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Proposal for a 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

Part 2 - ANNEXES

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Commission Staff Working Document

Proposal for a 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 UTILISATION IN THE UNION

Part 2 - Annexes

Annex 1: The Legal Framework established by the Nagoya Protocol

Genetic resources are widely used for a broad range of purposes. A significant part of EU researchers and industries directly or indirectly depend on reliable conditions for accessing and exchanging high quality samples of genetic resources. Examples include plant and animal breeding, natural material as input for modern biotechnology, or the analysis of genes found in nature as basis for developing new drugs.

States hold sovereign rights over genetic resources that originate within their jurisdiction (similar to crude oil). The CBD establishes a general obligation on its Parties to facilitate access to their genetic resources and to share benefits for resources utilised from other Parties. The general ABS framework set out by the CBD has not performed well. This has created frustrations on both sides of the ABS relationship: the technical capability for nature-based research have increased dramatically, however, EU users often face restrictions and legal risks when acquiring research material in other countries. Countries providing genetic resources in contrast, are reluctant to provide access if there is no commitment that agreed benefit-sharing obligations will be respected once a resource has left their jurisdiction and is used in another country.

Access and Benefit-sharing in the CBD/ Nagoya Protocol and other international instruments

Access and benefit-sharing for genetic resources and for traditional knowledge associated with such resources is addressed in the framework of the CBD and its Nagoya Protocol, but also in other international institutions. This includes the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, the FAO Commission on Genetic Resources for Food and Agriculture, the WTO Agreement on Trade Related Aspects of Intellectual Property Rights, the World Intellectual Property Organization, the World Health Organization, the UN Convention on the Law of the Sea, and various indigenous and human rights bodies.

The CBD has the character of a global framework agreement that is based on principled ideas and obligations. It applies to all genetic resources over which states hold sovereign rights. The Nagoya Protocol has the same broad coverage than its "mother instrument". However, its provisions are much more specific and operational. It is therefore important that the Nagoya Protocol explicitly clarifies how it relates to activities in other international fora. The Protocol explicitly does not apply to specialized access and benefit-sharing instruments. Instruments in this sense are the 2001 FAO International Treaty on Plant Genetic Resources for Food and Agriculture and the 2011 WHO Pandemic Influenza Preparedness Framework. Furthermore, Parties to the Protocol must seek to establish a mutually supportive relationship with other relevant international instruments and processes.

Another reflection of the Protocol's broad coverage is its explicit mentioning of some "special considerations": 1) Each Party must create conditions to promote research that contributes to the conservation of biological diversity, including through simplified access for non-commercial research; 2) Each Party must pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health; and 3) each Party must give special consideration to the importance of genetic resources for food and agriculture and their role for food security.

Objective, geographic and temporal scope of the Nagoya Protocol

The fair and equitable sharing of benefits arising from the utilization of genetic resources is the main objective of the Protocol (Article 1). Effective benefit-sharing is considered as an important incentive for the conservation and sustainable use of biological diversity. The geographical scope of the Protocol is on genetic resources over which states hold sovereign rights (Article 3). The Protocol does not apply to genetic resources that are found in areas beyond national jurisdiction, such as the high seas or Antarctica. As regards temporal scope, the Protocol applies to all genetic resources and traditional knowledge associated with such resources that are accessed and utilized after the entry into force of the Nagoya Protocol for a Party. It does not apply to genetic resources that were acquired prior to the entry into force of the CBD, i.e. 29 December 1993. In the view of some legal scholars, the Protocol also applies to the new or continued utilization of genetic resources that were acquired after the entry into force of the Convention, but before the entry into force of the Protocol for a Party. However, this interpretation is contested by other scholars. Parties must make a choice whether to follow this interpretation in their implementing measures or not. The Nagoya Protocol also does not apply to plant genetic resources covered by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

Access to genetic resources and to traditional knowledge associated with such resources

The Nagoya Protocol establishes detailed obligations how Parties must regulate access if they decide to require benefit-sharing for the utilization of their genetic resources (Article 6). Importantly, the Protocol defines that "utilization of genetic resources" means to conduct research and development on the genetic or biochemical composition of genetic resources (Article 2c)). This means the Protocol expects Parties to address in their domestic access framework not only the use of genes, but also the use of naturally occurring biochemicals found in acquired genetic material.

The Protocol obliges Parties that require benefit-sharing for the use of their genetic resources to establish a domestic regulatory framework that oblige potential users to obtain an access permit (so called *prior informed consent, PIC*) and also enter into a contract that sets out specific benefit-sharing conditions (so called *mutually agreed terms, MAT*). The Protocol provisions on access oblige Parties to create clear and transparent access frameworks, based on fair and non-arbitrary rules, which result in robust and reliable access decisions, in a cost-effective manner and within a reasonable period of time.

Special access obligations apply in relation to research with non-commercial purpose (Article 8(a)), in case genetic resources have pathogenic properties that threaten or damage human, animal or plant health (Article 8(b)), as well as in relation to genetic resources for food and agriculture (Article 8(c)).

The Protocol also establishes obligations for Parties on how to involve indigenous and local communities whenever access is sought to traditional knowledge associated with genetic resources held by a community or to genetic resources over which a community holds established rights (Articles 7, 12, 5.2 and 6.2). Effective implementation of these obligations will pose a challenge to some developing countries with little administrative and scientific capacity. This underlines the importance of targeted capacity-building, for example through bilateral partnerships.

EU laws do not regulate access to genetic resources or to associated traditional knowledge within the Union. EU nature legislation is indirectly relevant for *in-situ* collecting activities in EU protected areas. Furthermore, Member States which decide to require benefit-sharing and to develop an access framework in accordance with the Protocol, will need to ensure that

eventual restrictions on access are consistent with the fundamental freedoms and with applicable EU legislation on, for example, plant variety protection, or animal and plant health.

User-compliance

The Nagoya Protocol obliges Parties to take measures to ensure that only legally acquired genetic resources and associated traditional knowledge are utilised within their jurisdiction (Articles 15 and 16). Parties must take measures to monitor compliance of users under their jurisdiction, including by designating one or more checkpoints for this task (Article 17). They must take appropriate, effective and proportionate measures to address situations where users do not comply with their obligations. Parties must also ensure an opportunity for recourse in case of disputes arising from benefit-sharing agreements set out in MAT (Article 18). Importantly, the Protocol leaves Parties some flexibility through which measures to ensure user-compliance. The main user-compliance obligations of the Protocol are complemented by provisions on model contractual clauses (Article 19), codes of conduct (Article 20), or awareness raising activities (Article 21).

EU laws do not specifically address user-compliance. The only exception is a reference to the eventual utility of patent disclosure requirements in recital 27 of Directive 98/44/EC on the legal protection of biotechnological inventions as a means to monitor the use of genetic resources. User compliance measures have an apparent link to the functioning of the EU internal market. It depends on the design of EU implementing measures (point of intervention in value chain, type of measure) whether existing Union laws on intellectual property rights or product-approval are affected. As regards disputes arising from benefit-sharing agreements, Council Regulation (EC) No 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters seems relevant.

Benefit-sharing

The Nagoya Protocol establishes a general obligation on Parties to take measures so that benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization are shared in a fair and equitable way with the Party providing such resources (Article 5(1) and (3)). This obligation is closely related to the general objective of the Protocol (Article 1). Importantly, concrete benefit-sharing shall be on mutually agreed terms (MAT), that is on the basis of private law contracts negotiated between providers and users of genetic resources or associated traditional knowledge (Article 5(1), (2), and (5)). The Protocol makes conclusion of MAT an integral part of the administrative process of access-decisions of Parties that require benefit-sharing for the use of their resources. The content of MAT determines the type, time and amount of benefits to be shared. Users of genetic resources will need to know the content of applicable MAT to understand the reach of concrete benefit-sharing obligations in specific cases. Complementary measures on model contractual clauses or training in contract negotiations may help users and providers to more effectively engage in ABS activities.

EU laws do not specifically address benefit-sharing for genetic resources or associated traditional knowledge, be it in general terms or in relation to benefit-sharing contracts.

Institutional provisions, capacity-building, technology transfer, international cooperation

Parties to the Nagoya Protocol must designate a national focal point on access and benefit-sharing (Article 13(1)) and one or more competent national authorities responsible for practical decision-making on access and benefit-sharing (Article 13(2)). Furthermore, the

Protocol establishes an international information-sharing portal, the so called Access and Benefit-sharing Clearing House Mechanism, through which relevant information is made available. Parties are obliged to submit minimum information to the Clearing House on, for instance, domestic ABS measures and national focal points (Article 14(2)). They may submit further information, such as on model contractual clauses or codes of conduct (Article 14(3)).

The Nagoya Protocol also obliges Parties to cooperate in capacity-building (Article 22). It establishes a softly worded obligation on technology transfer to developing country Parties (Article 23). Various Articles oblige Parties to cooperate internationally for implementing the Protocol. This includes, for example, international cooperation in technical and scientific research and development programmes (Article 23), cooperation in case the same genetic resources are found in the territory of more than one Party (Article 11(1)), or cooperation in specific cases of alleged violations of domestic ABS requirements of a Party (Article 15(3) and 16(3)).

EU laws do not specifically address these aspects of Nagoya Protocol implementation. The Commission currently supports an ABS-capacity building initiative in the ACP countries, that aims at linking ABS policies to the management of protected areas.

ABS laws and policies of EU Member States

A survey of ABS laws and policies of eight EU Member States conducted in preparing this IA[1] showed that two Member States (ES, BG) have developed but currently do not apply access legislation, and none of the Member States surveyed had taken user-compliance measures as required under the Protocol. Some Member States (DK, NL, DE) have in the past or currently support ABS-related capacity-building activities, particularly in Africa.

[1] See Chapter 5 and the country case-studies on BE, BG, DE, ES, FR, NL, PL, UK found in Annex 1 of the IEEP/ECOLOGIC/GHK final report.

ANNEX 2: SYNOPSIS OF ALL PROVISIONS OF THE NAGOYA PROTOCOL

Article of the Nagoya Protocol	Description	Operational contents
1	This provision presents the **general objectives** of the Protocol: fair and equitable benefit sharing contributing to the conservation and sustainable use of biological diversity.	Implementing measures must be consistent with the objectives of the Protocol.
2	The provision defines **key terms** used in the treaty	Implementing measures must be consistent with the terms defined in the Protocol.
3	This provision describes the treaty's **scope**	The scope of implementing measures must be consistent with this Article
4	This provision explains the **relationship** of the Nagoya protocol with other international agreements and instruments.	Special agreements must be respected and a mutually supportive relationship to other relevant international agreements and instruments must be established
5(1) and (3)	The provision sets out the basis **benefit-sharing** obligation of Parties as regards the utilisation of **genetic resources**	Paragraph 1, first sentence establishes a general obligation to share benefits arising from research and development on the genetic or biochemical composition of genetic resources as well as from subsequent applications and commercialisation. The second sentence clarifies that concrete benefit-sharing commitments must be mutually agreed between provider and user, this means set out in (private law) contracts. Paragraph 3 obliges Parties to take appropriate measures for implementing paragraph 1.
5(2)	The provision addresses **benefit-sharing** in situations where **genetic resources are owned by indigenous and local communities**.	Parties with indigenous and local communities must take measures in support of channelling benefit-sharing to communities, wherever the domestic law of that state establishes rights of communities over genetic resources.
5(4)	The provision addresses **types of benefits** that may be shared.	The paragraph together with the Annex to the Nagoya Protocol provides Parties and stakeholders with an

		indicative list of benefits that may be considered when establishing concrete benefit-sharing agreements.
5(5)	The provision addresses **benefit-sharing** for the use of **traditional knowledge** held by indigenous and local communities.	Parties with indigenous and local communities must take measures that concrete benefit-sharing arrangements are concluded in case use is made of traditional knowledge associated with genetic resources that is held by a community in the jurisdiction of that Party and that the communities are the recipients of eventual benefits.
6(1) and (3)	This is the main Protocol provision on **access to genetic resources**.	All Parties to the Protocol that decide to require prior informed consent and benefit-sharing for the use of genetic resources over which they hold sovereign rights must establish domestic rules that comply with the "international access standards" in paragraph 3. The international access standards establish basic obligations in relation to legal certainty, clarity and transparency; and non-arbitrary rules. Parties must furthermore set out clear criteria and procedures for obtaining prior informed consent decisions and for the establishment of benefit-sharing contracts.
6(2) and 6(3) f	These are the main Protocol provisions dealing with **access to genetic resources** that are **"owned" by indigenous and local communities**	Parties with indigenous and local communities must take measures so that the prior informed consent or approval & involvement of indigenous and local communities is obtained where these have, in accordance with the domestic law of this Party, the established right to grant access to genetic resources.
7	This is the main Protocol provision on **access to traditional knowledge** associated with genetic resources that is held by indigenous and local communities.	Parties with indigenous and local communities must take measures with the aim of ensuring that traditional knowledge of their indigenous and local communities is accessed with the prior informed consent or approval and involvement of these communities and that benefit-sharing agreements are established. Parties have some flexibility on how to implement this obligation to accommodate for their specific domestic situations ("in

		accordance with domestic law").
8	The Nagoya Protocol, in principle, applies to all genetic resources over which states hold sovereign rights. Article 8 is a reflection of this broad coverage and identifies **specific issues** Parties must address in their implementing measures. These are **non-commercial research**, **public health emergencies**, and the special role of genetic resources for food and agriculture for **food security** and	In implementing the Protocol Parties must (a) create conditions to promote and encourage biodiversity research, particularly in developing countries, including through simplified access for non-commercial purposes (b) avoid that the Protocol's bilateral approach to access and benefit-sharing stands in the way of access to genetic resources in emergency situations that threaten, human, animal and plant health (c) reinforce food security through specific treatment and consideration of genetic resources for food and agriculture
9	The provision establishes that benefits-sharing must contribute to the **conservation** and **sustainable use** of biological diversity	Parties shall encourage users and providers to direct benefits arising from utilisation of GR to biodiversity conservation and sustainable use. The Protocol does not set out specific measures to this end.
10	The provision addresses the so called **Global Multilateral Benefit-sharing Mechanism**	The Protocol does not establish a Global Multilateral Benefit-sharing Mechanism. However, it obliges the collective of the Parties to consider the need for and modalities of such mechanism. If Parties agree that there is such need, the mechanism could be established at the earliest by a decision of the first meeting of the Parties to the Nagoya Protocol.
11	The provision deals with **transboundary cooperation** in situations of shared resources or shared traditional knowledge	The Article sets out a best endeavour obligation on Parties to cooperate with each other (i) where the same genetic resources are found within the territory of more than one Party, and (ii) where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties.
12	This is the main Protocol provision on **traditional**	The Article establishes different obligations that are

	knowledge associated with genetic resources.	primarily directed at Parties with indigenous and local communities. (1) In implementing the Protocol Parties must take into consideration customary laws, community protocols and procedures of indigenous and local communities (2) Parties must establish mechanisms for informing potential users of traditional knowledge about their obligations. These mechanisms must be developed with the effective participation of the communities concerned. (3) Parties must make a best endeavour effort to support indigenous and local communities in developing community protocols, minimum requirements for benefit-sharing contracts, and model contractual clauses. (4) Parties are obliged not to restrict the customary use and exchange of genetic resources and traditional knowledge within and amongst indigenous and local communities.
13	The provision sets out the roles of **national focal points** and **competent national authorities** that Parties must establish.	The Article obliges each Party must designate an ABS focal point for liasing with the international Secretariat and responding to information requests by stakeholders. Each Party must also designate one or more competent national authority that is responsible for granting access and advising on applicable procedures for requiring prior informed consent and entering into mutually agreed terms.
14	The provision establishes a **global information-sharing portal** managed by the international Secretariat, the so called Access and Benefit-sharing Clearing-House and identifies **information that must or may be shared** by Parties.	Paragraph 1 establishes the ABS Clearing-House. Paragraph 2 lists information that Parties must provide, without prejudice to the protection of confidential information. This includes national ABS laws, information on focal points and competent authorities

		and information on national access permits. Paragraph 3 lists information that Parties may make available. This includes information on indigenous authorities, on model contractual clauses, on codes of conduct, or technical tools for monitoring genetic resources flow. Paragraph 4 mandates the first meeting of the Parties to the Protocol to decide on the specific operating modalities of the Clearing-House.
15	This is the main Protocol provision on obligations of Parties in relation to the **ABS-compliance of users of genetic resources** within their jurisdiction.	Paragraph 1 obliges each Party to take domestic measures with legal effect so that users of genetic resources within its jurisdiction only utilise genetic resources that were legally acquired in provider countries in accordance with applicable requirements of these countries on prior informed consent and the establishment of mutually agreed terms. Paragraph 2 obliges each Party to take measures if users within its jurisdiction do not comply with its domestic measures on user-compliance. Paragraph 3 sets out a best endeavour obligation on Parties to cooperate with each other in case of alleged violations of domestic access frameworks of provider countries.
16	This is the main Protocol provision on obligations of Parties in relation to the **ABS-compliance of users of traditional knowledge associated with genetic resources** within their jurisdiction.	Paragraph 1 obliges each Party to take domestic measures with legal effect so that users of traditional knowledge associated with genetic resources within its jurisdiction only utilise knowledge that was legally acquired in accordance with applicable requirements of provider countries on prior informed consent and the establishment of mutually agreed terms. Paragraph 2 obliges each Party to take measures if users within its jurisdiction do not comply with its domestic

		measures on user-compliance. Paragraph 3 sets out a best endeavour obligation on Parties to cooperate with each other in case of alleged violations of domestic access frameworks of provider countries.
17	This is the main Protocol provision on **monitoring the utilisation of genetic resources**	Paragraph 1 first sentence obliges each Party to take appropriate measures for monitoring and enhancing transparency regarding the utilisation of genetic resources within its jurisdiction. The scope of the monitoring obligation is informed by the definition of "utilisation of genetic resources". The second sentence of Article 17.1 introduces a non-exhaustive list of ideas for monitoring and enhancing transparency. Each Party must designate at least one "checkpoint" with generally described functions, each Party must encourage users and providers to make use of contracts as monitoring mechanisms, and each Party must encourage the use of cost effective communication tools and systems for monitoring purposes Paragraph 2 establishes that domestic access permits that are made available to the Clearing-House Mechanism shall constitute internationally recognised certificates of compliance. All Parties must recognise such certificates as evidence of legal acquisition of the genetic resource covered (paragraph 3). Paragraph 4 sets out the minimum content of internationally recognised certificates.
18	This is the main Protocol provision on measures in support of **compliance with benefit-sharing contracts**	Paragraph 1 obliges each Party to encourage providers and users of genetic resources to include appropriate dispute resolution clauses in benefit-sharing contracts, as these will per se raise issues on where and how eventual disputes must be settled, and which laws would apply. Paragraph 2 obliges each Party to provide that

		opportunities for recourse are available under their legal systems in cases of disputes arising from benefit-sharing contracts. Paragraph 3 sets out a general obligation on access to justice and the use of mechanisms regarding mutual recognition of foreign judgments and arbitral awards. Paragraph 4 establishes that the effectiveness of Article 18 will be reviewed in accordance with the general review under Article 31.
19	The provision deals with **model contractual clauses**	The Article obliges each Party to encourage the development, update and use of model contractual clauses for benefit-sharing agreements. It also instructs the collective of the Parties to periodically take stock of the use of clauses.
20	The provision deals with **codes of conduct, guidelines and best practices or standards**	The Article obliges each Party to encourage the development, update and use of codes of conduct, guidelines and best practices or standards in relation to ABS. It also instructs the collective of the Parties to periodically take stock of the use of such codes, guidelines or practices and standards, and consider recognising some as best practice in the field.
21	The provision deals with **awareness-raising**	The Article obliges all Parties to take awareness raising measures, it also sets a non-exhaustive list of measures that may be taken for awareness-raising purposes.
22	The provision deals with **capacity-building** activities	The Article in its paragraph 1 sets out a general obligation on Parties to cooperate in capacity-building and capacity development to effectively implement the Protocol. The Article singles out the particular needs of developing country Parties in this regard. It also includes a detailed and non-obligatory list of areas and measures for building capacity.
23	The provision deals with **technology transfer**	The Article refers back to the relevant CBD provisions

		on technology transfer and stipulates in addition that the objective of such transfer is "to enable the development and strengthening of a sound and viable technological and scientific base for attainment of the objectives of the Convention and this Protocol."
24	The provision addresses the relationship of Parties to the Protocol with **non-Parties**.	The Article obliges Parties to encourage non-Parties to adhere to the Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.
25	The provision deals with the Protocol's **Financial Mechanism**	The Article establishes that the financial mechanism of the CBD – the Global Environment Facility - shall also be the financial mechanism of the Protocol. The Article also addresses how guidance to the financial mechanism must be developed and that the interests of developing and least developed countries must be considerations in developing such guidance.
26	The provision deals with **Meetings of the Parties** to the Nagoya Protocol	The Article establishes the meeting of the Parties to the Protocol as the supreme decision-making authority in Protocol matters. It addresses issues of participation in meetings, identifies a non-exhaustive list of functions of meetings of the parties, it also deals with rules of procedure. Importantly, it is established that the first meeting of the Parties to the Nagoya Protocol must be held concurrently with the first meeting of the Conference of the Parties to the CBD that is scheduled after the Protocol's entry into force.
27	The provision deals with **Subsidiary Bodies**	The Article establishes that subsidiary bodies of the CBD may also serve the Nagoya Protocol. It also addresses the participation status of CBD Parties that are not (yet) Parties to the Protocol in meetings of subsidiary bodies that serve the Protocol.
28	The provisions deals with the international **Secretariat**	The Article establishes that the Secretariat to the CBD

		also serves as Secretariat for the Nagoya Protocol and that necessary budgetary arrangements must be decided by the first meeting of the parties.
29	The provision deals with **monitoring and reporting.**	Each Party to the Protocol must regularly report on the measures taken for implementing the Protocol. The reporting dates and format are determined by the conference of the Parties.
30	The provision deals with the Protocol's **compliance mechanism**	The Nagoya Protocol does not establish a compliance mechanism. However, Article 30 obliges the first meeting of the Parties to "consider and approve cooperative procedures and institutional mechanisms to promote compliance" with the Protocol provisions and to address cases of non-compliance.
31	The provision deals with the **assessment and review**	The provision establishes that a first review of the effectiveness of the Protocol shall be undertaken four years after the Protocol's entry into force and at to be determined intervals thereafter.
32	The provision deals with the Protocol **signature**	The provision establishes that the Protocol was open for signature from 2 February 2011 to 1 February 2012. During that time it received 92 signatures.
33	The provision deals with the Nagoya Protocol's **entry into force**	Paragraph 1 establishes that the Protocol shall enter into force on the ninetieth day after the deposit of the fiftieth instrument of ratification. Paragraph 2 addresses the entry into force of the Nagoya Protocol for a Party. Paragraph 3 establishes that instruments of ratification deposited by regional economic integration organizations (such as the EU) are not counted additional to those deposited by its member states.
34	The provision addresses the issue of **reservations**.	The Article establishes that Parties are not allowed to make reservations to the Protocol. This is standard practice in multilateral environmental agreements. The

		Article is necessary since general rules of international treaty law would enable states to make specific reservations when ratifying the Protocol.
35	The provision deals with the possibility of a Party to the Protocol to **withdraw** from being a Party.	Paragraphs 1 and 2 establish set out the substantive and formal conditions for withdrawing from the Protocol.
36	The provision deals with the **authentic texts** of the Protocol	The Nagoya Protocol was negotiated in English. The Article establishes that the Arabic, Chinese, English, French, Russian and Spanish language versions of the Protocol are considered as equally authentic. This is important for interpretation purposes.

ANNEX 3: RESULTS OF THE PUBLIC CONSULTATION CONDUCTED IN SUPPORT OF THE IA

I. Summary

The list of questions together with the results of the web-based public consultation have been published in the website of the European Commission under the following link:
http://ec.europa.eu/environment/consultations/abs_en.htm

1. Overview of the participants

The Commission received 42 responses to the questionnaire and one contribution by the Government of Norway. The relatively small number of replies received actually represents a much broader number of respondents, since more than 40% of the replies came from stakeholder associations with hundreds or thousands of members each. The breakdown of the respondents is as follows:

– Associations of stakeholders: 17 replies (41% of the total answers)

– Universities, collections and Research Institutions: 17 replies (40% of the total answers)

– Individual Industries: 4 replies (10% of the total answers)

– EU Working Groups on genetic resources: 2 replies (5% of the total answers)

– NGOs: 1 reply (2% of the total answers)

– Indigenous and local communities: 1 reply (2% of the total answers)

2. Main messages from the consultation

a) The vast majority of respondents pleaded for a *harmonised approach at EU level* especially on user compliance to effectively implement the NP and its objectives in the EU, while certain of them even pleaded for a harmonised approach worldwide. Respondents judged a harmonised approach at EU level as cost effective, non-discriminatory and supportive of research activities

All respondents (except few neutral replies) agreed on the need for a *harmonised approach at EU level* to effectively implement the NP and its objectives in the EU.

REASONS:
- Avoid increase in administrative burden, time and costs
- Mechanisms to access, transport and control of genetic resources must be international
- Avoid discrimination against holders of traditional knowledge and fail to protect them
- Avoid limitation for intra-EU commerce of finished products
- Support to research activities
- Ensuring common interpretation

Several times it was even emphasized to strive for harmonisation worldwide.

Except for CABI (International Non-Profit Organisation occupied with environmental and agricultural issues) and the neutral replies, **all** respondents strive for a harmonised approach at EU level regarding establishing *access legislation* in the EU.

CABI's reason not to support the idea of a harmonised approach: Additional legislation is not necessary at the EU-level; controls should be implemented at national level and these may simply be community operational guidance where failure to comply means exclusion from the market.

b) The major part of respondents prefer a Regulation as the **most appropriate legislative instrument** for guaranteeing harmonised application of ABS rules in the EU, among them most industries and industry associations, gene banks and NGOs. Regulations bring clarity and legal certainty thus facilitating transactions related to genetic resources utilization.

1. The respondents striving for **a regulation** being the most appropriate legislative instrument for EU legislation on ABS are (24/42 = **57%**):

- GROUP I (most industries and associations within pharmaceutical, health&beauty, breeding, seeds, and biotechnology sectors) (19)
- Genebank (1)
- NGO supportive of Indigenous and Local Communities (ILCs) (1)

REASONS:
- On the issue of respect for ILCs rights, a regulation harmonising obligations of EU MS is more appropriate
- A regulation will enforce MS to implement directly into their national legislation and guarantee harmonisation
- assures clarity and legal certainty

2. The respondents striving for **a directive** being the most appropriate legislative instrument for EU legislation on ABS are (5/42 = **12%**):

- Botanical Garden (1)
- National Museum (1)
- University (1)
- Industry (herbal medicinal products) (1)

REASONS:
- Assures that main goals will be achieved while some adaptation remains possible
- Although it will require time for assessment and practices, this is the preferable legislative instrument
- For BGs, assures the continuous role of supporting and explaining issues pertaining to the biodiversity crisis

3. Certain respondents do not prefer one or the other, however, they express clearly that any legislative instrument should not impede the good functioning of the organisation (3/42 = **7%**). The remaining respondents voted blanco (10/42 = **24%**).

c) Regarding the **administrative burden**, respondents can be divided into two groups, one that expects an increase, another which considers the effects will depend on the way of implementation.

d) With regard to the effects on **competitiveness and the economy**, respondents generally agree that it will depend on the way the Protocol will be implemented. There will be positive effects if the EU ABS regime promotes wider sustainable use of genetic resources on the basis of clear, transparent and predictable rules.

positive effects when:
- Regime promotes wider sustainable use and confidence
- Regime is user-friendly leading to smooth flow in R&D and

negative effects when:	innovation - Regime is transparent, simple, clear and predictable - Regime promotes extra administrative burden - Unclear ABS requirements lead to uncertainties - Loss of business confidential information (loss of competitive advantage) - Lack of clearly designated approval authorities - Regime is unclear, creates trade barriers and has lack of uniformity
e) particular categories of users, especially the group of industries and associations found in the **health & beauty, seeds, breeding, pharmaceutical and biotechnological sectors** expressed certain specific concerns such as :-	
– The need to take into consideration the lengthy supply chains and their implications for the burden of compliance;	
– Non-existence of information on PIC and MAT does not imply lack of compliance with national rules (bio-piracy);	
– Checkpoints should be effective and not be seen as a 'policing' mechanism	
f) Institutions and organisations within the **health sector** are mainly concerned about the threat on development of new (veterinary) medicinal products, and its consequences on (animal/public) health and the competitiveness of the industry. To avoid complication or delay of both R&D and production, in particular for emerging diseases, within this sector it is stated clearly that pathogens used in the pharmaceutical industry should be excluded from the NP.	
g) **Botanical Gardens** especially emphasized their concern about staff reallocation problems (in particular for the smaller gardens). Furthermore, whatever the legislative instrument will be, it must not impede botanical gardens being facilitators of the 3 objectives of the CBD.	
h) **Research Institutions** mostly communicated the importance of clear, simple, transparent and accessible procedures to avoid missed opportunities for collaborations with providers. Within this sector, the risk of something not fully clarified at the time of access and the possible sanctions later on, often discourages researchers to collaborate. Consequently, benefits from such collaborations will not accrue nor add to the conservation of biodiversity.	
i) Many respondents proposed the use of standard clauses or model contracts for MAT, such as found in the ITPGRFA.	

II. **DETAILS OF THE RESPONSES TO THE PUBLIC CONSULTATION**

1. MAJOR CHALLENGES ARISING FROM THE ENTRY INTO FORCE OF THE NAGOYA PROTOCOL

Concerns of stakeholders with respect to the new legal situation that will result from the entry into force of the Nagoya Protocol

Mechanisms, countries will put in place to implement the Nagoya Protocol, as well as the multiplication of national legislations and competent authorities in provider countries, will

impact on research activities in the EU and exchanges of samples. Access to genetic material used for sustainable, non-profit public activities may be compromised or denied and R&D discouraged.

The lack of harmonisation between legal frameworks worldwide may increase administrative burdens and huge upfront costs. For instance, certain sectors collecting in the wild, like microbial collections, are not in a position to negotiate in advance individual agreements since the number and nature of collected microorganisms are at this stage unknown and the isolated microorganisms are multifunctional and can be utilised in many different sectors. It will be not envisageable for them to sign agreements for each individual organism for each use as the number of agreements will be enormous. A different solution for benefit sharing might be useful in this case such as an end use triggered sharing of benefits.

Several users also pointed out that insecurity and insufficient capacity of authorities in provider countries to deliver in conformity with the Protocol may create disruption even in the existing raw materials supply chain while others pointed out the risk of competition between users in the case they request access to the same genetic resource.

There will be a challenge to maintain close relationship between the 3 objectives of the CBD if interpretation/application of the NP is not consistent i.e. ABS regulatory frameworks focus only on monetary incentives and do not integrate broader social values associated with the use/exchange of GRs such as conservation and sustainable use.

Problems deriving from the absence of a clear legal framework in provider countries

Existing ABS regimes are very different and diverse while the research activities, especially those based on biotechnology, are global and located inside and outside the EU. Rules and procedures in existing ABS regimes are not clear for obtaining PIC and users are facing a series of difficulties to verify conformity with existing rules. This is worsened by different and diverse bureaucratic systems which are often ineffective and inefficient.

Since a few years many countries are making the rules for obtaining GRs more stringent and the process for obtaining PIC seems to become more and more politicised, including for example a link between obtaining IPRs and ABS, or introducing retroactive measures, thereby substantially increasing legal uncertainty.

Rights and obligations as defined in national implementation regulations are neither clear nor practical; the absence of clear rules creates legal uncertainty and increases costs. As a consequence users might decide that obtaining GRs entails too much risk because:

- Access is time-consuming and burdensome
- Users might face further requirements or sanctions later, while further developing or commercialising products, thereby undermining the value of an eventual commercial product, or even facing a situation of alleged non-compliance with rules that came into existence years after work on a specific product began.
- Users will not be able to obtain PIC and MAT in case a provider country has unrealistic views on the potential commercial value of a GR

Expected positive/negative economic impacts in comparison with current practices

Bring awareness, guidance and legal certainty for ethical sourcing practices is a positive expectation of most of the users. Clarification of procedures will help users to secure long-term sourcing while managing scientific risks.

The entry into force of the ABS Protocol is an opportunity for the EU to develop an all-encompassing ABS regime providing for clear predictable rules, guaranteeing access to GRs and providing for a workable and fair benefit sharing mechanism. Such a regime could be beneficial for users and result in an ABS regime that promotes wider sustainable use of GRs and increases confidence in the way ABS is taking place.

The adoption of a user-friendly ABS regime in the EU will encourage a smooth flow in R&D and innovation involving users. The EU has a wide range of very reputed and important academia, research institutions and companies which in addition are working together with stakeholders in developed and developing countries, thereby enhancing biodiversity on a global scale.

If access rules in provider countries are too restrictive, unclear or discriminatory users could avoid entire markets as sources for new innovation and if disparate rules are adopted in the different EU countries, the legal certainty will decrease and this will have a negative competitive impact on all EU stakeholders or stakeholders with European interests. Such negative impacts might include:

- The need for increased investments of time and resources due to the potentially unclear, impractical and non-transparent rules and administrative requirements. Users may have to deploy more financial, personal and time resources for these activities.
- A decrease in development and commercialisation of products based upon or derived from GRs, undermining the promotion of biodiversity conservation and the use of biodiversity to create benefits and products for the society as a whole.
- A decrease of the importance of the EU as a region for R&D activities in biotechnology and commercialisation of products developed through it; all sectors might be severely harmed.

2. ADDED VALUE OF EU IMPLEMENTING MEASURES

Appropriate level for establishing implementing legislation

Laws and regulations on ABS should seek to inform, facilitate and promote good practices, encouraging the responsible engagement of users and take into account the specificities of different sectors. The EU should ensure that harmonised rules and procedures are applied throughout the EU and avoid inconsistencies among various national legislations implementing the Nagoya Protocol. This approach will ensure a common interpretation of the key elements of the Protocol such as the rules on compliance; it will ensure legal certainty regarding applicable rules in the EU as a whole and will ensure that the implementation of the Protocol in the EU provides for a coherent example for national or regional implementation elsewhere, thereby safeguarding the interest of the EU user and provider sectors.

Certain users pointed out that national implementing legislation on individual Member States might be sufficient for implementing the Protocol but might not be the appropriate direction to take. Access to national resources should be regulated by national norms but common aspects should be regulated at EU level. This will ensure one common interpretation of and approach to some key elements of the Protocol such as compliance, certificates or checkpoints.

Other users put the accent on the need to avoid creating barriers to collaboration that eventually counteract the objectives of the CBD. A positive attitude should be adopted allowing the necessary development of research activities supporting sustainable use of biodiversity. For instance the same check points at European level could be opportunities to facilitate relationship between users and between users and providers and serve as leverage for development activities. National solutions would impose another layer of administrative burden and barriers of entry as well as limitation for intra-EU commerce of finished products.

Effects on the internal market

The application of different ABS rules in different Member States could have an impeding effect on the free movement of material and goods in the EU, thereby hindering exchange of material in the framework of R&D activities and the free movement of commercial products. Every intended exchange of material would need extra tie to find out the special conditions of the particular country and transaction costs will become too high. If the Protocol is implemented at Member States level without any harmonisation at EU level, there may be a risk that the different interpretations/application of key provision will result in obstacles to the internal market. In order to be sure that the free movement of goods is not hindered in such a way within the EU, harmonized application at least of key provisions of the Protocol would be necessary. From a business point of view it would be very useful to have the same kind of checkpoints in all Member States; it should be also ensured that once a document is accepted as evidence of PIC and MAT by one Member State, the movement of material and goods is not blocked in another Member State because the latter does not accept the same document as evidence or requires further documents.

Botanical gardens and other scientific institutions with non-commercial focus pointed out that a harmonised approach would even be desirable on a global basis. For those institutions an EU harmonised approach with simplified, legally validated procedures is likely to reduce administrative burdens. The same approach is also likely to reduce administrative burden at government level, especially if elements of best practices and simplified models for material exchange between scientific institutions for scientific purposes are included.

3. SPECIFIC IMPLEMENTING ISSUES

Maintaining current practices

It needs to be stressed that it is an established practice in certain sectors such as the biotech sector that all transfers of GRs between users and providers are done under a material transfer agreement to define terms and conditions of the transfer, rights and obligations of all parties

and secure traceability of GRs. Respondents to the public consultation indicated that currently used practices that function well must be maintained.

Certain user/providers have developed sector specific standard clauses/model contracts for MAT. These MAT include the grant of PIC and define the conditions governing the collection and use of GRs, including benefit sharing. A degree of flexibility needs also to be acknowledged, taking into account specific and unique circumstances of each case.

These are contractual arrangements between provider and user creating MAT and forming a legal framework within which transfer of material (including GRs) can take place. These contractual arrangements are in principle governed by national contract laws. As to arrangements in relation to benefit sharing, it needs to be noted that the Protocol recognises that it should be based upon MAT and can take the form of monetary and non-monetary benefit sharing.

Advantages both for users and for providers can be derived from such agreements as they provide the necessary legal certainty for the access and transfer of GRs. While expectations must be realistic and take into account the potentially high failure rate of projects, benefits that may become available from such arrangements include up-front payments, investment in infrastructure, technology transfer arrangements, and collaboration agreements. In fact, many of these advantages will be available even in cases where no commercial product is ever developed. Where new commercial products are developed as a result of such arrangements, they provide the possibility of including provisions on royalties derived from future revenue streams, where those may exist.

Moreover, the Bonn Guidelines represent until today a useful tool in providing guidance to providers and users on potential contractual terms for the drafting of ABS arrangements. In the seed industry, a relevant example of model agreements are the "Bioprospecting agreements" which are included in the Guidelines developed in 2005 by BIO. These Guidelines also provide for a "Model Material Transfer Agreement".

Below are examples with respect to model clauses/contracts in a few industries:

- *Biotechnology*: Relevant examples of model agreements are the "Bioprospecting Agreements" which are included in the Guidelines developed in 2005 by the Biotechnology Industry Organization and are therefore implemented by its members. (see http://www.bio.org/articles/bio-bioprospecting-guidelines). In practice, such agreements, which are concluded between the Transferor and the Transferee of a GR in the case of collection of the resource, include the regulation and grant of prior informed consent and set out the conditions governing the collection and use of regulated genetic resources, including benefit sharing. In order to provide greater clarity, the above mentioned Guidelines also provide for a "Model Material Transfer Agreement" (which can be incorporated into a Bioprospecting Agreement or even replace one in specific situations) whose primary purpose is that of transferring possession of GR.

- *Plant genetic resources for plant breeding*: The IT PGRFA has, in its Article 10.2, set up a Multilateral System in order to ensure access and benefit-sharing in respect of PGRFA.

Facilitated access to PGRs in the Multilateral System is realized through a standardised simplified contractual mechanism.

Costs and Administrative burden

Compliance with additional rules on ABS will logically impose an additional burden on all stakeholders and involve the need for more financial, personnel and time resources into activities which involve genetic resources such as gathering knowledge on the applicable ABS rules, checkpoints and **compliance requirements, and dealing with the competent authority (ies).**
Art 14 of the Protocol foresees the establishment of an ABS clearing house. Upon the condition that information provided through the ABS clearing house is always up to date and legally reliable, this could be a real facilitating mechanism to enhance transparency and reduce the administrative burden and transaction costs.
The administrative burden and transaction costs can also be substantially reduced in case the reality of lengthy supply chains is acknowledged and the burden of compliance is traced back to the party originally accessing the GR. To minimise the administrative burden, the EU should ensure that there is a harmonised approach, or at a minimum harmonised rules and procedures applicable in each EU country.
To minimize administrative burden and costs, respondents suggest:
- A harmonized EU implementation of the NP as far as compliance elements are concerned;
- Implementation of Article 15 (Compliance) in a way that recognizes the reality of lengthy supply and development chains for many sectors, and places the burden of compliance on the original party accessing the GR and/or associated TK;
- Preferably an EU authority on ABS as check point, since it will also be the most familiar with original accessing parties which obtained PIC and MAT at the point of access;
- Clarity as to what the ABS regime will and will not cover with specific regard to the single industries.

ANNEX 4: POLICY OPTIONS CONSIDERED BUT DISCARDED IN THE IA

OPTION ON BUSINESS AS USUAL

1) No Union ratification

This business as usual option was considered for the sake of completeness. It is outside the instruction given to DG Environment to analyse and develop measures for implementing the Nagoya Protocol in the Union. It also seems inconsistent with the proactive political engagement of the Union in the Nagoya Protocol negotiation that lasted from 2004 to 2010, and the fact that the Union joined the consensus of the 194 Parties to the CBD that adopted the Protocol in October 2010. It furthermore contradicts the formal act of Union signature of the Protocol in June 2011 and repeated statements on swift Union implementation and ratification.[2]. By signing the Protocol, the Union has committed itself under international law to work towards implementation and ratification, and to abstain from any action that could undermine the objective or purpose of the Nagoya Protocol.

If the Union would not ratify the Protocol, it seems certain that some Member States will do so unilaterally to participate at COP/MOP1 in 2014 as a Party and thereby avoid that the interests of their researchers and companies that are involved in nature-based research and development, or their interests as provider of genetic resources suffer from the non-Party status. The governments of ES and DK have – in view of a Commission proposal – so far delayed presenting legislative proposals for implementing the Nagoya Protocol to their parliaments. Presumably, these Member States would move swiftly ahead with legislation and ratification should the Commission indicate that it does not anymore plan to propose implementing measures at Union-level. BE, DE, FR, NL and UK have held public consultations or initiated studies that equally prepare the ground for domestic implementing measures. Of these Member States at least FR and DE would appear committed to ratify unilaterally in the absence of Union ratification. Other Member States with little nature-based research and development activities and low levels of biodiversity might, however, decide to stay out. If the Union does not ratify the Nagoya Protocol, it seems almost certain that by 2014 some Member States would be Parties to the Protocol while others would not.

The expected negative effects of such a situation are of the same quality as those identified in the analysis of Option UC-1, only of even greater magnitude.[3] It would certainly have very negative impacts on researchers and companies within the EU, and negatively affect the functioning of the EU internal market and the European Research Area. It would also result in systems of implementing measures at Member State level that are less effective and efficient than in the case of an EU-coordinated approach. At last, it would create a politically much more challenging starting point for any future consideration of EU-level measures for implementing the Nagoya Protocol. – This option was therefore considered but discarded.

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2 Council Conclusions of December 2010, of June 2011, of June 2012,

3 For an overview see table XX in the main part of the study.

POLICY OPTION ON ACCESS TO GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

1) EU-wide waiver of the PIC requirement

Some Member States explicitly give free access to the genetic resources over which they hold sovereign rights. The option of an EU-wide waiver of the PIC requirement was therefore considered. However, this option was not retained for further analysis. Some Member States have already developed access legislation, although it is not yet applied in practice (ES, BG), and others are in the process of doing so (FR).[4]

2) EU-wide minimum requirements on access-frameworks of Member States deciding to require PIC

Furthermore, the option of an EU Framework Directive establishing EU-wide minimum requirements on access-frameworks of Member States deciding to require prior informed consent was considered. This option would establish an EU-level playing field in all Member States requiring prior informed consent. In abstract, this would seem particularly beneficial to researchers and SMEs. However, this option was not retained for further analysis. No Member State presently requires benefit-sharing for the use of its genetic resources and only three Member States are likely to do so in the future. So there is simply no need for EU-wide minimum access requirements. In addition, the choice of user-compliance Option UC-2, and particularly the choice of the preferred Option UC-3, would actively encourage EU *ex-situ* collections to streamline their practices of making available genetic resources to outside users. These measures will reduce the eventual need for EU-wide minimum requirements on access for material held in *ex situ* collections; which – as is shown in the EU baseline – are the predominant sources of new material for EU users.

3) EU-level regulation of access to traditional knowledge held by indigenous and local communities

It was furthermore considered to regulate access to traditional knowledge held by indigenous and local communities at EU level but regarded as unnecessary. Only few Member States (for example SE, FI, ES) have ILCs under their jurisdiction. And although it is possible to argue for the existence of Union competence in the field, one must note that Member States have throughout the Nagoya Protocol negotiation stressed that in their view access to traditional knowledge held by ILCs falls in the exclusive competence of MS.

POLICY OPTIONS ON USER-COMPLIANCE

1) Amending EU legislation on the recognition and enforcement of judgements

The option was considered to amend EU legislation on the recognition and enforcement of judgements[5] in view of Article 18 Nagoya Protocol. However, this option was discarded. The Protocol does not oblige its Parties to take such measures. It is sufficient if Parties provide a general system for the ajudication of contractual disputes related to ABS. This corresponds

[4] For details see expert study pp. XX

[5] Regulations XXXX Brussels I and II Regulations

with a major EU demand in the negotiation. An amendment of the Brussels I and II Regulations is also not necessary for implementing the soft obligation of Parties as regards access to justice. This can efficiently be done through soft measures (eg., information on applicable rules, financial aid) at Union or Member State levels.

2) General prohibition on EU nationals to acquire genetic resources and associated traditional knowledge in a Party to the Protocol in violation of obligations set out in the domestic access legislation or regulatory requirements of this Party

It was also considered to establish a general prohibition on EU nationals to acquire genetic resources and associated traditional knowledge in a Party to the Protocol in violation of obligations set out in the domestic access legislation or regulatory requirements of this Party. However, this option was discarded. First, the Nagoya Protocol does not oblige its Parties to take such measures. Article 15 and 16 oblige Parties to take measures in view of the utilisation of genetic resources and associated traditional knowledge within their jurisdiction; they do not oblige Parties to take measures in view of activities of their nationals in other jurisdictions. Second, the option is difficult to reconcile with legal certainty and the principle of proportionality. If violations of the EU prohibition would be a simple/ automatic reflex of the violation of regulatory requirements in a third country, then EU authorities would need to establish a breach of EU laws based on factual and legal considerations established in a non-EU jurisdiction. This type of recognition of administrative and judicial decisions of foreign countries is normally only done on the basis of strict reciprocity. Strict reciprocity helps avoiding difficult situations, such as, for example, that a behaviour must be sanctioned within the EU, although it would be perfectly legal if conducted within EU jurisdiction, or that an EU national would need to be punished under EU law although it only breached an administrative ordinance in a third country. Establishing a more flexible approach for enforcing such prohibition would raise political problems - in addition to concerns about the lack of predictability for EU users – as it would necessarily imply value judgements by EU officials or EU courts on the credibility and integrity of findings of administrative and judicial authorities of third countries.

3) General prohibition on EU collections to hold genetic resources or associated traditional knowledge in their collection unless there is proper documentation giving evidence of the legal acquisition

It was also considered to establish a general prohibition on EU collections to hold genetic resources or associated traditional knowledge in their collection unless there is proper documentation giving evidence of the legal acquisition. However, this option was discarded. The apparent benefit of an early and strong intervention in the genetic resources value chain under EU jurisdiction is clearly outweighed by the expected difficulties of particularly smaller EU collections to comply with such norm and also the very significant costs for monitoring compliance of collections with thousands or even hundreds of thousands of samples that were collected often long-time ago.

4) Applying a broad concept of traditional knowledge associated with genetic resources

As regards user-compliance measures in relation to the utilisation traditional knowledge associated with genetic resources, the option was considered to base implementing measures on a broad understanding of this concept. However, this option was discarded. The Protocol does not define the term "traditional knowledge associated with genetic resources". It leaves Parties a wide margin of discretion to define in their domestic law what traditional knowledge means to them and how to engage with indigenous and local communities holding such knowledge. It would create unacceptable legal uncertainties to base EU user-compliance measures on something not clearly defined in EU law but varying with the respective definition of this term found in the domestic laws of potentially more than 170 countries. For legal certainty, it is imperative that EU implementing measures have a clear and identifiable scope. Legal certainty can be achieved, if implementing measures focus only on traditional knowledge that is directly associated with genetic resources as documented in domestic access permits and in mutually agreed terms. This excludes all other types of traditional knowledge that may indirectly become relevant to the utilisation of genetic resources within the EU.[6] This approach is also supported by consistency arguments. Applying a broad concept of traditional knowledge when implementing the Nagoya Protocol would, at this stage, most likely conflict with ongoing negotiations in the Intergovernmental Committee on Genetic Resources, Folklore and Traditional Cultural Expressions of the World Intellectual Property Organization. There, the international community considers whether international rules on intellectual property rights will be modified to provide for an effective protection of traditional knowledge holders under international law. These negotiations have implications that go much beyond the specific context of traditional knowledge associated with genetic resources. Indeed, the CBD COP10 decision adopting the Nagoya Protocol also suggests that implementing measures should be developed in consideration of the ongoing WIPO negotiations.[7]

POLICY OPTIONS ON COMPLEMENTARY MEASURES

1) Placing reference samples collected in free access situations in identified collections

Option C-5 would have multiple benefits. It would facilitate compliance by all users with their due diligence obligation if reference samples of genetic resources acquired in free access situations were available in reference collections, preferably collections enlisted in the EU register of "trusted sources", with unique identification numbers and documentation showing that these samples were collected under a free access policy. It would also significantly contribute to the conservation of genetic resources. Samples stored in collections are prevented from disappearing and can be used. A recent study on wild varieties of agricultural crops concluded that the key reason for the dramatic loss of genetic diversity in

[6] For example, if information about TKaGR is published in a scientific journal that is read by a university-based researcher and inspires this person to look into a specific direction in an ongoing research project.

[7] CBD decision X/1 adopting the Nagoya Protocol decided in paragraph 6 that the first review of the effectiveness of the Protocol under Article 31 of the Protocol shall assess the implementation of Article 16 in light of developments in other relevant international organizations, including, *inter alia*, the World Intellectual Property Organization.

this area is the insufficient availability of quality samples and related information.[8] Another apparent benefit of this option is that it would create research and development opportunities on quality samples of genetic resources that may be used without benefit-sharing obligations attached. This translates into a more enabling context for achieving the social and conservation objectives.

Despite these benefits, the option was discarded because of unclear cost-implications. As regards costs for those collecting genetic resources these were assumed to be minimal. It is routine practice today to include GSP positioning data into documentation of samples collected in the wild.[9] The only additional costs for collectors above the baseline of their collecting activity would thus be eventual costs for shipping reference samples to identified collections. Quite unclear, though, would be the costs of this Option for the reference collections where such samples would be deposited. The costs for such collections depend on the number of samples received and the costs of handling and storage per sample. Recent studies on ex situ plant conservation, that also consider new storage technologies such as cryopreservation, suggest that storage costs per sample could be between 0.20 to 50 € per sample per year[10.] This would need to be multiplied by the number of samples collected under free access conditions. Depending on the number of samples, this could be limited or indeed very significant. In that context, one would also need to consider that the option does not predetermine who would incur the costs. If the Member State holding the sovereign right decides that such samples should be included in a public reference collection under its own jurisdiction, the Member State would presumably also compensate this collection for the additional costs incurred. If the Member State would identify a private collection or a collection in another country as recipient, the question of who carries the costs would depend on the specific agreement reached. Overall, the costs of this option would primarily arise for the Member State holding the sovereign right, although financial contributions from philanthropic sponsors can also be imagined.[11]

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8 See the study contracted by DG AGRI "Independent Expert Valuation of Council Regulation (EC) No. 870/2004 of 1 June 2012.

9 See, for instance, element 3.A. of the data standard for barcode records (standard v.2.4 of 28 February 2012) used by the Global Barcoding of Life consortium (http://www.barcodeoflife.org/).

10 See Li and Pritchard (2009) *The science and economics of ex situ plant conservation*. Trends in Plant Science 14:614-621. The range reflects that different types of plants require different storage techniques. Costs at the higher end of this range seem, however, less likely for Option C-5 since the figures are based on average maintenance costs of collections of different sizes, whereas it must be assumed that reference collections identified by a Member State will be amongst the larger collections in the field. Larger collections have significantly lower costs per sample stored.

11 See for instance, the list of contributors to the Global Crop Diversity Trust (<http://www.croptrust.org/content/donors>).

ANNEX 5: DETAILED ANALYSIS OF OPTIONS FOR IMPLEMENTING THE ACCESS PILLAR OF THE NAGOYA PROTOCOL

Section I presents a comprehensive analysis of the 2 options considered in detail for implementing the access pillar of the Nagoya Protocol in the EU. To facilitate comparison, the substantive arguments are translated into a grading. We apply the following categories:

"0" neutral impact

"+" positive impact

"++" significant positive impact

"-" negative impact

"--" significant negative impacts

"unclear" – not possible to assess because of data limitations

"n.a." – the criteria is not meaningful for analysing the specific measure

Option A-1: No EU level action

Criteria for analysing impacts	Grading	Motivation of the grading against the criteria
Criteria specific to Access and Benefit-sharing and to the Nagoya Protocol		
- Specialised ABS agreements and processes (respect and mutually supportive)	-	It is considered a disadvantage that the EU would not be directly involved in choices by Member States on the relationship of their domestic access-measures to specialised ABS systems.
- Handling of Party-non-Party relationships	unclear	It seems unclear and would entirely depend on choices by Member States how to address the relationship with researchers or companies from non-Parties to the Protocol.
- Coherence with existing EU laws	-	Some EU laws (eg, nature legislation, sectoral legislation on agricultural genetic resources and on human, plant or animal health) may be affected by domestic access-frameworks of Member States. Although the Commission has the authority under the treaties to take action in case a domestic access framework is considered to conflict with the EU treaties or an obligation under the acquis

		(e.g. if criteria applied are openly discriminatory), it seems preferable to discuss eventual questions at the time when access requirements are developed rather than forcing a re-opening of (access) legislation once it is established. The option does not provide a basis for such discussion.
- Support to special considerations	-	The EU would not be involved the choices of Member States on special considerations in relation to access for non-commercial research, in case of emergency situations that threaten and damage health, and as regards the special role of genetic resources for food and agriculture. If different Member States take diverging decisions on how to address these situations it could raise questions on the Union's compliance with the Protocol.
- Ability to accommodate differences between sectors	n.a.	The criteria is relevant for user compliance measures, not for access
- Flexibility to allow for future development and fine-tuning	+	A positive feature of this option, that it leaves room for future development in the form of a focussed intervention at Union-level, should the need for such intervention become apparent.
- Improving the knowledge base about acquisitions, transfer and use of genetic resources in the EU	0	The knowledge base might improve at the Member State level, depending on their choices.
Economic impacts		
- Creation of an EU-level playing field	-/0	It seems certain that Option A-1 will not result in an EU-level playing field on access to genetic resources. Member States with free access systems will exist alongside other Member States that require prior informed consent for access to their genetic resources. This will create additional costs, for example if a publicly funded biodiversity research project foresees field research in three Member States with differing access systems.
- Correspondance with existing utilisation practices	n.a.	The criteria is relevant for user compliance measures, not for access
- Legal certainty and legal risks	-/0	If Member States requiring prior informed consent would establish widely different substantive preconditions for granting access or for sharing of benefits, it will raise transaction costs for users and could create legal risks to them. To give one example: it is typical for SMEs in parts of the biotechnology industry to conduct high-throughput screening of thousands or tens of thousands of samples against a specific target to identify interesting compounds. Obviously, this type of utilisation activity would be facilitated if the specific conditions for utilising genetic resources were

		streamlined, at least to some extent. Option A-1 does not provide a basis for such streamlining.
- Distribution of impacts along the value chain	0	Access conditions are relevant for those actors in the genetic resources value chain that either collect in the wild or that source from existing collections. Differing access conditions create different challenges and costs for the same actors in the chain; those that seek access as part of their activities. Such differences do not appear to result in different distributions of impacts along the value chain.
- SMEs and micro-enterprises	-	Significant differences in the possibility to use samples would create the highest relative costs for SMEs and micro-enterprises with the least capacity to adjust their operations.
- Research and development opportunities	0	It is assumed that Member States deciding to require prior informed consent will establish domestic access frameworks that better facilitate access to genetic resources and that create more research and development opportunities than Member States that do not invest in facilitating access to their genetic resources, but simply decide to allow for free access. This said, it seems too far-fetched to draw any conclusions on positive or negative effects on research and development opportunities
- International competitiveness	0	Expanding on the above, it equally seems too far-fetched to draw any conclusions on positive or negative effects on the EU's international competitiveness.
- Monitoring (effectiveness, efficiency) and costs)	n.a.	The criteria is relevant for user compliance measures, not for access
- Public costs (EU-level, MS level, one-off, recurring)	+ (Union level) unclear (MS)	The Option would not entail any costs at Union level. Costs at Member State level depend on choices taken by them.
Social impacts		
- Potential to contribute to social objectives (health, food security, nutrition etc)	unclear	Difficult to identify, it depends on choices taken by the Member States
- Protection of the rights of indigenous and local communities	unclear	Difficult to identify, it depends on choices taken by the Member States
Environmental impacts		
- Enhancing knowledge base for	unclear	Difficult to identify, it depends on choices taken by the Member States

biodiversity conservation		
- Potential for generating non-monetary and monetary benefits in favour of conservation and sustainable use of biological diversity	unclear	Difficult to identify, it depends on choices taken by the Member States

Option A-2: EU platform for discussing access to genetic resources and sharing best practices

Criteria for analysing impacts	**Grading**	**Motivation of the grading against the criteria**
Criteria specific to Access and Benefit-sharing and to the Nagoya Protocol		
- Specialised ABS agreements and processes (respect and mutually supportive)	+	An EU platform for discussing access to genetic resources and for the sharing of best practices would actively engage the Member States, the Commission and EU stakeholders in a discussion on the design and performance of domestic access frameworks of the Member States. Although shared conclusions by the participants would not be binding, they would nevertheless likely influence considerations made by Member States and reduce eventual frictions with other specialised ABS systems
- Handling of Party-non-Party relationships	+	The EU Platform will likely influence considerations made by Member States in the relationship to non-Parties to the Protocol and help reducing frictions.
- Coherence with existing EU laws	+	The EU platform would facilitate identifying and resolving eventual tensions between domestic access frameworks and the EU acquis.
- Support to special considerations	+	Member State participants to the platform would benefit from the experiences of each other and thus contribute to collective learning. This seems particularly valuable regarding the special considerations on non-commercial research, emergency situation that threaten and damage health, and genetic resources for food and agriculture that Parties to the Protocol must address.
- Ability to accommodate differences between sectors	n.a.	The criteria is relevant for user compliance measures, not for access

- Flexibility to allow for future development and fine-tuning	+	The option leaves scope for future development and fine-tuning of measures.
- Improving the knowledge base about acquisitions, transfer and use of genetic resources in the EU	+	The EU platform would improve the knowledge base and also help building the case for an eventual binding EU-level intervention on access.
Economic impacts		
- Creation of an EU-level playing field	+	Option A-2 will not result in an EU-level playing field on access to genetic resources. Member States with free access systems will co-exist with other Member States that require prior informed consent for access to their genetic resources. It seems, however, reasonable to assume that the deliberations of the platform would result in some streamlining of access conditions in Member States requiring prior informed consent.
- Correspondance with existing utilisation practices	n.a.	The criteria is relevant for user compliance measures, not for access
- Legal certainty and legal risks	+	It seems reasonable to expect that – compared to Option A-1 – Option A-2 will reduce eventual legal risks associated with highly diverging access conditions.
- Distribution of impacts along the value chain	0	Access conditions are relevant for those actors in the genetic resources value chain that either collect in the wild or that source from existing collections. Differing access conditions create different challenges and costs for the same actors in the chain; those that seek access as part of their activities. Such differences do not appear to result in different distributions of impacts along the value chain.
- SMEs and micro-enterprises	0/+	It is assumed that the EU platform will contribute to some streamlining of access procedures. This will be beneficial for SMEs and recipients of public funds.
- Research and development opportunities	0/+	It is assumed that the EU platform would make a limited but positive contribution to research and development opportunities on genetic resources. Another effect of the EU platform is that it would showcase best practices. This would help Member States to learn from each other and create more favourable conditions for access to their genetic resources. It would also help users in identifying Member States with the most favourable access conditions. It is assumed to make a limited but positive contribution to research and

		development opportunities on genetic resources.
- International competitiveness	0	It seems too far-fetched to relate the assumed moderate increase in research and development opportunities to an increase of the EU's international competitiveness in nature-based products and services.
- Monitoring (effectiveness, efficiency) and costs)	n.a.	The criteria is relevant for user compliance measures, not for access
- Public costs (EU-level, MS level, one-off, recurring)	0/+ (Union level) Unclear (MS)	The operation of the EU platform would create limited costs. Depending on the number of meetings per year, it would require some staff time for preparing, participating in and following-up to meetings of the platform as well as travel costs to meetings for the Commission participant(s)
Social impacts		
- Potential to contribute to social objectives (health, food security, nutrition etc)	unclear	Difficult to identify, it depends on choices taken by the Member States.
- Protection of the rights of indigenous and local communities	unclear	Difficult to identify, it depends on choices taken by the Member States
Environmental impacts		
- Enhancing knowledge base for biodiversity conservation	unclear	Difficult to identify, it depends on choices taken by the Member States
- Potential for generating non-monetary and monetary benefits in favour of conservation and sustainable use of biological diversity	unclear	Difficult to identify, it depends on choices taken by the Member States

ANNEX 6: DETAILED ANALYSIS OF OPTIONS FOR IMPLEMENTING THE USER-COMPLIANCE PILLAR OF THE NAGOYA PROTOCOL

Section I presents a comprehensive analysis of the 4 options considered in detail for implementing the user-compliance pillar of the Nagoya Protocol in the EU. To facilitate comparison, the substantive arguments are translated into a grading. We apply the following categories:

"0" neutral impact
"+" positive impact
"++" significant positive impact
"-" negative impact
"--" significant negative impacts
"unclear" – not possible to assess because of data limitations
"n.a." – the criteria is not meaningful for analysing the specific measure

Option UC-1: Open method of coordination

Under this Option, each Member State would establish legally binding user-compliance measures for itself to implement the relevant Articles of the Nagoya Protocol and coordinate its own measures with those taken by other Member States.

Criteria for analysing impacts	Grading	Motivation of the grading against the criteria
Criteria specific to Access and Benefit-sharing and to the Nagoya Protocol		
- Specialised ABS agreements and processes (respect and mutually supportive)	--/-	One key legal and practical concern is on the exact scope of application of user-compliance measures of Member States in relation to existing specialised international ABS instruments. For example, it will be important to clarify how material transferred by means of the standardised Material Transfer Agreement adopted under the FAO Treaty on Plant Genetic Resources for Food and Agriculture would be treated by designated monitoring authorities of a Member State. The apparent draw-back of Option UC-1 is that it cannot guarantee finding an EU-harmonised solution to incompatible approaches taken by Member States. This might be damaging to the EU-interest, particularly where, the EU is a Party to a specialised ABS instrument - as is the case of the FAO

		Treaty.
- Handling of Party-non-Party relationships	--	Option UC-1 has apparent draw-backs as regards managing the relationship between Parties and non-Parties to the Protocol. First, in the absence of harmonised EU user-compliance measures, and given the very likely situation that not all Member States will ratify at the same time, Party-non-Party situations would arise within the EU itself. This could create very complex situations that conflict with fundamental freedoms under the treaties and negatively affect the performance of user-compliance systems of Member States that are Parties to the Protocol. Would, for example, Spain be allowed to prohibit its nationals to conduct research and development on Spanish genetic resources in other Member States of the Union? Or to restrict the sale of products that have received a market approval in another Member State on the basis that this product was allegedly developed using illegally acquired Spanish genetic resources? Even if one sets aside the possibility that a Member State could adopt user-compliance measures that would discriminate against EU nationals of other Member States or products approved in other Member States that have not yet ratified the Protocol, it seems a real possibility that differences in the approach of Member States to the treatment of researchers and companies from non-Parties would negatively affect the functioning of the European Research Area. For example, EU co-funding under the framework programmes for research promotes collaboration of research institutions from a minimum of 3 EU Member States. Significant differences in user-compliance obligations for research activities that involve the utilisation of genetic resources might mean that some projects, although they would be worthwhile, could not be funded.
- Coherence with existing EU laws	-	It seems an apparent advantage of Option UC-1 that it does not require legislative action at Union level. The Option leaves it entirely to the Member States to take such action. At the same time, though – and given the close relationship of user-compliance measures to internal market rules and relevant EU laws on the approval of products (eg. medicines, cosmestics, food) – Member States may face challenges in developing user-compliance systems that are effective and in full-compliance with the Nagoya Protocol while avoiding interferences with applicable EU law. To give one example: it would likely raise legal concerns if a Member State would wish to make compliance with applicable ABS obligations an additional condition for issuing a market approval for medicinal or cosmetic products. It would seem equally problematic if a Member State tasks a market approval authority established under EU law with the additional task of monitoring compliance of users with Nagoya Protocol implementing measures of this Member State. Overall, it

		seems that the apparent benefit of not legislating at EU-level will be outweighed by the constraints on Member States to *effectively* legislate on user-compliance measures, which could raise non-compliance concerns for them, but in consequence also for the Union.
- Support to special considerations	--	Option UC-1 has the further disadvantage that it cannot guarantee that Member States take a harmonious approach to the special considerations on non-commercial research, to situations of emergency health threats or damages, or to the special nature of genetic resources for food and agriculture. One particularly important issue here concerns the treatment of pathogens for the purpose of resistance breeding. This activity clearly does not qualify as an emergency situation addressed in Article 8b) Nagoya Protocol. However, it might be addressed under the special considerations given to genetic resources for food and agriculture. Differences in approach by the Member States on this issue could disrupt activities in the plant and animal breeding industries. However, it could also raise questions on the EU's compliance with the Nagoya Protocol.
- Ability to accommodate differences between sectors	--	Option UC-1 would not result in an EU-harmonised system of user-compliance measures. Member States would be free to explore the flexibility in relation to their obligations on user-compliance as they see best fit for their national interest. For example, the NL would carefully consider the interests of its plant and animal breeding companies. In DE, FR, UK and IT the interests of the pharmaceutical and chemical industries might receive particular attention. FR might also pay special attention to its cosmetics industry as some companies are world leaders. It is thus assumed that Member States would take differing choices on the design of user-compliance measures. This may result in *conceptually different* user-compliance systems in different Member States. It would certainly result in *differences in the details* of applicable requirements; such details are nonetheless critical for implementation efforts "on the ground" (e.g. exactly what is considered as "utilisation of genetic resources", how to manage ABS-related information, rules on burden of proof, etc.). These basic assumptions suggest that the "flexibility" of Option UC-1 would most likely not translate into advantages of EU user sectors that their respective sectoral interests are adequately addressed. Different approaches in different Member States for accommodating differences between sectors would have clearly negative effects on all users that operate in more than one Member State. For EU stakeholders it is important that the same basic user-compliance rules and the same flexibilities in implementing user-compliance measures apply. It would, for instance, seem quite ineffective if one Member State would recognise participation in a sectoral code of conduct as proof of user-compliance, whereas another Member State would oblige all users to present

		certificates of compliance or issue statutory declarations that they have fully complied with all relevant ABS requirements. Indeed, the main and unanimous message from the public consultation exercise was that stakeholders prefer an EU-harmonised approach to user-compliance measures as they would expect high costs from a fragmented approach to implementing these parts of the Protocol. The challenges for users seem obvious, if different Member States were to require different approaches to managing ABS-related information, if they would apply different rules on the burden of proof, allow for different exemptions, or apply different understandings of what exactly qualifies as "utilisation of genetic resources", etc.. While Option UC-1 would likely reduce some of these frictions, it would not give any assurance to EU stakeholders that their user-compliance efforts in one Member State would be recognised in another Member State.
- Flexibility to allow for future development and fine-tuning	0/+	Option UC-1 would not prejudge future developments at Union level. It would contribute in a limited way to gathering experience and information about user-compliance measures.
- Improving the knowledge base about acquisitions, transfer and use of genetic resources in the EU	0	It would entirely depend on the user-compliance and monitoring measures adopted by Member States whether these improve the knowledge based.
Economic impacts		
- Creation of an EU-level playing field	--	Despite the open method of coordination at EU-level, it seems that Option UC-1 would almost certainly result in some fragmentation of user-compliance rules throughout the Union. Considering the importance of details for the functioning of a system, an uneven playing field is much more likely to emerge than an EU-level playing field. This very real risk is echoed by the strong concerns from EU-stakeholders about such scenario. Fragmentation, if it occurs, could disrupt the practices of some players in the genetic resources value chain (particularly those of SMEs and micro-enterprises with little capacity) and stifle research and development on genetic resources. There is also the risk of "regulatory lock-in". If significant differences have been established, it is much more difficult to re-open such systems. A fragmentation of user-compliance systems would be particularly challenging in sectors such as plant, animal breeding or green biotech that are heavily populated by SMEs and micro-enterprises and thus face disproportionately higher costs when operating under different legal regimes. A fragmentation of user-compliance measures would also create difficulties for large companies that conduct research and development on genetic resources (pharmaceutical, cosmetics, food and

		beverage industries). Different user-compliance systems might also apply openly incompatible methods for monitoring user-compliance (e.g., based on the approach analysed in option UC-2 or the approach analysed in option UC-4) which would drastically raise transaction costs of EU users that operate in multiple jurisdictions.
- Correspondance with existing utilisation practices	--	Some user-compliance systems of Member States will likely correspond better with existing practices of genetic resources use than others. However, as shown in the above analysis on "sectoral flexibilities" it is the *difference* in user-compliance systems between the Member States that would raise significant costs and risks and will not be avoided under this Option.
- Legal certainty and legal risks	--	Even when assuming that all Member States would establish user-compliance rules that are clear and transparent, and which – by themselves –provide users with legal certainty, *differences* between such rules are likely to create legal incompatibilities or risks that are beyond the control of researchers and companies conducting research and development in more than one Member State.
- Distribution of impacts along the value chain	0	As regards the distribution of impacts along the EU genetic resources value chain, it seems that all actors in the value chain frequently act in more than one Member State, at least to some extent. It is thus assumed that all actors in the user chain would be equally negatively affected by a fragmentation of user-compliance systems.
- SMEs and micro-enterprises	--	The previous assumption on distribution of impacts also implies that a fragmentation of user-compliance systems will place a disproportionate burden on SMEs and micro-enterprises with limited capacities to comply. Concretely, this means it would particularly affect the plant and animal breeding industries, the biocontrol industry, and more generally publicly funded research.
- Research and development opportunities	--	A fragmented system of user-compliance measures could disrupt would very likely disrupt some research and development activities and negatively affect the European Research Area. Considering the particularly negative impacts of this option on SMEs and micro-enterprises, and the particular role of these actors in the early and middle part of the EU genetic resources value chain, it seems that disruptions would most likely arise where research material moves from collections or non-commercial research to SMEs and again, where research and development activities move from SMEs to larger companies that create the real economic value.
- International competitiveness	-	Major provider countries, particularly from the so called mega-diverse group of countries, would certainly consider a fragmented approach to user-compliance systems in the EU as a second-best solution and potentially as ineffective in protecting their sovereign rights over genetic resources or

		the rights of their indigenous and local communities over traditional knowledge associated with genetic resources. An ambitious user compliance system in one Member State, for example, might be quite ineffective where researchers and companies are free to move in the European Research Area and the EU internal market, and where approval procedures for nature-based products often result in an EU-wide approval. Given the clear political and legal links between provider country decisions on access and the existence of credible user-compliance systems in user countries, it seems that Option UC-1 would result in less secure access to quality samples of genetic resources for European researchers and companies. This would constrain the innovation potential of EU nature-based industries and is thus considered to be negative for the EU's international competitiveness in the field of nature-based research and development..
- Monitoring (effectiveness, efficiency) and costs)	unclear	The impacts entirely depend on user-compliance and monitoring measures adopted by Member States.
- Public costs (EU-level, MS level, one-off, recurring)	-	The initial public costs of Option UC-1 at EU-level would be minimal; Member States would have to bear the costs for administering their user-compliance systems. However, *the costs for EU stakeholders* would likely be very high. This also suggests that the future public costs for dealing with a fragmented landscape of user-compliance systems would be considerably higher than the costs of establishing a workable EU-level system in the first place. Costs at Member State level would entirely depend on the choices taken by them.
Social impacts		
- Potential to contribute to social objectives (health, food security, nutrition etc)	-/0	Option UC-1 has a significant risk of stifling research, development and innovation in some nature-based industries, with resultant reduction in potential welfare gains.
- Protection of the rights of indigenous and local communities	-/0	Given the difficulties of EU users to comply with differing user-compliance systems, it seems that this option would not result in an effective protection of the rights of indigenous and local communities over their traditional knowledge associated with genetic resources.
Environmental impacts		
- Enhancing knowledge base for biodiversity conservation	-/0	Taken together, the above consideration suggest that Option UC-1 would make only a limited contribution to generating critical knowledge for biodiversity conservation

- Potential for generating non-monetary and monetary benefits in favour of conservation and sustainable use of biological diversity	-/0	Taken together, the above consideration suggest that Option UC-1 would only generate limited benefits in favour of conservation efforts

Option UC-2: Self-standing general due diligence obligation on EU users

Criteria for analysing impacts	Grading	Motivation of the grading against the criteria
Criteria specific to Access and Benefit-sharing and to the Nagoya Protocol		
- Specialised ABS agreements and processes (respect and mutually supportive)	++	The due diligence approach would allow for full recognition of specialised ABS systems. Indeed, it seems to enhance the functionality of such specialised systems, as diligent EU users will also respect the specific rules of specialised ABS systems. A due diligence approach would also provide a good basis for establishing mutual supportiveness between Nagoya Protocol implementing measures and implementing measures under specialised ABS systems. Under this option, the Commission would develop and update EU-level guidance documents articulating how EU users would exercise their due diligence to establish mutual supportiveness in a specific context, for example in relation to the important work done by the FAO Commission on Genetic Resources for Food and Agriculture. It also seems possible to reference internationally agreed guidance documents (such as the FAO Interlaken Global Plan of Action on Animal Genetic Resources and future guidance developed by the FAO Commission on Genetic Resources for Food and Agriculture on invertebrates, trees, aquaculture etc.) for the purpose of the EU due diligence system. One significant advantage of the due diligence approach that can hardly be overstated is that it would side-step the very complex and ongoing international debate on how much legally binding force a specialised ABS system must have to be recognised as "specialised international ABS agreement" under the Nagoya Protocol. The FAO International Treaty on Plant Genetic Resources for Food and Agriculture is so far the only example for a legally binding specialised international treaty. The recently adopted Pandemic Influenza Preparedness Framework in the World Health Organization in contrast, appears to be a hybrid: it uses legally binding standard contracts for the sharing and transfer of virus samples in a non-legally binding framework. The legal status of this specialised ABS framework under the Nagoya Protocol is not entirely clear. Other issues arise in relation to the important work undertaken by the FAO Commission on Genetic Resources for Food and Agriculture, as a contribution to food security. Nevertheless, under current circumstances it is unclear whether there is a critical mass and sufficient momentum for agreeing on legally binding ABS systems beyond the 2001 International Treaty on Plant Genetic Resources. Certainly,

		however, the FAO Commission will conclude important guidance documents clarifying the expectations of states on how to apply ABS considerations to the use of animal genetic resources, in aquaculture, in the case of forest genetic resources, invertebrates etc. The due diligence approach would not only accommodate but actively support the effective implementation of such guidance.
- Handling of Party-non-Party relationships	+	A due diligence approach would facilitate interaction of EU stakeholders with partners from non-Parties to the Protocol. Partners in non-Parties are outside the reach of EU law on user-compliance. However, the possibility of complying with the due diligence obligation by implementing a recognised best practice standards also means that partners employing the same or similar standards, wherever they are located, would effectively also comply with EU user compliance rules. It must be noted in this context, that some existing best practice (BIO biotechnology industry organisation, IFPMA International Federation of Pharmaceutical Manufacturers & Associations) are as such of global nature or are used well beyond the EU (IPEN International plant exchange network, MOSAICC Micro-Organisms Sustainable use and Access regulation International Code of Conduct). Regularly, it is in the best economic interest of all sides to a partnership to employ the same or very similar management standards to reduce transaction costs and raise legal certainty. An EU-level due diligence system would actively encourage such approach.
- Coherence with existing EU laws	+	- Option UC-2 would require a focussed regulatory intervention by establishing a new norm of Union law in a new field of activity. It is considered as an advantage that the option would not require the re-opening of existing EU laws. - EU users, particularly those involved in applied research, product development and commercialisation are familiar with the due diligence concept. On 18 June 2012, the International Chamber of Commerce Task Force on ABS has explicitly identified a due diligence approach as suitable for implementing the Nagoya Protocol in a way that allows industry buy-in.
- Support to special considerations	++	Option UC-2 allows establishing special considerations on genetic resources for food and agriculture or on public health concerns and would actively work in support in support of such specialised rules.
- Ability to accommodate differences between sectors	++	It is characteristic of the due diligence approach that the required standard of care varies depending on the type of user, its capacity to take measures, its placement in the genetic resources value chain, or sectoral characteristics. Option UC-2 would therefore fully meet the requirements of EU stakeholders for flexibility to accommodate for their widely different situations and capabilities. On

		18 June 2012, the International Chamber of Commerce Task Force on ABS explicitly identified a due diligence approach as suitable for implementing the Nagoya Protocol in a way that allows industry buy-in and that accommodates for the widely differing realities in different parts of industry. Under this option, the Commission would, where it seems necessary to support consistent implementation, develop guidance documents that would articulate specific facets of the due diligence obligation for specific groups of users.
- Flexibility to allow for future development and fine-tuning	+	Option UC-2 is also well suited to adjust to future developments, particularly where the EU Regulation only sets out a "headline" due diligence obligation on EU users and leaves the articulation of this obligation in specific contexts to the users themselves, eventually supported by Commission guidance documents. In such setting, the general due diligence obligation set out in the EU Regulation would not need to be changed to account, for instance, to new developments in technical tools for tracking and monitoring genetic resources flow. It would only be necessary to inform users about the availability of such tools and eventually update relevant guidance documents.
- Improving the knowledge base about acquisitions, transfer and use of genetic resources in the EU	+	The due diligence approach is focussing on the activity of utilising genetic resources rather than on the tracking of individual transactions of specific genetic resources. All those engaged in utilisation activities would be obliged to seek, keep and pass-on the minimum information required for access and benefit-sharing to work. This suggests that, over a few years of operation, the due diligence system would very significantly improve the information base for assessing genetic resources flow and use in the EU and for evaluating the effectiveness of the policy.
Economic impacts		
- Creation of an EU-level playing field	+	The due diligence obligation would generally apply to all activities of utilisation within EU jurisdiction. It would create a common baseline of user-compliance efforts throughout the EU and establish an EU-level playing field. An EU-level playing field is particularly beneficial for SMEs and for the efficient use of public funds spent in favour of gene banks, botanical gardens, academic or applied research.
- Correspondance with existing utilisation practices	+/++	The due diligence approach would maximize correspondence with existing utilisation practices of genetic resources in the EU. As identified in the EU baseline, these practices are very diverse. Users face different challenges and opportunities in relation to ABS in different industries. Nevertheless,

		there are some common characteristics and common challenges in the upstream and in the downstream part of the genetic resources value chain in the EU. To comply with their due diligence obligation, EU users would need to add an ABS-specific element to their existing practices. They would need to identify for themselves how best to seek, keep and pass-on the minimum information required for access and benefit-sharing to work. This includes information on the origin or source of genetic material, on the time of acquisition and on eventually applicable benefit-sharing obligations set out in a benefit-sharing contract. It would be left to users to identify the most suitable and cost-effective way for meeting their obligation. Responses found will depend on their specific placement in the genetic resources value chain and on the type of research and development activity conducted. To give some examples: An SME in the biotechnology sector might decide making use of standardised or model material transfer agreements when acquiring or passing on research material. An academic research groups could decide to deploy a low-cost software tool for tracking and monitoring the flow of genetic resources utilised amongst members of the group. Companies from the biocontrol or cosmetics industries that directly collect genetic resources in the wild might subscribe to an industry-wide recognised best practice code of conduct.
- Legal certainty and legal risks	0/+	Option UC-2 foresees that the Commission would, where it seems useful to support consistent implementation, develop guidance documents that would articulate specific facets of the due diligence obligation for specific groups of users. The EU Regulation would furthermore establish that implementation of best practice codes of conduct is a way of complying with the due diligence obligation. Users of genetic resources that act in conformity with the guidance documents or that decide to implement a best practice code of conduct would have <u>legal certainty</u> of complying with their due diligence obligation.
- Distribution of impacts along the value chain	0/+	As regards the distribution of costs along the genetic resources value chain, it seems that two main factors are at play: First, the due diligence obligation requires all users to seek, keep and pass on minimum information required for access and benefit-sharing to work. Not one of the stakeholders that responded to the public consultation, that participated in ad hoc meetings, or that was interviewed by the external study team has indicated that it would be in principle impossible or unworkable for them to add some basic consideration on ABS issues to their current practices. Many stakeholders have clearly stressed, however, that they would prefer an approach to implementation that provides for flexibility across sectors and that minimizes necessary changes to current practices. On this basis, it

		seems safe to assume that the due diligence approach would not overburden any of the actors in the genetic resources value chain in the EU. Second, it is characteristic of the due diligence approach that the required standard of care varies depending on the type of user, its capacity to take measures, its placement in the genetic resources value chain, or sectoral characteristics. This means that the approach has flexibility to keep eventual costs proportional to the respective capacities of all particular actors in the value chain. It can, however, not be excluded that individual researchers, SMEs and micro-enterprises would face relatively higher costs for implementing the due diligence obligation than other actors with more capacity.
- SMEs and micro-enterprises	0/+	SMEs, micro-enterprises and individuals involved in basic research on genetic resources would particularly benefit from the creation of an EU-level playing field for the utilisation of genetic resources. As is apparent from the EU baseline, SMEs and micro-enterprises play critical roles in different sectors utilising genetic resources in the EU. One example for this is the biocontrol industry where SMEs represent the vast majority of companies in the market. Another example is the research-based pharmaceutical industry, where SMEs play a very important role in developing lead substances or candidate products for the large multinational companies. SMEs also play an important role in the cosmetics industry, where they co-exist with a few major international cosmetics companies. The positive effects on SMEs of creating an EU-level playing field for user-compliance measures might, however, be partially compensated by the relatively higher costs that SMEs would have for implementing their due diligence obligation, when compared with other actors with more capacity.
- Research and development opportunities	+	It is assumed that the legal certainty, low transactions costs and sectoral flexibility associated with Option UC-2 will translate into an enabling context for research on genetic resources or associated traditional knowledge. This will maximise research and development opportunities for EU researchers and EU companies engaged in markets for nature-based products and services.
- International competitiveness	+	Enhanced research and development opportunities are further expected to benefit the EU's international competitiveness. This effect will be particularly nuanced in relation to states with major user interests that have not (yet) ratified the Nagoya Protocol. Researchers and companies from non-Parties with predominant user interests might face increasing difficulties to secure access to quality samples of genetic resources, particularly from the so called mega-diverse group of countries.

- Monitoring (effectiveness, efficiency) and costs)	0/+	The compliance of EU users with their due diligence obligation would be monitored by public research funding agencies at EU and Member State levels and other designated authorities of the Member States. Both cases would not require the establishment of new administrative structures. To reduce the administrative burden from monitoring, users would be obliged to declare at designated points that they complied with their due diligence obligation.
- Public costs (EU-level, MS level, one-off, recurring)	0	Monitoring under this option would be primarily based on declarations by users at identified points that they have been diligent when utilising genetic resources. Such declarations would be channelled to already existing Member State authorities or to the national competent authority(ies) that each Party to the Nagoya Protocol must establish. In addition, Member State authorities would be empowered to do *ad hoc* compliance checks. These considerations suggest that the monitoring costs for this option would primarily arise at the level of the Member States, but would not require setting up new institutions or structures beyond those required for becoming a Party to the Protocol in the first place.
Social impacts		
- Potential to contribute to social objectives (health, food security, nutrition etc)	+	Option UC-2 would create an enabling context for research, development and innovation in nature-based industries. It would therefore positively contribute to the achievement of important social objectives, be it health, nutrition, food security or else.
- Protection of the rights of indigenous and local communities	+	The general due diligence obligation would also extend to benefit-sharing for the use of traditional knowledge associated associated with genetic resources as documented in domestic access permits and in mutually agreed terms. Option UC-2 would thus contribute to an effective protection of the rights of indigenous and local communities over their traditional knowledge.
Environmental impacts		
- Enhancing knowledge base for biodiversity conservation	+	Option UC-2 would maximise the likelihood of important discoveries
- Potential for generating non-monetary and monetary benefits in favour of conservation and sustainable use of biological diversity	+	Option UC-2 would maximise the generation of benefits that could flow to conservation purposes.

Option UC-3: General due diligence obligation on EU users complemented by formally recognising those collections that are "trusted sources" for genetic resources

Option UC-3 combines a due diligence system as described and analysed in Option UC-2 with a system to give formal recognition to collections with control measures in place to assure that only well documented samples of genetic resources are made available for their utilisation. Users of genetic resources that acquire sample from a recognised collection would thereby comply with a major part of their due diligence obligation. The below analysis repeats the analysis already done for Option UC-2 and highlights in form of underlined text aspects that are additional or different from Option UC-2 and where different gradings emerge.

Criteria for analysing impacts	Grading	Motivation of the grading against the criteria
Criteria specific to Access and Benefit-sharing and to the Nagoya Protocol		
- Specialised ABS agreements and processes (respect and mutually supportive)	++	The due diligence approach would allow for full recognition of specialised ABS systems. Indeed, it could enhance the functionality of such specialised systems, by obliging EU users to be diligent that the specific rules of specialised ABS systems are respected. A due diligence approach would also provide a good basis for establishing mutual supportiveness. The Commission could develop and update EU-level guidance documents that would articulate how EU users would exercise their due diligence to establish mutual supportiveness in a specific context, for example in relation to the important work done by the FAO Commission on Genetic Resources for Food and Agriculture. It would also seem possible to reference internationally agreed guidance documents (such as the FAO Interlaken Plan of Action on Animal Genetic Resources) for the purpose of the EU due diligence system.
- Handling of Party-non-Party relationships	++	The due diligence approach would also facilitate interaction of EU stakeholders with partners from non-Parties to the Protocol. Partners in non-Parties are outside the reach of EU law on user-compliance. However, the possibility of complying with the due diligence obligation by implementing a recognised best practice standards also means that partners that employ the same or similar standards, wherever they are located, would effectively also comply with EU user compliance rules. It must be noted in this context, that some existing best practice (BIO, IFPMA) are as such of global nature or are used well beyond the EU (IPEN, MOSAICC). Regularly, it is in the best economic interest of all sides to a partnership to employ the same or very similar management standards to reduce transaction costs and raise legal certainty. An EU-level due

		diligence system would actively encourage such approach. A system for formally recognising collections as trusted sources would strengthen networks of collections with major partner countries, including with collections from non-Parties to the Protocol. The EU baseline shows that it is a constitutive feature of collections in the EU and beyond to exchange samples between themselves. The system for recognizing collections as "trusted sources" would build on existing best practice codes of conduct such as IPEN or MOSAICC and thus increase their relevance and reach. The formal recognition of a collection under the EU system would thus strengthen its credibility in EU and international networks. One important benefit of this would be a more facilitated exchange with collections in major partner countries, including non-Parties. The recent case of the Svalbard Global Seed Vault shows that some countries are quite hesitant to deposit in permafrost duplicates of their genetic resources over which they hold sovereign rights in collections outside their jurisdiction, even if the depositor remains the owner of the deposit (no transfer of ownership to the seed vault).
- Coherence with existing EU laws	+	The due diligence approach would require a focussed regulatory intervention by establishing a new norm of Union law in a new field of activity. It is considered as an advantage that the option would not require the re-opening of existing EU laws. EU users, particularly those involved in applied research, in product development and commercialisation, are familiar with the due diligence concept. On 18 June 2012, the International Chamber of Commerce Task Force on ABS has explicitly identified a due diligence approach as suitable for implementing the Nagoya Protocol in a way that allows industry buy-in.
- Support to special considerations	++	The due diligence approach allows establishing special considerations on genetic resources for food and agriculture or on public health concerns. Indeed, as explained above, the general due diligence obligation could be used to strengthen, for example, the proper use of the WHO system on the rapid sharing of virus samples in case of pandemic threats.
- Ability to accommodate differences between sectors	++	It is characteristic of the due diligence approach that the required standard of care varies depending on the type of user, its capacity to take measures, its placement in the genetic resources value chain, or sectoral characteristics. The due diligence approach would therefore fully meet the requirements of EU stakeholders for flexibility to accommodate for their widely different situations and capabilities. Under this option, the Commission would, where it seems necessary to support consistent implementation, develop guidance documents that would articulate specific facets of the

		due diligence obligation for specific groups of users.
- Flexibility to allow for future development and fine-tuning	+	The general due diligence obligation is well suited to adjust to future developments. The general due diligence obligation would not need to be changed to account, for instance, to new developments in technical tools for tracking and monitoring genetic resources flow. It would only be necessary to inform users about the availability of such tools through an update of relevant guidance documents.
- Improving the knowledge base about acquisitions, transfer and use of genetic resources in the EU	++	The due diligence approach is focussing on the activity of utilising genetic resources rather than on the tracking of individual transactions of specific genetic resources. All those engaged in utilisation activities would be obliged to seek, keep and pass-on the minimum information required for access and benefit-sharing to work. This focus will, over a few years of operation, very significantly improve the information base for assessing genetic resources flow and use in the EU and for evaluating the effectiveness of the policy. Recognised collections would need to keep records of all genetic resources made available for their utilisation, establish unique identifiers and deploy low costs tracking tools to monitor the exchange of samples with other collections and the transfer of samples to commercial and non-commercial users outside their network. The EU baseline shows that the large majority of EU users acquire their samples for conducting research and development from collections, mostly from collections in the EU. Establishing an EU-system for recognising collections as trusted sources would therefore significantly improve the information base on how genetic resources in the EU are acquired and transferred. This improvement would be additional to the one achieved through Option UC-2 that is focussing more on utilisation activities.
Economic impacts		
- Creation of an EU-level playing field	++	The due diligence obligation would generally apply to all activities of utilisation within EU jurisdiction. It would create a common baseline of user-compliance efforts throughout the EU and establish an EU-level playing field. This would be particularly beneficial for SMEs and for the efficient use of public funds spent in favour of gene banks, botanical gardens, academic or applied research. Collections formally recognised as "trusted sources" under this option would become highly credible sources of genetic resources and would also be considered as particularly reliable partners in EU and international networks of collections. The existence of these collections would contribute

		to the establishment of a transparent EU market for quality samples of genetic resources and thus to establishing an EU-level playing field
- Correspondance with existing utilisation practices	+/++	The due diligence approach would maximize correspondence with existing utilisation practices of genetic resources in the EU. As identified in the EU baseline, these practices are very diverse. Users face different challenges and opportunities in relation to ABS in different industries. Nevertheless, there are some common characteristics and common challenges in the upstream and in the downstream part of the genetic resources value chain in the EU. To comply with their due diligence obligation, EU users would need to add an ABS-specific element to their existing practices. They would need to identify for themselves how best to seek, keep and pass-on the minimum information required for access and benefit-sharing to work. This includes information on the origin or source of genetic material, on the time of acquisition and on eventually applicable benefit-sharing obligations set out in a benefit-sharing contract. It would be left to users to identify the most suitable and cost-effective way for meeting their obligation. Responses found will depend on their specific placement in the genetic resources value chain and on the type of research and development activity conducted. To give some examples: An SME in the biotechnology sector might decide making use of standardised material transfer agreements when acquiring or passing on research material. An academic research groups could decide to deploy a low-cost software tool for tracking and monitoring the flow of genetic resources utilised amongst members of the group. Companies from the biocontrol or cosmetics industries that directly collect genetic resources in the wild might subscribe to an industry-wide recognised best practice code of conduct.
- Legal certainty and legal risks	+	The basic due diligence approach foresees that the Commission would, where useful to support consistent implementation, develop guidance documents articulating specific facets of the due diligence obligation for specific groups of users. The EU Regulation would furthermore establish that implementation of best practice codes of conduct is a way of complying with the due diligence obligation. Users of genetic resources that act in conformity with the guidance documents or that decide to implement a best practice code of conduct would have legal certainty of complying with their due diligence obligation. Users of genetic resources within the EU that acquire samples from recognised collections would have full legal certainty that they comply with their due diligence obligation insofar as it requires users to seek relevant information on eventually applicable ABS requirements. Users that acquire samples from other sources would need to be more diligent that information received with a sample

		is complete and reliable.
- Distribution of impacts along the value chain	+	As regards the distribution of costs along the genetic resources value chain, two main factors are at play: First, the due diligence obligation requires all users to seek, keep and pass on minimum information required for access and benefit-sharing to work. Not one of the stakeholders that responded to the public consultation, that participated in ad hoc meetings, or that was interviewed by the external study team has indicated that it would be in principle impossible or unworkable for them to add some basic consideration on ABS issues to their current practices. Many stakeholders have clearly stressed, however, that they would prefer an approach to implementation that provides for flexibility across sectors and that minimizes necessary changes to current practices. On this basis, it seems safe to assume that the due diligence approach would not overburden any of the actors in the genetic resources value chain in the EU. Second, it is characteristic of the due diligence approach that the required standard of care varies depending on the type of user, its capacity to take measures, its placement in the genetic resources value chain, or sectoral characteristics. This means that the approach has flexibility to keep eventual costs proportional to the respective capacities of all particular actors in the value chain. It can, however, not be excluded that individual researchers, SMEs and micro-enterprises would face relatively higher costs for implementing the due diligence obligation than other actors with more capacity. The main benefits of recognising collections as "trusted sources" would arise for EU users that typically acquire their research and development material from collections. The EU baseline shows that this includes academic researchers and several commercial sectors utilising genetic resources in Europe. Academic researchers heavily rely on genetic material from public collections, particularly from botanical gardens. Commercial users of genetic resources in contrast source material from public as well as from private collections. The horticultural industry, for example, predominantly relies on ex situ collections for its research and development; this includes in-house collections, commercial collections, or botanical gardens. The industrial biotechnology sector heavily relies on culture collections. Culture collections are also important sources of material for industries involved in natural products research as well as for the pharmaceutical and the food and beverage industries. Private and in-house collections are particularly important in the seed industry, in addition to public gene banks and the centres of the Consultative Group on International Agricultural Research. The

		benefits of Option UC-3 would particularly arise in the *early and middle part* of the genetic resources value chain.
- SMEs and micro-enterprises	+	SMEs, micro-enterprises and individuals involved in basic research on genetic resources would particularly benefit from the creation of an EU-level playing field for the utilisation of genetic resources. As is apparent from the EU baseline, SMEs and micro-enterprises play critical roles in different sectors utilising genetic resources in the EU. One example for this is the biocontrol industry where SMEs represent the vast majority of companies in the market. Another example is the research-based pharmaceutical industry, where SMEs play a very important role in developing lead substances or candidate products for the large multinational companies. SMEs also play an important role in the cosmetics industry, where they co-exist with a few major international cosmetics companies. The positive effects on SMEs of creating an EU-level playing field for user-compliance measures might, however, be partially compensated by the relatively higher costs that SMEs would have for implementing their due diligence obligation, when compared with other actors with more capacity. The above identified likely distribution of benefits from establishing recognised collections in the early and middle part of the genetic resources value chain also suggests that Option UC-3 would be particularly beneficial to *academic researchers and to SMEs and micro-enterprises*. As shown in the EU baseline, SMEs and micro-enterprises are particularly active in the research intensive part of the pharmaceutical industry value chain, in the food and beverage industries, but also in the seed and horticulture industries.
- Research and development opportunities	++	It is assumed that the legal certainty, low transactions costs and sectoral flexibility associated with the basic due diligence obligation will translate into an enabling context for research on genetic resources or associated traditional knowledge. This will maximise research and development opportunities for EU researchers and EU companies engaged in markets for nature-based products and services. The particular advantages of Option UC-3 translate into a better operating environment for academic researchers, SMEs and micro-enterprises which are the "powerhouse" for nature-based innovation in the EU. This suggests that Option UC-3 has a higher potential than Option UC-2 to maximise research and development opportunities on genetic resources.
- International competitiveness	++	Enhanced research and development opportunities are further expected to benefit the EU's

		international competitiveness. This effect will be particularly nuanced in relation to states with major user interests that have not (yet) ratified the Nagoya Protocol. Researchers and companies from non-Parties with predominant user interests might face increasing difficulties to secure access to quality samples of genetic resources, particularly from the so called mega-diverse group of countries. The more favourable innovation effects of Option UC-3 translate into a higher potential than Option UC-2 to benefit the EU's international competitiveness.
- Monitoring (effectiveness, efficiency) and costs)	0/+	The compliance of EU users with their due diligence obligation would be monitored by public research funding agencies at EU and Member State levels and other designated authorities of the Member States. Both cases would not require the establishment of new administrative structures. To reduce the administrative burden from monitoring, users would be obliged to declare at designated points that they complied with their due diligence obligation.
- Public costs (EU-level, MS level, one-off, recurring)	0	Monitoring under this option would be primarily based on declarations by users at identified points that they have been diligent when utilising genetic resources. Such declarations would be channelled to already existing Member State authorities or to the national competent authority(ies) that each Party to the Nagoya Protocol must establish. In addition, Member State authorities would be empowered to do *ad hoc* compliance checks. These considerations suggest that the monitoring costs for this option would primarily arise at the level of the Member States, but would not require setting up new institutions or structures beyond those required for becoming a Party to the Protocol in the first place. Collections that already implement best practice standards on access and benefit-sharing would incur only very limited costs for being formally recognised as "trusted sources". We do not have information on the costs for collections that do not yet meet these standards but wish to become registered. However, it seems important to recall that not becoming formally recognised as "trusted source" would entail no costs at all for collections. It would clearly be consistent with Option UC-3 if a Member State or the Commission decides to work with specific collections to help them being recognised as "trusted source" for genetic resources and thereby further add to an enabling context for those conducting research and development on genetic resources within the EU. The public costs for this Option would be the same at the EU-level as for Option UC-2. The administrative costs for recognising collections would fall on the Member States, but would be limited; they would not require establishing new administrative structures. The costs of establishing

		the EU-level register of recognised collections would be minimal. Such register, essentially a web-site, could be administered by the EU focal point for the Nagoya Protocol. The establishment of a focal point is an obligation on all Parties to the Protocol anyhow. Overall, it can be assumed that the limited additional costs for Option UC-3 compared to Option UC-2 would be outweighed by reduced costs for monitoring compliance of users with their due diligence obligation, particularly where monitoring is done on a risk-based approach. It would prima facie seem reasonable to assume that there is less risk of non-compliance by users sourcing from recognised collections, so less compliance checks would be in order for them.
Social impacts		
- Potential to contribute to social objectives (health, food security, nutrition etc)	++	Option UC-2 would create an enabling context for research, development and innovation in nature-based industries. It would therefore positively contribute to the achievement of important social objectives, be it health, nutrition, food security or else. Option UC-3 would contribute even more than Option UC-2 to an enabling context for research, development and innovation in nature-based industries. It would positively contribute to the achievement of important social objectives, be it health, nutrition, food security or else.
- Protection of the rights of indigenous and local communities	++	The general due diligence obligation would also extend to benefit-sharing for the use of traditional knowledge associated associated with genetic resources as documented in domestic access permits and in mutually agreed terms. Option UC-2 would thus contribute to an effective protection of the rights of indigenous and local communities over their traditional knowledge. Option UC-3 seems to have the same effect as Option B as regards protecting the rights of indigenous and local communities over their traditional knowledge.
Environmental impacts		
- Enhancing knowledge base for biodiversity conservation	++	Option UC-3 would contribute even more than Option UC-2 to raising the likelihood of important discoveries
- Potential for generating non-monetary and monetary benefits in favour of conservation and sustainable use of biological diversity	++	Option UC-3 would contribute even more than Option UC-2 to generating increased uses of genetic resources and consequently benefits that could benefit to conservation purposes

Option UC-4: Prohibition to utilise illegally acquired genetic resources or associated traditional knowledge with a "downstream" monitoring system

The main feature of Option UC-4 is a prohibition to utilize illegally acquired genetic resources or associated traditional knowledge in combination with a monitoring system that is based on an obligation of users to declare to public authorities at specific points in the value chain that genetic resources were utilised in conformity with applicable access and benefit-sharing requirements.

Criteria for analysing impacts	Grading	Motivation of the grading against the criteria
Criteria specific to Access and Benefit-sharing and to the Nagoya Protocol		
- Specialised ABS agreements and processes (respect and mutually supportive)	-	It would require very careful consideration to avoid that the prohibition has potentially disruptive effects on specialised access and benefit-sharing systems. One key question in this respect is on the nature of such systems to be excluded from the prohibition. Would a specialised ABS system necessarily be established through a binding international agreement, like the FAO Treaty on Plant Genetic Resources for Food and Agriculture? Would it suffice to have an international framework with some binding elements, such as the Pandemic Influenza Preparedness Framework recently agreed in the World Health Organization? Or would even genetic resource exchange in accordance with soft law instruments like the FAO Action Plan on Animal Genetic Resources for Food and Agriculture be excluded? And how to account for the fact that the standardised Material Transfer Agreement of the FAO Treaty is used for transactions of genetic resources that are not part of the multilateral system of this treaty? All of this is not clear. In part, it depends on global level considerations by the collective of the Parties to the Nagoya Protocol, in part on considerations and decisions taken by state representatives in the World Health Organization or in the UN Food and Agriculture Organization. This also means that the EU proposal would take a particular position on an issue that may well be decided in a different direction at global level a few years later, which would require a modification of the acquis and potentially significant adjustments to the practices of EU users of genetic resources.
- Handling of Party-non-Party relationships	-	In relation to non-Parties, it seems that a prohibition to utilise illegally acquired genetic resources could result in legal problems for maintaining collaborative partnerships and eventually also put EU

		users into a competitive disadvantage.
- Coherence with existing EU laws	-	A prohibition in an EU Regulation to utilise illegally acquired genetic resources is a new concept in Union law particularly in relation to the suggested system of disclosure obligations for monitoring compliance of users with the prohibition. Normally, the obligation of applicants to disclose information in intellectual property rights or product approval proceedings is balanced by legal protection received in form of an intellectual property right or a product approval. Option UC-4, however, suggests that disclosed information would potentially serve as basis for sanctions. This raises important questions on how to treat inadvertent disclosure of false or incomplete information, particularly considering the major challenge to users to obtain reliable information (see below). Option UC-4 would require the opening of a broad set of EU laws related to the marketing of products. This is a challenge in itself, as it might be difficult to limit the legislative discussion to only the issue of introducing a disclosure requirement. The alternative approach, waiting for a review of sectoral legislation, would not seem satisfactory for swift implementation and compliance with the Nagoya Protocol.
- Support to special considerations	-	It also seems unclear how the prohibition to utilise would relate to the special considerations required under the Protocol; particularly the link to genetic resources for food and agriculture would require clarification. One particularly important example concerns the treatment of pathogenic strains that are used for the purpose of plant resistance breeding. This activity clearly does not qualify as an emergency situation addressed in Article 8b) Nagoya Protocol. However, it might be addressed under the special considerations given to genetic resources for food and agriculture, or Parties may make it subject to their general ABS user-compliance system. The situation is not clear, but must be addressed and clarified by the collective of the Parties to the Nagoya Protocol to achieve a harmonious approach to implementation in an essentially global industry where the international exchange of breeding material and pathogenic strains for resistance breeding purposes is common day practice. It thus seems important not to pre-judge the basic approach taken to this matter. However, Option UC-4 would not give this flexibility.
- Ability to accommodate differences between sectors	--	It would seem equally unclear whether it is possible to craft the prohibition so that it works satisfactorily in all different sectors utilising genetic resources in the EU. The EU baseline shows different EU sectors utilise genetic resources in widely different ways and for different purposes. However, if the same prohibition applies to widely different research and development activities, EU users that wish to be on the right side of the law will need to determine very precisely for

		themselves when genetic resources were used to an extent that the prohibition applies and a utilisation activity must be disclosed. The definition of "utilisation of genetic resources" in Article 2(c) Nagoya Protocol provides a helpful starting point in this regard. However, it does not provide a clear conclusion in each and every case. It does not address, for instance, how to address situations where a genetic resource is used as a tool for facilitating other research and development projects (e.g. the use of laboratory animals in pharmaceutical research); it also does not give an indication whether an insight drawn from earlier research on genetic resources with ABS requirements attached that causally influences other research on genetic resources unrelated to ABS would still trigger the prohibition and disclosure obligations or not. These questions are anything but trivial. Absent full legal certainty on this point, some users – particularly those with limited profit margins (e.g. in the biocontrol industry) or limited means to obtain legal advice (e.g SMEs), or where very significant investments are made (e.g. pharmaceutical industry) - will rather discontinue the use of specific genetic resources than risking potentially heavy sanctions or losing an investment made.
- Flexibility to allow for future development and fine-tuning	-	Another downside of Option UC-4 is its limited flexibility for future development. There is no stricter measure than a prohibition to utilise. This means that any future adjustments to the Option could only go into the direction of softening the effects of the prohibition, by establishing specific exclusions or grace periods. This would be politically challenging.
- Improving the knowledge base about acquisitions, transfer and use of genetic resources in the EU	-	Option UC-4 would furthermore make only a limited contribution to improving the knowledge base. As it is designed, the system of prohibition and disclosure obligations would primarily generate information in cases where users have all necessary information at hand to proof their own compliance. It seems quite unlikely, however, that a user would voluntarily provide a public authority with information on its own non-compliance, with potential legal and economic consequences. The information generated under this Option would thus be largely irrelevant for understanding real flows of genetic resources throughout the EU economy or for analysing bottlenecks.
Economic impacts		
- Creation of an EU-level playing field	-/0	Although the prohibition to utilise illegally acquired genetic resources would apply to all EU users, it is quite certain not to result in an EU-level playing field. The main reason for this is the monitoring system that goes with the prohibition. Disclosure obligations would only selectively apply to some utilisation activities and thus result in a very uneven distribution of costs and risks. Collections and non-commercial researchers would normally not face disclosure obligations.

		However, such obligations would be unavoidable particularly for SMEs and micro-enterprises in the middle part of the genetic resources value chain that depend on intellectual property protection for creating commercial value and, where relevant, being able to sell innovations to bigger companies downstream. This group of actors would be caught between a rock and a hard place. A non-commercial researcher that has no risk of being checked has no reason to take on legal responsibility for the good legal status of material passed on for applied research. Larger companies at the end of the value chain (particularly in the pharmaceutical sector), however, would not be able to accept a legal guarantee from a SME as sufficient assurance that things are in order, knowing that SMEs regularly have limited means to verify ABS-compliance.
- Correspondance with existing utilisation practices	-	A prohibition to utilise illegally acquired genetic resources would apply to all activities defined as "utilisation" and all users that undertake such activities. In some case, such as collections (botanical gardens, culture collections, gene banks), a prohibition to utilise seems a manageable task. However, it would certainly create very significant if not insurmountable challenges where large sets of genetic resources are utilised. For example, it is typical for the applied research step in the pharmaceutical value chain to do high-throughput screening of tens of thousands of samples of a particular category in search of active compounds that react to a specified target. The screening activity as such qualifies as "utilisation of genetic resources" in the sense of the Nagoya Protocol. However, it would seem very unclear how, for example, a SME that is specialised on identifying and selling active compounds to the big pharmaceutical companies, could oversee or even verify at reasonable efforts or costs the good legal status of each of the tens of thousands of samples ordered from the catalogue of molecules of another company. This seems an unrealistic task. It is an entirely realistic task though, as would be the result of Option UC-2 or Option UC-3, to oblige the same company to actively seek information on the good legal status of a sample in relation to ABS if this sample has produced a "hit" in the screening exercise and now the SME wishes to research its properties in more detail with a view to identifying and isolating the active compound.
- Legal certainty and legal risks	--	A prohibition to utilise illegally acquired seems a clear obligation at face value. However, the EU baseline developed for the purpose of this IA shows that there is a real risk that establishing such prohibition would create legal uncertainty and legal risks for different EU users of genetic resources, particularly for SMEs and micro-enterprises. Two aspects appear particularly problematic: (i) knowing exactly when in legal terms the prohibition applies and disclosure must happen (see above) and (ii) the availability of critical information that allows users to determine where they factually stand in relation to the prohibition. This is a major challenge, particularly since

		the prohibition to utilise illegally acquired genetic resources would initially only be relevant for a fraction of genetic resources utilised in the EU; it would not apply to genetic resources acquired prior to the Convention's entry into force, nor to genetic resources collected in areas beyond national jurisdiction or to resources from free access jurisdictions. The EU baseline clearly shows that currently critical information about the origin or source of genetic resources and eventually applicable ABS requirements is not readily available to users. Worse, as shown above, the incentives created through this option would rather work against creating more transparency and information if early users in the chain have little incentive to provide all relevant information to subsequent users and indeed will regularly not be willing nor capable of issuing a legal guarantee for the good status of research material in relation to ABS. This means that users that must disclose would be left with a legal risk of disclosing false or incomplete information; a risk they could not manage themselves, if only through disrupting certain activities. Notably, the decision to disrupt an activity or not would be unrelated to the actual problematic character of material. In fact, it would be more likely on the expense of utilising genetic resources that are legitimately outside of the scope of ABS obligations, as it is easier for user to document compliance with ABS obligations where these exist (eg by presenting an internationally recognised certificate of compliance) rather than documenting the absence of such obligations. Users that are under the obligation to disclose will intend to negotiate with upstream user access conditions and guarantees that create legal certainty for them. To the extent the latter refuse, the user chain will be seriously disrupted.
- Distribution of impacts along the value chain	--	Option UC-4 would selectively apply to only some utilisation activities and thus result in a very uneven distribution of costs and risks. Collections and non-commercial researchers would normally not face disclosure obligations. However, such obligations would be unavoidable particularly for SMEs and micro-enterprises in the middle part of the genetic resources value chain that depend on intellectual property protection for creating commercial value and, where relevant, being able to sell innovations to bigger companies downstream. This group of actors would be caught between a rock and a hard place. A non-commercial researcher that has no risk of being checked has no reason to take on legal responsibility for the good legal status of material passed on for applied research. Larger companies at the end of the value chain (particularly in the pharmaceutical sector), however, would not be able to accept a legal guarantee from a SME as sufficient assurance that things are in order, knowing that SMEs regularly have limited means to verify ABS-compliance. As a result, one would need to expect disruptions in the genetic resources value chain where research material moves from collections or non-commercial research to SMEs and again, where

		research and development activities move from SMEs to larger companies that create the real economic value. This suggests that the prohibition to utilise illegally acquired genetic resources could stifle innovation in different sectors, and thus achieve exactly the opposite of what the Nagoya Protocol wants to achieve.
- SMEs and micro-enterprises	--	The costs of compliance under this option would fall on those involved in applied research and product development, be it public or private research institutes, SMEs or large companies. So a part of the user chain that is heavily populated by SMEs or micro-enterprises. Some of these players might decide to discontinue an utilisation activity rather than risking non-compliance with the prohibition. This also means that disruptive effects would likely affect the plant breeding and biocontrol sectors and also occur in the pharmaceutical value chain.
- Research and development opportunities	--	As regards research and development opportunities, one could argue that Option 3D essentially meet the demands of our international partners and will thus facilitate access to genetic resources for the benefit of EU users. However, this line of argument is not convincing. The EU-approach to user-compliance measures is unrelated to the capacity challenges of provider Parties, particularly those that are developing countries. Indeed, the more rigorous and inflexible the EU approach to user-compliance, the more difficult it would be to accept any but perfect implementation of the access provisions of the Protocol by provider countries. Second, the argument ignores that initially most genetic resources utilised in the EU will be legitimately outside of ABS requirements. It does not seem acceptable to make research and development on these genetic resources more difficult and reduce innovation potential by establishing a system that only works for genetic resources that have been acquired in third countries and that come with ABS requirements attached. Taken together, Option UC-4 as a real potential for stifling research and development, and innovation in different sectors. It would thus achieve exactly the opposite of what the Nagoya Protocol is supposed to achieve.
- International competitiveness	--	It is assumed that the negative impacts of this option on research and development and on innovation would translate into negatively effects for the EU's international competitiveness.
- Monitoring (effectiveness, efficiency) and costs)	--	As regards monitoring user compliance, it has already been observed that a prohibition that is linked to a system of disclosure obligations would systematically favour collecting information about compliant behaviour, but be unlikely to result in pertinent information on situations of non-

		compliance or reasons for non-compliance. - Another challenge, particularly for user sectors with long and complex innovation chains, is the focus of the disclosure obligation on facts and activities that happened in the past, often many years ago; when relevant information about legal access was generated or when such information should have been generated but actually was not. As shown above, under current circumstances it seems that users will face real difficulties in disclosing relevant information, when this is required. - It is even clearer though, that it is mostly beyond the means of public authorities of the Member States or the EU to identify situations where genetic resources were utilised in a relevant way and access and benefit-sharing obligations apply. - Indeed, the only way to establish this information with some certainty is if one knows the benefit-sharing contract concluded between the provider of a genetic resource and the first user. And this might be a document considered as partially confidential by providers and users. This suggests that the probation to utilise illegally acquired genetic resources cannot be effectively monitored unless there is an obligation on users to disclose relevant information and thereby self-identify as compliant with applicable ABS requirements or not. However, would it be consistent with notions of legal proportionality if a monitoring system only works if users are obliged to self-identify as potentially non-compliant and eventually face sanctions for utilising an illegally acquired genetic resource? In most situations, the burden of proof for illegal conduct rests on public authorities. Obligation on operators to document legal compliance before engaging in an activity is normally done for dangerous or inherently risky activities. Or it is done in situations where illegal behaviour would otherwise be the norm rather than the exception. Both aspects are not characteristic of the activity of utilising genetic resources. So Option UC-4 might raise concerns about being disproportionate as regards ends and means.
- Public costs (EU-level, MS level, one-off, recurring)	-/0	- A monitoring system based on an obligation on users to disclose relevant information would as such have limited costs. - However, as explained above, the proposed system is unlikely to be effective, except for identifying situations where users do comply with their obligations. The system would be largely ineffective in identifying situations of non-compliance. Obviously, monitoring authorities could put significant efforts into researching potential ABS-related problems of claims for intellectual property rights or product approvals. This might improve the effectiveness of this option, but would

		of course be quite costly and time-consuming.
Social impacts		
- Potential to contribute to social objectives (health, food security, nutrition etc)	--	Option UC-4 would very likely be damaging to research and development opportunities on genetic resources in the EU and thus not contribute to achieving important EU objectives on health, nutrition, or food security.
- Protection of the rights of indigenous and local communities	--	It would also not effectively support the protection of the rights of indigenous and local communities over their traditional knowledge that is associated with genetic resources.
Environmental impacts		
- Enhancing knowledge base for biodiversity conservation	--	Option UC-4 would very likely be damaging to research and development opportunities on genetic resources in the EU. It is thus assumed to negatively affect the enhancement of the knowledge base for biodiversity conservation.
- Potential for generating non-monetary and monetary benefits in favour of conservation and sustainable use of biological diversity	--	Given its overall difficulties, Option UC-4 would be unlikely to generate benefits in favour of the conservation and use of biological diversity.

ANNEX 7: THE GENETIC RESOURCES VALUE CHAIN

The Nagoya Protocol establishes a framework for acquiring and utilizing genetic resources over which states hold sovereign rights and primarily addresses the two sides of the ABS-relationship (providers and users). To better understand the implications of this framework, it is helpful to distinguish the typical steps taken in the genetic resources value chain. The value chain starts with the collection of some material and possibly ends with the successful commercialization of a final product.[12]

Step 1: Collecting genetic resources: Samples of genetic resources are collected from nature in a country. *In-situ* collecting activities are often complex endeavors, particularly where they require access to remote or sensitive areas, or engaging with indigenous and local communities. Foreign collectors will often collaborate with in-country-partners, such as local university institutes that participate in expeditions, help with identification of collected material, and keep reference-samples for inclusion in domestic collections.

Parties to the Nagoya Protocol that decide to require benefit-sharing for the use of their genetic resources must comply with the detailed access-related obligation of the Protocol. If implemented properly, these will result in transparent and enabling access frameworks with non-discriminatory, reliable, cost-effective and timely decisions.

Step 2: Storing samples of genetic resources in ex-situ collections: Samples of genetic resources, once identified and documented, are typically stored and maintained in *ex-situ* collections (botanical gardens, culture collections, gene banks). Collections in the countries where genetic resources were collected but also in third countries. Collections will keep relevant documentation on samples (scientific description, time and place of acquisition; collecting expedition, permits etc). They also exchange between each other information about samples or physically exchange samples through established (international) networks or cooperations. Collections also make samples available for R&D purposes. Very often, *ex-situ* collections in countries of origin will function as 'intermediaries' between those collecting samples in the wild and those conducting research on genetic resources.

The Nagoya Protocol does not explicitly mention *ex-situ* collections. However, Parties will work with *ex-situ* collections in the Protocol implementation. Collections in the countries where genetic resources were collected seem well placed to grant prior informed consent for access to genetic resources over which this Party holds sovereign rights. *Ex-situ* collections also hold critical information that helps assessing whether specific samples come with ABS-related rights and obligations.

Step 3: Basic research on genetic resources: Basic research does not pursue an economic purpose. Basic research on the genetic or biochemical properties of genetic resources is done within *ex-situ* collections and by researchers from universities or other research institutes. Such research generates critical knowledge important for biodiversity conservation and characterisation. It is thus directly linked to the ability of Parties to meet their conservation

[12] It must be noted that these steps will not necessarily be taken for each sample of genetic material collected in the wild. Not all collected material is stored in collections. In a few cases material is collected by an agent of a company specifically interested in a sample of a known organism. Also, most basic research will not result in concrete applications. And much applied research ends unsuccessfully without moving to the development of a product. Likewise, many development efforts never make it to the product approval stage.

obligations under the Convention. Typically, the results of basic research are published. They are also used as basis for further applied research. However, researchers involved in basic research will normally not be aware at this stage of an eventual commercial relevance of their findings.

The Nagoya Protocol considers basic research as "utilization of genetic resources". This reflects that basic research is normally the basis and starting point for further, applied and commercially oriented uses. The Protocol obliges its Parties to give consideration to the important role of non-commercial research, including through simplified access measures. Other important considerations include focusing on non-monetary benefit-sharing during this phase of utilization. The effective implementation of these obligations by provider Parties rest in part on credible user-compliance measures taken in 'user jurisdictions' to avoid that privileges given to non-commercial research create loopholes for benefit-sharing. Indeed, a key challenge for credible user compliance systems is to ensure that those engaged in non-commercial research maintain the link to eventual ABS-obligations, especially in case of change in intent.

Step 4: Applied research on genetic resources: Applied research seeks to identify specific value of genetic resources in a specific context. Interesting discoveries will normally be protected through available forms of intellectual property rights before publishing important findings in specialized journals. Applied research on genetic resources is done by a broad set of actors that includes publicly funded research institutes and many SMEs, particularly in the biotechnology sector. Applied research also happens in R&D departments of large companies that develop and sell products.

The Nagoya Protocol considers applied research as "utilization of genetic resources". Specific benefit-sharing obligations during this phase must be established in MAT. The key challenge for credible user compliance systems is to ensure that those engaged in applied research maintain the link to eventual ABS-obligations. This is also important for legal certainty. No responsible company will move from applied research to product development, and decide on the necessary investments, unless it can oversee the legal and economic risks involved.

Step 5: Developing products involving R&D on genetic resources: Genetic resources play a direct or indirect role in the development of a broad range of products in a wide range of industries. The EU situation in this regard is detailed in Annex 8.

The Nagoya Protocol considers the development of products that involve R&D on the genetic and/ or biochemical composition of genetic resources as "utilization" of such resources". Specific benefit-sharing obligations are established in MAT. They will constitute part of the economic calculation of the company developing a product.

Step 5: Commercializing products that are based on genetic resources: Genetic resources play a direct or indirect role in the development of products put on the market. In some sectors of activity, companies will need to obtain a permit or approval prior to the marketing of a product.

The Nagoya Protocol establishes that benefit-sharing claims for "subsequent applications or commercialization" of R&D on genetic resources must be pursued on the basis of MAT. Indeed, the scope and form of eventual benefit-sharing obligations can only be determined on the basis of a concrete benefit-sharing arrangement.

ANNEX 8: THE "EU BASELINE" - CURRENT PRACTICES OF UTILISATION OF GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE IN THE EUROPEAN UNION

Introduction

The information presented here provides an overview of the use and exchange of genetic resources and traditional knowledge associated with such resources as addressed in the Nagoya Protocol, for both commercial and non-commercial sectors affected by ABS issues in the EU. The information presented builds on 12 sectoral studies done by the external consultant team that are included in Annex 3 to the final report of the study[13].

Sectors analyzed were academic research, botanic gardens, culture collections, pharmaceutical industry, cosmetics industry, food and beverage industry, seed and propagating sector and horticulture, cultivated forest, animal breeding sector, biological control ("biocontrol") and industrial biotechnology. The baseline summarizes the findings of the sectoral studies and deals with issues such as the relevance of genetic resources and access and benefit sharing for each of these sectors, the different activities involved in the genetic resource user chain, the size and characteristics of the sectors, the types and role of genetic resources in the sectors, the relevance of research and development on genetic resources for innovation in the sectors, the sourcing of genetic resources and the sectoral approaches and practices regarding ABS.

As highlighted in the IA study proper, it must be noted that relatively little quantitative information is available on the use and exchange of genetic resources at sector level. Information gaps especially exist with respect to the amount of genetic resources (and 'wild' genetic resources in particular) utilised within most of the sectors; the sourcing of genetic resources (e.g. figures on the extent to which genetic resources are obtained from each type of source); and the economic relevance of the utilization of genetic resources (e.g. figures on revenues and profits from the sale of genetic resource based products). Available figures are often rough or indirect indicators of what is being sought. Therefore the analysis below is mainly qualitative rather than quantitative.

EU sectors involved in or affected by ABS activities

EU sectors "utilizing" genetic resources and/or traditional knowledge associated with genetic resources and commercializing products developed on the basis of such utilization are very diverse. The purpose and patterns of use and exchange of genetic resources as well as the structure of the sectors differ widely.

The following "sectors" were analyzed in developing the EU baseline:

[13] All bibliographic references have been taken from the contractors sectoral studies. Data collection methods for the sectoral studies involved a review of published and 'grey' literature, a review of the replies of stakeholders to the European Commission's public consultation on the implementation of the Nagoya Protocol and semi-structured interviews, phone calls and e-mail correspondence with stakeholders from each of the sectors (industry, government, NGOs and research institutions).

- Botanic gardens, defined as "institutions holding documented collections of living plants for the purposes of scientific research, conservation, display and education";

- Culture collections, defined as "organizations established to acquire, conserve and distribute microorganisms and information about them to foster research and education";[14]

- Academic research (universities and research institutes);

- The biocontrol sector, which mainly develops techniques for crop protection whereby predatory or parasitic living organisms (so-called "biocontrol agents") are being used to control pests;

- The industrial biotechnology sector, where companies develop, manufacture and sell products and services that "use or contain biological material as catalysts or feedstock to make industrial products", some of which develop enzymes, apply enzymes in biotransformation, develop whole cell catalysts and apply these in fermentation systems (HM Government, 2010);

- The plant breeding or seed industry, which engages in developing seeds and propagating material which are an essential input in crop production;[15]

- The horticulture sector, which includes a range of activities from plant breeding for ornamental purposes or amateurs (e.g. hobby gardening) to commercial production. The distinction between horticultural and agricultural production is difficult to make, but can be judged based on the scale of production;

- The cosmetics industry, which develops, manufactures and sells a range of products that include "traditional" cosmetics products, such as make-up and perfumes, as well as personal hygiene products such as tooth-care products, shampoos and soaps;

- The pharmaceutical industry, which engages in the discovery, development, and manufacture of drugs and medications;

- The farm animal breeding sector, which engages in the breeding and reproduction of farmed and companion animals. The five most important species for global agriculture are cattle, sheep, goats, pigs and chickens;

- The food and beverage industry;

- The Forestry and cultivated forest-based and related industries.

[14]Botanic gardens and culture collections (and other *ex situ* collections) are very much linked because they are often hosted by the same institutions, generally universities or public research institutes. In 2001, for example, 30% of the world's botanic gardens belonged to universities or higher education research institutes (Wyse Jackson *et al*, 2001). As for culture collections, 75% are estimated to belong to public sector entities (FAO, 2009).

[15]"Seed" refers to all planting material used in crop production, including seed grains, cuttings, seedlings, and other plant propagation materials.

Relevance of genetic resources and ABS for the sectors

Issues related to access and benefit-sharing to genetic resources affect many activities and sectors of the EU economy. While demand for access to 'wild' genetic resources has declined in most sectors, interest in research and development on genetic resources has increased overall (Laird and Wynberg, 2012). While some sectors, such as the biocontrol sector, rely heavily on genetic resources sourced from the wild, other sectors build most of their innovation on genetic resources that have already been subjected to improvements. Nevertheless there are common issues facing this wide range of sectors. These include: compliance with legislation in countries of origin related to the access to genetic resources and/or traditional knowledge associated with genetic resources, the difficulty of tracing the country of origin of genetic resources and conditions attached to their utilisation when resources are accessed through intermediaries, the issue of development costs and related issues of benefit sharing and good governance.

According to Laird and Wynberg (2012), demand for access to wild genetic resources has declined in most sectors, though interest in genetic resources overall has increased. The importance of ABS may vary amongst (and within) these sectors, as some sectors rely more on wild genetic resources than others.

The pharmaceutical industry relies partially on wild genetic resources: 26% of all new approved drugs over the last 30 years are either natural products or have been derived from a natural product (Newman and Cragg, 2012). ABS is particularly important for those pharmaceutical companies that are involved in natural products research, which only represents one segment of pharmaceutical R&D.

In the plant breeding or seed sector conventional breeders rely on modern varieties, though old varieties, landraces and crop wild relatives are still used to introduce specific features such as insect and disease resistance into breeding populations (Schloen *et al*, 2011). Therefore demand continues to be low for wild genetic resources. In fact demand for wild genetic resources in this sector has reduced in recent years to be replaced by sourcing from *ex situ* and private collections (Laird and Wynberg, 2012).

In the horticulture and animal breeding sectors, demand for wild genetic resources is also limited. In the horticulture sector, some companies continue to search for wild genetic resources with the aim to introduce novel ornamental species or to provide new variations of colour or other traits (Laird and Wynberg, 2012). In the animal breeding sector, demand for wild resources might increase somewhat in the future because of climate change. Many of the traits necessary to adapt to climate change may be found in locally adapted breeds (Hiemstra *et al*, 2010).

Overall the demand for wild genetic resources in the cosmetics sector is limited, as most cosmetics are reformulations of existing products. However, there is a niche market in cosmetics for which wild genetic resources are very important.

The food and beverage industries, on the other hand, rely significantly on wild genetic resources for their product development and marketing. In recent years interest in wild novel species and associated traditional knowledge has even increased. Demand for access to wild resources from these sectors is likely to be maintained as these help companies to market their products in competitive markets (Laird and Wynberg, 2012).

The biocontrol sector relies most heavily on wild genetic resources. The genetic resources used in biocontrol include plants, viruses, bacteria, fungi, insects, nematodes and invertebrates and are very often collected *in situ* as living organisms. Furthermore, EU *in situ* collections are as important as non-EU *in situ* collections (FAO, 2009).

For the forestry sector (Ad Hoc Working Group III on Climate Change and Forestry, November 2010), forest ecosystems play an important role in the global biochemical cycles. Forests act both as sources and sinks of greenhouse gases (GHG), through which they have significant influence on the climate. EU forests cover very varied environments, ranging from sub-arctic to Mediterranean and from alpine to lowland, including flood plains and deltas. Forests are home to the largest number of species on the continent (the Mediterranean region alone has 30,000 vascular plants), compared with other habitats, and provide important environmental functions.

For the non-commercial sectors, genetic resources originating from the wild are also very important. Botanic gardens, in fact, still substantially engage in bioprospecting activities, identification and documentation of new plant varieties, storage, basic research and, in particular, exchanges of plant genetic resources (mostly in the form of seeds) with other *ex situ* collections. Bioprospecting and basic research on microbial genetic resources also remains an essential activity for culture collections and microbiologists, due to the fact that most microbial genetic resources are still unknown.

Steps involved in the use and exchange of genetic resources – a general introduction

Figures 1 and 2 give a general cross-sectoral overview of the use and exchange of genetic resources in the EU. For the purpose of this study, a distinction has been made between “upstream” and “downstream” activities in the genetic resources user chain. "Upstream" activities are those at the beginning of the user chain and include collecting *in situ* genetic resources, importing genetic resources into the EU, storing genetic resources in *ex situ* collections (including identifying and documenting them for this purpose) and handing out genetic resources (see Figure)."Downstream" activities usually follow the upstream activities and include research (basic and applied) and development on genetic resources for both commercial and non-commercial purposes – i.e. activities that fall within the Protocol’s definition of “utilization” of genetic resources – and commercialization of genetic resource based products (see Figure 2). Figures 1 and 2 indicate that some players in the genetic resources user chain are typically involved in upstream activities, whereas others are typically involved in downstream activities. Actors typically involved in upstream activities include botanic gardens, culture collections, seed banks and other public or private *ex situ* collections. They are mainly involved in bioprospecting, collecting, identifying and storing genetic resources for public good purposes. These activities are also often linked because different collection types are often hosted by the same institutions, generally universities or public research institutes. A wide range of industries such as the biotechnology industry, the pharmaceutical industry, the plant breeding industry, the horticultural industry, the biocontrol industry, the cosmetic industry and the food & beverage industry are involved in downstream uses of genetic resources.

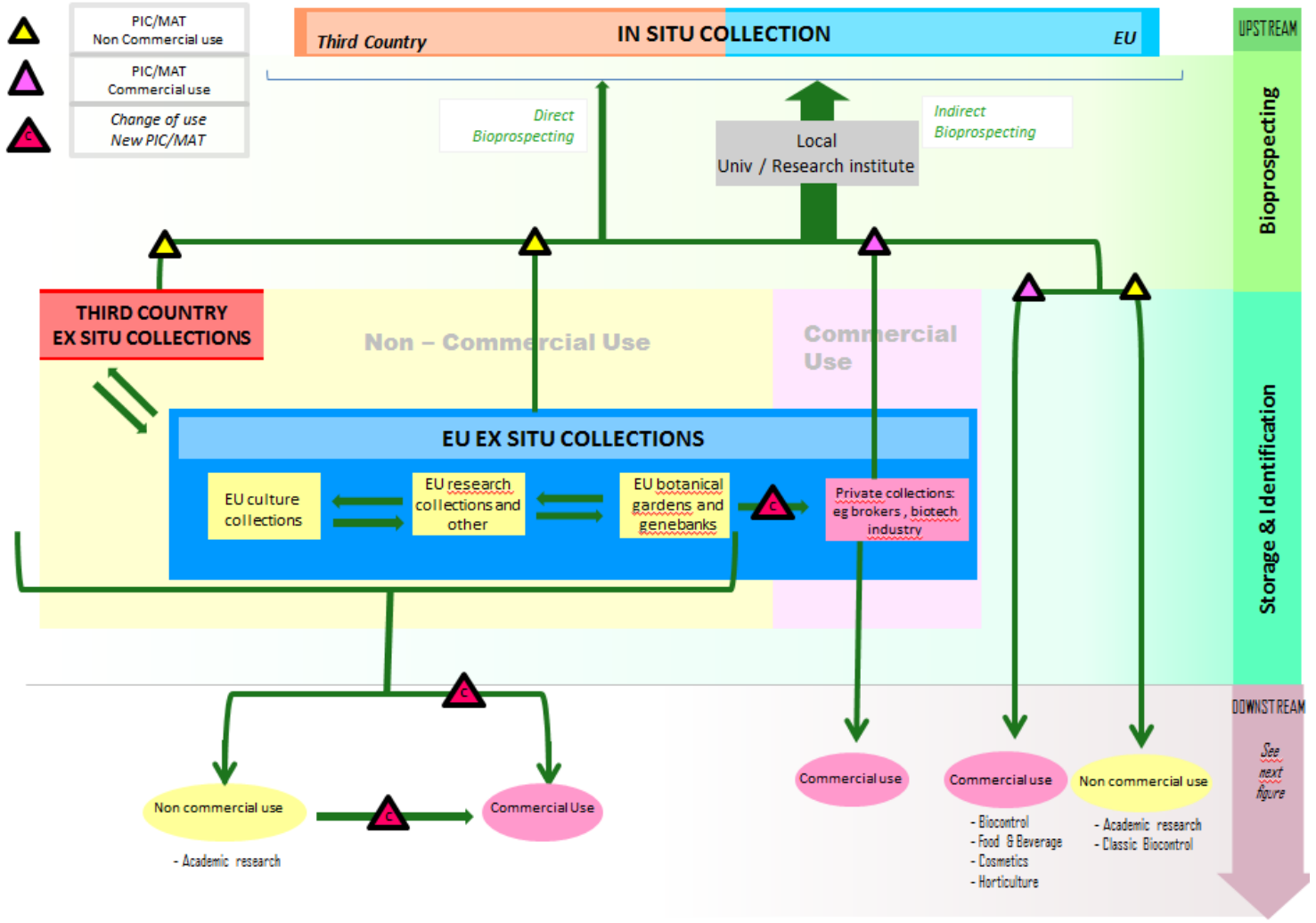
The distinction between upstream and downstream activities is useful for analytical purposes and for effectively implementing the Protocol in the EU. Firstly, actors engaged in the upstream part of the genetic resources user chain typically supply downstream users with genetic resource samples or valuable data related to genetic resources that may subsequently

be used for commercial R&D and eventually become the basis for a product. Secondly, the Protocol as it stands does not distinguish between upstream and downstream; it simply establishes a general obligation on Parties to ensure that genetic resources utilised in their jurisdiction were legally acquired in the country of origin. In the EU, it seems that upstream users, such as culture collections or botanic gardens, assume a major role as intermediaries in that they constitute the link between concrete access activities in source countries and subsequent utilization activities within the EU.

The upstream/downstream distinction applies to “types of activity” in the genetic resources user chain. While some sectors only engage in upstream or in downstream activities, other sectors (e.g. horticulture and academic research) are both involved in the upstream and downstream activities. Figures 1 and 2 below indicate the typical “placement” of sectors upstream and downstream.

In the following sections, we explain in more detail the upstream and downstream parts of the EU genetic resource user chain on the basis of the flowcharts in Figures 1 and.2.

Figure 1: EU upstream activities and actors involved



EU upstream activities and actors concerned

The first flow chart (Figure1) focuses on the upstream activities within the EU user chain. "Upstream" activities include collecting *in situ* genetic resources, importing genetic resources into the EU, storing genetic resources in *ex situ* collections (including identifying and documenting them for this purpose) and handing out genetic resources to downstream users or other *ex situ* collections. Actors typically involved in upstream activities include botanic gardens, culture collections, seed banks and other public or private *ex situ* collections. They are mainly involved in bioprospecting, collecting, identifying and storing genetic resources for public good purposes, except for private collections held by companies to support their commercial R&D. *Ex situ* collections (at least the public ones) are very much linked because they are often hosted by the same institutions, generally universities or public research institutes.

The flow chart shows that the bioprospecting or collecting of genetic resources *in situ* (either within or outside the EU) is mainly undertaken by botanic gardens, culture collections, universities and research institutes (referred to as "research collections" in the flow chart) and other *ex situ* collections (e.g. genebanks).[16] However, actors which engage more in commercial downstream activities (e.g. R&D) may also undertake bioprospecting; these include biocontrol companies and healthcare biotech companies. Bioprospecting can be done either directly or indirectly through partnerships with local universities and research institutes.

The indirect bioprospecting option is generally favoured as it provides for technical, scientific and administrative support. Local partners, for instance, can be helpful in dealing with the domestic procedures to obtain authorization for access to genetic resources. Where ABS procedures exist, authorities in the provider countries may require those who seek access to obtain "prior informed consent" (PIC) from the right holder – this right holder can be a private party (landowner), a national or regional authority or an indigenous or local community. Provider countries with authorization/ABS procedures in place usually also require those who seek access to negotiate mutually agreed terms (MAT) with the right holder on the further utilization of the genetic resources and the sharing of benefits arising from their utilisation. The PIC and MAT documents specify whether they cover utilisation for commercial or non-commercial purposes.

It should also be noted that EU actors (whether mostly active at the upstream or downstream level) might also source genetic resources from third country *ex situ* collections.

Major exchanges of genetic resources occur among the various *ex situ* collections both among EU *ex situ* collections and between EU and non-EU *ex situ* collections. This results *inter alia* from the need for identification of genetic resources by the collections. As this

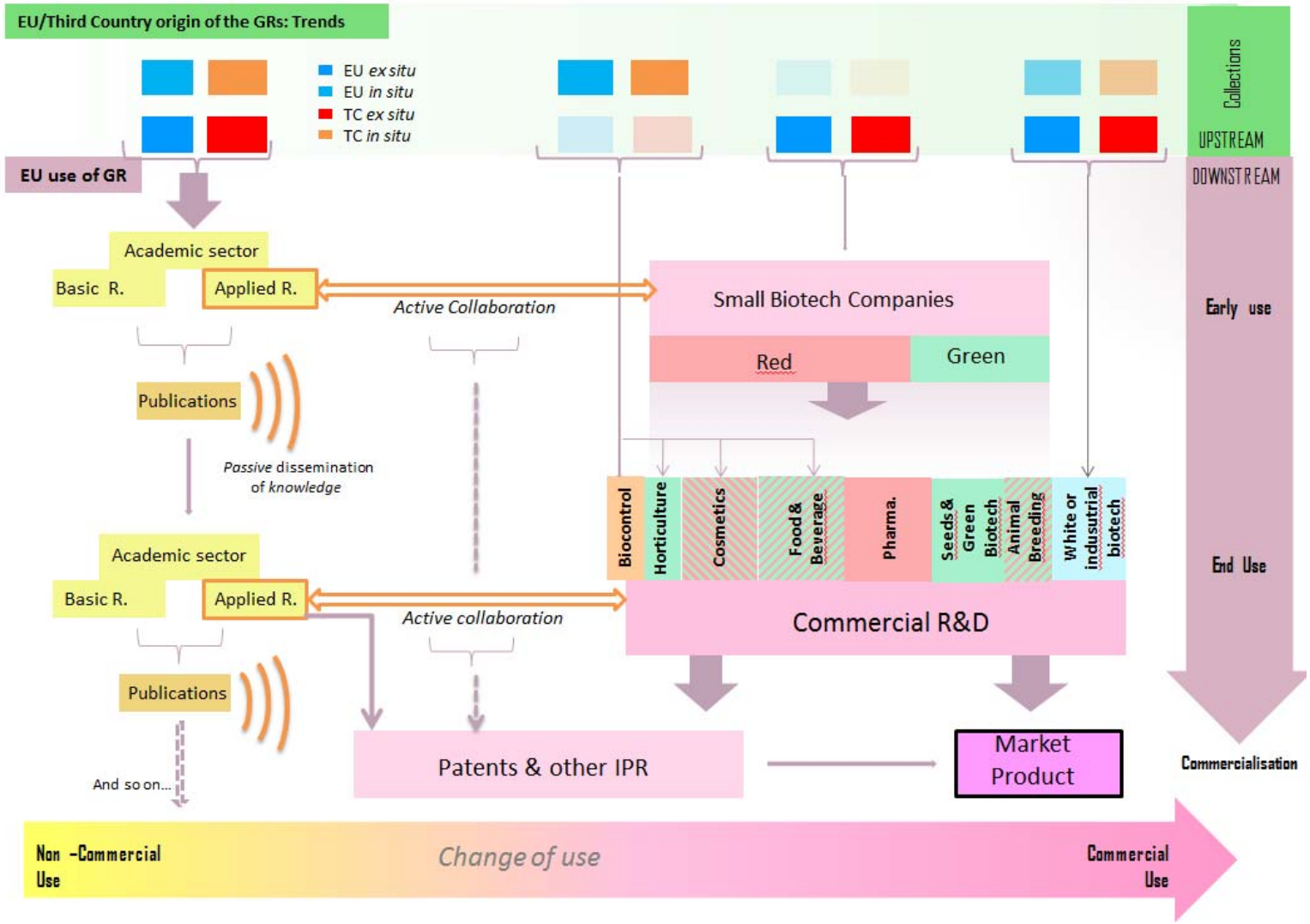
[16]Plant genebanks provide safe storage to ensure that the varieties and landraces of crops that underpin our food supply are secure and that they are easily available for use by farmers, plant breeders and researchers. Though genebanks are mainly used by universities, small companies and national agricultural research systems in developing countries, they are also sources of genetic material for plant breeding companies (Fowler *et al*, 2001; sCBD, 2008). Animal genebanks mainly fulfill conservation purposes and are less involved in the exchange of genetic material and its provision for breeding purposes (FAO, 2009; Schloen *et al*, 2011).

requires the scarce expertise of highly specialised taxonomists, international transfers of genetic resources are indispensable.

As Figure 1 shows, the actors that engage primarily in downstream activities (such as research and development on genetic resources) either obtain their genetic material directly from provider countries (through bioprospecting or third country *ex situ* collections) or indirectly through the EU *ex situ* collections.

When genetic material is transferred from *ex situ* collections (such as culture collections and botanic gardens) to commercial sectors active at the downstream level of the user chain, it must be checked whether the PIC and MAT documents that accompany the genetic resources coming from these *ex situ* collections allow for utilization with a commercial intent. This is often not the case. Hence, in many cases the downstream user or the *ex situ* collection will have to go back to the original provider country to obtain new prior informed consent from the right holder and to negotiate new mutually agreed terms in order to allow the genetic resources to be utilised for commercial purposes.

Figure 2: EU downstream activities and actors involved


EU/Third Country origin of the GRs: Trends
EU ex situ
EU in situ
TC ex situ
TC in situ
Collections
UPSTREAM
DOWNSTREAM
EU use of GR
Academic sector
Basic R.
Applied R.
Active Collaboration
Small Biotech Companies
Red
Green
Early use
Publications
Passive dissemination of knowledge
Biocontrol
Horticulture
Cosmetics
Food & Beverage
Pharma.
Seeds & Green Biotech
Animal Breeding
White or industrial biotech
Academic sector
Basic R.
Applied R.
Active collaboration
Commercial R&D
End Use
Publications
And so on...
Patents & other IPR
Market Product
Commercialisation
Non -Commercial Use
Change of use
Commercial Use

EU downstream activities and actors concerned

The second flow chart (Figure 2) focuses on the downstream activities within the EU user chain. "Downstream" activities include research (basic and applied) and development on genetic resources for both commercial and non-commercial purposes – i.e. activities that fall within the Protocol's definition of "utilization" of genetic resources – and commercialization of genetic resource based products which falls under the Protocol's provision for a fair and equitable benefit sharing. A wide range of industries such as the biotechnology industry, the pharmaceutical industry, the plant breeding industry, the biocontrol industry, the cosmetics industry and the food & beverage industry are involved in the downstream part of the genetic resources value chain.

In addition to the commercial sectors, the academic research sector is a major user of genetic resources, as it undertakes a lot of (primarily basic but also applied) research on genetic resources.Basic research on genetic resources is a fundamental starting point for further utilization of genetic resources. The academic sector is typically non-commercial; however, it maintains connections with commercial utilization of genetic resources. Academic publications, for instance, are freely used by economic sectors as inputs for commercial research and development. Furthermore, active collaboration with companies, including biotechnology firms, may result in applied research conducted within the academic sector contributing directly to commercial R&D. Finally, the academic sector undertaking applied research may seek intellectual property protection on innovations where industrial applications are possible and then negotiate license agreements with other downstream commercial users.

Another noteworthy sector in the downstream part of the user chain is the biotechnology sector. The sector is very much linked with agricultural input industries (such as the seed and animal breeding industry), the pharmaceutical industry and others, such as manufacturing industries, the "bioenergy" industry and the biomaterials industry, as it contributes directly to their research and development. Biotechnology can be subdivided as green, red and white biotechnology: green biotechnology refers to agricultural biotechnology; red biotechnology refers to pharmaceutical and medical biotechnology; and white biotechnology refers to industrial biotechnology. In reality, these subsectors may overlap. White biotechnology firms are separate in the flow chart as they are less dependent of the more downstream industries for the completion of a marketable product. This is different for instance from the red biotechnology companies which usually take care of the first stages of pharmaceutical research[17] and subsequently pass on – through outlicensing or acquisition – their products to the big pharmaceutical companies for further R&D and other subsequent stages in the value chain such as marketing (see also Figure 3).

At the most downstream part of the user chain one finds industries which undertake more downstream R&D and commercialize products; in terms of size the pharmaceutical industry and the food and beverage industries are the most significant, and the biocontrol industry is the smallest (see section 1.3 for more details). As far as the sourcing of genetic material is concerned, the industrial biotechnology sector differs from the agriculture and pharmaceutical

[17]Biotechnology companies are active across the user chain in the pharmaceutical industry, but their primary area of expertise is in the gene identification and target identification and validation stages upstream of product development and commercialisation.

biotechnology sectors. Industry biotechnology researchers regularly collect their own samples of materials, contrary to the case in the agricultural and pharmaceutical sectors (ten Kate & Laird, 1999). The biocontrol sector is also a special case as it relies heavily on its own bioprospecting activities.

Size and characteristics of relevant sectors

Global market/size and development prospects

Sectors primarily operating upstream include academic research, botanic gardens and culture collections. They often engage in non-commercial/not-for-profit activities, their main source of funding is public bodies and their activities are of important public, scientific and (downstream) commercial interest (biodiversity conservation, public education, storage and provision of genetic resources for downstream scientific research and product development).

Conversely, downstream users of genetic resources generally operate in larger markets. For instance, the global food and beverage industry was valued at $5.7 trillion in 2008, the global pharmaceutical market at $808 billion in 2009 (IMAP, 2011), the cosmetics market at $136 billion in 2006 (Global Insight, 2007), the global biotechnology industry revenues at $84.6 billion in 2010 (Ernst & Young, 2011) and the commercial seed market at $42 billion (ISF, 2011d). The global market for augmentative biocontrol was estimated at US$100-135 million in 2008 (FAO, 2009).

In summary, it can be concluded that economically very important activities take place downstream, whereas upstream activities are often non-commercial in nature, and often supported by public funds.

EU Market (size of market/sector and importance for EU economy)

Non-commercial sectors in the EU are quite important in terms of their share in their sectors' activities globally. For botanic gardens, of 3,021 botanic gardens worldwide, around 550 are based in the EU (van den Wollenberg et al, interview 2012).[18] In 2001, moreover, it was estimated that 50% of all living plant accessions in the world were collected in Europe (Wyse Jackson, 2001). Kew Gardens in the UK holds the largest living plant collection and one of the largest herbaria in the world.[19] As far as culture collections are concerned, of 593 worldwide, 158 collections are based in the EU, holding 33% of the global collection of strains. Japan follows with 13% and the US with 12% of the global share of strains collected.[20]

The commercial sectors in the EU utilizing genetic resources also tend to have significant shares in their respective global markets, with the highest shares in the animal breeding, cosmetics and biocontrol sectors[21]:

[18] For details on numbers of botanic gardens worldwide and in the EU *see*http://www.bgci.org/garden_search.php

[19] http://www.kew.org/collections/index.htm

[20] WFCC website (http://wdcm.nig.ac.jp/statistics.html#1)

[21] Note that figures/numbers and percentages in relation to EU markets do not necessarily match the figures on global markets. For some sectors the sources for global and EU figures differ (and hence the methods for generating these figures), for others the reference years differ. Only for some sectors have figures been found that entirely match. Also note that the percentages usually refer to the EU's share in the

- Pharmaceutical industry: size of the global market was $808 billion in 2009 with global market share for the EU of nearly 15% (IMAP, 2011);[22]

- Food and beverage industry: size of the EU market was €954 billion in 2009 with a share of global exports of 18.6% in 2009 (CIAA, 2010);

- Cosmetics industry: size of the EU market was $63.5 billion in 2006 with a global market share of 46.6% (Global Insight, 2007);[23]

- Biotechnology industry: revenues of the EU biotechnology industry amounted to $13 billion in 2010 with a share in global revenues of 15% and a share of 34.5% of global biotechnology patent applications at the European Patent Office (Ernst&Young, 2011; EC, 2007);

- Seed industry: size of the EU market was $6.8 billion in 2009 with a global market share of more than 20% (**www.esa.org**); the Netherlands was the global leader in vegetable crop seed exports in 2010 ($1 billion) and was second to the US in flower seed exports (US exports were $72 million, and Dutch exports were $57 million) (ISF, 2010c and 2010d). The top ten exporters of vegetable crops seeds also include France, Italy, Germany and Denmark; the top ten exporters of flower seeds include Germany, France and the UK. For agricultural crops, France is the largest agricultural crop seed exporter.

- Biocontrol industry: the EU is the largest market in the world for beneficial insects and the second largest for microbial biopesticides (FAO, 2009);

- Animal breeding industry: the economic gain (or added value) of animal breeding in Europe amounts to €1.89 billion per year, with global market shares of 90% for ducks, 100% for turkeys, 72% for broilers (poultry), 95% for layers (poultry) and 28.5% for pigs (figures from 2007) (FARBE-TP, 2008).

- Forestry: 2 million jobs in the forest sector in EU.

Economic relevance of "utilization" of genetic resources for the sector in Europe

The Nagoya Protocol defines "utilization of genetic resources" as "the conduct of research and development on the genetic or biochemical composition of genetic resources". While there is virtually no data specifically on the economic relevance of the utilisation of genetic resources, figures on R&D expenditure that are provided below, when combined with the qualitative information on the relevance of genetic resources for each sector under section 0,

global market in terms of sales, but in some cases might refer to other types of shares such as the share in global number of patents or the share in global exports.

[22] Note that the IMAP report does not provide a figure for the size of the EU market. It only provides a figure for the global market and the EU's global market share as a percentage. On the basis of these data, the size of the EU market can be calculated (about $121 billion).

[23] The "global" market *in casu* refers to the whole of the markets of the US, the EU27, Norway, Switzerland, Japan and China (Global Insight, 2007).

provide an indicative picture on the economic importance of the utilisation of genetic resources. A more qualitative assessment of the role of research and development on genetic resources for innovation in the sectors is provided in section 0.

As far as the pharmaceutical industry is concerned, it is estimated that it takes 10-15 years and costs $1.3 billion to develop a new drug (Laird and Wynberg, 2012; PhRMA, 2009). The research-based pharmaceutical industry amounts to 18.9% of total worldwide business R&D expenditure. In 2010 an estimated €27 million was invested in pharmaceutical R&D in Europe (EFPIA, 2011). Nevertheless, R&D productivity of the big pharmaceutical companies declined by 20% in the 2001-2007 period (IMAP, 2011). It should be noted however that natural products research is only one segment of pharmaceutical R&D. In addition, the probability that any genetic resource sample will lead to a commercial product is very low. It is estimated that one in 10,000 samples makes it into a commercial pharmaceutical product (PhRMA, 2005; Laird and Wynberg, 2008).

The seed and horticulture industries are also very research intensive. It can take for instance 5 to 10 years to identify and evaluate agronomically important traits from exotic germplasm and it might take another 10 years to develop a new improved crop variety that is acceptable to the farmer (Smith and Grace, 2007). The development of one wheat variety for instance may involve "thousands of plant breeding crosses and dozens of different individual lines, including wild ones" (Schloen *et al*, 2011). It is estimated that 10-14% of turnover in the seed industry is spent on R&D (ESA, 2012). Given that the size of the EU market was $6.8 billion in 2009, R&D spending in the European seed industry was probably between $680 million and $950 million.

In the cosmetics industry R&D investments are much lower than in the pharmaceutical and biotechnology sectors, though investments have increased in recent years. Time horizons for developing new products vary considerably. In some cases time horizons are very short and R&D is minimal. In other cases time horizons may be considerably longer, e.g. when cosmetics companies run screens involving as many as 100 substances to identify active compounds and undertake clinical trials. In those cases it may take 6 to 8 years to bring a product to market (EC public consultation, 2012).

Development cycles in the industrial biotechnology sector and food sector are much shorter. The development of food products generally does not take more than three years, whereas the development of an industrial biotechnology product – e.g. enzymes for biofuels or detergents – usually takes no more than one to two years from the moment a lead enzyme is identified (Laird and Wynberg, 2012; sCBD, 2008).

In the global animal breeding industry R&D investments are significantly lower than in the crop seed industry. R&D intensity (i.e. R&D spending as a percentage of sales) in 2006-2007 for the (global) animal breeding sector represented 7.3% across species, compared to 10-15% for the crop seed industry (15% in 2000 and 10.5% in 2009). Private R&D into animal breeding and genetics grew from $253 million in 1994 to $316 million in 2010. In nominal US dollars, private R&D spending in 2010 reached $339 million for animal breeding and genetics, whereas R&D spending in 2010 was $3,726 million for crop seed and biotechnology (Fuglie *et al*, 2011).

The activities of *ex situ* collections such as botanic gardens or culture collections are primarily non-commercial and relate to the collection (*in situ* or *ex* situ), storage, and further transfer of genetic resources to downstream users. Genetic resources are "utilised" by those actors as far as the majority of *ex situ* collections engage in basic research on the genetic or biochemical

composition of the material collected *inter alia* to identify and cataloguing new genetic material (Wyse Jackson *et al*, 2001). *Ex situ* collections further engage in utilization through scientific collaborations with academic institutions and downstream industrial users. For culture collections in particular, moreover, basic research activities consist not only of identifying the taxonomic nature of microbial strains, but also characterising their biological function and sequencing them to identify the genetic code (Stromberg *et al*., 2012). Thus, they clearly engage in the utilization of genetic resources in the sense of the Protocol. Apart from public funding, well organized culture collections generate additional income through the sale of microbial genetic resource samples and the provision of scientific services to customers (identification, characterization of strains, creation of databases with information on the genetic and biochemical composition of microbial genetic resources held in the collection) (Stromberg *et al*, 2012).

Are EU companies market leaders? Are EU organisations leaders in the sector?

EU companies are market leaders in a few sectors, such as the biocontrol and animal breeding sectors. The Dutch company Koppert for instance is a world market leader in biological crop protection. Examples of European world market leaders in animal breeding are Aviagen (Wesjohann GE Europe), with a global market share in the poultry sector (broliers) of 50% in 2007, and Hendrix (NL) with a share of 50% in the poultry sector (layers). The EU company PIC (= Genus) leads the global pig breeding market with a 10% share (FARBE-TP, 2008).

EU companies also play major roles in other economic sectors, despite not necessarily being world market leaders. Of the top 15 global pharmaceutical companies (2004-2008), seven companies have their headquarters in Europe: Novartis AG (Switzerland), Roche Holding AG (Switzerland), Bayer AG (Germany), GlaxoSmithKline PLC (UK), Sanofi-Aventis SA (France), AstraZeneca PLC (UK) and Boehringer Ingelheim Gmbh (Germany) (IMAP, 2011).

Of the 20 global companies that exceeded $100 million in total seed sales in 2009, 13 were based in Europe. Limagrain, KWS AG and Bayer ranked respectively fourth, fifth and sixth in 2009.

A significant number of major international cosmetics companies are based in Europe, primarily in France and Germany (Global Insight, 2007).

With regard to botanic gardens, the Royal Botanic Gardens Kew (UK) hold the largest living plant collection in the world and one of the largest herbaria. It also significantly engages in scientific research on plant material, producing around 350 publications per year. The garden employs 744 staff and has an annual income of €55.7 million (year 2010/2011), more than half of which originates from public funding with the rest mostly coming from private grants and fees charged for visiting the gardens (1.6 million visitors in 2010-11).[24]

Relevance of SMEs

The role of SMEs in the sectors varies. While some EU sectors such as the green biotechnology sector are dominated by big multinational enterprises, others such as the biocontrol sector are dominated by SMEs. SMEs also play different roles in relation to utilisation of genetic resources for innovation. While the field of pharmaceutical

[24]Kew Annual Report and Accounts 2010/11, Available at: http://www.kew.org/ucm/groups/public/documents/document/kppcont_038136.pdf

biotechnology, for example, is dominated by research-intensive SMEs, research on genetic resources for innovation in the horticulture industry is mostly carried out by large multinationals.

The pharmaceutical industry is dominated by large multinational companies, though SMEs (especially biotechnology companies) do also play a major role, especially in the early stages of the user chain (see Figure 3). On the one hand there are large pharmaceutical companies which need to be big because of uncertainties in the drug development process. On the other hand, there are smaller biotechnology companies, most of which do not have the capital or market access to commercialize a product (IMAP, 2011). A large proportion of companies working in healthcare biotechnology are research-intensive SMEs (Degen *et al*, 2011;Croplife, interview., 2012). Many of these SMEs are micro-enterprises consisting of 10 or fewer employees (Degen *et al*, 2011). Currently, some very large companies with big sales/marketing organizations and the capital and knowledge for late-stage clinical developments are systematically acquiring small biotechnology companies with interesting candidate products. Licensing deals with small biotech companies are also becoming increasingly important (IMAP, 2011).

The seed industry includes a significant number of SMEs, although the general trend is towards convergence and consolidation. There are many breeding companies in Europe with five or fewer employees (Plantum, interview, 2012). The green biotech sector, however, mainly comprises big multinational companies (Croplife, interview, 2012). There is however a small number of small and medium-sized green biotechnology companies, that generally do not sell seed but rather seek to commercialize a new genetic trait or biotechnology service or tool to other companies (Heisey and Fuglie, 2011).

The horticulture sector includes a small number of large multinational companies that represent most of the worldwide sales, and hundreds of SMEs (ten Kate, 1999). Nevertheless, it is the first group of large multinationals that deals the most with genetic resources by investing significant resources into the development of new products (ten Kate, 1999).

SMEs employing an average of 2-10 people represent the vast majority of biocontrol companies (FAO, 2009).

The cosmetics market is composed of hundreds of SMEs spread across the EU27, though a significant number of major international cosmetics companies are based in Europe, primarily in France and Germany (Global Insight, 2007).

A large number of SMEs dominate the food industry: 99% of the enterprises are SMEs, which employ 61% of the workers in the industry and account for 49% of the industry's total turnover. More specifically, micro-enterprises (1-9 employees) represent 79% of all companies. Small (10-49 employees) and medium-sized (50-249 employees) companies account for 17% and 4% respectively, while large companies (250+ employees) account for close to 1% percent of all European food industry companies (EMCC).

The animal breeding sector includes many SMEs, as well as several medium-sized and large international players. However, differences exist among the various animal breeding subsectors. For instance, most European beef cattle breeders are individual farmers who are members of farmer's cooperatives or breed societies, whereas dairy cattle breeders are mostly dairy farmer cooperatives. In the poultry sector, however, just a few large-scale but still relatively small (max €500-700 million annual turnover) private companies supply breeding stocks. European pig breeding organizations (only 14 in 2007) are half organized into cooperatives and half privately owned companies (FARBE-TP, 2008).

The forestry sector: In the EU, 60% of forests are private and 40% public; private forest holdings are managed by an estimated 16 million forest owners, being in most cases small-scale private forest owners. In 2005, forest-based industries in the EU employed about 3 million people in 350,000 enterprises, with a turnover of about EUR 380 billion, producing added value of around EUR 116 billion (Source: Eurostat, Statistics in focus 74/2008).

Types and role of genetic resources used in sectors in the EU / particular characteristics of some user chains

Types and role of genetic resources used in the various sectors

Diverse types of genetic resources are utilised within the various economic sectors in the EU. The pharmaceutical industry uses natural products or genetic resources from animal, plant and microbial origin (and their derivatives) from both terrestrial and marine environments as a starting point in developing active compounds for medicines, as inactive elements of final products, and as tools in the research and production processes (EFPIA, 2007).

The cosmetics industry uses harvested or cultivated products in many of its products. The raw materials used are typically bulk sourced and consist mainly of dried plant products and oils from a variety of organisms (Laird and Wynberg, 2012; Beattie, 2005). This includes a large number of derivatives, such as saponins, flavonoids, amino acids, anti-oxidants, and vitamins (Beattie, 2005).

The biological pest control sector uses a very broad range of genetic resources, including plants, viruses, bacteria, fungi, insects, nematodes and invertebrates. They are almost always collected directly *in situ* as living organisms (FAO, 2009).

Conventional and biotech seed companies rely on different types of plant genetic resources for use in breeding and variety development. The development of new varieties is usually based on the use of advanced genetic material, as it takes time and effort to bring less-advanced genetic material to the same performance levels (Schloen *et al*, 2011). The main source for genetic material for conventional breeders is modern varieties, though old varieties, landraces and crop wild relatives may be used to introduce specific features into breeding populations which allow for the development of varieties adapted to less favourable environmental conditions and low-input production systems (Schloen *et al*, 2011).

The industrial biotechnology sector uses microorganisms as the primary genetic resource. Companies are interested in genetic resources found in “areas with high species diversity, as well as in extreme or unique environments”, including salt lakes, deserts, caves and hydrothermal vents (CBD, 2011).

In the animal breeding sector, exchange of (animal) genetic material between owners is crucial for the development of livestock breeds and the livestock sector in many parts of the world. Genetic variation within lines or breeds is the main source for genetic improvement. Although (new) breeds and lines are being developed continuously in commercial breeding programmes, the introduction of “foreign” genetic material or “wild relatives” is much less relevant in animal breeding than in plant breeding (Kaal-Lansbergen and Hiemstra, 2003). For many domesticated livestock species no wild relatives exist, as they have become extinct, and for others wild relatives are very rare (Schloen *et al*, 2011). Furthermore, little or no demand exists in developed countries for breeding animals or specific (adaptive) traits from developing countries. This situation could however change as a result of climate change. Many of the traits necessary to adapt to climate change may be found in locally adapted

breeds. Climate change is therefore likely to increase the exchange of genetic material across the board, but might also lead to a bigger flow of genetic material from the South to the North (FAO, 2009; Schloen *et al*, 2011).

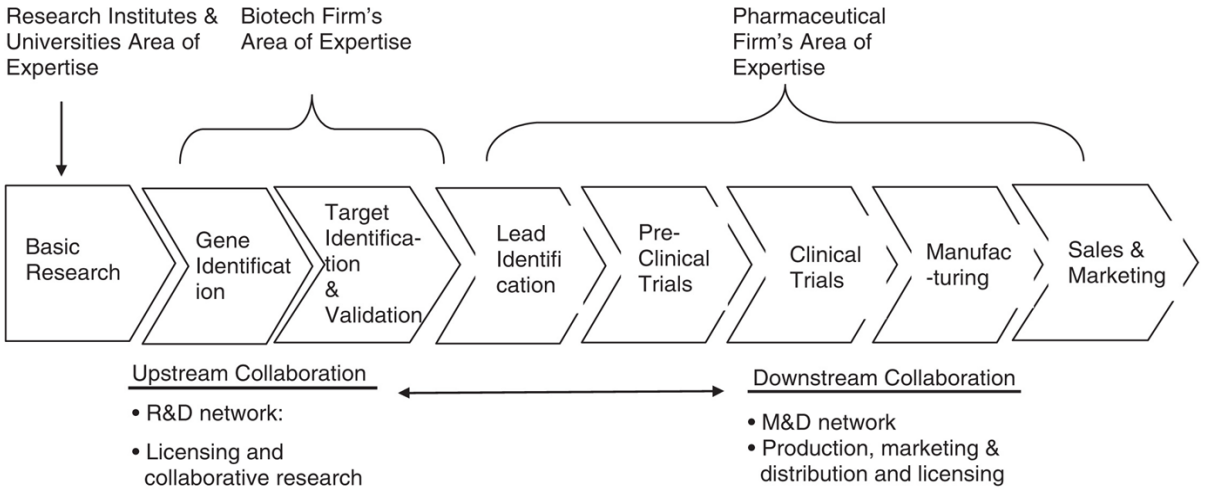
Relevance of research and development on genetic resources for (innovation in) the sectors

Research and development of commercial products from genetic resources is important for a wide range of sectors. However, the ways in which and the extent to which the sectors undertake research and development vary.

The pharmaceutical industry, for instance, is very R&D intensive. Drug development relies on the collaboration and effort of highly trained scientists at universities and private companies (see also Figure 10.1 which shows how the value chain in the sector might look). It takes about 10 to 15 years for a compound to make its way through R&D into commercialization. Only one in approximately 10,000 compounds screened is commercialized (PhRMA, 2005; Laird and Wynberg, 2008). According to EFPIA (2007), many thousands or even hundreds of thousands of samples must be screened to identify potential leads for investigation. Identified leads rarely generate compounds that merit serious research. Even fewer generate compounds that possess properties that merit the filing of a patent application; from these, only some are commercialized. As noted before, the research-based pharmaceutical industry amounts to 18.9% of the total worldwide business R&D expenditure. In 2010 an estimated €27 million was invested in pharmaceutical R&D in Europe (EFPIA, 2011). Nevertheless, R&D productivity of the big pharmaceutical companies declined by 20% in the 2001-2007 period (IMAP, 2011).

R&D on genetic resources, *in casu* natural products research, receives inconsistent support and is only one of many segments of pharmaceutical R&D (Laird and Wynberg, 2012). Currently only four large pharmaceutical companies maintain natural products programmes of any size, and have the capacity to undertake all facets of natural product drug discovery (Novartis, Wyeth, Merck and Sanofi-Aventis). Nevertheless, natural products research plays a major role in the discovery of leads for drug development and hence in innovation in the pharmaceutical sector. Most natural products research (especially research that involves bioprospecting) is done in academic and government research institutes or smaller discovery (biotech) companies (sCBD, 2008). Large pharmaceutical companies which engage in natural products research usually collaborate with this type of player, e.g. through in-licensing deals or acquisitions.

Figure 3: Value chain in the pharmaceutical industry

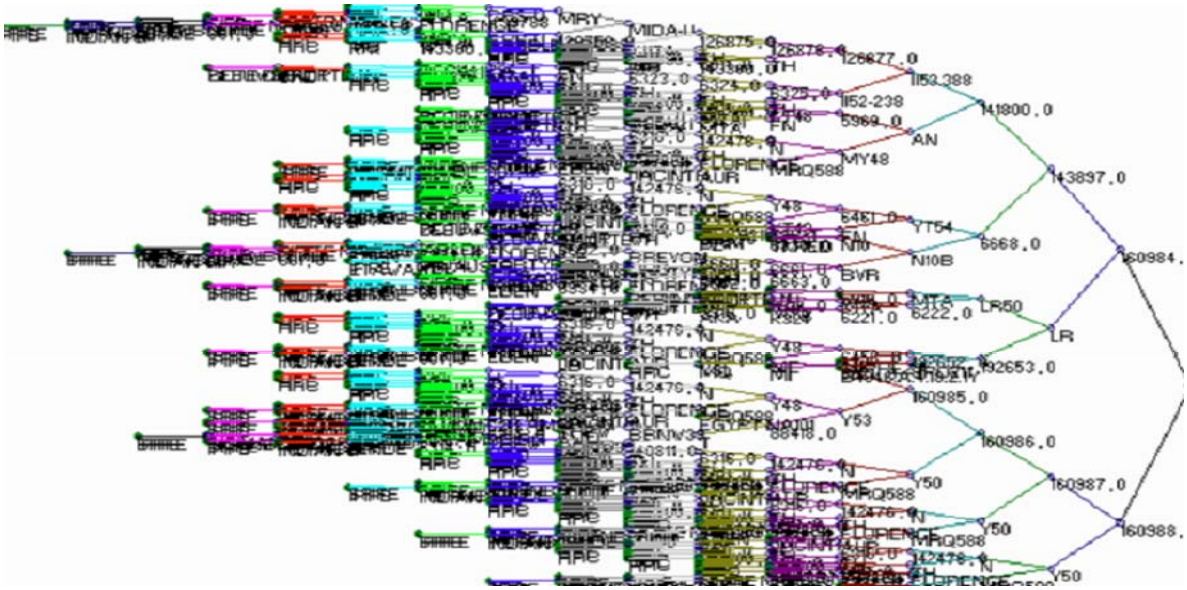


***Source*:** Advances in Strategic Management

The seed or plant breeding industry, which relies entirely on genetic resources, is characterised by important R&D investments. It is estimated that 10-14% of turnover is spent on R&D (ESA, 2012). Research intensity (R&D spending as a percentage of sales) for seed increased during the 1990s (related to the increasing dominance of modern biotechnology or genetic engineering) and has fallen since 2000, though it is still higher than for other "agricultural input industries" with high research intensities such as animal genetics and animal health. R&D investment varies by crop (Smolders, 2005). R&D investments in the European seed and biotechnology sector are both focused on biotechnology and conventional breeding. Plant breeding is traditionally characterised by long time horizons over which research and development of new products evolves from the original point of access to genetic resources. Often multiple plant genetic resources are used in species improvement (see Figure 4): the development of one wheat variety may involve "thousands of plant breeding crosses and dozens of different individual lines, including wild ones, from many countries and over many centuries" (Beattie et al, 2005; Schloen *et al*, 2011). In other words, plant breeding is a global activity in which many breeders from many different countries are involved.

The relevance of public R&D on unimproved material (landraces, crop wild relatives, etc) is rather high. Characterization, evaluation and pre-breeding largely take place in the public sector, with the product freely available to all breeders on a non-exclusive basis. The private sector is rather reluctant to work with unimproved material (Smolders, 2005).

Figure 4: pedigree picture of a particular wheat line



Source: CIMMYT

In the horticulture sector the relevance of R&D on genetic resources varies among the subsectors. There are many companies involved in the horticulture industry growing, distributing and selling ornamental plant varieties; few of these work directly with genetic resources (ten Kate, 1999). Those that do work with genetic resources include a small number of large companies that represent most of the worldwide sales in this industry, a larger number of national companies and hundreds of SMEs. It is the first group of large multinationals that invest significant resources into developing new products. Some breeding programmes use advanced technological approaches to plant breeding, which can cost several million dollars (e.g. for vegetables), while ornamental plants can be introduced with little selection or breeding in a relatively short period of time (ten Kate, 1999). It can be concluded that some segments of the horticulture sector are characterised by long time horizons over which R&D of new products evolves from the original point of access to genetic resources, whereas other segments have relatively short time horizons for R&D on genetic resources (i.e. selection and breeding of genetic material).

In the biocontrol sector the relevance of research and development on genetic resources is very high. At the planning stage, surveys about the pest and its natural enemies need to be undertaken to obtain information about the area of origin of the pest and the best places to look for natural enemies. Subsequently, natural enemies are identified and detailed studies undertaken to assess their potential use as biocontrol agents. This includes developing breeding methods for use in the laboratory and conducting impact studies in the field or in the laboratory (FAO, 2009). The last step consists of an evaluation by the target country authority of the risks and potential benefits of the introduction of the relevant pest. Permission for release may or may not be given. When permission is granted, release strategies and protocols will be developed together with monitoring and evaluation procedures (FAO, 2009).

In the cosmetics and food and beverage industries, R&D investments are much lower than in the pharmaceutical and biotechnology sectors. However, investments in R&D have increased in recent years as a result of rising demand for proven, effective and safe products. Research and development of new products, however, varies significantly. In some cases time horizons

are very short and the input of science and technology is minimal (e.g. when companies sell bulk unprocessed herbs and as such may or may not "utilise" genetic resources, or when companies process plants into extracts). In other cases time horizons may be considerably longer, e.g. when cosmetics companies run screens involving as many as 100 substances to identify active compounds and undertake clinical trials. In those cases it may take 6 to 8 years to bring a product to market (EC public consultation, 2012; Laird and Wynberg, 2012).

In the global animal breeding industry R&D investments are significantly lower than in the crop seed industry. R&D intensity in 2006-2007 for the (global) animal breeding sector accounted for 7.3% across species, compared to 10-15% for the crop seed industry (15% in 2000 and 10.5% in 2009) (Fuglie *et al*, 2011). In the animal breeding sector basic scientific research is mostly conducted in the public domain, whereas companies protect their knowledge generated in more applied research and breeding (Hiemstra *et al*, 2010). Like in the crop seed industry, the emergence of biotechnology has been very relevant for the animal breeding industry.

The forestry sector: (1) natural regeneration with the existing genetic resources at the stand is used as an important source for regeneration of the forests. Due to climate change, research is done on the genetic variation of natural regeneration and on possible reactions on the impact of climate change. The percentages of afforested and reforested forests vary between the Member states. (2) The genetic resources used for cultivated forest planting are usually seeds from identified stands or naturally regenerated trees. The source of breeding material is usually known. Genetic material is sometimes acquired from ex situ collections. In few cases, propagated material could be used for regeneration (e.g. poplar, willow). Due to climatic changes genetic resources are looked e.g. in the Mediterranean Region for a useful application in future climatic conditions in the European Union. At the moment the interest is mainly on a scientific level (research). Today, except for the overseas regions, the genetic resources coming from mega diverse countries are not of relevance for cultivated forests within the EU. The questions concern access to forest diversity for food, feed, renewable resources and energy. Plant genetic resources are located in situ and ex situ and are maintained by public and private forest owners as well as private or public forest companies.

Relevance of basic/academic research 'utilizing genetic resources' (for innovation) in sectors

Though it is hard to determine the exact relevance of basic/academic research for innovation in the sectors, one can state that in general basic academic research plays a major role for innovation in various economic sectors, though the relevance might vary across and within sectors.

Basic/academic research may indirectly contribute to a commercial innovation through publicly available publications/data (see box below). Published research results may be used by players with commercial interests as input for product development. Depending on the field of academic research, the likelihood of research results contributing to the development of new commercial products may vary. Academic disciplines such as taxonomy or ecology are less likely to contribute directly to commercial innovation, at least in the short term, than those such as clinical pharmacology or genomics.

Academic research institutes can also be actively involved in commercial R&D through partnerships with the private sector. The business sector indeed finances up to 6.6% of higher education R&D in the EU (EC, 2005). For instance, to improve knowledge sharing and to cut costs, pharmaceutical companies are highly interested in collaborating with academic

laboratories. Partly funded by the government, academia invests effort in basic research to identify potential new targets for drugs (e.g. membrane or intracellular receptors and their signaling pathways) and biomarkers to monitor the effect of a drug. Furthermore, academia can contribute by optimizing technology to accelerate drug development. In addition, academic laboratories are highly stimulated to collaborate with pharmaceutical companies. In the EU FP7 Health program for instance, projects are only selected for funding if a certain percentage of the EU budget goes to SMEs. Furthermore, in project application forms from national governmental agencies, academic researchers have to describe how they will valorise the results of the project. Other initiatives to stimulate interaction between academia and industry include platforms such as the Innovative Medicines Initiative (IMI), a European public-private initiative that supports collaborative research projects and builds networks of industrial and academic experts to boost pharmaceutical innovation in Europe (Smits, interview, 2012).

Role of academic publications used by the pharmaceutical industry for the development of a medicine (utilizing genetic resources/natural products)

An example is green fluorescent protein. This bioluminescent protein was extracted and purified from the hydromedusan Aequorea victoria by Osamu Shimomura (Shimomura, 1962). Later, the primary structure of the protein was revealed and published, also at an academic lab (Prasher *et al*, 1992). Now, it is widely used as a marker for gene expression, and also by pharmaceutical companies in order to study drug effects (Chalfie *et al*, 1994).

Basic research utilizing genetic resources is integral to the activity of culture collections and botanic gardens. For culture collections, for example, the key process of isolation and profiling of strains involves the basic study of biochemical and genetic properties of the strain. The added value of basic research consists not only of identifying the taxonomic nature of microbes, but also characterizing their biological function and sequencing them to identify the genetic code. Such information is organized in databases with molecular and physiological information diffused on collections' electronic databases, which may be used by downstream commercial and non-commercial users (Stromberg *et al*, 2012). Scientific or technical (basic) research on plant genetic resources is also a core activity of botanic gardens. Basic research on the properties of plant genetic resources may be undertaken by the garden on its own, e.g. taxonomic research for the purpose of identification and cataloguing of new species or varieties. Because of the specific expertise of the scientists working in those sectors, further basic research utilizing genetic resources is also undertaken through collaborations between those institutions and universities/research institutes or the private sector (Wyse Jackson, 2001; van den Wollenberg *et al*, interview, 2012).

As botanic gardens and culture collections also provide economic sectors with their genetic resources, the basic research carried out by them in terms of identification, documentation, profiling and further scientific research on the properties of genetic resources held in their collections is definitely relevant for some sectors. In a survey carried out in 2005, it was found that 23% of the genetic material provided by culture collections went directly to private sector users, whereas the other 77% went to universities, research institutes and other culture collections (Stromberg *et al*, 2006). The relevance of microbial genetic resources held in culture collections for commercial sectors is likely to be higher when one considers the further linkages down the utilisation chain between academic research institutes and private companies. The microbial genetic resources and information on their properties and genetic

profiles held by culture collections are mostly used for the biological control of pests and diseases in agriculture and horticulture, the production of natural products (e.g. valuable drugs, enzymes, and metabolites) for pharmaceutical, food and other applications, as well as the production of biofuels and bioplastics (agricultural and industrial biotechnology) (WFCC, 2008). Botanic gardens are mostly providers of genetic resources and related taxonomic information to universities and public research institutes, though they might also less frequently supply other downstream sectors such as green biotechnology, plant breeders, horticulture and the pharmaceutical sector (Wyse Jackson, 2001; van den Wollenberg *et al*, 2012).

Relevance of applied research 'utilising genetic resources' (for innovation) in the sector

Applied research is understood here as research with the objective of adding value to genetic resources to enable the potential development and commercialization of genetic resource based products. This stage of the innovation process involves the academic sector, but to a larger extent the biotechnology sector, which is engaged in a number of fields such as pharmaceuticals, agriculture and industry. This is an important stage of the value chain and it explains, for instance, the targeted acquisition within the pharmaceutical industry of small biotechnology firms to gain access to specific products or technologies (sCBD, 2008). The further development of products is generally undertaken by the downstream companies' own R&D departments.

Protection of innovations in the sectors (e.g. patents, plant variety rights and trade secrets)

Legal protection of innovations becomes particularly important in the 'downstream' part of the genetic resources user chain. However, currently the conditions for granting legal protection for an innovation are independent from the specific role the utilization of genetic resources or traditional knowledge has played in the creation of an innovation. A unique genetic resource may have been the decisive input enabling innovation. Conversely, a genetic resource with related ABS-obligations may have been only one of tens of thousands of reference samples used in the screening for an active ingredient. Furthermore, intellectual property rights such as patents or plant variety protection only cover the part of innovations involving the utilisation of genetic resources. Innovations of major economic importance may often fall outside the scope of intellectual property protection and kept as trade secret. The distribution of the different practices is explained below.

- **Plant variety rights**: Innovations in the conventional plant breeding industries are mostly protected through the plant variety protection system. As mentioned above, however, the development of a new wheat variety may involve thousands of plant breeding crosses and dozens of different individual lines (Schloen *et al*, 2011). EU legislation authorises only the protection of a new plant variety by means of the Community Plant Variety Right system (CPVR – Regulation (EC) No 2100/94) or national plant variety protection systems; those systems are conform to the UPOV convention (*Union pour la Protection des Obtentions Végétales*); the CPVR system protects mainly ornamental species (60%), agricultural crops (25%), vegetable crops (12%) and fruit species. Currently, less than 14% of registered varieties on the EU Common Catalogues (agricultural and vegetable crops) are protected within the CPVR. More than 18,000 protection titles are in force at EU level. The CPVR and UPOV systems are open systems because the variety, even protected for commercial use, remains free for research and breeding (compulsory breeder exemption) and for private use.

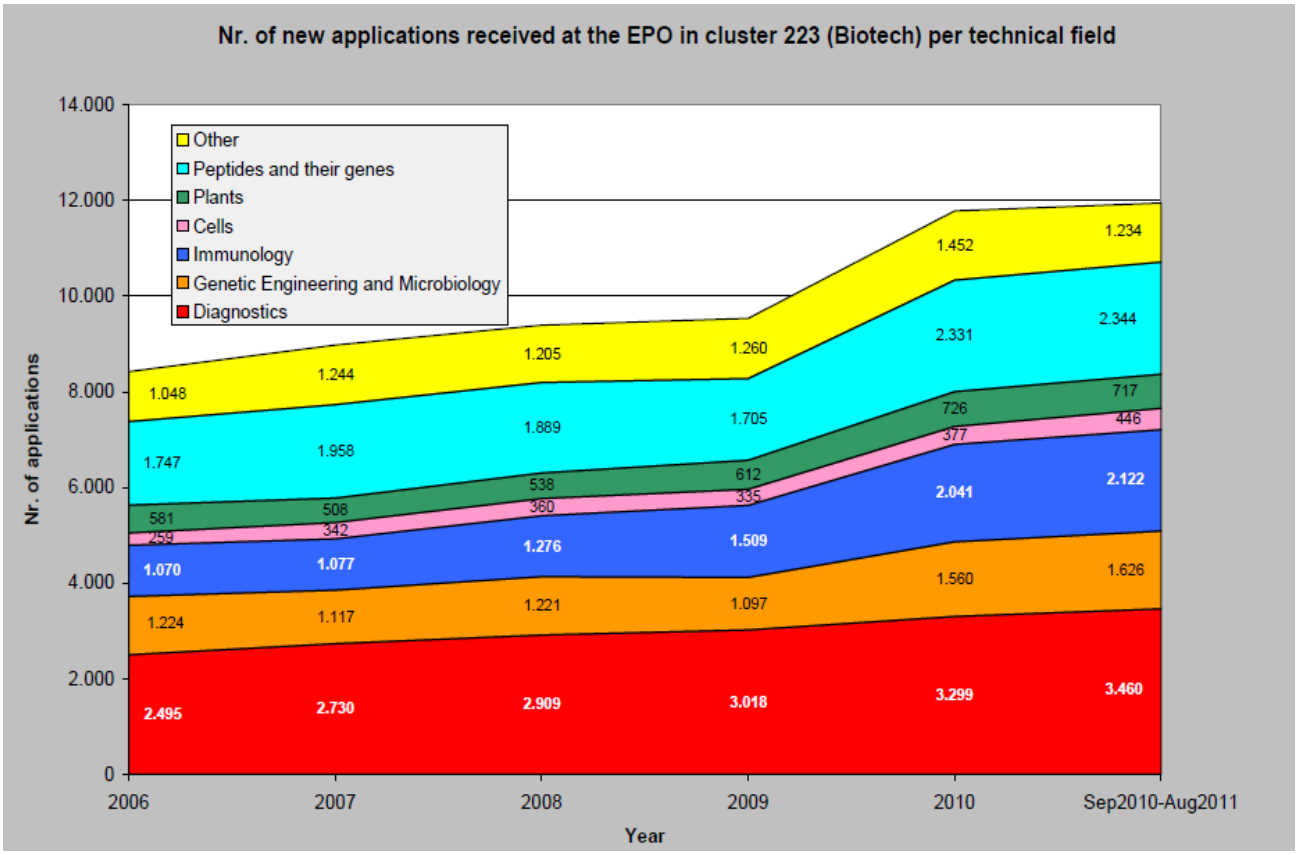
- **Patents**: Among the sectors covered by the present study, one of the most reliant on patents for protecting innovations is the pharmaceutical industry. In 2011, pharmaceuticals operators based in Europe filed 5,759 applications before the European Patent Office (EPO), representing 4% of the overall number of European patent applications before the EPO. Those figures represent a strong decline compared to the previous year (6,879 applications, representing 4.5% of the overall number of European patent applications).[25] In this sector, while only a small number of new chemical entities are approved annually, thousands of patents are applied for to protect variants of existing products and manufacturing processes. Patents are usually obtained by the time lead compounds have entered the stage of lead optimisation, even though many uncertainties with respect to commercial return remain (EFPIA, 2007).

The number of patent protection applications has grown significantly in recent years in the field of biotechnology (Ugalde, 2007), which is now among the 10 most active fields for applications before the EPO. In 2011, biotechnology operators based in Europe filed 5,865 applications before the EPO, representing 4.1% of the overall number of European patent applications before the EPO.[26] While a number of innovations in the academic research sector are not protected because the main aim of academic research is to increase scientific knowledge by disseminating research results through publications, patenting has increased in this sector since the 1990s in the field of biotechnology, where basic research is often likely to lead to industrial applicability (van Zeebroeck *et al*, 2008). In 2005, patent applications before the EPO from the government and higher education sectors amounted to merely 3.2%, whereas business enterprise sectors were responsible for 85.7% of the overall number of patent applications (Eurostat, 2010). In the field of biotechnology in 2002 university patent filings before the EPO accounted for 13% of the overall number of applications (van Zeebroeck, 2008).

To a smaller extent the cosmetics, food & beverage and farm animal breeding industries are also increasingly making use of patents to protect their inventions (ETB, 2010; Schloen *et al*., 2011).

Figure 5: Overall number of new applications received at the EPO in the field of Biotechnology

[25] http://www.epo.org/about-us/statistics/patent-applications.html
[26] *Ibid.*



***Source*:** S. Yeats EPO, 2011

- **Trade secret**: Protection of inventions through trade secrets is carried out by a number of sectors including the cosmetics, food & beverages, animal breeding, plant breeding and biocontrol industries. Information covered by trade secrets may range from production know-how in the biocontrol industry (i.e. the rearing methods used in the laboratory) to genetic information (Krattiger, 2007).

- **Geographical indications:** They are forms of identification which identify a product as originating in a region or locality in a particular country. For a GI product, its reputation for quality or authenticity is intimately linked to its geographical origin. Geographical Indications are usually geographical names. But non-geographical names can also be protected if they are linked to a particular place. There are three major conditions for the recognition of a sign as a geographical indication: it relates to a good although, in some countries, services are also included; these goods must originate from a defined area; the goods must have qualities, reputations or other characteristics which are clearly linked to the geographical origin of goods

Relevance of traditional knowledge associated with genetic resources for innovation in the sectors

The relevance of traditional knowledge varies by sector. The role of traditional knowledge in pharmaceutical discovery has been relatively small in recent decades and is likely to become even smaller. Several reasons are put forward for this trend: the emphasis of pharmaceutical drug development on disease categories that do not feature prominently in traditional medicine; the decreased role of plants in discovery; the increasing role of micro-organisms in discovery; and the fact that new research approaches do not easily integrate the type of

information available through traditional knowledge (sCBD, 2008; Laird and Wynberg, 2012).

In the seed sector, companies rely on their own private collection or prefer to work with material characterized through joined research projects with public institutions. The plant biotechnology avoids collecting traditional/farmer knowledge as far as possible because of legal and ethical implications. Most prefer to pass the responsibility of resolving these difficult benefit-sharing issues on to the gene banks, governments or intermediary institutions with whom they work (Laird and Wynberg, 2012).

The cosmetic and food and beverage industries, however, rely much more on traditional knowledge as the starting point for new product development. Novel species have become increasingly important in this sector, as well as the traditional knowledge associated with these species. In some countries, traditional knowledge is used as a marketing tool to demonstrate product efficacy and safety. These industries, however, are the least informed about CBD, the Protocol and their ABS requirements (Ibid).

As for the upstream sectors, it should be noted that a survey showed that 20% of academic research projects linked with genetic resources worked with traditional knowledge associated to these resources (WG-ABS, 2006). Botanic gardens often keep, alongside the plant material itself, related objects and information of ethno-botanical nature, e.g. information about use by indigenous and local communities of the relevant plant materials (botanic gardens, pers. comm. 2012). Furthermore, traditional knowledge often figures in scientific publications on the properties and uses of certain plant varieties (van den Wollenberg et al, interview, 2012).

In conclusion, with the exception of the cosmetic and food industries the use of traditional knowledge associated with genetic resources is relatively small in most commercial sectors in the EU. Traditional knowledge associated with genetic resources nevertheless still plays a relatively important role in the basic research activities of non-commercial sectors, as it may provide valuable insights into the properties and functions of certain genetic resources.

Sourcing of genetic resources (genes or naturally occurring biochemicals)

Relevance of bioprospecting

Bioprospecting involves searching for, collecting, and deriving genetic material from samples of biodiversity (plants, animals, microorganisms) for scientific research or commercial development. As Figure 1 shows, EU users engage either in direct or indirect bioprospecting. The reliance on 'wild' genetic resources and hence the relevance of bioprospecting varies across sectors (see also section 0).

For most botanic gardens and culture collections, bioprospecting remains a fundamental activity. For botanic gardens the collection and discovery of new species is an integral part of their conservation, educational and scientific activities: 42% of European threatened taxa, for example, is accessible in *ex situ* collections within their region of origin (Sharrock and Jones, 2009). According to a study based on data provided from 84 botanical gardens in Germany, Austria, Switzerland and Luxembourg, 12% of the plant material acquired by the botanic gardens every year was directly collected from the wild (Krebs *et al*, 2003).

For culture collections, *in situ* collection of microbial samples is also fundamental due to the fact that more than 99% of existing microbial genetic resources are still unknown.[27] 45% of

[27] http://www.mirri.org/background.html

genetic resources deposited every year come from the direct bioprospecting efforts of the collection itself (Stromberg *et al*., 2006). As micro-organisms easily develop novel properties in response to different environmental stresses, collection from industrial regions may often be as important as collection from gene-rich countries (Fritze, 2010).

Bioprospecting is very relevant in the biocontrol sector, which relies the most on wild genetic resources among the commercial sectors studied. The genetic resources used in biocontrol include plants, viruses, bacteria, fungi, insects, nematodes and invertebrates and are very often collected *in situ* as living organisms. EU *in situ* collections are as important as non-EU *in situ* collections (FAO, 2009).

The food and beverage industries also rely significantly on wild genetic resources for their product development and marketing. Materials are often bioprospected and bioprospecting activities are expected to continue to grow, as they help companies to market their products in competitive markets. New ingredients are regularly sought in nature, and identified through traditional knowledge.

The same conclusions hold for one particular segment in the cosmetics sector for which wild genetic resources are very important. However, the demand for wild genetic resources and the relevance of bioprospecting for the sector as a whole is limited.

Industrial biotechnology researchers regularly collect their own samples of materials, contrary to the case in the agricultural and pharmaceutical sectors (ten Kate & Laird, 1999). Ten Kate & Laird (1999) found that of the companies and organisations surveyed for their study, this collecting activity was a relatively unimportant method of acquisition for half of the respondents. For the other half, however, staff collecting activities represented more than 90% of their acquisitions. Many of these collectors come from universities, or from small companies spun off from universities.

In the pharmaceutical industry, which only relies partially on 'wild' genetic resources, bioprospecting is directly relevant for companies that are involved in natural products research. Many small (biotechnology) companies increasingly carry out (specific aspects of) research on natural products such as biosynthetic engineering and other genomic research. These smaller biotechnology companies develop hits and leads and form alliances with big pharmaceutical companies for the development of pharmaceuticals. This implies smaller companies are more likely than the largest companies to seek access to wild genetic resources (sCBD, 2008). These companies (and the few big pharmaceutical companies which still engage in natural products research, such as Novartis) usually work together with worldwide local partners such as universities, research institutions, botanic gardens and culture collections to undertake bioprospecting, as the practice of bioprospecting generally requires specific taxonomic expertise. Some bioprospecting might also be done by in-house scientists (such as marine biologists) (EFPIA, 2007; sCBD, 2008).

In the plant breeding or seed sector bioprospecting is very limited. Though a small demand continues to exist for old varieties, landraces and crop wild relatives to introduce specific features such as insect and disease resistance into breeding populations (Schloen *et al*, 2011), the demand for wild genetic resources has been replaced in recent years by *ex situ* and private collections (Laird and Wynberg, 2012). In the plant biotechnology sector, direct *in situ* bioprospecting activities are virtually non-existent (Europabio, interview, 2012).

In the horticulture sector bioprospecting is also very limited. In the animal breeding sector the introduction of "foreign" genetic material or "wild relatives" and hence bioprospecting is even less relevant than in the plant breeding sector.

In conclusion, the relevance of bioprospecting is highly variable across different sectors in the EU. Bioprospecting remains an important activity in non-commercial sectors. The discovery of new or rare genetic diversity in nature, in fact, is still of great interest for both scientific research and the conservation activities of some *ex situ* collections. In the commercial sectors, while bioprospecting remains important for some particular niches of innovation, such as biocontrol, industrial biotechnology and some small pharmaceutical biotechnology industries, the activity has declined or is no longer relevant for economically important research-intensive sectors such as the seed industry and a great proportion of the pharmaceutical and cosmetics industries.

Relevance of ex situ collections, gene banks, seed banks, databases

Culture collections are specialised deposits of microbial genetic resources which function as providers of microbial genetic resources to a wide range of downstream sectors. Generally, the addressees of 77% of the material provided by culture collections are public sector institutions, in particular research institutes, universities and other culture collections, while 23% goes to private sector users (Stromberg et al, 2006). The uses of microbial genetic resources stored in culture collections include the biological control of pests and diseases in agriculture and horticulture (biocontrol sector), the production of natural products (e.g. valuable drugs, enzymes, and metabolites) for pharmaceutical, food and other applications, and the production of biofuels and bioplastics (agricultural and industrial biotechnology). They also play a major role in soil fertility and plant and animal health and are employed in diagnostics, efficacy testing of drugs, biocides, vaccine production and disinfectants (WFCC, 2008).

Botanic gardens are mostly providers to universities and public research institutes. This does not exclude the possibility of other private downstream sectors utilizing genetic resources (e.g. green biotechnology, plant breeders, horticulture and pharmaceutical sector) sourcing from those institutions (van den Wollenberg et al, interview, 2012). This is particularly the case for well-established botanic gardens and others associated with or owned by the private sector, such as horticultural, agro-botanical and germplasm gardens, functioning as ex situ collections for plants of economic value (Wyse Jackson, 2001).

In the seed sector, conventional breeders usually source their material (mostly modern varieties) from private collections (i.e. breeding collections of private companies) and from other breeding companies (i.e. from their varieties available on the market in which case the breeder's exemption applies). Genebanks – such as national public genebanks and the centres of the Consultative Group on International Agricultural Research (CGIAR) – are also sources, but these are mainly used by universities, small companies and national agricultural research systems in developing countries (Fowler et al, 2001; sCBD, 2008). Most green biotechnology companies mainly source their material from their own collections, followed by national genebanks, 'in trust' collections maintained by CGIAR centres, and university collections (ten Kate & Laird, 1999). They only rarely source from botanic gardens. Many green biotech companies leverage investment in smaller companies and track exploratory work done in universities and small companies. Green biotech companies might enter into an in-licensing agreement with universities or small companies. Conventional breeding companies and green biotech companies source from both within and outside the EU. Green biotech companies source the majority of genetic resources from outside the EU (Croplife, interview, 2012).

It is difficult to get a clear picture of the exact significance of ex situ collections for pharmaceutical companies. The value creation chain in the sector is complex and continuously reshaped: many different steps need to be taken and many intermediaries are

involved. A pharmaceutical company might outsource several activities or buy and/or sell certain intermediate products (IMAP, 2012). The following information might give some indication as to where companies source their genetic R&D material and the role of ex situ collections within the sector. Aside from direct bioprospecting, pharmaceutical companies that intend to develop drugs on the basis of natural products may source the required genetic resources from: academic and government research institutes engaged in natural products research; the collections of smaller discovery/biotech companies (such as Pharmamar); culture collections (see above); or private suppliers of chemical compounds whose libraries/collections may include natural products or their derivatives and from in-house collections. As pharmaceutical companies are global players they source from both EU and non-EU ex situ collections.

The horticultural industry predominantly relies on genetic resources in ex situ collections, which represent the core of the industry. Most genetic resources, therefore, are sourced from in-house collections, commercial collections, national collections and botanic gardens (ten Kate, 1999).

The biocontrol sector almost always collects its genetic material in situ. From time to time, however, material is sourced from ex situ collections, such as microbial culture collections (FAO, 2009).

Next to bioprospecting, the industrial biotechnology sector relies heavily on culture collections to obtain genetic resources. Most of the cultures held in these collections predate the CBD (CABI, interview 2012). Samples are also obtained by companies and organisations from intermediaries including universities or from external collectors based in the country that provides the resources. Companies also maintain their own collections of genetic resources and their derivatives. For some of these, building and improving their collections is their primary activity, in order to license these to other users for research and product development (i.e. culture collections). For others, their collections form the basis for in-house product development (ten Kate & Laird, 1999).

European animal breeders usually source their material from within the company or from farmers, from both within and outside Europe. The majority of AnGR are kept in the form of live animals in situ (in their production environments). Only a limited amount of AnGR is stored ex situ for conservation purposes or for breeding activities such as artificial insemination and embryo transfer breeding. Relatively few AnGR are held in the public domain. Public ex situ collections and genebanks mainly fulfill conservation purposes and are less involved in the exchange of genetic material and its provision for breeding purposes (FAO, 2009; Schloen et al, 2011).

EU ex situ collections are not only relevant with regard to the provision of genetic resources to downstream users, but also for supplying genetic resources to other ex situ collections around the world. For example, it was estimated in 2003 that 58% of the plant material entering botanic gardens in the EU every year comes from other gardens through international exchange networks (Krebs et al, 2003). These benefit all members as they have the primary aim of keeping the collections around the world alive (Van den Wollenberg et al, interview 2012. The number of non-commercial transactions in plant material between botanic gardens in the EU is estimated to fluctuate around two million per year (Van den Wollenberg et al, interview, 2012; see also Krebs et al, 2003). Transactions with botanic gardens outside the EU are considerably lower but on the increase, with limitations imposed by legal uncertainties and low scientific standards in some collections and countries (Van den Wollenberg et al, interview, 2012). For culture collections the proportion of material coming from other service

collections is lower (20%); a further estimated 30% however is actively deposited from research collections and individual scientists to maintain a safe backup copy of important reference material (Stromberg et al, 2006).[28] The majority of the latter transactions are carried out nationally. However, a substantial number of depositors from India, the Philippines, China, Brazil, Columbia and Uruguay directly deposit strains from their countries in OECD collections, including EU collections (FAO, 2009).

In summary, EU ex situ collections play a fundamental role in the user chain acting as direct providers to both commercial and non-commercial users. In fact, several commercial sectors including the horticultural and seed industry source almost all their genetic resources from ex situ collections. The role of private and in-house ex situ collections is also important in various sectors including the horticulture and seed industry, where in-house collections are integral to the plant breeding process. Non-commercial sectors rely on ex situ collections even more strongly. This is particularly the case for botanic gardens, which rely on genetic material from other botanic gardens to keep their collections and conservation activities alive, but also for the academic research sector, which often owns or is affiliated to particular ex situ collections for the purposes of scientific research.

Existing approaches to ABS in each sector

Since the coming into force of the CBD in 1993 the general trend for EU sectors with regard to ABS has been towards the development of codes of conduct to ensure compliance with local ABS legislation, the formalization of transactions in genetic resources through Material Transfer Agreements (MTAs) and the improvement of documentation systems. Generally, sectors primarily operating upstream in the EU such as culture collections and botanic gardens have taken significant steps to bring their conduct into line with the ABS requirements of the CBD. Despite the general willingness to comply with the CBD by those sectors, however, the level of awareness of ABS legislation, formalisation of transactions and documentation of collections is often hampered by the lack of appropriate financial and human resources of the individual collections. Codes of conduct and other voluntary measures have also been developed by sectors primarily operating downstream. The level of awareness and commitment to ABS-compliant practices is however variable across those sectors.

As regards sectors primarily operating upstream, since the CBD, botanic gardens and culture collections have taken substantial steps towards the establishment of codes of conduct for bioprospecting and the formalization of transactions through the use of formal networks and MTAs to ensure compliance of users with local PIC and MAT requirements and ensure a climate of confidence in provider countries with regard to their practices. However, smaller gardens and collections lacking the necessary financial and human resources still engage in a high number of informal transactions (i.e. transactions of genetic material that are not subject to any written contract or agreement) (van den Wollenberg *et al*, interview, 2012; FAO, 2009; Stromberg *et al*, 2006). In 2005 it was found that only 13% of culture collections had a written policy for complying with the CBD and only 40% of the strains received were estimated to be accompanied by a formal MTA (Stromberg *et al*, 2006). With regard to botanic gardens, around 10 years since the development of the IPEN network only 130 out of 550 gardens in the EU are taking part in its code of conduct and formalised transactions.[29]The

[28]The number of deposits in 119 WFCC culture collections in 2005 was approximately 10,000 overall.
[29]http://www.bgci.org/resources/ipen/

aim of this network is to facilitate the exchange of living plant material between members while respecting the ABS requirements of the CBD.

Other significant codes of conduct developed by those sectors include the OECD Guidelines for Biological Research Centres (BRCs), which apply to a wide range of *ex situ* collections that intend to be part of the Biological Resource Centre Network. Practices of disclosure of information on the country of origin, documentation and respect of MAT when further transferring a certain material are requirements with which an *ex situ* collection will have to comply in order to be accredited as a BRC. Specific to culture collections is the MOSAICC code of conduct, which sets minimum standards for bioprospecting, promotes the use of the World Data Centre for Microorganisms tagging systems as a way to attach to new strains a global unique identifier as tracking device and the use of standard contracts such as the European Culture Collections Organisation core MTA for the further distribution of microbial genetic resources to other users in the chain.

With regard to the state of documentation systems in *ex situ* collections, in 2009 it was estimated that around 90% of all living plant collections of botanic gardens around the world pre-dated the entry into force of the CBD (Wyse Jackson, 2001). While it is common practice for botanic gardens to hold information on the year of access and country of origin of plant material, there is no consistent practice and much data has been lost through the widespread informal transfers of plant material that have taken place both before and after the CBD (van den Wollenberg *et al*, interview, 2012). For culture collections, it is estimated that 50% of the strains held worldwide were acquired before the CBD (FAO, 2009). In light of the well-developed electronic documentation systems of culture collections it would not be problematic to distinguish pre- and post-CBD material, although information on the country of origin has started to be systematically documented by culture collections only since the coming into force of the CBD (Fritze, 2010; Desmeth, interview, 2012).

The approach to ABS of universities and research institutes in the EU is generally characterised by informal transactions and relationships based on mutual trust, except when collaborating with other entities with well-established ABS practices (e.g. botanic gardens, culture collections, pharmaceutical firms etc) (Desmeth, interview, 2012). Microbial research collections, for example, are estimated to contain a much higher quantity of microbial strains than culture collections, which is nevertheless often not thoroughly documented and exchanged with other research institutes on an informal basis (FAO, 2009).[30] That said, sector specific voluntary instruments have recently been developed, including the "Guidelines on the Access to Genetic Resources and their Transfer" (2011) developed by CIRAD, INRAD and IRND (three major French public research institutes engaging with genetic resources) and the "Agreement on ABS for Non-Commercial Research" (2012), a standard contract developed by the Swiss Academy of Sciences to guide researchers in the negotiation of MAT.

As regards sectors primarily operating downstream, the approaches towards ABS and the level of awareness of ABS rules are highly variable across sectors.

In the pharmaceutical industry, the level of awareness and compliance with ABS requirements is high only for large pharmaceutical and pharmaceutical biotechnology companies that still substantially engage in natural products research (e.g. Novartis, Merck & Co.) (EFPIA *et al*, interview, 2012). For pharmaceutical companies in general, while the IFPMA (the International Federation for Pharmaceutical Manufacturers and Associations) has developed "Guidelines on Access to Genetic resources and Equitable Sharing of Benefits Arising out of

[30] http://www.mirri.org/background.html

their Utilisation", these are purely voluntary and were mostly conceived to respond to external political pressures rather than a reflection of common practice. The exercise of due diligence when sourcing genetic resources from intermediaries, for example, is not covered by the guidelines and is outside the practice of most pharmaceutical companies. Exercising due diligence over the origin of genetic resources sourced from intermediaries is considered impractical by most pharmaceutical companies due to the complexity of the utilisation chain (EFPIA *et al*, interview, 2012). The "Guidelines for Bioprospecting for BIO Members" are relevant for pharmaceutical biotechnology companies. Those guidelines are more far reaching than the ones developed by the IFPMA, establishing best practices for documentation and prohibiting the acquisition of genetic resources from intermediaries when unable to provide evidence on PIC and MAT. Regarding the general state of documentation systems in chemical libraries of pharmaceutical companies, apart from the specialised internal collections of companies systematically engaging in natural product research, it is estimated that the origin of collected compounds is often not documented. (EFPIA *et al*, interview, 2012).

In the plant breeding sector, while many exchanges between breeders, scientists, private people take place informally because of the breeder's exemption, scientific and private exemptions under the CPVR and UPOV plant variety protection systems, there is a general trend towards formalization of transactions (MTAs) in transfers from genebanks and other *ex situ* collections (Scholen *et al*, 2011). As far as PGRFA listed under Annex I of the ITPGRFA are concerned, exchange of plant genetic resources within the plant breeding sector (seed industries and research institutes) are carried out under the standard Material Transfer Agreement (sMTA) established under the multilateral system, covering around 440,000 transfers of genetic material per year (ITPGRFA, 2012). The same sMTA is also used by several genebanks for transfers of plant genetic resources falling outside the scope of Annex I. SMTAs are used *inter alia* because standard contracts keep transaction costs low compared to *ad hoc* bilateral agreements (Scholen *et al*, 2011). The ornamental sector, on the other hand, is considered to have low levels of awareness concerning ABS requirements. This may be partially due to the sector's low overall reliance on wild genetic resources (Laird and Wynberg, 2012). As a result, no specific sectoral code of conduct with regard to ABS has yet been developed, although there is ample evidence of ABS agreements being concluded in provider countries in partnerships with botanic gardens and local organisations.

For the biotechnology industry generally, the "Guidelines for Bioprospecting for BIO Members" issued by BIO, the world's largest biotechnology association, is the most important code of conduct regarding ABS (see above). For the green biotechnology sector, for example, it was maintained that the exercise of due diligence to ensure that genetic material has been properly sourced is a key practice of companies, which generally will only work with material acquired through MTAs. Because of the remaining legal uncertainties in the use of the IT-PGRFA sMTA, only 1 to 5% of PGRFA are accessed under such standard contracts. (CropLife International, interview, 2012).

In the biocontrol sector, genetic resources are often exchanged through free multilateral exchanges of biocontrol agents that take place through informal networks of practitioners or the International Organisation of Biological Control (FAO, 2009). The utilization of MTAs is common as far as sourcing from culture collections is concerned. As regards bioprospecting, no code of conduct has been developed but ABS agreements are often concluded with local research institutes. Because of the low profit margin of this sector, benefit sharing is generally non-monetary, taking the form of capacity building, training and joint research projects (FAO, 2009).

The cosmetics industry, while increasingly developing industry-wide as well as internal voluntary ABS due diligence systems, has historically been characterized by a general lack of awareness regarding ABS obligations (Laird and Wynberg, 2012). From 2007 onwards this sector has started participating in several initiatives aimed at improving awareness and compliance with ABS standards. This includes participation in the Union for Ethical Biotrade (2007), which provides for annual progress reports and external audits on companies' performance with regards to CBD objectives and the National Resources Stewardship Council guidelines (2010).

Access to and exchanges of genetic material and benefit sharing in the animal breeding industry are primarily regulated by private law agreements and a common understanding among breeders/providers on the rights over the material. As a result no ABS code of conduct has been developed by this sector. In fact, AnGR are generally protected by physical ownership, i.e. the owner of the farm animal determines to what extent and under which conditions their germplasm may be made available to prospective users (Kaal-Lansbergen and Hiemstra, 2003). Pig and poultry breeding companies, for example, use contracts forbidding the buyer from selling breeding material from the purchased animals or requiring the payment of a royalty on future profits (Hiemstra *et al*., 2006; FAO, 2009).

In the cultivated forestry sector existing approaches as regards ABS are not known. Such approaches may exist in the forest research sector.

Conclusion

The above description underlines that:

- Genetic resources and issues relating to ABS affect many activities and sectors of the EU economy - from botanic gardens, culture collections and research collections, to biocontrol, seed banks, agriculture/green biotech, to pharmaceuticals and industrial biotech, to cosmetics, horticulture, and the food and beverage sector (see also sectoral sheets in Annex 3).

- There are common issues facing this wide range of sectors. These include: compliance with legislation in countries of origin related to the access to genetic resources and/or traditional knowledge associated with genetic resources; the difficulty of tracing the country of origin of genetic resources and conditions attached to their utilisation when resources are accessed through intermediaries; the issue of development costs and related issues of benefit sharing and good governance.

- There is a diversity both across and within sectors (e.g. across large and small players and across subsectors) of the role and importance of genetic resources and traditional knowledge, used both for commercial and non-commercial activities.

- It is possible to differentiate between upstream players/activities (botanical gardens, cultural collections and research collections & private collectors) and downstream sectors/players (biocontrol, seed banks, agriculture/green biotech, pharmaceuticals and industrial biotech, cosmetics, horticulture, and the food and beverage sector) as they face many common challenges as regards the Protocol and have some common or at least inter-related activities.

- Some sectors have undertaken activities related to ABS issues of the Protocol – these are generally voluntary sector measures (e.g. codes of conduct and some *ad hoc* ABS agreements) in response to growing PIC/MAT requirements by providers in third countries.

- There is a significant gap between current practices and the requirements of the Nagoya Protocol.

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ANNEX 9: TRACKING AND MONITORING GENETIC RESOURCES FLOW

Executive summary of *G.M. Garrity, L.M. Thompson, D.W. Ussery, N. Paskin, D. Baker, P. Desmeth, D.E. Schindel and P.S. Ong,* "Studies on Monitoring and Tracking Genetic Resources", Document UNEP/CBD/WG-ABS/7/INF/2 of 2 March 2009.
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EXECUTIVE SUMMARY

Introduction

Technological innovations, in areas such as DNA sequencing and information technology are characterized by exponential development rates and lead to results that are typically unanticipated when first introduced. Three examples demonstrate this clearly. In 1995 it took Fleischmann *et al.* thirteen months to sequence the complete genome of the bacterium, *Haemophilus. influenzae* at a cost of approximately fifty cents per base pair. Today a bacterial genome can be sequenced in less than a day for pennies per base pair and the possibility of sequencing a complete bacterial genome in a few hours for under $1000 looms in the near future. In 1983 TCP/IP, the underlying protocol of the internet became operational (Internet, 2009). As of June 30, 2008, 1.463 billion people use the Internet according to Internet World Stats (2009) with the greatest growth in usage between 2000-2008 occurring in Africa (1,031.2 %), Latin America/Caribbean (669.3 %) and Asia (406.1 %). On August 6, 1991, the European Organization for Nuclear Research (CERN) publicly announced the new World Wide Web project. Eighteen years later the Indexed Web contains at least 25.9 billion pages (worldwidewebsize, 2009). According to the UN (2007), 64% of all mobile phone users can now be found in the developing world. With a compound annual growth rate of 49.3% over the last seven years Africa has become a key market for global telecom operators; and it is expected that this market will continue to grow faster than any other region over the next three to five years (Bachelerle *et al*, 2009) In parts of Africa, health teams are synchronizing their mobile devices and collecting data from rural clinics to provide better health care (Vital Wave, 2009). Clearly the digital divide that once existed is closing rapidly and databases and other digital resources are accessible to anyone anywhere today with an internet connection and a browser on a computer or handheld device, which may be a cell phone.

It is in this environment of rapid technological innovations and global information access in which the Convention on Biological Diversity (CBD) must work to ensure the *sustainable use* of biodiversity as a means to justify and underwrite its preservation. As part of this effort an international regime (IR) on accessing genetic resources and sharing benefits derived from their utilization (Article 15 of the CBD, Access and Benefit Sharing, ABS) is currently being negotiated by the Conference of Parties (COP) of the CBD. The purpose of this paper is to assist the COP in these negotiations by providing a detailed examination of the following technical issues:

(a) Recent developments in methods to identify genetic resources directly based on DNA sequences;

(b) Identification of different possible ways of tracking and monitoring genetic resources through the use of persistent global unique identifiers

(GUIDs), including the practicality, feasibility, costs and benefits of the different options.

Genetic resources

Genetic resources are used worldwide by many different industries, academic institutions and environmental organizations to achieve various goals, ranging from developing new commercial products and processes to exploring new research avenues for cataloging and preserving biotic specimens arising from biodiversity inventories. In Article 2 of the CBD, genetic resources are defined as "genetic material of actual or potential value" and are further defined as "any material of plant, animal, microbial or other origin containing functional units of heredity." The value of these resources need not be exclusively genetic material. It may also be derived information, such as functional or regulatory pathways, structural polymers or biological functions of an organism that are encoded for by the genetic material, including metabolic products that have some practical applications (*e.g.*, low molecular weight organic acids; anti-microbial agents, such as antibiotics, and other biopharmaceuticals, flavors and fragrances, enzymes for industrial applications).

Establishing provenance of genetic resources and tracking their movements and defining the terms of use

Currently, the use of, and access to, specified genetic resources are governed by contractual agreements between the providers and users of those resources. For the purpose of this study it is assumed that such agreements are in compliance with all the relevant existing legal and other instruments at national, regional and international levels relating to ABS.[31] Contractual negotiations that follow the voluntary Bonn Guidelines result in a set of accompanying documents that explicitly detail the terms of any agreement including prior informed consent (PIC) and material transfer agreements (MTAs) and possibly Mutually Agreed Terms (MATs) and Certificates of Origin (CoO). Such documents by themselves do not provide a means by which a specified genetic resource(s) can be singled out and tracked, but do establish an important part of the baseline information that must be collected and made accessible to various parties to the agreement. These agreements also establish the conditions for access to both the resources and information over time and should also specify what types of information are required to follow along with any genetic resource and any real or abstract derived products, either for fixed periods of time or in perpetuity. With this minimal information in hand, it becomes possible to devise reasonable and extensible models to track each genetic resource as it moves from its point of origin through one or more user organizations for a variety of purposes.

It should be understood that a large-scale tracking system that meets the needs of the IR does not yet exist. Smaller-scale implementations do, however; and have features that are desirable in the anticipated tracking system for genetic resources. These are discussed in detail in *Part II: Genetic Resources: Use of identifiers in tracking genetic resources*. We have drawn from prior experience with those smaller scale systems to gain useful insights into the requirements of a robust, reliable and trustworthy tracking system that could accommodate the needs of a diverse end-user community working in pure and applied research, international trade, regulation and enforcement. It is important to stress that development of a complete tracking system for genetic resources must consider non-technical issues as well, including realistic policies that address complex social, business, and scientific requirements. This will ensure

[31] An in-depth overview of recent developments at national and regional levels relating to ABS can be found in UNEP/CBD/WG-ABS/5/4 (Ad Hoc Group ABS, 2007).

widespread acceptance and usage. It is not uncommon for technically sound information systems to fail because user needs were not met or the system rigidly modelled practices that became obsolete because of changes in technologies external to the system, but critical to the organizational goals, that were not anticipated or could not be incorporated into the system. This is particularly true in the life sciences and is discussed in *Part III: Advances in genetic identification.*

Redefinition of genetic resources and consequences for tracking

Whereas whole organisms or parts of organisms were once the subject of study and trade, contemporary biology has expanded its focus to incorporate molecular and informatics methods (*in silico*). These newer methods allow us to describe living systems not only on the basis of readily observable traits, but also upon their genetic potential based on a direct analysis of selected portions of the genome or the entire genome. As a result, genetic resources are now being used in various forms ranging from extracted DNA (including from mixed populations in metagenomic studies) to various types of sequence data that are stored in public and private databases. These derived genetic resources are readily copied, mobile and readily accessible to a global audience and can be used for a variety of purposes (*e.g.*, expression in heterologous hosts, engineered chimeric pathways, synthetic life forms) that may have not been intended or anticipated in original agreements.

Therefore, it can be argued that rights and obligations under the IR may extend to the exploitation of genetic resources, regardless of how those resources are constituted. Although a discussion of the merits of such thinking is beyond the scope of our charge, we believe it prudent to consider the consequences. Under such an interpretation, a system for tracking genetic resources would have to provide a means for providers to track the uses of the data and information derived from their genetic resources. The task of tracking successive uses of such information, although complex, is theoretically feasible and would require the crafting of appropriate metadata, careful utilization and implementation of a persistent identifier (PID) system and development of custom tracking applications. However, it should also be understood that such a system would have to accurately reflect our current and future knowledge of biology. The vast majority of gene sequences is ubiquitous in nature and oftentimes occurs in distribution patterns that do not necessarily conform to national boundaries. It should also be understood that current technology allows the rapid synthesis and evolution of genes and pathways *in vitro* and *in silico*. Therefore, apparent misuse of a resource by a user or third party may not be actual misuse. Rather, it may be an instance of coincidental use of a like resource obtained independently. It is with these points in mind, that we offer the Secretariat and the COP our observations and recommendations on the agreed upon topics.

Single gene based identification methods

The rapid development of molecular technologies that enables characterization of organisms at a genetic level has opened new possibilities in species identification. In 1977 Woese and Fox produced the first phylogenetic classification of prokaryotes[32] based on the comparison of the nucleotide sequence of the 16S rRNA gene. This gene is universally distributed, highly conserved, evolves very slowly, and plays a key structural role in the ribosome, which in turn is part of the cellular machinery involved in protein synthesis. All life forms, as we know them, possess ribosomes, so according to the early proposals of Pauling and Zukerkandel, the

[32] The term prokaryote is a contentious but commonly used name to group bacteria and archaea together based on their absence of a nucleus; a feature found in all eukaryotes

sequence of this molecule could serve as a molecular chronometer, by which the evolution of different species could be traced.

Woese's work revealed that bacteria and archaea formed two deep and very distinct evolutionary lineages. The third lineage, based on this model of evolution, encompasses the eukaryotes (the plants and animals), which characteristically posses a membrane enclosed nucleus and organalles (including the mitochondria and chloroplasts). Eukaryotes possess ribosomes, which in turn contain an 18S rRNA. The eukaryotic 18S rRNA gene shares many homologous regions with the prokaryotic 16S rRNA gene. Thus, it is possible to make meaningful comparisons of all species based on the sequence of this gene. Since the sequence of the 16S rRNA gene is approximately 1540 nucleotides in length, there is sufficent information content to allow for very far reaching comparisons.

Woese's discovery has led to a radically different understanding of the evolutionary history of all life, which is generally well accepted and has led to the abandonment of alternative models of classification (e.g., Whittaker's five kingdoms). 16S rRNA Sequence analysis has become the principal method by which bacteria and archeae are now classified. In the past two decades, thousands of new taxa have been described based on this method, along with numerous taxonomic rearrangements. Concurrent improvements in sequenceing methodologies of have greatly accelerated this process. Today, 16S rRNA sequence data is routinely used to presumptively identify bacteria and archaea to the genus level and to deduce community composition in environmental surveys and in metagenomic analyses. These efforts are well supported by publicly available tools and highly curated data sets of aligned 16S rRNA (e.g., the Ribosomal II Database, ARB/Sylva project, GreenGenes).

But it is now well understood that a single gene may not be adequate to yield an accurate identification to the species or subspecies level and additional gene sequences along with other data may be required. Confounding issues include non-uniform distribution of sequence dissimilarity among different taxa and instances in which multiple copies of the 16S rRNA gene may be present in the same organism that differ by more that 5% sequence dissimilarity. This can lead to different presumptive identifications for the same individual, depending on which 16S rRNA gene is analyzed. We also understand that numerous instances of misidentification and taxonomic synonomies have accumulated prior to the widespread adoption of these methods and that discrepancies between names and correct classification remain to be resolve. In such instances, molecular evidence needs to be used to support taxonomic revision rather than attempting to force-fit earlier concepts into a classification based on reproducible molecular and genomic evidence.

These observations are relevant to the development of a tracking system for genetic resources because taxonomic names are commonly used in the scientific, technical and medical literature as well as in numerous laws and regulations governing commerce, agriculture, public safety and public health. But taxonomic names are not suitable for use as they are not unique, not persistent and do not exist in a one-to-one relationship with the abstract or concrete objects they identify.

Analogous developments are currently underway in the fields of botany and zoology. Sequence based methods have been applied on a limited basis to various species of eukaryotes for many years. However, it was not until recently that the community began to accept the possibility that a single gene could be used for identification of eukaryotes. This approach is now being applied in a highly coordinated fashion to build useful resources to identify plants, animals, fungi, protists and other distinct eukaryotic lineages. Consensus is beginning to emerge on a small number of preferred target genes, of which a partial sequence of the mitochondrial cytochrome

c oxidase subunit I gene is preferred. This highly coordinated effort is much more recent than the corresponding activities in microbiology, and championed by the Consortium for the BarCode of Life (CBoL) program.

Whole genome sequencing and its impact on tracking genetic resources

In *Part III: Advances in genetic identification* this paper provides an in-depth review of next generation sequencing (NGS) technologies. Because of the rapid pace at which these technologies are evolving this section should be viewed as a set of "snapshots" of the current state of the art, and a harbinger of the future of DNA based identification methods. We discuss methods that are currently in use; those that have just recently become available on the market, (near-future NGS methods); and those that are still under development. These NGS sequencing technologies enable the rapid evaluation of specific regions of the genome of a biological entity to determine to which genus, species, or strain it belongs. (*e.g.*, the *16S* rRNA gene for taxonomic purposes for bacteria; the use of cytochrome *c*-oxidase subunit I (*cox1*) for eukaryotes).

Fuelled by innovations in high-throughput DNA sequencing, high-performance computing and bioinformatics, the rate of genomic discovery has grown exponentially. To date, there are more than 500 complete genome sequences and more than 4000 ongoing genome and metagenome sequencing projects covering species ranging from bacteria to yeast to higher eukaryotes. The results that stream forth from these studies are constantly refining and reshaping our understanding of biological systems. As part of the funding requirement of various governmental and non-governmental agencies, the vast majority of these sequences are made publicly available from the INSDC databases (GenBank, DDBJ and EMBL) after brief embargo periods during which time the funding recipients may publish their results. Typically, after one year, the sequence data is open to anyone wanting to publish their own findings or mine those data for other purposes.

All indications are that future genome-based technologies will be "smaller, cheaper, faster". This will make genome-enabled detection tools available to a wide audience in both developed and developing nations. Clearly, very low cost sequencing technology along with sophisticated bioinformatics tools will soon be available to presumptively identify a genetic resource, with a high degree of accuracy and reliability, at the point of need.

Tracking genetic resources

The concept of identification is central to the goals of the CBD ABS regime, which rests on the fundamental principle that a user is legally obliged to share in the benefits obtained through the use of a particular genetic resource with the provider. Identification is one of the first steps in tracking an item over time. Under some circumstances, identification to the family, genus or species level may be adequate and identification methods based on a single gene may be appropriate (e.g., biotic inventories, wild-life management, ecological studies). However, there is ample evidence based on over half a century of natural product screening and supporting genomic data that such approaches may be inadequate if the trait of interest occurs in subpopulations within a species or is widely distributed across taxonomic boundaries as a result of horizontal gene exchange. A useful tracking system must accurately reflect current knowledge and readily incorporate new knowledge via continuous feedback over a long time frame as transactions involving genetic resources may be long lived (>20 yrs).

The number of items to be identified and tracked within the anticipated system is a challenge and the extent of the task will depend largely on the legally required "granularity" of the

identification. Although there is a tendency to view this as a taxonomic problem and the anticipated tracking system as a taxonomic resource, it is decidedly distinct. What is required is a mechanism to track the fate of multiple genetic resources as each is transferred from one party to another and various abstract and concrete products are generated along the way. In some cases the product may be useful for taxonomic purposes and in other cases taxonomic information may be useful for predictive purposes, but in most cases taxonomic information would be ancillary. Systems of such design are challenging as they are open-ended and must work with data of varying granularity. The point is not to define all the types of data *a priori*, but to define lightweight metadata models that define genetic resources and allow them to be permanently bound other to varying amounts and types of information that accumulate about that genetic resource over time. Inherent in such designs are links established through aggregates of foreign keys that may exist within a single system or on a remote systems accessible via the internet.

Persistent identifiers

In their simplest form, persistent identifiers are nothing more than unique labels that are assigned to objects in a one-to-one relationship. Such identifiers are well understood in computing systems and we present examples of identifiers as used in a large-scale laboratory information management system (LIMS) in *Part II: Genetic Resources: Use of identifiers in tracking genetic resources*. When used in the context of the internet, the concept of persistent identification is frequently coupled with the concept of "actionability", implying that the PID is persistently linked to a specific object and when actuated, will always return the same response to the end-user (typically a hyperlink to a specific web page or other form of digital content). In this context PIDs differ from URLs, which are used to create hyperlinks and provide the internet address of where a given object is stored. As the storage location is not persistent, some "behind-the-scenes" mapping of object identifiers to object locations is required (resolution). This topic is covered in more detail in *Part IV: Persistent identifiers*.

Persistent identifiers are a powerful enabling technology that provides a way to efficiently cope with chronic problems such as broken links and the general difficulty of reliable and reproducible information retrieval on the Internet. For example, PIDs associated with published articles allows rapid and accurate tracking of written works. PIDs are also in use within the life sciences such as the INSDC identifiers (*e.g.*, sequence accession numbers used at GenBank, EMBL, and DNA Database of Japan). However, these are largely institution specific, *i.e.*, used only within the institutions for which they were created, or are controlled by those organizations, such as the PubMed ID, issued by the National Library of Medicine.

Six PID schemes currently used across different domains and by a number of different organizations are reviewed and include: Uniform Resource Name (URN); Persistent Uniform Resource Locator (PURL); Archival Resource Key (ARK); Life Science Identifiers (LSID); Handle System (Handle); Digital Object Identifier System (DOI). This review also addresses the questions that need to be answered when an organization is assessing the need to incorporate a PID scheme into its data management plan.

Each of these identifiers is used in well-defined settings in which the data and metadata models of the underlying repositories were established *a priori*. The identifiers serve as a means of directly accessing a specific record or other form of digital content or the associated metadata. If the identifier is actionable, then it is possible to retrieve the linked object using the familiar interface of a web-browser. However, with the use of web services that provide structured access to the content of interest automatically (*e.g.* from a database or application

on a handheld device using embedded PIDs), similar results can be achieved where an interactive interface is not suitable.

An effective and durable PID scheme requires ongoing maintenance and therefore ongoing resources. While some tasks can be automated, responsibility for this ongoing task must be assigned to an agency, program or office or to a trusted third-party who can guarantee reliability and virtually constant up-time to meet the needs of various end-user communities. In the case of integrating a persistent identifier scheme within the ABS process, the use of a trusted third party with the appropriate expertise and resources is probably the best option, especially if that third party is already engaged in such activity for other purposes.

The selection of an appropriate PID for the CBD ABS and related activities will be critical for its broad utility and community acceptance. However, it does not obviate the importance of carefully defining precisely what the identifiers refer to, and what will be returned by queries of various types. It is possible to develop a range of PID services that could, for instance, provide a direct link to digital and paper copies of entire documents, such as PICs, MTAs, CoOs and other relevant agreements or permit tracking of genetic resources or parts of genetic resources in a future proof method, or do so on-the-fly. It could also be possible to track the transfer of materials and the corresponding agreements to third parties in a manner that is consistent with the rights and obligations of all parties to the initial agreement or to subsequent agreements. Similarly, the ability to track these genetic resources into the STM, general interest and patent literature is technically feasible.

Services such as these could be facilitated through the use of a trusted third party acting as a clearinghouse for registering ABS-related events (*e.g.*, PIC, MTAs, CoO and other relevant agreements) according to a set of well-understood business rules. With such a clearinghouse in place, it becomes possible to traverse a series of transactions backward and forward in time, even in instances where some ambiguity may exist. By drawing on highly interconnected information, it is possible to follow events, and to accurately recreate those events, when adequate documentation is available. Such a system would be useful for monitoring the use of genetic resources, especially since there will be instances in which long periods of time may exist between the time PICs, MTAs, and CoO are executed and some commercial or non-commercial product results. With the selection of the appropriate PID system a system of this design could support human and machine queries and facilitates the retrieval of all relevant documents from public and private databases, including the STM literature, patent and regulatory databases. This is discussed in more depth in *Part IV: Persistent Identifiers: Discussion* (CBD/ABS services)

Conclusion and Recommendations

Reduction to practice will require a commitment of interested parties from different sectors (*e.g.*, government, industries, botanical gardens, museums, academia, etc) to define standards for the key documents that are instrumental to implementing the ABS. Business rules and policies also need to be established in concrete terms so that useful prototypes can be built and assumptions (technical, legal and social) tested and refined. In *Part V: Conclusions and Recommendations* we offer the Secretariat and COP five broad recommendations along with our reasoning. In summary, these are:

1. Promptly establish the minimum information that must be contained in all relevant documents that are required for compliance with the IR (PIC, MTA, MAT, CoO). Stipulate which documents are mandatory and which are optional.

2. Adopt a well-developed and widely used Persistent Identifier PID system (*e.g.* DOI) that leverages an existing infrastructure and derives support from multiple sources rather than developing a new system or adopting one that is untested in commercial applications.

3. Carefully consider the current and future needs of genetic resource providers and users as the concept of resource tracking is deliberated. Biological and functional diversity of genetic resources are decidedly distinct. The system, including its human resource component, must be able to accommodate both with priority given to the latter as functional diversity is what leads to practical utility.

4. Deploy light-weight applications that use browser technology for interactive use and publish well documented application program interfaces to support other web service. Develop strong policies governing access and use of the resource to avoid data abuse

5. Deploy one or several prototype tracking systems to validate underlying concepts and refine critical elements that will be needed in a fully operational system. During the developmental phase address erroneous preconceptions and focus on making the system as transparent as possible.