by the Recipient.¹³

Specifications, if deemed necessary: _____

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

9.4 The Recipient shall furnish the Provider or the authority designated by the same with _____ (insert number) copies of any publication based on the utilization of the accessed genetic resources.

_____ **(insert name and address of authority if applicable)**

1. Overview of the Article

The objective of Article 9 is to provide for a non-monetary benefit-sharing through the sharing of the associated genetic knowledge with the Provider, applicable in the case of public domain agreement as well as in the case of proprietary agreement.

2. Legal Background

According to Annex to the NP, No. 2 (a), read together with Article 5 NP, the sharing of research and development results belongs to the (non-monetary) benefits that shall be shared with the Provider State.

Moreover, Article 6.3 (g) (ii) NP acknowledges that the mutually agreed terms might include terms on benefit-sharing.

3. Explanation of the Article in Detail

The Recipient is obliged to share with the Provider the associated genetic knowledge at the latest when it is submitted to the public domain, if public domain is agreed. The Recipient is also obliged to provide assistance in the assessment and interpretation of such knowledge in respect of the needs of the Provider that may vary according to the Provider’s scientific capacity.

If the Model Agreement allows for proprietary uses of the GR (see Article 4.3 and 4.4) the Recipient is still obliged to share such knowledge with the Provider, but in return the Provider commits itself not to prejudice any proprietary use by the Recipient. This means that the

¹² It may be agreed between the Parties that the Provider shall be informed before publication. This may allow the Provider to check if the requirements under Article 7 are fulfilled and/or if there is reason for pursuing proprietary purposes according to Article 4.5. In this case the Provider shall keep the knowledge confidential during the agreed period.

¹³ This clause will be negotiated along with the benefit-sharing arrangement: a Provider State will prefer to have access to the information (even if the country keeps it confidential as specified under 9.3), but a company might prefer to give a higher upfront benefit-sharing under article 11 as a *quid pro quo* for crossing this article.

Provider shall not obtain intellectual property rights on the knowledge nor publish it but rather treat such knowledge confidentially.

Finally the Recipient is obliged to give to the Provider an agreed number of copies of any publication based on the utilization of the accessed genetic resources. This clause of the Model Agreement applies both to a public domain and to a proprietary agreement. The clause is important from the point of view of scientists. If they publish in academic journals, access to which is subject to a charge, the clause will help scientists negotiate with publishers regarding their right to release their publications for free.

Article 10 Scientific Collaboration with the Provider State and Capacity-Building

As part of the Micro B3 project the Recipient agrees to collaborate with scientists from the Provider State in the utilization activities based on this agreement. Such involvement shall take the following forms:

14

(to be specified by negotiations)

1. Overview of the Article

Article 10 introduces a non-monetary benefit to be shared by the Parties of the agreement. It is a matter of negotiation between the Provider and the Recipient to further specify details of collaboration.

2. Legal Background

According to the Bonn Guidelines and the Nagoya Protocol the “cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities” is one of the possible non-monetary benefits to be shared that can be negotiated through mutually agreed terms.

Article 15.6 of the CBD states that “each contracting Party shall endeavour to develop and carry out scientific research based on GR provided by other Contracting Parties with the full participation of, and where possible in, such contracting Parties.”

Beyond foreseeing collaboration in a mutual relationship, the Parties to the Nagoya Protocol are required, as a general commitment, to engage in collaboration and co-operation in technical and scientific research and development programmes and to promote access to and transfer of technology to countries with less developed economies (Article 23 of the NP).

3. Explanation of the Article in Detail

Within the framework of capacity-building, the Model Agreement foresees collaboration between the Recipient and scientists from the Provider State. Since the collaboration is related to the utilization activities and given that the definition of utilization (see Article 2) includes

¹⁴ It should be noted that in the normal case of scientific collaboration the partners conclude a research collaboration contract/project (however usually the research collaboration is more a project rather than a contract, and it is not legally binding) in which the details of the collaboration are laid out. The ABS agreement should not be overloaded with such details. It will be advisable that the Parties to the ABS agreement make a reference to the research collaboration agreement/project.

research and development, Article 10 implies that the collaboration may extend to all the utilization activities.

The Parties have to indicate the actual level of involvement of the scientists from the Provider State from the sampling activities to the analyzing phase. This is left to the mutually agreed terms of the Model Agreement. However, given the shared research ethos of the Micro B3 project, it is expected to create the conditions for a strong collaboration between scientists. Moreover, it is important to notice that the Micro B3 project offers limited possibilities to attend training courses and summer schools on different relevant disciplines. This possibility could also be mentioned in the “specifications” of the Article, if agreed by the Provider and the Recipient.

Article 11 Benefit-Sharing in Case of Utilization for Proprietary Purposes

11.1 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 proprietary 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 3.2. The payment shall be transferred to the following account of the Provider: _____

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

11.2 If the Recipient utilizes the accessed genetic resources or uses the associated knowledge for proprietary purposes according to Articles 4.3 and 4.4, it must fairly and equitably share with the Provider any monetary benefit obtained.

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

11.4. (Alternatively to 11.3) 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)

11.5 If the Recipient utilizes the accessed genetic resources or utilizes the associated genetic knowledge for proprietary purposes without being entitled according to Articles 4.3 or 4.4, and therefore in breach of the conditions of this agreement, it must share with the Provider any monetary benefit obtained from such utilization or use. 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 in due time upon request by the same.

(Insert authority and account details if applicable)

(This Article or single paragraphs of it are to be crossed out if not applicable)

1. Overview of the Article

Article 11 determines the sharing of monetary benefits in cases of proprietary utilization of the accessed genetic resources. It covers those forms of proprietary utilization that were agreed upon between the Parties, and also forms of proprietary utilization that were not agreed and undertaken in breach of Articles 4.3. and 4.4.

2. Legal Background

Article 15.7 of the CBD requires the Parties to “take legislative, administrative, or policy measures the goal of which is the fair and equitable sharing of benefits with the Contracting Party providing genetic resources”. The determination of benefits that are to be shared is left to the negotiation of mutually agreed terms (Article 15.3). The CBD also foresees different types of benefits to be shared, among which are commercial or other benefits derived from utilizing the genetic resources (Article 15.7). The Nagoya Protocol (in its Article 5.4) expressly recognizes that there may be both monetary and non-monetary benefits derived from the utilization of genetic resources. The Protocol’s Annex contains an indicative list of monetary and non-monetary benefits, taken from Annex II of the Bonn Guidelines.

3. Explanation of the Article in Detail

In cases of utilization of the accessed GR for proprietary purposes the Recipient has to fairly and equitably share any monetary benefit obtained with the Provider. Article 11.1 foresees the possibility of an up-front payment. It is suggested that such payment shall preferably not be specified at the negotiation stage of the agreement, because at that moment the economic value of the genetic resources is usually 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 the benefits by further negotiation (11.3), 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 (11.4). This clause thus establishes the possibility for an *ex ante* compensatory liability scheme.

The Article goes further by imposing on the Recipient the share of the monetary benefits for 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.

Article 12 Other Laws to be Respected

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 any other concern.

1. Overview of the Article

According to this provision the Recipient is required to respect the domestic law of the Provider State, especially the law on the protection of health and the environment, on taxes and customs in the course of collecting, storing, transferring, utilizing and exporting the

genetic resources as long as the activity is carried out in the sovereign realm of the Provider State.

2. Legal Background

According to the international customary principle which affirms the state's sovereignty over its territory, the Recipient must respect the legal framework of the Provider State. Thus, the contractual clause is only of declaratory importance but it alerts the Recipient of this principle.

3. Explanation of the Article in Detail

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

Article 13 Duration of the Agreement

The agreement is of unlimited duration, except for the obligations under Articles 8.2 and 10 which shall end on [date to be inserted; e.g. 2 years after the termination of the Micro B3 project]:_____

1. Overview of the Article

The Article specifies the duration of the contract distinguishing between clauses of unlimited and limited duration.

2. Legal Background

The Article reflects requirements of general contract law. Any contract must decide on its duration.

3. Explanation of the Article in Detail

Most of the provisions of the Model Agreement shall be of unlimited duration because the utilization of the accessed genetic resources is of unlimited length. Some of the provisions will however be exhausted after implementation, such as the right to take specific samples under Article 3. Two clauses are limited in time because they are connected to project activities within the Micro B3 framework, i.e. Article 8.2 (Report on steps of utilization) and Article 10 (Scientific collaboration).

In addition, the agreement may terminate under the conditions of Article 16 (termination by mutual agreement and by default). The Parties are required to agree on a time limit for the obligations regulated in these two provisions. A possible time limit would be "two years after the termination of the Micro B3 project".

Article 14 Applicable Law

14.1 The applicable law on any matters relating to the interpretation and the application of the present agreement shall be: _____

14.2 The competent court for dispute settlement shall be: _____

1. Overview of the Article

The provision requires the contracting Parties to choose the applicable law relating to the interpretation and application of the agreement and the place of jurisdiction for disputes arising directly or indirectly out of the agreement.

2. Legal Background

The legal background of this Article is Article 18.1 (a), (b) NP. Mutually agreed terms shall include a clause on the jurisdiction to which the Parties will subject for dispute resolution, and a clause on the applicable law. For the eventual enforcement of contractual rights and obligations, the Parties should thus agree in this Article on the applicable law and the place of jurisdiction. This is no obligation, however. In the absence of an agreement on such clause, the question would be regulated by international private law and international civil procedural law.

3. Explanation of the Article in Detail

In the Model Agreement the Parties are free to determine if the law of the Provider State, or the law of the State where the Recipient is based, shall be applicable to matters relating to the interpretation and application of the agreement. It is recommended to make use of this choice as part of the negotiation of the mutually agreed terms of the agreement. First, because if the Recipient is, for example, willing to accept the Provider State as the place of jurisdiction, the Provider may possibly partially renounce the benefits to be shared. Second, because a regulation by law (see above) and not by the Parties is necessarily disadvantageous for one of the Parties. Third, the Parties avoid disputes on the interpretation of relevant provisions of international private law.

The place of jurisdiction does not necessarily have to be in the country of the applicable law. However, it would ease proceedings if the judges at court can apply their domestic law and are not constrained to engage in the apprehension of foreign law.

Article 15 Dispute Settlement

15.1 No Party shall, in the event of a dispute arising from this agreement, commence court proceedings (except proceedings for urgent interlocutory relief) before searching for an amicable solution according to paragraphs 2 and 3 of this Article.

15.2 A Party to this agreement claiming that a dispute has arisen under or in relation to this agreement must provide the other Party with a written notice specifying the

nature of the dispute on receipt of which the dispute resolution shall forthwith begin.

15.3 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, such as mediation and arbitration or similar techniques agreed to by them.

1. Overview of the Article

This provision addresses issues of dispute resolution. It strongly supports the idea of finding amicable solutions. The dispute resolution process starts with the Party claiming that a dispute has arisen and providing a written notice to the other Party. The dispute shall be solved by negotiation, and if negotiation fails the Parties should apply informal dispute resolution techniques such as mediation and arbitration. Court proceedings shall be the last means to the settlement of disputes.

2. Legal Background

This Article is inspired by Article 18.1 (c) of the NP. The Parties to the Protocol shall include provisions in mutually agreed terms to cover “options for alternative dispute resolution”.

3. Explanation of the Article in Detail

A dispute may be solved through a sequence of steps, indicating the degree of involvement and engagement of a third party:

- a.) Written notice by the Party claiming to the other Party that a conflict arose out of the agreement (formal requirement: the notice shall indicate the nature of the conflict)
- b.) Resolution by alternative dispute settlement
 - aa.) Resolution by negotiation (no third party involved)
 - bb.) (if aa. not successful) Resolution by mediation (third party is a bridge between the two parties and assists in the communication between the Parties – more passive role)
 - cc.) (if bb. not successful) Resolution by arbitration (third party reviews the evidence in the case and imposes a decision that is legally binding for both sides– both Parties must declare beforehand that they agree to be bound by the decision)
- c.) (if b. not successful) Jurisdictional proceedings

Article 16 Termination of the Agreement

16.1 The agreement may be terminated at any time by mutual agreement in writing.

16.2 The agreement may be terminated by default if the Recipient fails to satisfy any of the following obligations under this agreement: Articles 4.2, 4.3, 4.4, 5.1, 5.2, 5.3, 6.1, 6.3, 7, 8, 9.1 and 9.3, 11.2 and 11.5.

16.3 In the case of default the Provider may immediately terminate this agreement by giving written notice to the Recipient of the termination, provided that:

a) the Provider has given prior notice to the Recipient of the alleged default; and

b) the Recipient fails to respond to the Provider within the period specified by the notice (being not less than 20 business days and not more than 60 business days) to rectify or explain to the satisfaction of the Provider the reasons for the default.

16.4 If this agreement is terminated under paragraph 2 of this Article the Recipient will not thereafter utilize or transfer the accessed genetic resources or use or transfer associated genetic knowledge; and it will transfer back to the Provider or destroy, at the Provider's discretion, all genetic resources or associated genetic knowledge. The operation of this clause survives the termination of this agreement.

1. Overview of the Article

Article 16 focuses on the forms and conditions of the termination of the agreement before the mutual obligations have been fully implemented. There are two possible forms of termination: termination by mutual agreement and termination by default. In the first case (16.1), the Parties conclude a contract on the termination in which all the obligations that follow from the termination (handling of the GR and the associated knowledge, terms) will be regulated. In the second case the Recipient, in failing to satisfy one of his principal contractual obligations listed under 16.2, fulfils the conditions for the termination by default. In consequence the Provider has the right to terminate the contract unilaterally under the formal conditions of 16.3. The Recipient must immediately stop further utilization of the GR and use of the knowledge (16.4).

2. Legal Background

The Article reflects requirements of general contract law. A contract must be clear on its termination.

3. Explanation of the Article in Detail

Article 16.1 expresses the contractual freedom of the Parties to determine the termination of the contract and the resulting obligations.

Article 16.2 lists the principal obligations of the Recipient the non-fulfilment of which may lead to automatic termination under the formal conditions of 16.3. The relevant obligations are:

- Utilization for the public domain (4.2)
- Utilization for proprietary purposes (4.3)
- Change of intent (4.4)
- Transfer of genetic resources (5.1)
- Transfer of associated knowledge (5.2)
- PIC before transfer (5.3)
- Publication of associated knowledge (6.1)
- Acknowledging the contribution of the Provider State (7)
- Recording and Reporting (8)

- Sharing of knowledge for the public domain (9.1)
- Sharing of knowledge for proprietary purposes (9.3)
- Sharing of monetary benefits (11.2)
- Sharing of monetary benefits in case of breach of Article 4.3. or 4.4. (11.5)

The Provider has to comply, in terminating the contract, with the formal conditions under 16.3: It shall notify to the Recipient of the alleged default. Within an agreed period, specified by the Parties, the Recipient may respond to the notice. This reaction may allow for the possibility of finding an amicable solution as an alternative to the termination of the contract. If the Recipient fails to respond within the agreed period, the Provider may, without further delay, terminate the agreement by giving written notice to the Recipient.

No penalty for the Recipient is prescribed for causing the termination of the contract. However, the Recipient is bound by the prohibition to further utilize and transfer the accessed GR or use and transfer the associated knowledge. Eventually, he is required to transfer back to the Provider or destroy, at the Provider's discretion, the accessed GR.