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

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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まとめ

1．欧州連合における、名古屋議定書関連法である EU 規制(法律)が最終段階にあり、すでに欧州委員会、欧州議会、欧州理事会で合意が得られている。法律が成立するのは 2014 年 3 月中旬に予定されている欧州議会と欧州理事会である。その 3 か月後に欧州連合で法律として発効する。その後、EU 規制に基づく、より詳細な規制がすでに検討される。今年中には EU 規制の一部の条項について詳細規制案が発表される予定である。その後、更にそれをブレークダウンした指令（Directive：日本でいう規則）が次々には作成される予定である。

2．2014 年 7 月の欧州議会において、名古屋議定書批准決議がなされ、欧州連合が名古屋議定書を批准する予定である。その後、欧州連合各国が個別批准手続きに入るが、各国の事情により時期は異なると予想される。現在の名古屋議定書批准国が 29 か国なので、早ければ 2014 年 10 月、遅くとも 2015 年 3 月までには名古屋議定書は発効するものと予想される。

3．EU 規制は法律であり、欧州連合加盟国は国内法として受け入れなければならない。各国で追加できるのは罰則規定である。そのため、各国の関係研究機関では、EU 規制への対応策を検討している。

4．英国王立植物園では、現在のガイドライン、移転契約などの手直し、EU 規制への適合化を行っている。英国自然史博物館では、欧州の博物館とコンソーシアムを形成し、名古屋議定書、EU 規制に合致した原則、行動規範、ベストプラクティスなどを開発中である。ベルギー微生物学連合でも、現在ある行動規範 MOSAICC を見直し中である。

5．一方スイスでは、欧州連合とは別に、独自の名古屋議定書批准活動を行っている。すでに、自然文化遺産保護法の改正最終案を作成し、現在自治州理事会（各自治州代表者会議）で審議中であり、2014 年 3 月には成立予定である。成立すれば直ちに名古屋議定書の批准手続きに入る予定である。

6．スイスの植物園あるいはスイス連邦工科大学（ETH）などでは、改正案対応として“due diligence”のあり方などを検討しており、管理方法を探っている。しかし、研究者の理解の低さが課題であると考えている。

7．欧州の生物関連の学会の ABS 活動に日本の学会が参加できるよう、学会レベルでの ABS 関連の国際シンポジュームを開催することを提案したい。そこで、日本の現状を報告し、欧州の学会の ABS 活動を紹介してもらい、日本の学界の ABS 活動をいかにすべきかを考えるべきである。

目的

名古屋議定書の国内措置に関して、欧州の名古屋議定書批准進捗状況を把握することは重要事項である。特に、欧州連合において現在名古屋議定書の批准を前提とした規制案を議論中であり、すでに欧州議会を通過している。欧州規制が行われると、その影響が日本の研究者の研究活動に影響を及ぼすことが考えられる。日本が研究者を厳しく縛る国内措置が行われ、欧米の研究者との競争力を低下させないようにすることが必要である。実際に、大学の研究者より、欧米との研究の競争力を失わない観点でも頻繁に質問されることも背景にある。そのため、EU 規制がどのような形で成立するかをいち早く把握しなければならない。

インターネットにより調査を行ったところ、スイスあるいはドイツで遺伝資源へのアクセスと利益配分に関するガイドラインを完備している国もある。また、微生物学会や植物園などの学会や遺伝資源保存機関などでもガイドラインの運用を行っていることが判明した。しかしながら、インターネットでの調査には限界があり、実際の運営状況、現在の各組織の考え方などは、実際に現地の関係者との意見交換の必要がある。

すでに、2013 年 1 月に提供国の一例としてタイ事情を調査し、10 月にタイの当局関係者を招聘したワークショップを開催した。ヨーロッパの状況は、スイス科学アカデミー科学顧問を日本に招聘することで状況や意見交換を行った。

今回、欧州事情をスイス科学アカデミー、欧州委員会本部、ベルギーにある欧州微生物学会、英国の王立植物園、自然史博物館、遺伝資源 NPO などから取り組みの現状を聞く。現在、環境省の検討会で国内措置を検討しているが、来年度から国内措置の具体化議論段階となるため、2014 年 1 月下旬の現地調査を希望する。

訪問先

１．省庁関係　政策立案、研究開発活動
　スイス環境省フォーカルポイント、スイス科学アカデミー
　欧州委員会
２．コレクションセンター
　ベルギー微生物保存連合
　英国王立植物園キュー
　英国自然史博物館
３．民間 NGO 団体

Union for Ethical BioTrade

訪問記録

スイス環境省、スイス科学アカデミーとのミーティング

議題：①スイス名古屋議定書批准法案の進捗状況
　　②スイス国内措置の考え方と実施状況（ガイドライン議論）
日時：1 月 27 日(月)　13:00PM-15:00PM
出席者：

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内容：

スイスの名古屋議定書批准に向けた国内措置設定状況をスイス環境省担当者から説明を受ける。最終法案を入手した。現在自治州代表の理事会で議論中。2014 年 3 月頃には決定される見込みである。

遺伝資源の利用の解釈について、「単なる収集分析保存」は含まないとスイスでは考えている。名古屋議定書第 2 条の「“Utilization of genetic resources” means to conduct research and development」は research と development 両方持っていなければならないと解釈している。したがって、スイスの法案にもそのように書かれている。

日本の名古屋議定書国内措置状況についてプレゼンを行い、質疑応答を行う。スイス側の感想として、スイスの学術界の状況は日本と変わらない、同じ悩みを持っているとのコメントがあった。

その後、いくつかの課題について議論を行った。まず、due diligence に対する何らかのコントロールは必要であるかという点について議論した。チェックポイントが最終の製品申告では遅すぎる。企業がライセンスの時に厳しく出所を調べるようになっているので、それまでにきちんと書類を整えておかなければ、ライセンスを受ける会社がなく研究成果が無駄になる。このことを研究者がちゃんと理解しないで、自主的にやっていればよいという安易な誤解があると混乱する。非営利研究であっても、いつ営利研究に代わるか分からないのだから、営利研究になった途端になにも書類がないのでは困るのではないかと考える。

やはり due diligence に対する何らかのコントロールは必要である。少なくとも due diligence のガイドラインを作成して、理解を求めなければならない。あるいは、もっと研

究初期の時点でチェックポイントを入れることも考える必要がある。しかし、現実に特許出願で出所などを調べることをあまりやっていない現状では、実施は大変困難である。（スイスでは特許出願時の出所開示要件はすでに施行済みである）

不確実な遺伝資源の取り扱いは困難な課題である。スイスの法律が決まってから考えたい。何か方法があるはずと考えている。提供国への後出し PIC の可能性は提供国でも検討されていると聞いているので、提供国でも問題視しており、何らかの国際的な議論が起こると考える。

制度のある国と制度のない国の取り扱いについて、常に情報強化しなければならない。できた国の制度を精査することが国の役割として求められる。いままで、制度がないから対象外としていても、いつのまにか制度ができていることがあるからである。交渉途中で制度ができた場合などを考えると、国内監視について多少の猶予期間を設ける必要があるのではないか。

大学の MTA の取り扱いについていままでのやり方を変える必要がある。本来権威あるものがサインすべきだが、現状では残念ながら研究者個人がサインする場合が日本では多い。ETH では、素材移転ではほとんど MTA で済ませているし、サインするヒトは大学の権威あるものが行っている。

提供国の法律によって、研究に対しては大学や研究機関が PIC を発効することができる国があるので、MTA で PIC をカバーしている場合がある。しかし、多くの国は PIC を政府当局が直接出すようになっている。

大学に ABS のシステム構築が今後の課題である。これは日本でも同じと考える。大学に ABS システムを作り、大学が自ら ABS 管理しないと問題が起きてからの対処では遅い。しかし、大学が ABS システムを作る資金もないし、専門家もいない。また、大学によって ABS 意識が高いところと低いところと程度差がある。スイスの州立大学ではそれぞれの州の事情があるので、連邦で一律に制度を作ることはできない。

感想

スイスの学術 ABS 関係者も同じ悩みを持っていると思われる。しかし、スイスでは問題の解消は法律が成立してからとの立場をとっている。どのような修正があるかわからないので、いまからはできないからである。したがって、今後の活動に注目しなければならない。

スイスの大学でどのような ABS 管理組織を作るのか難しい課題と考えている。研究者の間で ABS に関する理解が進んでいない、熱心なところもあるがそうでないところも多いという悩みがあることが理解できた。

ABS 管理組織作りで問題なのは資金と人材である。資金獲得といっても、スイスでは連邦、州、欧州といくつも資金源があり、それぞれの資金の使い方や管理方法が異なるので、資金源が ABS コントロールすることも難しい。基本的に独立心が強い研究者の活動をすべてコントロールするのは難しいというのが一致した見方である。ただし、研究者にまかせないで、機関で行う仕組みは必須であるとの合意を見た。課題は、どのように研究者に ABS 報告のモチベーションを持たせるかにあると考えられた。

欧州委員会 CBD 担当責任者との面談

目的：①欧州規制案の進捗状況と課題
　　②欧州の名古屋議定書批准の見通
日時：1 月 29 日(水)　11:30AM-1:00PM
面談者：
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内容

EU 規制の進捗状況

欧州理事会の意見を入れた最終合意案[1]が 2014 年 1 月中旬に作成された(別添)。現在、最終

[1] http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/dv/envi20140122_abs_agreed_text_/envi20140122_abs_agreed_text_en.pdf.

合意案を各国語に翻訳中である。各国の意向を受けた理事による修正の可能性あるが、3 月に議会と理事会を通過する見通しである。最終的には EU 議会に立法の権限がある。そうなると、3 か月後の 7 月までに EU 規制が発効する。その後、各国法に移行されていく。

7 月に欧州議会で名古屋議定書批准の決議がなされる予定なので、その後、欧州連合が批准する。その後、欧州連合内の各国が批准手続きにはいる。少なくともデンマーク、スウェーデン、ドイツ、イギリス、オランダ、ベルギー等などは 7 月批准予定だが、フィンランド、フィンランドやスペイン等は国内事情により遅れる可能性はある。例えば、フィンランドやスウエーデンでは北部にラップ人という先住民がいるので、その取扱いを考えなければならない。

現在 EU 規制に基づいたより詳しい規制案を作成中である。特に due diligence の管理について詳しい方法を作成しなければ、実施に混乱を生じる。Due diligence はライセンスビジネスや他の法律（例えば材木管理法）ではなじみのある制度なので、欧州で due diligence の考え方を普及させるのはそれほど困難とは考えていない。コレクションセンターなどの専門家を招いて due diligence のやり方についてこれから検討していく。EU 規制が成立すれば、新しい規制の草案作成に入り、今年中には最終案を作成する予定である。来年には新たな規制が作られることになる。その後、更により詳しい指令（directive）がそれぞれの課題について作っていく予定である。

欧州連合内の遺伝資源の取り扱い

欧州連合内に存在する遺伝資源については規制を行わない。ただし、欧州連合内の遺伝資源が伝統的知識と関係する場合は、伝統的知識保持者から PIC を入手する義務の新設は必要と考えている。欧州連合内にも伝統的知識保有者や先住民族は存在する。例えば、フィンランド、スウエーデンに住んでいるラップ人などには伝統的知識がある。これらの地域から遺伝資源を入手する場合、伝統的知識が関与すると保有者から PIC を取らなければならない。グリーランドはデンマーク領であるが、欧州連合ではないというのが欧州連合の法律である。したがって、グリーンランドについては欧州連合規制の外にある。グリーンランドの遺伝資源についてはグリーンランド自身が判断できる。

保存サンプルの新利用

欧州委員会が昨年 7 月に作成した改正案にあった第 4 条 1a と 1b は、最終案から削除された。これは、保存されている不確実な遺伝資源の新たな利用に関するものである。理由は、EU 規制が発効してから新たに入手した遺伝資源に限り、それまでに入手したものには及ば

ないからである。しかし、国際的に不確実な遺伝資源の取り扱いについて明確な合意はない。欧州で先走ることは避けたいので、今後国際的に話し合うことと考えている。

分類研究は EU 規制では規制対象ではない

名古屋議定書では研究と開発両方をするのが利用の定義であると欧州連合では理解している。したがって、研究だけでは利用とならないと欧州では解釈している。つまり、遺伝資源の分類研究は EU 規制には入らない。これは欧州連合全体の決定である。ただし単なる研究と研究開発を分けるのは現実に難しい場合がある。また、欧州連合で規制しないだけなので、提供国の規制を受ける可能性はある。このように二つの状態が生じるのは実際の研究者に混乱を与えると考える。

国際普及

コレクションセンターや国際学会が今後の EU 規制を実施する上で重要な役割を持つ。EU 規制が国際学会等で基本になると、日本などの学会にも影響がでると予想される。したがって、欧州連合と日本は異なった制度を作るべきではない。国際学会等が積極的に EU 規制の普及活動を行うべきである。

日本の学者が国際学会で活躍するためには、EU 規制を理解している必要がある。特に、due diligence は自主的な規制であるので、研究者自身が EU 規制の新しい due diligence の考え方に深い理解と共に遵守を行わないと、今後国際的に認められなくなる。

感想：

法律家の意見であり実務家ではないので、現実にどうなるかあまり考えていないように見える。ABS 規制はできるが、あくまで名古屋議定書批准のためである。現実の世界でどのような影響、混乱がでるか、果たして EU 規制が実施可能であるかを考慮すると、Schally 氏は若干楽観的にみえる。EU 規制ができて、現場で大きな作業、労力がなく実行可能と思っているようだが、現実はそうではないだろうと予想する。

ベルギー微生物保存連合での面談

目的：①国際微生物連合の名古屋議定書への取り組み状況
　　②国際微生物連合作成の行動規範（MOSAICC）についての議論
日時：1 月 29 日(水) 3:00PM-5:00PM

面談者：

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内容：

EU 規制に対するコレクションセンターの対処

ヨーロッパで保存されている微生物の地位を明らかにして登録することにより、規制に書かれているコンプライアンスを実行することができると考えている。登録によって、微生物入手経緯の正当性が欧州連合では認められることになる。一旦正当性が認められると、欧州域内での移動は MTA のみで済むというメリットもある。

ベルギーでは、EU 規制に従って、登録方法の開発プログラムがスタートしており、資金がベルギー科学省から供給されている。Desmeth が主宰しているのは、主に保存微生物の登録であり、いくつかのコレクションセンターが協力して行っている。現在ある程度のドラフトができている。EU 規制が発効すれば、その第 5 条に従って、本方法で保存微生物を登録することになる。ドラフトは現在公開できない。

まず、大学や研究所のコレクションセンターは、EU 規制第 5 条に規定される登録に必要なステップを正しく理解することが求められる。すなわち、大学や研究所のコレクションセンターは、それぞれの保存コレクションについて第 5 条第 3 項に記載されている項目の適合性を評価する必要がある。同時にコレクションセンター連合として、ベストプラクティスを第 8 条から第 13 条に従って積極的に提案することが求められている。

基本的にできるだけ簡単な登録方式を取りたいと考えている。登録にむけた基本となる項目は以下の通りである。

- 科学的起源情報＋管理文書(PIC+MAT)のセット
- GPS 情報（可能な場合、正確な採取位置情報）
- 登録は政府機関で正統性の審査後に受理される
- 登録が受理された場合、正式な登録微生物として MTA だけで利用・移転可能

問題は、PIC や MAT がない、不確実な遺伝資源の場合にどうするかである。例えば、興味ある微生物だが提供元が明確でないものを日本の研究者からベルギーに寄託したいと言っ

て来たらどうするかという問題がでてくる。現在の案では、そのような不確実な微生物の寄託は受け入れることになっている。その際に、

- 起源が明らかでないことを登録の際にベルギー当局に届ける
- 当局がクリアリングハウスに載せるが、起源が不確実であることを明らかにする
- 分離した日本の研究者に入手元の提供国に届け出て、同様な手続きをとるように促す
- 提供国が合意した場合、提供国のグリアリングハウスに載せる
- PIC なしで研究活動に利用することは可能になるが、営利研究には提供国の PIC が改め取得することになる

プロセスの透明性が大事と考える。この方法では、PIC がないままに使われることになる。しかし、PIC がないことを公にすることにより、不確実な遺伝資源の信頼性が増すと考えている。不確実な遺伝資源でもその利用によって利益配分の可能性が高まる。ただし、提供国が合意しない、拒否した場合はこの方法の実施は困難になる。

いま考えているシステムでは、いくつかの課題がすでに議論されている。一つは、国際的な仕組みにしないと効果がないという点である。しかし、アメリカの ATCC は合意するのが難しいといっている。違う方針を持っているためである。アジア微生物グループである「微生物資源の保全と持続可能な利用のためのアジア・コンソーシアム（ACM)」とも話し合っている。微生物でモデルを構築しているが、植物や動物コレクションセンターとの連携も図る計画である。

次に、提供国がどのように考えるかが大きな課題である。資源国も遺伝資源が利用されないと学術的利益が上がらないので、同意すると考えるが、PIC の方法について提供国の理解を求めていかなければならない。

次に、科学が発達すると、遺伝資源の定義と関係していくつかの困難が今後予想される。伝統的知識が絡み、伝統的食品の微生物群や農業用微生物群は総体として判断され、個々の微生物は解明されていない場合が多い。日本酒の微生物群相は酒蔵によって異なると聞いている。そのため、個々の微生物を登録しても総体を表さないので、登録は困難になる。農業用の土壌菌なども、農業という伝統的知識と関連しており、個々の分離した微生物では総体をカバーできない。どのような具体案を考えればよいか明らかではない。

企業などのプライベートコレクションは秘密が絡むので、すべて登録・公開できない。この場合、秘密部分をどのように除くのか問題である。情報から化学合成した DNA 断片や合成生物の場合、まだなにも決まっていない。今話題にすると複雑になるだけである。このような合成生物は環境に耐えないと現在いわれているので、大きな問題にはならないかも

しれない。

Union for Ethical BioTrade（UEBT：環境 NGO）での面談
目的：①欧州規制案に対する考え方、対処方針
②資源国の名古屋議定書に対する情報収集
日時：1 月 30 日 14:00PM-15:30PM
面談者：
Mr. Rik Kutsch Lojenga　rik@ethicalbiotrade.org
Executive Director, Program officer for ABS
Union for Ethical BioTrade
Ms. Maria Julia Oliva Julia@ethicalbiotrade.org
Ms. Natalia Freitas　natalia@ethicalbiotrade.org

内容：

Union for Ethical BioTrade（UEBT）の役割

UEBT は遺伝資源提供国から素材を「敬意をもって」輸入することを促進する非営利団体である。オランダ中心の化粧品、食品、医薬品などの産業セクター36 社から出資されており、それらの会社の生物多様性促進事業を確実にするための指導を行っている。具体的には、伝統的知識と公正で衡平な利益配分を確実にするための活動である。協賛各社の R&D の中で ABS をどのように実行していくかを指導している。提供国としては、アフリカ諸国と中南米が中心であり、アジア進出は少ない。協賛企業向けにベストプラクティスを作っている。また、EU 規制案に対し意見書[2]を提出しているが、その指摘は正確であると思われる。

意見交換

欧州の食品業界特に小企業では、ABS の理解が進んでいない。したがって、現在は、これらの参加企業に普及活動や個別相談を行っている。関連企業同士でグループをつくるのは企業秘密の問題があり困難である。秘密保持はグループ内で規律を作り、お互いに信頼関係で行うしか方法はないと思われる。

EU 規制ができて今後欧州の産業界はどのように変わるか予測が難しい。ABS に対する理解進むと思うが、問題そのものの解決は当面困難である。なぜなら、提供国の制度がすぐ

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

にできるとは思えないからである。あと 5 年はかかるだろう。提供国があいまいなままでは、確実な PIC/MAT を取ることも難しい。ペルーなどはどうしてよいかわからないくらい複雑な制度になっている。ブラジルは制度が整った方だが、政府の末端までその制度が理解されていないので、プロセスがスローである。提供国の伝統的知識がからむとより話が複雑になる。食品や化粧品などは必ず伝統的知識が絡むので、PIC/MAT を取るのは困難になり、時間がかかる。

解決にはベストプラクティスを積み重ね、良い方向に持っていくのが最良の方法ではないか。難しいから何もしないのでは進歩がない。よい例を公開し、みんながまねをできるようにすることが必要である。特に、中小企業は担当者もいないので、どうしてよいかわからない状態にある。なにかまねのできるような例を提示し、それにそって個別事情に対応できるようにすることが必要である。また、中小企業集団で取り組むのも効果がある。すでに、化粧品原料企業でコスメバレーを作り、集団で解決しようとしている例がある。確かに、企業秘密があり難しいかもしれないが、合同でできることもあるはずである。この方向性に賛同し、当方からコンソーシアム案(下図)を提示した。

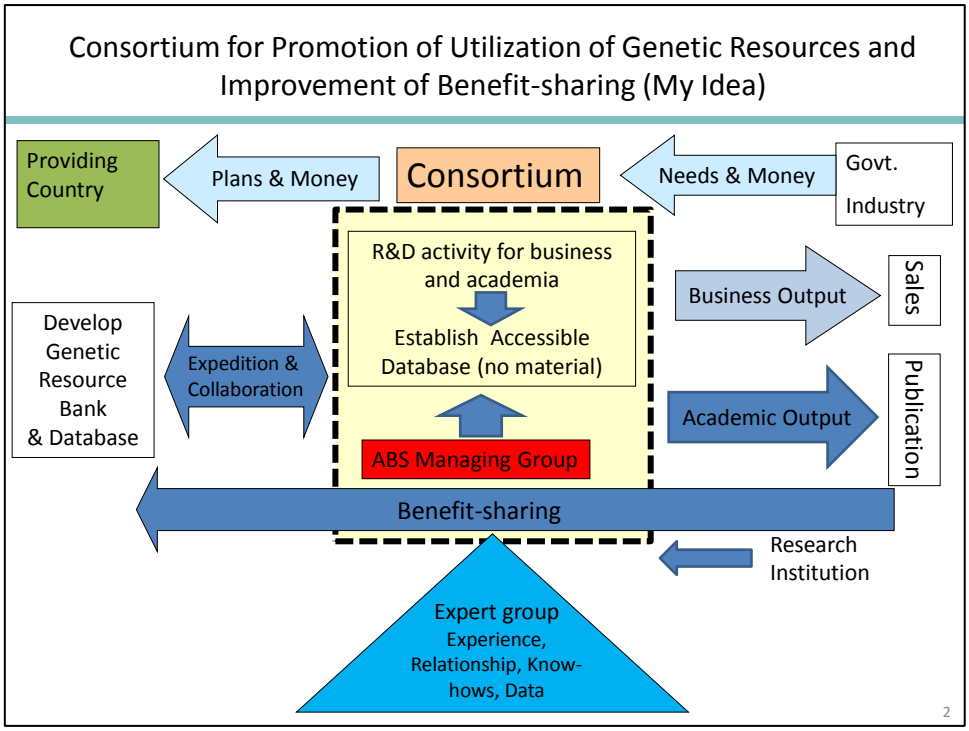

図 1　遺伝資源利用促進コンソーシアム構想

英国王立植物園キューでの面談

目的：①キューガーデン（植物園）での CBD 取り組み状況
②ガイドライン、行動規範に関する最新情報
日時：1 月 31 日(金) 3:00PM-5:00PM
面談者：
Ms. China Williams
CBD Unit Royal Botanic Gardens, Kew
c.williams@kew.org
Noel McGough
Head, Coventions and Policy Section
n.mcgough@kew.org

内容：

英国王立植物園キューの現在の活動・組織について

英国王立植物園キューの収入の半分は科学技術省の援助であるが、政府の財政難で減少傾向にある。残りは植物園収入や鑑定料がある。鑑定では、ワシントン条約関連の輸入品に対する税関での鑑定やその指導、病院などでの毒キノコ鑑定などを行っている。税関検査の専門家がいなくなってしまった。独立した組織として、自立する方向に行かざるを得ない。現在保存している植物標本数は世界一と思われる。ダーウインの標本もある。現在は施設内で植物ゲノム研究も行い、データベースの充実も図っている。現在、国際的に種子標本保存運動[3]を主宰している。

ただし、古い標本には明確なアイデンティファイアーがないので、過去のものを登録するのは困難で、時間と費用がかかる。英国王立植物園キューが、商用の植物育種のために生体標本を分譲することはない。営利活動はしない。研究活動のみに譲渡することはあるがあくまで研究目的のみである。

英国環境、農業、地域問題省（Defra）と直接的な関係はないが、ABS 問題では連携している。ABS 活動は英国王立植物園キュー独自で CBD の発効以来行ってきた。英国王立植物園キューの実際の運営については、理事会が最高決定機関であり、理事長は女王によって

[3] Millennium Seed Bank: Partnershiphttp://www.kew.org/science-conservation/save-seed-prosper/millennium-seed-bank/index.htm.

任命される。理事会には外部のものも入っている。今後のCBD活動も理事会で決定される。

英国王立植物園キューには、ABS 対応を行う条約と政策ユニットがあり、主に 3 人が法的部分の対応をしている。主な仕事は、

- 英国王立植物園キュー職員や海外の関係者に CBD 問題に対する助言
- 英国王立植物園キュー職員に対して、協力契約、素材移転契約、利益配分契約、ガイド、訓練資料などの実施ツールを提供、契約交渉、締結
- 生息域外保存機関を代表して、ABS 政策の実行案を作成
- 英国のコレクションセンター、植物園のために英国政府 Defra への ABS 政策立案助言
- 植物園、植物標本館、大学等への能力開発ツール開発、普及

英国王立植物園キューでは、海外での植物収集活動を年間 600 件ほど行っている。多くの場合は英国連邦内である。600 件は継続が多い。提供国と信頼関係ができ、継続していることが契約にとっては重要となる。継続の場合、すでにある協力契約のような包括契約のもとで行っている。その中で、ケース毎の PIC/MAT をもらうことになる。関係のない初めての国に行く場合もある。当然初めての場合は ABS 契約を締結している。しかし、時間がかかる。

英国王立植物園キューでは外部から利害関係のない人をいれた活動管理委員会が理事会の下にあり、そこが英国王立植物園キューの収集活動の報告を受けている。外部者をいれた管理委員会がすべての収集活動を把握しているので、活動の透明性は高いと考えている。ABS に関する制度を決定するのもこの委員会である。

ABS に関する制度は CBD が発効したときから整えてきている。(いくつかの見本入手、別添) まず提供国政府との協力契約（包括研究契約）がある。これによって PIC 取得が比較的簡単になっている。第三者移転に関する MTA は、いくつかのケースに分けて整えている。英国王立植物園キューで研究を行う外部研究者の受け入れ契約もあり、外部研究者が英国王立植物園キューで研究する場合の決まりを作っている。

EU 規制に対する今後の課題

問題点は、コレクションセンターのコンプライアンスをどうするかであると考えている。つまり、due diligence の自主的コントロール方法である。第三者移転は MTA で管理するが、何回も第三者移転を行っていると、最初の契約内容を最終契約者が守っているかどうか最初の契約者は全くわからなくなる。この場合提供国と契約した最初の契約者が、提供

国に報告する義務があるにもかかわらず、最後の移転先がなにをしているか分からないので報告もできないし、利益配分もできないという問題がある。

コンプライアンス方法のアイデアとして、DNA バーコード計画の取り組みがある。どこに遺伝資源が移転され、たとえ製品になったとしてもある程度起源をフォローすること可能になる。もちろん現在はコストがかかりすぎる、インフラがないなどで困難だが、将来コストが下がれば、提供国で普及する可能性はある。GPS 情報を付加すれば、更に位置情報も加わるので、正確性が増すと考えられる。

登録制度が EU 規制に入る（EU 規制第 5 条）

博物館、植物園などコレクションセンターがどのようにして登録を行うか、行動規範を現在検討中である。EU 規制にいう due diligence のコントロールの一つの方法ととらえている。欧州の博物館、植物園のグループで最終案を検討しているが、EU 規制が 2014 年 3 月に決まるので、それを待って最終にする予定である。

その他

分類学研究は EU 規制の対象外との話についてどう考えるかという質問について、現在の EU 規制案では、「利用」は名古屋議定書と同じことしか書かれていない。「利用」の解釈問題で、R&D 両方がある場合のみ「利用」であり、それ以外の「R」のみでは、範囲外と EU では解釈しているようである。しかし、これは国際的に合意された解釈ではない。現在の傾向では、提供国は積極的に「R」部分を利益配分の対象にしているので、EU でこのような解釈をすれば、現場で混乱が生じる可能性が高いと思われるとの意見である。

もう一つは、第三者移転で、非営利から営利に変わったことをフォローすることができないのが現実の問題として大きいとの意見である。たとえ分類研究であっても、いつか営利研究に発展することはあり得る。この場合、最初が EU 規制外なので、営利研究をどのように規制するのか問題となってくる。そもそも、営利研究を行おうとしても、なにもなければだれも怖くて行えないのではないか、あとから PIC/MAT を取れといっても、もっと難しいと考えられる。したがって、一旦非営利研究とランク付けされたものは、営利研究に展開することは困難となるのではないか、そして due diligence も行わないとなるとますます難しくなる。

英国自然史博物館担当者との面談

目的：①博物館（動物）での CBD 取り組み状況
　　②使用しているガイドライン、行動規範等の入手
日時：2 月 1 日(土)　10:00AM
面談者：
Dr Chris Lyal FRES, FZS
GTI NFP
Researcher, Entomology, Life Science Department, Terrestrial Invertebrates Division
Natural History Museum
c.lyal@nhm.ac.uk

内容

EU 規制の現状認識

Dr. Lyal は英国政府の CBD ナショナルフォーカルポイントである。EU 規制は今年 3 月に議決され、7 月に発効する見込みと考えている。欧州連合が名古屋議定書批准決議を行えば、すぐに英国は名古屋議定書を批准する予定である。英国環境、農業、地域問題省（Defra）と話し合いでは、すでに政府内での批准合意ができている。その他、デンマーク、スウェーデン、ベルギー、ドイツなどが批准する予想されている。ただし、スペインやフィンランドなどは国内遺伝資源、伝統的知識問題があり、国内で対応するため批准は遅れるであろう。EU 規制が成立した後、実際の対応を考える必要があるというのが現在各国の一致した考えである。

EU 規制への英国博物館等コレクションセンター等の対応案

現在ある ABS ルールの見直しを行い、なにが不足しているか明らかにしてきた。最も ABS 対応で進んでいるのは英国王立植物園キューである。英国王立植物園キューの例を参考にして、それぞれの組織の原則等の見直しを行い、改革の必要性について最高運営組織（理事会等）で承認を受けているのが現状である。

EU 規制に対応して具体的になにを行うかは検討中であるが、そのうちの 2 つの活動を紹介する。第一は、博物館、植物園、コレクションセンターの欧州コンソーシアム[4]の原則、行

[4] Consortium of European Taxonomy Facilities（CETAF）; http://cetaf.biodiv.naturkundemuseum-berlin.de/index.php.

動規範、ガイドライン等の作成がある。(ドラフト入手)(ICNP3 で概要発表予定)英国王立植物園キューのいままでに確立した方法をベースに検討している。この方法を今年中に実施に移したいと考えている。英国では環境、農業、地域問題省(Defra)の指導の下、英国王立植物園キューと自然歴史博物館が中心にプロジェクトを引っ張っていく。

第二はゲノムバンクの ABS 対応方法を検討している。(ドラフト入手) データベース作りは難しい。DNA データ解析している部分と分類研究している部門は異なり、なかなか両者が合同で実施することはない。いままで分類研究で行ってきた方法をデジタル化する費用もない。しかし、これからは分類データと DNA データを統合する方法を考えなければならないと考えている。

更にデータベースの中に、それぞれの標本に対応した ABS 書類を入れるとなると、科学的データベースに PIC や MAT 情報を加えるというとてつもなく難しい作業になる。現在、ABS 書類のコピーイメージを添付することを検討している。これから収集するものをデータベース化するのは、システムがあれば容易であるが、現在保存している収集品をデータベース化するのは人力と資金が必要である。データベースに入ったデータのバリデーションをどうするかという課題もある。専門家が常時監視しているわけにはいかない。

普及・教育活動

博物館では、現在でも毎年数千件の収集・保存活動を行っている。大部分は過去からの継続であり、提供国との信頼関係の中で行っている。不法なことはないと信じている。英国連合が採取地として選ばれる場合が多いので、信頼関係があり問題になることは少ない。しかし、アフガニスタンなどの政治不安定な国にでかけなければならないこともあるので、きちんとした対処方法を確立する必要がある。

博物学に関係する多くの研究者は ABS に無知、無理解であると思っている。また、面倒な手続きを嫌う傾向がある。そのため、なぜそのようなことを行うのかモチベーションを上げる教育を行う必要性を感じている。できるだけ簡単な方法を用いたい。(教育プレゼン資料入手)

各コレクションセンターに専門家を設置するためのツール開発が必要である。そのため、国際的に協力してツールを作ることを提案する。(名古屋議定書第 20 条対応) 国際的な教育ツール開発の情報交換、議論を行うことを約束した。事例研究、Q&A などのツールが有効であると意見が一致した。

その課題について

遺伝資源の複合体（同定不可能なもの）の定義：腸内細菌叢、土壌微生物叢、ヨーグルトなど発酵食品微生物叢、動物、植物病原微生物叢は、総体として現在の CBD や名古屋議定書では判断できない。PIC を取ることも難しい。個々の単離された微生物は全体の価値を表していない。腸内細菌や土壌細菌は DNA でのみ存在が確認されているだけで、実際の微生物は単離されていない。このような科学進歩に対応した新しい ABS 解釈が必要である。

所有者の変更の場合：MTA で所有者が変更する場合を設定している。（見本 MTA を入手）遺伝資源は一元的に提供国のものであるが、所有者が変わる場合があるのか？答えは明確ではない。

不確実な遺伝資源の取り扱い：PIC/MAT がない標本も保存している。保存標本のかなりな部分は不確実な遺伝資源と思われる。そのままでは新たな利用は困難であるし、過去の利用成果も公表できない場合がでてくる。各保存施設で不確実な遺伝資源に対する ABS 基準を決め、みんなで共通のルールを作るべきである。それを公開し、提供国の理解を求めることが透明性を高める誠実な方法であると考える。そうでなければ、少なくとも他の保存機関とのサンプルの受け渡し、譲渡が困難であるし、混乱を招くことが予想される。

個人が保存する昆虫標本の死後寄贈を受けることが困難になった例がある。当該の個人所有標本には法的な確実性がない場合が多い。収集家自身は死んだので、出所を明らかにするものが存在しない。そのため、受け入れ基準を決めると受け入れが困難になる。そうなると遺族が標本を捨ててしまうことになるので大変な損失である。

不確実性な遺伝資源を受け入れる必要が生じたら、まず事実を公開することが due diligence のために重要な一歩であると考える。また、不確実遺伝資源の利用によって成果がでれば、提供国と利益配分を行う姿勢を明確に示すべきである。不確実であってもクリアリングハウスに載せる方向で検討する。提供国の後付 PIC を得ることも検討していきたい。

第三者への移転のコンプライアンスの監視責任：素材移転契約で学術用に標本を第三者に移転しても、更に次々に移転が進み、ある時期に商用研究に転用されても最初の受け入れ者には全く報告がないし、調べることも困難である。また、素材移転契約に最初の提供国との契約を守ることと最後の遺伝契約に書かれていても、どのようにするのかだれもわからなくなる。最初がだれかさえわからなくなる。これでは、契約のコンプライアンスが守れない。第三者への移転に対して、今後なんらかのコンプライアンス方法を考案していか

なければならない。

今後の課題

欧州では、EU 規制が発効した後の対応について議論が盛んである。特に植物園や博物館を中心にコレクションセンターと呼ばれる組織体が、コンプライアンスの方法について連携して取り組んでいる。王立植物園キューのように先進的取り組みを行っているところを中心に、いままでの原則、行動規範、ガイドラインを見直し、新たな EU 規制対応を行っている。同時に研究者に対する啓発、教育ツールの開発も盛んである。

このような状況を踏まえ、欧州のコレクションセンターの ABS 対応の活動に照応した活動を日本で始めることが必要である。日本における名古屋議定書国内措置が明確になっていない現状では、日本の国内措置に対する対応は困難であるが、少なくとも学会レベルでは国際的な動きに合わせる活動を開始することが重要である。動物関連学会、植物関連学会、微生物関連学会などが、欧州の対応する学会と連携し、早急な国内学会活動を開始すべきであると考える。欧州で行われている学会組織の ABS 活動には、米国などは参加しているが日本人の名前が少ないことから、ABS 分野で日本の学会の国際参加は遅れていると感じられる。

これらの国際学会における ABS 活動に日本の学会が参加できるよう、学会レベルでの ABS 関連の国際シンポジュームを開催することを提案したい。そこで、日本の現状を報告し、欧州の学会の ABS 活動を紹介してもらい、日本の学界の ABS 活動をいかにすべきかを考えるべきである。

啓発・教育活動を強化する必要がある。欧州でもまだまだ研究者レベルの ABS 意識は低いようである。そのため、啓発・教育活動に力を注いでおり、多くの教育ツールを開発している。日本でも欧州の教育活動と連携を図り、今後教育ツールの開発に力を注ぎたい。

また、教育機関に対する ABS 対応管理体制を整える動きが欧州でも見られる。民間団体でも活動を行っている。そのためには、中心となる ABS の専門家を育成することが急務である。講習会等を開催し、ABS 対応管理の専門家を育成し、各機関での中枢となって管理体制を構築することが早道であると考える。

参考資料

EU 規制最終案（1/22/2014 版）EC 入手版

ANNEX

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

on *compliance measures for users from the Nagoya Protocol on* Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their *Utilisation* in the Union

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

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1 OJ C , , p. .
2 OJ C , , p. .

Whereas:

(1) A broad range of ***users and suppliers*** in the Union, including academic, ***university and non-commercial*** researchers and companies from different sectors of industry, use genetic resources for research, development and commercialisation purposes; some also use traditional knowledge associated with genetic resources.

(2) Genetic resources represent the gene pool in both natural and cultivated or domesticated ***species*** and play a significant and growing role in many economic sectors, including food production, forestry, ***and the*** development of medicines, ***cosmetics and*** bio-based sources of ▌ energy. ***Genetic resources play a significant role in the implementation of strategies designed to restore damaged ecosystems and safeguard endangered species.***

(3) Traditional knowledge that is held by indigenous and local communities may provide important lead information for the scientific discovery of interesting genetic or biochemical properties of genetic resources, ***including knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity***.

(4) The main international instrument ***providing a general framework for the conservation, sustainable use of biodiversity and the fair and equitable sharing of the benefits arising out of the utilisation*** of genetic resources is the Convention on Biological Diversity (***"***Convention***").*** ***In accordance with*** Council Decision 93/626/EEC[1] the Convention ***was*** approved ▌ on behalf of the Union.

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[1] ***Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity*** (OJ L 309, 13.12.***1993***, p. 1***).***

(4a) ***Genetic resources should be preserved in situ and utilised in sustainable ways and the benefits arising from their utilisation should be shared fairly and equitably. This would contribute to poverty eradication and, thereby, to achieving the United Nations Millennium Development Goals, as acknowledged in the preamble of the Nagoya Protocol. The implementation of the Nagoya Protocol should also aim to realise that potential.***

(5) The Convention recognises that ***States*** have sovereign rights over natural resources found within their jurisdiction and the authority to determine access to their genetic resources. The Convention imposes an obligation on all Parties to ***endeavour to create conditions to*** facilitate access to genetic resources, ***for environmentally sound uses by other Parties,*** over which they ***exercise*** sovereign rights. It also makes it mandatory for all Parties to take measures ***with the aim of sharing*** in a fair and equitable way the results of research and development and the benefits arising from the commercial and other ***utilisation*** of genetic resources with the Party providing ***such*** resources. Such sharing ***is to*** be upon mutually agreed terms. The Convention also addresses access and benefit-sharing in relation to the knowledge, innovations and practices of indigenous and local communities ***which are*** relevant for the conservation and sustainable use of biological diversity.

(6) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity ("Nagoya Protocol") is an international treaty adopted on 29 October 2010 by the Parties to the Convention[3]. The Nagoya Protocol ***further elaborates*** the general rules of the Convention on access and ***monetary and non-monetary*** benefit-sharing ***in relation to utilisation*** of genetic resources and traditional knowledge associated with genetic resources.

(7) ***In accordance with*** Council Decision ***.../2013/EU***[4]* the Nagoya Protocol ***was approved*** on behalf of the Union.

(7a) The Nagoya Protocol applies to genetic resources falling within the scope of Article 15 of the Convention as opposed to the wider scope of Article 4 of the Convention. This implies that the Nagoya Protocol does not extend to the full jurisdictional scope of Article 4, such as to activities taking place in marine areas beyond national jurisdiction. Research on genetic resources is gradually being extended into new areas, especially the oceans, which are still the planet's least explored and least well-known environments. The deep ocean in particular represents the last great frontier on the planet and is attracting growing interest in terms of research, prospecting and resource exploration.

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3 Annex I to Document UNEP/CBD/COP/DEC/X/1 of 29 October 2010.

4 ***Council Decision .../2013/EU of ... on the conclusion, on behalf of the Union, of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.***

* ***OJ: please insert the number, date and the publication reference for the Decision in doc. 6852/13.***

(8) It is important to set out a clear and sound framework for implementing the Nagoya Protocol that should ***contribute to the conservation of biological diversity and sustainable use of its components, the fair and equitable sharing of the benefits arising from the utilisation of genetic resources and poverty eradication while at the same time enhancing*** opportunities available for nature-based research and development activities in the Union. It is also essential to prevent the ***utilisation in the Union of*** genetic resources or traditional knowledge associated with genetic resources ***which were not accessed in accordance with the national access and benefit-sharing legislation or regulatory requirements of a Party to the Nagoya Protocol*** and to support the effective implementation of benefit-sharing commitments set out in mutually agreed terms between providers and users. ***It is also essential to improve the conditions for legal certainty in connection with the utilisation of genetic resources and traditional knowledge associated with genetic resources.***

(8a) The framework created by this Regulation will contribute to maintaining and increasing trust between Parties as well as stakeholders, including indigenous and local communities, involved in access and benefit-sharing of genetic resources.

(9) In order to ensure legal certainty, it is important that the rules implementing the Nagoya Protocol ***apply*** only ▌ to genetic resources ***over which States exercise sovereign rights within the scope of Article 15 of the Convention, and to*** traditional knowledge associated with genetic resources ***within the scope of the Convention, which*** are accessed after the entry into force of the Nagoya Protocol for the Union.

(10) ***The Nagoya Protocol establishes that each Party, in the development and implementation of its access and benefit-sharing legislation or regulatory requirements, is to consider the importance of genetic resources for food and agriculture ("GRFA") and their special role for food security. In accordance with*** Council Decision 2004/869/EC of 24 February 2004 concerning the conclusion, on behalf of the European Community, of the International Treaty on Plant Genetic Resources for Food and Agriculture ***("ITPGRFA")[5] the ITPGRFA was*** approved ▌ on behalf of the Union. ***The ITPGRFA*** constitutes a ***specialised*** international access and benefit-sharing instrument ***within the meaning of Article 4 (4) of the Nagoya Protocol*** that should not be affected by the rules implementing the Nagoya Protocol.

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5 OJ L 378, 23.12.2004, p. 1.

(10a) Many Parties, in the exercise of their sovereign rights, have determined that PGRFA under their management and control and in the public domain, not contained in Annex I, will also be subject to the terms and conditions of the standard material transfer agreement (sMTA) for the purposes set out under the ITPGRFA.

(10aa) The implementation of the Nagoya Protocol should be done in a way that is mutually supportive with other international instruments that do not run counter to its objectives or to those of the Convention.

(10b) The Convention defines, in its Article 2, "domesticated species" as any species in which the evolutionary process has been influenced by humans to meet their needs and "biotechnology" as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. The Nagoya Protocol defines, in its Article 2, "derivatives" as 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.

(10c) ***Article 8(b) of the Nagoya Protocol establishes that each party is to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. On 24 May 2011, the Sixty-fourth World Health Assembly adopted the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits ("PIP Framework"). The PIP Framework applies only to influenza viruses with human pandemic potential and specifically does not cover seasonal influenza viruses. The PIP Framework constitutes a specialised international access and benefit-sharing instrument consistent with the Nagoya Protocol that should not be affected by the rules implementing the Nagoya Protocol.***

(10d) ***It is important to include in this Regulation the definitions from the Nagoya Protocol and the Convention that are necessary for the implementation of this regulation by users. It is important that the new definitions contained in the Regulation, which are not included in the Convention or in the Nagoya Protocol, are consistent with the definitions of the Convention or the Nagoya Protocol. In particular the term "user" should be consistent with the Nagoya Protocol term "utilisation of genetic resources".***

(10e) ***The Nagoya Protocol establishes the obligation to promote and encourage biodiversity-related research, and in particular with non-commercial intent.***

(12) It ***is*** important to recall ***paragraph 2 of Decision II/11 of the Conference of the Parties to the Convention which reaffirms that*** human genetic resources ***are not included within*** the framework of the Convention.

(13) There is currently no internationally agreed definition ***of*** "traditional knowledge associated with genetic resources". ***Without prejudice to the competence and responsibility of the Member States for matters relating to traditional knowledge associated with genetic resources and the implementation of measures to safeguard indigenous and local communities' interests***, in order to ensure flexibility and legal certainty for providers and users, this Regulation should make reference to traditional knowledge associated with genetic resources as described in benefit-sharing agreements.

(14) With a view to ensuring ***the*** effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with ***genetic*** resources should ▌exercise due diligence to ascertain that ▌genetic resources and ▌traditional knowledge ***associated with genetic resources*** were accessed in accordance with applicable legal ***or regulatory*** requirements and to ensure that, where relevant, benefits are ***fairly and equitably shared. In that context, competent authorities should accept internationally recognised certificates of compliance as evidence that the genetic resources covered were legally accessed and that mutually agreed terms were established for the user and the utilisation specified therein. The specific choices made*** by users on the tools and measures ***to apply in order to exercise*** due diligence should be supported through the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses ▌ and guidelines with a view to increasing legal certainty and reducing costs. The obligation on users to keep information ***which is*** relevant for access and benefit-sharing should be limited in time ***and in accordance*** with the time-span for ***potential*** innovation.

(14a) ***The successful implementation of the Nagoya Protocol depends on users and providers of genetic resources or of traditional knowledge associated with genetic resources negotiating mutually agreed terms that lead to fair benefit-sharing and contribute to the Nagoya Protocol's wider objective of contributing to the conservation and sustainable use of biological diversity. Users and providers are also encouraged to raise awareness of the importance of genetic resources and of traditional knowledge associated with genetic resources.***

(15) The due diligence obligation should apply to all users irrespective of their size, including micro, small and medium-sized ***enterprises. This*** Regulation should offer a range of measures and tools to enable micro, small and medium-sized ***enterprises*** to comply with their obligations at ***an affordable*** cost and with high legal certainty.

(16) Best practices developed by users should play an important role in identifying due diligence measures that are particularly suitable for achieving compliance with the system of implementation of the Nagoya Protocol ***at an affordable cost and*** with high legal certainty ▌. Users should ▌ build on existing access and benefit-sharing codes of conduct developed for the academic ***and university and non-commercial research sectors*** and different industries. Associations of users should be able to request that the Commission ***determine*** whether a specific combination of procedures, tools or mechanisms overseen by an association may be recognised as best practice. Competent authorities of the Member States should consider that the implementation of a recognised best practice by a user reduces that user's risk of non-compliance and justifies a reduction in compliance checks. The same should apply to best practices adopted by ▌ the Parties to the Nagoya Protocol.

(17) ***The Nagoya Protocol establishes that the check-points must be effective and should be relevant to the utilisation of genetic resources. At*** identified points in the chain of activities that constitute ***utilisation users should declare and provide evidence when requested*** that they have exercised due diligence. ***One suitable point*** for such ***a declaration is when research funds are received. Another suitable point is at the final stage of the utilisation, that means at the stage of final development of a product before requesting*** market approval for a product developed ***via the utilisation of genetic resources or traditional knowledge associated with such resources or at the stage of final development of a product before first placing on the Union's market*** where a market approval is not required. ***In order to ensure the effectiveness of check-points, while at the same time increase legal certainty for users, implementing powers should be conferred on the Commission in accordance with Article 291(2) of the Treaty of the Functioning of the European Union. The Commission should make use of those implementing powers to determine the stage of final development of a product in accordance with the Nagoya Protocol in order to identify the final stage of utilisation in different sectors.***

(17a) ***It is important to acknowledge that the Access and Benefit-Sharing Clearing House would play an important role in implementing the Nagoya Protocol. In accordance to Article 14 and 17 of the Nagoya Protocol information would be submitted to the Access and Benefit-Sharing Clearing House as part of the internationally recognised certificate of compliance process. The competent authorities should cooperate with the Access and Benefit-Sharing Clearing House to ensure that the information is exchanged to facilitate the monitoring by the competent authorities of the compliance of users.***

(18) ***The collection*** of genetic resources in the wild is mostly undertaken for non-commercial purposes by ***academic,*** university ***and non-commercial*** researchers or collectors. In the vast majority of cases and in almost all sectors, ▌newly -collected genetic resources ***are accessed*** through intermediaries, collections, or agents that acquire genetic resources in third countries.

(19) Collections are major suppliers of genetic resources and traditional knowledge associated with genetic resources ***utilised in the Union. As suppliers they can play an important role in helping other users in the chain of custody to comply with their obligations. In order to do so a system of registered*** collections ***within the Union*** should be set in place ***through the establishment of a voluntary register of collections to be maintained by the Commission. This system*** would ensure that collections included in the register ▌effectively apply measures to only supply samples of genetic resources to third persons with documentation providing evidence of legal ***access*** and the establishment of mutually agreed terms, where required. A system of ***registered*** collections ***within the Union*** should substantially lower the risk that ***genetic resources which were not accessed in accordance with the national access and benefit- sharing legislation or regulatory requirements of a Party to the Nagoya Protocol are utilised*** in the Union. Competent authorities of Member States would verify if a collection meets the requirements for recognition as ***a*** collection ***for inclusion in the register***. Users that ***obtain*** a genetic resource from a collection ***included*** in the ▌register should be considered to have exercised due diligence as regards the seeking of all necessary information. This should prove particularly beneficial for academic***, university and non-commercial*** researchers as well as small and medium -sized enterprises ***and contribute to a reduction in administrative and compliance requirements.***

(20) Competent authorities of Member States should check whether users comply with their obligations ***and have obtained prior informed consent and established*** mutually agreed terms ▌. Competent authorities should also keep records of the checks made and relevant information should be made available in accordance with Directive 2003/4/EC[6].

(21) Member States should ensure that infringements of the rules ***implementing*** the Nagoya Protocol ▌ are sanctioned by means of effective, proportionate and dissuasive penalties.

(22) Taking into account the international character of access and benefit-sharing transactions, competent authorities of the Member States should cooperate ***with each other***, with the Commission, and with ***the competent national*** authorities of third countries ***in order*** to ***ensure that users*** comply with ***this Regulation and support an effective application of the rules*** implementing the Nagoya Protocol.

(22a) The Union and the Member States should act in a proactive manner to ensure the objectives of the Nagoya Protocol are achieved in order to increase resources to support conservation of biological diversity and the sustainable use of its components globally.

▌

(24) The Commission and the Member States should take appropriate complementary measures to enhance the effectiveness of ***the implementation of*** this Regulation and to lower costs, particularly where this would benefit academic***, university and non-commercial*** researchers and small and medium -sized enterprises.

▌

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6 ***Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information (***OJ L 41, 14.2.2003, p. ***6).***

(27) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[7].

(28) ***Since the*** objectives of this Regulation, ***namely*** to support the fair and equitable sharing of ***the*** benefits ***arising*** from the ***utilisation*** of genetic resources ***in accordance with the Nagoya Protocol*** cannot be ***sufficiently*** achieved by the Member States ▌ and can therefore, by reasons of their scale and to ensure ***the*** functioning of the internal market, be better achieved at Union level, ***the*** Union may ▌ adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve ***this objective.***

(29) The date of entry into force of this Regulation should be directly correlated to the entry into force of the Nagoya Protocol for the Union in order to ensure equal conditions at Union and global levels in activities related to access and benefit-sharing of genetic resources,

HAVE ADOPTED THIS REGULATION:

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7 ***Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (***OJ L 55, 28.2.2011, p. 13***).***

CHAPTER I
SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation establishes rules governing ***compliance with*** access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources ***in accordance with the provisions of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity ("Nagoya Protocol"). The effective implementation of this Regulation will also contribute to the conservation of biological diversity and the sustainable use of its components***, in accordance with the provisions of the ▌Convention on Biological Diversity (***"Convention").***

Article 2

Scope

1. This Regulation applies to genetic resources over which ***States*** exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union. It also applies to the benefits arising from the ***utilisation*** of such genetic resources and ▌traditional knowledge associated with genetic resources.

2. This Regulation does not apply to genetic resources for which access and benefit-sharing is governed by ▌ specialised international ***instruments that are consistent with, and do not run counter to, the objectives of the Convention and the Nagoya Protocol.***

2a. ***This Regulation shall be without prejudice to Member States rules on access to genetic resources over which they exercise sovereign rights within the scope of Article 15 of the Convention and to Member States provisions on Article 8(j) of the Convention concerning traditional knowledge associated with genetic resources.***

3. ***This Regulation applies to genetic resources and traditional knowledge associated with genetic resources for which access and benefit-sharing legislation or regulatory requirements of a Party of the Nagoya Protocol are applicable.***

3a. ***Nothing in this Regulation shall oblige a Member State to supply information the disclosure of which it considers contrary to the essential interests of its security.***

Article 3

Definitions

For the purposes of this Regulation, the ***definitions of the Convention and the Nagoya Protocol as well as the*** following definitions ***shall*** apply:

▌

(2) "genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity;

(3) "genetic resources" means genetic material of actual or potential value;

(4) "access" means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol ▌***;***

(5) "user" means a natural or legal person ***utilising*** genetic resources or traditional knowledge associated with genetic resources;

(6) ***"utilisation*** of genetic resources" means to 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***;

(7) "mutually agreed terms" means the contractual ***arrangements*** concluded between a provider of genetic resources or of traditional knowledge associated with genetic resources and a user [redacted], 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***;

(8) "traditional knowledge associated with genetic resources" means traditional knowledge held by an indigenous or local community that is relevant for the ***utilisation*** of genetic resources and that is as such described in the mutually agreed terms applying to the ***utilisation*** of genetic resources;

(8a) "illegally accessed genetic resources" means genetic resources and traditional knowledge associated with genetic resources which were not accessed in accordance with the national access and benefit-sharing legislation or regulatory requirement of the provider country that is a Party to the Nagoya Protocol requiring prior informed consent;

(9) "collection" means ***a set*** of collected samples of genetic resources and related information that is accumulated ***and*** stored ▌ whether ***held*** by public or private entities;

(10) "association of users" means ***an organisation established in accordance with the requirements of the Member State in which it is located that represents*** the interests of users ***and*** that is involved in developing and overseeing ***the*** best practices ***referred to in*** Article 8 ▌***;***

(11) "internationally recognised certificate of compliance" means ***a*** permit or its equivalent issued ***at the time of access as evidence that the genetic resource it covers has been accessed in accordance with the decision to grant prior informed consent and the establishment of mutually agreed terms for the user and the utilisation specified therein*** by a competent ▌ authority in accordance with Article 6(3)(e) ***and Article 13(2) of the*** Nagoya Protocol, that is made available to the Access and Benefit-sharing Clearing-House ***established under Article 14(1) of the Nagoya Protocol.***

▌

CHAPTER II
USER COMPLIANCE

Article 4

Obligations of users

1. Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources ***which they utilise have been*** accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and that ▌ benefits are fairly and equitably shared upon mutually agreed terms, ***in accordance with any applicable legislation or regulatory requirements***.

1a. Genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilised in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements.

2. ***For the purposes of paragraph 1, users*** shall ▌ seek, keep and transfer to subsequent users ▌ :

(a) the internationally recognised certificate of compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users; or

(b) ***where no internationally recognised certificate of compliance is available, information and relevant documents on:***

(i) the date and place of access of genetic resources ***or of*** traditional knowledge associated with ***genetic*** resources;

(ii) the description of ***the*** genetic resources or ***of*** traditional knowledge associated with ***genetic*** resources ***utilised***;

(iii) the source from which ***genetic*** resources or ***traditional*** knowledge ***associated with genetic resources*** were directly obtained as well as subsequent users of genetic resources or traditional knowledge associated with ***genetic*** resources;

(iv) the presence or absence of rights and obligations related to access and benefit-sharing ***including rights and obligations regarding subsequent applications and commercialisation***;

(v) access ***permits***, where applicable;

(vi) ***mutually agreed terms, including benefit-sharing arrangements, where applicable.***

2a. ***Users acquiring PGRFA in a country that is a Party to the Nagoya Protocol and which has determined, that PGRFA under its management and control and in the public domain, not contained in Annex I of the ITPGRFA, will also be subject to the terms and conditions of the standard material transfer agreement for the purposes set out under the ITPGRFA shall be considered to have exercised the due diligence requirements set out in paragraph 2 of this Article.***

2b. ***When the information in their possession is not sufficient or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms; or discontinue utilisation.***

▌

3. Users shall keep the information relevant for access and benefit-sharing for twenty years after the end of the period of ***utilisation***.

4. Users ***obtaining*** a genetic resource from a collection ***included*** in the ▌ register of ▌ collections ***within the Union*** referred to in Article 5(1) shall be considered to have exercised due diligence as regards the seeking of information ***listed in paragraph 2.***

5. *Users acquiring a genetic resource that is determined to be the causing pathogen or likely to be the causing pathogen of a present or imminent public health emergency of international concern, in the sense of the International Health Regulations (2005) or of a serious cross-border threat to health as defined in the Decision of the European Parliament and of the Council on serious cross-border threats to health, for the purpose of public health emergency preparedness in not yet affected countries and response in affected countries, shall fulfil the obligations listed in paragraph 2 or 3 at the latest*

(a) one month after the imminent or present threat for public health is terminated or

(b) three months after commencement of utilisation of the genetic resource

or discontinue utilisation.

The condition that is fulfilled first will apply.

In case of request of market approval or placing on the market of products deriving from utilisation of such a genetic resource, obligations listed in paragraph 2 or 3 apply entirely and without delay.

In the absence of Prior Informed Consent timely obtained and Mutually Agreed Terms established and until an agreement is reached with the provider country, no exclusive rights of any kind will be claimed by such a user to any developments made via the use of such pathogens.

Specialised international access and benefit-sharing instruments as mentioned in Article 2 remain unaffected.

Article 5

Register of collections

1. The Commission shall establish and maintain a ▌ register of ▌ collections ***within the Union. The Commission shall ensure that the*** register ***is*** internet-based ***and*** easily accessible to users. ***It*** shall include the ***references of the*** collections of genetic resources, ***or of parts of those collections,*** identified as meeting the criteria ***set out in paragraph 3.***

2. ***A*** Member State shall, upon request by a collection ***holder*** under its jurisdiction, consider the inclusion of ***that*** collection, ***or part of it, held by that collection holder*** in the ▌ register of ▌ collections ***within the Union***. After verifying that the collection ***or part of it*** meets the criteria set out in paragraph 3, the Member State shall notify the Commission without ***undue*** delay of ***the*** name ***and*** contact details ***of the collection and of its holder***, and type ***of collection concerned***. The Commission shall without delay include the information thus received ***in*** the ▌ register ▌ .

3. In order for a collection ***or part of a collection*** to be included in the ▌register▌, a collection ▌ shall demonstrate its capacity to:

(a) apply standardised procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third persons for their ***utilisation in line with the Convention and the Nagoya Protocol***;

(b) ***supply*** genetic resources and related information ▌ to third persons for their ***utilisation*** only with documentation providing evidence that the ***genetic*** resources and the ***related*** information were accessed in accordance with applicable ***access and benefit sharing legislation or regulatory*** requirements and, where relevant, ***with*** mutually agreed terms ▌;

(c) keep records of all samples of genetic resources and related information supplied to third persons for their ***utilisation***;

(d) establish or use unique identifiers, ***where possible,*** for samples of genetic resources supplied to third persons; ***and***

(e) use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.

4. Member States shall regularly verify that each collection ***or part of a collection*** under their jurisdiction included in the ▌register ***meets the criteria*** set out in paragraph 3.

▌

Where there is evidence ***on the basis of information provided pursuant to paragraph 3*** that a collection ***or part of a collection*** included in the ▌register▌ does not ***meet*** the ***criteria*** set out in paragraph 3, the Member State concerned shall without ***undue*** delay identify remedial actions ***or measures*** in dialogue with the ▌collection ***holder*** concerned.

A Member State which determines that a collection or part of a collection within its jurisdiction no longer complies with paragraph 3 shall inform the Commission thereof without undue delay.

Upon receipt of that information, the Commission shall remove a collection from the ***register.***

6. The Commission shall▌ adopt implementing acts, to establish the procedures for implementing paragraphs 1 to ***4. Those*** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Article 6

Competent authorities and focal point

1. Each Member State shall designate one or more competent authorities responsible for the application of this Regulation. Member States shall notify the Commission of the names and addresses of their competent authorities as of the entry into force of this Regulation. Member States shall inform the Commission without ***undue*** delay of any changes to the names or addresses of the competent authorities.

2. The Commission shall make public, including on the internet, a list of the competent authorities ***of the Member States***. The Commission shall keep the list up -to -date.

3. The Commission shall designate a focal point on access and benefit-sharing responsible for ***liaising*** with the Secretariat of the Convention ***with regard to matters covered by this Regulation.***

3a. ***The Commission shall ensure that the Union bodies established under Council Regulation (EC) No 338/97 contribute to the achievement of the objectives of this Regulation***[8].

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[8] ***OJ L 61, 3.3.1997, p. 1.***

Article 7

Monitoring user compliance

1. Member States and the Commission shall request all recipients of ▌ research funding involving ***the utilisation*** of genetic resources and traditional knowledge associated with genetic resources to declare that they ▌ exercise due diligence in accordance with Article 4.

2. ***At the stage of final development of*** a product developed ***via*** the ***utilisation*** of genetic resources or traditional knowledge associated with such resources, ***users shall declare to the competent authorities referred to in Article 6(1) that they have fulfilled the obligations under Article 4 and shall simultaneously submit:***

   (a) the relevant information from the internationally recognised certificate of compliance, or

   (b) the related information as referred to in Article 4(2)(b) i)-v) and 4(2b), including information that mutually agreed terms were established, where applicable.

   Users shall further provide evidence to the said competent authority upon request.

3. Competent authorities shall transmit to the ***Access and Benefit-Sharing Clearing House the global information-sharing portal established under Article 14(1) of the Nagoya Protocol, to the Commission and, as appropriate, to the competent national authorities referred to in Article 13(2) of the Nagoya Protocol*** the information received on the basis of paragraphs 1 and 2. ▌

3a. The Competent authorities shall cooperate with the Access and Benefit-Sharing Clearing House to ensure the exchange of the information listed in Article 17(2) of the Nagoya Protocol for monitoring the compliance of users.

3b. The competent authorities shall take due account of the respect of confidentiality of commercial or industrial information where such confidentiality is provided for by national or Union law to protect a legitimate economic interest, notably concerning the designation of the genetic resources and the designation of utilisation.

4. The Commission shall ▌ adopt implementing acts, to establish the procedures for implementing paragraphs 1, 2 and 3 of this Article. ***In this implementing act, the Commission shall determine the stage of final development of a product in order to identify the final stage of utilisation in different sectors. This implementing act*** shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Article 8

Best practices

1. ***Associations*** of users ***or other interested parties*** may submit an application to the Commission ***to have*** a combination of procedures, tools or mechanisms developed and overseen by ***them recognised as a best practice in accordance with the requirements of this Regulation***. The application shall be supported by evidence and information.

2. Where, on the basis of ***evidence and*** information ***provided pursuant to paragraph 1,*** the Commission determines that the specific combination of procedures, tools or mechanisms, when effectively implemented by a user, enables the user to comply with its obligations ***under*** Articles 4 and 7, ▌ shall grant recognition as best practice.

3. An association of users ***or other interested parties*** shall inform the Commission of any changes or updates made to a ▌ best practice for which ***recognition*** was granted ▌ in accordance with paragraph 2.

4. If ***there is*** evidence ***of*** repeated ***or significant*** cases where users implementing a best practice fail to comply with their obligations under this Regulation, the Commission shall examine in dialogue with the relevant association of users, whether ***those*** cases ▌ indicate possible deficiencies in the best practice.

5. The Commission shall withdraw the recognition of a best practice ▌ when it has determined that changes to the best practice compromise a user's ability to ***comply with its obligations under*** Articles 4 and 7, or when repeated ***or significant*** cases of non-compliance by users relate to deficiencies in the ***best*** practice.

6. The Commission shall establish and keep up -to -date an internet-based register of recognised best practices. That register shall ▌, in one section, ***list*** best practices recognised by the Commission in accordance with paragraph 2 of this Article and ▌, in another section, ***list*** best practices adopted on the basis of Article 20(2) ***of the*** Nagoya Protocol.

7. The Commission shall ▌ adopt implementing acts, to establish the procedures for implementing paragraphs 1 to 5 of this Article. ***Those*** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Article 9

Checks on user compliance

1. The competent authorities ***referred to in Article 6(1)*** shall carry out checks to verify ***whether*** users comply with ***their obligations under Articles 4 and 7, taking into account*** that the implementation by a user of a best practice ***in relation to access and benefit-sharing*** recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol ***may reduce*** that user's risk of non-compliance.

1a. Member States shall ensure that the checks in paragraph 1 are effective, proportionate and dissuasive and detect cases of non-compliance with the Regulation by users.

▌

3. ***These checks shall*** be conducted ***:***

(a) in accordance with a periodically reviewed plan developed using a risk-based approach;

(b) when a competent authority is in possession of relevant information, including on the basis of substantiated concerns provided by third parties, ***regarding a user's*** non-compliance ▌ with this Regulation. ***Special consideration shall be given to such concerns raised by provider countries.***

4. The checks referred to in paragraph 1 ***may*** include ▌:

a) examination of the measures taken by a user to exercise due diligence in accordance with Article 4;

b) examination of documentation and records that demonstrate the exercise of due diligence in accordance with Article 4 in relation to specific use activities;

▌

d) examination of instances where a user was obliged to make declarations under Article 7.

On the spot checks may also be carried out as appropriate.

▌

6. Users shall offer all assistance necessary to facilitate the performance of the checks referred to in paragraph 1 ▌.

7. Without prejudice to Article 11, where, following the checks referred to in paragraph 1 ▌, shortcomings have been detected, the competent authority shall issue a notice of remedial ***action or measures*** to be taken by the user.

Depending on the nature of the shortcomings ▌, Member States may ***also*** take immediate interim measures ▌.

▌

Article 10

Records of checks

1. The competent authorities shall keep records of the checks referred to in Article 9(1), indicating, in particular, their nature and results, as well as ***records*** of ***any*** remedial actions and measures taken under Article 9(7) ▌ for at least five years. ▌

2. The information referred to in paragraph 1 shall be made available in accordance with Directive 2003/4/EC.

Article 11

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements ▌ of Articles 4 and 7 ▌ and shall take all measures necessary to ensure that they are implemented.

2. The penalties provided for ***shall*** be effective, proportionate and dissuasive. ▌

▌

3. ***By...****, Member States shall notify the rules referred to in paragraph 1 to the Commission ▌ and shall notify it without delay of any subsequent amendments ***thereto***.

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* ***OJ: please insert the date: one year after the date of entry into force of the Nagoya Protocol for the Union***

CHAPTER III

FINAL PROVISIONS

Article 12

Cooperation

The competent authorities ***referred to in Article 6(1)*** shall ***:***

(a) ***cooperate with each other and with the Commission in order to ensure*** that ***users*** comply ***with this Regulation;***

(b) ***consult, if appropriate, with stakeholders on the implementation of the Nagoya Protocol and this Regulation;***

(c) ***cooperate with the competent national authorities referred to in Article 13(2) of the Nagoya Protocol in order to ensure that users comply with this Regulation;***

(d) ***inform the competent authorities of other Member States and the Commission of any serious shortcomings detected by means of the checks referred to in Article 9(1) and on the types of penalties imposed in accordance with Article 11;***

(e) ***exchange information on the organisation of their system of checks for monitoring user compliance with this Regulation.***

Article 14

Complementary measures

The Commission and Member States shall, as appropriate:

(a) ***promote and encourage*** information, awareness raising and training activities to help stakeholders ***and interested parties*** understand their obligations ***and the implementation of*** this Regulation ***and of the relevant provisions of the Convention and the Nagoya Protocol in the Union***;

(b) ***encourage*** the development of sectoral codes of conduct, model contractual clauses, guidelines and best practices, particularly where they would benefit academic, ***university and non-commercial*** researchers and small and medium-sized enterprises;

(c) ***promote*** the development and use of cost-effective communication tools and systems in support of monitoring and tracking the ***utilisation*** of genetic resources and traditional knowledge associated with genetic resources by collections and users;

(d) provide technical and other guidance to users, taking into account the situation of academic, ***university and non-commercial*** researchers and ***of*** small and medium-sized enterprises, in order to facilitate compliance with the requirements of this Regulation;

(e) ***encourage users and providers to direct benefits from the utilisation of genetic resources towards the conservation of biological diversity and the sustainable use of its components in accordance with the provisions of the Convention;***

(ea) ***promote measures in support of collections that contribute to the conservation of biological diversity and cultural diversity.***

Article 15

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

1. ▌

4. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 15a

Consultation Forum

The Commission shall ensure a balanced participation of representatives of Member States and other interested parties in issues related to the implementation of this Regulation. They shall meet in a consultation forum. The rules of procedure of that forum shall be established by the Commission.

Article 16

Reports and review

1. ***By ... [**] and every five years thereafter, unless otherwise determined in accordance with Article 29 of the Nagoya Protocol,*** Member States shall submit to the Commission ▌ a report on the application of this Regulation.

2. Not later than one year after the time-limit for submission of the ▌ reports ***referred to in paragraph 1,*** the Commission shall ***submit*** to the European Parliament and the Council ***a report on the application of this Regulation, including*** a first assessment of the effectiveness of this Regulation.

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[*] ***OJ: please insert the date: three years after the date of entry into force of this Regulation.***

3. Every ten years after its first report the Commission shall, on the basis of reporting on and experience with the application of this Regulation, review the functioning and effectiveness of this Regulation ***to achieve the objectives of the Nagoya Protocol***. In its ***review*** the Commission shall, in particular, consider the administrative consequences for public research institutions, ***micro,*** small or medium-sized enterprises and ***specific sectors***. It shall also consider the need ***to review the implementation of the provisions of this Regulation in light of developments in other relevant international organisations***.

4. The Commission shall report to the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on the measures ***taken by*** the Union ▌ to implement ***compliance measures with*** the Nagoya Protocol.

Article 17

Entry into force and application

1. ▌This Regulation shall enter into force on the twentieth day following ***its publication in the Official Journal of the European Union.***

1a. As soon as possible following the deposit of the Union's instrument of acceptance of the Nagoya Protocol, the Commission shall publish a notice in the Official Journal specifying the date on which the Nagoya Protocol enters into force for the Union. This Regulation shall apply from that date.

2. Articles 4, 7, and 9 shall apply one year after the date of entry into force of ***the Nagoya Protocol for the Union***.

▌

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at …,

For the European Parliament	*For the Council*
The President	*The President*

Non-official translation: *Draft of 10 April 2013*

Federal Act on the Protection of Nature and Cultural Heritage

(NCHA)

Section 3*c*: Genetic Resources *(new)*

Art. 23n *Due diligence requirement*

1 Any person who - according to the Nagoya Protocol[1] - utilises genetic resources or directly benefits from their utilisation (users) shall apply due diligence appropriate to the circumstances to ensure that:

a. the resources have been accessed lawfully; and

b. the benefits are shared in a fair and equitable way.

2 Utilisation of genetic resources in terms of paragraph 1 means to conduct research and development on the genetic or biochemical composition of genetic resources, including through the application of biotechnology.

3 Access in terms of paragraph 1 letter a is lawful, if by virtue of the Nagoya Proto- col it is in accordance with the domestic access and benefit-sharing regulatory requirements of the Party to the Nagoya Protocol that has provided the resource.

4 If the requirements of paragraph 1,letters a and b are not complied with, the user

shall ensure that they are fulfilled subsequently, or shall renounce using the genetic

resources concerned or benefiting directly from their utilization.

5 The Federal Council shall regulate what information must be recorded on the utilised genetic resources and passed on to subsequent users.

Art. 23o *Notification requirement*

1 Compliance with the due diligence requirement must be notified to the Federal Office for the environment FOEN before market authorisation for utilised genetic resources or, if such authorisation is not required, before the commercialisation of the same.

2 Information related to compliance with the due diligence requirement may be passed on to the international clearing-house described in Article 14 of the Nagoya Protocol and to the competent national authorities of Parties to the Nagoya Protocol.

The name of the person proceeding with the notification,the product to be commercialized,the utilised genetic resource, the date at which it has been accessed as well as its source are made publicly available.

3 The Federal Council shall designate competent authorities responsible for verifying compliance with the notification requirement. It may provide for exemptions to the notification requirement if the verification of compliance with the due diligence requirement can be ensured by other means.

Art. 23p *Traditional knowledge*

Articles 23*n* and 23*o* also apply to traditional knowledge of indigenous or local communities associated with genetic resources.

Art. 23q *Genetic resources in Switzerland*

1 The Federal Council may make access to genetic resources in Switzerland subject to an authorisation and to an agreement that regulates the utilisation of genetic resources and the sharing of benefits arising out of their utilisation.

2 The Confederation may support the conservation and sustainable use of genetic resources.

Art. 24a

1 Any person who intentionally fails to provide information or provides false infor- mation under Article 23*o* shall be liable to a fine of up to 100,000 francs; if the offender acts through negligence, the fine shall be up to 40,000 francs.

2 ... *(Current sole paragraph of Article 24a will become Article 24a paragraph 2)*

Art. 24h *Federal enforcement powers (new)*

1 …

2 …

3 The Confederation shall enforce the regulations on genetic resources (Art. 23*n*–23*q*); it may delegate certain tasks to the Cantons.

4 …

Art. 25d *Transitional provision to the amendment of ... (new)*

Articles 23*n*–23*p* apply to circumstances relating to access to genetic resources or associated traditional knowledge that has occurred after the said provisions came into force.

王立植物園のアクセスと利益配分契約

ACCESS AND BENEFIT-SHARING AGREEMENT

BETWEEN

THE LEBANESE AGRICULTURAL RESEARCH INSTITUTE

AND

THE BOARD OF TRUSTEES OF THE
ROYAL BOTANIC GARDENS, KEW, UNITED KINGDOM

An AGREEMENT made the day of 2005 between the Lebanese Agricultural Research Institute, Tal Amara, Rayak, Lebanon (hereafter “LARI”) and The Board of Trustees of the Royal Botanic Gardens, Kew, Richmond, Surrey, TW9 3AE United Kingdom (hereafter "RBG Kew").

WHEREAS:

RBG Kew is a body incorporated in the United Kingdom by statute and an exempt charity whose mission is: "to ensure management of the Earth's environment by increasing knowledge and understanding of the plant and fungal kingdoms - the basis of life on earth",

In pursuit of this mission, RBG Kew:

- collects and curates plant specimens, including seeds and herbarium specimens;
- carries out research projects regarding the evaluation and conservation of global plant biodiversity; and
- exchanges plant specimens with other research institutes world wide.

LARI is a governmental organisation under the Agricultural Minister Provision. It was established in 1957. It is an autonomous agency with a General Director and Board of Directors. The institute consists of seven research centres located at different sites

throughout Lebanon. The institute conducts scientific research for the development and advancement of the agricultural sector in Lebanon. It offers a variety of services for farmers and academic universities. The major research subjects being carried out in all sites of the institute are: Crop Science, Soil Science, Animal Science, Food Science, Environmental Science, Ecology, Irrigation and Water Quality, Biotechnology, and Economics.

RBG Kew and LARI wish to work together to ensure the collection, study and conservation of Lebanese flora by *inter alia*:

- The establishment of a verified and well-documented seed collection of plant species indigenous to the Lebanon; and
- The establishment of mutually beneficial conservation training, research and educational programmes.

Furthermore, RBG Kew and LARI will share the benefits arising out of such collaboration fairly and equitably thereby creating incentives and providing resources for the conservation of the biological diversity of the Lebanon;

The Parties are committed to implementing the letter and spirit of the 1992 Convention on Biological Diversity (CBD), the 2004 FAO International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA), the 1975 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and other relevant international, regional, national and sub-national laws and policies concerning biodiversity.

NOW THEREFORE IT IS HEREBY AGREED AS FOLLOWS:

DEFINITIONS

1. In this Agreement the expressions set out below shall mean as follows:

1.1 “Agreement” shall mean this Access and Benefit Sharing Agreement together with any appendices and annexes.

1.2 "Commercialise" and "Commercialisation" shall include, but not be limited to, any of the following: sale, filing a

patent application, obtaining, or transferring intellectual property rights or other tangible or intangible rights by sale or licence or in any other manner; commencement of product development; conducting market research and seeking pre-market approval;

1.3 "Genetic Resources" shall mean any biological material of plant, animal, microbial, fungal or other origin of actual or potential value containing functional units of heredity transferred under this Agreement and its progeny and derivatives, including modified or unmodified extracts and purified compounds;

1.4 "Material" shall mean the plant, animal, microbial or fungal biological material transferred under this Agreement;

1.5 "Notification of transfer" shall mean the list of Material transferred between the parties from time to time under this Agreement, a pro forma copy of which is attached to the Agreement as Annex 2.

1.6 "Material Supply Agreement" shall mean the RBG Kew document setting out the terms under which RBG Kew may supply Material to a Third Party. A pro forma copy of the current RBG Kew Material Supply Agreement for seed is attached to the Agreement as Annex 3.

1.7 "Seed Bank" shall mean the Seed Bank maintained by RBG Kew at Wakehurst Place, Ardingly, West Sussex, United Kingdom.

1.8 "Third Party" shall mean any person or institute other than LARI and RBG Kew.

ACTIVITIES

2. Subject to the terms and conditions set out in this Agreement, RBG Kew will work together with LARI to

collect, study and conserve the flora of the Lebanon. For example, RBG Kew will:

a) Conduct joint field work collecting expeditions with LARI;
b) Receive Material sent to RBG Kew by LARI;
c) Accession a representative, viable portion of the Material collected and/or received into its collections at RBG Kew;
d) Conduct taxonomic research upon the Material, its progeny or derivatives;
e) Conduct seed viability tests upon the Material, its progeny or derivatives to determine the longevity of seeds in store at the Seed Bank and for conservation purposes.

A full list of activities is set out in Annex 1 to the Agreement.

EXCHANGE

3.1 In consideration of the undertakings given by RBG Kew in this Agreement, LARI undertakes the following:

3.1.1 LARI will collaborate with RBG Kew in the activities described in Clause 2 and Annex 1 of this Agreement; and

3.1.2 LARI will help RBG Kew to secure the prior informed consent of any competent national and local Lebanese authorities and of any other appropriate stakeholders to enable RBG Kew to:

a) Access the Material;
b) Enter the land in the Lebanon on which the activities described in Annex 1 will take place; and,
c) Conduct the aforesaid activities.

3.2 Furthermore, where LARI collects or acquires Material and

sends it to RBG Kew, LARI hereby warrants that the Material was acquired and is supplied in accordance with all applicable laws and regulations and that it is entitled to supply and does supply the Material to RBG Kew on the terms set out in this Agreement

NOTIFICATION OF TRANSFER

4. Material collected by or sent to RBG Kew in accordance with Clauses 2 and 3 above will, on each occasion, be listed in a Notification of Transfer, a *pro forma* copy of which is attached to this Agreement as Annex 2. All Material will be transferred pursuant to the terms of this Agreement.

NON COMMERCIALISATION

5.1 RBG Kew will not Commercialise any Genetic Resources transferred under this Agreement.

5.2 Without prejudice to the above, any Commercialisation to which Kew and LARI may agree will be subject to a separate written agreement.

BENEFIT SHARING

6.1 RBG Kew and LARI agree to work together to ensure the fair and equitable sharing of any benefits that arise from the collection, study or conservation of Material, its progeny and derivatives transferred under this Agreement.

6.2 Benefits arising from the collection, study or conservation of Material transferred under this Agreement may include, but shall not be limited to, the following:

a) The accession of a representative, viable portion of the Material into the collections at RBG Kew;
b) The processing and viability testing of Material, its progeny or derivatives;
c) The taxonomic identification of Material, its progeny or derivatives;
d) The acknowledgement of LARI as the source of Material in research publications;

e) Joint authorship of publications as appropriate;
f) The mutual provision of copies of the results of all such scientific study, research and publications;
g) The mutual provision of information regarding any relevant opportunities for training and/or study by appropriate staff personnel at LARI or RBG Kew;
h) The encouragement of appropriate staff personnel at LARI or RBG Kew to take up any such opportunity for training and/or study.

TRANSFER TO THIRD PARTIES

7.1 RBG, Kew may supply any of the seed collected pursuant to this Agreement and any of the seed previously collected by LARI and RBG Kew and listed in Annex 4 to this Agreement to a Third Party provided:

a) Prior written permission has been obtained from LARI for such supply, such permission not to be unreasonably withheld; and
b) The Third Party signs a Material Supply Agreement with RBG Kew, prohibiting, *inter alia*, any Commercialisation or exploitation of the seed, its progeny or derivatives.

7.2 RBG Kew may loan or supply samples from the duplicate herbarium specimens collected pursuant to this Agreement and any of the herbarium material previously collected by LARI and RBG Kew and listed in Annex 4 to this Agreement to a Third Party provided that the Third Party signs a Material Supply Agreement with RBG Kew, prohibiting, *inter alia*, any Commercialisation of the material supplied to that Third Party.

DURATION, RENEWAL AND AMENDMENT

8.1 This Agreement shall be come into effect on the date at the head of this document. It will be valid for a term of five (5) years after such date.

8.2 It can be renewed and extended for further defined periods through mutual agreement expressed in writing signed on behalf of LARI and RBG Kew.

8.3 It can be amended at any time through mutual agreement expressed in writing signed on behalf of LARI and RBG Kew. Such amendments, once agreed by the parties, will become part of the Agreement.

8.4 The obligations and rights contained in Clauses 1, 2.c, 2.d, 2.e, 3.2, 5, 6, 7, 11, 12, 14 and 16 inclusive shall survive the expiration or other termination of this Agreement unless mutually agreed to the contrary.

TERMINATION

9. Notwithstanding Clause 8 above, either party to this Agreement may give six (6) months written notice to the other party to terminate this Agreement.

FORCE MAJEURE

10.1 Neither party shall be liable to the other party for any delay or non-performance of its obligations under this Agreement arising from any cause beyond its reasonable control, including, but not limited to, any of the following: Act of God, governmental act, war, fire, food, explosion, civil commotion or industrial disputes of a third party or impossibility of obtaining gas or electricity or materials

10.2 The affected party must promptly notify the other party in writing of the cause and the likely duration of the cause. Such notice having been given, the performance of the affected party's obligations, to the extent affected by the cause, shall be suspended during the period the cause persists.

10.3 Without prejudice to the above, the affected party must take all reasonable measures to minimise the impact of any force majeure on the performance of its obligations under the

Agreement and to ensure, as soon as possible, the resumption of normal performance of the obligations affected by the force majeure.

DISPUTE RESOLUTION

11. Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination (a "Dispute"), shall, to the extent possible, be resolved by good faith negotiation. Unless the parties to the Dispute otherwise agree, the applicable law of the Agreement shall be English law. For the purposes of this clause, “good faith” means in accordance with standards of honesty, sincerity or lawfulness of purpose and applies to both the substance of and the machinery of any such negotiations.

NOTICE

12.1 Any notice or other document to be served under this Agreement must be delivered by hand or sent by registered mail or by international courier service to be served at the address below or at such other addresses as it may have notified to the other parties in accordance with this clause. Any notice shall be marked for the attention of the person and at the address indicated below.

RBG, Kew:
William WEBB, Esq., Head of Corporate Services, Royal Botanic Gardens, Kew, Richmond, Surrey TW9 3AB, UNITED KINGDOM

LARI:
Dr. Michel AFRAM, Chairman of the Board of Trustees, Lebanese Agricultural Research Institute, LEBANON.

12.2 All notices or documents shall be deemed to have been served at the date and time of delivery of the said notices or documents to the recipient party.

ENTIRE AGREEMENT 13 The provisions of this Agreement constitute the entire Agreement between the parties relating to the subject matter and the parties do not make any representations or warranties except those contained in this Agreement.

NO ASSIGNMENT 14 This Agreement is personal to the parties and none of the rights or the obligations under this Agreement may be assigned or transferred without the prior written consent of the other party.

INDEPENDENT ENFORCEABILITY 15. The provisions contained in each clause and sub-clause of this Agreement shall be enforceable independently of the rest of the Agreement and the validity of a clause or sub-clause shall not be affected if any of the other clauses or sub-clauses are invalid.

NO PARTNERSHIP 16. Nothing contained in this Agreement shall constitute a partnership in law between RBG, Kew and LARI or constitute either of them the agent of the other.

COUNTERPARTS 17. This Agreement may be executed in any number of identical copies, all of which, taken together, shall constitute one and the same agreement.

AS WITNESSED IN TWO IDENTICAL COPIES IN THE ENGLISH LANGUAGE, BOTH COPIES BEING EQUALLY AUTHENTIC, BY THE DULY AUTHORISED REPRESENTATIVES OF THE PARTIES HERETO

SIGNED BY:	**SIGNED BY:**
For and on behalf of the Lebanese Agricultural Research Institute, Lebanon	**For and on behalf of the Board of Trustees of the Royal Botanic Gardens, Kew, United Kingdom**

ANNEX 1

ACTIVITIES IN THE LEBANON

COLLECTION 1

T`e RBG, Kew, and staff of LARI named below will collect material from the species detailed below, from the geographical areas detailed below.

STAFF LARI

Staff of LARI as decided by the Director-General

STAFF Royal Botanic Gardens, Kew

Staff of RBG Kew as decided by the Director

TARGET AREAS:

- Collections shall be made from all provinces of the Lebanon and will be subject to the parties obtaining the necessary consent(s) and permission(s) from the relevant Authorities and any other appropriate stakeholder(s).
- The target areas will be those with high biodiversity, high endemism and threatened areas. The areas where collecting will be carried out will be identified first and then the species to be collected in these areas will be identified.

TARGET SPECIES:

- Within the broad remit of conserving species, this selection is mainly based on national conservation plans and priorities (rare and endangered species) when existing.

- To conserve biodiversity in its broadest sense, endemic species, recognised as being under particular threat because of their restricted distribution, will be emphasised.
- In order to ensure the sustainable development of Lebanon's indigenous flora, those species with known potential human value, which are not cultivated in agriculture or horticulture, will also be included.

STORAGE 2 RBG Kew will provide long term duplicate storage of seeds, thereby underwriting the continued existence of wild plant species, in support of the CBD. Seed material will be accessioned and stored under optimal, internationally approved conditions at the Millennium Seed Bank, Wakehurst Place, Ardingly, West Sussex, RH17 6TN. Duplicate herbarium specimens will be accessioned and stored at the Herbarium, Kew, Richmond, Surrey, TW9 3AB.

RESEARCH 3 To assess the viability of collected seeds through germination tests which substantially overcome seed dormancy and monitor the moisture status of seed collections to mutually agreed standards. To carry out the comparative observation, characterisation and analysis of duplicate herbarium specimens to better understand its identification, classification and evolution;

BENEFIT-SHARING 4 Benefits arising form the collection and storage of material shall be shared on an equitable basis with all parties to the agreement and shall include, *inter alia*:

- facilities for long term storage of duplicate material
- processing and viability testing of stored material
- taxonomic identification and verification of material
- data arising from the collecting, processing, storage and research upon the material

- joint authorship of publications as appropriate
- financial support of seed collecting activities
- technical expertise for the development of in-country seed conservation facilities
- provision of informal training in seed handling, storage and research techniques
- access to formal training courses to be held at RBG Kew.

FINANCIAL ARRANGEMENTS

5 LARI and RBG Kew will engage in joint activities. Their respective source of funding is as follows:

Source of funding for RBG Kew:

RBG Kew is financially resourced through a Grant in Aid provided by the Department for Environment, Food and Rural Affairs ("Defra") of Her Majesty's Government (formerly known as the Ministry of Agriculture, Food and Fisheries). Additional funds for seed conservation are received from monies raised by the Kew Foundation and the Friends of Kew.

RBG Kew will pay for all those additional costs related to the field collection of material and the conservation of resulting collections held in the Millennium Seed Bank and the Kew Herbarium. All costs relating to the Kew staff members participating in the collecting and material conservation activities will be met by RBG Kew.

LARI will provide for all salary costs of appropriate Lebanese staff participating in the field collecting and material conservation activities. Access to vehicles, equipment and any other institutional facilities and expertise as required will be met by LARI in accordance with existing possibilities.

ANNEX 2

PRO FORMA

NOTIFICATION OF MATERIAL TRANSFERRED UNDER THE ACCESS AND BENEFIT-SHARING AGREEMENT BETWEEN

THE LEBANESE AGRICULTURAL RESEARCH INSTITUTE ("LARI")
AND
THE BOARD OF TRUSTEES, ROYAL BOTANIC GARDENS, KEW ("RBG Kew")

The following Material is transferred between LARI and RBG Kew in accordance with the terms and conditions of the Access and Benefit-Sharing Agreement between LARI and RBG Kew, dated …….. 2005.

DATE COLLECTED	SEED COLLECTION No.	FAMILY	GENUS or SPECIES	No. OF HERABIUM DUPLICATES (IF ANY)

SIGNED BY: DATE:
For and on behalf of The Lebanese Agricultural Research Institute

Name:

Title:

SIGNED BY: DATE:

For and on behalf of the Board of Trustees of the Royal Botanic Gardens, Kew, United Kingdom

Name:

Title:

A copy of this document signed on behalf of LARI will be forwarded to RBG Kew with each consignment of seed and herbarium specimens. Upon receipt of the plant material, RBG Kew will countersign this copy and return it to LARI as acknowledgement of receipt by RBG Kew under the terms of the Access and Benefit-Sharing Agreement.

ROYAL BOTANIC GARDENS KEW	NON COMMERCIAL MATERIAL SUPPLY AGREEMENT FOR SEED MATERIAL (with effect from September 2004)

The Royal Botanic Gardens, Kew (Kew) is committed to the letter and spirit of the Convention on Biological Diversity (CBD) and expects its partners to act in a manner consistent with the CBD. This agreement is designed to promote scientific research and exchange, whilst recognising the terms on which Kew acquired the plant material and the important role played by *ex situ* collections in the implementation of the CBD. Kew reserves the right not to supply any plant material if such supply would be contrary to any terms attached to the material and/or to the CBD.

Kew will supply the plant material listed on the reverse of this agreement ('Material') subject to the following terms and conditions:

1. The recipient may only use the Material, its progeny or derivatives for the common good in scientific research, education, conservation and the development of botanic gardens;

2. The recipient shall **not sell, distribute or use for profit or any other commercial application**[5] the Material, its progeny or derivatives;

3. The recipient shall **share fairly and equitably** the benefits arising from its use of the Material, its progeny or derivatives in accordance with the CBD;

4. The recipient shall **acknowledge** Kew, as supplier, in all written or electronic reports and publications resulting from its use of the Material, its progeny and derivatives and shall **lodge a copy** of all such publications and reports with Kew;

5. 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;

6. The recipient may only **transfer** the Material, its progeny or derivatives to a bona fide third party such as a botanic garden, university or scientific institution for **non-commercial** use in the areas of scientific research, education, conservation and the development of botanic gardens. All transfers shall be subject to the terms and conditions of this agreement. The recipient shall **notify Kew** of all such transfers and, on request, shall provide Kew with copies of the relevant material transfer agreement;

7. The recipient shall maintain **retrievable records** linking the Material to these terms of acquisition and to any accompanying Data provided by Kew;

8. Unless otherwise indicated, **copyright** in all information or data ("Data") supplied with the Material is owned by Kew or Kew's licensors. You may use this Data on condition that it is used solely for scholarly, education or research purposes; that it is not used for commercial purposes; and that you always acknowledge the source of the Data with the words "With the permission of the Board of Trustees of the Royal Botanic Gardens, Kew";

[5] 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 licence or in any other manner; commencement of product development; conducting market research; seeking pre-market approval; and/or the sale of any resulting product.

9. Kew 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 or its progeny or derivatives, or as to the accuracy or reliability of any Data supplied. The recipient will indemnify Kew from any and all liability, including arising from any ecological damage, arising out of the Material or its progeny or derivatives, the Data and their use or transfer. This agreement is governed by and shall be construed in accordance with English law;

10. The recipient will contact Kew to request **prior permission** from Kew or, where appropriate, from the provider of the Material to Kew, for any activities not covered under the terms of this agreement.

I agree to comply with the conditions above:

Signed:	Date: dd/mm/yy
Address:	Name/Position:
E-mail:	Organisation/Department:
Tel. Number:	
Please return a signed copy to: Plant Reception, Seed Conservation Department, Wakehurst Place, Ardingly, Haywards Heath, West Sussex, RH17 6TN United Kingdom	

LIST OF PLANT MATERIAL SUPPLIED

	Kew Staff Initial: Date: dd/mm/yy:

ANNEX 4

Plant Material collected by RBG Kew and LARI between 1996 – 1998 and stored at the Millennium Seed Bank, Wakehurst Place, United Kingdom

1996			
MSB Serial number	**Collection number**	**Genus**	**Species**
115238	354	*Papaver*	*syriacum*
115249	355	*Hirschfeldia*	*incana*
115250	356	*Conium*	*maculatum*
115412	357	*Onopordum*	*heteracanthum*
115423	358	*Notobasis*	*syriaca*
115261	359	*Rapistrum*	*rugosum*
115272	360	*Sinapis*	*arvensis*
115283	361	*Silybum*	*marianum*
115294	362	*Torilis*	*leptophylla*
115308	363	*Torilis*	*tenella (& nodosa)*
115319	364	*Rumex*	*dentatus*
115320	365	*Festuca*	*arundinacea*
115331	366	*Anthemis*	*cotula*
115342	367	*Salvia*	*palaestina*
115353	368	*Alcea*	*rufescens*
115364	369	*Tragopogon*	*buphtalmoides*
115375	370	*Reseda*	*lutea*
115386	371	*Oryzopsis*	*miliacea*
115397	372	*Sisymbrium*	*orientale*
115401	373	*Lepidium*	*sativum var. spinescens*
115434	374	*Melilotus*	*indica*
115445	375	*Ranunculus*	*cornutus*
115456	376	*Bupleurum*	*subovatum*
115467	377	*Foeniculum*	*vulgare*
115478	378	*Amaranthus*	*retroflexus*
115489	379	*Vaccaria*	*pyramidata*

115490	380	*Silene*	*venosa*
115504	381	*Galium*	*tricorne*

1997			
MSB Serial number	**Collection number**	**Genus**	**Species**
121770	549	*Juncus*	*inflexus*
121781	550	*Papaver*	*hybridum*
121792	551	*Phalaris*	*minor*
121806	552	*Myagrum*	*perfoliatum*
121817	553	*Datura*	*stramonium*
121828	554	*Taeniatherum*	*caput-medusae*
121839	555	*Plantago*	*lagopus*
121840	556	*Ecballium*	*elaterium*
121851	557	*Lepidium*	*spinosum*
121862	558	*Rumex*	*dentatus*
121873	559	*Cynoglossum*	*creticum*
121884	560	*Lepidium*	*sativum ssp. spinescens*
121895	561	*Arum*	*dioscorides*
121909	562	*Galium*	*aparine*
121910	563	*Bolboschoenus*	*maritimus*
121921	564	*Portulaca*	*oleracea*

1997 (continued)			
MSB Serial number	**Collection number**	**Genus**	**Species**
121932	565	*Polygonum*	*equisetiforme*
121943	566	*Veronica*	*anagallis-aquatica*
121954	567	*Phalaris*	*aquatica*
121965	568	*Centaurea*	*pallescens*
121976	569	*Hyoscyamus*	*aureus*
121987	570	*Salvia*	*palaestina*
121998	571	*Poa*	*bulbosa*
122009	572	*Reseda*	*lutea*
122010	573	*Verbascum*	*agrimoniifolium ssp. syriacum*
122021	574	*Phagnalon*	*rupestre*

122032	575	*Juncus*	*articulatus*
122043	576	*Veronica*	*anagallis-aquatica*
122054	577	*Teucrium*	*divaricatum ssp. villosum*
122065	578	*Oryzopsis*	*holciformis*
122976	579	*Alcea*	*kurdica*
122987	580	*Torilis*	*radiata*
122098	581	*Scrophularia*	*hierochuntina*
122102	582	*Moluccella*	*laevis*
122113	583	*Lagoecia*	*cuminoides*
122124	584	*Medicago*	*sativa*
122135	585	*Euphorbia*	*macroclada*
122146	586	*Glaucium*	*leiocarpum*
122157	587	*Silene*	*vulgaris*
122168	588	*Peltaria*	*angustifolia*
122179	589	*Galium*	*libanoticum*
122180	590	*Ochthodium*	*aegyptiacum*
122191	591	*Hyoscyamus*	*reticulatus*
122205	592	*Eremostachys*	*laciniata*
122216	593	*Salvia*	*Sp*
122227	594	*Ononis*	*natrix*
122238	595	*Moluccella*	*spinosa*
122249	596	*Daucus*	*aureus*
122250	597	*Ammi*	*visnaga*
122261	598	*Euphorbia*	*cybirensis*
122272	599	*Glycyrrhiza*	*echinata*
122283	600	*Sorghum*	*halepense*
122294	601	*Cephalaria*	*joppica*
122308	602	*Vitex*	*agnus-castus*
122319	603	*Daucus*	*carota*
122320	604	*Capparis*	*spinosa var. parviflora*
122331	605	*Ruta*	*chalepensis*
122342	606	*Typha*	*Latifolia*

1998

MSB Serial number	Collection number	Genus	Species
128953	750	*Orobanche*	*ramosa*
128964	751	*Verbascum*	*leptostachyum*
128975	752	*Crambe*	*orientalis var. aucheri*
128986	753	*Scaligeria*	*meifolia*
128997	754	*Medicago*	*sativa*
129008	755	*Centaurea*	*virgata var. squarrosa*
129019	756	*Alcea*	*rufescens*
129120	757	*Butomus*	*umbellatus*

1998 (cgntinued)			
MSB Serial number	**Collection number**	**Genus**	**Species**
129031	758	*Gypsophila*	*perfoliata var. anatolica*
129042	759	*Bupleurum*	*lancifolium*
129053	760	*Nigella*	*oxypetala*
129064	761	*Crepis*	*alpina*
129101	762	*Isatis*	*lusitanica*
129112	763	*Crepis*	*syriaca*
129123	764	*Onopordum*	*carduiforme*
129134	765	*Johrenia*	*dichotoma*
129145	766	*Spartium*	*junceum*
129156	767	*Trigonella*	*caelesyriaca*
129167	768	*Rumex*	*acetosella*
129178	769	*Halimium*	*umbellatum var. syriacum*
129189	770	*Prunus*	*spinosa*
129190	771	*Allium*	*rotundum*
129204	772	*Cistus*	*creticum*
129215	773	*Nepeta*	*italica*
129226	774	*Smyrnium*	*connatum*
129237	775	*Nepeta*	*curvifolia*
129248	776	*Ptilostemon*	*diacantha*
129259	777	*Asphodelus*	*lutea*
129260	778	*Sanguisorba*	*minor ssp. minor*
129271	779	*Torilis*	*arvensis ssp. neglecta*

129282	780	*Conyza*	*bonariensis*
129293	781	*Amaranthus*	*viridis*
129307	782	*Molucella*	*spinosa*
129318	783	*Tordylium*	*carmeli*
129329	784	*Ricinus*	*communis*
129330	785	*Melissa*	*officinalis*
129341	786	*Asphodelus*	*aestivus*
129352	787	*Cyperus*	*alopecuroides*
129363	788	*Cephalaria*	*joppica*
129374	789	*Xanthium*	*strumarium*
129385	790	*Stachys*	*viticina*
129396	791	*Lavatera*	*trimestris*
129400	792	*Mentha*	*longifolia*
129411	793	*Ferula*	*tingitana*
129422	794	*Allium*	*affine*

王立植物園と提供国との共同研究覚書

Memorandum of Collaboration

between

The Board of Trustees of the Royal Botanic Gardens, Kew

and

[Insert name of counterparty]

A MEMORANDUM OF COLLABORATION (“**MoC**”) made on this the [insert date] day of [insert month 200[ ]] between the Board of Trustees of the Royal Botanic Gardens, Kew (“**RBG Kew**”), whose principal place of business is at Kew, Richmond, Surrey TW9 3AB and [insert name of counterparty] (“[insert brief name of counterparty]”), whose principal place of business is at [insert place of business].

BACKGROUND

A. RBG Kew is a botanical garden incorporated in the United Kingdom by the National Heritage Act 1983 and an exempt charity whose mission is to inspire and deliver science-based plant conservation worldwide, enhancing the quality of life. RBG Kew is supported by the United Kingdom Department of Environment, Food and Rural Affairs ("**Defra**"), which is ultimately responsible to Parliament for RBG Kew's key aims and activities.

B. In pursuit of its not-for-profit mission, RBG Kew works together with international partners to:

Collect and curate plant material, including seeds, herbarium specimens and tissue samples for DNA extracts;
Carry out scientific research projects to better evaluate and conserve plant biodiversity, for example, taxonomic verification of herbarium plant material and
Exchange plant material with other research institutes for further scientific study world-wide; and

C. [Insert description and mission of counterparty].

D. ***Either:***
RBG Kew and [insert name of counterparty] have worked together over [many/some] years on mutually beneficial projects [focused on the collection, study and conservation of the flora of [insert county of counterparty]] and wish formally to recognise this [long-standing] relationship, and to promote its continuance for many years into the future.

Or:
RBG Kew and [insert name of counterparty] wish to work together on mutually beneficial projects focused on the collection, study and conservation of the flora of [insert county of counterparty].

E. The parties to this MoC are committed to implementing the letter and the spirit of the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora ("**CITES**"), the 1992 Convention on Biological Diversity ("**CBD**") and relevant national and regional laws and regulations concerning biodiversity including laws relating to access to plant genetic resources, associated benefit sharing and traditional knowledge.

ARTICLE 1

Institutional Co-ordinators

1.1 For RBG Kew: [insert name of lead scientist on partnership].

For [insert counterparty name]: [insert name of lead scientist on partnership].

1.3 The Institutional Co-ordinators shall be responsible for overseeing and progressing the activities of their respective institutions pursuant to this MoC.

ARTICLE 2

Areas of Co-operation

2.1 RBG Kew and [insert name of counterparty] wish to work together to collect, study and conserve plant material such as seeds, herbarium specimens [and tissue samples] for science and to create and exchange associated data and images. All co-operation will be implemented in accordance with CITES, the CBD and relevant national and regional laws and regulations concerning biodiversity including laws relating to access to plant genetic resources, associated benefit sharing and traditional knowledge.

2.2 Areas of co-operation may include, but will not be limited to:

(a) [Continued collaboration and support in specific joint projects already underway, such as [insert names of any such projects];]

(b) The conducting of joint fieldwork expeditions, to be carried out in accordance with all applicable access laws and regulations and in accordance with all applicable permits, prior informed consents and/or licences and in an ecologically sustainable manner;

(c) The transfer of duplicate plant material (the "**Material**") and associated data and images (respectively, the "**Transferred Data**" and the "**Transferred Images**") by [insert name of counterparty] to RBG Kew for accession into the collections at RBG Kew to be used as set out in Article 3 below;

(d) Capacity-building in the areas of [insert relevant areas] to ensure greater long-term conservation of plant genetic resources in [insert name of counterparty country];

(e) Attendance by appropriate staff members of [insert name of counterparty] at relevant training courses run by RBG Kew;

(f) Support by RBG Kew to training initiatives at [insert name of counterparty];

(g) Collaboration on *ex situ* and *in situ* conservation in [insert name of counterparty country], including species and habitat conservation assessments;

(h) The exchange of relevant institutional literature, such as the RBG Kew Bulletin and [insert name of any counterparty literature];

[(i) The generation and dissemination of appropriate scientific information to encourage and facilitate conservation by, for instance, joint publications in peer-reviewed journals; and]

(j) The preparation and submission of applications to national and/or international bodies for funding to enable further collaboration between RBG Kew and [insert counterparty name].

2.3 The technical detail of the above-mentioned areas of co-operation will be developed and reviewed on a regular basis by RBG Kew and [insert counterparty name] in accordance with available funds.

ARTICLE 3

Use of the Material by RBG Kew

3.1 The Material [and the Transferred Data and the Transferred Images] shall be accessioned into the RBG Kew collections at Kew, Richmond Surrey..

3.2 [Insert name of counterparty] confirms that RBG Kew shall be permitted to use the Material and the Transferred Data and the Transferred Images for scientific research by RBG Kew staff and by authorised visitors to RBG Kew, and for the purposes of education and long-term conservation. The Material and the Transferred Data may be digitally imaged and, together with the Transferred Images, may be published in freely available botanical databases available on the internet and/or used by RBG Kew for publicity and fundraising purposes.

3.3 Scientific research carried out on the Material may include, but will not be limited to:

(a) Herbarium studies, such as the comparative observation, characterisation, analysis, databasing and imaging of the herbarium specimens to better understand their identification and classification, including the carrying out of sampling for pollen, DNA and anatomical preparations;

(b) Horticultural studies, such as cultivation of plant material to better understand how to grow and reproduce the plant, including the use of micropropagation techniques where required;

[(c) Genetic studies, such as DNA extraction and banking, PCR amplification, DNA sequencing and fingerprinting and DNA barcoding from tissue samples, for use to infer phylogenetic relationships or to study and help conserve the diversity of genes and genomes at the population level.]

3.4 RBG Kew shall not, without the prior written consent of [insert counterparty name], sell, distribute, transfer or use the Material and/or the Transferred Data and the Transferred Images for profit or for any other commercial application.

3.5 RBG Kew may loan or supply the Material or any derivatives from the Material and the Transferred Data and the Transferred Images to other institutions for the purposes of scientific research or education, provided that such loan or supply is on terms which prohibit commercialisation.

ARTICLE 4

Permissions to collect, transfer, study and conserve the Material; Notification of Transfer

4.1 [Insert name of counterparty] shall work with the appropriate [insert name of counterparty country] authorities [and relevant stakeholders], and RBG Kew shall work with the appropriate British authorities, to facilitate the acquisition of the necessary authorisation(s) to enable the lawful collection and transfer of the Material to RBG Kew.

4.2 Each party shall, on request, provide the other with reasonable assistance in obtaining

the necessary authorisation(s) to enable the lawful attendance of appropriate staff personnel at relevant courses, workshops and research projects in [insert counterparty country] and in the United Kingdom.

4.3 All plant material transferred by [insert name of counterparty] to RBG Kew shall be listed in a Notification of Transfer, a proforma copy of which is attached at Annex 1. All plant material transferred by [insert name of counterparty] to RBG Kew which is listed in a Notification of Transfer shall be transferred pursuant to the terms of this MoC.

4.4 The signature of the authorised representative of [insert name of counterparty] on a Notification of Transfer shall confirm that the plant material has been collected and is being transferred into the collections at RBG Kew in accordance with all applicable laws and regulations, permits, consents and/or licences.

ARTICLE 5

Benefit Sharing

RBG Kew and [insert name of counterparty] shall work together to share fairly and equitably the benefits that may arise from the collection, study and conservation of the Material and the Transferred Data and the Transferred Images.

[Benefits to be so mutually shared may include, for instance:
Informing one another of the results of relevant scientific studies;
Sharing specimen data and images, where appropriate;
Providing one another with copies of relevant subsequent publications;
Informing one another of relevant opportunities for formal or informal training and/or study by appropriate staff personnel at [insert name of counterparty] or at RBG Kew; and
Acknowledging [insert name of counterparty] and the origin of the Material in publications arising out of this collaboration.]

5.2 The parties also agree to consider whether it is appropriate to effect the sharing of any benefits arising from the collection, study and conservation of the Material and the Transferred Data and the Transferred Images with other relevant stakeholders.

ARTICLE 6

Duration, Renewal and Amendment

7.1 This MoC will come into force on the date of the final signature. It will be valid for [insert number of years in text and number] years from that date.

7.2 This MoC can be renewed for further periods of [insert number of years in text and number] years through mutual agreement expressed in writing.

7.3 This MoC can be amended at any time through mutual agreement expressed in writing. Such amendments, once approved by the parties, will become part of this MoC.

ARTICLE 7

Termination

8.1 Either party may terminate this MoC by giving the other party [insert number] months' notice in writing.

8.2 A party (the "**Non-defaulting Party**") may by notice to the other party (the "**Defaulting Party**") terminate this MoC with immediate effect if the Defaulting Party is in material breach of any provision of this MoC which is not remediable or, if remediable, is not remedied with a period of thirty (30) days after the Non-Defaulting Party has given notice to the Defaulting Party requiring such breach to be remedied.

8.3 Articles 3, 5 and 6 shall survive termination or expiry of this MoC unless mutually agreed to the contrary, such mutual agreement being expressed in writing.

ARTICLE 8

Dispute Resolution, Jurisdiction and Choice of Law

9.1 In the event of any dispute between the parties arising in connection with this MoC, the Director of RBG Kew and [insert name of senior official at counterparty] will communicate using their best efforts to resolve the dispute or disagreement.

9.2 If the dispute cannot be so resolved, the parties will refer it to an independent mutually agreed expert or, in the absence of any agreement between the parties, [insert name of an appropriate figure], and ask that expert to recommend a resolution of the dispute.

9.3 Neither party may commence any proceedings in any court of law in relation to any dispute arising in connection with this MoC until it has attempted to settle the dispute by use of the procedure set out in this Article 9 and that procedure has failed to produce an outcome satisfactory to both parties, provided that nothing in this clause shall prevent either party seeking a preliminary injunction or other judicial relief at any time if in its judgment such action is necessary to prevent irreparable damage.

9.4 This MoC shall be governed by English law and subject to the exclusive jurisdiction of the English courts.

ARTICLE 9

General

10.1 This MoC in no way restricts either party from any involvement in similar activities with other public and private organisations and individuals.

10.2 [Nothing in this MoC shall be construed as placing a financial commitment upon either party.]

10.3 Neither party may use any brand name, logo, trade mark or other similar mark of the other party without the prior written consent of that other party.

10.4 Subject to Article 10.5 and save that RBG Kew shall have the right to acknowledge [insert name of counterparty] and the origin of the Material in publications arising out of this collaboration in accordance with Article 5.1, neither party may make any press release or other public statement relating to this MoC or the relationship established under this MoC without the prior written consent of the other party.

10.5 [Insert counterparty name] acknowledges that RBG Kew may be subject to obligations

relating to freedom of information, for example, under the Freedom of Information Act 2000. RBG Kew will make reasonable efforts to inform [insert counterparty name] of any proposed disclosure under freedom of information obligations in relation to this MoC or the relationship established under this MoC but shall not be bound to obtain the prior consent of [insert counterparty name] to any such disclosure.

10.6 [Insert counterparty name] agrees to keep confidential, and use only for the purposes of carrying out its obligations under this MoC, any documents, information or other data relating to the business or affairs of RBG Kew.

10.7 Each party acknowledges that the other party may be prevented, either temporarily or permanently, from carrying out projects under this MoC by reason of force majeure.

10.8 Any notice or other document to be served under this MoC must be delivered by hand or sent by registered mail or international courier service to the address below or to such other address as has been notified to the sending party.

For RBG Kew: Head of Legal and Governance, the Royal Botanic Gardens, Kew, Richmond, Surrey TW9 3AB, United Kingdom.

For [insert counterparty name]: [Insert post and address].

10.9 All notices or documents shall be deemed to have been served at the date and time of delivery of the said notices or documents to the recipient party.

10.10 Nothing in this MoC is intended to, or shall be deemed to, constitute a partnership or joint venture of any kind between the parties, nor constitute either party the agent of the other for any purpose. Neither party shall have authority to act as agent for, or to bind, the other party party in any way

10.11 This MoC is personal to the parties and neither party may assign or charge any of its rights under or the benefit of all or part of this MoC or transfer, delegate or sub-contract any of its duties or obligations under this MoC.

10.12 Each party shall execute such deeds or documents or do such acts or things as may be necessary to give full effect to the provisions of this MoC.

THE PARTIES TO THIS MEMORANDUM OF COLLABORATION SHOW THEIR AGREEMENT TO ITS TERMS BY SIGNING BELOW.

Signed:	Signed:
For and on behalf of RBG Kew	For and on behalf of [insert party name]
Name:	Name:
Position:	Position:
Date:	Date:

Annex 1

PRO FORMA

NOTIFICATION OF TRANSFER

The following plant material is transferred to the Board of Trustees of the Royal Botanic Gardens, Kew, United Kingdom ("RBG Kew") in accordance with the terms and conditions of the Memorandum of Collaboration between [insert name of counterparty] and RBG Kew, dated [insert date].

By signing this Notification of Transfer, [insert name of counterparty] hereby confirms that the plant material and associated data has been collected and is being transferred into the collections at RBG Kew in accordance with all applicable laws and regulations, permits, consents and/or licences.

DATE COLLECTED	**COLLECTION No.**	**FAMILY**	**GENUS or SPECIES**	**No. OF HERBARIUM DUPLICATES**

SIGNED: DATE:

For and on behalf of [insert name of counterparty]

Name:
Position:

SIGNED: DATE:

For and on behalf of the Board of Trustees of the Royal Botanic Gardens, Kew

Name:

Position:

A copy of this document signed by [insert name of counterparty] will be forwarded to RBG Kew with each consignment of plant material. RBG Kew will countersign this copy and return it to [insert name of counterparty] as acknowledgement of receipt by RBG Kew under the terms of the Memorandum of Collaboration

アクセスと利益配分に関する Consortium of European Taxonomic Facilities (CETAF)の行動規範、ベストプラクティス案

―DRAFT……
CETAF Code of Conduct and Best Practice for Access and Benefit-Sharing

Introduction to the package of documents

In order to fully support the operations of taxonomic collection-holding and non-commercial biological research institutions in complying with the Nagoya Protocol of the Convention on Biological Diversity (CBD), and the pending European Access and Benefit-Sharing (ABS) Regulation, a package of documents is needed. This first draft of the ABS package of documents was developed by CETAF's legislations and Regulations Liaison Group. The function of these documents is (i) to explain to both providers and users how biological specimens are used by CETAF institutions, which will support the negotiation of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) with providers; (ii) outline the principles under which collections are operated, and (iii) provide details of best practices undertaken to ensure those principles are followed.

The draft package of document is submitted to the CETAF 34th General Meeting for consideration and feedback. Eventually, the documents shall be made available to CETAF Members and, equally, to any other institution that, while not being a member of the Consortium, wishes to implement the principles and the content of the documents included in this package.

This first draft package of documents contains several elements:

1) Use statement (p.3-5): This outlines the uses to which the biological resources (specimens) may be put, including details of utilization of genetic resources. This will support obtaining Prior Informed Consent and provides a useful reference for text in the other documents.
2) Code of Conduct (p. 5-8): This provides the overview of the way in which the signatory institutions operate, through baseline standards for use of biological resources.

3) Best Practice (o. 8-15): This provides detail of how the code of conduct should be implemented, including recommendations for policies and processes.

Annex 1(p.16-18): Glossary
Annex 2 (p. 18): List of non-monetary benefits
Annex 3 (o. 19): Retention of records

In addition to the documents listed here, two more will be developed:

4) Standard Material Transfer Agreement (MTA). This sets out the terms under which specimens are transferred from one party to another. A standard MTA will provide consistency when transferring specimens from one collection to another.
5) Draft templates for MAT & PIC as guidance for ABS negotiations with Providing Countries /Countries of Origin.

1) Use Statement

This document sets out the typical/usual ways in which biological resources[6] accessioned into the collections of [Institution name] [Institution acronym]"), will be used. This includes use both in facilities managed or owned by the legal body and in facilities owned or managed by others but used for specific purposes under the direct responsibility of the institution (for example temporary use of external labs such as for DNA sequencing). If suppliers of biological resources do not wish their material to be treated in this way or wish to place any specific restrictions on use, this needs to be expressly set out in writing when granting access, or when donating or exchanging the resources with [institution]. lf the supplier does not place any express written restrictions on these uses, then the material will be accessioned and used by [institution] under the conditions set out below.

[Institution] is a member of [network name] and subscribes to the [network name] Code of

[6] In the definitions provided by the CBD 'biological resources' include 'genetic resources' (GR). Because some of the uses to which biological specimens are put in research do not include utilization of genetic resources the more inclusive term is used in this document where appropriate.

Conduct and Best Practice.

CETAF Use of Biological Material

Research at [institution]: Any biological resources at [institution] will be made available to its staff and authorized visitors for non-commercial scientific research on systematics, ecology, conservation, genetics, horticulture, morphology, physiology, molecular biology, genomics, environmental genomics and sustainable use. Such work may involve making anatomical and cytological preparations, carrying out isotope analysis, and sampling for pollen, spores, and/or chemicals. DNA, RNA, proteins or other biomolecules may be sequenced or otherwise analysed.

Research results: Results of research will be made available through publication in printed or online form (books, scientific journals, publically-available databases, published images or internet sites).DNA sequence data will be deposited in publicly-available databases such as GenBank and referenced to the respective biological specimens stored at [institution]. It is usual practice for [institution] to provide a copy of published research results to its local counterpart(s) and to acknowledge its counterpart(s) in any such publications.

Information and images: As a scientific institution it is important that [institution] makes its collections as accessible as possible to its direct scientific counterparts and to the wider scientific and conservation community. This may involve the digital imaging of specimens and of associated data, and publication of such images and information to be freely available on the internet. Images and data may also be presented in research publications. [Institution] will maintain data records on the biological resources stored in its collections to enable its origin and associated records such as PIC and MAT to be retrieved.

Loans: [institution] may lend biological resources (specimens) to third parties in other scientific research institutions for identification, further scientific research or for educational purposes subject to the standard Loan Conditions of the [institution] [Optional text: *URL if Loan Conditions are*

available on the internet]. The terms of these Conditions include that the specimens may only be used [**optional text, but some description is required here**: for non-commercial purposes/in a way consistent with the Mutually Agreed Terms under which the material was obtained from the Providing Country /in a way consistent with this Use Statement and the CETAF Code of Conduct on Access and Benefit Sharing] unless there is specific permission from [institution]. Such permission would only be given [**optional text**: if the third party agrees MAT with the Providing Country / with permission from the Providing Country / or, for material acquired prior to the entry into force of the CBD [29th December 1993], in a way consistent with this Use Statement and the borrower is from an institution that is signatory to the CETAF Code of Conduct on Access and Benefit Shoring].

Permanent Supply to third parties: [institution] may supply biological resources permanently to other scientific research institutions and/or to individual scientists for scientific research or for educational purposes, including through donation and exchange for other specimens or samples or parts thereof, unless this is excluded by the Providing Country in the respective MAT. Transfer will be effected when the recipient institution or individual has signed a "Material Transfer Agreement "with [institution] [**Optional text**: excluding only commercialisation or other utilization of genetic resources not in accordance with the original MAT (if appropriate) arising from utilization of any genetic resources supplied and has signed the CETAF Code of Conduct on Access and Benefit Sharing/ has agreed MAT with the Providing Country].

Propagation and public display: Live specimens will be made available to [institution] staff and authorized visitors for [**optional alternatives**[7] propagation'/breedings[8]]. Any specimens grown from such [**Optional alternatives**: propagation /breeding], or otherwise acquired, may be put on public display at [institution]. [Institution] will maintain data records on any specimens grown from such [propagation/breeding] to enable its origin and associated records such as PIC and MAT to be retrieved.

Traditional Knowledge:

Traditional Knowledge (TK) in the public domain may be used in research and may be published in paper or electronic formats. The [institution] will, as far as is practicable and reasonable, for TK known to be in its collections, store it in such a way that it is not made available to third parties or released into the public domain without PIC and MAT, if the

[7] For botanical collections

[8] For zoological collections

holder is known.

Commercialisation

[institution] is a not-for-profit institution and is [**Optional alternatives**: not/only under exceptional conditions] involved in commercialisation of its genetic resources. However, as part of its mission, [institutional] investigates [**Optional alternatives**: animals/plants/microorganisms/fungi/genomic samples] and their constituents for taxonomic and other scientific research, and this research may lead to the discovery of potential commercial uses of certain genetic resources.

[institution] will not commercialise any [**Optional alternatives**: biological/genetic] resources collected after the Convention on Biological Diversity came into force (29th December 1993) and prior to the coming into force of the Nagoya Protocol without the prior informed consent of the Providing country and any bodies within that country as required, including local communities.[Institution] also undertakes to share any benefits arising from such Commercialisation fairly and equitably, as far as is possible.

Should [institution] wish to commercialise any genetic resources collected before the Convention on Biological Diversity came into force (29th December 19 93], [institution] will, as far as is possible, share benefits fairly and equitably.

Benefit-sharing

At all times, and regardless of when biological resources were acquired by [institution], [institution] will use its best efforts to share fairly and equitably with the Providing Country, or appropriate stakeholders[9], any benefits arising from the utilisation of genetic resources obtained from that country. Non-monetary benefits may involve, inter alia: scientific training, education and capacity building; collaboration on relevant scientific work programmes; and the mutual sharing of research results and of associated publications (*N*agoya Protocol Annex: non-monetary benefits; see also Annex 2 to this document).

2) CETAF Code of Conduct on Access and Benefit-sharing

CETAF is a networked consortium of non-commercial scientific institutions in Europe formed to promote training, research and understanding of systematic biology and

[9] 4 Using the Global Multilateral Benefit Sharing Mechanism where necessary and appropriate, once this is in place.

palaeobiology. Together, CETAF institutions hold very substantial biological (zoological and botanical), palaeobiological, and geological collections and provide the resource for the work of thousands of researchers in a variety of scientific disciplines.

CETAF Member Institutions commit themselves to the following Code of Conduct on access to genetic resources and benefit-sharing. This is to be read in the context of the "Use of Biological material" document.

Convention on Biological Diversity and laws related to access to genetic resources and associated traditional knowledge and benefit-sharing
Participating institutions will:

- Honour the letter and spirit of the CBD, The Nagoya Protocol to the CBD, The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and other relevant international agreements.
- Abide by international and national laws and regulations relating to Access and Benefit-sharing, including those relating to Traditional Knowledge.
- Comply with PlC, MAT and other agreements entered into with and within the Providing country (and also the provider if from ex situ source).

Acquisition of genetic resources
CETAF Member institutions will:

- In order to obtain Prior Informed consent, provide a full explanation of the purposes for which the biological resources will be acquired and used and how genetic resources will be utilized (within current technical understanding).
- When accessing genetic resources from in situ conditions, (i) obtain information on the Providing Country's access laws and the procedures for obtaining Prior Informed Consent and relevant permits, and for agreeing Mutually Agreed Terms, and {ii) obtain Prior Informed Consent and relevant permits from the Government of the Providing country and any other relevant stakeholders, and (iii) agree terms, according to applicable law and best practice
- When acquiring genetic resources from ex situ collections, agree terms under which the material can be utilized with the body governing the ex situ collection.

- When acquiring genetic resources from ex situ sources, whether from scientific collections, commercial sources or individuals, evaluate available documentation and,

where necessary, take appropriate steps to ensure, as far as is reasonably possible, that the genetic resources were acquired in accordance with applicable law and best practice.

Use and supply of genetic resources
CETAF Member institutions will:

- Utilize genetic resources and their derivatives on terms and conditions consistent with those under which they were accessed or otherwise acquired.
- Use Traditional Knowledge only on the terms and conditions under which it was acquired.
- Request new PIC and MAT agreements if a new use is proposed that triggers the need for additional agreements, and not change the use without such agreements.
- Supply biological resources and their derivatives to third parties on loan only on terms and conditions consistent with those under which they were acquired. Should a third party seek to utilize genetic resources in a way not covered by the original agreements or that triggers the need for additional agreements, the GR will not be supplied until the third party has approached the Providing Country and secured appropriate PIC and MAT.
- Transfer genetic resources and their derivatives permanently to third parties only with copies of the documentation showing agreements with the Providing Country, where applicable, including PIC, MAT or other relevant permits. Should a third party seek to utilize genetic resources in a way not covered by the original agreements, the GR will not be supplied until the third party has approached the Providing Country and secured appropriate PIC and MAT.

Use of written agreements
CETAF Member institutions will:

- Access or otherwise acquire genetic resources and Traditional Knowledge using written agreements, where required by applicable law and best practice, ensuring there is a record of Prior Informed Consent (PIC) by the appropriate national bodies and any relevant bodies within the Providing country, and setting out the terms and conditions under which the genetic resources may be acquired, used and supplied and resulting benefits shared (Mutually Agreed Terms). These documents may be separate as outlined, take the form of a permit where appropriate under national legislation, or any other required form.

- Supply genetic resources and derivatives, and Traditional Knowledge to Third Parties using written Material Transfer Agreements (MTA), where required by applicable law and best practice, setting out the terms and conditions under which the genetic resources may be acquired, used and supplied and resulting benefits shared (MAT).

Traditional Knowledge

CETAF Member institutions will:.

- As far as practicable maintain a permanent record of any Traditional Knowledge (TK) known to be in its collections, including in its library, archives or associated with specimens, in order to ensure appropriate management.
- As far as is practicable and reasonable safeguard TK information and store it in such a way that it is not made available to third parties or released into the public domain without PIC and MAT, if the holder is known.

Benefit-sharing

CETAF Member institutions will:

- Share benefits arising from their utilization of genetic resources and their derivatives fairly and equitably with the Providing Country and other appropriate stakeholders.
- Strive to share benefits arising from the use of genetic resources accessed or otherwise acquired prior to the entry into force of the CBD, as far as possible, in the same manner as for those acquired thereafter.

Curation[10]

In order to comply with these Principles, CETAF Member institutions will maintain records and mechanisms to:

- record the terms and conditions under which genetic resources and traditional knowledge are accessed or otherwise acquired;
- track their utilization of GR, and benefits arising from that utilization.
- record supply to third parties, including the terms and conditions of supply; and.
- record when and how genetic resources and traditional knowledge records pass out of custodianship, including complete consumption of samples or disposal.

[10] It has been suggested that this also include the duration of custodianship, the default being permanent, but of course dependent on the conditions of the MAI/MTA.

Custodianship

CETAF Member Institutions will retain genetic resources and TK permanently and manage them as it manages other resources within the collections it cares for unless otherwise stipulated by MAT or NTA.

Policies

CETAF Member institutions will:

- Prepare, adopt and communicate institutional policies setting out how the Participating Institution will implement these Principles.
- Prepare a transparent policy on utilization of genetic resources and their derivatives.

3) CETAF Best Practice on Access and Benefit-sharing

CETAF Member Institutions endorse the following Best Practice on access to genetic resources and benefit-sharing.

Preamble

These Best Practice components are designed to indicate routes to implement the CETAF Code of Conduct on Access and Benefit-sharing, and cover uses of biological specimens, including genetic resources, as set out in the Use Of Biological Material statement.

The Best Practice on Access and Benefit-sharing outlines the requirements that should be considered when conducting day-to-day work at the institution. Not all parts of this practice may be relevant or applicable for all institutions to implement.

The following components are covered:

- Policies.
- Data management/curation
- Staff training
- Fieldwork
- Utilization
- Utilization by third parties
- Benefit-sharing
- Disposal of collections

Policies

The policies and associated processes should ensure:

- The institution understands its rights and responsibilities under the appropriate treaties and relationships with Providers;
- Its staff, authorised visitors and associates abide by appropriate national, intranational and international laws and regulations when working In or on behalf of the institution
- biological resources entering the repository are obtained with appropriate legal certainty
- biological resources deposited in the repository can legally be retained;
- terms and conditions (PlC[11], MAT[12], MTAs[13], Permit(s) and MoC[14]s) governing samples are complied with by the repository, including staff of the repository and third parties using the repository, and that renegotiation takes place in the case of proposed change in utilization from that previously agreed;
- terms and conditions (PlC, MAT, MTAs, Permit(s) and MoCs) governing biological resources are recorded and can be accessed effectively to manage use of those resources, including third-party transfer and disposal. This should include incorporation within a records management system and data management system;
- the institution can address benefit-sharing issues regarding Genetic Resources held that were accessed prior to the requirement for PlC, MAT or Permit, or from countries where such requirements do not exist, or which have not signed and ratified the Nagoya Protocol.

Any policies on GRs should be explicit about who is obliged to follow them (e.g. staff, whether on-site or elsewhere, including when working as a visitor in another institution, students attached to the institution, associates (e.g. Research Associates, Honorary Associates), volunteers, visitors working in the institution etc).

Clear policies should be adopted to cover the institution's work in all areas where relevant, e.g. provisions arising from the Nagoya Protocol and other ABS regulations and legislation might apply. They need to govern activities or points in workflows where decisions have to be taken which have an ABS implication or are governed by ABS considerations ABS concerns have to be managed.

The institution should have an overall Access and Benefit-Sharing policy (this can be an

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11 PIC - Prior Informed consent - see glossary
12 MAT - Mutually Agreed terms - see glossary
13 MTA - Material transfer Agreement - see glossary
14 MoC - Memorandum of Cooperation - see glossary

'umbrella' policy covering all aspects of Access and Benefit-Sharing and be used as a reference in other policies). Aspects that may be considered for separate policy statements include:

Acquiring new specimens:

1. Field Collecting - to cover all aspects of collecting, including the requirement to obtain appropriate permits, PIC and MAT.
2. Object Entry - governing what legal documentation is required by the institution when specimens enter the institution, including, and how both entry and documentation are managed by the institution.
3. Accession - governing the conditions required for specimens to be added to the collections and pass under the ownership of the institution. The policy may need to address:

    a. Documents required (e.g. PlC, MAT. MTA, Transfer of Title document);
    b. Authorising individual within institution;
    c. Means of managing compliance with MAT;
    d. Issues associated with the legal framework governing the collections and how this can accommodate persistent obligations (e.g. the fairly common inclusion in MAT that newly-described holotypes be returned to the Country of Origin).
4. Incoming research loans - setting out conditions under which loans received by staff or other associates of the institution can be accepted in the context of ABS. This is important since staff in this circumstance risk being in breach of terms under which genetic resources were accessed if they are unaware of those terms, or of illegally utilizing genetic resources if they were illegally collected.

Managing the collection

5. Frozen tissue / DNA collections - where these are separate. Since such collections are comparatively novel for many institutions, they may have separate policies; these should include reference to ABS requirements.
6. Living collections - Utilization of cultures and other bred and propagated organisms in collections, including agreements required for supply to third parties.
7. Traditional Knowledge - covering all aspects of the institution's collecting, documenting, storing and release of Traditional Knowledge. Should include how it is stored, who can access it, conditions under which it can be made public.

8. Long-term loans and material held in trust for provider countries. Should include documentation required, MAT.
9. Destructive and invasive sampling - covers use of frozen and other collections for DNA extraction, and consequently requirements to observe restrictions and requirements agreed with the Providing Country or other provider of genetic resources. May also cover utilization of genetic resources by third parties (e.g. recipients of loans, visitors), and protocols for publicizing sequence data (e.g. through GenBank).
10. Incoming and outgoing exhibition loans/acquisition - although not utilized for scientific research such loans may require ABS permits (including for Traditional Knowledge). They also may be required to comply with additional requirements such as CITES compliance.
11. Outgoing research loans - conditions under which users in other institutions can borrow Biological resources, including:

    a. what analytical processes loan recipients are permitted to carry out on material received, including compliance with terms under which material was acquired;
    b. return or disposal of any residual samples / aliquots / derivatives that have not been consumed for analysis;
    c. any subsequent utilization by a borrower;
    d. requirements for documentation to be provided with loans (e.g. copies of original PIC and MAT or summary thereof);
    e. action should commercialisation be requested by the third party (e.g. requirement for renegotiation of PIC, MAT or MTA by borrower with the Providing Country);
    f. action should the third party undertake inappropriate utilization.

12. Research –governing access to GR, utilization of GR and publication of results during research activities by the institution. This may be covered by other ABS policy elements, or a separate policy may be required.

13. Data management and documentation - all data management that includes ABS-related documentation or information, including:

    a. storage and access to ABs-related documents and associated information;
    b. sharing content of ABS documents with third parties, including through reporting;
    c. special treatment of sensitive information (e.g. TK, information restricted under

PIC and MAI).

d. Record-keeping (see Annex 3).

14. Internal Collections Audit- Regular audit of a sample of genetic resources to determine if the institution is managing its ABS documentation, compliance with agreements and associated processes effectively and whether improvements are required or possible.

Removal of specimens from the collection

15. Dispatch and object exit - covering all items leaving the institution temporarily or permanently, including:
    a. documentation required internally, with special regard to consumption of (sub) samples and derivates thereof;
    b. documentation required by recipient;
    c. situation under which renegotiation of PIC/IMAT or MTA is required;
    d. documentation required by the Country of Origin or Provider Country.

Some of the above is covered under 'Outgoing research loans'.

16. Loss - the course of action to be taken with regard to ABS requirements (e g. under MAT), including documentation, in the event of loss of specimens from the collections.
17. Disposals (including exchanges and transfers) - Governing how specimens leave the ownership of the Institution, which may be governed by Mutually Agreed terms or a Material Transfer Agreement.

Institutions may find it helpful to manage all required intranational, national and international legal documentation under the same policy umbrella; by doing this they will be able to use common database solutions and provide more effective staff training. Such documentation may include:.

- Collecting permits.
- Research permits.
- Prior Informed Consent documents.
- Mutually Agreed Terms. Material Transfer Agreements
- Export permits.
- Import permits.
- Memoranda of Cooperation.
- National /international laws regulating ownership of specimens, such as CITES permits.

- Nagoya Protocol international Certificate of Compliance.
- Further relevant permissions negotiated at local, national or international level

Where possible policies should echo wording in accepted legal frameworks, including, when agreed, the EU Regulation on Access and Benefit-Sharing; this has been done in the example in Annex 3.

Each of these policies should be accompanied by a process document to set out what actions staff have to take in various situations in order that they and the institution are compliant. Work flow diagrams can be helpful.

Data management/Curation
Best Practice will require the following elements:

a. Data management system to support the policies outlined above;
b. Period of retention of all legal documentation covering Genetic Resources (to comply with the draft on European ABS Regulation this is 20 years; CITES requires permanent documentation; for Best Practice documentation should be retained permanently;
c. Means to track where a GR was originally collected or originated from (core data);
d. Means to trace where a GR under its responsibility is at any given time;
e. Means to track where a GR has been while under its responsibility (including incoming loans) and what processes (including utilization) have been carried out on it;
f. Means to discover rapidly what legal requirements and restrictions are associated with a specimen and, if necessary, efficiently transfer this information to a user in another institution when the specimen or any subsample, part or derivative of it is transferred;
g. Means to discover rapidly if and how commitments linked to genetic resources (i.e. as set out in Mutually Agreed Terms, Material Transfer Agreements, or other relevant permits or legal obligations linked with the sample) have been met, and manage their delivery;
h. Apply, as far as possible {or required by the EU Regulation), unique identifiers to appropriate data items allowing tracking of specimens (especially for processed DNA samples);
i. Record entry, accession, loans, identification, processes carried out (including consumption of tissues and DNA aliquots), and deaccession of material;
j. Record core data associated with GR, including:

a. the date and place of access of genetic resources and traditional knowledge associated with such resources;
b. the source from which the resources or the knowledge were directly obtained as well as subsequent users of genetic resources or traditional knowledge associated with such resources;
c. associated legal documentation.

The institutional data management system should provide staff with information on permits required for countries where fieldwork is carried out, MoCs with relevant organisations and governments, current projects, etc.

Permits, MATs, PIC and other documents, or information that certain specific documents are not needed (exemptions), should be deposited as original signed copies with the Registrar or equivalent office in the institution, and a mechanism developed to ensure that the provisions within them are associated with the specimens or samples to which they apply.

Staff training

All staff whose work involves collecting, managing and researching on specimens, including those undertaking laboratory works and managing loans to other institutions, should receive training in implementing the ABS policy and ABS aspects of other policies. An identified staff member should be responsible for coordinating delivery of training and keeping records of training being delivered. A handbook to the institution's policies and processes regarding ABS should be made available digitally or in hard copy.

Fieldwork

Prior to undertaking fieldwork staff should be aware of the required permissions and legal documentation that are required to carry out fieldwork, and seek to obtain the relevant documentation. In cases where the permits cannot be obtained outside the Providing Country staff should not undertake any fieldwork in that country until the requisite permits are agreed and finalised, or appropriate written guarantees received. Staff should carry out fieldwork only in accordance with the laws and regulations of the sovereign nation in whose territory they are working.

Staff should only sign Mutually Agreed Terms if the institution is able to meet the terms agreed, and if they are consistent with the Code of Conduct. Institutions should draw up

guidelines to assist staff in this process.

Activities involving collecting specimens or samples while on fieldwork should be carried out only for and in the name of the institution responsible for the fieldwork; additional acquisition of genetic resources for private or other use, including on behalf of or for sale to third parties, should be prohibited.

Where possible, fieldwork in countries other than that of the institution should be conducted as part of a collaborative venture with a museum, botanic garden, university, or other recognized scientific research organization in the Providing Country.

Utilization

Institutions should ensure that data indicating all restrictions on the use of individual samples or parts thereof follow each sample and that a mechanism is in place which ensures that staff and users are informed about the restrictions.

Use that is not congruent with the conditions agreed for Access, where these exist, should not be undertaken.

Records should be kept of utilization. An institution should have clear and robust policies for how it handles inappropriate utilisation (which may occur either inadvertently or purposefully) by staff and third parties.

Publications resulting from the utilization of genetic resources, and other use of biological resources, should in most if not all cases cite the Providing Country of the specimens, and ideally include an identifier of the permit or other agreement covering the collecting (access to) and use of the specimens. This includes paper and electronic publications, including databases such as GenBank.

Utilization by third parties

The paragraphs below apply to specimens accessed after 1993 and thus covered by the Articles of the CBD and, after 2014, the provisions of the NP. For specimens accessed before that date the institution should develop its own policy, recalling the Code of Conduct and Best Practice sections on Benefit Sharing.

Any restrictions or requirements arising from the conditions under which the specimens

were obtained, or others arising from institutional policy should, if relevant, be communicated to the user. This may require paper or electronic copies of relevant Mutually Agreed Terms, collecting permits and Material Transfer Agreements in some cases (especially where the specimen, sample or (processed) subsample is being permanently transferred).

Temporary use (e.g, loans / sharing of tissues/DNA subsamples)
Third party use that is consistent with the conditions under which the specimens were obtained should be permitted where the custodianship of the specimen does not pass out of the institution, (unless constrained by the agreement covering acquisition by the institution). This includes temporary use as a loan from the institution or within the institution (e.g. research cooperation).

Processes should be developed to ensure that if a temporary Third Party user requests a change of utilisation (including those potentially leading to commercialisation), appropriate action can be taken, which may include renegotiation with the Providing Country. An institution should have clear and robust policies for how it handles inappropriate utilisation (which may occur either inadvertently or purposefully) by Third Parties.

Any commercial sequencing facility to which samples are sent as a part of research (e.g. for DNA sequencing) should be required to return or destroy residues following completion of the work.

Records should be maintained of specimens or samples borrowed by Third Parties, including utilization of GRs if it takes place.

Permanent transfer to Third Parties
Specimens should not be permanently transferred to another institution if prohibited under the original PIC and MAT. If transfer is not prohibited under the original PIC and MAT, specimens maybe freely transferred between signatories to the CETAF Code of Conduct and who have adopted this Best Practice. Both institutions should retain records of the transfer. If transfer is not prohibited

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under the original PIC and MAT, specimens may be transferred to third parties who have not signed the CETAF Code of Conduct or adopted this Best Practice, either on their signature of an appropriate Material Transfer Agreement by which they undertake to utilize the specimens only in a manner compliant with the original PIC and MAT or if planning a different utilization, with evidence that they have agreed PIC and MAT with the Providing Country.

Records should be maintained of specimens or sampled transferred permanently to Third Parties.

Benefit-sharing
Genetic Resources should be treated uniformly regarding benefit-sharing irrespective of whether they were accessed before or after the Nagoya Protocol comes into force.

Processes should be developed to ensure that any benefits generated from utilization of genetic resources accessed prior to the coming into force of the Nagoya Protocol are shared fairly and equitably.

Institutions should keep a record of benefits shared.

An indicative list of non-monetary benefits likely to be delivered as a result of non-commercial biodiversity research is provided in the Annex to the Nagoya Protocol (Annex 2 to this document).

Deaccession and Disposal of collections
Disposal should only take place if it is in accord with the conditions agreed with the Providing Country.

Records should be kept of any consumption of samples or disposal, including to a third party for permanent deposit.

Mutually Agreed terms may require that specimens be destroyed following use (e.g. DNA sent for sequencing to a third-party laboratory) or returned to the Providing Country. Destruction should only be carried out if congruent with any restrictions or requirements. Broadly, other than under MAT requirements or through consumption of samples as a necessary part of application of molecular techniques, specimens should not be destroyed

unless they cannot be used to provide further scientific information. Institutions should have a process in place to ensure genetic resources have been destroyed in line with the original PIC, MAT or MTA and confirming this with the provider Country.

Annex 1: Glossary

Access - Permission to collect/sample genetic resources as granted by the country that has sovereign right over those resources (Providing Country). Note that this term has not been defined in the Convention on Biological Diversity or the Nagoya Protocol, and may be used differently by some countries or organisations. An agreed definition should be included in all legal documents.

Benefits arising from the use of genetic resources - Not defined, but may include: (1) Monetary when research and developments leads to a commercial product (e.g. royalties, milestone payments, licensing fees); (2) Non-monetary (e.g. technology transfer, enhancement of research skills, sharing research results, research partnerships, Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies, etc)

Biological resources - includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity (definition from Article 2 of the Convention on Biological Diversity). Biological collections refer to specimens; (often discrete individuals of one or more species), 'samples' (generally unsorted collections of many individuals from individual locations) and 'material' (term covering specimens and samples in a collection, or part of a collection).

Biorepository – A biological materials repository that collects, processes, stores, and distributes biospecimens to support future scientific investigation. See also Collection.

Biotechnology - any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

Collection - a group of specimens or samples that can be seen, studied, and kept together. They are generally associated through sharing some feature, e.g. being of the same taxon (e.g. mammals, insects, sharks), from the same general locality or ecosystem, or collected by the aimed by collection-holding institutions. The term biorepository may also be used, to include specimens which are not necessarily of whole organisms, and even include human specimens.

Commercialisation and Commercialise - 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.

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Competent National Authority –The body or individual in a country authorised to sign ABS agreements.

Country of origin of genetic resources - the country which possesses those genetic resources in in-situ conditions (definition from Article 2 of the Convention on Biological Diversity). See also 'Country providing genetic resources'.

Country providing genetic resources - 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 Article 2 of the Convention on Biological Diversity. - see also 'Providing Country'

Derivative - 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).

Exchange - also ‘Transfer’, and ‘Permanent supply’. Permanent transfer of specimens to a third party to the original agreement.

Genetic resources - genetic material of actual or potential value (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity)

Genetic material - any material of plant, animal, microbial or other origin containing

functional units of heredity (definition from Nagoya Protocol, repeated from Article 2 of the Convention on Biological Diversity).

Mutually Agreed Terms (MAT) - An agreement reached between the providers of genetic resources and users on the conditions of access and use and the benefits to be shared between both parties.

Memorondum of Cooperotion (MoC) -an agreement between two or more institutions to cooperate. In the context of the CETAF Code of Conduct and Best practice this will include reference to ABS.

Material Transfer Agreement (MTA) - an agreement between two institutions stipulating the terms and conditions for transferring specimens or samples, including genetic material.

Participating institution, - A member of CETAF who has signed the CETAF Code of Conduct and agreed to follow CETAF Best Practice.

Prior Informed Consent (PlC) -the permission given by the competent national authority of a provider country to a user prior to access in genetic resources, in line with an appropriate national legal and institutional framework i.e. what a user can and cannot do with the material.

Providing Country - The country providing genetic resources; this may be the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention on Biological Diversity (see 'Country of origin' and 'Country providing genetic resources')

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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 NP.

Utilization (of genetic resources) - to 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).

Annex 2:Non-monetary benefits

The indicative list of non-monetary benefits below is that given in the Annex to the Nagoya Protocol. 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 programs, particularly biotechnological research
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 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.

Annex 3: Retention of records.

Institutional policies on data management should include clarity of what information will be held and a statement of how long documents will be kept. For example:

"The [institution] will seek, keep and transfer to subsequent users as appropriate information on:

a. the date and place of access of genetic resources and traditional knowledge associated with such resources;
b. the description of genetic resources or traditional knowledge associated with such resources used, including available unique identifiers;
c. the source from which the resources or the knowledge were directly obtained as well as subsequent users of genetic resources or traditional knowledge associated with such resources;
d. the presence or absence of rights and obligations related to access and benefit-sharing;
e. access decisions and mutually agreed terms, where applicable;

Information relevant for access and benefit-sharing, including originals of relevant permits and other documents, will be retained for at least twenty years after the period of utilization of genetic resources" [NB this is taken from the draft text of the European Regulation on ABS; institutions will wish to retain the information permanently]. This will allow agreements about use or utilization to be honoured indefinitely, as may be required. In many cases even if information is removed from the system (for example if the specimen or sample is consumed, destroyed or deaccessioned) it is helpful or necessary to keep a record of what was removed.

世界ゲノム多様性ネットワークの標準ゲノム素材移転契約案

Global Genome Biodiversity Network Standard Material Transfer Agreements for provision of Genomic samples

Introductory notes

The Original Requirements were for an MTA that would:

- cover both temporary and permanent transfer (including material to be destroyed during sampling or at the end of the agreement)
- be for use between members of the GGBN, not between members of the GGBN and other bodies [this turned out not to be achievable for reasons stated below].
- deal with non-commercial use, with commercialisation only permitted with permission from the supplier.
- be restricted in coverage to genomic samples and analyses.

It became apparent that a single MTA would not cover all requirements. For outgoing material, the requirements for temporary transfer of material (loans) and permanent transfer are very different.

- Temporary transfer / loan refers to material where there is no change of ownership in the transaction. The Material may not be returned in whole or in part if it is consumed by analysis.
- Permanent transfer refers to material where there is a change in ownership, the new owner taking on the rights and responsibilities attendant on the material.

In addition to MTAs covering outgoing material it was decided that one covering incoming material would be useful.

Consequently three documents are presented below:

MTA 1 - GGBN Standard Material Transfer Agreement for provision of Genomic samples with no change in ownership

MTA 2 - GGBN Standard Material Transfer Agreement for provision of Genomic samples with change in ownership

MTA 3 – GGBN Standard Material Transfer Agreement for receipt of Genomic samples with change in ownership

Compilation of the documents

To construct the documents MTAs from a number of GGBN members, CETAF members and others were examined and tabulated to identify clauses in common. (see "MTAs used as a basis" below).

Use of the documents

We recognise that institutions within GGBN may have clear and established protocols for loans and permanent transfers already in place, in some cases including MTAs for genomic samples. The documents below contain clauses which we believe to be appropriate for genomic samples and together form a complete MTA. Institutions may wish to use these in part or entirety, or to inform their current documents. Members could review the documents against their current

documentation to check for duplications or inconsistencies, and amend the latter as required. The document for transaction without change in ownership (MTA1) could, with appropriate modification, be used as an annex to existing loan agreements.

The document has not as yet been reviewed by a legal expert, and we recommend that this is done. Because the legal jurisdiction will depend on the location of the supplier institution, each institution may wish to do this separately with legal advice in their own country. European members are advised to consider the implications of the Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, currently in draft but expected to be ratified in 2014.

The document might usefully be translated into the language of each country for legal scrutiny and general employment.

The document may be signed by both Parties; this is most likely to be of importance for change of ownership, but this should probably be discussed with legal advice.

Distinction between GGBN members and non-GGBN members

The original intent was to have a specific MTA for GGBN members in order to facilitate transfer between them. However, the GGBN MoC is non-binding and, although stating that the members will adhere to ethical standards / codes of conduct, it does is not binding ("Nothing in GGBN's Code of Conduct should be viewed as contradicting or superseding institutional codes and/or standards of conduct").

This situation can be contrasted by the much more formal agreement between IPEN members and the developing code of conduct of CETAF members, which are both intended to provide clarity and confidence in suppliers about the utilization and benefit-sharing arrangements of members.

The MTA will be effective in the context of a legal agreement between the Providing Country / Country of Origin and the original accessing body or individual. The MTA is also a legal agreement, transferring not only the material but also the legal responsibilities that accompany it. Given the lack of legal certainty of the GGBN members it appears that an MTA between members of GGBN can be any different from one between members and non-members.

Notes on individual clauses:

Some clauses may seem problematic or surprising to some readers; this section explores the rationale for their inclusion.

MTA 1 - GGBN Standard Material Transfer Agreement for provision of Genomic samples with no change in ownership

Clause 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:"

It has been suggested that the annex detailing the material should be in the form of a table

Sample No.	*Unique Identifier in collection*	*Taxonomy*	*Country of origin*	*Permits / restrictive conditions attached*

Clause 10
"Unless otherwise indicated, copyright in all information or data ("Data") supplied with the MATERIAL is owned by the SUPPLIER. You 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 you always acknowledge the source of the Data with the words "With the permission of [SUPPLIER]"

This clause is included because it is already used by some GGBN members. CB asked: "Do we need to be specific regarding material in the physical sense vs. data? Seems that use of data without permissions can be problematic. I have heard of instances of data being used improperly long after the material was consumed. Perhaps address in a preamble as well as in definitions?" We might strengthen clause 10 to give a period over which the data may be used (at least in certain circumstances).

Clause 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.*") also relates to records, and CB asks: "Should we clarify the intended type of record? I foresee inventory, treatment, data, etc types of records. Or does this mean that the recipient cannot retain information after the Material has been used for the purposes prompting the temporary custody (loan)?" If we specify, can we agree on what? (enhanced bionomic / geographical data, unique identifiers applied, any transcribed label data, processes undergone?)

Clause 11
"Data / metadata should not be modified in publications without permission from the SUPPLIER"

This is to avoid users publishing, for example, with different georeference data (this example is given because researchers have been known to 'smooth' or change data to avoid identifying sites where rare species are found, and any such change might suggest original Access in a place for which there was not a permit).

Clause 13
"Relevant documentation, including Access Permits, Mutually Agreed terms with the Country of Origin, reference number of the Internationally-Recognised 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."

This has been added to facilitate compliance (for EU users) with the EU Regulation on ABS when it comes into force. It is also relevant given that elsewhere in the document reference is made to PIC and MAT, and the RECIPIENT needs to have clarity on what these are.

See also Cause 7 of MTA 2 and clause 7 of MTA 3. It might be helpful to include a table, as with MTA3.

Clause 16
"The RECIPIENT will provide the SUPPLIER with all publications of the sample research prior [to] its publication."

At least 2 GGBN members (University of Copenhagen and STRI) require users to notify them prior to publication of results, the former in order to assess whether there is anything patentable in the publication. The text given is that used by STRI. Rationales for this include that prior notification (even a simple abstract) might be useful for SUPPLIER to maximise benefits, it could act as a trigger for renegotiating PIC/MAT if commercial potential arises, and it will build trust. For general use some organisations might find this too restrictive, and that it would discourage users.

Clause 17
"The RECIPIENT shall share fairly and equitably the benefits arising from their utilisation 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: www.biodiv.org/programmes/socio-eco/benefit/bonn.asp and the Annex to the Nagoya Protocol http://www.cbd.int/abs/text/articles/default.shtml?sec=abs-37"

We are not in agreement whether to include reference to monetary benefits in this clause. The arguments against doing so note that the emphasis of the MTA is on non-commercial applications (and this probably non-monetary benefits), and that mentioning finance may raise expectations. However, several partners have noted that although commercial use is not foreseen, unexpected commercial applications may arise and consequently this eventuality needs to be covered in the document. A further point is that, as pointed out under 'use of documents' above, member institutions may chose individually to amend this text. A phrase such as not See also Clause 11 of MTA2.

Clause 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."

The Smithsonion adds a further element: *"If, at any time, any product or process derived from Materials shipped under the terms of this Agreement, whether or not such product or process is subject to intellectual property protection, is identified as having potential commercial use, the Receiving Institution* ***shall immediately cease all further research and activity undertaken in connection with the Materials and shall promptly notify the Smithsonian.*** *The Receiving Institution* ***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 Smithsonian pertaining to the use of genetic heritage and benefit-sharing.***"

This may be more effective wording.

Clause 20

"The RECIPIENT shall acknowledge the SUPPLIER as the source of the MATERIAL in all written and electronic publications and reports."

This is only present in 2 of the MTAs examined. The provision may be challenging, especially when very many samples are discussed. An alternative would be to "refer to repository data, including citing the SUPPLIER'S unique identifier or voucher number".

Clauses 22-23

"The RECIPIENT agrees to acknowledge the Country of Origin as the source of the MATERIAL in any and all publications applications arising from its utilisation."

"The RECIPIENT agrees to acknowledge the Country of Origin as the source of the MATERIAL in any and all patent applications arising from its utilisation."

These are really best practice statements, and differ from the earlier clauses in this section, which are more about legal protection. If we think they should be included, then they should probably be both in the other MTAs and GGBN best practice statements.

Clauses 24-28

These are taken from one CETAF member; it is possible that individual members may wish to consider these clauses but equally they may be inapplicable to most.

Clause 19a (earlier version)

Originally the following clause was included:

"19 a. *The RECIPIENT agrees that MATERIAL or PROGENY designated Hazard Group 2 or above (as defined by the national regulations where the SUPPLIER is located) constitute known pathogens and that other MATERIAL, not so designated may be pathogenic under certain conditions.*"

This refers to a UK Hazard rating, and can probably be omitted.

We are not in agreement whether to include reference to monetary benefits in this clause. The arguments against doing so note that the emphasis of the MTA is on non-commercial applications (and this probably non-monetary benefits), and that mentioning finance may raise expectations. However, several partners have noted that although commercial use is not foreseen, unexpected commercial applications may arise and consequently this eventuality needs to be covered in the document. A further point is that, as pointed out under 'use of documents' above, member institutions may chose individually to amend this text. A phrase such as not See also Clause 11 of MTA2.

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"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."

The Smithsonion adds a further element: "*If, at any time, any product or process derived from Materials shipped under the terms of this Agreement, whether or not such product or process is subject to intellectual property protection, is identified as having potential commercial use, the Receiving Institution* ***shall immediately cease all further research and activity undertaken in connection with the Materials and shall promptly notify the Smithsonian.*** *The Receiving Institution* ***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 Smithsonian pertaining to the use of genetic heritage and benefit-sharing.***"

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Clauses 22-23

"The RECIPIENT agrees to acknowledge the Country of Origin as the source of the MATERIAL in any and all publications applications arising from its utilisation."

"The RECIPIENT agrees to acknowledge the Country of Origin as the source of the MATERIAL in any and all patent applications arising from its utilisation."

These are really best practice statements, and differ from the earlier clauses in this section, which are more about legal protection. If we think they should be included, then they should probably be both in the other MTAs and GGBN best practice statements.

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Originally the following clause was included:

"19 a. *The RECIPIENT agrees that MATERIAL or PROGENY designated Hazard Group 2 or above (as defined by the national regulations where the SUPPLIER is located) constitute known pathogens and that other MATERIAL, not so designated may be pathogenic under certain conditions.*"

This refers to a UK Hazard rating, and can probably be omitted.

An undertaking to inform the Country of Origin when it is transferred (either automatically when previously agreed or on request) was listed by two of the MTSs examined: CBS and DNA Bank Network; the formulation used is from the second of these. We think it more applicable to permanent transfer than loan.

Clause 14 (earlier version)
Originally the following clause was included:

"14. Warranty and Exclusion: The SUPPLIER:
(a) 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;
(b) does not exclude or limit the application of any statute if the exclusion or limitation would contravene that statute or cause any part of this AGREEMENT to be void;
(c) excludes all conditions, warranties and terms implied by custom, general law or statute that lawfully can be excluded, including warranties of merchantability or fitness for purpose"

The first sub-clause (26a) is now included as clause 5. The other two sub-clauses are now removed as probably unnecessary, although legal advice may be helpful here.

MTA 3 – GGBN Standard Material Transfer Agreement for receipt of Genomic samples with change in ownership

Clause 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:"

It has been suggested that the annex detailing the material should be in the form of a table

Sample No.	*Unique Identifier in collection*	*Taxonomy*	*Country of origin*	*Permits / restrictive conditions attached*

Clause 7
"Relevant documentation is annexed to this agreement:" followed by a set of check-boxes

The need for these check-boxes was questioned within the group. There is a concern that this may deter some donors, and the necessity has been questioned.

The rationale for inclusion is that the document transfers ownership from the supplier to the recipient, and states the rights of the recipient over the material, giving legal certainty to the recipient. If there are restrictions and rights on the material exercised by the Country of Origin (which would be stated in a permit, PIC or MAT document) then these should be part of the Transfer of Title, otherwise there cannot be legal certainty. For EU users, the forthcoming EU Regulation implementing the Nagoya Protocol will require transfer of documents (Internationally-Recognised Certificate of Compliance, Permits, MAT). The NHM Registrar strongly recommends inclusion of the check-boxes; this is likely to be a feature of forthcoming NHM documents.

See also Cause 13 of MTA 1 and clause 7 of MTA 2.

Clause 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]"

Several institutions of which the MTAs were used as a model allow restrictions on use of the material post acquisition (AMNH: AMCC, ZFMK Biobank, University of Guelph). These include, for a set

period of years, restriction of physical or electronic access, right to veto loan requests, right to be notified of loan requests. The rationale is if the donor is actively working on the material.

One of the models allows such conditions to be requested within one month of receipt of material; the current document requires any agreement on restriction to be a part of the overall AGREEMENT.

For UK institutions this could be an issue under the Freedom of Information legislation and for many in conflict with an open access policy.

Transport of Material

Currently the MTA contains no reference to this. However, the Smithsonian incoming MTA (for Brazil – it is effectively an outgoing MTA from Brazil) includes the following clause: "*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.*" Do we need this?

Additional (optional) clause for EU members.

The NHM includes the following clause on its Transfer of Title form, which may be helpful for some.

"The [Institute] has obligations under UK and EU law (e.g. the Data Protection Act 1998 & Freedom of Information Act 2000). Therefore the NHM is hereby permitted to disclose to third parties any information that it may hold in relation to the item(s) specified below."

Such a clause could be added to any of the MTAs.

MTAs used as a basis of proposed MTAs 1 and 2:

I tabulated clauses from a number of relevant institutions, including GGBN members, to identify clauses a considered relevant. The spreadsheet with many of these clauses extracts is attached. The MTAs were from:

- Australian Tree Seed Centre (ATSC) (http://www2.sl.life.ku.dk/dfsc/Extensionstudy/Forest%20Reproductive%20Material%20website/FRM-2844.htm)
- CBS (a CETAF member) (http://www.cbs.knaw.nl/pdf/MTA-CBS.pdf)
- Center for Molecular Biodiversity, Zoologisches Forschungsmuseum A. Koenig, ZFMK
- Danida Forest Seed Centre (DFSC) (http://www2.sl.life.ku.dk/dfsc/Extensionstudy/Forest%20Reproductive%20Material%20website/FRM-2844.htm)
- DNA Bank Network (GGBN) (http://ggbn.org/ggbnDocuments.html)
- International Poplar Commission (IPC) (Working Party on Genetics, Conservation and Improvement) (http://www2.sl.life.ku.dk/dfsc/Extensionstudy/Forest%20Reproductive%20Material%20website/FRM-2844.htm)
- Kew BDN Bank (GGBN member) (http://apps.kew.org/dnabank/MTA.html)
- NYBG (http://sciweb.nybg.org/Science2/pdfs/Material_Transfer_Agreement.pdf)
- Ocean Genome Legacy (GGBN) (http://www.oglf.org/MTA.htm)
- Oxford Forestry Institute (OFI) (http://www2.sl.life.ku.dk/dfsc/Extensionstudy/Forest%20Reproductive%20Material%20website/FRM-2844.htm)
- Senkenberg (GGBN) (http://ggbn.org/ggbnDocuments.html)
- STRI (GGBN) (http://www.stri.si.edu/english/research/applications/permits/anam/export_req.php)
- University of Copenhagen: (http://www.ku.dk//MTA_general_PST.doc). See also http://healthsciences.ku.dk/phd/current/supervision_and_research_environments/collaboration/University_of_Copenhagen_Guide_to_Reseachers_and_External_Partners.pdf/

MTAs used as a basis of proposed MTA 3:

- AMNH
- BIO, Canadian Centre for DNA Barcoding
- NHM UK – Transfer of Title to the Natural History Museum; Transfer of Title to the Natural History Museum Of Illicitly or Illegally Acquired Material
- RBG Kew - Donation of materials to the Royal Botanic Gardens, Kew (v1.0 2012)
- Smithsonian Institution, NMNH
- University of Guelph
- ZFMK Biobank

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

Preamble

1. 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 be returned*] (delete as necessary).
2. GGBN's activities are guided by the Convention on 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 recognising 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:

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 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 right 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 used for commercial purposes; and that the RECIPIENT always acknowledges the source of the Data with the words "With the permission of [*SUPPLIER*]";

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[1] http://www.cbd.int/convention/text/

[2] http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

11. Data / 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-Recognised 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 utilisation 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 utilisation.
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 utilisation.

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

[3] www.biodiv.org/programmes/socio-eco/benefit/bonn.asp
[4] http://www.cbd.int/abs/text/articles/default.shtml?sec=abs-37

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 MATERIAL 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 MATERIAL, 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 SUPPLIER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, also will either destroy the DERIVATIVES or remain bound by the 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]

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.

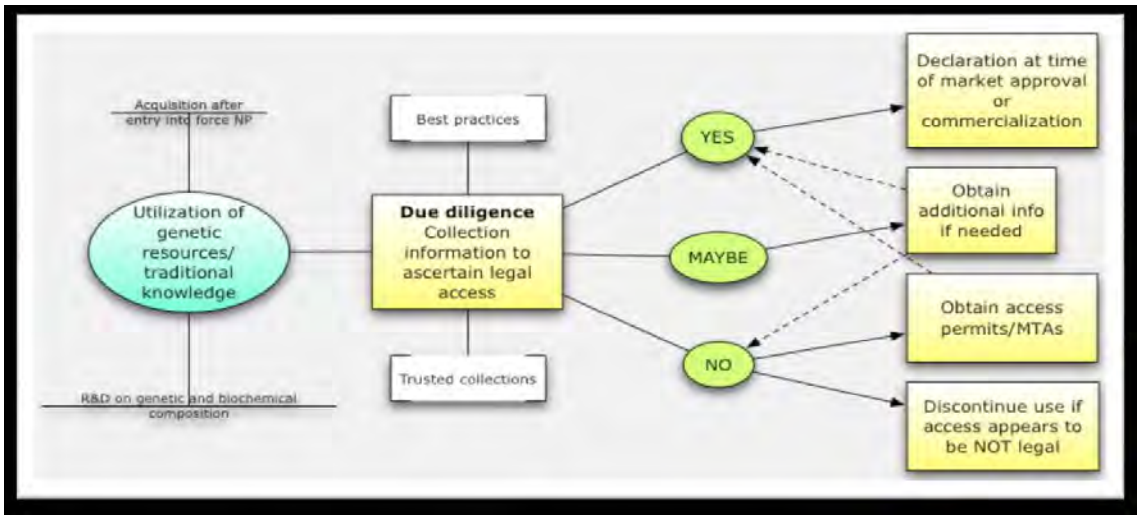
What is due diligence?

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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