BeFOre
Bioresources For Oliviculture

2016, December 21fst

"Smart Version"

Guidelines for Legal and ethical management of the genetic resources and traditional knowledge associated to genetic resources.

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2016, December 21fst

GUIDELINES

Section 1: Legal general framework and aims

The international organisations, to avoid the depredation of the natural resources of the developing countries until the 90's, adopted legal texts focused on the principle of the «sovereign rights» of the State on its natural resources.

These principles were established by the Convention on Biological Diversity /CBD (Article 15, para. 1) and by other following international treaties especially by International Treaty on Plant Genetic Resources for Food and Agriculture/ITPGRFA (Article 10.1) and by the Nagoya Protocol/NP.

All the activities of BeFOre Consortium will be carried out in strict compliance with the Convention on Biological Diversity, in particular as follows (see Article 12 of the Convention):

- Promote and encourage research, which contributes to the conservation and sustainable use of biological diversity;
- Promote and cooperate in the use of scientific advances in biological diversity research in developing methods for conservation and sustainable use of biological resources.

The research will observe the fundamental principle (established by Article 19 of the Convention and the EU legal sources) of the benefit of the Country/ies involved in the experimental actions.

According to the CBD (Article 15, par. 1), the «sovereign rights» of the States consist in particular in the authority to determine access to genetic resources in accordance with the national laws.
States has sovereign rights over the natural resources including genetic resources.

States can legislate over the access of genetic resources, but not implies necessary the State ownership over the genetic resources. In other words, the owner could be the State, private owners, or Indigenous or Local communities.

According to the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with genetic resources should exercise due diligence to ascertain whether genetic resources and traditional knowledge associated with genetic resources have been accessed in accordance with applicable legal or regulatory requirements and to ensure that, where relevant, benefits are fairly and equitably shared.

In the context of Access and Benefit-sharing/ABS, due diligence means that you did your very best to establish which access and benefit-sharing conditions apply to the genetic resources you wish to access and that you have taken care to meet these conditions.

The EU legislation will be used as main legal reference in order to face the legal and ethics of the Project (see Reg. (EU) No 511/2014; Reg. (EU) 2015/1866).

Section 2. Non-compliance of Access and Benefit-sharing system: the impact on the Before Project.

The non compliance with the ethical principles, Nagoya Protocol and Reg. 2014/511 means:

a) Negative impact on developing the project funded by the EU program in the framework of the ethical and legal issues of the project (Point (25) Reg. (EU) No 511/2014 /Art. 5 Reg. (EU) 2015/1866)

b) The grant may be reduced (see Articles 34.4 and 43 Grant Agreement)

c) The Agreement or participation of the beneficiary may be terminated (see Articles 34.4 and 50 Grant Agreement).

d) No legitimisation of possible plant patents granted if they started from genetic resources and traditional knowledge associated with genetic resources (see EU Directive 98/44/EC).

e) Civil liability for user's failure to act with “due diligence”.

Section 3: How to do

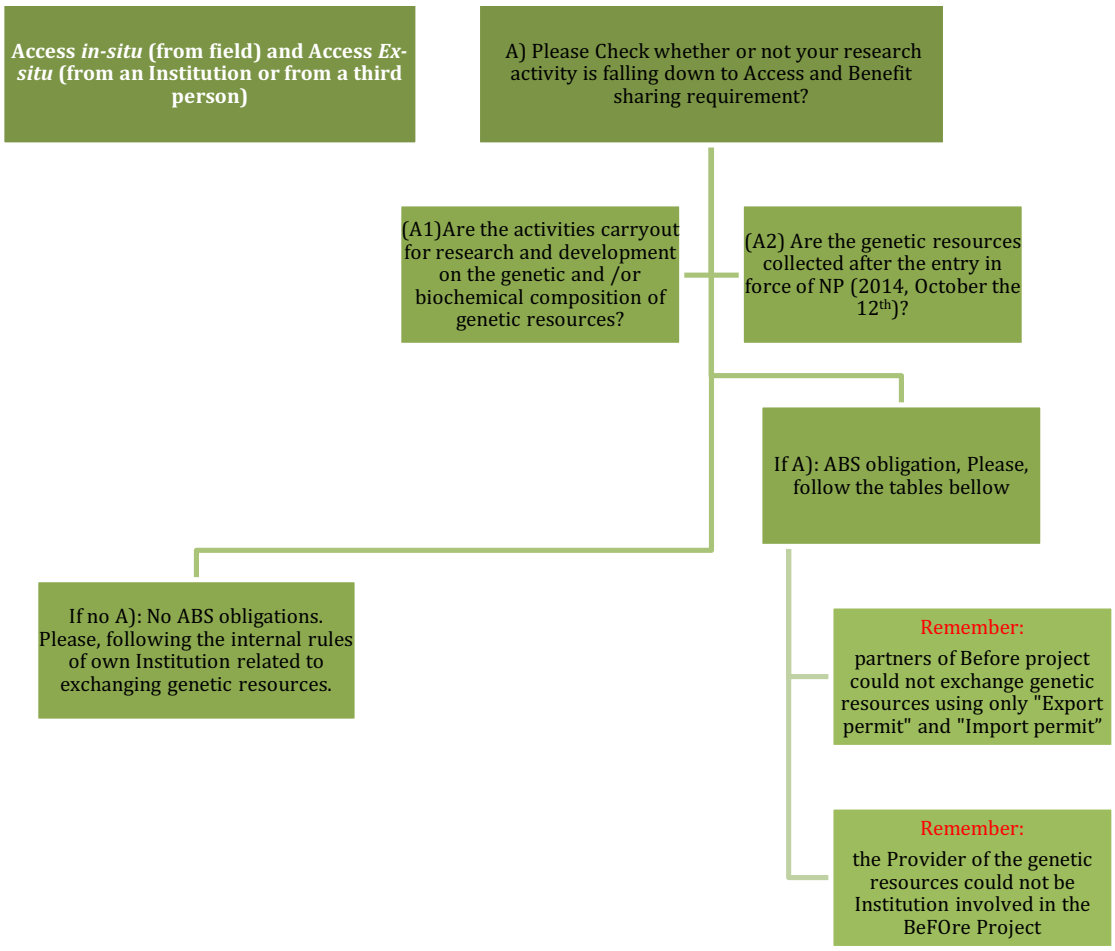

Table 1: Check before to start activity

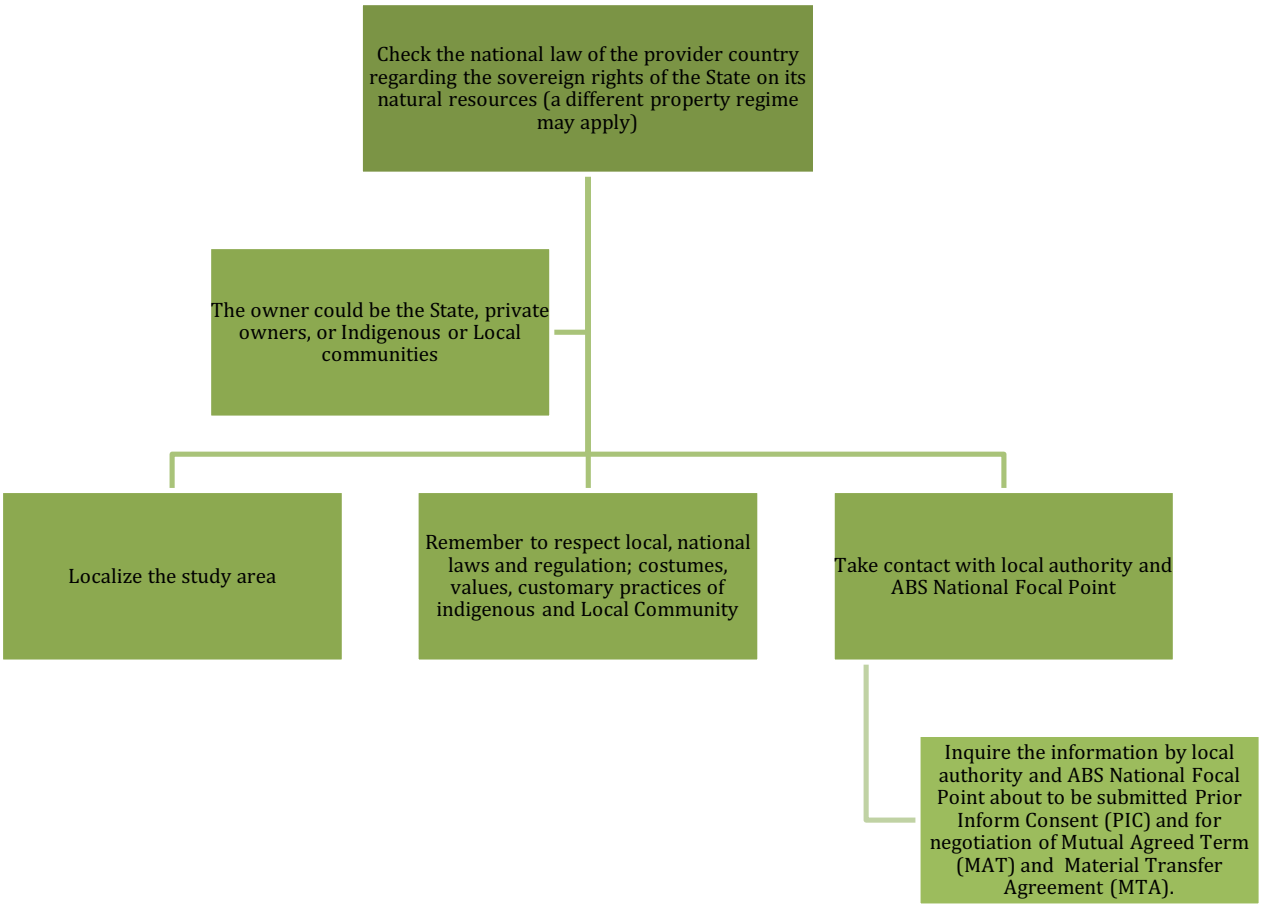

Table 2: Sovereign rights on natural resources

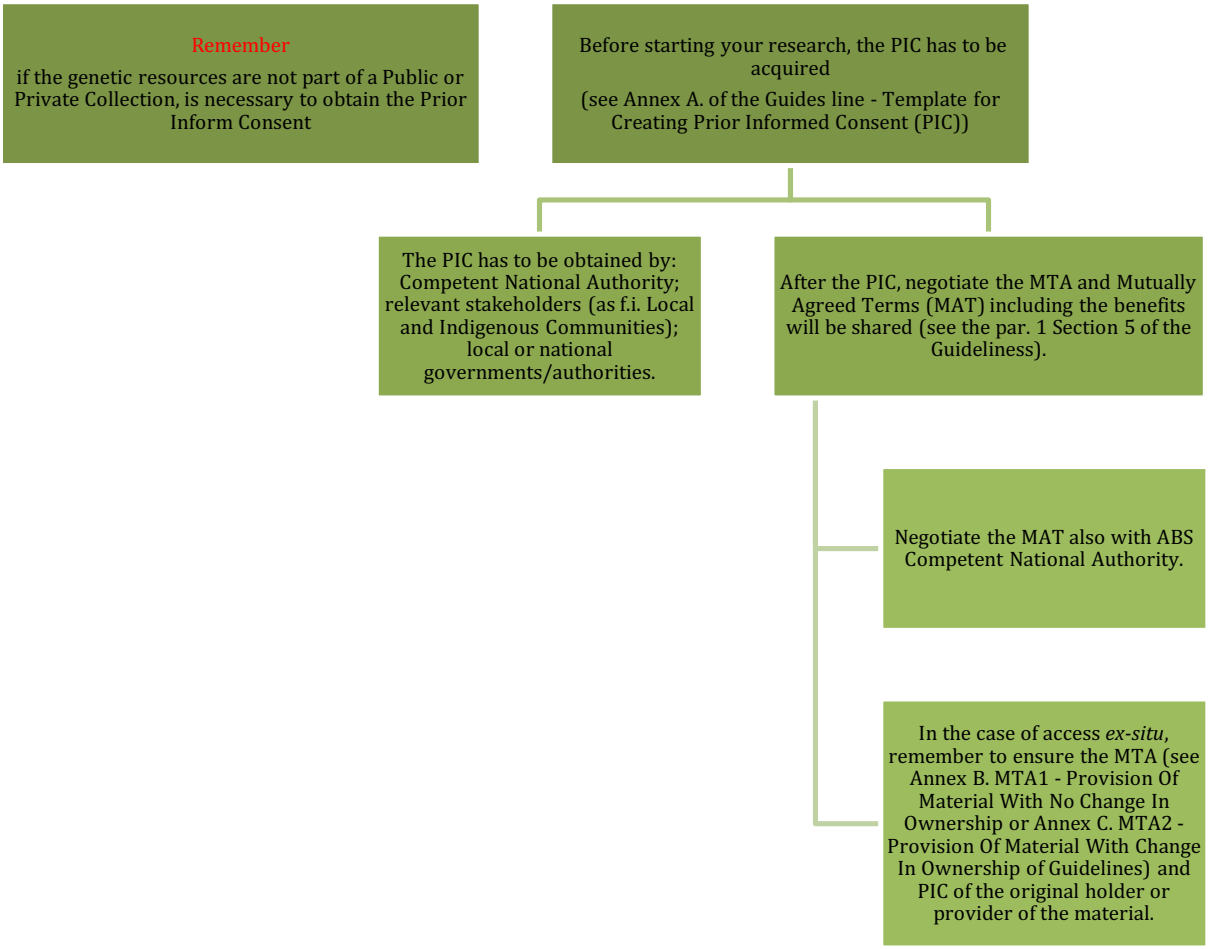

Table 3: PIC_MTA_MAT and Negotiation

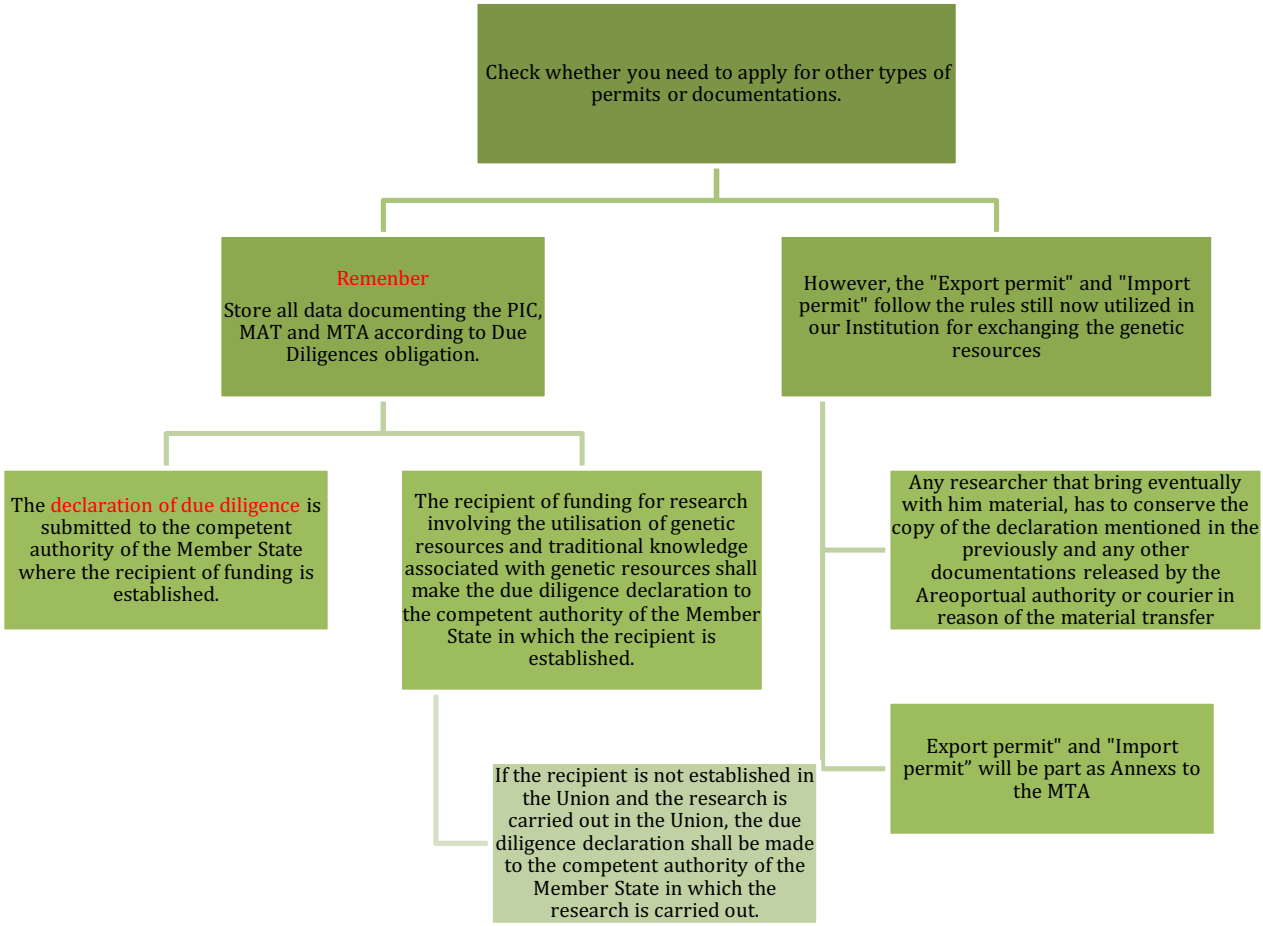

Table 4: Documentation.

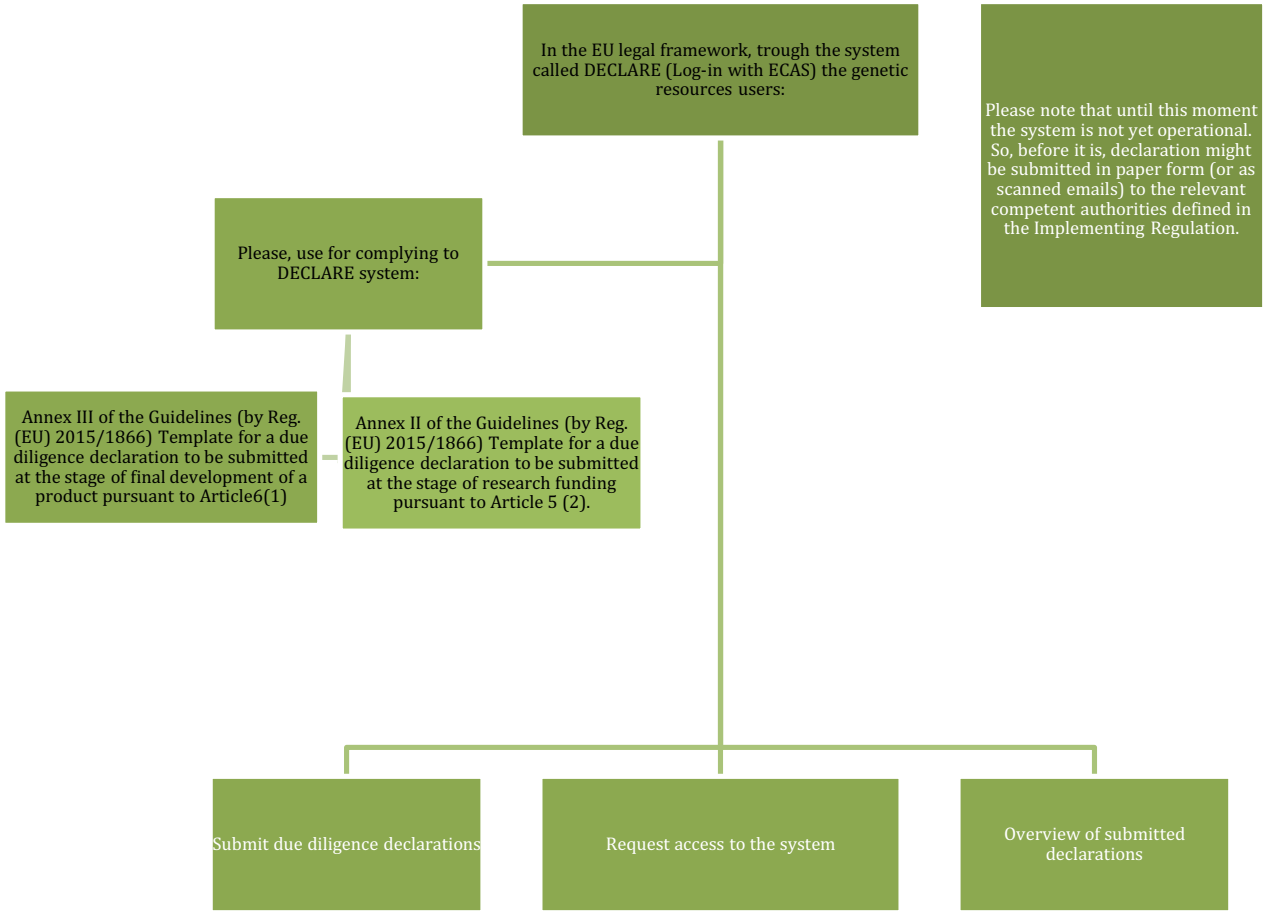

Table 5: DECLARE system

ANNEXES

Annex A.

Template for Creating Prior Informed Consent

Prior Informed Consent for research activity related to Genetic Resources or Traditional Knowledge associated to Genetic Resources

……. [Name/Surname, Affiliation/Local Community/etc., place]
Hereinafter referred to as “Provider”

Warning:

Please, taking attention on follow information:

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve.

Please read the following information carefully.

Please ask the researcher if there is anything that is not clear or if you need more information.

TITLE OF RESEARCH ACTIVITY

[Insert title]

PRINCIPAL INVESTIGATOR

[Name]
[Department]
[Address]
[Phone]
[Email]

The Principal Investigator is carrying out a research activity, as members of the consortium established to implement the Project “Bioresources for Oliviculture”, funded by the Marie Sklodowska Curie - Horizon 2020 Research and Innovation Staff Exchange (RISE) of the European Union (hereinafter referred to as “BeFOre”)

PURPOSE OF RESEARCH ACTIVITY

The purpose of this study is to…… [*please, briefly describe purpose of researcher activity*]

RESEARCH ACTIVITY PROCEDURES

[*List all procedures, preferably in chronological order, which will be employed in the study Point out any procedures that are considered experimental*].

RISKS

[*List all reasonably foreseeable risks, if any, of each of the procedures to be used in the study, and any measures that will be used to minimize the risks*].

BENEFITS

[*List the benefits you anticipate will be achieved from this research. Include benefits to participants, others, or the body of knowledge.*

The PRINCIPAL INVESTIGATOR's Institution within specific Material Transfer Agreement shall share fairly and equitably the benefits arising from the researcher activity of the refers to Genetic Material, Genetic Resources or Traditional Knowledge associated to Genetic Resources, its progeny or derivatives in accordance with the CBD. In accordance with the Nagoya Protocol, the following monetary and/or non-monetary benefits will be granted to the PRINCIPAL INVESTIGATOR's Institution[1].

1 A non-exhaustive list of non-monetary and monetary benefits is given the Annex to the Nagoya Protocol:
Monetary benefits may include, but not be limited to:
(a) Access fees/fee per sample collected or otherwise acquired;
(b) Up-front payments;
(c) Milestone payments;
(d) Payment of royalties;
(e) Licence fees in case of commercialisation;
(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
(g) Salaries and preferential terms where mutually agreed;
(h) Research funding;
(i) Joint ventures;
(j) Joint ownership of relevant intellectual property rights.
Non-monetary benefits may include, but not be limited to:
(a) Sharing of research and development results;
(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
(c) Participation in product development;
(d) Collaboration, cooperation and contribution in education and training;
(e) Admittance to ex situ facilities of genetic resources and to databases;
(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and the most favorable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
(g) Strengthening capacities for technology transfer;
(h) Institutional capacity-building;
(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
(j) Training related to genetic resources with the full participation of countries providing genetic resources,

CONFIDENTIALITY

For the purpose of this Prior Informed Consent, Confidential Information include, by way of example, but without limitation, the research activity, the purpose of research activity, research activity procedures as above mentioned, Genetic Resources or Traditional Knowledge associated to Genetic Resources, specifications, formulae, test reports, equipment, business strategies, customer lists, know-how, drawings, pricing information, inventions, ideas, trial reports, and other information, or its potential use, that is owned by or in possession of Provider and Principal Investigator to this Prior Informed Consent.

Any Confidential Information is shall be disclosed by Provider and Principal's Investigator until the Material Transfer Agreement is completed.

CONTACT INFORMATION

If you have questions at any time about this researcher activity, or you experience adverse effects as the result of participating in this researcher activity, you may contact the researcher whose contact information is provided on the first page.

If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator, please contact the Institutional ……

VOLUNTARY PARTICIPATION

Your participation in this researcher activity is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to transfer/give access/etc [*please, indicate the activities asked to the provider*) to genetic resources or traditional knowledge associated to genetic resources, you will be asked to sign a consent form. After you sign the consent form until the date of the subscription of Material Transfer Agreement, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the researcher activity before Material Transfer Agreement is completed, your data will be returned to you or destroyed.

CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this researcher activitity.

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and where possible, in such countries;
(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
(l) Contributions to the local economy;
(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
(o) Food and livelihood security benefits;
(p) Social recognition;
(q) Joint ownership of relevant intellectual property rights.

Provider's signature _____ Date _____

Principal Investigator's signature _____ Date _____

Annex B.

Template MATERIAL TRANSFER AGREEMENT (MTA) PROVISION OF MATERIAL WITH NO CHANGE IN OWNERSHIP

MTA1 - PROVISION OF MATERIAL
WITH NO CHANGE IN OWNERSHIP
*****

BETWEEN

1. 'the Provider ':

……., with its registered office in ….represented by… acting as Head of [please indicate the legal representative of the legal entity/branch of the legal entity]

and

2.'the User:

with its registered office in ….represented by… acting as Head of [please indicate the legal representative of the legal entity/branch of the legal entity]

Whereas

(1) The PROVIDER and the USER are carrying out a research activity, as members of the consortium established to implement the Project "Bioresources for Oliviculture", funded by the Marie Skłodowska Curie - Horizon 2020 Research and Innovation Staff Exchange (RISE) of the European Union (hereinafter referred to as "BeFOre");
(2) The above mentioned activity shall be carried out in compliance with the Convention on Biological Diversity (CBD)[2] and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS)[3].
(2-bis) [*Additional clause for EU members*]**:** and in the specific case of European legal framework, by Regulation (EU) No 511/2014[4] and Commission Implementing Regulation (EU) 2015/1866[5] of 13 October 2015 that lays down detailed rules for the implementation of Regulation (EU) No 511/2014**.**
(3) This Material transfer agreement is designed to promote scientific RESEARCH and EXCHANGE.

Now Therefore It has been Agreed as Follows

With the preamble making integral and substantial part of this Material Transfer Agreement (hereinafter referred to as "MTA")

[2] http://www.cbd.int/convention/text/
[3] http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf
4 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511
5 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

Art. 1
Purpose

1. MTA shall regulate the temporary transfer of MATERIAL containing genetic resources for non-commercial analyses and research between members of the BeFOre Consortium .
2. At the end of the duration of MTA the MATERIAL not consumed by analysis will [be destroyed / will be returned] [*delete as necessary*].

Art. 2
Definitions

1. Definitions of terms are provided in Annex 1 enclosed to this MTA.

Art. 3
Provider's obligations

1. The PROVIDER shall supply the MATERIAL listed within Annex 2 enclosed to this MTA.
2. The PROVIDER shall warrant the absence of any third party rights in the MATERIAL that would preclude it from supplying the MATERIAL to the USER in accordance with this MTA.
3. The PROVIDER shall be entitled to not supply any MATERIAL if such supply would be contrary to any terms attached to the MATERIAL and/or is not consistent with provisions of the CBD.

Art. 4
Ownership

1. The MATERIAL and DATA shall remain on the property of the PROVIDER, subject to conditions set out with the Providing Country by the MUTUALLY AGREED TERMS (see Annex F).
2. The MATERIAL shall not be transferred wholly or partially by the USER to third parties, without prior written authorization from the PROVIDER
4. The USER shall be aware that the PROVIDER will be free, at its sole discretion, to distribute the MATERIAL to others for any USE and to USE the MATERIAL for its own purposes
5. The USER shall be the owner of the following results of its activities:
i. MODIFICATIONS (except that, the PROVIDER retains ownership rights to the MATERIAL included therein), and
ii. those substances created through the USE of the MATERIAL or MODIFICATIONS, but which are not UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL or UNMODIFIED DERIVATIVES)[6].

Art. 5
User's obligations

1.The USER, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources, shall as follows:
a) USE the MATERIAL and resulting derivatives for non-commercial purposes in scientific RESEARCH, education and conservation;
b) not sell, distribute or USE for profit or any other commercial application the MATERIAL, related derivatives or any direct or indirect results obtained from analysis or use of the MATERIAL;
c) maintain retrievable records linking the MATERIAL to these terms of acquisition and to any accompanying DATA provided by the PROVIDER

[6] If either i) or ii) results from the collaborative efforts of the PROVIDER and the joint ownership may be negotiated under a separate agreement.

d) provide the PROVIDER with copies of the publications resulting from the USE;
e) acknowledge the PROVIDER as the source of the MATERIAL in all written and electronic publications and reports, including repository DATA, such as unique or voucher number where available;
f) agree to acknowledge the Providing Country as the source of the MATERIAL in any and all publications arising from its USE;
g) agree to acknowledge the Providing Country as the source of the MATERIAL in any and all patent applications arising from its USE.

Art. 6
Copyright, rights and license

1.Nothing in this AGREEMENT shall or may be construed as granting the USER any right or license to the MATERIAL for any USE other than the purpose described herein.
2. Unless otherwise indicated, copyright in all DATA supplied with the MATERIAL is owned by the PROVIDER. The USER may USE these DATA on condition that they are used solely for scholarly, education or RESEARCH purposes; that they are not used for commercial purposes; and that the USER always acknowledges the source of the DATA with the words "With the permission of [*PROVIDER*]

Art. 7
Relevant documentation

1. Relevant documentation, as indicated below, is annexed to this document if relevant to the MATERIAL, and forms part of the AGREEMENT:
Annex A) Collecting Permit (CP)
Annex B) Prior Informed Consent (PIC)
Annex C) Export permit
Annex D) Import permit
Annex E) Letter informing Providing Country of third-Party Transfer
Annex F) Mutually agreed terms (MAT)
Annex G) The Internationally-Recognised Certificate of Compliance number(s) is/are:….. (*If possible*)

Art. 8
Benefit-sharing Benefit-sharing

1. The USER within the MAT shall share fairly and equitably the benefits arising from their USE of the MATERIAL, its progeny or derivatives in accordance with the CBD.
2. In accordance with the Nagoya Protocol, the following monetary and/or non-monetary benefits will be granted to the PROVIDER by the USER [A non-exhaustive list of non-monetary and monetary benefits is given the Annex to the Nagoya Protocol][7]:

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7 **Monetary benefits may include, but not be limited to:**
(a) Access fees/fee per sample collected or otherwise acquired;
(b) Up-front payments;
(c) Milestone payments;
(d) Payment of royalties;
(e) Licence fees in case of commercialisation;
(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
(g) Salaries and preferential terms where mutually agreed;
(h) Research funding;
(i) Joint ventures;
(j) Joint ownership of relevant intellectual property rights.
Non-monetary benefits may include, but not be limited to:
(a) Sharing of research and development results;
(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
(c) Participation in product development;
(d) Collaboration, cooperation and contribution in education and training;

2. If, at any time, any product or process derived from MATERIAL shipped under the terms of this MTA, whether or not such product or process is subject to intellectual property protection, is identified as having potential commercial USE not previously discussed with the PROVIDER, the USER shall immediately cease all further RESEARCH and activity undertaken in connection with the MATERIAL and shall promptly notify the PROVIDER. The USER shall be prohibited from continuing to engage in the activity for which the commercial potential was identified until it has entered into a written agreement with the PROVIDER pertaining to the USE of genetic heritage and benefit-sharing .

Art. 9
Publications

1. In any publication, or with submission to a public database, the USER should include the following data USE statement: "[Data on genetic material contained in this paper /These data] are published for non-commercial USE only.
2. USE for purposes other than non-commercial scientific RESEARCH may infringe the conditions under which the GENETIC RESOURCES were originally accessed, and should not be undertaken without contacting the [corresponding author of the paper / depositor of the sequence data] and/or seeking permission from the original provider of the genetic material

Art. 10
Risks and Warranties

1. The USER shall be the solely responsible for safe receipt, USE, storage and disposal of MATERIALS and derivatives.
2. The USER shall indemnify the PROVIDER, its officers, employees and agents ('those indemnified') against all expenses, losses, damages and costs (including legal costs on a full indemnity basis) incurred by or awarded against those indemnified arising out of a claim by any person in relation to:

(e) Admittance to ex situ facilities of genetic resources and to databases;
(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and the most favorable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
(g) Strengthening capacities for technology transfer;
(h) Institutional capacity-building;
(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
(l) Contributions to the local economy;
(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
(o) Food and livelihood security benefits;
(p) Social recognition;
(q) Joint ownership of relevant intellectual property rights.

(a) the RECIPIENT's USE of the MATERIAL and its derivatives, and any other exercise of rights under this AGREEMENT; and
(b) breach of this MTA by the RECIPIENT

3. The PROVIDER shall makes no representation or warranty of any kind, either express or implied, as to the identity, safety, merchantability or fitness for any particular purpose of the MATERIAL, its progeny or derivatives, or as to the accuracy or reliability of any DATA supplied.
4. The PROVIDER shall not be liable for failures in any analysis (e.g., DNA extraction, PCR product, sequencing reaction, etc.).

Art. 11
Transport of MATERIAL

1. The USER shall take all appropriate and necessary measures to import (and return, where appropriate) the MATERIAL in accordance with relevant laws and regulations.
2. The USER shall be responsible for ensuring that it can provide all required permits to the PROVIDER if requested.

Art. 12
Termination

1. This AGREEMENT shall terminate on the earliest of the following dates:
a. on completion of the BeFOre Project; or
b. on thirty (30) days written notice by either party to the other; or
c. On the predetermined closure of this Contract/Material Transfer Agreement [date: DD/MM/YYYY].

Art. 13
Effects of the Termination

1. Upon the effective date of termination, or if requested, the deferred effective date of termination, USER will discontinue its USE of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any unconsumed MATERIAL and related DERIVATIVES. The RECIPIENT, at its discretion, also will either destroy the DERIVATIVES or remain bound by the terms of this MTA as they apply to DERIVATIVES.
2. If termination occurs, the USER shall discontinue its USE of the MATERIAL, upon direction of the PROVIDER, and it shall

- return any unconsumed MATERIAL and related derivatives
- destroy any unconsumed MATERIAL and all DERIVATIVES
- destroy any unconsumed MATERIAL but remains bound by the terms of this AGREEMENT as they apply to DERIVATIVES.
- notify the PROVIDER in written form about the disposal of unconsumed MATERIAL and all related DERIVATIVES, such as PCR products, cycle-sequencing products or similar by-products, enabling the PROVIDER to determine the starting point of the 20 year reporting obligation laid down in EU (No) 511/2014.

3. The expiration or termination of this MTA, shall not affect the obligations contained in this MTA.

Art. 14
Applicable Law

1.This MTA is governed by and shall be construed in accordance with the law of [country of PROVIDER].

Art. 15
Settlement of Disputes

1. All disputes or differences arising in connection with this MTA which cannot be settled amicably shall be finally settled by arbitration in Paris under the rules of arbitration of the International Chamber of Commerce by one or more arbitrators to be appointed under the terms of those rules. In any arbitration in which there are three arbitrators, the chairman shall be of juridical education.
2. The award of the arbitration will be final and binding upon the Parties concerned.
3. The place of arbitration shall be Paris if not otherwise agreed by the conflicting Parties.

4. The Parties may instead elect to resolve by mediation a dispute or difference arising in connection with this MTA, which cannot be settled amicably.

Art. 16
Final dispositions

1. Neither party may assign or otherwise transfer this MTA and the rights acquired hereunder without the written consent of the other party.
2. Any permitted assignee should agree in writing to be bound by the terms of this MTA.
3. Each party will ensure that its officers, employees and agents comply with the obligations imposed on it by this AGREEMENT as if personally bound by those obligations.
4. In the event that the PROVIDER terminates this MTA under 12(b), other than for breach of this MTA or conflict with prior Mutually Agreed Terms, the PROVIDER will defer the effective date of termination for a period of up to one year, upon request from the RECIPIENT, to permit completion of RESEARCH in progress.

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Annex 1

Definitions

'DATA' unless otherwise stated, information, including locality and other collecting information, permits and other agreements, and any other information provided by the PROVIDER with the MATERIAL.
'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 (definition from Nagoya Protocol Art 2).
'EXCHANGE' also '*Transfer*', and '*Permanent supply*'. Permanent transfer of SPECIMENs to a Third Party to the original agreement .
'GENETIC MATERIAL' means any material of plant, animal, microbial or other origin containing functional units of heredity
'GENETIC RESOURCES' means genetic material of actual or potential value
'MATERIAL' refers to Genetic Material, Genetic Resources and items listed on the Annex 2 of this Material Transfer Agreement
'MODIFICATIONS' substances created by the User by using the MATERIAL which are not the ORIGINAL MATERIAL, PROGENY, or UNMODIFIED DERIVATIVES and which have new properties. MODIFICATIONS include, but are not limited to, recombinant DNA clones.
'MUTUALLY AGREED TERMS' contractual arrangements concluded between a provider of genetic resources, or of traditional knowledge associated with genetic resources, and a user, that set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources, and that may also include further conditions and terms for such utilisation as well as subsequent applications and commercialisation
'PROVIDING COUNTRY / PROVIDER OF MATERIAL' (or "Country providing GENETIC RESOURCES") means the country supplying GENETIC RESOURCES collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country. (Definition from CBD Art 2)
'RESEARCH' The systematic investigation into and study of materials and sources in order to

establish facts and reach new conclusions. This does not include any development of commercial applications.
'USE' The purposes to which samples and SPECIMENs (biological and genetic material) are put, including but not limited to 'UTILIZATION' in the sense of the Nagoya Protocol; and 'UTILIZATION (of genetic resources)' means the conduct RESEARCH and development on the genetic and/or biochemical composition of GENETIC RESOURCES, including through the application of biotechnology as defined in Article 2 of the Convention (definition from the Nagoya Protocol).
'USER' means a natural or legal person that utilises genetic resources, genetic material, material and also the organisation to whom the Provider sends the MATERIAL.

Annex 2

MATERIAL

Annex A)

Collecting Permit (CP)

Annex B)

Prior Informed Consent (PIC)

Annex C)

Export permit

Annex D)

Import permit

Annex E)

Letter informing Providing Country of third-Party Transfer

Annex F)

Mutually agreed terms (MAT)

Annex G)

The Internationally-Recognised Certificate of Compliance

2016, December 21fst

Annex C.

Template MATERIAL TRANSFER AGREEMENT (MTA) PROVISION OF MATERIAL WITH CHANGE IN OWNERSHIP

MATERIAL TRANSFER AGREEMENT (MTA)

MTA2 - PROVISION OF MATERIAL WITH CHANGE IN OWNERSHIP

*****

BETWEEN

1. 'the Provider ':

……., with its registered office in ….represented by… acting as Head of [please indicate the legal representative of the legal entity/branch of the legal entity]

and

2.'the User':

with its registered office in ….represented by… acting as Head of [please indicate the legal representative of the legal entity/branch of the legal entity]

Whereas

(1) The PROVIDER and the USER are carrying out a research activity, as members of the consortium established to implement the Project "Bioresources for Oliviculture", funded by the Marie Skodowska Curie - Horizon 2020 Research and Innovation Staff Exchange (RISE) of the European Union (hereinafter referred to as "BeFOre");
(2) The above mentioned activity shall be carried out in compliance with the Convention on Biological Diversity (CBD)[8] and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS)[9].
(2-bis) [*Additional clause for EU members*]**:** and in the specific case of European legal framework, by Regulation (EU) No 511/2014[10] and Commission Implementing Regulation (EU) 2015/1866[11] of

[8] http://www.cbd.int/convention/text/
[9] http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf
10 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511
11 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

13 October 2015 that lays down detailed rules for the implementation of Regulation (EU) No 511/2014.
(3) This Material transfer agreement is designed to promote scientific RESEARCH and EXCHANGE.

Now Therefore It has been Agreed as Follows

With the preamble making integral and substantial part of this Material Transfer Agreement (hereinafter referred to as "MTA")

Art. 1
Purpose

1. MTA shall regulate the transfer with change of ownership of MATERIAL containing genetic resources for non-commercial analyses and research between members of the BeFOre Consortium .

Art. 2
Definitions

1. Definitions of terms are provided in Annex 1 enclosed to this MTA.

Art. 3
Provider's obligations

1. The PROVIDER irrevocably and unconditionally transfers, free of charge, title in the item, including any rights, copyright or any other use and commercial rights of the MATERIAL listed within Annex 2 enclosed to this MTA.
2. The PROVIDER shall supply the MATERIAL listed within Annex 2 enclosed to this MTA.
3. The PROVIDER shall warrant the absence of any third party rights in the MATERIAL that would preclude it from supplying the MATERIAL to the USER in accordance with this MTA.
4. The PROVIDER shall guarantee the USER that will make no consequent claim as to ownership or indemnity for transfer title item above-mentioned against the USER.
3. The PROVIDER shall be entitled to not supply any MATERIAL if such supply would be contrary to any terms attached to the MATERIAL and/or is not consistent with provisions of the CBD.

Art. 4
User's obligations

1.The USER, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources, shall maintain retrievable records linking the MATERIAL to these terms of acquisition and to any accompanying DATA provided by the PROVIDER.

Art. 5
Copyright, rights and license

1.The PROVIDER grants the USER any right or license to the MATERIAL for any USE other than the purpose described herein.
2. The copyright in all DATA supplied with the MATERIAL is owned by the USER.

Art. 6
Relevant documentation

1. Relevant documentation, as indicated below, is annexed to this document if relevant to the MATERIAL, and forms part of the AGREEMENT:
Annex A) Collecting Permit (CP)
Annex B) Prior Informed Consent (PIC)
Annex C) Export permit
Annex D) Import permit
Annex E) Letter informing Providing Country of third-Party Transfer

Annex F) Mutually agreed terms (MAT)
Annex G) The Internationally-Recognised Certificate of Compliance number(s) is/are:….. (*If possible*)

Art. 7
Benefit-sharing Benefit-sharing

1. The USER within the MAT shall share fairly and equitably the benefits arising from their USE of the MATERIAL, its progeny or derivatives in accordance with the CBD.
2. In accordance with the Nagoya Protocol, the following monetary and/or non-monetary benefits will be granted to the PROVIDER by the USER [A non-exhaustive list of non-monetary and monetary benefits is given the Annex to the Nagoya Protocol][12]:

12 **Monetary benefits may include, but not be limited to:**
(a) Access fees/fee per sample collected or otherwise acquired;
(b) Up-front payments;
(c) Milestone payments;
(d) Payment of royalties;
(e) Licence fees in case of commercialisation;
(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
(g) Salaries and preferential terms where mutually agreed;
(h) Research funding;
(i) Joint ventures;
(j) Joint ownership of relevant intellectual property rights.
Non-monetary benefits may include, but not be limited to:
(a) Sharing of research and development results;
(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
(c) Participation in product development;
(d) Collaboration, cooperation and contribution in education and training;
(e) Admittance to ex situ facilities of genetic resources and to databases;
(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and the most favorable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
(g) Strengthening capacities for technology transfer;
(h) Institutional capacity-building;
(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
(l) Contributions to the local economy;
(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
(o) Food and livelihood security benefits;
(p) Social recognition;
(q) Joint ownership of relevant intellectual property rights.

2. If, at any time, any product or process derived from MATERIAL shipped under the terms of this MTA, whether or not such product or process is subject to intellectual property protection, is identified as having potential commercial USE not previously discussed with the PROVIDER, the USER shall immediately cease all further RESEARCH and activity undertaken in connection with the MATERIAL and shall promptly notify the PROVIDER. The USER shall be prohibited from continuing to engage in the activity for which the commercial potential was identified until it has entered into a written agreement with the PROVIDER pertaining to the USE of genetic heritage and benefit-sharing .

Art. 8
Publications

1. The USER shall have unrestricted rights to publish the results from the USE of the MATERIAL or DATA supplied with the MTA.

Art. 9
Risks and Warranties

1. The USER shall be the solely responsible for safe receipt, USE, storage and disposal of MATERIALS and derivatives.
2. The USER shall indemnify the PROVIDER, its officers, employees and agents ('those indemnified') against all expenses, losses, damages and costs (including legal costs on a full indemnity basis) incurred by or awarded against those indemnified arising out of a claim by any person in relation to:
   (a) the RECIPIENT's USE of the MATERIAL and its derivatives, and any other exercise of rights under this AGREEMENT; and
   (b) breach of this MTA by the RECIPIENT
3. The PROVIDER shall makes no representation or warranty of any kind, either express or implied, as to the identity, safety, merchantability or fitness for any particular purpose of the MATERIAL, its progeny or derivatives, or as to the accuracy or reliability of any DATA supplied.
4. The PROVIDER shall not be liable for failures in any analysis (e.g., DNA extraction, PCR product, sequencing reaction, etc.).

Art. 10
Transport of MATERIAL

1. The USER shall take all appropriate and necessary measures to import (and return, where appropriate) the MATERIAL in accordance with relevant laws and regulations.
2. The USER shall be responsible for ensuring that it can provide all required permits to the PROVIDER if requested.

Art. 11
Termination

1. This AGREEMENT shall terminate on the earliest of the following dates:
a. on completion of the BeFOre Project; or
b. on thirty (30) days written notice by either party to the other; or
c. On the predetermined closure of this Contract/Material Transfer Agreement [date: DD/MM/YYYY].

Art. 12
Effects of the Termination

1. The expiration or termination of this MTA, shall not affect the obligations contained in this MTA.

Art. 13
Applicable Law

1. This MTA is governed by and shall be construed in accordance with the law of [country of PROVIDER]

Art. 14
Settlement of Disputes

1. All disputes or differences arising in connection with this MTA which cannot be settled amicably shall be finally settled by arbitration in Paris under the rules of arbitration of the International Chamber of Commerce by one or more arbitrators to be appointed under the terms of those rules. In any arbitration in which there are three arbitrators, the chairman shall be of juridical education.
2. The award of the arbitration will be final and binding upon the Parties concerned.
3. The place of arbitration shall be Paris if not otherwise agreed by the conflicting Parties.
4. The Parties may instead elect to resolve by mediation a dispute or difference arising in connection with this MTA, which cannot be settled amicably.

Art. 15
Final dispositions

1. Neither party may assign or otherwise transfer this MTA and the rights acquired hereunder without the written consent of the other party.
2. Any permitted assignee should agree in writing to be bound by the terms of this MTA.
3. Each party will ensure that its officers, employees and agents comply with the obligations imposed on it by this AGREEMENT as if personally bound by those obligations.
4. In the event that the PROVIDER terminates this MTA under art.11(b), other than for breach of this MTA or conflict with prior Mutually Agreed Terms, the PROVIDER will defer the effective date of termination for a period of up to one year, upon request from the RECIPIENT, to permit completion of RESEARCH in progress.

******

Annex 1

Definitions

'DATA' unless otherwise stated, information, including locality and other collecting information, permits and other agreements, and any other information provided by the PROVIDER with the MATERIAL.
'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 (definition from Nagoya Protocol Art 2).
'EXCHANGE' also '*Transfer*', and '*Permanent supply*'. Permanent transfer of SPECIMENs to a Third Party to the original agreement .
'GENETIC MATERIAL' means any material of plant, animal, microbial or other origin containing functional units of heredity
'GENETIC RESOURCES' means genetic material of actual or potential value
'MATERIAL' refers to Genetic Material, Genetic Resources and items listed on the Annex 2 of this Material Transfer Agreement
'MODIFICATIONS' substances created by the User by using the MATERIAL which are not the ORIGINAL MATERIAL, PROGENY, or UNMODIFIED DERIVATIVES and which have new properties. MODIFICATIONS include, but are not limited to, recombinant DNA clones.
'MUTUALLY AGREED TERMS' contractual arrangements concluded between a provider of

genetic resources, or of traditional knowledge associated with genetic resources, and a user, that set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources, and that may also include further conditions and terms for such utilisation as well as subsequent applications and commercialisation

‘PROVIDING COUNTRY / PROVIDER OF MATERIAL’ (or "Country providing GENETIC RESOURCES") means the country supplying GENETIC RESOURCES collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country. (Definition from CBD Art 2)

‘RESEARCH’ The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions. This does not include any development of commercial applications.

‘USE’ The purposes to which samples and SPECIMENs (biological and genetic material) are put, including but not limited to ‘UTILIZATION’ in the sense of the Nagoya Protocol; and ‘UTILIZATION (of genetic resources)’ means the conduct RESEARCH and development on the genetic and/or biochemical composition of GENETIC RESOURCES, including through the application of biotechnology as defined in Article 2 of the Convention (definition from the Nagoya Protocol).

‘USER’ means a natural or legal person that utilises genetic resources, genetic material, material and also the organisation to whom the Provider sends the MATERIAL.

Annex 2

MATERIAL

Annex A)

Collecting Permit (CP)

Annex B)

Prior Informed Consent (PIC)

Annex C)

Export permit

Annex D)

Import permit

Annex E)

Letter informing Providing Country of third-Party Transfer

Annex F)

Mutually agreed terms (MAT)

Annex G)

The Internationally-Recognised Certificate of Compliance

Annex D.
ABS National Focal Point.

According with the CBD a ABS National Focal Point contains information that is relevant to all public institutes, companies and individuals using genetic resources for research and development. It shall provide basic guidance for users seeking access to genetic resources as well as background information on the relevant international agreements, and explains various terms that are often used.

In the framework of the Before Consortium, the ABS National Focal Points are:

- **Argentina**: Directora General de Asuntos Ambientales Dirección General de Asuntos Ambientales Ministerio de Relaciones Exteriores y Culto Calle Esmeralda 1212, piso 14 Capital Federal 1007 Ciudad Autónoma Buenos Aires.

- **Chile**: División de Recursos Naturales, Residuos y Evaluación de Riesgo Ministerio del Medio Ambiente San Martin 73 Santiago.

- **France** has two ABS National Focal Point. The ABS National Focal Point in Officer Directorate General for Nature and Sea Protection Ministry of the Environment.

- **Jordan** the ABS National Focal point are Director Nature Protection Directorate Ministry of Environment P.O. Box 1408 Amman 11941.

- **Lebanon**: Head Department of Conservation of Natural Wealth Ministry of Environment Lazarieh Building P.O.Box 11-2727 Beirut.

- **Mexico**: Directora General Sector Primario y Recursos Naturales Renovables Secretaría de Medio Ambiente y Recursos Naturales (SEMARNAT) Blvd. Adolfo Ruiz Cortines 4209, Col. Jardines en la Montaña Tlalpan, Distrito Federal México D.F. C.P. 14210 .

- **Morocco**: Chef du Service des Sites Naturelles Ministère délégué auprès du Ministre de l'Energie, des Mines, de l'Eau et de l'Environnement - Chargé de l'Environnement 9, Avenue Al Araar, Section 16 Hay Ryad 10100 Rabat .

- **Spain**: Subdirector General de Medio Natural Dirección General de Calidad y Evaluación Ambiental y Medio Natural Ministerio de Agricultura, Alimentación y Medio Ambiente Rios Rosas, 24 4 planta 28003 Madrid.

- **Italy**: Anna Maria Maggiore Directorate General for Nature and Sea Protection. Address: Ministry for the Environment, Land and Sea Directorate for Nature and Sea Protection Via C. Colombo 44 Rome.

- **European Union**: the reference is the Desk Officer for ABS, Unit E2 Global Sustainability, Trade & Multilateral Agreements, DG Environment European Commission Office BU9 3/124 1049 Brussels.

ANNEX I

Information to be provided with a request for inclusion in the register of collections pursuant to Article 3(1)

PART A

Information to be included in the register

Pursuant to Article 3(1) the information to be provided with a request for inclusion in the register of collections is as follows:

1. Information on the holder of the collection (name, type of entity, address, e-mail, telephone number).

2. Information on whether the application concerns a collection or part of a collection.

3. Information on the collection or the relevant part thereof (name; identifier (code/ number), where available; address (es), website, where available; link to the collection's online database of genetic resources, where available).

4. A brief description of the collection or the relevant part thereof.

   Where only part of a collection is to be included in the register, details on the relevant part(s) and its(their) distinctive features should be provided.

5. Collection category

   The application should provide information on the category to which the collection or part thereof belongs.

Table of categories

		Specificities					
		Entire specimens (1)	Parts				
			Seeds, sexual spores, or embryos	Gametes ♀	Somatic cells	Nucleic acids	Other parts (2)
Animal	Vertebrate						
	Invertebrate						
Plants							
Algae							
Protista							
Fungi							
Bacteria			[redacted]				
Archaea							
Viruses							
Other groupings (3)							

Notes
(1) When no particular parts of a specimen are concerned, refer to the appropriate cell of 'entire specimens'.
(2) 'Other parts' include asexual reproductive parts, vegetative reproduction structures, such as stem, cutting, tuber, rhizomes.
(3) 'Other groupings' include slime molds, etc.

PART B

Evidence of the capacity of the collection or of the relevant part thereof to comply with Article 5(3) of Regulation (EU) No 511/2014

Any of the following documentation may be attached (or linked) to the application as evidence of the capacity of the collection or the relevant part thereof to comply with Article 5(3) of Regulation (EU) No 511/2014:

(a) codes of conduct, guidelines or standards, whether national or international, developed by associations or organisations, and adhered to by the collection, and information relating to the collection's instruments for the application of those codes of conduct, guidelines or standards;

(b) relevant principles, guidelines, codes of conduct or manuals of procedures, developed and applied within the collection, and any additional instruments for their application;

(c) certification of the collection under relevant schemes, whether national or international;

(d) information about participation of the collection in any international collection networks, and about associated applications for inclusion in the register of collections filed by partner collections in other Member States (optional);

(e) any other relevant documentation.

2016, December 21fst

Template for a due diligence declaration to be submitted at the stage of research funding pursuant to Article 5(2)

PART A

Information to be transmitted to the ABS Clearing House pursuant to Article 7(3) of Regulation (EU) No 511/2014

If the information provided is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please provide it nonetheless, tick the respective box and provide the justification for confidentiality at the end of this Annex.

If you marked as confidential essential information (such as about the genetic resources or traditional knowledge associated with genetic resources, access place, form of utilisation), without which the record would not be published on the website of the ABS Clearing House, this information will not be shared with the ABS Clearing House, but it may be passed on directly to the competent authorities of the provider country.

At least one declaration is required per grant received, i.e. different recipients under one grant may choose to submit either individual declarations or a joint declaration, through the project coordinator.

I am making this declaration for the utilisation of:

Please tick the appropriate box or boxes:

☐ Genetic resources

☐ Traditional knowledge associated with genetic resources

1. Subject matter of the research or identification code of the grant:

   ☐ Confidential

2. Recipient or recipients of funding, including contact details:

   Name:

   Address:

   E-mail:

   Telephone:

   Website, where available:

3. Information on exercise of due diligence:

   (a) ☐ An internationally recognised certificate of compliance (i) was issued for my (entity's) access or (ii) covers the terms of this access to the genetic resource(s) and traditional knowledge associated with genetic resources.

   Where this box is ticked, please indicate the unique identifier of the internationally recognised certificate of compliance:

   Please go to point 1 of Part B.

   (b) Where the box in point (a) has not been ticked, please fill in the following information:

   (i) Place of access:

   ☐ Confidential

(ii) Description of the genetic resources or traditional knowledge associated with genetic resources utilised; or unique identifier(s), where available:

☐ Confidential

(iii) Identifier of access permit or its equivalent ([1]), where available:

☐ Confidential

Please go to point 2 of Part B.

PART B

Information not to be transmitted to the ABS Clearing House

1. I declare that I will keep and transfer to subsequent user(s) a copy of the internationally recognised certificate of compliance as well as information on the content of the mutually agreed terms relevant for subsequent users.

   Please go to point 3.

2. I declare that I am in possession of the following information, which I will keep and transfer to subsequent user(s):

   (a) date of access;

   (b) person or entity having granted prior informed consent, where applicable;

   (c) person or entity to whom prior informed consent was granted (where applicable), if not granted directly to me or my entity;

   (d) mutually agreed terms, where applicable;

   (e) the source from which I or my entity obtained the genetic resource and traditional knowledge associated with genetic resources;

   (f) presence or absence of rights and obligations relating to access and benefit-sharing, including rights and obligations regarding subsequent applications and commercialisation.

3. Where the genetic resource(s) was(were) obtained from a registered collection, please provide the registration code of the collection:

4. The research grant is funded by the following sources:

   Private ☐ Public ☐

5. Member State(s) in which the research involving utilisation of genetic resources and traditional knowledge associated with genetic resources takes place or has taken place:

Confidentiality

If you have declared that some information is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please state the reasons for each piece of information for which you have declared that confidentiality applies:

Date:

Place:

Signature ([2]):

2016, December 21fst

Template for a due diligence declaration to be submitted at the stage of final development of a product pursuant to Article 6(1)

PART A

Information to be transmitted to the ABS Clearing House pursuant to Article 7(3) of Regulation (EU) No 511/2014

If the information provided is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please provide it nonetheless, tick the respective box and provide the justification for confidentiality at the end of this Annex.

If you marked as confidential essential information (such as about the genetic resources or traditional knowledge associated with genetic resources, access place, form of utilisation) without which the record would not be published on the website of the ABS Clearing House, this information will not be shared with the Clearing House but it may be passed on directly to the competent authorities of the provider country.

If the utilisation has involved more than one genetic resource or any traditional knowledge associated with genetic resources, please provide relevant information for each genetic resource or any traditional knowledge utilised.

I declare that I have fulfilled the obligations under Article 4 of Regulation (EU) No 511/2014. I am making this declaration for the utilisation of:

Please tick the appropriate box or boxes:

☐ Genetic resources

☐ Traditional knowledge associated with genetic resources

1. Name of the product or description of the result of the utilisation [1] or description of the outcome of the utilisation [2]:

   ☐ Confidential

2. Contact details of the user:

   Name:

   Address:

   E-mail:

   Telephone:

   Website, where available:

3. The declaration is made on the occasion of the following event:

   Please tick the appropriate box:

   ☐ (a) market approval or authorisation is sought for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;

   ☐ (b) a notification required prior to placing for the first time on the Union market is made for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;

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[1] 'Result of the utilisation of genetic resources and traditional knowledge associated with genetic resources' means products, precursors or predecessors to a product, as well as parts of products to be incorporated into a final product, blueprints or designs, based on which manufacturing and production could be carried out without further utilisation of the genetic resource and traditional knowledge associated with genetic resources.

[2] Where the utilisation in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union.

☐ (c) placing for the first time on the Union market a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources, for which no market approval, authorisation or notification is required;

☐ (d) the result of the utilisation is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);

☐ (e) the utilisation has ended in the Union and its outcome is sold or transferred in any other way to a natural or legal person outside the Union.

4. Information on exercise of due diligence:

(a) ☐ An internationally recognised certificate of compliance (i) was issued for my (entity's) access or (ii) covers the terms of this access to the genetic resource(s) and traditional knowledge associated with genetic resources.

Where this box is ticked, please indicate the unique identifier of the internationally recognised certificate of compliance:

Please go to point 2 of Part B.

(b) Where the box in point (a) has not been ticked, please fill in the following information:

(i) Place of access:

☐ Confidential

(ii) Description of the genetic resource or traditional knowledge associated with genetic resources utilised, or unique identifier(s), where available:

☐ Confidential

(iii) Date of access:

☐ Confidential

(iv) Identifier of access permit or its equivalent ([1]), where available:

☐ Confidential

(v) Person or entity who granted prior informed consent:

☐ Confidential

(vi) Person or entity to whom the prior informed consent was granted:

☐ Confidential

(vii) Is the utilisation of genetic resources and traditional knowledge associated with genetic resources subject to mutually agreed terms?

Yes ☐ No ☐

☐ Confidential

Please go to point 1 of Part B.

([1]) Evidence of the decision to grant prior informed consent or approval for access to genetic resources and traditional knowledge associated with genetic resources.

2016, December 21fst

PART B

Information not to be transmitted to the ABS Clearing House

1. Information on exercise of due diligence:

   (a) Direct source of the genetic resource and the traditional knowledge associated with genetic resources:

   (b) Are there any restrictions in the mutually agreed terms limiting the possible utilisation of the genetic resource(s) or the traditional knowledge associated with genetic resources, e.g. allowing for non-commercial utilisation only?

   Yes ☐ No ☐ Not applicable ☐

   (c) Have there been rights and obligations agreed regarding subsequent applications and commercialisation in the mutually agreed terms?

   Yes ☐ No ☐ Not applicable ☐

2. If the genetic resource(s) was(were) obtained from a registered collection, please provide the registration code of the collection:

3. If you are implementing a best practice recognised under Article 8 of Regulation (EU) No 511/2014, please provide the registration number:

4. Which category best describes your product (optional)?

   ☐ (a) cosmetics

   ☐ (b) medicinal products

   ☐ (c) food and beverage

   ☐ (d) biological control

   ☐ (e) plant breeding

   ☐ (f) animal breeding

   ☐ (g) other, please specify:

5. Member State(s) in which the utilisation of genetic resources and traditional knowledge associated with genetic resources has taken place:

6. Member State(s) in which the product is to be placed on the market, following the procedure for approval, authorisation or notification referred to in Article 6(2)(a) and (b) of Commission Regulation (EU) 2015/1866 or placed on the market in accordance with Article 6(2)(c) of that Regulation:

Confidentiality

If you have declared that some information is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please state the reasons for each piece of information for which you have declared that confidentiality applies:

Date:

Place:

Signature (1):