

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

Result of Micro B3 WP8

<http://www.microb3.eu/>

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The MICROB3 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, MICROB3 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. Besides, the project offers tools for specific capacity building to the research community.

These marine scientific research activities need to be organized according to a set of protocols in order to respect national and international legal commitments in the states involved, and to achieve legal certainty that is beneficial for the research community, the provider countries and also the possible private investors. The guidelines and model contract below illustrate the steps to be followed within MICROB3 project, but they can inspire other projects as well.

1. Possible purposes of the MICRO B3 agreement

The MICRO B3 model agreement applies to full commercial, hybrid and full non-commercial use at the point of access. This agreement can cover 3 situations:

- (A) PUBLIC DOMAIN: The recipient envisions only public domain uses of genetic resources when you access the resource. Therefore, only conditions for public domain uses are negotiated at the moment of first access (article 4.2.). If needed commercial uses can still be envisioned in 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 in intent (consent clause under article 4.4).
- (B) HYBRID: The recipient envisions public domain uses of some genetic resources/some use of genetic resources and already knows at the point of access some potential commercial uses for other genetic resources/other uses of the accessed genetic resource.
- (C) PURE COMMERCIAL: The recipient envisions commercial uses for all the genetic resources accessed and decides to negotiate the benefit sharing conditions for commercial uses upon the access of the genetic resources. In this case only article 4.3. if the model contract applies (delete articles 4.2 – 4.4).

2. Core benefits

By signing the agreement, the provider country gives the research consortium the permit to sample in its seas and enters into a partnership. In such partnership some mutual benefits are automatically included and others can be decided/negotiated while signing the agreement (in the specific conditions of article 4). These benefits are summarized below:

Automatic benefits from the contract (for the Provider country)

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

List of additional specific benefit-sharing items which can be agreed on upon accessing the sample in the specific provisions of article 10

Related to the sampling

- Mentoring of provider country scientists by MICRO B3 project scientists that provide information and training on sampling and sampling processing
- Participation of the provider country 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 Argon national lab/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)

3. Core elements of the MICRO B3 agreement

Article 4.2 on non-commercial use (public domain uses, with renegotiation in case of change of intent)

Within the framework of upstream basic research, the agreement allows using the collected resources for the public domain (article 4.2.). The application of this clause implies that the knowledge resulting from research and development on the collected materials has to be publicly available to the maximum possible extent. When patent rights are granted permission has to be obtained from the collection and the provider of the genetic material. There should be no expenses to accede to the knowledge acquired from the material accessed (apart from normal costs for dissemination), therefore every scientist with the adequate expertise will be able to access the scientific knowledge/information resulting from the project.

The agreement includes a renegotiation clause in case of change in intent from non-commercial use to commercial use. This clause is activated when the produced knowledge is used with exclusive protection, including products and processes developed. In those situations, the scientist/scientific institution will have to seek the consent of the provider

country and to negotiate benefit-sharing.

Article 5: Viral license clause for improved monitoring, with consent procedure upon transfer to third parties

The viral licence concept means that the contract travels with the resource and the data upon transfer.

The agreement offers a viral license clause in article 5. This clause guarantees that all the obligations of the initial agreement will be imposed on subsequent use of the materials and the produced data when transferred. When the viral licence clause is used, the scientist/scientific institution is allowed to transfer the material to third parties if they sign a new contract in which they commit themselves to respect the conditions of the initial ABS agreement. Every transfer to new third parties will require the signature of a Material Transfer Agreement (MTA) that makes the initial ABS agreement binding. The initial ABS should be attached to the MTA as an annex. At each transfer however, according to the Nagoya Protocol, consent is required from the competent national authority in the provider country (PIC or Prior Informed Consent). Here two situations can be distinguished:

- If you use the viral licence clause, a notification to the competent national authority can be considered as the required prior informed consent.
- In case of modifications of contractual conditions, new consent has to be obtained from the competent national authority.

Article 1.3: Other implementation issues

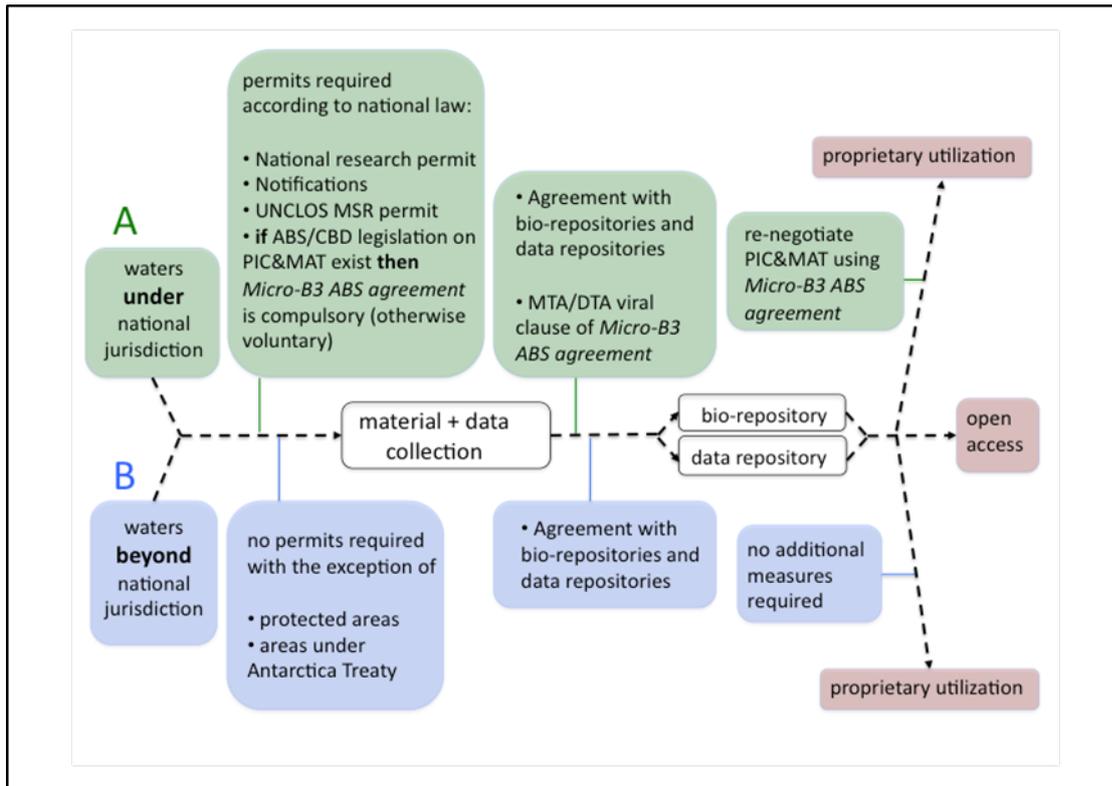
For increasing legal certainty and facility of use, a copy of the contract will be made available to the registered users of the Micro B3 information system.

4. Access procedure

The figure below summarizes the legal workflow regarding the legal steps to be undertaken in accessing the genetic resources and in transferring material and data to third parties, bioarchiving institution or sequencing institutions.

Well in advance of the sampling activities, around 12 months ahead, contact both the National Focal Point to the CBD (or the equivalent information point within the environmental ministry) in the country and the embassy (when you are sampling in foreign national waters) and ask

- if there is a PIC/MAT requirement in national legislation. If so, please contact that authority with the contract and explanatory document and enter the negotiation phase.
- if there are others authorities to be informed/notified or which need to provide approval/permits.



The legal steps are the following:

- Original agreement to access the sample (this is the full template) and any other permit/authorization/notification required according to the national legislation
- Agreement to transfer the sample (Material Transfer Agreements): clause 5.1 of the template and a copy of the original contract in attachment
- Agreement to transfer data (Data Transfer Agreement): clause 5.2 of the template and a copy of the original contract in attachment

Agreement on Access to Marine Microorganisms and Benefit-Sharing

THIS AGREEMENT is made

BETWEEN:

[Insert the name of the Provider State institution¹ and its representative and the full contact details]

(“the Provider”)

AND:

[Insert the name of the Recipient institution² and its representative and the full contact details]

(“the Recipient”)

hereinafter referred to as “the Parties”.

PREAMBLE

Considering that the European Union funded research project Micro B3 (hereinafter the “Micro B3 Project”) is a scientific research program with the following objectives:

- to cooperatively sample marine microbial biodiversity at various sites, including through global coordinated actions called “Ocean Sampling Days”
- to generate large-scale knowledge on marine microbial genomes in an environmental context and on actual or potential biotechnological applications
- to develop innovative bioinformatics approaches for the large scale integration of genomic data of marine microbes with environmental and ecosystems data
- to make the resulting knowledge accessible for the research and development community for policy makers and the public at large,

¹ The Provider must be empowered to represent the Provider State concerning the granting of a permit and the conclusion of an agreement on access to marine genetic resources, the utilization of genetic resources, the transfer of genetic resources and knowledge and the sharing of benefits drawn from its use.

² The Recipient shall not be the individual researcher but the institution which employs the researcher. This ensures that the agreement survives changes of personnel and that its implementation is surveyed.

Recalling that access to and utilization of genetic resources taken from the marine internal waters, territorial sea, exclusive economic zone or continental shelf of coastal states should be consistent with the provisions of the Convention on Biological Diversity (CBD) taking into account their specifications by the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization, and, where appropriate, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (NP, not yet in force), as well as with the United Nations Convention on the Law of the Sea (UNCLOS) and the customary law expressed by UNCLOS,

Recalling that according to these provisions access to and utilization of genetic resources taken from the above described maritime zones is subject to prior informed consent of the coastal state and mutually agreed terms if the coastal state so requires,

Recalling that according to these provisions coastal states have the right to regulate, authorize and conduct marine scientific research in their marine internal waters, territorial sea, exclusive economic zone and on their continental shelf; and that in the case of research undertaken by other states or international organizations the coastal state has the right, if it so desires and if practicable, to participate or be represented in the marine scientific research project and to access data and samples and receive preliminary reports, and final results,

Recalling that according to these provisions non-monetary and/or monetary benefits from the utilization of the genetic resources shall be shared with the Provider State if the same so requires and as it is set out in mutually agreed terms,

Recalling that according to these provisions the transfer of genetic resources to third parties shall be set out in a material transfer agreement,

Recalling that according to these provisions measures on access for non-commercial research purposes shall be simplified with a view to contribute to the conservation and sustainable use of biodiversity, and

Acknowledging that research and development on genetic resources can be for the public domain or for proprietary purposes,

The Parties to this agreement hereby agree as follows:

Article 1 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 Agreement³. 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.

Article 2 DEFINITIONS OF TERMS

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

- a) **Access** means collecting genetic resources from the location where they are found.
- b) **Accessed genetic resources** means the genetic resources collected on the basis of this agreement.
- 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.
- 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.
- 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.
- f) **Micro B3 partner** means an institution that is a Party to the Micro B3 Consortium Agreement.
- 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.
- 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*.
- i) **Third party** means any institution other than Micro B3 partners.
- 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 associated knowledge secret, making the associated 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.

³ The Consortium Agreement is publicly accessible at the Micro B3 website www.microb3.eu

- 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.
- l) **Utilization of genetic resources** means research and development on the genetic and/or biochemical composition of the accessed 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.

Article 3 ACCESS TO GENETIC RESOURCES

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

- a) Kinds of samples⁴, including the kind of genetic resources⁵, if known:

- b) Number and quantity of samples: _____
- c) Geographical location of collection⁶: _____
- 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)⁷

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 resources⁸.

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

⁴ E.g. seawater, sediment.

⁵ The kind of genetic resources to be extracted from the sample, i.e. virus, bacteria, fungi, microorganism.

⁶ E.g. GPS coordinates.

⁷ Not applicable if kind of genetic resources included is known *ex ante* under 3.1.a)

⁸ All other transfers are considered transfers to third parties and bound by the conditions under Article 5.

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.

Article 4 UTILIZATION OF THE 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)

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 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:⁹

- 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]

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 Sample Days.

Specifications if deemed necessary: _____

⁹ 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 uses) as proposed here would also be to the advantage of the Provider country because this allows the Recipient to transfer GR or knowledge during the non-commercial stages more easily and this might lead to increased commercial product development in later stages, in which a new negotiation with the Provider country is initiated according to the renegotiation clause in Art. 4.4.

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.

Article 7 ACKNOWLEDGING THE CONTRIBUTION OF THE PROVIDER STATE

7.1 When making associated genetic knowledge publicly available under Article 6 the Recipient shall indicate the country of origin of the utilized genetic resource.

7.2 When making associated genetic knowledge publicly available under Article 6 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.

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 knowledge¹⁰.

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)

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

Specifications if deemed necessary¹¹: _____

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.¹²

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)

¹⁰ 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.

¹¹ It may be concluded 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.

¹² This clause will be negotiated along with the benefit-sharing arrangement: a provider country will prefer to have access to the information (even if the country keeps it confidential as specified under 9.2), but a company might prefer to give a higher upfront benefit-sharing under Article 11 as a *quid pro quo* for crossing this Article.

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:

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(to be specified by negotiations)

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)

¹³ It should be noted that in the normal case of scientific collaboration the partners conclude a research collaboration contract 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.

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)

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.

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]: _____

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:

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 serve 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.

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.

(Location, Date)

(Provider)

(Recipient)