2013 年度 ABS 関連調査研究

ヨーロッパ行政機関及び大学調査まとめ

下

ABS 学術対策チーム

森岡　一

期間

2014 年 1 月 26 日（日）から

2014 年 2 月 3 日（月）まで

2014 年 2 月 12 日

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1. Global Genome Biodiversity Network Standard Material Transfer Agreement for provision of Genomic Samples with no Change in ownership

Preamble This AGREEMENT is for temporary transfer of genomic MATERIAL or tissues for genomic analyses between members of the Global Genome Biodiversity Network(GGBN),with no change in ownership/permanent custodianship. At the end of the AGREEMENT the MATERIAL will [have been consumed/will returned](delete as necessary).	
2. GGBN's activities are guided by the Convention Biological Diversity(CBD)[1] and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization(ABS)[2].MATERIAL is transferred between partners on the condition that Users agree to use samples & data in compliance with international laws and conventions. This AGREEMENT is designed to promote scientific research and exchange, whilst recognizing the terms on which the SUPPLIER acquired the MATERIAL The SUPPLIER reserves the right not to 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.	
3. Definitions of terms are provided in the Annex to this AGREEMENT. Parties to AGREEMENT SUPPLIER:	

RECIPIENT Institution: RECPIENT Scientist:	
4. The SUPPLIER will supply the specimens or sample listed on the attached to this AGREEMENT("MATERIAL")subject to the following terms and conditions: Ownership of MATERIAL and relevant information	
5. The SUPPLIER warrants that it is not aware of third party right in the MATERIAL to the that would preclude it from supplying the MATERIAL to the RECIPIENT in accordance with this AGREEMENT.	
6. The MATERIAL remains the property of the SUPPLIER(subject to conditions set out in Mutually Agreed Terms with the Country of Origin).	
7. Nothing in this AGREEMENT shall or may be construed as granting the RECIPIENT any light or license to the MATERIAL for any use other than the purpose described herein.	
8. The SUPPLIER shall be free, at its sole discretion, to distribute the MATERIAL to others for any use and to use the MATERIAL for its own purposes.	
9. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent or Patent application. The SUPPLIER makes no representation or	

warranty that the use of the MATERIAL will not infringe any third party patent or other proprietary right.	
10. Unless otherwise indicated, copyright in all information or data("Data")supplied with the MATERIAL is owned by the SUPPLIER, The RECIPIENT may use these data on condition that they are used Solely for scholarly, education or research purposes; that they are not use for commercial purposes; and that the RECIPIENT always acknowledges the source of the Data with the words "With the permission of [SUPPLIER]" ;	
11. Data I metadata should not be modified in publications without permission from the SUPPLIER	
12. The MATERIAL may not be transferred wholly or partially by the RECIPIENT to third parties, without prior written authorization from the SUPPLIER.	
13. Relevant documentation, including Access Permits, Mutually Agreed terms with the Country of Origin, reference number of the Internationally-recognized Certificate of Compliance, and confirmation that the Country of Origin has been informed (if necessary under MAT), is annexed to this document if relevant to the MATERIAL, and forms part of the AGREEMENT.	
14. The RECIPIENT shall maintain retrievable records linking the MATERIAL to these terms of acquisition	

and to any accompanying Data provided by the SUPPLIER	
Use of MATERIAL 15. The RECIPIENT may only use the MATERIAL and its derivatives for non-commercial purposes in scientific research, education, and conservation; the RECIPIENT shall not sell, distribute or use for profit or any other commercial application the MATERIAL, its derivatives or results obtained from analysis.	
16. The RECIPIENT will provide the SUPPLIER with all publications of research on the sample prior to their publication.	
Benefit-sharing 17. The RECIPIENT shall share fairly and equitably the benefits arising from their utilization of the MATERIAL, its progeny or derivatives in accordance with the CBD. A non-exhaustive list of non-monetary and monetary benefits is given at Appendix II to the Bonn Guidelines[3] and the Annex to the Nagoya Protocol[4].	
18. The RECIPIENT will contact the SUPPLIER to request prior permission from the SUPPLIER or, where required by the SUPPLIER, from the PROVIDING COUNTRY / COUNTRY OF ORIGIN of the MATERIAL to the SUPPLIER, for any activities not covered under the terms of this AGREEMENT.	

19. The RECIPIENT will provide the SUPPLIER with copies of any records of the MATERIAL caused to be made by RECIPIENT in electronic format, when appropriate. The Recipient will also provide the SUPPLIER with copies of the publications resulting from the utilization.	
20. The RECIPIENT shall acknowledge the SUPPLIER as the source of the MATERIAL in all written and electronic publications and reports.	
21. The RECIPIENT must register sequence data with GenBank/EMBL/DDBJ and provide the SUPPLIER with a list of such deposits including reference numbers. Any data sent to GenBank/EMBL/DDBJ should be linked to the original specimen and accession or similar unique identifier used by the SUPPLIER.	
22. The RECIPIENT agrees to acknowledge the Country of Origin as the source of the MATERIAL in any and all publications applications arising from its utilization.	
23. The RECIPIENT agrees to acknowledge the Country of Origin as the source of the MATERIAL in any and all patent applications arising from its utilization.	

Risks and Warranties 24. The RECIPIENT declares that within their laboratory: a. access to the MATERIAL will be restricted to personnel capable and qualified to safely handle said MATERIAL and b. The RECIPIENT shall exercise the necessary care, taking into account the specific characteristics of the MATERIAL, to take the appropriate precautions to minimize any risk of harm to persons and property and to safeguard it from theft or misuse.	
25. The RECIPIENT is solely responsible for safe receipt, use, storage and disposal.	
26. The RECIPIENT acknowledges that the risks represented by any organisms received from the SUPPLIER should be assessed on the basis of intended use and the experience of the workers exposed to them, and that under certain circumstances organisms normally considered non-pathogens may cause disease.	
27. The RECIPIENT agrees that any handling or other activity undertaken in their premises with the MATERIAL will be conducted in compliance with all applicable laws and regulations.	

28. The RECIPIENT acknowledges that it uses the MATERIAL and its derivatives and exercises its rights under this AGREEMENT at its own risk.	
29. The RECIPIENT indemnifies the SUPPLIER, 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. RECIPIENT's use of the MATERLAL and its derivatives, and any other exercise of rights under this AGREEMENT; and b. breach of this AGREEMENT by the RECIPIENT.	
30. The SUPPLIER 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 MATENAL, its progeny or derivatives, or as to the accuracy or reliability of any Data supplied.	
31. The SUPPLIER is not liable for failures in any molecular analysis (DNA extraction, PCR product, sequencing reaction, etc).	
Transport of MATERIAL 32. The RECIPIENT shall take all appropriate and necessary measures to import the MATERIAL in accordance with relevant laws and regulations and to	

contain the MATERIAL, its progeny or derivatives so as to prevent the release of invasive alien species;	
33. The RECIPIENT is responsible for ensuring that all permits required for the RECIPIENT to receive its order are obtained and that sufficient proof of such permits can be provided to the SUPPLIER if requested.	
Agreement 34. Neither party may assign or otherwise transfer this AGREEMENT and the rights acquired hereunder without the written consent of the other party. Any permitted assignee must agree in writing to be bound by the terms of this AGREEMENT.	
35. 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.	
36. This AGREEMENT will terminate on the earliest of the following dates: a. on completion of RECIPIENT's current research with the MATERIAL; or b. on thirty (30) days written notice by either party to the other; or c. On the predetermined closure of the loan [date: / /].	

37. If termination occurs under 36(a), the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the SUPPLIER, return or destroy any remaining MATERIAL. The RECIPIENT will also either destroy the DERIVATIVES or remain bound by the terms of this AGREEMENT as they apply to DERIVATIVES.	
38. In the event that the SUPPLIER terminates this AGREEMENT under 36(b), Other than for breach of this AGREEMENT or for cause such as an imminent health risk or patent infringement, the SUPPLIER 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. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the SUPPLER ,return or destroy any remaining NIATERJAL The RECIPIENT, at its discretion, also win either destroy the DERIVATIVES or remain bound by terms of this AGREEMENT as they apply to DERIVATIVES.	
39. The expiration or termination of this AGREEMENT, shall not affect the obligations contained in this AGREEMENT. 40 This AGREEMENT is governed by and shall be construed in accordance with the law of [country of SUPPLIER]	

Global Genome Biodiversity Network Standard Material Transfer Agreement for provision of Genomic samples with change in ownership

Preamble This AGREEMENT is for permanent transfer of genomic MATERIAL or tissues for genomic analyses between members of the Global Genome Biodiversity Network (GGBN), with a change in ownership / permanent custodianship.	
GGBN's activities are guided by the Convention on Biological Diversity (CBD)s and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS). MATERIAL is transferred between partners on the condition that users agree to use samples & data in compliance with international laws and conventions' This AGREEMENT is designed to promote scientific research and exchange, whilst recognizing the terms on which the SUPPLIER acquired the MATENAL. The SUPPLIER reserves the right not to 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.	
Definitions of terms are provided in the Annex to this AGREEMENT	

Parties to agreement SUPPLIER: RECIPIENT Institution： RECIPIENT Scientist:	
4. [The SUPPLIER] will supply the specimens or samples listed on the annex attached to this AGREEMENT ("MATERIAL") subject to the following terms and conditions:	
Ownership of MATERIAL and relevant information 5. The SUPPLIER warrants that it is not aware of third party rights in the MATERIAL that would preclude it from supplying the MATERIAL to the RECIPIENT in accordance with this AGREEMENT.	
6. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent or patent application. The SUPPLIER makes no representation or warranty that the use of the MATERIAL will not infringe any third party patent or other proprietary right.	
7. Nothing in this AGREEMENT shall or may be construed as granting the RECIPIENT any light or license to the MATERIAL for any use other than the purpose described herein.	
8. The SUPPLIER shall be free, at its sole discretion, to distribute the MATERIAL to others for any use and to use the MATERIAL for its own purposes.	
9. The RECIPIENT acknowledges that the	

MATERIAL is or may be the subject of a patent or Patent application. The SUPPLIER makes no representation or warranty that the use of the MATERIAL will not infringe any third party patent or other proprietary right.	
10. Unless otherwise indicated, copyright in all information or data("Data")supplied with the MATERIAL is owned by the SUPPLIER, The RECIPIENT may use these data on condition that they are used Solely for scholarly, education or research purposes; that they are not use for commercial purposes; and that the RECIPIENT always acknowledges the source of the Data with the words "With the permission of [SUPPLIER]" ;	
11. Data I metadata should not be modified in publications without permission from the SUPPLIER	
12. The MATERIAL may not be transferred wholly or partially by the RECIPIENT to third parties, without prior written authorization from the SUPPLIER.	
13. Relevant documentation, including Access Permits, Mutually Agreed terms with the Country of Origin, reference number of the Internationally-Recognized Certificate of Compliance, and confirmation that the Country of Origin has been informed (if necessary under MAT), is annexed to this document if relevant to the MATERIAL, and forms part of the AGREEMENT.	

14. The RECIPIENT shall maintain retrievable records linking the MATERIAL to these terms of acquisition and to any accompanying Data provided by the SUPPLIER.	
Use of MATERIAL 15. The RECIPIENT may only use the MATERIAL and its derivatives for non-commercial purposes in scientific research, education, and conservation; the RECIPIENT shall not sell, distribute or use for profit or any other commercial application the MATERIAL, its derivatives or results obtained from analysis.	
16. The RECIPIENT will provide the SUPPLIER with all publications of research on the sample prior to their publication.	
Benefit-sharing 17. The RECIPIENT shall share fairly and equitably the benefits arising from their utilization of the MATERIAL, its progeny or derivatives in accordance with the CBD. A non-exhaustive list of non-monetary and monetary benefits is given at Appendix II to the Bonn Guidelines[3] and the Annex to the Nagoya Protocol[4].	
18. The RECIPIENT will contact the SUPPLIER to request prior permission from the SUPPLIER or, where required by the SUPPLIER, from the PROVIDING COUNTRY/COUNTRY OF ORIGIN of the MATERIAL to the SUPPLIER, for any activities not covered under the terms of	

this AGREEMENT.	
19. The RECIPIENT will provide the SUPPLIER with copies of any records of the MATERIAL caused to be made by RECIPIENT in electronic format, when appropriate. The Recipient will also provide the SUPPLIER with copies of the publications resulting from the utilization.	
20. The RECIPIENT shall acknowledge the SUPPLIER as the source of the MATERIAL in all written and electronic publications and reports.	
21. The RECIPIENT must register sequence data with GenBank/EMBL/DDBJ and provide the SUPPLIER with a list of such deposits including reference numbers. Any data sent to GenBank/EMBL/DDBJ should be linked to the original specimen and accession or similar unique identifier used by the SUPPLIER.	
22. The RECIPIENT agrees to acknowledge the Country of Origin as the source of the MATERIAL in any and all publications applications arising from its utilization.	
23. The RECIPIENT agrees to acknowledge the Country of Origin as the source of the MATERIAL in any and all patent applications arising from its utilization.	

Risks and Warranties 24. The RECIPIENT declares that within their laboratory: a. access to the MATERIAL will be restricted to personnel capable and qualified to safely handle said MATERIAL and b. The RECIPIENT shall exercise the necessary care, taking into account the specific characteristics of the MATERIAL, to take the appropriate precautions to minimize any risk of harm to persons and property and to safeguard it from theft or misuse.	
25. The RECIPIENT is solely responsible for safe receipt, use, storage and disposal.	
26. The RECIPIENT acknowledges that the risks represented by any organisms received from the SUPPLIER should be assessed on the basis of intended use and the experience of the workers exposed to them, and that under certain circumstances organisms normally considered non-pathogens may cause disease.	
27 . The RECIPIENT agrees that any handling or other activity undertaken in their premises with the MATERIAL will be conducted in compliance with all applicable laws and regulations.	
28. The RECIPIENT acknowledges that it uses the MATERIAL and its derivatives and exercises its rights under this	

AGREEMENT at its own risk.	
29. The RECIPIENT indemnifies the SUPPLIER, 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 MATERLAL and its derivatives, and any other exercise of rights under this AGREEMENT; and (b) breach of this AGREEMENT by the RECIPIENT.	
30. The SUPPLIER 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 MATENAL, its progeny or derivatives, or as to the accuracy or reliability of any Data supplied.	
31. The SUPPLIER is not liable for failures in any molecular analysis (DNA extraction, PCR product, sequencing reaction, etc).	
Transport of MATERIAL 32. The RECIPIENT shall take all appropriate and necessary measures to import the MATERIAL in accordance with relevant laws and regulations and to contain the MATERIAL, its progeny or derivatives so as to prevent the release of invasive alien species;	
33. The RECIPIENT is responsible for	

ensuring that all permits required for the RECIPIENT to receive its order are obtained and that sufficient proof of such permits can be provided to the SUPPLIER if requested.	
Agreement 34. Neither party may assign or otherwise transfer this AGREEMENT and the rights acquired hereunder without the written consent of the other party. Any permitted assignee must agree in writing to be bound by the terms of this AGREEMENT.	
35. 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.	
36. This AGREEMENT will terminate on the earliest of the following dates: a. on completion of RECIPIENT's current research with the MATERIAL; or b. on thirty (30) days written notice by either party to the other; or c. On the predetermined closure of the loan [date: / /].	
37. If termination occurs under 36(a), the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the SUPPLIER, return or destroy any remaining MATERIAL. The RECIPIENT will also either destroy the DERIVATIVES or remain bound by the terms of this AGREEMENT as they apply to DERIVATIVES.	

38. In the event that the SUPPLIER terminates this AGREEMENT under 36(b), Other than for breach of this AGREEMENT or for cause such as an imminent health risk or patent infringement, the SUPPLIER 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. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the SUPPLER, return or destroy any remaining NIATERJAL The RECIPIENT, at its discretion, also win either destroy the DERIVATIVES or remain bound by terms of this AGREEMENT as they apply to DERIVATIVES.	
39. The expiration or termination of this AGREEMENT, shall not affect the obligations contained in this AGREEMENT.	
40 This AGREEMENT is governed by and shall be construed in accordance with the law of [country of SUPPLIER]	

Global Genome Biodiversity Network Standard Material Transfer Agreement for provision of Genomic samples with change in ownership

Preamble This AGREEMENT is for permanent transfer of genomic MATERIAL or tissues for genomic analyses between members of the Global Genome Biodiversity	

Network (GGBN), with a change in ownership / permanent custodianship.	
GGBN's activities are guided by the Convention on Biological Diversity (CBD)s and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS). MATERIAL is transferred between partners on the condition that users agree to use samples & data in compliance with international laws and conventions' This AGREEMENT is designed to promote scientific research and exchange, whilst recognizing the terms on which the SUPPLIER acquired the MATENAL. The SUPPLIER reserves the right not to 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.	
Definitions of terms are provided in the Annex to this AGREEMENT	
Parties to agreement <u>SUPPLIER:</u> <u>RECIPIENT Institution：</u> <u>RECIPIENT Scientist:</u>	
4. [The SUPPLIER] will supply the specimens or samples listed on the annex attached to this AGREEMENT ("MATERIAL") subject to the following terms and conditions:	
Ownership of MATERIAL and relevant information 5. The SUPPLIER warrants that it is	

not aware of third party rights in the MATERIAL that would preclude it from supplying the MATERIAL to the RECIPIENT in accordance with this AGREEMENT.	
6. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent or patent application. The SUPPLIER makes no representation or warranty that the use of the MATERIAL will not infringe any third party patent or other proprietary right.	
7. Relevant documentation, including Access Permits, Mutually Agreed terms with the Country of Origin, reference number of the Internationally-Recognized Certificate of Compliance, and confirmation that the Country of Origin has been informed (if necessary under MAT), is annexed to this document if relevant to the MATERIAL, and forms part of the AGREEMENT.	
8. The RECIPIENT shall maintain retrievable records linking the MATERIAL to these terms of acquisition and to any accompanying Data provided by the SUPPLIER;	
Benefit-sharing 9. The RECIPIENT agrees to abide by the Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) and any other conditions under which the MATERIAL was originally acquired, providing this is made available, and will contact the Country of Origin prior to any activities	

that might conflict with the PIC and MAT.	
10. Any proposed commercial interest, utilization or other use of the MATELIAL is, where required under original access conditions or by the policy of the SUPPLIE & to be negotiated with the respective Country of Origin of the original samples, and Mutually Agreed Terms reached prior to provision of the MATERIAL by the SUPPLIER.	
11. The RECIPIENT shall share fairly and equitably the benefits arising from their use of the MATERIAL, its progeny or derivatives in accordance with the CBD. A non-exhaustive list of non-monetary and monetary benefits is given at Appendix II to the Bonn Guidelines[7] and the Annex to the Nagoya Protocol[8].	
12. The SUPPLIER will forward information on the MATERIAL supplied on request to the national authority in charge for implementation of the CBD in the country of origin of the samples.	
Risks and Warranties 13. The RECIPIENT is solely responsible for safe receipt, use, storage and disposal.	
14. The RECIPIENT acknowledges that the risks represented by any organisms received from the SUPPLIER should be assessed on the basis of intended use and the experience of the workers exposed to them, and that under certain circumstances organisms normally considered non-pathogens may cause disease.	
15. The RECIPIENT acknowledges that it	

uses the MATERIAL and its derivatives and exercises its rights under this AGREEMENT at its own risk.	
16. The RECIPIENT indemnifies the SUPPLIER, 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: the RECIPIENT's use of the MATERIAL and its derivatives, and any other exercise of rights under this AGREEMENT; and breach of this AGREEMENT by the RECIPIENT.	
Transport of MATERIAL 17. The RECIPIENT shall take all appropriate and necessary measures to import the MATERIAL in accordance with relevant laws and regulations and to contain the MATERIAL, its progeny or derivatives so as to prevent the release of invasive alien species;	
18. The RECIPIENT is responsible for ensuring that all permits required for the RECIPIENT to receive its order are obtained and that sufficient proof of such permits can be provided to the SUPPLIER if requested Agreement	
19. Neither party may assign or otherwise transfer this AGREEMENT and the rights acquired here under without the written consent of the other party. Any permitted assignee must agree in writing to be	

bound by the terms of this AGREEMENT.	
20. 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.	
21. This AGREEMENT is governed by and shall be construed in accordance with the law of [country of SUPPLIER]	

Global Genome Biodiversity Network Standard Material Transfer Agreement for Receipt of Genomic samples with change in ownership

Preamble 1. This standard agreement covers acceptance of genomic material or tissues for genomic analyses by a member of the Global Genome Biodiversity Network (GGBN).	
2. GGBN's activities are guided by the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS).	
3. The [RECIPIENT] reserves the right not to accept any material if such acceptance would be contrary to any terms attached to the material and/or to the CBD.	
Parties to agreement SUPPLIER: RECIPIENT Institution: RECIPIENT Scientist:	

4.The SUPPLIER will supply the specimens or samples listed on the annex attached to this agreement (*MATERIAL"), and the RECIPIENT accept the MATERIAL subject to the following terms and conditions:	
Ownership of MATERIAL and relevant information 5. The SUPPLIER warrants that it is not aware of third party rights in the MATERIAL that would preclude it from supplying the MATERIAL to the RECIPIENT in accordance with this agreement;	
6. The SUPPLIER certifies that the MATERIAL has been obtained, exported and imported in accordance with the applicable statutory regulations, with special consideration of the CBD.	
7. Relevant documentation is annexed to this agreement: ☐ Collecting Permit ☐Mutually-Agreed Terms ☐ Prior Informed Consent ☐ Export permit ☐Import permit ☐ CITES Registry certificate of SUPPLIER ☐Other (please specify) The Internationally-Recognized Certificate of Compliance number(s) is/are:	
8. The RECIPIENT shall maintain retrievable records linking the MATERIAL to these terms of acquisition	

and to any accompanying Data provided by the SUPPLIER.	
9. The SUPPLIER irrevocably and unconditionally transfers, free of charge, title in the item(s), including any rights, including copyright or any other use and exploitation rights, that may reside with the legal owner to [the RECIPIENT], and confirms that the SUPPLIER will make no subsequent claim as to ownership or indemnity for transfer of the said item(s) or ownership of said item(s) rights against the recipient. This includes the unrestricted right of the RECIPIENT to handle, process, publish or pass on the material or data, as far as held by the SUPPLIER to the extent permissible in the conditions under which the MATERIAL was accessed (permits, PIC,MAT etc) and subsequent modifications to this, and any restriction annexed to this agreement under Paragraph l3 below.	
Conditions of acceptance 10. The RECIPIENT accepts the MATERIAL in the understanding that: a. The specimens have to be relevant to and consistent with the purposes and activities of the RECIPIENT. b. The RECIPIENT is in principle willing, but not forced to accept biomaterial and data for storage. Acceptance of samples can be declined before or after investigation of the samples. c. Simultaneously with the samples, the donor will submit to RECIPIENT full	

collecting data and as deep a taxonomic determination as possible, by using a valid digital form provided by RECIPIENT. If a molecular subsample of the full specimen is donated to RECIPIENT, voucher information is to be supplied as well (i.e. the deposition data of the morphological voucher, incl. voucher ID).	
Use of MATERIAL 11. Should the SUPPLIER wish to block access by third parties to the MATERIAL or in other .ways restrict its use they must declare this in writing in an annex to this AGREEMENT. Otherwise the SUPPLIER loses this right. Material can be blocked for ... [add reason according to policy]	
Benefit-sharing 12. The RECIPIENT agrees to abide by the Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) and any other conditions under which the MATERIAL was originally acquired, providing this is made available, and will contact the Country of Origin prior to any activities that might conflict with the PIC and MAT.	
13. The RECIPIENT will negotiate any proposed commercial interest or utilization of the MATERIAL with the Country of Origin of the original samples, and Mutually Agreed Terms reached prior to commercialization.	
Agreement 14. This agreement is governed by and shall be construed in accordance with the	

law of [country of RECIPIENT]	

Annex to MTAs 1 and 2. Definitions of terms

AGREEMENT:	
this document. COMMERCIAL PURPOSES: the use of the MATERIAL for the purpose of profit.	
Or For the purposes of this AGREEMENT, commercial application shall mean: applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or license or in any other manner; commencement of product development; conducting market research; seeking pre-market approval; and/or the sale of any resulting product.	
Or the sale. lease, or license of MATERIAL, PROGENY, or DERIVATIVES; or uses of MATERIAL, PROGENY, or DERIVATIVES by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale; or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or PROGENY or DERIVATIVES to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or PROGENY or DERIVATIVES for COMMERCIAL PURPOSES per se, unless any of the above conditions of this	

definition are met.	
Or - applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or license or in any other manner, commencement of product development, conducting market research, and seeking pre-market approval and/or the sale of any resulting product based on utilization of the original genetic resource or derivatives thereof. Handling fees (e.g. for providing DNA samples), entrance charges etc, fall under the scope of management and/or administration of public research facilities, do not involve the utilization of GR, and are not considered as a commercialization of research activity on GR.	
CONFIDENTIAL INFORMATION: is all information disclosed by either SUPPLIER or SUPPLIER SCIENTIST or RECIPIENT or RECIPIENT SCIENTIST relating to the MATERIAL and marked as confidential.	
CONTRY OF ORIGIN: means the country which possesses those genetic resources in in-situ conditions (Definition from CBD Art.2).	

DERIVATIVE: means all MATENALs other than progeny that are derived in whole or in part from or made with the use of the MATERIAL. Some examples include, but are not limited to, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins, monoclonal antibodies secreted by a hybridoma cell line, proteins isolated from cell lines supplied by the SUPPLIER, or proteins expressed by DNA/RNA supplied by the SUPPLIER, including proteins expressed from modified versions of said DNA/RNA	
Or 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).	
Evaluation: means both the formulation of the MATERIAL and the testing of the MATERIAL.	
LEGITIMATE EXCHANGE: the transfer of the MATERIAL, within the same Company or Institution or Research Group (including partners in different institutes collaborating on a defined joint project This also includes the transfer of MATERIALS between named public service culture collections/Biological Resource Centres (BRC) for accession purposes, provided the further distribution by the receiving	

collection/BRC is under comparable MTA conditions as those in place at the supplying collection.	
MATERIAL: ORIGINAI MATERIAL, PROGENY and UNMODIFIED DERIVATIVES.	
Or "MATERIAL" shall mean [description of MATERIAL to be provided] supplied by the SUPPLIER, any progeny and derivatives thereof and any confidential disclosure, written, oral or visual, pertaining to the intellectual property rights, production or use of said MATERIALs. The MATERIAL might be plant, animal, fungal or microbiological in origin, but the document excludes material of human origin.	
Or "MATERIAL" means ORIGINAL MATERIAL, PROGENY, and DERIVATIVES thereof.	
Or MATERIAL listed on the reverse of this AGREEMENT	
MODIFICATIONS: substances created by the RECIPIENT 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.	

MODIFICATIONS: substances created by the RECIPIENT 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.	
NONPROFIT ORGANISATION (S): A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the lnternal Revenue Code of 1954(26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.	
ORIGINAL MATERIAL: that which was originally supplied to the SUPPLIER by the depositor.	
Or specification to be written on document [in this context apparently the same as 'MATERIAL']	
PROGENY: unmodified descendant (e.g. subculture or replicate) from the MATERIAL	
Or a descendant from the MATERIAL, including altered forms of MATERIAL, such as virus from virus, cell from cell, or organism from organism. Some examples include, but are not limited to, subclones	

of unmodified and modified cell lines	
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 major may not have originated in that country. (Definition from CBD Art 2)	
RECIPIENT: the GGBN partner organization to whom the SUPPLIER sends the MATERIAL.	
RECIPIENT SCIENTIST: The researcher in the RECIPIENT organization who is studying and taking responsibility for the MATERIAL.	
SUPPLIER: The GGBN partner supplying the MATERIAL.	
UNMODIFIED DERIVATIVES: replicates or substances which constitute an unmodified functional or product expressed by the MATERIAL, such as, but not limited to, purified or fractionated subsets of the MATERIAL, including expressed proteins or extracted or amplified DNA/RNA	

Union of Ethical BioTrade（UEBT）の EU 規制案（2012 年 EC 版）に対するコメント
本コメントは 2012 年に発表された EU 規制案に対するコメントであり、2014 年 1 月時点での EU 規制案に対応していない部分もある。しかし、Due diligence に対する考え方など参考になる点があるので掲載する。

EU Draft Regulation on ABS – Technical Brief[15]

In October 2012, the European Commission presented a draft regulation on access and benefit sharing. Access and benefit sharing or "ABS" refers to the set of rules and principles governing the use of genetic resources and associated traditional knowledge, established by the Convention on Biological Diversity (CBD) and its Nagoya Protocol on ABS.

ABS principles are based on the rights of countries to regulate access to genetic resources for their utilization in research and development. For example, countries may require that the acquisition of plant samples for research on their biochemical properties take place only on the basis of prior informed consent and mutually agreed terms. At the same time, countries where the utilization of genetic resources takes place are required to take measures to ensure compliance with ABS requirements established by the provider country – the country where those genetic resources exist in their natural habitats and are being acquired.

The draft EU regulation on ABS aims to implement relevant international obligations within the European Union (EU). The main focus of the draft regulation is on 'user measures,' given that genetic resources and associated traditional knowledge are widely utilized in the EU for research and development purposes in sectors such as plant breeding, cosmetics, food and beverage, and pharmaceuticals. The draft regulation also proposes an EU platform on access to genetic resources and associated traditional knowledge that would contribute to streamlining any conditions established by EU member states on access to their genetic resources and associated traditional knowledge.

The objective of this technical note, prepared by the Union for Ethical BioTrade (UEBT), is to provide a brief overview of the draft EU regulation on ABS. In particular, it considers the proposed measures addressing the utilization of genetic resources and associated traditional knowledge, as well as their possible implications for companies involved in biodiversity-based research and development. The technical note is based on a review of the draft regulation, the European Commission study assessing the economic, social and environmental impacts of different policy options for implementing the Nagoya Protocol (Impact Assessment), and verbal communications with the EC. It is important to consider,

[15] http://ethicalbiotrade.org/dl/benefit-sharing/UEBT-technical-note-draft-EU-regulations-on-ABS.pdf.

however, that the draft regulation is only the beginning of the EU legislative procedure and may significantly change prior to its entry into force.

ABS and the utilization of genetic resources

The Nagoya Protocol on ABS establishes a set of legally binding rules to facilitate, promote and ensure the implementation of ABS principles. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources. To advance fair and equitable benefit sharing, the Nagoya Protocol also addresses appropriate access to genetic resources – how companies or other organizations acquire genetic resources for their use in research and development. Moreover, the Nagoya Protocol obliges all countries to introduce measures aimed at ensuring the observation of ABS requirements across national borders.

Measures to ensure compliance with ABS requirements are thus required not only at the point where companies or other organizations access the genetic resources and associated traditional knowledge, but also in the jurisdictions where the utilization of these resources takes place. Measures taken by provider countries may include, for instance, requiring specific information or commitments prior to granting a permit to export samples of indigenous plants. In turn, other countries are obliged to support compliance with these ABS requirements, by ensuring that their utilization takes place in accordance with relevant laws and regulations. Possible user measures identified by international mechanisms; disclosure obligations in procedures such as applications for patents or marketing approval; market-based incentives; and mandatory requirements to enter into ABS contracts at the time of access to genetic resources.

> **Utilization of genetic resources** refers to research and development on the genetic or biochemical composition of genetic resources. It includes basic research, applied research and product development. Research on the properties of extracts and molecules from plants, for example, and their development and commercialization as ingredients in pharmaceuticals, cosmetics or nutraceuticals would entail the utilization of genetic resources.

Regulating the utilization of genetic resources in the EU

In the EU, genetic resources are utilized for a wide range of purposes, by a variety of different actors. For example, the Impact Assessment notes that the utilization of genetic resources is at the core of plant and animal breeding companies, biotechnology companies and the biocontrol industry. Other actors, such as companies involved in industrial biotechnology or pharmaceuticals, utilize genetic resources when searching for molecules

or genes with interesting properties for product development. Finally, companies in the cosmetics or food and beverage industry, for example, are involved in the use of genetic resources when developing products on the basis of naturally occurring biochemical compounds. The draft regulation on ABS includes a set of obligations for users of genetic resources and associated traditional knowledge in the EU. As mentioned, user measures aim to monitor and enhance transparency about the utilization of genetic resources. To this end, the draft regulation establishes a system of due diligence, which would generate and circulate basic information on ABS along biodiversity-based value chains. Companies conducting biodiversity-based research and development would be required to introduce policies and procedures to gather and share information on whether the acquisition of genetic resources and associated traditional knowledge took place in accordance with legal requirements in the providing country. Monitoring and examination of compliance with due diligence would take place through declarations required from companies and other users of genetic resources at specific points in the value chain, as well as the risk-based inspection of measures taken and documentation retained by users.

Scope of obligations

The draft EU regulation would apply to those genetic resources accessed – i.e. physically acquired – in a Party to the Nagoya Protocol, after the entry into force of this agreement in the EU. For example, an EU company would be required to exercise due diligence in regards to genetic resources acquired in country X, if such acquisition takes place once the Nagoya Protocol is in force both in the EU and country X, and this country has established access requirements. The due diligence requirement would not apply to genetic resources acquired before such a time, even if there is new or continuing research and development. Though such an approach runs counter to some interpretations of the Nagoya Protocol, incorporating obligations for new or continuous utilization of genetic resources was deemed to raise too many legal and practical questions in the EU context. Access is defined as the acquisition of genetic resources or associated traditional knowledge. As a result, the due diligence requirement would need to look at access to plant material, even in cases in which, initially, there was no intention of use of the genetic resources or associated traditional knowledge.

Traditional knowledge

The draft EU regulation covers not only genetic resources but also traditional knowledge associated with these resources. Given the lack of internationally agreed definitions, the proposal only encompasses traditional knowledge that is recognized as such in the mutually agreed terms relating to the genetic resources. That is, the draft regulation would only cover traditional knowledge if there were a contract on access to genetic resources that specifically mentioned associated traditional knowledge. In practice, however, it is unclear how such traditional knowledge might be addressed in a due diligence system. Companies using traditional knowledge associated to genetic resources would need to consider such knowledge in their policies and procedures to gather and transmit basic information on ABS. However, no measures would need to be taken to verify compliance with ABS requirements in the provider country unless the traditional knowledge was expressly covered by mutually agreed terms.

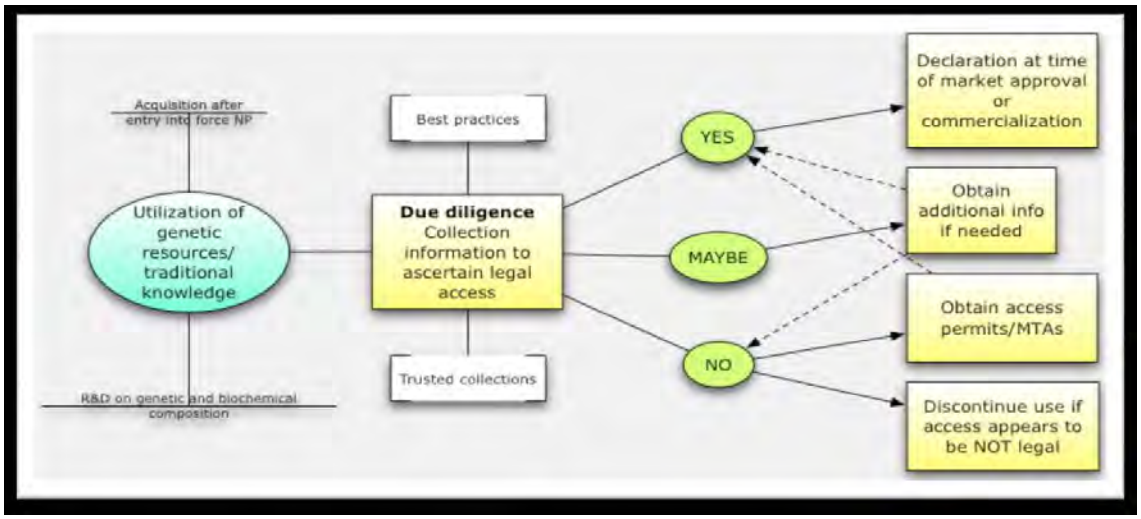
What is due diligence?

The draft EU regulation on ABS establishes a system of due diligence for the utilization of genetic resources and associated traditional knowledge. A system of due diligence implies an obligation to meet a reasonable standard of care. In the draft regulation, companies and other organizations involved in biodiversity-based research and development must exercise due diligence to ascertain the legal acquisition of genetic resources and associated traditional knowledge. As a result, policies would need to be established and measures taken to gather and transmit information on applicable ABS requirements along biodiversity-based value chains. Steps would need to be taken to comply with these requirements.

Key elements of the due diligence system in the draft regulation include:

- *Collecting information to ascertain legal access*: The user must seek, keep and transfer to subsequent users, information to ascertain whether access to the genetic resources and associated traditional knowledge took place in accordance with the legal requirements in the country where such acquisition took place. Minimum information required – including on traceability of the resources and, where relevant, necessary permits – is listed in the draft regulation. If the existing information is not sufficient to clarify the legal situation of the genetic resources or associated traditional knowledge, the user must obtain additional information or evidence. It is important to note that the obligation of due diligence would not encompass checking compliance with the terms of permits or agreements.
- *Avoiding use of illegally accessed resources:* If it appears that access to the genetic resources or associated traditional knowledge was not in accordance with applicable legal requirements, the user must obtain necessary permits and agreements or discontinue its use of the resources.

Proposed Due Diligence System



The due diligence system is thus a comprehensive approach to monitoring the utilization of genetic resources in the EU. All companies and organizations involved in biodiversity-based research and development would need to be able to demonstrate – through policies, practices and resulting documentation – that efforts have been made to gather, transmit and act upon basic information on ABS for all utilization of genetic resources and associated traditional knowledge. The exact measures would vary depending on the type of user, its capacity to take action, or sectoral characteristics. Due diligence could be described as a best endeavors obligation: companies and other organizations would need to "do their best" – to take all reasonable measures – to ensure compliance with ABS requirements in countries providing the genetic resources and associated traditional knowledge. By the same token, in a due diligence system, if the objective is not achieved, it does not necessarily mean that there is breach of relevant obligations. In principle, it would not constitute a breach of obligations in the draft regulation if, despite due diligence, it was determined that the genetic resource utilized had been illegally acquired earlier in the value chain. Nevertheless, in that case, the user would be required to request the permits required in the provider country for the utilization of their genetic resources, or discontinue the use of these resources.

Trusted sources

The draft EU regulation proposes trusted sources of genetic resources as a complement to the due diligence system. These trusted sources would be public or private collections with control measures in place to assure that only well documented samples of genetic resources are made available for their utilization. Users of genetic resources that acquire samples from trusted sources would thereby comply with their due diligence obligation.

Best practices

The draft EU regulation foresees a formal recognition of procedures, tools or mechanisms that, when effectively implemented by a user, would fulfill its due diligence obligation. Any association of users could submit its system for recognition as best practice, supported by relevant evidence and information. Best practices would thus be benchmarks for observing due diligence. In addition, the proposal considers that implementation of a recognized best practice would reduce the risk of non-compliance, and thus minimize the need for checks on those users.

How is due diligence monitored and enforced?

Compliance with these requirements is monitored through requiring users to declare that they have exercised due diligence at different stages of their activities. Information gathered would serve to monitor and enhance transparency on the utilization of genetic resources in the EU, as required by the Nagoya Protocol. The different instances in which declarations would be required by the draft regulation include receiving public funding; requesting market approval; and commercializing a product based on genetic resources or associated traditional knowledge. Each EU member state would designate one or more competent authorities responsible for such monitoring, as well as for communicating the information received back to the European Commission. Competent authorities would also carry out checks to verify if users comply with due diligence requirements. These checks would be determined on the basis of risk, but could also be conducted on the basis of substantiated concerns provided by third parties. Checks would look at, for instance, the measures taken and documentation gathered to exercise due diligence, as well as the relevant declarations made. Penalties foreseen for lack of compliance with due diligence and declaration requirements include fines, suspension of specific use activities and confiscation of illegally acquired resources.

UEBT and the draft EU regulations on ABS

The fair and equitable sharing of benefits derived from the use of biodiversity constitutes a key element of Ethical BioTrade. UEBT members are required to take measures to comply with legal requirements on ABS, complying requirements in the Ethical BioTrade standard on equitable benefit sharing for all sourcing activities and on incorporating ABS principles such as prior informed consent, mutually agreed terms and supportive patent policies in relation to their biodiversity-based research and development activities.

UEBT has contributed or featured in various stages in the development of the draft EU regulations on ABS, including participating in 2011 web-based public consultation on key aspects of implementing the Nagoya Protocol in the EU. Moreover, in the expert study

commissioned to inform the Impact Assessment for the draft regulations, UEBT was mentioned among best practices in the food and cosmetics sectors.
Looking forward, UEBT will follow the draft regulations as they proceed through the EU legislative process. Moreover, it will consider how the UEBT system and tools such as the Ethical BioTrade Standard could be recognized as best practice under the proposed EU regulation, and thus facilitate compliance with the due diligence obligations of UEBT members.

For more information

More information on UEBT work on benefit sharing, as well as additional resources on ABS, are available at www.ethicalbiotrade.org.

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