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Subject:	Commission staff working document The Impact Assessment *accompanying the 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 Utilization in the Union

Delegations will find attached Commission document SWD(2012) 292 final / Part 1.

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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the 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 Utilization in the Union

Part 1

{COM(2012) 576 final}
{SWD(2012) 291 final}

COMMISSION STAFF WORKING DOCUMENT

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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 1

This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

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1. INTRODUCTION

Genetic resources - the gene pool in both natural and cultivated stocks - play a significant and growing role in many economic sectors: food, the development of medicines, development of bio-based sources of renewable energy, etc. 26% of all new approved drugs over the last 30 years are either natural products or have been derived from a natural product.[1]

The European Union and all of its 27 Member States are Parties to the Convention on Biological Diversity[2] (CBD). The CBD recognizes that states have sovereign rights over genetic resources found within their jurisdiction and the authority to determine access to such resources. The Convention obliges all Parties to facilitate access to genetic resources over which they hold sovereign rights. It also obliges all Parties to share in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Party providing these resources.

The CBD also addresses the rights of indigenous and local communities that hold traditional knowledge associated with genetic resources, and which may provide important lead information for the scientific discovery of interesting genetic or biochemical properties.

However, the CBD currently provides little detail on how access and benefit-sharing (ABS) for the use of genetic resources and associated traditional knowledge should be done in practice. Particularly industrialized country Parties have been very reluctant to adopt measures supporting effective benefit-sharing of their researchers and companies. As one consequence, some countries have established increasingly restrictive conditions for access to genetic resources or associated traditional knowledge. At the same time and in the absence of clear rules, European researchers and companies have been accused of 'biopiracy' by countries claiming a violation of their sovereign rights. These problems have seriously undermined global progress to conserve and sustainably use biological diversity; not least since states that are considered as 'biodiversity-hotspots' stand to gain the most from an effective ABS framework.

The issue of ABS is also relevant in international fora outside the Biodiversity Convention. Most prominently, the International Treaty on Plant Genetic Resources for Food and Agriculture was negotiated and in November 2001 adopted in the framework of the UN Food and Agriculture Organization as a specialised ABS instrument. The FAO Commission on Genetic Resources for Food and Agriculture has embarked on a multi-year programme of work on the relevance of ABS to different types of genetic resources used for food or agriculture purposes. More recently, members of the World Health Organization have adopted a Pandemic Influenza Preparedness Framework that balances interests in the rapid sharing of virus samples with the interest in sharing related benefits. The issue of ABS is also being discussed under the UN General Assembly in the context of a broader framework of measures to protect biological diversity in the high seas. In addition, intellectual property rights aspects of protecting innovations based on the utilisation of genetic resources and traditional knowledge associated with such resources are discussed in both the World Intellectual

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1 Newman and Cragg (2012), "Natural Products as Sources of New Drugs over the 30 Years from 1981 to 2010". *Journal of Natural Products*, 75(3), pp 311–335.

2 Convention on Biological Diversity (Rio de Janeiro, 5 June 1992, in force 29 December 1993). The treaty is available at <http://www.cbd.int/convention/text/>.

Property Organization and in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights.

The "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity" (hereinafter: Nagoya Protocol) is a new international treaty adopted on 29 October 2010 by the 193 Parties to the CBD by consensus. It is a treaty with legally binding effects that significantly expands the general ABS framework of the CBD. The Nagoya Protocol is expected to enter into force in 2014. Once operational, the Nagoya Protocol will generate significant benefits for biodiversity conservation in states that make available the genetic resources over which they hold sovereign rights. It will in particular:

- Establish more predictable conditions for access to genetic resources.
- Ensure benefit-sharing between users and providers of genetic resources.
- Ensure that only legally acquired genetic resources are used.

The EU and its Member States are politically committed to become Parties to the Protocol to secure access of EU researchers and companies to quality samples of genetic resources, based on reliable access decisions at low transaction costs.[3] This will create new opportunities for nature-based research, and contribute to the development of a bio-based economy.[4]

This report presents the assessment of the impacts of EU implementation of the Nagoya Protocol. Starting from the main obligations of Parties to the Nagoya Protocol, particularly those on access and on user-compliance, it identifies different options for meeting these obligations (as there is still flexibility on key issues), and it analyses for each option how it would impact on the EU acquis and on existing practices of providing and utilizing genetic resources and associated traditional knowledge in the EU, and on our relationship with major international partners. In particular, it examines the value-added of EU action in the form of coordinating and setting common rules compared to a baseline where Member States decide to implement the Nagoya Protocol in their own way.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The CWP 2012 foresees the adoption of an "ABS package" implementing the Nagoya Protocol for the third quarter of 2012 (2012/ENV/002).

2.1. Inter-service group

A Commission Impact Assessment Steering Group was established in February 2012. The group was led by DG Environment. The following Commission services indicated their interest to follow the work: SG, AGRI, DEVCO, EEAS, ENTR, JUST, LS, MARE, MARKT, RTD, SANCO, TAXUD, TRADE. The group met 3 times to discuss drafts of the consultant study, and 2 times to discuss this IA study. All members of the group were regularly informed and consulted by email.

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[3] See Council Conclusions of 20 December 2010 (paragraphs 1 and 21), 23 June 2011 (paragraph 14), European Parliament Resolution of 20 April 2012 (paragraph 101), Commission Communication on an EU Biodiversity Strategy to 2020 (COM (2011) 244) (Action 20).

[4] Commission Communication on a Bioeconomy for Europe (COM (2012) 60 final).

2.2. Consultations

Consultations with the EU Member States

The Commission regularly informed Member States in meetings at Council Working Party level on the state of play in the development of EU implementing measures without prejudging in any shape or form the necessary discussion between Commission services. Regular informal meetings with ABS experts of Member States confirmed that the two Member States (ES, DK) that initially indicated their intention to unilaterally move ahead to implement and ratify the Nagoya Protocol, have decided to wait for the presentation of an eventual EU proposal. The broad majority of Member States, particularly those with major user interests (DE, UK, FR), have consistently stressed that they would see the need for an EU-coordinated approach to implementation. The need for an EU-coordinated approach to implementation and ratification was also stressed in an opinion of the Council Legal Service.

Public Consultation

The Commission held a web-based public consultation from 24 October to 30 December 2011 to seek feedback on a list of questions that addressed key aspects of Nagoya Protocol implementation. 43 replies were received that represented a much broader number of respondents, since the majority of replies came from European or international associations with hundreds or thousands of members each. The respondents covered most sectors potentially affected by implement measures under the Nagoya Protocol. All respondents (except a few neutral replies) pleaded for an EU-harmonised approach to user-compliance measures, with a clear majority considering an EU-Regulation as the most appropriate instrument for achieving harmonised implementation. The majority of respondents considered that implementing measures could have positive effects on competitiveness and on administrative burden, but stressed that such effects depend on the specific implementing measures chosen. Industrial users (e.g. pharmaceutical, biotechnology, seeds, health&beauty) stressed their lengthy supply chains and that information about prior informed consent and benefit-sharing arrangements is currently not available at points in the chain where it may be needed. Research institutions stressed the importance of clear, simple and transparent rules and the need for clarifying ABS-related issues at the time of access to avoid difficulties later on. A summary of the public consultation is included in Annex 3.

Ad hoc consultations

DG Environment organised a technical meeting with EU stakeholders on 26 January 2012. It invited all respondents to the public consultation, Brussels-based representatives of stakeholders, and experts nominated by Member States. At the meeting, the Commission presented its summary of the public consultation, whereas members of the consultant team presented tentative findings of their work. Participants used the opportunity to challenge the consultant team on some of their findings.

DG Environment officials held many meetings with representatives of botanical gardens, culture collections, industry federations or individual companies and participated in various expert conferences on the Nagoya Protocol. The consultant team conducted semi-structured interviews with representatives of stakeholders and companies.

Consultations with third countries

In 2011, DG Environment asked several EU delegations in third countries to seek information from major partner countries on the state of play and their concrete ideas for Nagoya Protocol

implementation. The feedback received was complemented by more detailed bilateral discussions with Australia, Brazil, India, Japan, Mexico and Switzerland.

Expert study

To support the impact assessment process, the Commission contracted external consultants to analyse the legal and economic impacts of implementing the Nagoya Protocol in the European Union. Information from the consultant study was used as input to this IA. The consultant work included twelve sectoral studies on different groups and sectors utilising genetic resources in the Union. The sectoral studies were complemented by interviews with experts from the groups and sectors studied and overall helped – together with the information already available to the Commission – to understand the relevance of genetic resources to EU users, current approaches to ABS by users, existing bottlenecks, as well as the expectations of stakeholders and their views on main policy options.

2.3. Impact Assessment Board

The draft Impact Assessment was submitted to the Board on 20 June 2012 and discussed at the Board meeting of 18 July 2012.

The key amendments made to the impact assessment following the issuing of the Board opinion are:

– A clearer description of the international legal and political context through amendments to the introduction and the problem definition of the study.

– A more elaborate explanation of current practices of genetic resources utilisation in the Union.

– A clearer explanation on why a unilateral implementation of the user-compliance pillar of the Protocol is likely to negatively affect the internal market including by providing more specific examples.

– Clarification on the appropriate legal basis for implementing the Nagoya Protocol and more detailed considerations on why binding EU-level measures on access currently would not seem justified.

– Development of more elaborate monitoring indicators linked to the objectives and the proposed implementing measures.

– A general explanation on the rationale behind the design of the policy options considered in this study and particularly how the due diligence option would be implemented, monitored and enforced, and the sanctions envisaged. These additions are complemented by more detailed considerations on eventual impacts and costs.

– More detailed considerations as regards the creation of a level playing field, and the impacts and benefits of the due diligence option particularly for SMEs and effects on the use of public funds.

– A clearer explanation of the rationale for and benefits of introducing a system of 'trusted sources'.

– The results of the public consultation were summarised in much greater detail.

3. PROBLEM DEFINITION

The EU and most of its Member States[5] have signed the Nagoya Protocol and thereby committed themselves to work towards its implementation and ratification. This political commitment is also expressed in statements by the European Parliament, the Council of the European Union, and by the Commission.[6]

Other industrialized countries that have signed are Australia, Japan, Norway, Korea, Switzerland and the Ukraine. The US cannot ratify the Protocol as it is not a Party to the CBD. Only Norway has so far put in place implementing legislation. Switzerland is advanced in developing implementing legislation, but likely to wait with finalization until there is more clarity on the EU's approach. Other major partners (e.g., Korea, Japan) have signaled their intention to develop implementing measures in view of the EU's approach to achieve a level-playing field for their researchers and companies. Australia arguably has the worlds best functioning domestic access framework and would thus benefit from ratification and indeed it has expressed its interest in close collaboration with the EU on user-compliance measures. Nevertheless, like New Zealand and Canada, Australia is engaged in discussion with its indigenous communities as regards rights over resources, including genetic resources. These three countries may not ratify the Protocol before they have significantly advanced their domestic discussion on this matter.

Many countries from the emerging economies and developing countries group had put in place domestic access frameworks prior to the adoption of the Nagoya Protocol. The main political reason for the launching of the Nagoya Protocol negotiation was a perception by these countries that their efforts on access would not be supported by complementary efforts of user countries, such as the EU and its Member States. After the Protocol's adoption and its signature by many industrialized countries, there is now a strong expectation that industrialized countries such as the EU and its Member States will take effective implementing measures, particularly in the field of user-compliance. Some emerging economies and developing countries are now revising their access frameworks in light of the Protocol. Most have little experience with the user-compliance measures required under the Nagoya Protocol. Particularly emerging economies that need to balance provider with user interest (e.g., Brazil, India) have expressed their interest in a close dialogue with the EU particularly on user-compliance measures.

Overall, there is a major expectation that the EU and its Member States will swiftly ratify and implement the Nagoya Protocol. This expectation also presents a major opportunity, since the EU's approach to user-compliance will become a main reference point for user-compliance measures taken by other industrialized countries and in emerging economies. It also seems that failure of the EU and its Member States to ratify and implement the Nagoya Protocol would deepen the frustration of major provider countries, particularly from the so called "mega-diverse" group of countries. This would very likely result in increasing restrictions on EU researchers and companies that wish to access quality samples of genetic resources from

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5 Except Latvia, Malta and Slovakia.

6 See Council Conclusions of 20 December 2010 (paragraphs 1 and 21), 23 June 2011 (paragraph 14), European Parliament Resolution of 20 April 2012 (paragraph 101), Commission Communication on an EU Biodiversity Strategy to 2020 (COM (2011) 244) (Action 20).

these countries and thereby compromise important EU objectives and hamper the commercial and non-commercial interests of EU users (see 3.2.1 below).

The problem addressed in this IA is to identify a legally sound, effective and efficient way of implementing the Nagoya Protocol in the Union, through measures that satisfy our international obligations under the Protocol and that create legal certainty and an enabling context for those involved in research and development on genetic resources in the EU.[7]

3.1. Implementing the Nagoya Protocol: is the EU legal framework fit for the purpose?

Box 1 sets out a hypothetical, best-practice case of access and benefit-sharing that would be consistent with the basic access and benefit-sharing framework of the CBD.

Box 1: A hypothetical, best-practice case of access and benefit-sharing

A French researcher seeks to collect a little-known marine sponge from the Great Barrier reef in north-eastern Australia for basic research on its genetic and biochemical properties. The researcher logs on to the internet and applies electronically to the Queensland ABS authority for a permit to collect marine sponges for non-commercial research in a specified area of the reef. He receives the permit within ten working days after the Queensland ABS authority has done a basic check on the information provided. The collecting activity takes place after the french researcher has also (electronically) signed the standardised benefit-sharing arrangement for non-commercial research, which is a private law contract under Australian law. The contract allows the french researcher to do non-commercial research on the collected samples, it excludes any use for commercial purpose. He must put a reference sample of each collected species in the collection of Queensland University and also commits to sending them a copy of publications resulting from research on the collected sponges. Publications must mention the existence of the benefit-sharing contract and the use restrictions on the samples. The researcher is allowed to pass on samples to other researchers provided that these also agree to be bound by the conditions set out in the benefit-sharing contract.

A small biotech company in Germany is specialised in developing molecules for use in cancer medication. One of its scientists reads a paper published by the above french researcher on molecules from marine sponges from the Great Barrier reef, and considers that these molecules could help in an ongoing project. He gets in touch with the reference collection at Queensland University and applies for access to the samples identified in the publication, he indicates the commercial interest and accepts paying the standardised small fee for preparation and shipment of the samples. He also signs a standardised benefit-sharing contract that allows patenting of discoveries made in return for a commitment to sharing 2% of economic revenues that may result from an invention. The german biotech company discovers that one of the samples from Queensland University contains a molecule that is highly reactive with a specific type of tumor cells. Through various steps and modifications, company scientists manage to suppress unwanted properties of the molecule, while maintaining its reactivity. The company successfully obtains a patent on this discovery.

Practice has shown, however, that effective ABS transactions may face typical "problem" situations. For example:

– Genetic resources are collected in violation of the laws of the country of origin. International law would not support a claim by a representative of this country in the court of an EU Member State where the illegally acquired resources are utilised.

[7] A more detailed description of the legal framework established by the Nagoya Protocol is found in Annex 1. A synoptic overview of all 36 Articles of the Protocol is included in Annex 2.

– The responsible authorities of a country grant a permit for bioprospecting in indigenous territories without prior consultation with indigenous representatives. Is the European researcher allowed to use the obtained samples or not?

– A benefit-sharing contract between a provider and a research institute in the EU excludes commercial uses, samples are nevertheless passed on to other users for applied research without mentioning the ABS-related restrictions. One of these samples is used some years later by a company for developing a nature-based product. The company that successfully sells its nature-based product is alleged of "biopiracy". Is the lack of awareness by that company an acceptable defense? Is the person that broke the information-chain liable?

Access and Benefit-sharing according to the Nagoya Protocol

The CBD does not provide clarity how its Parties must address these and other "problem" situations. The Nagoya Protocol is much more detailed. It rests on two main pillars.

The **access pillar** leaves Parties discretion whether they wish to regulate access, and require prior informed consent and benefit-sharing for the use of their genetic resources or not. However, if a Party decides to do so, then it must implement the fairly detailed "international access standards" set out in the treaty. The Protocol also clarifies that states must engage with their indigenous and local communities in case access is sought to traditional knowledge or to genetic resources held by these communities. Main Protocol ideas in relation to access include: (i) government authorities or indigenous representatives must give their prior informed consent before access can take place, (ii) specific benefit-sharing obligations must be set out in private law contracts between a provider and a user, and (iii) access frameworks must be clear and transparent, based on non-arbitrary rules, and result in reliable and timely decisions, in a cost-effective manner.

The discretion of Parties to require prior informed consent or not means that states may ratify the Nagoya Protocol without requiring prior informed consent and benefit-sharing for the use of genetic resources over which they hold sovereign rights. Nevertheless, Parties that choose to require prior informed consent must comply with the Protocol obligations on access; it is not possible to comply with these access-provisions through voluntary measures.

The **user-compliance pillar** of the Protocol obliges all Parties to the Protocol to take measures that only legally acquired genetic resources and associated traditional knowledge are utilized within their jurisdiction. Parties must monitor the compliance of users within their jurisdiction and designate one or more checkpoints for this task. They must also take appropriate, effective and proportionate measures in cases where users within their jurisdiction do not comply with their ABS-related obligations. Parties must also ensure that disputes arising from specific benefit-sharing contracts can be taken to court.

It is not possible for a Party to comply with the user compliance obligations of the Protocol without taking legally binding measures. However, different than in the case of access, the user-compliance provisions of the Nagoya Protocol leave Parties quite some discretion on the type and mix of implementing measures chosen.

The Nagoya Protocol does not make an explicit statement on its temporal application. Academic commentators hold different views on this issue.[8] Parties must therefore address the temporal application of their implementing measures: whether these will apply only to genetic resources and associated traditional knowledge acquired after the Protocol's entry into force (expected for 2014) or also to uses of genetic resources and traditional knowledge that were acquired after the entry into force of the CBD in December 1993.

Further aspects that **must** be addressed concerns: (a) the obligation of Parties to respect existing specialized ABS instruments[9] and to establish a mutually supportive relationship with other relevant instruments and processes, (b) the obligation to promote and encourage non-commercial research, (c) the obligation to pay due regard to genetic resources with pathogenic properties, and (d) to consider the special characteristics of genetic resources for food and agriculture. Another important issue concerns (e) the management of relations with non-Parties to the Protocol.

The Protocol also obliges its Parties to establish a National Focal Point on ABS to liaise with the international Secretariat and to respond to information requests by stakeholders. Parties must also designate one or more Competent National Authority responsible for granting access and advising on applicable procedures for requiring prior informed consent and entering into mutually agreed terms. Parties may designate a single entity to fulfill the functions of both focal points and competent national authority.

Is EU law fit for the purpose?

The Nagoya Protocol is a so called "mixed agreement". It allows both the Union and the Member States to become Parties to the treaty at the same time. In this case, the Union and each of its Member States must be able to demonstrate for itself full compliance with all Protocol obligations. How this is achieved is an entirely internal matter to the EU and its Member States. In principle, the spectrum of possibilities ranges from the adoption of legally binding measures only at the level of the Member States with supportive, soft measures at Union-level to a full harmonization of legally binding measures at Union level supported by soft measures at the level of the Member States. The concrete approach chosen for implementing the Nagoya Protocol in the EU and its Member States rests on legal and practical considerations: any EU-level intervention presupposes the existence of Union competence and the demonstration of added value that will not be achieved through implementing measures under the sole responsibility of Member States.

The Protocol's **access pillar** is not implemented at the *Union-level*, as currently no Union-level law would establish whether access to genetic resources in the EU requires prior informed consent and benefit-sharing. Some Member States strongly feel that the decision whether to require prior informed consent and benefit-sharing or not is an issue of national sovereignty and cannot be regulated in Union law. Nevertheless, if a Member States chooses to require prior informed consent and benefit-sharing, its domestic access framework could become relevant to the acquis: EU nature legislation seems indirectly relevant for collecting activities in the wild. Other EU laws regulate the exchange of specific genetic resources used for agriculture or health purposes. It can also not be excluded that Member State access

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8 See Annex 1 for a detailed description of the differing views.

9 For example, the International Treaty on Plant Genetic Resources for Food and Agriculture concluded in 2001 in the context of the UN Food and Agriculture Organization and to which the EU is a Party. For details see Annex 1.

systems could come in tension with fundamental principles of non-discrimination, or that widely differing approaches to access could negatively affect the freedom of researchers or the free movement of goods.

A survey of *ABS laws and policies of eight EU Member States* conducted in preparing this IA[10] showed that only two Member States (ES, BG) have so far developed access legislation. Other Member States have explicitly decided not to require prior informed consent (NL). Upon ratification of the Nagoya Protocol, further Member States might decide to require prior informed consent in the future. France, for instance, has indicated that it is working on domestic access legislation at least for its overseas territories. Member States that decide to move into this direction must comply with the detailed access-provisions of the Nagoya Protocol. In doing so, they can also build on experience with domestic access frameworks in, for example, Australia or Latin America.

The Protocol's **user-compliance pillar** is not implemented at *Union-level*. Nevertheless, the activities that must be regulated are closely related to the EU internal market. Differing obligations on users to manage ABS-related information in different Member States, for example, could create significant costs and barriers for EU researchers and companies that are active in more than one Member State. Furthermore, some user measures, particularly where these would require changes in product approval procedures, cannot be implemented without changes to the acquis.

The above-mentioned survey of *ABS laws and policies of eight EU Member States* showed that none of the Member States surveyed has so far taken user-compliance measures as required under the Protocol. Member States legislating on user-compliance would have significant discretion how to design such measures. Only few examples are in place worldwide (eg, Norway) or under development (eg, Switzerland), and these are based on conceptually different intervention logics.

The analysis concludes that:

– the **access pillar** of the Nagoya Protocol establishes detailed obligations on Parties that decide to require prior informed consent and benefit-sharing for the use of their genetic resources. A main problem addressed in this study hence is to analyze whether it seems appropriate to leave this part of the Protocol implementation to the Member States or whether an EU-level intervention for implementing the access pillar of the Protocol would create clear added value.

– The **user-compliance pillar** requires legally binding measures but leaves significant discretion on the design and mix of implementing measures chosen. One main problem addressed in this study is to analyze whether it seems possible to leave this part of the Protocol implementation to the Member States or whether an EU-level intervention for implementing the user-compliance pillar of the Protocol is needed.

3.2. Current practices of access to and utilization of genetic resources and associated traditional knowledge (the "EU baseline")

ABS is a new field of policy and activity, thus data limitations have been encountered in the course of this study. Gaps exist particularly with respect to the amount of genetic resources

[10] The country studies focussed on BE, BG, DE, ES, FR, NL, PL, and the UK.

utilised within sectors and the economic relevance of such utilisation within the EU. Nevertheless, the sectoral studies conducted in support of this IA provide a thorough understanding of the current practices of access to and utilization of genetic resources and associated traditional knowledge within the EU. This section highlights important features of these practices. A much more detailed description is found in Annex 8 to this study and served as the "EU baseline" for identifying suitable implementing measures and for understanding their impacts.

3.2.1. Access and use of genetic resources and associated traditional knowledge in the EU today

Genetic resources are utilized for a wide range of purposes, by a wide range of different actors with different interests. Traditional knowledge associated with genetic resources is relevant in specific cases but of limited relevance overall.

Multiple actors intervene at different stages of the genetic resources value chain. This value chain ranges from collecting, storing, and making available genetic resources for research and development, over basic and applied research on genetic resources, to the eventual development and commercialization of products and services.[11] Box 2 introduces the main actors and their place in the EU genetic resources value chain and explains how genetic resources and associated traditional knowledge are important to them (Annex 8 contains more information).

The importance of genetic resources for the EU varies across sectors. For some EU actors use of genetic resources is their core-business. This includes collections and some academic researchers. However, it also includes all commercial uses that by definition innovate and develop products on the basis of organisms, genes or biochemicals, such as plant and animal breeding companies, biotechnology companies, or the bio-control industry. Other actors use material found in nature mainly for its informational value, when searching for molecules or genes with interesting properties that might help meeting specific challenges in product development (e.g. industrial biotechnology or pharmaceutical industries). Other actors again build products on extracts from material found in nature. This is in particular the case for some companies in the cosmetics or food and beverage industry. A disruption of the supply of genetic resources from the wild and from collections would negatively affect all EU users, although to different degrees. For plant and animal breeders and the biocontrol industry it would effectively disrupt their business. For pharmaceutical or industrial biotechnology companies it would limit the range of available sources of information and inspiration in R&D activities and thus lower their innovation potential. Companies in the cosmetics or food and beverage industry would need to search for different sources for the needed extracts, identify synthetic substitutes or modify the recipes used. They might also need to stop the sale of products that are branded as based on specific natural ingredients.[12]

Traditional knowledge about properties and functions of plants and animals in relation to their environments is generally recognized as important, particularly as regards adaptation to climate change. Such knowledge may provide lead information in scientific research for

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[11] The typical steps in the genetic resources value chain are described in Annex 9 to this IA.

[12] For details see Annex 8, pp. 57-59.

interesting properties of plants or species. Overall, however, EU users make only limited use of traditional knowledge associated with genetic resources.[13]

Box 2: Main actors and their placement in the EU genetic resources value chain

Botanic gardens, hold documented collections of living plants for scientific research, conservation, display and education. 550 botanic gardens out of 3021 worldwide are within the EU and the EU botanic gardens are amongst the largest in the world (more than 50% of living plant accessions are collected in Europe). Botanic gardens collect some of their new samples in the wild, but also exchange samples with other botanic gardens. They also provide samples to outside users.

Culture collections acquire, conserve and distribute microorganisms and information about them to foster research and education. Among the 601 culture collections worldwide 207 are located in Europe and 161 in the EU. Culture collections rely heavily on the collecting of new material from the wild (45% of their acquisitions); since most microbial genetic resources are still unknown and since material collected must be stored alive.

Gene banks[14] collect, process, store, and distribute biological specimens and associated information to support scientific research. Plant gene banks 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. Animal genebanks mainly fulfill conservation purposes and are less involved in the exchange of genetic material for breeding purposes. Gene banks in the EU make a major contribution to the conservation and utilisation of cultivated / domesticated diversity and related wild species.

Academic research institutions conduct basic research on genetic resources to identify its taxonomic nature or new properties or ingredients. Academic researchers frequently collect genetic resources in the wild. Their research on genetic resources, including through consideration of associated traditional knowledge, is critical for biodiversity conservation. Some findings of academic researchers are later used in product development.

The **farm animal breeding industry** breeds animals for agriculture production. Its most important species are cattle, sheep, goats, pigs and chicken. European breeders are world leaders. They usually source material from within their company or from connected farmers. The industry currently makes little use of species found in the wild. Its future demand for wild species is, however, expected to increase because of climate change.

The **plant breeding or seed industry**[15] develops seed grains, cuttings, seedlings, and other plant propagation material as an essential input for crop production, especially for agricultural, vegetable and fruit plants. Plant breeders depend on the utilisation of genetic resources. Most of the genetic resources used exist in *ex-situ* collections. Indeed, breeders base their activity on a fairly small number of species developed over decades (100-200 species in floriculture and approximately 500 species as house plants). In 2009, the EU had a global market share of more than 20%.

The **biocontrol industry** develops and sells techniques for crop-protection that uses 'biocontrol agents' (ie select predatory or parasitic living organisms) to control pests. This industry entirely relies on the utilization of genetic resources. They heavily source new material from the wild, but some also from *ex-situ* collections. Europe is the largest market in the world for this industry in constant growth.

The **cosmetics industry** develops, manufactures and sells traditional cosmetics products (e.g. perfumes, make-up) and personal hygiene products (e.g. shampoos, soaps, tooth-care). The overall

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13 The contrast between the principled recognition of the importance of traditional knowledge and its limited use in practice reflects the practical challenges and often significant costs involved in working with indigenous and local communities to obtain access to some of their knowledge.

14 Botanic gardens, 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.

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

demand for wild genetic resources in the sector is limited. However, collecting activities in the wild are very important for a niche market. European cosmetics companies are among the 10 world leaders of the sector. The EU has a 50% share of the global market.

The **food and beverage industry** is one of the largest industrial sectors in the world and the largest manufacturing sector in the EU. It covers a wide range of activities from farming to food processing. However, parts of the industry rely on genetic resources collected in the wild for developing new products on the basis of new natural ingredients and extracts.

The **horticulture industry** includes activities that range from amateur plant breeding to commercial production for ornamental purpose. New products are developed by utilising genetic resources that are mainly taken from *ex situ* collections and sometimes collected in the wild. The size of the industry in Europe and worldwide is relatively small.

Companies in the field of **industrial biotechnology** develop, manufacture and sell products and services that use or contain biological material as catalysts or feedstock to make industrial products. The industry relies by definition on the use of genetic resources and heavily invests in R&D. The EU is one of four established biotechnology centres globally, next to the US, Canada and Australia. 90% of new material in this sector is taken from the wild.

The **pharmaceutical industry** engages in the discovery, development, and manufacture of drugs and medications. It partially relies on access to genetic resources collected from the 'wild' to identify promising compounds for product development. Biotechnology-based pharmaceuticals account for an increasing share of the market and access to genetic resources is particularly important for segments of the industry involved in natural products research. In the last 30 years, 26 percent of new approved drugs were either natural products or had been derived from a natural product. The future trend is unclear. The market for pharmaceuticals is one of the biggest world-wide, dominated by the US, and followed by the EU and Japan.

As regards the sourcing of genetic resources and associated traditional knowledge, EU users may be grouped in two broad categories. On the one hand side, there are collecting activities in the wild, on the other hand side, users acquire samples and related information from ex situ collections (gene banks, seed banks, databases). The discovery of new or rare genetic diversity in nature is of great interest for scientific research and some ex situ collections. It is therefore mostly university-based researchers and scientists affiliated with ex situ collections that engage in bioprospecting activities, mostly with an explicitly non-commercial purpose. Commercial users of genetic resources, in contrast, rarely collect genetic resources in the wild, except in some particular niches of innovation, such as the biocontrol industry, parts of industrial biotechnology, and some small pharmaceutical biotechnology companies. Overall, however, it seems that the interest of commercial users to engage in bioprospecting has declined. In part this reflects reluctance to directly deal with provider countries, in part collecting activities in the wild have become less important for some of the economically important and research-intensive sectors such as the seed industry and a great proportion of the pharmaceutical and cosmetics industries.[16]

In contrast, the research done for this study shows that EU ex situ collections play a fundamental role in the EU 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 of their genetic resources from ex situ collections. Private and in-house collections are 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

[16] For details see Annex 8 pp. 77-79.

for the academic research sector, which often owns or is affiliated to particular ex situ collections for the purposes of scientific research. However, it is also the case for research done in botanical gardens or culture collections (e.g. taxonomic work). Such research often relies on genetic material exchanged with other collections, also to keep their collections and conservation activities alive.[17]

Box 3: The Korean National Biodiversity Research Institute (NIBR)

The NIBR was established in 2007. It is mandated to conserve Korean biological resources that are considered as national assets and precious source materials for the country's biotechnology industry. NIBR provides the Korean bio-industry with access to samples and/or information on wild species for basic and applied research. NIBR has developed a national biological resources database network. It supports policy development on biodiversity issues and also serves as an educational centre for the general public to raise awareness about the importance of conserving and wisely using biological resources. The Institute collaborates with various international partners such as botanic gardens, museums or biological institutes to exchange samples and further enrich its own collections as well as to exchange staff and experience, to establish educational and training programmes, and to engage in joint research activities

Source: <http://www.nibr.go.kr/english/main/main.jsp>

3.2.2. How Demand for genetic resources and associated traditional knowledge will evolve

The research undertaken for this study indicates that demand for access to 'wild' genetic resources has declined in most sectors, while interest in research and development on genetic resources has increased overall. The future demand for genetic resources is therefore expected to grow or at least to remain stable. Securing continued and improved access to genetic resources therefore seems a major EU priority. As explained above, this also suggests that the EU has a genuine interest not to frustrate important partners particularly from the mega-diverse group of countries. More restricted access practices in provider countries in the future could compromise important EU objectives (see Box 4) and also hamper the commercial and non-commercial interests of EU users.

Overall, the future demand for traditional knowledge associated with genetic resources is likely to decline even further. Such knowledge will remain relevant for some niche markets in the cosmetic and food industries. However, advances in scientific research methods make traditional knowledge less and less relevant as lead information for discovering interesting properties of genetic resources found in the wild. This latter finding applies to all research-intensive value chains, including the pharmaceutical, green, red and white biotechnology[18].

Box 4: Some examples how genetic resources utilisation contributes to public goods

Future breeding programmes: Conserving and documenting wild relatives of plant and animal species for future breeding programmes is widely considered as an insurance against the impacts of climate change on food production systems.

Source: <http://www.fao.org/docrep/meeting/022/mb393e.pdf>

Environmentally sustainable pest control: Pest control with biological agents is an important component of integrated pest management and reduces the use of plant protection products such as pesticides.

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17 For details see Annex 8 pp. 79-81.

18 "Green" biotechnology refers to biotechnological applications in agriculture, "red" to its application in medical processes, "white" to uses of biotechnology in industrial processes.

Source: <http://lamar.colostate.edu/~hufbauer/Pages/biologicalcontrol.html>

Identifying active compounds for medicine development: In April 2012, the Danish company LEO obtained FDA-approved for a topical gel against a precursor to skin cancer. The main active ingredient of this gel is derived from the Euphorbia peplus plant found in Australia, after an extraction, purification and crystallization process of about five months. LEO will now seek market approval in other major markets.

Source: <http://www.leo-pharma.us/>

Genetic resources also play a major role in developing **nature-based renewable energy** to face the energy challenges of a growing word population while ensuring biodiversity and environmental protection and make the transition to a post-petroleum economy.

Source: Commission press release on the "Bioeconomy for Europe" (Memo/12/97 of 13 February 2012)

3.2.3. The EU genetic resources value chain

The beginning of the EU genetic resources value chain is characterized by long-term perspectives, low-risks, low-costs, and the predominance of public funding; while the end of the genetic resources value chain is characterized by high investments, high costs and high-risks.

Genetic resources, and sometimes also associated traditional knowledge, are of diverse importance across and within sectors, be it for commercial or non-commercial activities. Analytically, it is useful to distinguish between activities and players at the beginning of the genetic resources value chain ("upstream") and activities and players at its end ("downstream"). Those involved in "upstream" activities (collecting in the wild, description of collected material, storing in collections) face many common challenges in relation to access and benefit-sharing, the same goes for those involved in "downstream" activities (basic and applied research, product development and commercialisation).

Actors at the beginning of the genetic resources value chain (mostly collections and academic researchers) are in direct contact with the laws and authorities of provider countries and must play a key role in establishing ABS-related information and linking it to specific samples collected or stored. Upstream actors are heavily dependent on public funding. In itself, their activity is neither costly nor risky. These first actors pass on samples of genetic resources and first research results to other users that engage in basic or applied research. Actors situated at the end of the genetic resources value chain make substantial investments in developing new products. They often take on huge economic risks. They engage in often lengthy development activities with uncertain outcomes and work in highly competitive markets. Many of these downstream actors are strongly interested in collaborating with academic research to reduce risks and accelerate product development. These downstream actors largely depend on material and information passed on to them from earlier users in the chain, including in relation to ABS.

EU users of genetic resources are world leaders or play important roles globally at the high-value end of the genetic resources value chain as well as at its beginning

EU collections, particularly culture collections and botanical gardens, are amongst the largest in the world, holding millions of samples and undertaking yearly thousands or even millions of exchange transactions between themselves as well as with collections outside the EU. Collections are the major supplier of research and development material and related

information for users further down in the chain. As regards the latter, several EU companies, especially the pharmaceutical, breeding, food or biotechnology industries are world leaders in their field with substantial market shares. They contribute substantially to the EU's gross domestic product.

SMEs are very important in some sectors using genetic resources (e.g. biocontrol, plant and animal breeding, horticulture), they are also important in some steps of the genetic resources value chain (e.g. cosmetics, food, pharmaceuticals) where the major investments are made by large, multinational corporations. In sectors such as cosmetics or food, SMEs and micro-enterprises are dominating the market close to some multinational companies that are world leaders. In other sectors, such as the breeding or biocontrol industries, particularly the medium-sized companies are themselves international players.

3.2.4. ABS best practices and voluntary measures

Since the entry into force of the CBD in 1993, some EU users have engaged in the development of codes of conduct, the formalization of transactions of genetic resources through material transfer agreements, and the improvement of documentation systems. Primarily actors in the up-stream part of the EU user chain (particularly culture collections and botanic gardens) have taken significant steps to bring their conduct in line with the ABS requirements of the CBD and to respect the laws of provider countries. Further advances in this regard have been hampered by the lack of appropriate financial and human resources of individual collections. As regards downstream activities, ABS best practices exist but appear to be of less significance overall. This reflects some variability in the level of awareness and commitment to ABS-compliance practices in different sectors using genetic resources as well as the fact that existing voluntary codes have different levels of ambition and detail. Some examples of ABS best practice codes of conduct are described in Box 5. Overall, it seems important to consider existing voluntary initiatives on ABS as stepping stones for a credible system of EU implementing measures.

Box 5: Examples of ABS best practice codes of conduct

Code of conduct developed by the World Federation for Culture Collections: The code of conduct ("MOSAICC") translates the CBD provisions on ABS into practical procedures for facilitated access to and transfer of microbial genetic resources. One important part addresses the collection of new samples of microorganisms in the wild. The code of conduct further promotes the systematic use of a Global Unique Identifier to be attached to any item accessed *in situ* either at the point of isolation of the microbial genetic resource or at the point of deposit in the culture collection. MOSAICC also seeks to achieve full transparency for all transactions from and between culture collections, ranging from the request of specific ABS-related information, to the use of model contracts, and standardised procedures for the transfer of microbial genetic resources. While MOSAICC falls short of measures for monitoring the user chain but, its implementation helps that members of the WFCC have readily accessible information on the origin and conditions related to any microbial genetic resources they hold, receive or transfer. It is expected that this will greatly facilitate efforts of tracking the use of microbial genetic resource throughout the value chain.

Source: <http://bccm.belspo.be/projects/mosaicc/#brochure>

The International Plant Exchange Network (IPEN): IPEN was initially developed by the association of botanic gardens in german speaking countries. Since 2002, IPEN is managed by the European Consortium of Botanic Gardens. Presently, 150 botanic gardens worldwide actively participate in the network, of which 130 are based in the EU; this is about one-fourth of botanic gardens in the EU. The network facilitates the exchange of living plant material between its members, while respecting the ABS requirements of the CBD. The Code of Conduct addresses four main

aspects: 1) ensuring the legality of living plant material that enters the network, 2) clear terms and conditions for the circulation of material within IPEN, 3) sharing benefits arising from non-commercial use with countries of origin, 4) transfers of plant material to users outside the network.

Source: http://www.bgci.org/resource/ipen/

IFPMA "Guidelines on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization": The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) represents national industry associations and research-based pharmaceutical, biotechnology and vaccine companies from both developed and developing countries. It has developed "Guidelines on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization". These guidelines set out best practices to be followed by companies that engage in bioprospecting, they do not take into consideration sourcing from intermediaries. One recommended best practice is to obtain prior informed consent for the acquisition and use of genetic resources controlled by a country or indigenous people. Another is to disclose the intended nature and field of use of the genetic resources when obtaining prior informed consent.

Source: <www.ifpma.org>

BIO "Guidelines for Bioprospecting": The Biotechnology Industry Organization (BIO) is the world's largest biotechnology association. Its "Guidelines for Bioprospecting" seek to assist BIO members involved in bioprospecting activities. They envision that BIO members would enter into a "Bioprospecting Agreement" before collecting physical samples of genetic resources *in situ* or accessing such resources maintained *ex situ*. Such agreement would address the granting of prior informed consent and list terms and conditions governing the collection and use of the genetic resources. The guidelines further stipulate that records should be maintained on the handling, storage and physical movement of collected material and that companies should be prepared to share such records upon request with the country providing the genetic resources. The guidelines also stipulate that companies should not accept samples of collected genetic resources from a third party that is not able to provide evidence of compliance with PIC and established conditions governing the use of a sample.

Source: <http://www.bio.org/articles/bio-bioprospecting-guidelines>

3.3. The EU's right to act and justification

The Nagoya Protocol to the Convention on Biological Diversity is a global environmental agreement that establishes a legally binding framework for maximising the benefits of genetic resources use in favour of the conservation and sustainable use of biological diversity worldwide. The system of EU measures for implementing the Nagoya Protocol can therefore be based on the Union's **environment competence**. The creation of an EU-wide system of user-compliance measures could, in principle, also be based on the Union's **competence for the internal market** as it avoids negative effects on the internal market in nature-based products and services that would result from a fragmentation of user-compliance systems in the Member States. Nevertheless, given the context and overarching objective of the system of measures, a use of the Union's environment competence seems more pertinent.

An EU-harmonised approach to implementing the **user-compliance pillar** of the Protocol would provide for legal certainty and establish a level playing field for all actors in the EU genetic resources value chain, minimising their risks of operation and maximising research and development opportunities for researchers and companies. It would also prevent situations where differences in user-compliance obligations between different Member States create costs and barriers for researchers and companies that are active in more than one

Member State. Notably, stakeholders unanimously supported an EU harmonised approach to user-compliance in the public consultation.[19]

However, the EU competence is not so evident in addressing the provisions of the **access pillar** of the Protocol, Some Member States strongly feel that the Union does not have competence to decide whether access to genetic resources over which Member States hold sovereign rights shall in the future be subject to prior informed consent and benefit-sharing requirements or not. Arguably, Union competence is much clearer in case where a Member State has decided to require prior informed consent and benefit-sharing and the specific design of the domestic access framework of that Member State will need to respect fundamental treaty disciplines on non-discrimination or sectoral EU laws for instance in the field of the exchange of agricultural genetic resources. Whatever the case may be, it seems that there is currently no need for the Union to take binding Union-level measures on access. So far, only two Member States have legislated on access, there is very limited practical experience with the functioning of their access frameworks, and no indication that these would raise issues under the acquis. Thus, in ratifying the Nagoya Protocol the Union may choose to implement measures that repond to only some of the Protocol's requirements, leaving others to its Member States.

4. OBJECTIVES

4.1. General objective

The general objective of this IA study is to identify appropriate measures for implementing the Nagoya Protocol in the EU and to enable the Union to ratify and comply with the Protocol.

4.2. Specific objectives

Union ratification of the Nagoya Protocol and appropriate implementing measures should contribute to the following specific objectives:

– Support the conservation and sustainable use of biological diversity within the EU and worldwide;

– Provide EU collections, and researchers and companies in Europe with improved and reliable access to quality samples of genetic resources at low cost and with high legal certainty for acquired material;

– Maximise opportunities for research, development and innovation in nature-based products and services, while establishing a level playing field for all EU users of genetic resources, with particular benefits for SMEs and for publicly funded, non-commercial research;

– Protect the rights of indigenous and local communities that grant access to their traditional knowledge associated with genetic resources in accordance with the domestic laws of Parties to the Nagoya Protocol;

[19] See summary of the public consultation in Annex 3.

– Fully respect other international specialised access and benefit-sharing instruments and be mutually supportive with other relevant international instruments and processes.

4.3. Operational objectives

The chosen implementing measures should also support achieving the following operational objectives:

– Establish a credible system for user-compliance measures;

– Improve information on access and utilisation of genetic resources in the EU;

– Minimise overall implementation costs and burdens, particularly for affected SMEs.

5. POLICY OPTIONS

The policy options developed and considered for the purpose of this study were drawn from a range of sources: the Nagoya Protocol, existing legislation in third countries, EU experts, academic literature, etc. The main criteria applied was that an option would need to implement particular aspects of the Nagoya Protocol and that the totality of options developed would need to address all aspects of the Protocol implementation. The main options analysed in this study were also, where appropriate, discussed with experts and stakeholders to sharpen their focus and to deepen the understanding of their eventual impacts.

Table 1 summarises all policy options that were considered in the course of this IA. The table highlights those options that are described and analysed in detail in the report. More options were identified in the initial screening of options, however they have been discarded. Annex 4 presents more information on options that were considered but discarded and explains clearly the reasons for discarding them. The main motivations related to doubts about EU competence, no apparent need to intervene at EU-level, or apparent and major legal and practical difficulties.

Table 1: Overview of all policy options considered for this IA (* identifies discarded options)

Business as Usual	- No Union ratification* - Union ratification without implementing measures by Union or Member States (**BAU**)	
Access pillar	*Binding measures at MS level*	- No EU action (**A-1**) - EU platform (**A-2**)
	Binding measures at EU-level	- EU-wide waiver of PIC requirement* - EU-wide minimum standards on access to genetic resources* - EU-wide minimum standards on access to traditional knowledge*
User-compliance pillar	*Binding measures at MS level*	Member States take binding measures with soft coordination at EU-level (**UC-1**)
	Binding measures at EU-level	- Amending EU legislation on recognition of judgements* - Broad understanding of traditional knowledge associated with genetic resources* - Prohibition on EU nationals to collect in violation of third country

		laws* - Prohibition on botanical gardens, gene banks and culture collections to include illegally acquired samples into their collection* - General due diligence obligation on EU users (**UC-2**) - General due diligence obligation on EU users and system for formal recognition of collections as "trusted sources" (**UC-3**) - Prohibition to utilise illegally acquired genetic resources and "downstream" monitoring (**UC-4**)
Temporal application	*In case of binding EU-level measures…decision on* - Application of binding rules to future acquisitions of genetic resources (**T-1**) - Application of binding rules as of entry into force of the CBD in 1993 (**T-2**)	
Complementary measures	- Bilateral agreements between EU and major provider countries or regions (**C-1**) - Sectoral codes of conduct and contractual model clauses (**C-2**) - Technical tools for tracking and monitoring (**C-3**) - Awareness raising and training activities (**C-4**) - Obligation on those collecting genetic resources in Member States with a free access policy to place reference samples in identified collections*	

As regards **business as usual**, the study considered two distinct options: first, the Union decides not to ratify the Protocol and second, the Union ratifies the Protocol but implementing measures are not taken neither at Member State nor at Union level.

Different options are considered for implementing the Protocol's **access pillar** and for implementing its **user-compliance pillar**. To fully implement the Protocol, one access-option and one user-compliance option must be chosen. For both categories of measures, the study analyses a situation where binding measures are only taken at the level of the Member States as baseline for identifying the value added of a possible EU-level intervention.

In the case of support for binding EU-level rules, a further decision is needed on the **temporal application** of such rules.

To complete the picture, the IA also analyses **complementary measures** that could be combined with the main options on access and on user-compliance to enhance their effectiveness and to lower costs. The value added of selecting one or all of these complementary measures depends on primary choices on access and on user-compliance.

5.1. The Business as Usual (BAU)

Option BAU: Union ratification without implementing measures at Union or Member State level

As shown in the problem definition, main obligations of the Nagoya Protocol are currently neither implemented at Union level nor by the Member States. If the Union ratifies the Protocol without action at Member State or Union level, it will be in breach of its international obligations. This would expose the Union to potential challenges under the

Protocol's non-compliance mechanism.[20] As one likely consequence, European collections, researchers and companies would face more restrictive access conditions in third countries. The "EU baseline" shows, however, that EU users depend on reliable conditions for access to quality samples of genetic resources. Union non-compliance would also have broader consequences for the EU's credibility in global biodiversity policy-making and could undermine the effectiveness of the CBD as the main global framework for addressing the dramatic loss of species and habitats worldwide.[21] Union ratification of the Nagoya Protocol requires implementing measures at Member State or Union level. This option is therefore not further analyzed in this IA.

The EU baseline of current user practices as described in the problem definition and further detailed in Annex 8 constitutes **the main reference point** for assessing and comparing all other options analyzed in this IA.

5.2. Options for addressing the Access pillar of the Protocol

OPTION A-1: No EU level action

Option A-1 leaves it entirely to the discretion of Member States whether to require benefit-sharing or not, and if so, how to comply with the relevant obligations of the Nagoya Protocol. It reflects that currently no Member State has an operational access framework in place and that most Member States consider it outside of Union competence to determine through Union law the legal status of genetic resources under the sovereignty of Member States.

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

The establishment of an EU platform on access to genetic resources would be a flexible way for discussing access practices between EU ABS focal points, competent national authorities, and EU stakeholders. Deliberations would not be legally binding on participants and could include: access to genetic resources in Member States requiring PIC and MAT; simplified access for non-commercial research; access practices of EU ex-situ collections; access of EU stakeholders in non-EU countries; and the sharing of best practices. The deliberations of this platform would also help in identifying a need for EU-level measures on access.

5.3. Options for addressing the User-Compliance pillar of the Protocol

Each of the four options presented would apply to the utilisation of genetic resources and to traditional knowledge that is directly associated with such resources. Each option also addresses relevant monitoring measures, sanctions, and administrative aspects.

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[20] Article 30 Nagoya Protocol

[21] It must also be noted that the US, which is not a Party to the CBD and therefore unlikely to ratify the Nagoya Protocol, has established domestic legislation (eg, US Lacey Act, specialised legislation for some US national parks) and guidelines (eg, for the National Institutes of Health) that at least partially support taking user-compliance measures as required under the Nagoya Protocol. The US furthermore seeks to minimise eventual negative impacts from its non-Party status on US researchers, collections and companies by engaging with major provider countries of genetic resources through large-scale public-private partnership projects (e.g. US Panama).

OPTION UC-1: Open method of coordination

This option leaves maximum discretion to Member States on how to implement the user-compliance provisions of the Nagoya Protocol. Supportive EU-level coordination would aim at harmonising the approach to implementing measures taken by the Member States. Coordination could, for instance, include the basic approach to user-compliance taken by Member States, the choice of checkpoints for monitoring user-compliance, the type of information that would need to be collected or disclosed, and who would carry the burden of information.

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

Under this option EU users would need to take steps to the best of their ability to ensure that genetic resources and associated traditional knowledge utilised have been acquired in line with access laws of provider countries and that resulting benefits are fairly and equitably shared. This due diligence obligation would apply to all activities that constitute "utilization of genetic resources" as defined in Article 2(c) Nagoya Protocol. This means to all conducting research and development on the genetic or biochemical composition of genetic resources within EU jurisdiction (i.e. basic research, applied research, product development). The basic due diligence obligation and its core elements would be set out in an EU Regulation.

An important feature of the due diligence concept is that it does not establish an absolute obligation of result, but only requires meeting a reasonable standard of care. For example, it would not constitute a breach of the obligation if a user has been diligent but it eventually turns out that a specific genetic resource utilised was illegally acquired in a provider country by an earlier actor in the chain. The required standard of care under a due diligence system varies depending on the type of user, its capacity to take measures, its placement in the genetic resources value chain, or sectoral characteristics. What is reasonable will also evolve over time and may, for example, reflect new developments in codes of conduct or best practices in a sector, or progress in technical tools for tracking and monitoring genetic resources flow.

Option UC-2 foresees that the implementation of (existing or future) best practice codes of conduct groups of users (eg., botanical gardens, cosmetics industry, breeding industries) can be considered as evidence of compliance with the due diligence obligation. To support consistent implementation, the Commission would complement the Regulation with guidance documents for specific groups of EU users. Monitoring of user compliance with the due diligence obligation could focus on observable activities within EU jurisdiction. It would be proportionate under this system to oblige users of genetic resources to declare at identified points that they (have) exercise(d) due diligence.

Suitable points for such declarations are, for instance, the receipt of public research funds or when users intent to market a product. Such declarations would be made upon the occasion of the marketing of a product but formally independently from eventually needed product approval permits. The declarations would be made to the competent national authorities of Member States designated for the purpose of implementing the EU Regulation, they would not be made to the authorities eventually involved in granting a permit. Information about user-compliance could also be included in regular company audit reports. Furthermore, designated Member State authorities would be empowered to do *ad hoc* compliance checks on users. Such compliance check would be undertaken on a risk-based approach. Competent authorities would check compliance with the obligation of users to make declarations as well

as compliance with the due diligence obligation more generally. Checks could include the gathering of information on due diligence measures taken, the check of documentation on how due diligence was exercised in specific cases as well as the physical inspection of sites. In case of non-compliance with the Regulation users would be subject to penalties that should includes administrative fines, but might also include in certain situations the confiscation of illegally acquired genetic resources. The competent national authorities of the Member Statess would be obliged to regularly report in summary form to the Commission on due diligence declarations received and checks and eventual findings made. and to the EU competent national authority. The Commission would make information on the main features and the performance of the EU's due diligence system available to the global information sharing portal established by the Nagoya Protocol (the so called "Access and Benefit-sharing Clearing House Mechanism").

Given the importance of the details for the reliable functioning of the system and for creating legal certainty to stakeholders, an EU Regulation would seem appropriate to ensure the highest level of harmonization and avoid the existence of different approaches to implementation between Member States.

OPTION UC-3: General due diligence obligation on EU users complemented with a system to formally recognize collections as "trusted sources" of genetic resources

Option UC-3 has two elements. It combines a due diligence system as described in Option UC-2 with a system to identify collections with control measures in place to assure that only well documented samples of genetic resources are made available for utilisation. The concept of "trusted sources" reflects that EU ex situ collections play a fundamental role in the EU user chain, acting as direct providers to both commercial and non-commercial users. It is assumed that a system of trusted sources would substantially lower the risk that illegally acquired genetic resources enter the genetic resources value chain, and that EU users more easily comply with their due diligence obligation in case they are sourcing their material from a trusted source.

The contact details of collections identified as "trusted sources" would be listed in an EU-level register, which would simply be a web-site.[22] The EU Regulation would make explicit that users of genetic resources which acquire samples from a collection listed in the EU-register would comply with a major part of their due diligence obligation. The substantive criteria for identifying collections as "trusted source" would build on existing best practice standards, such as IPEN[23], and be set out in an EU implementing act. The Option would leave it to Member States to identify collections under their jurisdiction on the basis of the EU-level criteria and to enter the contact details of such collections in the EU-level register.

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

Opion UC-4 reflects the preferred user-compliance approach of developing countries in the Nagoya Protocol negotiation. The option is based on a general prohibition on users within EU jurisdiction to utilise genetic resources or associated traditional knowledge that were illegally

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22 To indicate the magnitude: there are 550 botanical gardens in the EU of which 130 participate in IPEN.

23 See Box 5 above.

acquired in Parties requiring prior informed consent and the establishment of mutually agreed terms. Compliance with the prohibition is monitored by obliging users to declare to public authorities at specific points whether they utilised genetic resources in conformity with applicable ABS requirements. The focus of the monitoring measures is to establish whether present uses of genetic resources were/ are consistent with applicable rules of provider countries and eventual benefit-sharing obligations. The basic prohibition and the disclosure obligations would be set out in an EU Regulation.

Collections and those conducting non-commercial research within the EU would not be affected by disclosure obligations as they do not aim to create genetic resources based products and services. Such obligations would be established towards the end of the genetic resources value chain, when an intellectual property right is applied for or a market approval is sought. Users would be obliged to disclose at designated points whether an innovation or a product is directly based on the utilisation of genetic resources or associated traditional knowledge. In the affirmative case, they would be further obliged to provide information on the origin or source of genetic resources or associated traditional knowledge used and whether relevant ABS requirements were complied with.

To comply with their disclosure obligation, downstream users would need to determine whether earlier actors in the chain utilised genetic resources or associated traditional knowledge to an extent that this use must be disclosed. Disclosed information – for example on the origin or source of genetic resources utilised, on compliance with provider country laws at the time of access, or on compliance with eventually applicable benefit-sharing obligations – would hence often depend and build on information made available by earlier actors in the chain.

The designated monitoring authorities (e.g., intellectual property rights offices, product approval authorities) would channel the information received to the competent authorities of the Member State or the EU that would have the obligation to check for compliance with applicable ABS requirements, or to provider Parties or to the global ABS Clearing House Mechanism. Failure to disclose, disclosure of false information, or a violation of the prohibition to utilise illegally acquired genetic resources would be subject to sanctions.

5.4. Options on the Temporal Application of binding EU-level measures

OPTION T-1: Applying implementing measures to genetic resources or associated traditional knowledge acquired after entry into force of the Nagoya Protocol for the EU

It is a legally sound interpretation of the Protocol's temporal scope to apply implementing measures only to genetic resources or associated traditional knowledge acquired (and utilized) after the entry into force of the Nagoya Protocol for a party.[24] Option T-1 would exclude all material acquired before entry into force of the Nagoya Protocol from the scope of implementing measures. This includes, for example, samples held in collections in the EU that were acquired after the entry into force of the CBD from a country that had established access legislation. Option T-1 is consistent with the political position of the EU throughout the Protocol negotiation.

[24] The different academic views on the Protocol's temporal application are described in Annex 1.

OPTION T-2: Applying implementing measures to genetic resources or associated traditional knowledge acquired since entry into force of the CBD and utilized after entry into force of the Nagoya Protocol for the EU

In the view of some legal scholars the Protocol applies to genetic resources or associated traditional knowledge acquired in the future but also to new uses of genetic resources that were acquired after the entry into force of the CBD on 29 December 1993.[25] Compared with Option T-1, Option T-2 would bring an amount of samples of genes and naturally occurring biochemicals currently held in EU collections, gene banks and catalogues into the scope of implementing measures. This would expose EU researchers and companies to legal and economic risks that are difficult to reconcile with the principle of legal certainty and might raise constitutional problems in some Member States. Option T-2 has nevertheless been retained for transparency purposes as it corresponds with the expectations of some of our international partners, particularly biodiverse-rich developing countries, and of civil society groups.

5.5. Options for Complementary measures in support of the Protocol implementation

The options in this section could be combined with the main options on access and on user-compliance described above to enhance their effectiveness and efficiency, and to lower costs. In part, they reflect soft obligations of Parties under the Protocol (C2, C3, C4). In all cases, their specific added value to EU implementation depends on the main choices made on access and on user-compliance.

OPTION C-1: Bilateral cooperation between the EU and provider countries or regions

Bilateral cooperation between the EU and major provider countries or regions of genetic resources, particularly with countries that are recognised as "biodiversity hotspots", could usefully complement EU measures implementing the Protocol. Bilateral cooperation could become important for targeted capacity building measures to help partner countries implement the quite demanding Protocol obligations on access to genetic resources and associated traditional knowledge. It would also allow for collaborative projects focussing, for example, on building partnerships between researchers involved in non-commercial biodiversity research that involves the documenting and description of genes and naturally occurring biochemicals found in situ conditions in partner countries. Such cooperation should also include strenghtening networks of ex situ collections in Parties to the agreement. It would also provide opportunities for developing a mutual understanding on how access for non-commercial research is practically facilitated to researchers and collections from both sides and might also raise the mutual understanding of user-compliance systems in the Parties involved. Bilateral cooperation might also allow discussing, in close dialogue with relevant collections on both sides, potential modalities for applying access and benefit-sharing principles to pre-Nagoya Protocol acquisitions of genetic resources that originate in Parties to the agreement.

Bilateral cooperation could take many forms ranging from regular dialogues over Memoranda of Understanding to formal bilateral agreements. EU measures implementing the Nagoya Protocol could include a general reference to the possibility of bilateral cooperation in support of more effective implementation of the Nagoya Protocol in the Union. Such cooperation

[25] The different academic views on the Protocol's temporal application are described in Annex 1.

would normally start with dialogues or joint projects, and if there is mutual interest, eventually move to more formalised cooperation in the form of a Memorandum of Understanding or even a bilateral agreement. The latter would require a formal authorisation from the Council of the European Union.

OPTION C-2: Supporting the development of sectoral codes of conduct and model contractual clauses

Parties to the Nagoya Protocol must encourage the development, updating and use of model contractual clauses and of voluntary codes of conduct, guidelines and best practices or standards. Model contractual clauses would facilitate and lower costs for transactions of genetic resources and ABS-related information, particularly for the benefit of academic researchers and SMEs with only limited capacity and also for developing country partners that provide genetic resources. Different models for material transfer agreements already exist and are widely used, particularly in basic and applied research in the biosciences to facilitate exchanging samples between research teams. Although these model agreements were not developed for the purpose of ABS, they may be expanded to this end.[26] Parts of the research community and commercial users of genetic resources have furthermore developed best practice codes of conduct specifically for the purpose of ABS. The specific contribution of sectoral codes and of model clauses to ABS compliance will depend on the design of the primary compliance measures taken for implementing the Nagoya Protocol in the Union. Under Option C-2, the Commission would work with EU stakeholders to identify the specific contribution of codes of conduct and of model clause to ABS compliance and for identifying and further developing codes and clauses considered as best practice.

OPTION C-3: Supporting the development and deployment of technical tools for tracking and monitoring genetic resources flow

The Nagoya Protocol obliges its Parties to encourage the use of cost-effective communication tools and systems in support of monitoring user-compliance. States involved in the Nagoya Protocol negotiation asked the CBD Secretariat to launch a study on the availability of technical tools for tracking and monitoring genetic resources flow. This study identifies a range of relevant tools that would – with some adjustments – be available at very low or no cost. It also sets out the steps needed for deploying such tools in practice.[27] Under option C-3, the Commission would work with information technology experts and ABS stakeholders to support the rapid testing and more widespread deployment of technical tools for tracking and monitoring genetic resources flow.

OPTION C-4: Awareness raising and training activities

ABS is a new field of activity. Awareness raising and training activities would help EU stakeholders to understand their relevant obligations better and achieve more effective implementation at lower cost. Actors broadly familiar with the concept would benefit from information about the specificities of EU implementing measures. Under this option, the Commission and the Member States would support targeted awareness raising and training activities in collaboration with major stakeholders groups.

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[26] See for example the model agreements made available by the US National Institutes of Health <http://www.ott.nih.gov/forms_model_agreements/>.

[27] The full reference and executive summary of this study are included in Annex 9.

6. ANALYSIS OF IMPACTS

6.1. General remarks

6.1.1. Methodology for analysing impacts and data limitations encountered

The analysis proceeds in four steps. **Step 1** involves an analysis of the policy options on access followed by an analysis of the policy options on user-compliance. Each of the options for implementing the access and the user-compliance pillar of the Protocol are analysed on the basis of the full set of impact assessment criteria described below.

To facilitate a comparison between options from the same pillar, the performance of each option against specific impact assessment criteria is graded.[28] The specific IA criteria cover four wider issues and impacts examined, i.e. issues specific to the Protocol, as well as economic, social and environmental impacts. The IA criteria are not excluding each other, some are relevant only for analysing options implementing one of the pillars of the Protocol.

This part of the IA report presents the main observations from the detailed analysis, illustrative examples supporting them and a summary table that shows the grading given to this option with regard to the assessment criteria. The detailed analysis of the options on access and on user-compliance and the motivation for each grading are included in Annex 5 (access pillar) and Annex 6 (user-compliance pillar). The analysis proceeds with a comparison between the identified options for the two pillars of the Protocol. Step 1 concludes with a tentatively identified best performing option on access and a tentively identified best performing option on user-compliance.

Step 2 of the analysis addresses how different choices on the temporal application of binding EU-level measures would impact on their performance. Rather than applying again the full set of IA criteria, particular attention is given to understand the implications for legal certainty and how these would relate to the overall effectiveness of EU-level measures, and ultimately achieving the objectives identified. Step 2 concludes by identifying the best performing option on access and the best peforming option on user-compliance.

Step 3 brings together the preferred options for implementing the access and the user-compliance pillar of the Protocol. The analysis presents by way of hypothetical scenarios how the preferred access and the preferred user-compliance options would work together in practice. These scenarios also help to analyse the potential added value of the complementary measures set out in Options C-1 to C-4.

Step 4 analyses for each complementary option if it would create additional costs but also if there are expected gains in effectiveness, efficiency and cost-savings for the retained choices on access and on user-compliance.

ABS is a new field of policy and activity, thus **data limitations** have been encountered. There is little quantitative information available on the use and exchange of genetic resources at sector level. Gaps exist particularly with respect to the amount of genetic resources utilised

[28] The 5-step grading system applied ranges from "++" for significant positive impact; over "0" for neutral impact; to "--" for a significant negative impact; "n.a." indicates that an assessment criteria is not meaningful for analysing a specific measure (e.g., a criteria that is relevant only for user-compliance is not meaningful for analysing the performance of an access-related measure); "unclear" indicates instances, where an analysis cannot be made because of date limitations.

within sectors and the economic relevance of such utilisation (eg., figures on sales/profits deriving from products based on genetic resources, importance of genetic resources for the turnover of the sector, jobs). Available figures are often rough or indirect indicators of what is being sought, and generally do not allow for comparison within or between sectors. Thus the IA mostly builds upon qualitative arguments that are developed against the detailed description of current user practices set out in the EU baseline. To give one example: an option is considered to be low cost and preferable if it corresponds with existing practices of genetic resources use as identified in the EU baseline. An option is considered problematic or costly where it would necessitate a sigificant change in practices, and generally as unacceptable where it would run against the basic economic model of a specific sector.

6.1.2. Criteria stemming from the specificities of Access and Benefit-sharing and from the Nagoya Protocol

Access and benefit-sharing for genetic resources and associated traditional knowledge is addressed not only in the CBD and its Nagoya Protocol, but also in various other international instruments. Attention is given to analysing how an option would respect existing specialised international ABS instruments and be mutually supportive with other relevant international instruments and processes. An option that fully respects specialised ABS instruments and is fully supportive of other relevant instruments and processes is preferable over an option that only partially achieves these aims.

Another important consideration concerns the legal and practical effects of an option for the relationship between Parties and non-Parties to the Nagoya Protocol. The Protocol obliges its Parties to encourage non-Parties to adhere to the Protocol. It does not oblige them to take special safeguards in the relationship with non-Parties. An option is considered preferable if it encourages ABS-conformity in the interaction with ABS stakeholders from non-Parties and does not disrupt existing collaboration or partnerships simply because they involve partners from non-Parties.

As regards coherence with existing EU law, options that would entail a focussed regulatory intervention consistent with the overall design and approach of the EU acquis are considered preferable over options that would introduce new legal concepts or require revising a broad set of existing EU laws.

The analysis also examined issues specific to the Nagoya Protocol implementation. These relate to:

- *Special considerations*: The Nagoya Protocol obliges Parties to give special consideration to non-commercial research, to eventual threats or danger to human, animal or plant health, and to the special nature of genetic resources for food and agriculture. Options that better allow for these special considerations are considered preferable over others that offer less flexibility.
- *Accomodating for differences between sectors*: The Nagoya Protocol in principle applies to all uses and all types of genetic resources unless explicitly excluded from its scope. Since genetic resources are used by a wide range of different actors for different purposes and with different interests, it seems important that implementing measures offer some flexibility to accommodate for differences between different sectors utilising genetic resources. An option is considered preferable if it better balances the need for clear and certain rules with flexibility to accommodate for sectoral differences.

- *Flexibility to allow for future developments*: Access and benefit-sharing for genetic resources is a new field of activity for the EU and its Member States. Given the discretion of the Parties on how precisely to implement their obligations under the Nagoya Protocol, it is considered as advantageous if an option allows for future development and fine-tuning of measures in light of implementing measures taken by partner countries and in light of future sectoral initiatives. Conversely, it is considered a disadvantage if the EU system of implementing measures would "lock-in" one system that might prove to be disfunctional in the medium or long-term and can only be changed at high cost.
- *Improving the knowledge base:* Given the data limitations encountered, it is considered as important that an option helps to improve the information base on how genetic resources are acquired, transferred and utilised in the Union. This will facilitate future evaluations of the policy.

6.1.3. Assessing Economic impacts

An EU-level playing field for access and benefit-sharing activities implies more opportunities for engaging in research and development on genetic resources, lower transaction costs and lower risks. An EU-level playing field would be particularly beneficial to SMEs and also ensure a more efficient use of public funds spent in favour of gene banks, botanical gardens, academic or applied research. It would also generate more positive effects for the conservation of biodiversity. Options that create an EU-level playing field are therefore considered as preferable over options that would leave significant differences in applicable rules throughout the EU.

An option is generally considered to be more cost-effective and thus preferable if it provides for user-compliance but better corresponds with existing practices of genetic resources use as identified in the EU baseline. It is generally considered problematic if an option would necessitate a sigificant change in practices, and as unacceptable where it would run against the basic economic model of a specific sector.

Innovations flowing from research and development on genetic resources must not be compromised by legal risks. As evidenced by the stakeholder consultation, legal certainty is a major priority for all those potentially affected by access and benefit-sharing requirements. An option is considered preferable if it would provide a greater level of legal certainty to those involved in ABS activities. Where an option entails some legal risk, an important consideration is whether such risks can be controlled by those exposed and if so, at what cost. Options that allow users to control a risk at reasonable costs are considered preferable over options that do not offer such possibilities and leave users exposed. Furthermore, the same type of risk seems generally more preferable at the beginning of the genetic resources value chain, where activities generally have low economic value; rather than at the end of the chain, that is characterised by high investments, high economic value and potentially significant economic losses.

The analysis also considers the distribution of impacts along the genetic resources value chain, which stakeholders would be affected and how. An overburdening of any one activity in the genetic resources value chain would imply the breaking down of the chain, the discontinuation of research and development activities and ultimately the loss of benefits and related conservation gains. An option is considered acceptable if it is proportional to the respective capacities of all particular actors in the genetic resources value chain; it is not considered acceptable where it would clearly overburden a particular player in the chain.

Particular attention is given to analysing the impacts on SMEs. An option is preferable if it maximises economic opportunities for SMEs at low cost, if it is compatible with existing business models and provides for legal certainty and if remaining risks can be controlled at low costs.

Improved access to quality samples of genetic resources with high legal certainty and at the lowest possible transactions costs will maximise research and development opportunities on genetic resources. Although favourable conditions for research and development are no guarantee for important scientific discoveries and the development of valuable products and services, there is nevertheless a clear correlation between improved conditions for R&D in nature-based industries and an increase in the likelihood of important discoveries that will result in innovative products and services. Options that maximise research and development opportunities for EU users are therefore considered preferable over options that create less opportunities, while options that could stifle research and development on genetic resources are considered as prima facie unacceptable.

At last, economic impacts analysed include also a consideration of the effects of an option on the EU's international competitiveness.

The Nagoya Protocol requires that compliance of users with implementing measures is effectively monitored. It is considered as easier and more effective to monitor an observable activity within EU jurisdiction rather than to identify the presence or absence of non-tangible information that relates to facts and findings in a third country, often many years ago. It is also considered more cost-effective to collect relevant information as part of already established activities rather than to establish new monitoring procedures. Furthermore, it is considered more cost-effective to focus on monitoring activities/ information that is available without confidentiality concerns involved. At last, monitoring costs can be reduced, where it is practical and proportional to put the burden of information on economic operators. Costs for monitoring will vary with the effectiveness of monitoring and enforcement measures taken. An option is preferable if it creates the maximum amount of pertinent information at the lowest possible cost.

As regards additional administrative costs for implementation, the IA distinguishes between one-off costs and recurring costs. Generally, low cost options are preferred over high cost options. And costs that occur only once or over a clear time-frame are preferred over costs that are of recurring nature.

6.1.4. Assessing Social impacts

Innovation in nature-based industries is expected to contribute to the achievement of important social objectives, be it health, nutrition, food security, or else. Options that maximise research and development opportunities for EU users are therefore considered preferable over options that create less such opportunities. More benefit-sharing arrangements with providers from developing countries would also contribute to the transfer of knowledge and technology to partners in those countries. Furthemore, it is expected that jobs in the sectors utilising genetic resources will be safeguarded and even increased if access to these resources is assisted and if the user compliace requirements create legal certainty, minimise risks and generate more opprotunities for a wider use of these resources. Although it is not possible to quantify this impact, due to the significance of the sectors utilising genetic resources in the European and global economy, it is expected that impacts to whichever direction could be of a significant magnitude.

A particular social aspect in this IA is the contribution of an option to the effective protection of the rights of indigenous and local communities over their traditional knowledge associated with genetic resources. Options that effectively protect indigenous rights are preferable over options that do not achieve this aim.

6.1.5. Assessing Environmental impacts

Better conditions for R&D in innovative nature-based industries, will enhance the knowledge-base for effective biodiversity conservation and environmentally sound uses of natural resources. It will also raise the likelihood of important discoveries and developments and related benefit-sharing in favour of biodiversity conservation. An enabling and effective access and benefit-sharing system will also raise awareness of the economic value of genetic diversity found in nature and held in ex situ collections. Options that maximise research and development opportunities for EU users are therefore considered preferable from an environmental impact perspective over options that create less such opportunities. More benefit-sharing arrangements with providers from developing countries would also contribute to the transfer of knowledge and technology to partners in those countries.

Conversely, options that create higher costs or that stifle research and development are considered to generate less knowledge and less benefits for biodiversity conservation.

6.2. Access Pillar

6.2.1. Option A-1: No EU level action

Under Option A-1 all Member States and the Union will have ratified the Nagoya Protocol by the time of its entry into force in 2014 or 2015. Before ratifying, Member States must decide whether to require prior informed consent and benefit-sharing or not; and if so, implement their access-related obligations under the Protocol. The Union will not have to make any decision of the kind. It seems almost certain that by 2015 Member States with free access systems will co-exist with other Member States that require prior informed consent. This situation would be in conformity with the Nagoya Protocol that recognises the sovereign right of each Party to require benefit-sharing for the utilisation of its genetic resources or not.

Although the Protocol regulates domestic access frameworks in quite some detail, it is an apparent shortcoming of Option A-1 that it would not support a coordinated approach to addressing issues that will arise. One such issue concerns the choices taken by Member States on how their domestic access-framework relates to specialised ABS agreements. The most important example of a specialised agreement is the International Treaty on Plant Genetic Resources for Food and Agriculture. The Nagoya Protocol obliges Parties to respect specialised ABS agreements. However, the precise relationship between Nagoya Protocol implementing measures and the use of genetic resources in accordance with the FAO International Treaty is not clear. It could raise questions on the EU's compliance with the Nagoya Protocol if Member States were to take differing choices on this matter. Similar difficulties could arise in relation to the obligation to apply special considerations in relation to research or to public health concerns, if Member States were to implement these fairly general obligations in different ways.

Another draw-back of Option A-1 is that it leaves the management of eventual tensions between access frameworks of Member States and the acquis to *ad hoc* interventions by the Commission. It seems much preferable to discuss relevant questions at the time when

Member States that wish to require prior informed consent and benefit-sharing are developing access frameworks rather than forcing a re-opening of such frameworks once established.

As indicated in the below table, it is difficult to precisely identify further impacts – whether positive or negative – of Option A-1. These will depend on future choices taken by the Member States. Clearly, Option A-1 will not result in an EU-level playing field on access: Member States with free access systems will co-exist with Member States that require prior informed consent and benefit-sharing. One general issue of concern is, however, that it could have negative economic impacts for EU researchers and also for SMEs if Member States would establish widely differing substantive access conditions. For example, it is typical for parts of the biotechnology industry (with a high level of SMEs) to conduct high-throughput screening of tens of thousands of samples in search for new compounds. Obviously, such activities benefit from a streamlining of access conditions, as generally also legal certainty will increase and legal risks will be minimal if access conditions are harmonised across the EU. While Option A-1 does not provide a basis for establishing a solid response, at least it would not create costs at EU-level; costs at Member State-level would depend on the choices taken by them.

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

Under Option A-2, by 2014 or 2015 all Member States and the Union would have ratified the Nagoya Protocol and Member States with free access systems will co-exist with other Member States that require prior informed consent. However, the EU platform for discussing access-related issues and for sharing best practices would actively engage the Member States, the Commission and EU stakeholders in a discussion on the design and the performance of access frameworks in the Member States. It seems reasonable to assume that the platform would contribute to collective learning and thus influence choices made by Member States in relation to specialised ABS systems, on how to apply special considerations, how to deal with access requests by researchers or companies from non-Parties, etc. The deliberations of the platform would also be beneficial for any future consideration of a focussed EU-level policy intervention on access.

The EU platform would have some potential to streamline access conditions applied by Member States that require prior informed consent, although this will not result in an EU-level playing field on access. Nevertheless any narrowing of differences between Member State access frameworks will lower transaction costs and hence be particularly beneficial for SMEs and recipients of public funds.

Another effect of the EU platform is that it would showcase best practices on access. This would not only help Member States to learn from each other. It would also help potential users to identify the Member State with the best functioning access frameworks. Both aspects could positively contribute to research and development opportunities in the EU.

It is difficult to precisely identify further impacts of this option – whether positive or negative; this depends on future choices taken by the Member States. A well-functioning EU platform

on access will likely influence these choices; however, it cannot determine them. The operation of the EU platform would create limited costs at EU-level.[29]

6.2.3. Comparison of Options A-1 and A-2

The results of the analysis as summarised in Table 2 below shows that Option A-2 creates limited costs at EU-level, whereas Option A-1 would entail no costs. The added value of Option A-2 over Option A-1 is nevertheless apparent. Option A-2 would create benefits for Member States, for the Commission, and for EU stakeholders. It would particularly benefit academic researchers and SMEs or micro-enterprises. **Option A-2 is therefore tentatively identified as the preferable option for implementing the access-pillar of the Nagoya Protocol.**

Table 2: Comparison of Options for the access pillar of the Protocol

Criteria for analysing impacts	**Grading**	
	Option A-1	**Option A-2**
Specific Criteria to Access and Benefit-sharing and to the Nagoya Protocol		
- Specialised ABS agreements and processes (respect and mutually supportive)	-	+
- Handling of Party-non-Party relationships	Unclear	+
- Coherence with existing EU acquis	-	+
- Support to special considerations	-	+
- Ability to accommodate differences between sectors	n.a.	n.a.
- Flexibility to allow for future development and fine-tuning	+	+
- Improving the knowledge base about acquisitions, transfer and use of genetic resources in the EU	0	+
Economic impacts		
- Creation of an EU-level playing field	-/0	+
- Correspondence with existing utilisation practices	n.a.	n.a.
- Legal certainty and legal risks	-/0	+
- Distribution of impacts along the value chain	0	0
- SMEs and micro-enterprises	-	0/+
- Research and development opportunities	0	0/+
- International competitiveness	0	0
- Obligatory monitoring related to user-compliance (effectiveness, efficiency, and costs)	n.a.	n.a.
- Administrative costs (EU-level, MS level, one-off, recurring)	+ (Union level)	0 (Union level)
Social impacts		
- Potential to contribute to social objectives (health, food security, nutrition etc)	Unclear	Unclear
- Job creation or maintaining existing jobs in the sectors	Unclear	Unclear
- Protection of the rights of indigenous and local communities	Unclear	Unclear
Environmental impacts		
- Enhancing knowledge base for biodiversity conservation	Unclear	Unclear
- Potential for generating non-monetary and monetary benefits in favour of conservation and sustainable use of biological diversity	Unclear	Unclear

Note: "n.a." identifies criteria that have not been analysed as they are specific to the user-compliance pillar of the Protocol.

[29] Essentially staff time for organising meetings of the platform 2-4 times per year and travel costs in case of meetings outside of Brussels.

6.3. User-Compliance Pillar

6.3.1. Option UC-1: Open method of coordination

Under Option UC-1 all Member States and the Union become Parties to the Nagoya Protocol, and all Member States will adopt legally binding measures on user-compliance at national level; the Union would not adopt binding measures in the field.

There is little practical experience with user-compliance measures, the Protocol leaves significant discretion on how to design such measures, and different reference points exist.[30] Despite the soft EU-level coordination, one would expect that Member States develop user-compliance measures primarily on the basis of their national interests. 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.). The need for 27 national legislative proceedings finally suggests that not all Member States would become Parties to the Nagoya Protocol at the same time. These basic assumptions translate into mostly negative scores for Option UC-1.

The analysis of current user practices in the EU suggests that even small differences in user compliance requirements between the Member States could create major difficulties and costs for EU researchers and companies active in more than one Member State. One Member State might generally require users to manage ABS-related information in the most suitable form. Another Member State might oblige users to present so called "internationally recognised certificates of compliance". Both systems would oblige users to take a different approach to managing ABS-related information. It is against this background, that respondents in the public consultation unanimously pleaded for an EU-harmonised approach to user-compliance measures, preferably on the basis of an EU-Regulation.

The existence of the EU-internal market and the fundamental freedoms also implies that different Member State approaches to user-compliance would result in an overall lower performance of national systems. For example, Member State A might largely exempt basic research from its user-compliance system, whereas the user-compliance system of Member State B might oblige those involved in basic research to pass on minimum information on ABS. Researchers that participate in the European Research Area would need to manage these differences. In result, costs for ABS compliance in Member State A would increase, despite the exemption for basic research, and there would likely be an increase in the non-compliance risks of researchers in Member State B.

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[30] Norway, for example, has adopted user-compliance measures that are conceptually based on Option UC-4, although it seems unclear how monitoring and enforcement works (for a critical account see Tvedt and Fauchald, The Journal of World Intellectual Property (2011), Vol. 14, no. 5, pp. 383–402). Switzerland opened a public consultation in May 2012 on a legislative proposal that seems similar to Option UC-2 (see <http://www.sib.admin.ch/?id=756&L=1>).

A fragmented approach to user-compliance could also lower the benefits for Member States of ratifying the Protocol. To give one hypothetical example: Spain ratifies the Nagoya Protocol before most other Member States. A Spanish biotechnology company applies for a permit to collect samples of marine genetic resources in the Exclusive Economic Zone of a biodiversity-rich island state in the Indian Ocean. The competent authority of the island state requests that collected samples are only used in Spain, not in other EU Member States that have not yet ratified the Protocol. Would Spanish authorities that support the enforcement of such conditions comply with Spain's obligations under the EU Treaties? The answer is not straightforward and the island state might refuse granting access if it expects that material collected may also be used in other EU Member States that are not Parties to the Protocol.

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

One important positive feature of the due diligence approach is that it would actively support the functioning of specialised ABS agreements and systems. By *generally* obliging EU users to be diligent, EU users would also be diligent that genetic resources are utilised in accordance with *specialised* ABS systems. This would be beneficial for the ABS system established through the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, but also for the Pandemic Influenza Preparedness Framework recently adopted by the World Health Organization. The due diligence approach would similarly support respect for the special considerations that are obligatory under the Protocol.

The due diligence obligation would generally apply to all activities of utilisation within EU jurisdiction. It would thereby create a common baseline of user-compliance efforts throughout the EU and establish an EU-level playing field. In effect, all users of genetic resources in the Union would each at their respective place in the utilisation chain seek, keep and transfer information relevant to ABS. The establishment of an EU-level playing field on user compliance measures is particularly beneficial for SMEs that would face disproportionately higher costs than larger companies to cope with differing user-compliance standards in different Member States of the Union. An EU-level playing field of user-compliance measures also implies a more efficient use of public funds spent in favour of academic or applied research, as researchers need to spend less of their time to cope with potentially different user-compliance standards. The positive aspects of an EU level playing field on user-compliance are particularly apparent when comparing this Option with the concerns related to the expected fragmentation of user-compliance measures that would most likely result from Option UC-1. It must also be stressed in this regard that respondents in the public consultation unanimously pleaded for an EU-harmonised approach to user compliance, precisely because of concerns over high costs from fragmentation. Furthermore, it is noteworthy that the International Chamber of Commerce explicitly supports a due diligence approach to implementing the user-compliance pillar of the Nagoya Protocol.[31]

The due diligence approach is also flexible to accommodate differences between sectors utilising genetic resources and associated traditional knowledge. Users could identify for themselves a suitable and cost-effective way of meeting their obligation. Considering current utilisation practices in the EU, it is assumed that users will take different measures, reflecting their specific placement in the EU genetic resources value chain. An SME in the biotechnology sector might decide making use of standardised contracts when acquiring or passing on research material. Academic research groups could decide to deploy a low-cost,

[31] See ICC Document "Nagoya Protocol Implementation in the EU", No. 450/1075 of 18 June 2012.

open source software tool for tracking and monitoring the use of genetic resources 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 best practice code of conduct. Users in specific sectors of the EU economy could further reduce their eventual compliance costs and raise legal certainty by implementing a recognised best practice. As detailed in Annex 8 to this study, a range of codes of conduct have already been developed for different sectors and activities, currently their practical relevance varies. This option would very likely raise the practical relevance of such existing codes. It would also reward those users which have already in the past, absent binding rules, made an effort to comply with the ABS provisions of the CBD.

The ability of users to comply with their due diligence obligation by implementing best practice codes of conduct would have further positive effects for the interaction with partners from non-Parties to the Protocol. Partners in non-Parties are outside the reach of EU user-compliance rules. Nevertheless, if non-EU partners were to apply the same or similar best practice standards on ABS, they would effectively also comply with EU user compliance rules. It seems significant in this context that some existing best practice codes are indeed of global nature or used well beyond the EU.[32]

It would largely be in the hands of users and their professional associations to identify the most cost-effective ways of implementing the due diligence obligation for their respective utilisation activities. The flexibility inherent in the due diligence concept will ensure that users can tailor their due diligence measures as much as possible to their existing practices, and thereby also reduce eventual costs. In that regard it seems very significant that not one respondent in the public consultation, no participant in the many *ad hoc* meetings, and no person interviewed by the consultant team indicated that it would, in principle, be impossible or unworkable to add some basic consideration of ABS issues to its current utilisation practices.

The monitoring costs for users would be limited. The declarations would need to be made at points where users would anyhow already be obliged to summarise and evaluate relevant information on their research and development activities. As regards declarations in the context of public research funding, it is already standard practice today that recipients of EU funds commit themselves to respect applicable laws when using public funds and later on need to declare their compliance with this general obligation. As regards declarations on the occasion of a product approval or the commercialisation of a product, users already today prepare a dossier describing the product for which a permit is sought or that is put on the market. The only situations where real costs might arise is indeed in cases where a user has not been diligent and failed to seek relevant information on ABS when acquiring a genetic resource, and later on needs to re-establish such information.

As regards administrative costs, these would fall primarily fall on the Member States and the competent authorities designated for receiving due diligence declarations by users and for checking compliance. Notably, the due declarations could be made to already existing authorities of the Member States or to the national competent authority(ies) that each Party to the Nagoya Protocol must establish. The compliance checks would most likely be done by specialised authorities existing in a given sector. Importantly, competent authorities of different Member States could cooperate amongst each other and with the Commission if this

[32] See the examples in Box 5.

would be more effective. This is one apparent advantage in effectiveness and costs over a situation where 27 Member States develop 27 distinct user-compliance systems with distinct monitoring systems and different types of checks.

As regards the distribution of costs, it appears that the limited costs for making due diligence declarations would arise for all researchers using public funds, it would not arise for privately funded research. Furthermore declarations would need to be made by users that have successfully developed a product on the basis of genetic resources. They would not need to be made by other users in case their research and development activities never result in a product. As regards administrative costs, it seems that costs will be higher in those Member States where more utilisation activities occur and where more genetic resource based products are commercialised. This suggests that public costs for monitoring will tend to correlate with benefits related to the successful marketing of products based on genetic resources (e.g., additional tax revenues).The main effect of this option would be that all those utilising genetic resources or traditional knowledge associated with such resources in the EU will establish and maintain a baseline of ABS-related information throughout the EU genetic resources value chain. In some cases, such information would be trivial: for genetic resources acquired prior to 1993, the CBD and the concept of ABS did not apply. So any material identified as stemming from before this date could comfortably be utilised. Nevertheless, it would be important also for subsequent users that this specific information is actively passed on with the eventual transfer of a sample. In other cases, information passed on by a previous user might indicate that a specific set of samples may only be utilised for non-commercial purposes and convey information about the contact point of the Party holding the sovereign right for seeking permission to undertake applied research.

6.3.3. Option UC-3: General due diligence obligation on EU users complemented by identifying 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 identify collections with control measures in place to assure that only well documented samples of genetic resources are made available for their utilisation. The EU Regulation would clarify that users of genetic resources that acquire samples from a "trusted source" would thereby comply with a major part of their due diligence obligation. This option scored higher than Option UC-2 in respect to key implementation aspects (EU-level playing field, legal certainty, impacts on SMEs) due to two main reasons:

First, the identification of certain collections as "trusted sources" would add a focus on the quality of research material utilised to the basic due diligence system; the latter focuses on the activity of utilisation. To recall: situations might occur where a user was diligent but it eventually turns out that a concrete genetic resource used was illegally acquired. This would not constitute a breach of the due diligence obligation. A system of "trusted sources" would, however, very significantly reduce the risk that illegally acquired or incompletely documented genetic resources enter the EU genetic resources value chain. The analysis of current utilisation practices shows that the very large majority of commercial EU users acquire new samples of genetic resources from ex-situ collections; mostly from collections within the EU. A system of "trusted sources" would hence have further positive effects for establishing an EU-level playing field of quality samples of genetic resources, it would improve legal certainty and lowers risks for all users that source from recognised collections. It would also lower costs for monitoring user compliance, as it seems reasonable to assume less risk of non-compliance by users sourcing from recognised collections.

Second, it is apparent that the additional compliance benefits of Option UC-3 would particularly arise for those EU users that acquire their research and development material from EU collections. In the EU this includes academic researchers and several commercial sectors. The horticultural industry, for example, predominantly relies on ex situ collections for its research and development. 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. Importantly, actors from these groups that acquire the material from collections are to a very significant extent individual academic researchers, SMEs and micro-enterprises. Particularly this group would benefit from the lower costs and enhanced legal certainty of Option UC-3.

These particular characteristics of Option UC-3 also translate into significantly high scores for the expected impact on research and development opportunities in the EU and will have positive social and environmental impacts.

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

Particular features of Option UC-4 are a general prohibition to utilise illegally acquired genetic resources, a focus on specific uses of specific material, and a monitoring system based on obligations for users to actively disclose at certain points in the genetic resources value chain how they comply with eventually applicable ABS requirements. The negative or very negative grading of this option reflects fundamental problems that stand in stark contrast to the initial reaction of many which, when first exposed to the issue of ABS, would support a prohibition to utilise illegally acquired genetic resources.

The first fundamental problem of Option UC-4 is that currently EU users do not have sufficient information to determine where they stand in relation to the prohibition. The prohibition would initially only be relevant for a small fraction of genetic resources utilised within the EU: it would not apply to genetic resources acquired prior to the CBD entry into force, nor to genetic resources collected in countries that do not require prior informed consent and benefit-sharing, nor to genetic resources collected in areas beyond national jurisdiction. Nevertheless, to comply with the prohibition EU users would need to know for each individual sample utilised where it came from, when it was acquired, and if some ABS-related obligations apply. To be on the safe side, users would need to have this information for all genetic resources utilised, not only for those that actually come within the scope of the Nagoya Protocol. The analysis of utilisation practices in the EU shows that the necessary information is currently not available at all places of the EU genetic resources value chain. It seems that the prohibition would have relatively small negative impacts on well-staffed and funded botanical gardens where almost all samples held are fully documented. However, it would most likely create very significant legal uncertainty for some commercial users of genetic resources. Biochemical libraries, for example, include molecules isolated from biological material as well as molecules developed through computerised permutations. Once the chemical structure of a naturally occurring molecule is known, it can be re-built and further modified[33], irrespective of where it originally came from; information on the origin of

[33] This is markedly different from genetic material as such.

molecules has often not been kept. Parties to the Nagoya Protocol must apply their user-compliance measures to the "utilisation of genetic resources", and this term explicitly includes research and development on the *biochemical* composition of genetic resources.[34] A prohibition to utilise illegally acquired genetic resources would therefore also become relevant for research and development on biochemicals already extracted from natural material and currently held in biochemical libraries used by the pharmaceutical, chemical and biotechnology industries. It seems unrealistic in the short- and medium-term to generate ABS-related information for all entries in such catalogues.[35]

A second fundamental problem of Option UC-4 is one of legal delimitation: it would require very careful consideration to avoid that a prohibition has potentially disruptive effects on the functioning of specialised access and benefit-sharing systems. One unresolved question in this respect is on the legal nature of specialised systems for them to be excluded from the Nagoya Protocol, and hence from the prohibition. Must a specialised ABS system in the sense of the Nagoya Protocol necessarily be established through a binding international agreement, like the FAO International Treaty on Plant Genetic Resources? Or does it suffice to have an international framework with only some legally binding elements, such as the recently established Pandemic Influenza Preparedness Framework in the World Health Organization? This question is of practical relevance not only in the area of human, animal and plant health, but also for the ongoing work of the FAO Commission on Genetic Resources for Food and Agriculture that plays a critical role in global food security policies.

A third fundamental problem of this Option is its negative impacts on individual researchers, SMEs and micro-enterprises. While the prohibition would apply to all utilisation activities, the system of disclosure obligations would only selectively apply to some utilisation activities in the downstream part of the utilisation chain. This would very likely result in an uneven distribution of costs and risks. Collections and non-commercial researchers would normally not face disclosure obligations. However, such obligations would be unavoidable 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 and chemical industry), 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. It is thus very likely that Option UC-4 would cause 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 disruption may also cause negative impacts on jobs, in particular within SMEs. Thus a prohibition to utilise illegally acquired genetic resources would stifle innovation in different sectors, and thus achieve exactly the opposite of what the Nagoya Protocol wants to achieve.

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[34] Article 2c) Nagoya Protocol.

[35] To show the magnitude of this challenge, one major company providing biochemical compounds for industrial users offers well over 90 million different molecules in its catalogue (see, for example, www. http://www.sigmaaldrich.com/).

6.3.5. Comparison of Options UC-1 to UC-4

Table 3: Analysis of options addressing the User Compliance pillar of the Protocol

Criteria for analysing impacts	**Grading**			
	Option UC-1	**Option UC-2**	**Option UC-3**	**Option UC-4**
Criteria specific to Access and Benefit-sharing and to the Nagoya Protocol				
- Specialised ABS agreements and processes (respect and mutually supportive)	--/-	++	++	-
- Handling of Party-non-Party relationships	--	+	++	-
- Coherence with existing EU laws	-	+	+	-
- Support to special considerations	--	++	++	-
- Ability to accommodate differences between sectors	--	++	++	--
- Flexibility to allow for future development and fine-tuning	0/+	+	+	-
- Improving the knowledge base about acquisitions, transfer and use of genetic resources in the EU	0	+	++	-
Economic impacts				
- Creation of an EU-level playing field	--	+	++	-/0
- Correspondence with existing utilisation practices	--	+/++	+/++	-
- Legal certainty and legal risks	--	0/+	+	--
- Distribution of impacts along the value chain	0	0/+	+	--
- SMEs and micro-enterprises	--	0/+	+	--
- Research and development opportunities	--	+	++	--
- International competitiveness	-	+	++	--
-Obligatory monitoring related to user-compliance (effectiveness, efficiency, and costs)	Unclear	0/+	0/+	--
- Administrative costs (EU-level, MS level, one-off, recurring)	-	0	0	-/0
Social impacts				
- Potential to contribute to social objectives (health, food security, nutrition etc)	-/0	+	++	--
- Jobs (creation or maintaining)		+	++	--
- Protection of the rights of indigenous and local communities	-/0	+	++	--
Environmental impacts				
- Enhancing knowledge base for biodiversity conservation	-/0	+	++	--
- Potential for generating non-monetary and monetary benefits in favour of conservation and sustainable use of biological diversity	-/0	+	++	--

As Table 3 suggests, Option UC-1 will almost certainly result in a fragmentation of user-compliance systems in the EU with very negative effects on EU stakeholders and partially disruptive effects in some genetic resources value chains. Option UC-2 and 3C both create workable systems compatible with the concerns and utilisation practices of EU economic sectors and other stakeholders. Option UC-3, however, has better scores than Option UC-2 in respect to key implementation aspects (EU-level playing field, legal certainty, impacts on SMEs, positive economic impacts). It will particularly be more beneficial to academic researchers, SMEs and micro-enterprises. Option 3D combines high legal and economic risks for EU stakeholders with a low probability that the etablished user-compliance system will function. Thus **Option UC-3** is therefore **tentatively identified** as the **preferable option for implementing the user-compliance pillar of the Nagoya Protocol.**

6.4. Temporal Application of Binding EU-level measures

This part of the study analyses how different choices on the temporal application of EU-level measures would impact on their performance. The binding EU-level measures analysed are Options UC-2, UC-3 and UC-4. Rather than applying again the full set of IA criteria, particular attention is given to understanding the implications for legal certainty and how these would relate to the overall effectiveness of measures on access and on user-compliance, and ultimately on achieving social and environmental objectives.

6.4.1. Option T-1: Applying implementing measures to genetic resources or associated traditional knowledge acquired after entry into force of the Nagoya Protocol for the EU

The option creates a high level of legal certainty and clarity for EU users. This is particularly important for industries where research and development processes typically span many years (e.g. pharmaceutical industry, plant breeding), and where a new legal regime that creates doubt on its implications for an activity that started 10 years ago, could put ongoing research and development activities under threat.

Option T-1 would be consistent with and support the smooth functioning of Options UC-2 or UC-3. It would also be consistent with Option UC-4, although it would not be able to soften the fundamental problems of this option.

6.4.2. Option T-2: Applying implementing measures to genetic resources or associated traditional knowledge acquired since entry into force of the CBD and utilised after entry into force of the Nagoya Protocol for the EU

The main drawback of Option T-2 is its effect on legal certainty of EU users. The creation of new obligations under EU law for "new or continuous" utilisation activities would raise many legal and practical questions. When would a research and development activity be considered as sufficiently different to earlier research to be qualified as "new "? It is typical for research and development processes, particularly in the early part of the genetic resources value chain, that discovery processes are "chaotic" in the sense that it is not clear at the beginning what will come out at the end. Would it, for instance, constitute a "new utilisation" if the result of an experiment is different from what was initially expected, but then the course of research is changed to profit from the unexpected discovery? Legal uncertainty would arise particularly in industries where research and development processes typically span 5, 10 or even 20 years (e.g., pharmaceutical industry, plant breeding). It would also take multiple years and a fairly large number of concrete cases before courts in the Member States would have established a typology of cases representative for the different sectors. Option T-2 might also conflict with constitutional principles on the retroactive application of laws in some of the Member States.

The legal uncertainty associated with Option T-2 would most likely stifle research and development on material acquired post-CBD, particularly for actors with little (legal) capacity or where high economic stakes are involved. This also suggests that the expanded coverage of material under Option T-2 would most likely not translate into enhanced benefit-sharing opportunities and conservation gains; but just the opposite. Option T-2 could also call into question initiatives of collections in the EU that voluntarily apply ABS principles to all samples held, whenever these were acquired.

The legal uncertainty associated with Option T-2 would clearly lower the performance and functioning of Options UC-2 or UC-3. Option T-2 would add another challenge to the already fundamental problems of Option UC-4.

6.4.3. Comparison on Temporal Application and identification of best performing options on access and on user-compliance

Option T-1 is clearly preferable. It combines legal certainty for EU users with a higher likelihood to meet important social and environmental objectives. Conversely, Option T-2 would raise many economic and legal, in part constitutional, concerns and also would be unlikely to contribute to fulfilling the set social and environmental objectives.

Overall assement for options on Access, User Compliance and Temporal scope

Against this background, the preferable option on access is the establishment of an EU platform for discussing access to genetic resources and sharing best practices (**Option A-2**), whereas the preferable option on user-compliance is a due diligence obligation on EU users complemented by a system to formally recognise collections as "trusted sources" of genetic resources (**Option UC-3**). The measures under Option UC-3 would only apply to genetic resources and associated traditional knowledge that are acquired and utilised after the entry into force of the Nagoya Protocol for the EU (**Option T-1**).

6.5. Hypothetical scenarios

Up to this point, the access pillar options and the user-compliance pillar options were analysed separately. The hypothetical scenarios in Box 6 seek to illustrate how Options A-2 and UC-3 would work together in practice. The scenarios also facilitate the subsequent analysis of the complementary measures.

Box 6: Hypothetical scenarios

Scenario 1: By 2020, ES and FR are the only two EU Member States that require prior informed consent and benefit-sharing for the use of their genetic resources. Both have put in place transparent, well-functioning access frameworks and both have decided to establish a national centre of excellence for biodiversity research similar to the NIBR established in South Korea[36]. Discussions between Member State experts and EU stakeholders in the EU access platform show that academic researchers and SMEs favour 'regulated' access in ES and FR over access in Member States that have a 'free access' policy but do not provide any support in identifying and acquiring quality samples for research and development.

Scenario 2: In 2021, a small UK company, specialised in developing ingredients for the food industry, works with the ABS competent national authority of Kenya and a representative of the Maasai tribe to obtain access to leafs of a plant traditionally used by the Maasai for its hunger-suppressant properties. After concluding a benefit-sharing agreement with the Maasai, the UK company receives the access permit by the Kenyan authority. Company scientists identify the hunger suppressant ingredients of the plant and develop a process for extracting and stabilising them. The UK company sells its innovation to a multinational company specialised in functional foods that markets its products mainly in Europe and the US. The legal compliance unit of the multinational company, mindful of the due diligence obligation, seeks information from the UK company on eventually applicable ABS requirements.

[36] See Box 3.

After acquiring the innovation, the multinational company negotiates a benefit-sharing agreement with the Maasai that includes establishing a fund in support of education projects in the Maasai community fed by a percentage of royalties from the sales of functional foods developed on the basis of the plant.

Scenario 3: A scientific journal publishes an article on marine sponges from the Great Barrier Reef. The article provides unique identification numbers of samples held in a collection listed in the EU register of "trusted sources". A scientist from a small biotech company seeks access to the samples. The collection website informs that these specific samples are owned by the University of Queensland in Australia and are available for non-commercial use based on a standardised contract; however, requests for commercial use must be directed to the reference collection of Queensland University.

Scenario 4: Researchers based at the Berlin botanical garden cooperate with Cuban colleagues to collect particular flowers in Cuba. In a dinner conversation, team members discover that a flower species held in the Berlin garden, which was collected by Alexander von Humboldt in Cuba in 1799, is apparently extinct in the wild. This raises the question of a "repatriation" of this flower to Cuba.

Scenario 5: The Nagoya Protocol enters into force in 2014. In early 2015, an expert group set up by the World Federation of Culture Collections (WFCC)[37] presents a report to the Executive Board of the WFCC on potential adjustments to the practices of WFCC members to ensure full compliance with the Nagoya Protocol. The report proposes developing a standardised Material Transfer Agreement for the supply of samples to outside users, building on work done by European members of the federation. It also proposes establishing a fully electronic system for tracking the exchange of samples within the WFCC network. The group also recommends that all members of the WFCC that can demonstrate use of the tracking tool and the standard Material Transfer Agreement should seek registration in the EU register of "trusted sources".

6.6. Complementary Measures

To recall, the analysis of complementary measures is only undertaken in relation to the identified package of main measures (Options A-2 and UC-3) to understand how the additional costs incurred by them would relate to expected gains in effectiveness, efficiency and cost-savings for these main choice on access and on user-compliance.

6.6.1. Option C-1: Bilateral cooperation between the EU and major provider countries or regions

The eventual costs of bilateral cooperation depend on what is being done, the benefits on what is being achieved. There is a spectrum of cooperation activities ranging from bilateral /regional dialogues, project-based cooperation, to more formal cooperation on the basis of a Memorandum of Understanding or a formal bilateral agreement. Bilateral dialogues on ABS and the Nagoya Protocol are already ongoing between the Commission and important partners and managed within existing resources. Further collaborative projects could be developed, particularly by using existing Science and Technology Agreements with third countries.

Given the flexibility inherent in core obligations of the Nagoya Protocol, particularly in relation to user-compliance, one major focus of bilateral cooperation would be to enhance the mutual understanding of implementing measures taken. This will facilitate access of EU researchers and companies to quality samples of genetic resources and to associated traditional knowledge in non-EU countries (see *scenario 2* in Box 6). Scientific cooperation projects, particularly where it involves collections recognised as "trusted sources", would also enhance access of EU researchers to quality samples of genetic resources with positive effects on research and development opportunities and new discoveries important for conservation

[37] <http://www.wfcc.info/home/>.

efforts and benefit-sharing (*scenario 4*). A particularly sensitive issue, also touched upon in *scenario 4,* concerns the issue of "**repatriation**" of samples held in EU collections by their countries of origin. Bilateral cooperation seems an appropriate framework for addressing such issues.[38]

Overall, ***soft cooperation under Option C-1 is considered to have a very positive cost-benefit-ratio***, particularly in the early stages of Nagoya Protocol implementation. More formalised cooperation in the form of bilateral agreements would require prior formal authorisation by the Council and possibly a self-standing impact assessment.

6.6.2. Option C-2: Support developing sectoral codes of conduct and contractual model clauses

Sectoral codes of conduct and contractual model clauses have very significant potential for enhancing the effectiveness of EU implementation measures that are based on a due diligence system. As was explained earlier, the availability of best practice codes of conduct would support compliance of EU users with their due diligence obligation. This would be particularly beneficial to SMEs and non-commercial resarchers with little capacity. As regards access to genetic resources, model clauses could support a streamlining of access practices in Member States that do require prior informed consent and benefit-sharing (*scenario 1* in Box 6). Such streamlining would be particularly beneficial for non-commercial researchers and SMEs. Model clauses are also useful tools for strengthening collections and the networks between them (*scenario 5*). A further aspect that could be addressed in codes of conduct is how to document acquisitions in states wih a free access policy (*scenario 1*).

If the EU implements the Nagoya Protocol based on a due diligence approach, it seems reasonable to assume that some user sectors in the EU, possibly also at global level, will take the initiative for refining or developing sectoral codes and contractual model clauses that work best for them. Foreseeably, Commission representatives would be invited to participate in such processes. Initially such participation could be done within existing resources. However, it might require resources additional to the competent authority / focal point the Commission must designate if the Union ratifies the Nagoya Protocol. As part of this option, the Commission should also undertake an initial stock-taking exercise of existing relevant codes of conduct and model clauses. This should be supported by an expert study.

Overall, there appear to be very significant first-mover advantages on this issue. EU-based researchers and industries utilising genetic resources constitute a critical mass of ABS stakeholders globally. Codes and model clauses that support compliance in the EU thus have the potential for becoming *de facto* best practice standards at global level. An early priority to Option C-2 would thus create lasting benefits for EU stakeholders.

Option C-2 ***entails some costs at EU-level***. However, an early priority on this option is considered to create lasting benefits for EU stakeholders that far outweigh initial costs.

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[38] For an interesting project by Kew botanical garden in the UK to "repatriate" information on herbarium data for North-Eastern Brazil see <http://www.kew.org/science/tropamerica/repatriation.htm>.

6.6.3. Option C-3: Support developing and deploying technical tools for tracking and monitoring

A "common thread" of all considerations on user-compliance in this IA is that without a common baseline of ABS-related information throughout the EU genetic resources value chain, it challenging to expect respect by users for applicable ABS requirements set out in access-permits of provider countries and in benefit-sharing contracts between the provider and the first recipient of material. The EU due diligence obligation on user-compliance would create a strong incentive for all EU users of genetic resources to systematically seek, keep and transmit ABS-related information (*scenarios 2, 3 and 5* in Box 6). The EU baseline of current practices of genetic resources use suggests that this is a feasible approach for EU users of genetic resources and associated traditional knowledge. The costs for meeting this challenge could, however, be minimised by employing low cost, technical tools for tracking and monitoring genetic resources flow. The expert study (see Annex 9) underlines that the challenge is not one of availability of technical tools or potential costs. Tools that could be deployed are readily available with few adjustments. Some tools are open-source and could be available at minimal costs to users. What is necessary, however, is to deploy the available technical tools in a specific regulatory context.

Under this option, the Commission would immediately after adoption of the EU Regulation work with information technology experts and EU stakeholders to support the rapid testing and more widespread use of technical tools for monitoring genetic resources flow. This requires some human resources (approx. 1/3 desk officer for 2 years) time and the organisastion of a limited number of meetings (4 per yer for 2 years), while an initial technical scoping study would be helpful.

Option C-3 has ***some but limited costs at EU level***. An early priority to this option is, however, assumed to create lasting benefits for EU stakeholders and for an effective implementation of the EU Regulation that far outweigh the initial costs.

6.6.4. Option C-4: Awareness raising and training activities

Access and benefit-sharing is a new field of activity. The Nagoya Protocol obliges its Parties to take awareness raising measures, and gives an indication of suitable measures to this end.[39]

EU-internally, the early and effective implementation of the EU Regulation would strongly benefit from full awareness of EU stakeholders (*scenario 2* in Box 6). As regards awareness raising activities, the necessary Q&A material accompanying the EU Regulation will be an important first step. This information will be prepared by the Commission and made available on the Europa web-site. It is assumed that this work will be undertaken by the desk officer(s) responsible for the EU Regulation. As regards training activities, it seems premature to determine what exactly is required and where the main needs will be. For the purpose of this study it is assumed, however, that training activities are primarily undertaken by the Member States and only complemented by Commission activities (e.g., by "training the trainers").

Internationally, if the EU has ratified the Nagoya Protocol it will be expected to contribute to awareness raising and training activities also internationally, mostly in favour of developing country Parties. As regards the CBD, the Commission currently uses funds from the ENRTP to support internationally agreed activities that it considers as political priorities. The ability

[39] Article 21 Nagoya Protocol.

of the Union to contribute to international awareness raising activities agreed by Parties to the Nagoya Protocol will in any case depend on the outcome of the ongoing discussion on the Multiannual Financial Framework 2014-2020, and cannot be prejudged in this IA study.

Option C-4 has ***limited EU-level costs for EU-internal awareness raising and capacity building activities***. The importance and benefits of stakeholder awareness and capacity for an early and effective implementation of an EU Regulation do, however, seem very significant and far outweigh the limited costs incurred. Option C-4 does not prejudge eventual future EU support for international-level awareness raising activities.

6.7 Overview of the analysis results

Table 4 below provides a synoptic overview of the results of the analysis on the policy options.

Table 4: Overview of the results of the analysis on the policy options

Business as Usual	- Union ratification without implementing measures by Union or Member States (**BAU**) *=> The BAU option is clearly not workable. Nevertheless, together with the detailed description of current user practices in the EU in Annex 8, it was used as the main reference point for assessing and comparing all other options.*	
Access pillar	*Binding measures at MS level*	- No EU action (**A-1**) - EU platform (**A-2**) *=> Option A-2 is preferable over Option A-1 with only limited additional costs at EU-level*
	Binding measures at EU-level	
User-compliance pillar	*Binding measures at MS level*	Member States take binding measures with soft coordination at EU-level (**UC-1**) *=> Option UC-1 will almost certainly result in a fragmentation of user-compliance systems in the EU with very significant costs to EU stakeholders and partially disruptive effects in some genetic resources value chains.*
	Binding measures at EU-level	- General due diligence obligation on EU users (**UC-2**) - General due diligence obligation on EU users and system for formal recognition of collections as "trusted sources" (**UC-3**) *=> Option UC-2 and 3C both create workable systems compatible with the concerns and utilisation practices of EU stakeholders. Option UC-3, however, has better gradings than Option UC-2 in respect to key implementation aspects (EU-level playing field, legal certainty, impacts on SMEs). It will be more beneficial to academic research, SMEs and micro-enterprises.* - Prohibition to utilise illegally acquired genetic resources and "downstream" monitoring (**UC-4**) *=> Option UC-4 combines high legal and economic risks for EU stakeholders with a low probability that the etablished user-compliance system will function.*
Temporal application	*In case of binding EU-level measures…decision on* - Application of binding rules to future acquisitions of genetic resources (**T-1**) - Application of binding rules as of entry into force of the CBD in 1993 (**T-2**)	

	=> Option T-1 is clearly preferable. It combines legal certainty for EU users with a higher likelihood to meet important social and environmental objectives. Conversely, Option T-2 would raise many economic and legal, in part constitutional, concerns and also would be unlikely to contribute to the identified social and environmental objectives.
Complementary measures	- Bilateral cooperation between EU and major provider countries or regions (**C-1**) - Sectoral codes of conduct and contractual model clauses (**C-2**) - Technical tools for tracking and monitoring (**C-3**) - Awareness raising and training activities (**C-4**) *=> Options C-1 to C-4 would all create contribute positively to the functioning of the main measures identified in the study (A-2 and UC-3).*

Table 5 indicates how the particular mix of implementing measures identified as the most preferable support achieving the objectives of this IA study. The preferable options are a combination of **A-2** (EU platform), **UC-3** (General due diligence obligation on EU users and system for formal recognition of collections as "trusted sources"), **T-1** (application of binding rules to future acquisitions of genetic resources) and the different complementary actions **(C-1, C-2, C-3, and C-4).**

Table 5: **How the implementing measures identified support achieving the set objectives**

General objective	**Identified measures supporting the objectives**
Identify appropriate measures for implementing the Nagoya Protocol in the EU and to enable the Union to ratify and comply with the Protocol.	- The totality of measures in the package would allow Union ratification and achieve full EU compliance. - Member States would have discretion whether or not to require prior informed consent and benefit-sharing for genetic resources that belong to them. Their decisions on this would not be a precondition for Union ratification.
Specific objectives	
Support the conservation and sustainable use of biological diversity within the EU and worldwide.	- The combination of a due diligence obligation for all EU users with a system of 'trusted sources' of collections would maximise research and development opportunities on quality samples of genetic resources. The resulting new scientific insights about biodiversity are an important conservation contribution in itself. - The maximising of research and development opportunities would translate into benefit-sharing opportunities in favour of the conservation and sustainable use of biological diversity within the EU and worldwide. - Bilateral agreements with major provider countries would provide opportunities for strengthening commitments to channel benefits to conservation purposes.
Provide EU collections, and researchers and companies in Europe with improved and reliable access to quality samples of genetic resources at low cost and with high legal certainty for acquired material.	- The system of 'trusted sources' would enhance the availability of quality samples at low cost and with high legal certainty. - Bilateral agreements with major provider countries or regions would create further opportunities for accessing quality samples. - The support to model clauses and technical tools for monitoring and tracking would strengthen EU and international networks of collections, including by improving the availability of quality samples and information about their availability.
Maximise opportunities for research,	- The combination of a due diligence obligation for all EU users

development and innovation in nature-based products and services, while establishing a level playing field for all EU users of genetic resources, with particular benefits for SMEs and for publicly funded, non-commercial research.	with a system of 'trusted sources' of collections would maximise research and development opportunities on quality samples of genetic resources. - The due diligence obligation as such would apply to all EU users and thus establish an EU-level playing field. This would be particularly beneficial to SMEs and publicly funded research. - Publicly funded research and SMEs would also particularly benefit from the establishment of the system of 'trusted sources' of collections. - Support for model contractual clauses would also particularly benefit SMEs and non-commercial research with little capacity.
Protect the rights of indigenous and local communities that grant access to their traditional knowledge associated with genetic resources in accordance with the domestic laws of Parties to the Nagoya Protocol.	- The combination of a due diligence obligation for all EU users with a system of 'trusted sources' of collections will ensure that traditional knowledge associated with genetic resources documented in domestic access permits and in benefit-sharing contracts is only used for the identified purposes and that agreed benefits are shared. - The work on contractual model clauses would help indigenous and local communities achieving fair and equitable terms when giving access to their knowledge
Fully respect other international specialised access and benefit-sharing instruments and be mutually supportive with other relevant international instruments and processes	- The due diligence approach would not only respect but actively support the performance of specialised ABS instruments and other relevant international instruments and processes
Operational objectives	
Establish a credible system for user-compliance measures.	- The basic due diligence obligation for all EU users would ensure that future utilisation activities in the EU comply with applicable ABS requirements set out in domestic access permits and in benefit-sharing contracts. - The system of 'trusted sources' of collections would step by step increase the share of 'ABS proof' quality samples of genetic resources utilised in the EU and gradually squeeze out the utilisation of genetic resourcse that are not properly documented in relation to ABS. - The due diligence approach also gives a strong incentive to EU users to implement ABS best practice codes of conduct and use contractual model clauses. The early priority on supporting users in developing further such codes and clauses has a strong potential for making the EU approach to user-compliance de facto the global standard.
Improve information on access and utilisation of genetic resources in the EU	- User declarations on their compliance with the due diligence obligation will generate information on activities utilising genetic resources in the EU; - The system of 'trusted sources' of collections will generate information about specific genetic resources accessions; - The increased utilisation of low-cost electronic monitoring and tracking tools by collections and some user groups will further add information about genetic resources flow; - Member States deciding to require prior informed consent will also contribute information about access permits issued.
Minimise overall implementation costs and burdens, particularly for affected SMEs	- The general due diligence approach allows users to identify ways for seeking, keeping and passing on ABS-related

	information that fits best to their activities, their business model, and their placement in the EU genetic resources value chain. - The system of 'trusted collections' will considerably lower compliance efforts by all those sourcing their research material from registered collections and subsequent users of such material. - Existing best practice policies of collections in the EU mean that these could seek to become 'trusted sources' with minimal further effort, thus rewarding the early measures taken. - Complementary measures on model clauses, codes of conduct, technical tools for tracking and monitoring, or awareness raising all combine to an enabling operating environment for EU users of genetic resources and assoiated traditional knowledge. The ability to build on existing codes of coduct and best practice standars rewards early movers in the field, be it collections.

7. MONITORING AND EVALUATION

Parties to the Nagoya Protocol must regularly report to the Meeting of the Parties on the implementing measures undertaken, in a format and at intervals that will be determined by the Meeting of the Parties.[40] The Protocol also establishes that Parties will undertake four years after the Protocol's entry into force (likely in 2018 or 2019) a review of the Protocol's effectiveness.[41] These obligations will apply equally to the EU and its Member States. Monitoring and evaluation measures done for the purpose of this EU Regulation should ideally provide the majority of input for complying with these global level obligations.

While Member State authorities would be expected to report to the Commission on the way the EU Regulation is applied by their designated competent authorities, the Commission will receive, keep and analyse such information.

The following information will be available on the basis of the implementing measures and may be used for monitoring and evalution purposes:

– Information on Union trusted collections and eventual difficulties in their operations;

– Records on genetic resources and related information that were supplied by Union trusted collections to third persons;

– Declarations by users of genetic resources on how they exercised due diligence;

– Records on checks of user-compliance conducted by competent authorities and eventualy remedial actions and measures taken.

– information obtained through regular meetings of the EU Platform on access, with the help and participation of the Member States experts on issues relevant to the access pillar of the Protocol.

The Commission would launch in 2017 or 2018 a technical study documenting practices of EU sectors utilising genetic resources. This study should take the empirical work

[40] Article 29 Nagoya Protocol.
[41] Article 31 Nagoya Protocol.

underpinning this IA study as starting point and analyse through appropriate means, also drawing on some of the information listed above, the effects and effectiveness of the EU Regulation for implementing the Nagoya Protocol in the EU.

Key indicators for monitoring and evaluation will be developed together with Member States experts, but could include 1) number of collections identified as Union trusted sources, and relevance of these collections to EU users of genetic resources; 2) number of declarations made by users on their compliance with the due diligence obligation, and relevance of missing, incomplete or false declarations in relation to all declarations made. 3) Number of checks conducted on users and number of non-compliance situations identified; 4) Number of non-compliance situations that occurred where material was sourced from a trusted collection as compared to the overall number of non-compliance situations; 5) Availability of best practices to EU users, and relative importance of best practices for utilisation activities overall; 6) Number of non-compliance situations that occurred where a user was implementing a best practice as compared to the overall number of non-compliance situations.

GLOSSARY OF KEY TERMS USED IN THE CONTEXT OF "ACCESS AND BENEFIT-SHARING"

ABS: Acronym for "Access and Benefit-Sharing". It is used to refer to the way in which genetic resources or traditional knowledge associated with such resources is accessed and how the benefits that result from uses of such resources and knowledge are shared with the countries or indigenous and local communities providing them.

Access to genetic resources: The term is used to describe the acquisition of genetic resources in line with the access rules of a providing country that requires prior informed consent and the establishment of a benefit-sharing contract.

Access and Benefit-sharing Clearing-House Mechanism: The term refers to the global information portal that is established by the Nagoya Protocol and will be maintained by its international Secretariat. The Protocol identifies information that Parties must submit to the Clearing-House as well as information that they may submit.

Acquisition of genetic resources: The term is used to describe the activity of obtaining physical possession of samples of genetic resources.

Biodiversity: Is a term defined in the CBD and refers to the variability that exists among living organisms from all sources including among other things, terrestrial, marine and other aquatic ecosystems and the ecological complexes which they are part of. It includes diversity within species, between species and their ecosystems.

Biological resources: Is a term defined in the CBD and refers to genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

Bio-piracy: There is no common understanding of the term 'bio-piracy'. It is mostly used to denounce situations in which companies or researchers seek intellectual property protection over traditional seeds or traditional knowledge on particular properties of plants or animals without sharing benefits with the rightful holders. Sometimes the term is used to reject, in principle, the idea of private property rights in relation to nature.

Bioprospecting: The term refers to the process of looking for potentially valuable genetic resources and biochemical compounds in nature.

Convention on Biological Diversity (CBD): the CBD is one of the three global environmental agreements adopted by the 172 states that participated in the 1992 UN Conference on Environment and Development in Rio de Janeiro. 108 heads of state and government attended the meeting.

Competent National Authorities (CNAs): Domestic administrations established by governments and responsible for granting access to their genetic resources. They represent providers on a local or national level. The Nagoya Protocol obliges its Parties to establish competent national authorities for ABS.

Compliance: Compliance is either a state of being in accordance with established guidelines, specifications, or legislation or the process of becoming so. In the context of public international law and the Nagoya Protocol it describes the situation where a state fulfils its

obligations as they arise from an international treaty. The term **user-compliance** in contrast is used when referring to the fulfilment of users of genetic resources or associated traditional knowledge with specific ABS requirements that may be set out in domestic access frameworks of provider countries, in access permits, in specific benefit-sharing contracts, or in general user-compliance laws of countries where genetic resources and associated traditional knowledge are being utilised.

Genetic material: Is a term identified in the CBD and means any material of plant, animal, microbial or other origin containing functional units of heredity.

Genetic resources: Is a term identified in the CBD and means all genetic material of actual or potential value. Essentially, the term encompasses all living organisms (plants, animals and microbes) that carry genetic material potentially useful to humans. Genetic resources can be taken from the wild, domesticated or cultivated. They are sourced from: Natural environments (*in situ*) or human-made collections (*ex situ*) (e.g. botanical gardens, gene banks, seed banks and microbial culture collections)

Genetic resources value chain: The term is used to describe the totality of typical steps taken to create environmental, social and economic value on genes and naturally occurring biochemicals found in nature. The genetic resources value chain starts with the collection of some material and possibly ends with the successful commercialization of a final product. Typical steps taken are the collection of genetic resources, the storage of collected material, basic research on genetic resources, applied research on genetic resources, the development of products and eventually the commercialization of products. Not all these steps will necessarily be taken for each sample 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. The genetic resources value chain is generally explained in Annex 7. The particular characteristics of the genetic resources value chain in the EU are detailed in Annex 8.

Indigenous and Local Communities (ILCs): The CBD and the Nagoya Protocol do not define this term. It is left to the Parties of the Protocol to define this term in their implementing measures. In the context of the Nagoya Protocol the term ILCs is generally understood to encompass communities living close to nature and holding genetic resources of traditional knowledge associated to such resources. ILCs play an important role in achieving the objectives of the Nagoya Protocol.

In-situ & Ex-situ: Genetic resources can be wild, domesticated or cultivated. "In-situ" genetic resources are those found within ecosystems and natural habitats. "Ex-situ" genetic resources are those found outside their normal ecosystem or habitat, such as in botanical gardens or seed banks, or in commercial or university collections.

Internationally recognised certificate of compliance: The Nagoya Protocol establishes that domestic access permits that are made available to the Protocol's Clearing-House Mechanism shall constitute "internationally recognised certificates of compliance". All Parties with users in their jurisdiction must recognise such certificates as evidence of legal acquisition of the genetic resource covered. The possession of an internationally recognised certificate of compliance thus shields a user against allegations of "bio-piracy".

Meeting of the Parties: As per usual practice, the Nagoya Protocol identifies that the regular meetings of the collective of the Parties to the Protocol function as its supreme decision-making body. These meetings are referred to as "meeting of the parties" or "meeting of the Parties to the Protocol". The Protocol establishes that the first meeting of the Parties to the Nagoya Protocol, after its entry into force must be organised concurrently with the first meeting of the supreme decision-making body of the CBD, the "conference of the parties", that is scheduled after the Protocol's entry into force. This will likely be in 2014.

Mutually Agreed Terms (MAT): Is a term used in Article 15 CBD and establishes that specific benefit-sharing conditions must be "mutually agreed" between providers and users of genetic resources. The term is also used in the Nagoya Protocol. Given their "mutually agreed" nature, MAT are contractual arrangement and will normally be set out in private law contracts.

National Focal Points (NFPs): Domestic administrations responsible for providing information on ABS, such as the requirements for gaining access to genetic resources. All Parties to the Nagoya Protocol must establish a National Focal Point.

Prior Informed Consent (PIC): In the context of ABS and the Nagoya Protocol PIC refers to the administrative permit given by the competent national authority of a provider country to a user, prior to accessing genetic resources. However, the term is also used in relation to the right of indigenous and local communities to take a free and informed choice on whether they wish to give access to traditional knowledge associated with genetic resources. Parties to the Nagoya Protocol are obliged to protect this right of ILCs and to take measures that traditional knowledge associated with genetic resources is accessed with the "prior informed consent or the approval and involvement" of ILCs.

Providers of genetic resources: States have sovereign rights over their natural resources. Within the exercise of this sovereignty, states will determine who holds rights over genetic resources in their domestic legal order and who has the authority to grant access to genetic resources and who should be involved in the negotiation of mutually agreed terms with potential users. The possibilities range from public ownership over genetic resources, to a system where the rights over genetic resources follow the private property rights over the land. Even in case of public ownership over genetic resources, a national government will typically delegate the authority to grant prior informed consent to a sub-national (e.g. regional authority) or non-state entity (e.g. a reference collection).

Traditional knowledge associated with genetic resources: The CBD and the Nagoya Protocol do not define this term; it is left to the Parties of the Protocol to define this term in their implementing measures. Eventually, a definition may result from ongoing negotiation in the World Intellectual Property Organization. In the Nagoya Protocol, the term is used in relation to the knowledge, innovations and practices of indigenous and local communities that result from the close interaction of such communities with their natural environment, and specifically to knowledge that may provide lead information for scientific discoveries on the genetic or biochemical properties of genetic resources. It is characteristic of traditional knowledge that it is not known outside the community holding such knowledge. In the context of ABS this means, that traditional knowledge may easiest be identified if described or referred to in a specific benefit-sharing contract.

Users of genetic resources: A diverse group, including botanical gardens, industry researchers such as pharmaceutical, agriculture and cosmetic industries, collectors and

research institutes. They seek access for a wide range of purposes, from basic research to the development of new products. The main users in the EU genetic resources value chain are described in Box 2 of the main IA study.

OVERVIEW OF TABLES AND BOXES

Boxes

Tables