



Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union

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Abbreviations

ABS	Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization
ABS-CH	Access and Benefit-Sharing Clearing-House (in CBD Clearing-house Mechanism)
Bonn Guidelines	Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (adopted by CBD COP6 in 2002)
Biopatents Directive	Directive 98/44/EC on the legal protection of biotechnological inventions
CAP	Common Agricultural Policy
CBD	Convention on Biological Diversity
CNA	Competent national authority
CoC	Certificate of Compliance
COP	Conference of the Parties
EAFRD	European Agricultural Fund for Rural Development
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FAO	UN Food and Agriculture Organization
FLEGT	Forest Law Enforcement Governance and Trade
GR	Genetic resources
ICNP-1	First meeting of the Open-ended ad hoc Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilization (Montreal, Canada, 5-10 June 2011)
IGC	WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
ILC	Indigenous and local community
IPR	Intellectual property rights
IT-PGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually agreed terms

MS	EU Member State
NGO	Non-governmental organisation
OMC	Open Method of Coordination
PIC	Prior informed consent
PCT	Patent Cooperation Treaty
PLT	Patent Law Treaty
Protocol/NP	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
R&D	Research and Development
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
SME	Small and Medium-sized Enterprise
TEU	Treaty of European Union
TFEU	Treaty on the Functioning of the European Union
Timber Regulation	Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market
TK	Traditional Knowledge
TKaGR	Traditional knowledge associated with genetic resources
UNCLOS	United Nations Convention on the Law of the Sea
UNPFII	United Nations Permanent Forum on Indigenous Issues
WG-ABS	Ad Hoc Open-ended Working Group on Access and Benefit-Sharing
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 INTRODUCTION

1.1 Background to this report

This final report forms part of a study for the European Commission, entitled *Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union*.³ The report provides technical support to inform the Commission's Impact Assessment before it takes the necessary initiatives towards the ratification of the Nagoya Protocol and its implementation by the Union and its Member States.

The primary aim of the study is to help identify the most effective way of implementing the Protocol in the EU by analysing the existing legal tools, any requirements for their reform, available implementation options and the likely effects of different options.

The study involves two main phases of work:

- A comprehensive stock-taking (baseline analysis) of relevant EU policies and existing rules of the *acquis*, together with a study of law and practice in selected Member States and third countries (users and providers); and
- An in-depth legal and economic review to identify, analyse and compare the potential building blocks for effectively implementing the Nagoya Protocol in the EU, taking account of stakeholder consultations.

1.2 Objectives and scope of this report

The objective of this final report is:

- To present the findings from the stock-taking of EU ABS policies and potentially relevant EU legislation and of policies of selected EU Member States and non-EU countries.
- To present the policy options for implementing the Nagoya Protocol in the EU.
- To present the assessment of the options against a range of criteria to provide an evidence base to support the Commission's impact assessment

1.3 Methodology and approach

Chapter 2 gives a short **introduction to the Protocol**, followed by a more detailed examination of the **core obligations arising from the Protocol** in chapter 3.

Chapters 4 to 6 **take stock of existing EU ABS policies**, of **potentially relevant EU legislation** (chapter 4), of **policies of selected EU Member States** (chapter 5) and of **ABS practices in the EU** (chapter 6). Chapter 7 takes stock of **policies of selected non-EU countries**. The EU

³ Service Contract ENV.E.2/2011/ETU/599073.

Member States that have been examined are Belgium, Bulgaria, France, Germany, the Netherlands, Poland, Spain and the United Kingdom. The non-EU CBD Parties whose policies have been analysed are Australia, Brazil, India, the Philippines, Uganda and Switzerland.

Chapter 8 of this report examines the **core and subsidiary obligations under the Protocol** in the specific legal and institutional context of the EU, analysing the **division of competencies between the EU and Member States** for each obligation. This breakdown makes it possible to identify Protocol obligations for which the EU has exclusive or shared competence for implementation, paving the way later in the report for examining options for implementation consistent with the principles of subsidiarity and proportionality.

Chapter 9 presents **different options on how the EU could implement obligations arising out of the Nagoya Protocol**, thereby discussing some of the legal issues involved. The chapter discusses the scope of a future EU ABS regime, the options for the EU to take in its capacity as a provider of GR/TKaGR and the options on EU user compliance measures. Bilateral agreements and supplementary measures are discussed separately. The chapter takes account of opportunities and gaps under the current policy baseline and identifies where additional measures may be necessary to fulfil obligations under the Protocol. Insights from ABS experience gained in individual countries in and outside the EU are used where appropriate to suggest possible models for the EU and its Member States.

Chapter 10 presents the **EU baseline** which provides an **overview of the use and exchange of genetic resources** (falling within the scope of the Nagoya Protocol) **for both the commercial and non-commercial sectors** affected by ABS issues in Europe. This builds on the sectoral studies that are included in a separate Annex (Annex 3) to this report. Sectors involved are academic research, botanic gardens, culture collections, pharmaceutical industry, cosmetics industry, food and beverage industry, seed industry, animal breeding industry, horticulture, biological control and industrial biotechnology.

Chapter 11 presents the **assessment of the options** presented in chapter 9 against a range of selected impact assessment criteria, both for provider access measures and user compliance measures.

This report was prepared through standard research and legal methodology. It comprised a comprehensive **literature review and desk study** covering:

- In-depth analysis of the Protocol's provisions, taking account of the *travaux préparatoires* leading to its adoption in 2010;
- The broader framework of CBD obligations and guidance;
- Relevant outcomes of the First Meeting of the Open-ended Ad Hoc Intergovernmental Committee of the Protocol (ICNP-1);⁴
- International agreements and processes that also cover ABS-related issues and need to be considered within the EU's policy development process;

⁴ Open-ended Ad Hoc Intergovernmental Committee of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ICNP-1) (6-10 June 2011, Montreal, Canada).

- Review of legal and scientific literature on the regulation and monitoring of access and benefit sharing of genetic resources;
- Searches of relevant legal databases;⁵ and
- Consideration of non-legislative measures, including information campaigns, guideline development, codes of conduct and voluntary standards, and possible labelling systems.

The desk study (especially for the country studies) was complemented with **targeted interviews** with national ABS experts and/or focal points from the EU Member States, stakeholders in EU Member States and some ABS officials from some of the selected non-EU countries.

1.4 Structure of the report

The following chapters are:

- Introduction to the Nagoya Protocol and the EU's Role
- Analysis of core obligations under the Nagoya Protocol
- EU Measures relevant to ABS
- EU Member States legislation and policies
- ABS practices in the EU
- Policies of non-EU countries – synthesis of country reports
- Division of competence between the EU and Member States with regard to Protocol obligations
- Identification and analysis of options for implementation
- EU baseline
- Impact assessment

This is followed by three annexes:

Annex 1: Country reports EU Member States
 Annex 2: Country reports non-EU countries
 Annex 3: Sectoral sheets

⁵ For example, the CBD databases on national implementation (<http://www.cbd.int/abs/measures>).

2 INTRODUCTION TO THE NAGOYA PROTOCOL AND THE EU'S ROLE

2.1 The Nagoya Protocol

The Convention on Biological Diversity (CBD) is a comprehensive global legal instrument for the conservation and sustainable use of biodiversity and ecosystems. The CBD has significantly expanded since the treaty entered into force on 29 December 1993. The EU and its 27 Member States, as active Parties, have contributed significantly to implementation, monitoring and evaluation activities through a range of legislative and economic measures and innovations.

The CBD is the only international legal instrument comprehensively addressing biological diversity. Of the CBD's three core objectives – to conserve biological diversity, sustainably use its components and ensure fair and equitable sharing of benefits arising from the utilization of genetic resources – the third has taken the longest to take legal shape. The CBD itself established only general obligations on access to genetic resources and the sharing of the benefits arising from their utilization (ABS). The respective provisions, namely Articles 15 (Access to Genetic Resources) and 8(j) (Traditional Knowledge) are rather broad, which has led to ambiguity over their implementation.⁶

Articles 15(1) and 15(7) of the CBD acknowledge the sovereign rights of provider countries to regulate access to genetic resources under their sovereignty, i.e. on their territory or acquired in line with the CBD. Article 15(2) contains a requirement for provider countries not to impose restrictions that hinder access to genetic resources and thereby restrain conservation and sustainable use of biodiversity. Art 15(4) stipulates that access shall be granted on mutually agreed terms (MAT). Article 15(7) of the CBD sets forth that all parties, including users of genetic resources, shall take legislative, administrative or policy measures, with the aim of sharing benefits arising from the utilization of genetic resources with provider countries. According to Article 8(j), Parties have an obligation to encourage the sharing of benefits from the utilization of traditional knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for conservation and sustainable use of biological diversity (Kamau *et al*, 2010). However, this is subject to national legislation.

17 years after the CBD entered into force, few effective and efficient ABS measures or regimes are in place. Only a limited number of Parties, mostly provider countries, have adopted comprehensive ABS legislation, mostly focusing on access. As a consequence of the lack of clear rules at the international level, the conditions for access in some provider countries have become very restrictive.² Based on the recognition of the importance of genetic resources for achieving food security worldwide and for the sustainable development of agriculture in the context of poverty alleviation and climate change, and on the acknowledgment of the interdependence of all countries with regard to genetic

⁶ Secretariat of the Convention on Biological Diversity (2011) 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

resources for food and agriculture, a first specialised international agreement on ABS, the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA), was developed in harmony with the CBD and concluded in 2001 under the auspices of the FAO (Food and Agriculture Organisation of the United Nations); it entered into force in 2004.

The non-binding Bonn Guidelines⁷, adopted by the sixth CBD Conference of the Parties (COP6) in 2002, were intended to guide both users and providers of genetic resources in the implementation of the access and benefit-sharing provisions of the CBD, for instance by offering guidance regarding the access procedures in provider countries. They also provide an indicative list of clauses to be included in mutually agreed terms, and possible monetary and non-monetary benefits. Although comprehensive, these voluntary guidelines were not considered to be very effective with regard to triggering concrete measures by providers or users.

The World Summit on Sustainable Development (Johannesburg, September 2002) called for the negotiation of an international regime, within the framework of the CBD, to promote and safeguard the fair and equitable sharing of benefits arising from the utilization of genetic resources. In 2004, the seventh session of the CBD Conference of the Parties responded by mandating an 'Open-ended Ad Hoc Working Group on ABS' (OEWG ABS) to elaborate and negotiate, in consultation with the Working Group on Article 8(j), an international regime on access to genetic resources and benefit-sharing. The objective of the new regime was to effectively implement Articles 15 and 8(j) of the CBD (Decision VII/19).

After six years of negotiations, a legally binding instrument dedicated to ABS was agreed in Nagoya, Japan on 29 October 2010. On that date, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention of Biological Diversity (hereafter referred to as the Protocol or NP) was formally adopted by the tenth session of the Conference of the Parties to the CBD. Agreement on the ABS Protocol was a *sine qua non* for reaching an overall agreement at Nagoya on the 20 targets under the CBD Strategic Plan 2011-20. The European Union and its Member States had been very active in the negotiations and are regarded as having been instrumental in bringing about consensus among the 193 Parties to the CBD.

The Protocol was opened for signature by CBD Parties between 2 February 2011 and 1 February 2012, and during that time has been signed by 92 States. The CBD Strategic Plan 2011-2020 (Aichi Target 16), foresees the Protocol to be in force and operational by 2015, but many signatories are aiming for an earlier entry into force.

The international community is now shifting its attention from negotiating a legally binding instrument to ensuring its entry into force and implementation. The eleventh session of the Conference of the Parties to the CBD (COP11) will take place in Hyderabad, India, from 8 to 19 October 2012. Some signatories of the Protocol hope that the Protocol's first meeting of

⁷ The guidelines are part of Decision VI/24, <http://www.cbd.int/decision/cop/?id=7198>

⁸ <http://www.cbd.int/decision/cop/?id=12268>

the Parties (COP-MOP1) could be convened at the same time. To achieve this, the Protocol would have to enter into force no later than 8 October 2012, with the 50th instrument of ratification deposited no later than 10 July 2012.

2.2 The Nagoya Protocol and the EU

The Council of the EU authorised the Commission in 2009 and again in 2010 to participate in the Nagoya Protocol negotiations on behalf of the Union with respect to matters falling within Union competence (CEU 2011). At the Council's insistence, Art 175(1) EC (now Art 192(2) TFEU), the environmental competence norm, in conjunction with Art 300(1) EC (now Art 218(1) TFEU) (on external competence for the conclusion of international agreements) provided the legal basis for the negotiations conducted by the Commission (CEU, 2009).

The negotiating directives issued by the Council recognised that the Protocol's operational provisions would affect several areas under EU competence. These include environment, public health, common commercial policy, customs cooperation, free movement of persons, agriculture, approximation of laws, development cooperation and research and technological development. Nearly all of these are areas of shared competence between the Union and the Member States, as defined in the Lisbon Treaty. The only area explicitly excluded from the Commission's negotiating mandate was traditional knowledge associated with genetic resources held by indigenous and local communities, which was directly handled by the Member State holding the Presidency of the Council (CEU, 2009).

Following the Nagoya conference, the Council of the European Union welcomed the adoption of the Protocol and invited the Commission to sign it at the earliest opportunity.⁹ Furthermore, the Council encouraged the Commission to start preparations for timely ratification and implementation.

According to Art 34(2) CBD, the EU, as a regional economic integration organization that is a Contracting Party to the CBD, is also entitled to become a Party to its Protocols. Art 34(2) CBD further provides that where a regional economic integration organization becomes a Contracting Party together with one or more of its Member States, "the organization and its member States shall decide on their respective responsibilities for the performance of their obligations" under the Protocol. In its instrument of approval, according to Art 34(3) CBD, the EU shall declare the extent of its competence with respect to the matters governed by the Protocol. This declaration of competence serves to inform the other Parties of the division competences between the EU and the Member States and to make them fully aware of who is responsible for the performance of the various obligations and exercise of the rights arising from the Protocol. Since the legal position may evolve depending on developments in the internal law of the EU, the same provision of the CBD puts an obligation on the Union to "inform the Depositary of any relevant modification in the extent of [its] competence" that may occur after it has become a Party.

⁹ Council conclusions of 20 December 2010.

As a matter of international law, the division of competences between the Union and its Member States in implementing the Protocol is, hence, an internal question for the EU. If the EU were to ratify the Protocol without any of its Member States being a Party it would be bound by all the obligations arising from the Protocol. However, since the Council, in its above-mentioned decisions, recognised that the Protocol is a mixed agreement from the perspective of EU law, the Union cannot consent to be bound by the Protocol before at least one or more of the Member States have also expressed their consent to be bound, either prior to the Union or at the same time.

Thus, the EU and the Member States need to agree on the internal division of competences between them before ratifying the Protocol, in line with the competence provisions of EU primary law (discussed in section 9 below). This agreement on competences shall be formalised in the declaration of competence that is to be included in the Union's instrument of approval. Such declaration of competence is normally annexed to the Council Decision authorising approval that is adopted pursuant to Art 218(6) TFEU. The Commission's proposal for such a decision shall therefore include a draft declaration of competence. Since the entry into force of the Lisbon Treaty, the European Parliament's consent is required for the Council to be able to adopt decisions concluding international agreements covering fields to which the ordinary legislative procedure applies, as is the case for environmental agreements referred to in Art 191(4) TFEU.

3 ANALYSIS OF CORE OBLIGATIONS UNDER THE NAGOYA PROTOCOL

This section provides a first overview of the core obligations set forth in the Nagoya Protocol, relating to objective and scope (Art 1,3) access (Art 6), benefit-sharing (Art 5), compliance (Art 15-18) and the building of institutions (Art 13-14). The Protocol contains additional, less central, and frequently softer obligations which will be addressed in the section on options from implementation. Moreover, this overview focuses on giving a broad overview, while legal details are, where needed, discussed in subsequent sections.

3.1 Objective and scope of the Protocol

The objective of the Protocol as established in Article 1 is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by access to these resources, technology transfer and funding. This, in turn, is to contribute to the conservation of biological diversity and the sustainable use of its components. Thus, Art 1 re-phrases and makes more concrete the CBD's objectives.

The scope of the regime established by the Protocol is set out in Art 3 NP. Accordingly, the regime applies to genetic resources within the scope of Art 15 CBD, i.e. such resources that are within the national sovereignty of a country or that have been acquired in line with the CBD. The details of the temporal and substantive scope of the Protocol are rather complex, and are discussed further below. However, it is clear which activities the Protocol covers, namely:

- Access to such resources;
- Sharing of benefits arising from the utilization of such resources;
- Access to traditional knowledge associated with such resources;
- Sharing of benefits arising from the utilization of such knowledge.

Parties have specific obligations with respect to each of these matters. In addition, they have obligations with regard to facilitating and ensuring users' compliance with related legislation of provider countries', as well as monitoring and access to justice.

3.2 Obligations with respect to benefit sharing for genetic resources

The core obligation on benefit-sharing is set out in Art 5(1) and 5(3) NP. It requires Parties to take appropriate legislative, administrative or policy measures with the aim of ensuring that benefits arising from the utilization of genetic resources (including subsequent applications and commercialization) are shared in a fair and equitable way, upon mutually agreed terms, with the Party providing such resources. This is either the country of origin of such resources or another Party that has acquired the genetic resources in accordance with the relevant provisions of the CBD. It should be noted that unlike Art 5(2) NP and later articles, such as Art 15, 16 of the Protocol, Art 5(3) NP does not explicitly condition this obligation on the existence of national legislation in provider countries. However, Art 5(3) serves the

implementation of Art 5(1) which refers back to Art 15(7) CBD. It sets forth that benefit-sharing shall be on mutually agreed terms. The establishment of MAT, in turn, pre-supposes the involvement of both providers and users of genetic resources. Nonetheless, the general benefit-sharing obligation in Art 5(1) does not explicitly presuppose that provider countries adopt ABS legislation. It may also be interpreted to suggest that Parties must take some measures to provide for benefit-sharing for the utilisation of genetic resources that were acquired since entry into force of the CBD outside the more operational framework of access and user-compliance measures that must be put in place under Protocol Articles 6, 7 and 15, 16 respectively.

A subsidiary obligation is laid down in Art 5(2) NP, which provides that, where genetic resources are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these resources, Parties shall take appropriate legislative, administrative or policy measures with the aim of ensuring that benefits arising from the utilization of such resources are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms. This obligation is explicitly conditioned on the existence of established rights over genetic resources recognised by the domestic legislation of the provider country concerned. However, some legal observers have noted that the rights of ILCs may also be established through other means than national law (e.g. international law) (IUCN, 2012). This raises the question on what would apply in case a Party does not respect its international obligations vis-à-vis ILCs under its jurisdiction. Article 5(2) does not address this issue. The general conflict clause in Article 4(1) of the Protocol, however, suggests that Parties to the Protocol may not use the restrictive wording of Article 5(2) to defend lack of respect for indigenous rights over genetic resources in their domestic legal system, since the Nagoya Protocol does not affect existing international obligations of Parties on indigenous and human rights.

3.3 Obligations with respect to access to genetic resources

The basic principle governing access is set out in Art 6(1) NP which refers to the sovereign rights of states over their natural resources; accordingly, access to genetic resources for their utilization shall be subject to the prior informed consent (PIC) of the Party providing such resources unless otherwise determined by that Party (in its internal legislation). The Party providing the resource is either the country of origin of such resources or another Party that has acquired the genetic resources in accordance with the relevant provisions of the CBD. Accordingly, access to genetic resources shall be subject to domestic ABS legislation or regulatory requirements in provider countries. The provider countries have the right to determine more concretely what obligations prospective users have when they wish to access genetic resources in their countries, and they may also opt for not requiring prior informed consent at all.

Art 6(2) NP provides that where indigenous and local communities (ILCs) have the established right to grant access to GRs, appropriate measures shall also be taken with the aim of ensuring that the prior informed consent or approval and involvement of those communities is obtained for access to such resources. If PIC is required from ILCs thus

depends on the prior existence of established rights, which, however, do not necessarily have to be established by the provider state, but could also result, e.g. from international law (IUCN 2012, 100). However, again, the involvement of ILCs is to be determined in accordance with domestic laws of provider countries, giving them considerable freedom as to how to involve ILCs.

The obligations of Parties that decide to require prior informed consent are set out more specifically in Art 6(3) NP. Such Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to establish fair and non-arbitrary rules and procedures on accessing genetic resources, providing for legal certainty, clarity and transparency. These rules and procedures shall provide for the issuance at the time of access of a permit or its equivalent as evidence of the granting of PIC and of the establishment of mutually agreed terms. This shall be in the form of a clear and transparent written decision by a competent national authority, delivered in a cost-effective manner and within a reasonable period of time. Domestic ABS legislation shall also establish clear rules and procedures for requiring and establishing mutually agreed terms. MAT shall be in writing and may include, inter alia, provisions on dispute settlement, benefit-sharing, including in relation to intellectual property rights, subsequent third-party use, if any, of the genetic resources, and terms on changes of intent, where applicable. Finally, where applicable, a provider country shall also set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources.

Altogether, Art 6 confirms the right of any Party to decide, in its capacity as a potential provider of genetic resources, whether or not it wishes to require prior informed consent for access to these resources. If it decides to require PIC, it has to lay down the required rules and procedures in its internal legislation, including minimum requirements for mutually agreed terms and observing the requirements that the Protocol sets forth concerning legal clarity, transparency and fairness. Where it recognises, in its internal law, that certain ILCs have rights over genetic resources, domestic ABS legislation also has to specify how ABS requirements are to be complied with for such genetic resources.

3.4 Obligations with respect to ABS for traditional knowledge

When reading the Nagoya Protocol's provision relating to traditional knowledge it should be noted first that while the Protocol uses the term traditional knowledge, it does – like other international legal instruments – not define it (Buck and Hamilton, 2011). It is thus not clear what precisely counts as traditional knowledge (see for a more in-depth discussion below). The same is true for the term indigenous and local communities. Nonetheless, the fact that TK needs to be “held” by ILCs would seem to imply that public TK, i.e. knowledge which is widely spread, would not trigger any ABS obligations (Joseph, 2010).

The core obligation with regard to access to traditional knowledge associated to genetic resources (TKaGR) is contained in Art 7 NP. It obliges each Party to take measures, as appropriate, with the aim of ensuring that TKaGR held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these communities, and that mutually agreed terms have been established. Again, however, this obligation is in “accordance with domestic law”. Logically, this can only refer to the

domestic law of countries where an ILC is located. Again, it is possible to read this in the wider sense that provider countries have the freedom to define in their national orders what traditional knowledge they legally recognise, and only in respect of this TKaGR access-related measures must be taken, or to read it more narrowly, as saying that implementing measures need to be tailored to the domestic legal order of Parties where ILCs are located.

The core obligation with regard to benefit-sharing for TKaGR is set out in Art 5(5) NP. It requires Parties to take legislative, administrative or policy measures in order that the benefits arising from the utilization of traditional knowledge associated genetic resources are shared in a fair and equitable way, upon mutually agreed terms, with indigenous and local communities holding such knowledge. This obligation is not conditioned on the existence of established rights over TKaGR. It also does not seem to be contingent on the decision of a Party to require PIC and MAT for access to its genetic resources under Article 6 (1) and (3), or a specific role of ILCs in access procedures. It is thus a strong obligation towards benefit-sharing for the use of TKaGR (IUCN, 2010).

Art 12(1) NP further provides that, in implementing their obligations under the Protocol, and in accordance with their domestic law, Parties shall take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources. Parties shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, with the effective participation of the indigenous and local communities concerned. Furthermore, in their implementation of the Protocol, Parties shall, as far as possible, refrain from restricting the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities. Finally, Parties have a very softly worded obligation to provide support to indigenous and local communities for developing community protocols in relation to access to traditional knowledge associated with genetic resources and related ABS, minimum requirements for mutually agreed terms and model contractual clauses for benefit-sharing arising from the utilization of TKaGR. All obligations under Article 12, although formally for all Parties to the Protocol, can most usefully implemented by Parties with ILCs under their jurisdiction. However, user countries such as the EU could for example support ILCs in developing the instruments mentioned in Art 12(3).

3.5 Obligations with respect to user compliance¹⁰, monitoring and enforcement

The core obligations on supporting user compliance with provider countries' ABS legislation are laid down in Articles 15 and 16 NP. According to Art 15(1), 16(1) each Party has the obligation to take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources (respectively traditional knowledge associated with genetic resources) utilized within its jurisdiction have been accessed in

¹⁰ The term "user compliance" is used here to indicate that these measures relate to the behavior of individual users of genetic resources or traditional knowledge associated with such resources. In addition to rules on user compliance, the Nagoya Protocol, as most international agreements, also contains rules on the compliance of state Parties with its rules.

accordance with prior informed consent (including involvement of indigenous and local communities with respect to traditional knowledge) and that mutually agreed terms have been established, as required by the domestic ABS legislation or regulatory requirements of the other Party concerned. Parties also have a duty to take appropriate, effective and proportionate measures to address situations of non-compliance with their domestic measures adopted on the basis of Art 15(1), 16(1), and to cooperate as far as possible in cases of alleged violations of domestic ABS legislation or regulatory requirements. These provisions give Parties a substantial degree of flexibility regarding the type of measures they wish to take (Buck and Hamilton, 2011).

As supportive measures for establishing user compliance, Article 17 NP sets out further obligations of Parties on measures to monitor and to enhance transparency about the utilisation of genetic resources and also defines an 'internationally recognised certificate of compliance'. The main obligation on monitoring measures is found in Article 17(1). Importantly, this provision does not cover monitoring the utilization of TKaGR. It includes three concrete actions that parties must, but are not limited to taking:

- Designating one or more checkpoints (Art 17(1)(a)), and
- Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements (Art 17(1)(b)), and
- Encouraging the use of cost-effective communication tools and systems (Art 17(1)(c)).

Of these three concrete actions, the obligation on the designation of checkpoints is spelt out in much greater detail than the others, reflecting the centrality of the issue of checkpoints in the negotiations (see on this point Buck and Hamilton, 2011). Nonetheless, the rules on checkpoints in several instances contain the term “as appropriate”, giving Parties a certain leeway in the implementation of the related rules.

Art 17(1)(a) specifies the following features of checkpoints:

- They are to collect or receive relevant information on the source of genetic resources, prior informed consent, mutually agreed terms and or/the utilisation of genetic resources (Art 17(1)(a)(i)). As a corollary parties shall oblige users of genetic resources to provide this information, depending on the characteristics of the relevant checkpoints (Art 17(1)(a)(ii)).
- Non-compliance of users with such information obligations would need to be sanctioned through appropriate, effective and proportionate measures (Art 17(1)(a)(ii)).
- The information gathered by checkpoints must be provided to either relevant national authorities, to the Party that has granted PIC, or to the future ABS Clearing-House. Confidential information is to be protected in this context (Art 17(1)(a)(iii)).
- Finally, Art 17(1)(a)(iv) establishes that checkpoints must be effective, and that designated checkpoints should be relevant to the utilization of genetic resources or the collection of relevant information, inter alia, at any stage of R&D, innovation, pre-commercialization or commercialization. It should be noted that the

establishment of relevant checkpoints is a soft obligation (“should”), leaving parties discretion to identify the most suitable intervention points that are effective under their specific circumstances.(Kamau *et al*, 2010).

Finally, Art 17(2) to (4) define an internationally recognised certificates of compliance. Essentially, these certificates are a tool for facilitating the monitoring of the utilisation of genetic resources in user countries and establishing legal evidence of acquisition of genetic resources covered in accordance with the access requirements of the relevant provider country. According to Art 17(2) access permits or equivalent acts issued pursuant to Art 6(3)(e) NP and made available to the future ABS Clearing-House, constitute such certificates. These certificates, according to Art 17(3), are evidence that provider countries’ ABS rules have been observed. The minimum information to be contained in such certificates is specified in Art 17(4).

While Articles 15 and 16 NP set out Party obligations in relation to the utilisation of genetic resources or traditional knowledge associated with genetic resources within their jurisdiction and Art 17 contains provision on monitoring, Article 18 establishes further obligations in support of effective enforcement of benefit-sharing arrangements set out in Mutually Agreed Terms. The latter are generally understood to constitute private law contracts.

Art 18 contains provisions on dispute resolution and access to justice as means of ensuring compliance with mutually agreed terms. The central obligation of Parties, as laid down in Art 18(2) NP, is to ensure that an opportunity to seek recourse is available under their legal systems in the event of disputes arising from mutually agreed terms. Recourse shall be consistent with applicable jurisdictional requirements. Art 18(1) contains a corresponding obligation on Parties to encourage providers and users of genetic resources and traditional knowledge to include provisions on dispute resolution in their mutually agreed terms, covering issues such as jurisdiction and applicable law, as well as options for recourse to alternative modes of dispute resolution such as mediation or arbitration. Furthermore, according to Art 18(3) Parties shall take effective measures, as appropriate, regarding access to justice and mutual recognition and enforcement of foreign judgments and arbitral awards.

The wording of Art 18 is ambiguous as to the extent to which it requires Parties to take specific measures going beyond general legislative provisions allowing access to justice for the enforcement of international contracts where their courts possess jurisdiction to entertain such claims in accordance with normal jurisdictional requirements. A minimalist reading of Art 18 would imply that the responsibility to ensure that issues of jurisdiction and applicable law are properly addressed falls on users and providers when they establish mutually agreed terms, which are mostly international contracts under private law (IUCN 2012, 183). Whether recourse is effectively available will then largely depend on the contractual provisions in the mutually agreed terms, as interpreted by the court of the Party where a claim is brought in accordance with that Party’s general legislation governing the jurisdiction of its courts.

A more extensive interpretation of Art 18(3) would imply measures to provide wider access to justice, potentially extending to stakeholders who are not formally parties to a particular MAT agreement, and potentially including measures to ensure that court proceedings are not prohibitively expensive. The fact that access to justice is mentioned in Art 18 (3)(a) specifically and additionally to the obligations to ensure that an opportunity to seek recourse is available contained in Art 18(2) supports such a wider reading.

3.6 Further institutional provisions

Besides the provisions on checkpoints in Art 17, the Nagoya Protocol also contains provisions on other institutions, namely national focal points and competent national authorities (CNAs) in Art 13 and the ABS Clearing-House in Art 14.

According to Art 13(1), each Party shall designate a national focal point on ABS. It must provide information on access to genetic resources and traditional knowledge, competent authorities, ILCs and relevant stakeholders. A further task of the national focal point is to liaise with the CBD Secretariat (Art 13(1)). CNAs are, in turn, responsible for granting PIC or issuing written evidence that access requirements have been met (Art 13(2)). This implies that it is not necessarily the CNA itself that has to grant PIC. One single entity can fulfil the functions of both the focal point and the competent authority (Art 13(3)).

While focal points and competent authorities are entities to be established at the national level, the ABS Clearing-House (CH) laid out in Art 14 will be established at the international level, as part of the already existing Clearing House Mechanism of the CBD. Its function is to make available information, which in turn the Parties are obliged to provide it with (Art 14(2), 14(3)). The minimum information that Parties have to provide to the ABS CH is defined Art 14(2) and relates to ABS measures put in place, national focal points/competent national authorities and permits or their equivalents serving as evidence of the compliance with provider countries' ABS legislation, i.e. internationally recognised certificates of compliance.

4 EU MEASURES RELEVANT TO ABS

This chapter is intended to provide a brief overview of measures in the field of ABS taken by the EU or with EU support prior to the adoption of the Nagoya Protocol, pursuant to the relevant CBD provisions and the Bonn Guidelines (4.1) and an overview of EU legislative measures that could be affected by the implementation of the Nagoya Protocol (4.2).

4.1 EU ABS measures

4.1.1 *Intellectual property rights*

The EU has not introduced comprehensive legislation concerning ABS. Directive 98/44/EC on the legal protection of biotechnological inventions (the biopatents Directive) is the only EU legislative instrument that specifically takes into consideration the CBD's provisions on ABS, encouraging recognition of the geographical origin of biological material used in biotechnological inventions on patent applications. The Directive was introduced to improve patent protection for biotechnological inventions in support of the EU's biotechnology industry, by harmonising and clarifying existing national legislation.¹¹

Recital 27 of the Directive states that *'if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known ...'*. This implies that the Directive encourages patent applications to include information on the geographical origin of biological material, but the relevant provisions are non-binding and voluntary in nature.

Alongside Recital 27, Recital 55 requires Member States to give weight to CBD Article 8(j) when introducing laws, regulations and administrative procedures to implement the Directive. Recital 56 takes note of COP Decision III/17, calling for further work on the links between IPRs, the TRIPs Agreement and relevant CBD provisions relating to technology transfer, the conservation and sustainable use of biodiversity and the equitable sharing of benefits arising out of the use of genetic resources. As elements of the Directive's preamble, Recitals 27 and 55 are non-binding, intended only to specify the reasons why the operative provisions of the Directive were adopted and assist in the interpretation of the Directive's binding articles. Non-compliance does not affect the processing of patent applications or the validity of rights arising from granted patents (EC, 2002; Straus, 2001).

In addition, the Directive states that where an invention involves the use of or concerns biological material that is not available to the public and that cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description must be considered inadequate for the purpose of

¹¹ European Community, Second report of the European Community to the Convention on Biological Diversity – Thematic report on access and benefit-sharing, October 2002, www.cbd.int/doc/world/eur/eur-nr-abs-en.doc.

patent law, unless the application contains such relevant information as is available to the applicant on the characteristics of the biological material deposited (Article 13(1)(b)). The disclosure of the geographical origin serves only the purpose of enabling others to reproduce an invention, and it would be applied in only a small number of cases (Commission of the European Communities, 2003; Richerzhagen, 2010).

4.1.2 Promotion of cooperation and standardized contracts

The EU has promoted guidelines for bilateral cooperation on a voluntary basis, especially where only a few countries have or need access to the genetic resources concerned.

In this respect the EU has given support to the development of institutional policies and codes of conduct on ABS, including the MOSAICC initiative for microbial collections launched in 1997 by the Belgian Coordinated Collections of Micro-organisms (BCCM). MOSAICC is a voluntary code of conduct to facilitate access to microbial genetic resources in line with the CBD and other applicable national and international law, and to ensure that the transfer of material takes place under appropriate agreements between partners and is monitored to secure benefit-sharing (European Community, 2002).

Under the 6th Research Framework Program the EU also funded the MOSAICS project which was launched in 2004 by a consortium of 15 microbiological resources providers and users.¹² MOSAICS stands for 'Microorganisms Sustainable use and Access management Integrated Conveyance System'. The project aims to give an answer to questions from culture collections on how to implement the various international and national rules regulating the flows and uses of biological resources. It aims in particular to develop an integrated conveyance system that has reliable tools to evaluate the economic value of microbiological resources, that disposes of validated model documents with standard provisions to enable tracking via an uncomplicated procedure, widely applied by microbiologists and that combines valuation and tracking in one system for trading of microbiological resources, with balanced benefit sharing for those that are entitled to be rewarded for the services and products they provide to society.

4.1.3 Promotion of ABS and CBD Article 8(j)

The EU Biodiversity Action Plan contains measures in relation to ABS (Article 15 CBD): e.g. 'Action A8.1.3, Promote full implementation of the CBD Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits (ABS) arising out of their Utilisation, and other agreements relating to ABS such as the FAO Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA) – and continue to contribute to negotiation of an international regime on ABS'.

¹² <http://bccm.belspo.be/projects/mosaics/description.php>

The European Commission and several Member States have made specific efforts to raise awareness and promote implementation of the Bonn Guidelines. The Commission dedicated €20 million from the European Development Fund to a project called 'Biodiversity and Protected Areas Management in African, Caribbean and Pacific (ACP) Countries' (BIOPAMA). The project comprises a component for ABS in the ACP countries which aims to contribute to the 'Access and Benefit Sharing Capacity Development Initiative'. This initiative aims to further build the ABS capacities of stakeholders in each of the three ACP regions and is implemented through a trust fund managed by the German Cooperation Agency (GTZ) (European Commission, 2010).

In 2004, the EU approved the IT-PGRFA which is a specialised ABS regime for plant genetic resources for food and agriculture. The EU subsequently contributed to the successful adoption of the standard Material Transfer Agreement (sMTA) for the exchange of such genetic resources under the IT-PGRFA in June 2006.

The EU has also actively contributed to the negotiations on the Protocol on ABS. The Commission and several Member States provided the majority of funds to organise and negotiate expert and ABS working group meetings of the CBD. In line with the EU objectives outlined in the Conclusions of the EU Environment Council adopted in June 2007 and March 2008, the EU sent a series of notifications to the CBD Secretariat and participated constructively in the CBD ABS negotiations (European Commission, 2010).

The EU Biodiversity Action Plan also contains measures in relation to traditional knowledge, innovations and practices (Art 8(j)): e.g. 'Action A8.1.9: Apply principle of prior informed consent when commercially using traditional knowledge relating to biodiversity and encourage the equitable sharing of benefits arising from the use of such knowledge'.

The European Commission has raised awareness of Article 8(j) of the CBD and relevant parts of the Bonn Guidelines throughout its services and in EC delegations in third countries. A special Interservice Group on Indigenous Issues regularly reflects on indigenous issues in the Commission's work. Since 2005, the Commission's DG External Relations has convened regular trainings for staff of Commission delegations in third countries, including a module on the CBD and Article 8(j). Traditional knowledge is recognised as part of biodiversity-related research. The European Commission and the Member States have provided financial support to enable representatives of indigenous groups to participate as observers in CBD meetings, including in international ABS negotiations. In the negotiations on the Protocol, the EU defended the view that the prior informed consent of indigenous and local communities must be obtained whenever traditional knowledge associated with genetic resources is accessed.

The European Commission and the Member States have also pushed for advancing work on the protection of traditional knowledge in the World Intellectual Property Organisation (WIPO) and for recognition of the UN Declaration on the Rights of Indigenous People adopted on 13 September 2007 in relevant international forums. More specifically, the Commission and Member States supported the adoption by the WIPO General Assembly in September 2009 of a mandate to undertake text-based negotiations in WIPO on a legal

instrument (or instruments) to effectively protect genetic resources, traditional knowledge and traditional cultural expressions (European Commission, 2010).

4.2 Relevant EU legislation

The EU has not introduced comprehensive legislation concerning ABS, even though it has, as shown above, undertaken some ABS-related activities. However, a large number of legislative instruments might potentially be affected by or relevant for the implementation of the Protocol. For instance a legislative instrument is potentially relevant if it provides a procedure through which applicants are required to provide information to a national authority to get (for instance) permission to place a particular product on the market in whose production genetic resources may have been used. Such a procedure could be used in the future to impose an obligation upon the users of genetic resources to disclose the country of origin of the resources utilized for the production of the product in question.

The legislation listed and discussed in the following section relates to, inter alia:

- Intellectual property rights, especially patents, plant variety rights and geographical indications of origin;
- The placing on the market of various products, including biotechnology, food stuffs, pharmaceuticals and cosmetics, plant reproductive material;
- Funding for different purposes, including research, development cooperation, the environment and agriculture;
- Legislation concerning different types of inspections, conformity assessments and accreditation.

It should be noted that the following identification and analysis of relevant EU legislation is conducted in abstract, in order to gain an overview of the scope of Union rules and competence on activities that are required or encouraged under the Protocol or might be affected by its implementation. It does not prejudice the discussion of concrete options below in Section 10.

4.2.1 Intellectual property rights

It should be noted that one the relevant pieces of legislation, the biopatents Directive, was already discussed above.

Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights¹³

This Regulation might be relevant to the implementation of the Protocol in several respects:

¹³As amended by Council Regulation (EC) No 2506/95 of 25 October 1995, Council Regulation (EC) No 07/2003 of 14 April 2003, Council Regulation (EC) No 1650/2003 of 18 June 2003, Council Regulation (EC) No 873/2004 of 29 April 2004 and Council Regulation (EC) No 15/2008 of 20 December 2007.

First, applicants for a community plant variety right are required to state the geographic origin of the variety (Article 50), but not on the origin of genetic resources used as parents in the breeding and crossing. This is part of the information that the Protocol requires checkpoints to collect or receive. Moreover, applicants for a community plant variety right also have to indicate “the name of the breeder and an assurance that, to the best of the applicants knowledge, no further persons have been involved in the breeding, or discovery and development, of the variety; if the applicant is not the breeder, or not the only breeder, he shall provide the relevant documentary evidence as to how the entitlement to the Community plant variety right came into his possession”. This piece of information could also help in monitoring and in implementing user compliance measures, as the disclosure of an actual contribution of any ILCs to the breeding of a certain variety might be expected under this requirement. The fact that some of the information to be collected by Parties according to the NP is being gathered by the Community Plant Variety Office already makes it a possibility to entrust this Office with a checkpoint function.

Second, there are some links between the Regulation and Art 8(c) of the Nagoya Protocol which sets forth that in the development of ABS legislation parties should consider the importance of genetic resources for food and agriculture and their special role for food and agriculture and food security. Under the Regulation, while farmers retain the right to use the product of the harvest of the protected variety on their own holding which they have obtained by planting, on their own holding, propagating material of a variety (Article 14(1)), they must, in the cases of certain species, pay an equitable remuneration to the holder of the right on the new protected varieties when doing so (Article 14(3)). Small farmers are exempt from paying remuneration (Article 14(3)). There is no such obligation for non-protected varieties where farmers can freely use their harvest of non-protected varieties for re-planting. This compares to the situation before where farmers could freely use their harvest for re-planting or exchange with other farmers.

With regard to using protected varieties for research purposes, the Regulation contains in Art 15 a broad exemption for breeders; plant variety rights do not extend to uses of protected varieties for breeding and research purposes. This clause could be read as being supportive of the objectives contained in Art 8(c) of the Protocol.

Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs

The Regulation enables groups and natural or legal persons to register designations of origin and geographical indications for agricultural products and foodstuffs. Both terms describe the region, specific place or, in exceptional cases, a country where an agricultural product or foodstuff originates.

Designation of origin covers agricultural products and foodstuff which originate in that region, specific place or country and which are produced, processed and prepared in the defined geographical area. Geographical indications also cover agricultural products and foodstuff which originate in that region, specific place or country. However, agricultural products and foodstuff do not need to be produced and processed and prepared in the

defined geographical area. It is sufficient if at least one of these stages take place in the defined geographical area. Designations of origin cover agricultural products and foodstuff the quality or characteristics of which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors. Geographical indications, however, cover agricultural products and foodstuff which possess a specific quality, reputation or other characteristics attributable to that geographical origin.

A third country may apply for the registration of a designation in its territory and the European Commission has the authority to negotiate agreements with third countries for the reciprocal protection of designations.

To qualify for protection in the Member States, geographical indications and designations of origin should be registered at Community level. This registration requirement at EU level might be useful for monitoring the utilization of genetic resources and traditional knowledge associated with them. The competent authorities could act as checkpoints.

Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialties guaranteed

The Regulation enables associations of producers or processors working with the same agricultural product or foodstuff to register an agricultural product or foodstuff produced using traditional raw materials, or characterised by traditional composition or a mode of production and/or processing reflecting a traditional type of production and/or processing as 'traditional speciality guaranteed'. As with geographical indications, a country outside the EU may, at the request of its producers, apply for a Community 'traditional speciality guaranteed'. This Regulation can be considered as an instrument aiming to protect a specific type of traditional knowledge within the EU.

Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases

The Directive makes no reference to the CBD, though it may help to secure compliance with requirements for prior informed consent and mutually agreed terms for access.¹⁴ The Directive extends copyright protection¹⁵ to the content of databases, and potentially enables the protection of information derived from the collection and use of genetic resources and the associated traditional knowledge, innovations and practices. Databases are defined as collections of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means. To qualify for protection, the database must be the author's own intellectual creation, whether

¹⁴European Community, Second report of the European Community to the Convention on Biological Diversity – Thematic report on access and benefit-sharing, October 2002, www.cbd.int/doc/world/eur/eur-nr-abs-en.doc.

¹⁵ The Directive grants the author the right to authorise, amongst others: reproduction; translation, adaptation, arrangement and any other alteration; distribution, communication, display or performance to the public; as well as first sale in the Community (Article 5).

by selection or arrangement of contents. The Directive also extends *sui generis* protection in respect of databases involving a substantial investment in obtaining, verifying or presenting contents (finance, time, effort or energy).¹⁶

4.2.2 Approval and notification procedures relating to marketing

Placing on the market of biotechnology and novel food, other GMO-related legislation

Regulation (EC) No 1829/2003 of 22 September 2003 on genetically modified food and feed

The Regulation covers GMOs for food and feed use, as well as food and feed containing, consisting, or produced from GMOs. The Regulation lays down EU procedures for the authorization and supervision and for the labelling of genetically modified food and feed and establishes also an EU register of genetically modified food and feed authorized by this Regulation available to the public. The Regulation is supplemented by Regulation 1830/2003/EC which ensures traceability and labelling of GMOs placed on the market.

According to Regulation 1829/2003/EC, GM feed and food can be placed on the market only if they have been positively assessed by the European Food Safety Authority. The authorisation is granted for 10 years with the possibility of renewal.

As to genetically modified food for instance, Article 4 of the Regulation establishes that a genetically modified product cannot be introduced in the market for food use unless it is covered by an authorization in accordance with the Regulation. To obtain the required authorization the genetically modified food is to meet the following requirements: not having an adverse effect on human health, animal health or the environment; not misleading the consumer; not differing from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

The Regulation is thus relevant to monitoring and user compliance measures in the context of the NP as it allows insights into which genetic resources are used in the EU and allows interventions at the point of market approval.

Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms

The Directive regulates the release of GMOs into the environment in the EU, covering experimental releases as well as placing on the market.

¹⁶ This grants the holder the right to prevent extraction and re-utilisation of the whole or a substantial part of the contents of a protected database.

The Directive establishes two systems of notification: one for deliberate release for any purpose other than 'placing on the market' (part B) and the other for 'placing on the market' of genetically modified organisms (part C).

Part B of the Directive stipulates that for releasing a GMO a consent of the respective Member State competent authority is needed. In order to get such consent, a 'notification' to the relevant competent authority is needed, which must include a technical dossier supplying information necessary for an environmental risk assessment (specified in Annex III). Information to be supplied is for instance general information relating to the GMO; specifications for information on the conditions of release and the potential receiving environment; information on the interactions between GMOs and the environment; and, information on monitoring, control, waste treatment and emergency response plans.

Also under Part C of the Directive, a consent is needed before the product can be placed on the market. It is stipulated that the manufacturer or importer to the Community is required to submit a notification to the competent authority of the Member State where the product is to be placed on the market for the first time. The notification must supply the necessary information for 'an environmental risk assessment' (Annexes II and III); details on use and handling conditions; labelling and monitoring; packaging proposals which meet the requirements of Annexes IV, VI and VII and a summary of all of the above 'dossier'. The consent procedure is, however, more complex in comparison with the procedure under part B.

Like Regulation 1829/2003, the Directive is thus relevant to monitoring and user compliance measures in the context of the NP as it allows insights into which genetic resources are used in the EU and allows interventions at the point of market approval.

Regulation (EC) No 1946/2003 on the transboundary movements of genetically modified organisms

This Regulation aims to implement the provisions of the Cartagena Protocol on preventing biotechnological risks. The aim of the Protocol is to ensure an adequate level of protection for the transfer, handling and use of genetically modified organisms (GMOs) that may have adverse effects on the environment and human health, and specifically focusing on transboundary movements (the movement of GMOs between two States with the exemption of intentional movements between parties to the Cartagena Protocol within the European Community).

The Regulation establishes a common system of notification and information for the transboundary movement of GMOs. It thus complements other EU measures on the use of GMOs by establishing an adequate level of protection for the safe transfer, handling and use of GMOs, taking into account risks to biodiversity and human health. In particular, it responds to concerns about the international movement of GMOs, including imports into the EU from third parties. The Regulation establishes amongst others procedures for the keeping of information in a widely accessible form on the Biosafety Clearing-House.

This Regulation has also established notification procedures which might be useful in the context of monitoring the utilisation of genetic resources. The competent authorities might fulfil roles as checkpoints for the purpose of implementing the Protocol.

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients¹⁷

The novel food Regulation applies *inter alia* to food and food ingredients consisting of or isolated from plants. It sets forth a notification duty before placing such products on the market, which in some cases is followed by a full-fledged authorization procedure.

Thus, under the Regulation information on the utilisation of genetic resources within the EU is collected. In the context of implementing the Protocol, the Regulation could be harnessed for monitoring purposes by integrating an obligation to provide information required under the Protocol to competent authorities. The latter could also be assigned a role in compliance.

Placing on the market of pharmaceuticals and cosmetics

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products and Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

The Cosmetics Directive, as amended and adapted, was adopted in order to ensure the free circulation of cosmetic products on the internal market and to ensure the safety of cosmetic products. The Directive stipulates that the Commission shall compile an inventory of ingredients employed in cosmetic products, on the basis in particular of information supplied by the industry concerned. The Directive also includes provisions on the phasing out of animal testing. Directive 76/768/EEC, however, will be repealed by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (the Cosmetics Regulation). Most of the provisions of this new Regulation will be applicable as from 11 July 2013.

The Regulation provides for a notification procedure through which the responsible person, prior to placing the cosmetic product on the market, submits electronically certain information to the Commission such as: the category of cosmetic product and its name or names; the name and address of the responsible person where the product information file is made readily accessible; the country of origin in the case of import; the Member State in which the cosmetic product is to be placed on the market; the presence of nanomaterials; the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified

¹⁷As amended by Regulation (EC) No 1829/2003 of 22 September 2003, Regulation (EC) No 1882/2003 of 29 September 2003, Regulation (EC) No 1332/2008 of 16 December 2008 and Regulation (EC) No 596/2009 of 18 June 2009.

as carcinogenic, mutagenic or toxic for reproduction; frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

The Regulation could become relevant in the context of implementing the monitoring rules of the Protocol. For example, the Regulation might be amended in order to introduce a requirement to disclose the information that parties to the NP are obliged to collect.

Regulation (EC) No 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use

Directive 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products

The Regulation lays down a procedure for the authorisation of medicinal products for human use and a procedure for the authorisation of medicinal products for veterinary use.

The particulars and documents that need to be included in each application for the authorisation of a medicinal product for human or veterinary use are specified in respectively Directive 2001/83/EC and Directive 2001/82/EC. These particulars might be amended in order to introduce a requirement to disclose the country of origin or, if unknown, the specific source of any genetic resources used for the production of medicinal products for human or veterinary use.

These legislative acts could therefore become relevant in the context of implementing the monitoring rules of the Protocol. For example, the Regulation might be amended in order to introduce a requirement to disclose the information that parties to the NP are obliged to collect. The relevant authorities could be assigned checkpoints functions. Moreover, the approval procedures could be used in the context of compliance measures.

Placing on the market of pesticides

Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market

Directive 98/8/EC on placing of biocidal products on the market

Regulation (EC) No 1107/2009 lays down rules for the authorization of plant protection products, in commercial form and for their placing on the market, use and control. The Regulation provides for an approval procedure for active substances, safeners, synergists, adjuvants and co-formulants on the one hand, and for an authorization procedure for placing plant protection products on the market. The approval of microorganisms for the use in plant protection products is obtained for single isolates which are identified by a number in an internationally recognised culture collection. This number is published in the

Official Journal of the EU and on the Commission website together with detailed information about the approval itself. Thus, the monitoring of micro-organisms for the purposes would not require extra-measures, but could happen through the existing system.

Directive 98/8/EC establishes a common framework of rules relating to the authorization and placing on the market of biocidal products, requiring Community approval of all active ingredients for biocide products, but leaving approval of the product formulations with Member States acting in accordance with the common framework.

Concerning the directive, it is doubtful whether for implementing the Protocol, it would play major role. Only a limited number of plant protection products are made from plants or micro-organisms, and such products only represent a small market share. Thus, while the Directive could theoretically be adapted in order to impose upon applicants (i.e. those willing to have active substances authorized or those willing to place biocidal products on the market) a requirement to disclose the information that parties to the NP are obliged to collect, this would likely only be of limited use in monitoring the utilisation of GR.

Certification and marketing of seeds

Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (repealed Directive 70/457/EEC)

Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (repealed Directive 66/400/EEC)

Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (repealed Directive 70/458/EEC)

Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties

Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties (Text with EEA relevance)

Commission Directive 2010/60/EU of 30 August 2010 providing for certain derogations for marketing of fodder plant seed mixtures intended for use in the preservation of the natural environment Text with EEA relevance

Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (repealed Directive 66/403/EEC)

Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (consolidated Directive 69/208/EEC)

Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties

Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed

Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed

Council Directive 68/193/EC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine

Council Directive 1998/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants

Council Directive 92/33/EEC of 28 April 1992 on the marketing of vegetable propagating and planting material, other than seed

Council Directive 92/34/EEC of 28 April 1992 on the marketing of fruit plant propagating material and fruit plants intended for fruit production

Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material

The EU legislative framework for marketing seed and propagation material is currently under revision. It is complex, consisting of specific legislative acts for different crops. One important element is, however, the common catalogues of varieties of agricultural plant species and of vegetable species respectively. The catalogues cover 36 vegetables species and rootstocks and 87 agricultural crops. Seed of varieties that are registered in these catalogues can be marketed throughout the EU. Generally, varieties can only be registered in the catalogues when they fulfil a set of criteria, notably to be distinct from other varieties, uniform and stable across generations. More traditional varieties often do not fulfil these criteria. Directives 2010/60, 2009/145 and 2008/62 therefore contain derogations, according to which certain conservation varieties/landraces or mixture of fodder crops, which are important for conservation of genetic diversity or are adapted to specific conditions, can be marketed under less restrictive requirements with regard to the above criteria. However, there are other requirements restricting their marketing (e.g. an overall quantitative restriction). Nonetheless, in an on-going ECJ court case, the Advocate General has recently held that the prohibition in Directive 2002/55 to market seed that does not fulfil the above criteria violates the proportionality principle and is thus inconsistent with EU

law.¹⁸ However, the ECJ has not followed this line of reasoning and has upheld Directives 2002/55 and 2009/145.¹⁹

Many of the varieties included in the catalogues are within the scope of the ITPGRFA, not the Kyoto Protocol. For varieties under the Protocol, the catalogues could be relevant for monitoring purposes under the Protocol.

Finally, if the circulation of seed on the EU market was to be facilitated in future legislation, and hence their wider cultivation encouraged, this could be seen as contributing to the fulfilment of the EU's obligation from Art 8(c) of the Protocol. Art 8(c) mandates Parties to consider the importance of genetic resources for food and agriculture for food security, when designing their ABS measures.

Approval and marketing of forestry material

Directive 1999/105/EC of 22 December 1999 on the use of reproductive material in forestry

The Directive regulates *inter alia* to the approval and marketing of recognised reproductive material, including the development of national registers and development of a Community list to facilitate tracing, including from third countries. It requires Member States to ensure that only approved basic material is used for the production of forest reproductive material which is to be marketed.

The Directive has established notification procedures. Moreover, it stipulates that in the case of non-autochthonous or non-indigenous basic material the origin must be stated if known. This requirement is part of the minimum requirements that need to be fulfilled in order to have the basic material approved.

Given that certain information relating to genetic resources which is also relevant under the Nagoya Protocol is already collected under the Directive, the Directive could be relevant in the context of monitoring the utilization of forest reproductive material (which can be used as genetic resources) within the EU. The competent authorities might serve as checkpoints for the purpose of the implementing the Protocol.

4.2.3 Inspections, certification and conformity assessments

Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code

¹⁸ Final statement of Advocate General Juliane Kokott of 19 January 2012, Case C-59/11, Association Kokopelli vs. Graines Baumaux SAS.

¹⁹ ECJ, Judgement of 12 July 2012, C-59/11, Association Kokopelli vs. Graines Baumaux SAS

Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code

Customs offices might be given a role in ensuring ABS compliance and monitoring the utilization of genetic resources at the point of import²⁰ in to the EU. In this case, these regulations may have to be amended.

Regulation No 765/2008 of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products

This regulation establishes a broad legislative framework covering the general marketing of products. Therefore it only applies to products not covered specifically by other more specific rules. Specifically, it lays down the framework for a harmonised system of accreditation of products, by *inter alia* establishing a central European Accreditation body with the function of harmonising established national accreditation institutions. These are to accredit conformity assessment entities. It also requires cooperation between competent authorities at national level and across borders in exchanging information, investigating infringements and taking action to bring about their cessation, by reinforcing measures to identify non-conforming products (to harmonised EU standards taken by the relevant standardisation institution), mainly in seaports and external borders.

Depending on the EU's approach to compliance, such conformity assessment bodies could be given a role in monitoring ABS compliance. The national accreditation bodies might then have to accredit such assessment bodies.

Regulation (EC) No 1221/2009 of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)

Participation in a certification system can improve the user's reputation and provide a basis for provider countries to feel more confident about their potential ABS partners. The EMAS-scheme offers an interesting example that might be considered for the development of voluntary certification schemes for organizations complying with the Protocol (Richerzhagen, 2010). It could thus become part of a wider system of measures to ensure user compliance within the EU.

4.2.4 Funding

²⁰ Specific rules exist with regard to the importation of plant reproductive material from third countries and equivalence of third country rules for the certification of plant reproductive material with regard to plant reproductive material field inspection and maintenance of variety (Decisions 2003/17/EC, 2005/834/EC, 2008/16152/EC).

Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)

Under this Regulation, funding can be provided for rural development projects involving the conservation of genetic resources in agriculture within the EU, including animal, plant, tree and micro-organisms genetic resources. Two types of support are provided under multiannual agri-environmental commitments for:

- threatened local animal breeds and plant genetic resources under of threat of genetic erosion (Article 39(1-4) of the Regulation) and
- targeted actions promoting the ex situ and in situ conservation, characterization, collection and utilization of genetic resources in agriculture; web-based inventories, gene banks and databases; concerted actions promoting the exchange of relevant information within the EU; information, dissemination and accompanying actions promoting advisory actions, training courses and preparation of technical reports (Article 39(5) of the Regulation).

A similar stream of actions is likely to be supported under the new legislative proposal for the EAFRD.

Potentially, the funding could be used for raising awareness among users of genetic resources on ABS matters, and could thus help the EU to fulfil its compliance-related commitments.

Council Regulation (EC) No 870/2004 of 26 April 2004 establishing a Community programme on the conservation, characterisation, collection and utilisation of genetic resources in agriculture

The programme, established by this Regulation, promotes genetic diversity and the exchange of information including close coordination between Member States and between the Member States and the European Commission for the conservation and sustainable use of genetic resources in agriculture. It also facilitates coordination in the field of international undertakings on genetic resources, in particular within the CBD, the IT-PGRFA and the FAO's Commission on Genetic Resources.

The budget allocated to this programme, which complements the actions co-funded by the new Rural Development Council Regulation (EC) No 1698/2005 (Article 39(5)), amounts to €10 million.

The actions supported by the programme take place within the timescale 2007-2011 and there is no process yet to put in place a successor instrument. The current actions cover all plant, microbial and animal genetic resources that are or could prove useful for agriculture and rural development, including forest genetic resources of the EU. The aims are not identical with the ABS aims but complementary: to conserve genetic resources and increase the use of under-utilized breeds and varieties in agricultural production in the EU, thus helping maintain biological diversity, improve the quality of agricultural products, contribute

to increase diversification in rural areas and reduce inputs and so contribute to the sustainable development of rural areas. The actions must go beyond the existing legislative baseline.²¹ The adoption of the Protocol would create leverage for putting in place a successor instrument.

As a general rule, the actions funded by the programme are to be carried out by participants from within the EU. However, those actions can be carried out in partnership, when appropriate, with organizations from other regions of the world. The programme might be relevant for the implementation of the Protocol to the extent that organisations from provider countries are involved in these actions. The programme therefore might be used as a mechanism to provide benefits to provider countries through participation in research projects concerning genetic resources for agriculture, as far as the genetic resources concerned do not fall within the scope of the IT-PGRFA.

Decision No 1982/2006/EC of the European Parliament and of the Council concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007–2013)

The European multi-annual Research Framework Programmes (such as the Seventh Framework Programme) may be used to leverage ‘cooperation in the field of Union research, technological development and demonstration with third countries and international organisations’.

The Framework Programme or successor legislation could be relevant to the implementation of the Protocol in several ways. First, by fostering ABS related research the EU could fulfil the obligation in Art 8(a) to create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries.

Moreover, research funding could be made instrumental to monitoring and fostering user compliance. For example, applicants could be required to state in their applications whether any genetic resources they intend to use were accessed in compliance with PIC/MAT requirements and funding could be made conditional on compliance. Moreover, by collecting information on applications for research projects that deal with genetic resources, DG Research could also contribute towards monitoring and could be made to fulfil checkpoint functions.

Regulation (EC) No 614/2007 concerning the Financial Instrument for the Environment (LIFE+)

LIFE+ is the EU's only dedicated environment fund. It aims to contribute to the implementation, updating and development of EU environment policy and legislation, in

²¹ This involves the CAP Pillar 1 cross-compliance and other norms involving e.g. marketing of cereal seed, the vegetative propagation of vine, planting material other than seed, fruit plant propagating material, ornamental plants, forest reproductive material, varieties of agricultural plant species etc.

particular contributing to the integration of environmental aspects into other policies and to sustainable development in the EU.

The current LIFE+ instrument will expire in 2013. The legislative proposal on the post-2013 LIFE instrument has recently been published. The proposal suggests to focus some of the funding to the EU's commitments with respect to implementing international environmental regimes.

This would give the EU the opportunity to provide funding for projects supporting developing countries to build capacity to implement the Protocol and in particular to build capacity to negotiate and implement ABS agreements. The funding could thus be used in the context of implementing provider access and benefit-sharing measures. It could also play a role with regard to compliance by raising awareness among EU users on ABS matters and assisting in the development of codes of conduct, model contractual clauses etc.

Regulation (EC) No 1905/2006 of the European Parliament and of the Council of 18 December 2006 establishing a financing instrument for development cooperation

The EU provides support to indigenous and local communities through a range of programs for development cooperation. In this respect the EU has several financial instruments. One of those financial instruments, the development cooperation instrument (DCI), is governed by Regulation (EC) No 1905/2006. The DCI covers all the developing countries except the countries eligible for the Pre-Accession Instrument. Another instrument targeting developing countries is the European Development Fund (EDF), which covers cooperation with African, Caribbean and Pacific Countries (ACPs) and Overseas Countries and Territories (OCTs).

These financial instruments might be adapted with a view to support the sharing of benefits derived from the utilization of traditional knowledge associated with genetic resources and held by indigenous and local communities. In this respect it should be noted that the Commission has published on 7 December 2011 proposals on these and other external action instruments as part of its proposals for the Multi-Annual Financial Framework 2014-2020. The EDF will remain outside the general EU budget. The package will be transmitted to the European Parliament and the Council and is expected to be adopted in 2012.

The EU could use these financial instruments to fulfil its obligations under Art 12 NP, concerning ABS related support for ILCs, and Art 22 relating to capacity building.

4.2.5 Nature conservation

Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (Habitats Directive)

The Habitats Directive sets forth a framework for the conservation of endangered species and natural habitats. Its rules may become relevant to access and benefit-sharing in the EU.

For example, the access to certain species and habitats is limited as a consequence of the Directive, and competent national authorities may need to consult with conservation authorities before access is granted. Equally, access in protected areas could be linked to a benefit-sharing agreement which would require the related funds to be used for the conservation of genetic resources.

4.2.6 *Environmental crime*

Directive 2008/99/EC of 19 November 2008 on the protection of the environment through criminal law (Environmental Crime Directive)

The Environmental Crime Directive contains a list of activities that must be punishable as crime in the Member States legal order.

If the EU wished to make serious breaches of ABS rules a crime, the environmental crime directive could be modified accordingly, in order to help the EU fulfil its compliance-related obligations from the Protocol.

4.2.7 *Animal breeding*

Council Directive 2009/157/EC of 30 November 2009 on pure-bred breeding animals of the bovine species

Council Directive 88/661/EEC of 19 December 1988 on the zootechnical standards applicable to breeding animals of the porcine species

Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats

Council Directive 90/427/EEC of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae

Directive 2009/157/EC stipulates that Member States need to ensure that intra-Community trade in pure-bred breeding animals of the bovine species, and intra-Community trade in the semen, ova and embryos of pure-bred breeding animals of these species will not be prohibited, restricted or impeded on zootechnical grounds. In effect, there should be free trade in this class of breeding animals and their genetic material. Member States also need to ensure that the establishment of herd-books and the recognition of organisations or associations which maintain herd-books will not be prohibited, restricted or impeded on zootechnical grounds, so that a level playing field is established. The Directive also stipulates that the following shall be determined through comitology: performance monitoring methods and methods for assessing cattle's genetic value; the criteria governing the recognition of breeders' organisations and associations; the criteria governing the establishment of herd-books; the criteria governing entry in herd-books; the particulars to be shown on the pedigree certificate.

The other directives contain similar provisions for porcine species, pigs and goats and equidae respectively.

The legislation is currently under revision.

4.2.8 Animal and plant health

Regulation (EC) No 882/2004 of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

In the current state of EU law, this Regulation does appear to have (direct) relevance for the implementation of the Protocol. However, it does contain rules on the performance of official controls, relating to sectors where genetic resources are used (feed and food law, animal health and animal welfare rules) and the role of reference laboratories. The regulation is currently under revision and part of a package on animal health, plant health, plant reproductive material and official controls to be presented by the Commission in autumn 2012. If as part of EU user compliance measures controls and on-site inspections were to be adopted, changes could be integrated into the on-going revision.

Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community

Commission Directive 2008/61/EC of 17 June 2008 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections

Directive 2008/61/EC obliges Member States to ensure that approval is required use of for the use of certain harmful organisms, plants, plant products for trial or scientific purposes. An application is to be submitted to the responsible bodies prior to the introduction into, or movement within, any Member State or relevant protected zones thereof, of any such material. The application shall, inter alia, specify the place of origin of the material, with appropriate documentary evidence for material to be introduced from a third country; (iv) the duration, nature and objectives of the activities envisaged, including, at least, a resume of the work and a specification for trial or scientific purposes or work on varietal selections. Thus, a part of the information that the NP requires Parties to receive or collect as part of monitoring the utilisation of genetic resources needs to be submitted by applicants under these directives. Moreover, the MS also have reporting duties under theses directives.

The competent authorities could thus have a role in monitoring the utilisation of genetic resources under the NP.

4.2.9 Access to justice and information

Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Brussels I)

The Regulation puts forward harmonized rules on jurisdiction and the recognition and enforcement of judgments. The Regulation only relates to civil and commercial matters. It does not extend to fiscal, customs and administrative matters, to the status or legal capacity of natural persons, rights in property arising out of a matrimonial relationship, wills and succession, bankruptcy, proceedings relating to the winding-up of insolvent companies or other legal persons, legal arrangements, compositions and analogous proceedings, social security or arbitration.

The Regulation stipulates among others that judgments given in a Member State bound by this Regulation (i.e. all Member States except Denmark) shall be recognized in another Member State bound by this Regulation without any special procedure being required. The Regulation furthermore stipulates that a judgment given in a Member State and enforceable in that State shall be enforced in another Member State when it has been declared enforceable there.

Regulation No 1367/2006 of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community Institutions and Bodies

The Aarhus Regulation contains rules on access to environmental information and access to justice.

The information gathered in the course of the NP-related monitoring activities might constitute environmental information in the sense of the Aarhus Regulation. Checkpoints, national focus points or competent national authorities may thus be faced in the future with requests for providing information on the utilization of genetic resources within the EU. However, it is not entirely clear whether such information indeed fulfils the definition of environmental information in Art 2 of the Regulation.

The 'access to justice' rules of the Regulation are, in turn, unlikely to become relevant for the implementation of the Protocol. According to the Regulation, certain environmental NGOs are awarded standing in certain matters in front of the ECJ. The ECJ is, however, unlikely to be the right judicial forum for settling ABS related disputes.

4.2.10 Indigenous and local communities

Protocol No 3 on the Sami people of the Act of Accession of Austria, Finland and Sweden to the EU (1994)

The Protocol is potentially relevant to implementation of the traditional knowledge provisions of the Nagoya Protocol, though it makes no specific reference to traditional knowledge (whether or not associated with genetic resources). The Protocol grants the Sami exclusive rights to reindeer husbandry notwithstanding the provisions of the EC Treaty. Article 2 of Protocol No 3 provides that it may be extended to any further development of exclusive Sami rights linked to their traditional means of livelihood. In principle, this provision could be read as encompassing traditional knowledge within the meaning of the Protocol.

5 EU MEMBER STATES LEGISLATION AND POLICIES

In the following paragraphs a brief synthesis of the EU country reports is given. The full reports can be found in the annexes to this interim report. The following countries have been studied: Belgium, Bulgaria, France, Germany, the Netherlands, Poland, Spain and the United Kingdom.²²

5.1 User-side legislative and policy measures

In the eight Member States studied no specific ABS user legislation has been put in place. This implies that currently no measures are in place in these countries to ensure that genetic resources used within in their jurisdiction have been accessed in accordance with prior informed consent or that mutually agreed terms have been established, where required by provider countries.

The only legislative measures that specifically take into consideration the CBD's provisions on ABS are measures transposing the biopatents Directive, though these measures mostly only *encourage* recognition in patent applications of the geographical origin of biological material used in biotechnological inventions (see below for more details).

In the case of the Netherlands the absence of specific ABS user legislation results from the fact that no additional legislative measures were deemed necessary by the Dutch government for the implementation of the CBD and the FAO IT-PGRFA. Both international instruments were only approved by the Dutch Parliament. The United Kingdom took a similar position. It did not develop any ABS user legislation. It has been assumed that ABS issues were effectively covered in the national legal systems by well-established laws on property, trespass, statutory protection of species and site protection. This was considered to be adequate for CBD requirements according to a 2005 review of the experience of implementing ABS arrangements under the CBD (Latorre, 2005).

France has no general national legislation, applicable to the whole of its territory, to implement ABS provisions under the CBD or the Bonn Guidelines (FRB, 2011). The full suite of user-related provisions (scope, benefits, compliance and monitoring) therefore needs to be developed. It is also acknowledged that for its Overseas Territories with competence for natural resource management, the French State is not able to 'ensure' fair and equitable benefit-sharing. Nonetheless, as all of the main French public research bodies carry out work in the Overseas Territories, the French researchers seeking to use genetic resources originating from there are bound by local access requirements, where in place. Two Overseas Territories (*Province Sud, Nouvelle-Calédonie; Guyane*) have adopted legislation pursuant to Article 15 CBD, although this is only operational in one of them. In addition, measures are under development in French Polynesia.

²² Please note that the country studies have been conducted in the second half of 2011 and have not been updated since then. Therefore the country studies may not take into account recent legislative and policy developments in the countries studied.

To the extent that policy measures have been taken in EU Member States, these have been broadly limited to informing stakeholders about ABS, supporting developing countries and developing voluntary codes of conduct.

Intellectual property rights

In some EU Member States (and Norway) the concept of disclosure of geographical origin when applying for intellectual property protection has already been implemented in the form of a stand-alone disclosure requirement. This implies that non-compliance with the disclosure requirement has no effect on patentability or patent enforcement. In countries such as Denmark, Germany and Norway for instance non-compliance does not affect the processing of a patent application dossier or the validity of a patent. In other Member States such as Spain disclosure of geographical origin has not been turned into a binding requirement. As in the Directive the concept is only mentioned in the preamble of the national patent legislation.

Belgium has introduced a formal requirement for disclosure of geographical origin, non-compliance with which could result, at least in theory, in the patent application not being processed. In practice, however, the Belgian patent office does not check compliance with this requirement. As a result, it is unlikely that an application will not be handled because of a failure to disclose the origin of the genetic resources involved or because the information submitted is wrong (Richerzhagen, 2010).

Awareness raising activities

Several Member States have made specific efforts to raise awareness and promote implementation of the Bonn Guidelines and/or the Protocol. We mention here in particular the efforts of Belgium, the UK and France.

In 2006 the Belgian Government ordered a study on the awareness of Belgian users concerning CBD provisions on ABS and the Bonn Guidelines. The main results indicate that the Convention is better known in upstream activities (e.g. fundamental research) than in downstream activities (e.g. commercial products). Collections and research sectors, both private and public, have a good understanding of the CBD, while other sectors, predominantly composed of private actors, have little or no knowledge. Concerning the implementation of ABS provisions, the report shows that PIC-related provisions seem to be relatively widespread, whereas benefit-sharing provisions are nearly inexistent. When benefit-sharing does occur, it mostly implies research cooperation with the providing country (Frison and Dedeurwaerdere, 2006).

In 2010 the federal Belgian government adopted the Federal Plan for the integration of biodiversity in four key sectors. ABS-related actions within the plan are mainly focused on awareness-raising and capacity building of the private sector. However, the implementation of these actions has been delayed as priority was given to the Protocol negotiations and the implementation study. The actions envisaged include the organization of biodiversity training sessions for four target groups concerned with the implementation of the sections 'economy' and 'transport' (EU, 2011).

Belgium has informed and consulted the different stakeholders on the implications of the Protocol through the organization of a stakeholder workshop in the summer of 2011. Belgium will continue and step up these efforts, amongst other in the framework of its impact study on the implementation of the Protocol. As part of this impact study two stakeholder workshops will be organized during the first half of 2012.

The UK authorities (i.e. Defra) commissioned in 2005 a review of the experience of implementing ABS arrangements under the CBD (Latorre, 2005). The study represented Defra's first effort to work more closely with stakeholders on ABS issues and was intended to identify the most important issues and needs of the various stakeholder groups. Defra has also recently commissioned a new study to assess the potential impacts and options for implementing the Protocol in the UK, which will include a survey of stakeholders as well.

In the absence of legislation, the French Environment Ministry²³ cannot issue formal authorisations that qualify as prior informed consent or mutually agreed terms under Article 15 CBD. However, it is taking steps to build researchers' awareness and promote voluntary best practice for projects concerning non-protected species and habitats. For example, a 2011-2012 letter from the Ministry viewed for this study (confidential details removed) set out agreed terms for doctoral research on non-protected plant resources, aligned with the Protocol and covering:

- Geographic location of collection activities. Additional requirements would apply if the project was modified to require access to protected areas or species (prior consultation of competent body plus derogation procedures);
- Purpose and goal of the research (number of specimens, mitigation of environmental impacts, maximum percentage of individuals from a single population);
- Duration of access, and of the project as a whole ;
- Commercial or non-commercial nature of research (for the latter, the source of funding should be specified). The ABS Focal Point must be contacted if the intended use changes (i.e. non-commercial research becomes commercial and/or genetic resources material is transferred to a third party);
- Benefits to be shared. Non-monetary benefits generated included sharing a synthesis of information and results with the Focal Point and the National Museum of Natural History; publishing data on a public database at project end; and making samples available to the relevant university's botanic garden.

Support to developing countries

In 2005, the German Agency for Technical Cooperation (GTZ, now GIZ) joined forces with the Directorate-General for International Cooperation (DGIS) of the Dutch Ministry of Foreign Affairs to organize a regional ABS capacity development workshop for African countries. This multi-stakeholder workshop was held in October 2005 in Addis Ababa, Ethiopia. Their collaboration established the multi-donor Dutch-German ABS Capacity-Building Initiative for Africa in 2006. This initiative offers strategic Africa-wide multi-

²³ Ministère de l'écologie, du développement durable, des transports et du logement (MEDDTL).

stakeholder workshops, as well as thematically specific or regionally focused ABS workshops and trainings. The Initiative now involves several other donors.

In Germany the Federal Ministry of Education and Research (BMBF) supported a major research and development programme ('ProBenefit', 2003-2008) in developing a fair benefit-sharing model for the use of biological resources in the Amazon lowlands of Ecuador.²⁴ The German Federal Ministry for Economic Cooperation and Development (BMZ) also provided assistance to a regional ABS programme in the Eastern Himalayas.²⁵

The Wageningen University Centre for Development Innovation (CDI) runs an international programme of short courses on genetic resource management and genetic resource policies. CDI and CGN co-organise yearly courses in Wageningen and abroad, lately in Ethiopia and in India.

Requirements for funded research

The German national research foundation has adopted guidelines for funding proposals concerning research projects within the scope of the CBD. Applicants for funding involving research using biological material are required to state in their application the status of preparations in the host country, including contacts with national authorities. Applicants are also to certify that they are familiar with CBD rules and are committed to complying with them. The German Ministry for Education and Research also includes clauses in relevant funding contracts that oblige the recipients of these funds to comply with CBD rules (Quintern, 2005).

5.2 Provider-side legislative and policy measures

Access to genetic resources

In most EU Member States studied no provider-side access legislation exists. Exceptions are France, Spain and Bulgaria. It should be noted that the Netherlands has an explicit free access policy whereby no prior informed consent is required to access its genetic resources. Poland also aims for unrestricted access to genetic resources.

In **France**, genetic resources are considered to be implicitly covered by Article L.110-1 of the Environment Code which broadly provides that components of biodiversity constitute a national common heritage. This definition covers resources in terrestrial, aquatic and marine systems. Traditional knowledge associated with genetic resources does not have an equivalent status. Government stakeholders consider that the existing 'common heritage' classification could provide a legal basis to designate the State as the competent national authority and as genetic resources access provider, subject to the rights of third parties with physical ownership/control of the relevant area. Recognition of the State as genetic resources provider could provide leverage for greater benefits for biodiversity conservation and sustainable use because the State would contract directly with the user. This could also

²⁴ <http://www.probenefit.de>

²⁵ <http://www.icimod.org/?q=280>

have advantages for business in terms of administrative streamlining i.e. to avoid individual genetic resources contracts with multiple owners on small parcels.

Under such a framework, authorisation by the French State would be deemed as equivalent to prior informed consent. However, this approach would *a priori* be non-contractual as it would involve a simple administrative permit. To incorporate contractual elements into the mechanism, a preliminary negotiation phase would be needed i.e. the application form would give rise to a two-way procedure with the State responding to proposals from the applicant, requesting further information and eventually reaching agreement on '*prescriptions*' (permit conditions) which would be deemed as equivalent to mutually agreed terms and could provide additional legal security for users.

Two of France's Overseas Territories have showed some limited progress on the ABS legislation implementation. In the Southern Province of New Caledonia a dedicated local legislation was adopted in 2009. Access permit applications are decided by the Provincial Environment Directorate which is responsible for ensuring compliance with sampling conditions set out in the permit. Local police (*gendarmerie*), national police agents and customs officials also have powers to enforce the regulations. On the benefit sharing side, the law provides for two thirds of monetary benefits to be returned/directed/paid to the landowner, rather than to traditional populations (cf. Brazil, Peru). In response to stakeholder concerns, though, the public administration affirmed that the concept of 'landowner' does not exclude indigenous and local communities (MEDDTL 2011b). Currently, draft legislation is under consideration which would address all ABS issues and clearly specify that property law covers private property, public property and land held under customary rules. For access to genetic resources on customary lands, mutually agreed terms for benefit sharing would be fixed by a customary discussion procedure (*palabre coutumier*) rather than a contract (MEDDTL 2011b).

In French Guyana, collective use rights may be attributed in defined areas to indigenous communities that traditionally subsist on forest-based products. In 2006, the French State has delegated competence for ABS to the Amazonian National Park (ANP), though no equivalent framework is present for the rest of the territory. The Regional Council in French Guyana is designated as the competent authority to grant access permits, subject to a favourable opinion from the General Council and consultation with the public park management authority. The law delegating power to ANP also provides a basis for prosecuting offences related to fraudulent acquisition of resources within the Park. However, implementing regulations have not yet been issued which means that ABS aspects of this act are not yet operational. The Park Charter, due to be adopted by end 2012, will set out the strategic parameters for ABS. In the meantime, a draft code of conduct has been developed by the Park for genetic resource users.

Spain is a particular case. Its law 42/2007 on natural heritage and biodiversity puts forward some rules on access to **wild, terrestrial genetic resources** and sharing the benefits from their utilization. It states in particular that an implementing measure (*Real Decreto*) may stipulate that prior informed consent and mutually agreed terms may be required for access to wild genetic resources. The 2007 law also stipulates that the *Comunidades Autónomas* may adopt additional access legislation if this is considered necessary for the conservation

of their genetic resources. However, no national implementing measure or regional legislation has been adopted so far. This implies that currently no prior informed consent or mutually agreed terms requirements are being imposed on users of Spain's wild genetic resources.

Spain has also legislation (law 30/2006) that stipulates rules on access to those **plant genetic resources for food and agriculture** which are not part of the IT-PGRFA's multilateral regime. Also here the *Comunidades Autónomas* are allowed to adopt additional legislation on access needed for their conservation. The law stipulates that these resources can only be accessed for research, genetic improvement, conservation and sustainable use purposes. Foreign nationals and companies can only get access if a material transfer agreement (MTA) is concluded or conventions or bilateral treaties on access are in place. The law also states that recipients shall not claim any intellectual property or other rights that limit access. Furthermore, it stipulates several duties for the recipients: they must report every two years and over a period of 20 years in total on the research carried out with the genetic resources and on any practical application resulting from this research. In addition, when a recipient commercialises a product derived from the plant genetic resources received, the recipient must ensure that the product is freely available to anyone in Spain for purposes of research and genetic improvement. However, the **intellectual property rights** of the recipient are to be respected in this case.

To conclude, law 30/2006 stresses that **farmers** must obtain some of the benefits arising from the utilization of plant genetic resources for food and agriculture. To this end, relevant authorities are required to take measures to facilitate the conservation, use and trading of seeds and nursery plants of local varieties in danger of extinction that farmers conserve on their farms in limited quantities.

Just like Spain, **Bulgaria** has general legislation on access to its genetic resources which is not further elaborated through implementing measures. Access to its genetic resources is regulated by the 2002 Biological Diversity Act, whereas access to genetic resources protected by patents or other intellectual property rights is regulated by the respective legislation on intellectual property rights. The Biodiversity Act stipulates that genetic resources can be accessed and used by other countries if an advance agreement is concluded in writing on the sharing of benefits arising from the utilization of the genetic resources under mutually advantageous terms. The Act stipulates that the agreement should include the following benefits: the disclosure by the user State of the natural origin of the genetic material; provision by the user State of the research results and the technologies obtained from, related to, or derived from the genetic resources concerned; payment of part of the financial resources resulting from the utilization of the material and derivatives for commercial purposes; and, participation by Bulgarian researchers in joint scientific studies. The law also foresees gratuitous access to genetic resources for non-commercial purposes, which are set to include scientific research, education, conservation of biological diversity and public health. The Biodiversity Act further stipulates that the specific terms and procedures for the provision of access to genetic resources shall be established by a regulation adopted by the Council of Ministers. Such regulation, however, has not yet been adopted.

In addition, Bulgaria has adopted relevant regulations in the field of medicinal plants and forestry. It has put in place a system which regulates the use of medicinal plants for commercial purposes.²⁶ Under this system the competent authorities under whose jurisdiction the medicinal plants are placed (e.g. municipal administrations and directorates of national parks), have to issue licenses for the commercial use of medicinal plants. Thereby several charges have to be paid: a charge for the utilization of medicinal plants, a charge for the collection of herbs and a charge for the collection of genetic material to be used for the cultivation of medicinal plants or other purposes. The funds collected from these charges are to be used for activities specified in the legislation, for example, the maintenance, rehabilitation and assessment of resources, culturing, establishment of information systems and training programs. The new Forest Act also includes relevant provisions. It includes in particular provisions on access to non-timber products, some of which contain genetic material of value (e.g. seeds, mushrooms, medicinal and aromatic plants). The Act states that the use of non-timber forest products for commercial purposes is only allowed if this is provided for in the forest management plan. With regard to medicinal plants, reference is made to the Medicinal Plants Act. The use of mushrooms, berries, medicinal and aromatic plants for non-commercial purposes is free of charge.

The Netherlands currently has a no-PIC policy. This means that prior informed consent for exporting Dutch genetic resources is not required. The Dutch government explicitly stated in 2002 that it does not deem it necessary to secure its national sovereignty regarding access and use of its own *in-situ* genetic resources (van de Wouw and Visser, 2011). This policy was established mainly on the premise that sustainable use is an important incentive for conservation. It should be noted however that this general policy of not requiring prior informed consent for getting access to plant genetic resources is without prejudice to other existing legislation such as legislation in the field of nature protection.

As a result of the Dutch policy of free availability of plant genetic resources, collections of valuable genetic resources are easily accessible and plant genetic resources are actively distributed in and outside the Netherlands. For farm animal breeds, genetic resources are the property of the cattle farmers or breeding organizations. They have full authority over the access to their resources and over the level of protection of their breeding populations. In practice, the rights to the genetic material are transferred to the buyers of animal breeds (Ministry of Agriculture, Nature and Food Quality, 2002).

For access to the plant genetic resources managed by CGN, the IT-PGRFA's sMTA is used. Resources from the botanic gardens are distributed with the internationally agreed IPEN MTA, based on the provisions of the CBD, and their access is limited to internal use and research purposes (CGN, 2011). Types of uses not covered by the international agreements are not regulated by specific policy measures (van de Wouw and Visser, 2011).

A team at the Belgian Science Policy Office (BELSPO) coordinates the activities of the Belgian Co-ordinated Collections of Micro-organisms (BCCM). Under the auspices of BCCM, a voluntary code of conduct to facilitate access to microbial genetic resources has been

²⁶ <http://chm.moew.government.bg/nnps/IndexDetailsE.cfm?vID=11>

developed. BCCM also developed an MTA for accessing the resources from its public collection.

Simplified access procedures for non-commercial research

Though no simplified access procedures for non-commercial research exist in the EU Member States examined, it is worthwhile to mention the French ideas in this respect. The inter-ministerial working group is considering the possibility of differentiated procedures for different uses of genetic resources e.g. simplified procedures for non-commercial research, with a come-back/review provision if the purpose changes. One approach would be to set out general principles, then decide whether further simplification is appropriate for certain types of research. The group also envisages multi-year permits for similar activities conducted by the same organisation (specific to the institute/structure concerned under a partnership contract with the Ministry) but has not decided whether such permits would be limited to non-commercial research or also open to industry.

Traditional knowledge

France and Spain are the only EU countries from those studied in which traditional knowledge-related measures are being developed; for France this applies only to the different Overseas Territories.

Spain has put in place some legislation as there is significant knowledge concerning the use of biological resources which is considered as 'traditional knowledge'. More than 2,000 species are still used traditionally in Spain, many for medicinal and food purposes. Article 9 of Law 42/2007 mandates the establishment of an inventory of the natural heritage and biodiversity which is to include traditional knowledge on the natural heritage and biodiversity (IEPNB). Article 70 of Law 42/2007 contains an obligation for authorities to preserve, maintain and support traditional knowledge and practices. Moreover, they must support the fair sharing of benefits arising out of the use of traditional knowledge. Article 70 also requires the establishment of inventories of traditional knowledge to be integrated into the IEPNB. More details are included in an implementing measure adopted in 2011. However, the inventory of traditional knowledge has not yet been established, though other parts of the IEPNB have been established and are already being filled gradually. As to access to traditional knowledge, the implementing measure stipulates that the IEPNB is to be made publicly available, though procedures are to be put in place to protect intellectual property rights. These procedures are still to be elaborated.

The Spanish law 30/2006 also stipulates that relevant authorities need to take measures to protect, conserve and develop traditional knowledge associated with plant genetic resources for food and agriculture.

Several French Overseas Territories have indigenous and local communities that are concerned by implementation as holders of traditional knowledge associated with genetic resources and/or as rights holders on land where genetic resources are located. Despite that, traditional knowledge is not yet clearly addressed in ABS legislation and policies. In France, genetic resources are considered to be implicitly covered by Article L.110-1 of the Environment Code which broadly provides that components of biodiversity constitute a national common heritage. This definition covers resources in terrestrial, aquatic and

marine systems. However, traditional knowledge associated with genetic resources does not have an equivalent status. It should be noted though that the New Caledonian government is currently developing territory-wide proposals for traditional knowledge. In addition, French government stakeholders recognise the need for national support for monitoring by Overseas Territories, possibly through the creation of a traditional knowledge register available for consultation by patent offices.

Farmers' rights

The Spanish law 30/2006 stresses that **farmers** must obtain some of the benefits arising from the utilization of plant genetic resources for food and agriculture. To this end, relevant authorities are required to take measures to facilitate the conservation, use and trading of seeds and nursery plants of local varieties in danger of extinction that farmers conserve on their farms in limited quantities.

6 ABS PRACTICES IN THE EU

Several stakeholder initiatives have been taken in the EU as to the development and implementation of policies and codes of conduct in relation to ABS.

6.1 Institutional policies and codes of conduct

Scientific research institutes and networks of *ex situ* collections have developed institutional policies and codes of conduct on ABS to facilitate the acquisition and exchange of genetic resources.

The European microbiological community has developed the so called ECCO Core MTA for the supply of samples of biological material that ECCO holds in its collections.²⁷ ECCO is the European Culture Collections' Organisation (ECCO). It aims to promote collaboration and exchange of ideas and information about all aspects of microbial culture collection activity and comprises more than 60 corporate members, including microbial culture collections being charged with the task of accessioning and supplying of living microbiological material. The implementation of the Core MTA aims to make the core biological material available from ECCO collections under the same core conditions. The Core MTA stipulates among others that the recipient may use the material in any lawful manner for non-commercial purposes. If the recipient wishes to use the material or modifications for commercial purposes, it is required, prior to such use, to negotiate the terms of any benefit sharing with the appropriate authority in the country of origin of the material.

The International Plant Exchange Network (IPEN) Code of Conduct is the unified policy of the network of botanical gardens.²⁸ It covers acquisition, maintenance and supply of living plant material by the gardens as well as benefit-sharing. Under the Code, the botanical gardens commit themselves to act in compliance with the CBD and CITES. The Code further provides an MTA to be used for exchanges with institutions that are not member of the IPEN network for non-commercial uses. The Code has been developed by the *Verband Botanischer Gärten* (an association of gardens in German speaking countries) and was taken over by the European Consortium of Botanic Gardens.

Under the auspices of IPEN and the Royal Botanic Gardens, Kew 'Principles on Access to Genetic Resources and Benefit-Sharing for Participating Institutions' have been developed by 28 botanic gardens and herbaria from 21 countries worldwide.

The UK's Natural History Museum (NHM) has also developed a system to ensure that specimens are accessed with the appropriate permissions and used as per terms of the access agreement. Its system takes a risk-based approach informed by the likelihood of exploitation by third parties, primarily aiming to generate and maintain trust with provider countries and demonstrate that there is a robust process in place.

²⁷ <http://www.eccosite.org/>

²⁸ <http://www.bgci.org/resources/ipen>

MOSAICC or 'Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct' is a voluntary code of conduct to facilitate access to microbial genetic resources in line with the CBD, the TRIPS Agreement and other applicable national and international law, and to ensure that the transfer of material takes place under appropriate agreements between partners and is monitored to secure benefit-sharing. The code of conduct results from the MOSAICC project launched in 1997 by the Belgian Co-ordinated Collections of Micro-organisms (BCCM) (European Community, 2002).

The Centre for Genetic Resources, The Netherlands (CGN), maintains collections of crops, domestic animals, and trees and shrubs. CGN has traditionally adhered to a policy of unrestricted availability of germplasm held in its genebank. In the interest of keeping this material available for future research and utilization, CGN has undertaken not to claim legal ownership over the germplasm held in its genebank, or to seek any intellectual property rights over that germplasm or related information. As part of its activities CGN regularly organises missions to collect genetic resources from all over the world. These collection missions are usually governed by Memorandums of Understanding (MoU). Since 2006, MoUs use the sMTA of the IT-PGRFA as a basis for collecting material.

BCCM uses the general BCCM MTA for getting access to the genetic resources of its public collection.²⁹ If necessary the MTA can be amended with additional conditions possibly already attached to the biological material. The resources are distributed for a fee covering expenses. The MTA stipulates that anyone seeking to access genetic resources held by the BCCM has the responsibility to obtain any intellectual property licenses necessary for its use and agrees, in advance of such use, to negotiate in good faith with the intellectual property rights owner(s) to establish the terms of a commercial license.

However, at national level many public research institutions still have a long way to go. In Spain for instance the recommendations on good scientific practice of the National Bioethics Committee do not mention ABS. The same holds for the code of good scientific practice of the *Agencia Estatal Consejo Superior de Investigaciones Científicas*, the biggest public research institution in Spain. As to botanical gardens, the IPEN Code of Conduct is a good thing. However, in Spain only a small share of botanical gardens are member of IPEN. National studies on users of genetic diversity (such as a 2005 German study and a 2006 Belgian study) often indicate there is a lack or low level of awareness on ABS rules.

6.2 Corporate policies and codes of conduct

Some European pharmaceutical and biotechnology companies have developed corporate policies on ABS. Other sectors such as horticulture and botanical medicines do not appear to have developed comprehensive corporate or sector-based policies and codes of conduct on ABS.

²⁹ http://bccm.belspo.be/services/bccm_mta.php

Europabio, the European Association for Bioindustries, has developed so-called 'Core Ethical Values', by which all members are bound. In these, Europabio states: 'We support the principles embodied in the United Nations Convention on Biological Diversity (CBD) to protect biological diversity including adherence to the principles of access and benefit sharing.'

At least seven French companies were involved in the creation of the Natural Resources Stewardship Circle (NRSC) in Grasse, France in 2006, which covers the cosmetics, perfume, flavour and fragrance industries. The NRSC adopted best practice Common Guidelines in September 2010, aligned with CBD provisions and based on a Corporate Social Responsibility approach for sustainable development with reference to ethical sourcing. The Guidelines are intended to direct member company interactions with indigenous and local communities and support capacity-building (see country report for more details).

Venometech is a new French biotechnology company with origins in public research. It aims to develop novel therapeutic molecules based on venom compounds to produce medicines for pain relief, cancer and illnesses of the central nervous system. Its commercial potential is directly linked to genetic resources access and it ensures full compliance with applicable legislation, including CITES requirements. Its ABS corporate policy supports voluntary compliance with NP benefit-sharing provisions, even before this becomes obligatory (see country report for more details).

However, with the exception of France no corporate policies or codes of conduct in the private sector have been identified or mentioned in the EU country reports.

Though Europabio states that its members are bound by its Core Ethical Values, the ethical code of ASEBIO, the Spanish Association of Biotechnology Companies does not refer to CBD or ABS, though it contains a general commitment to biodiversity conservation. None of the codes of Farmaindustria, the Spanish Association of the Pharmaceutical Industry, mention a commitment to ABS.

Though we did not identify examples of corporate policies in the Netherlands, the Dutch association for the plant reproduction material sector (Plantum), underlines that several Dutch plant-breeding companies have started to integrate attention to ABS measures in their policies. In Germany relevant industry sector have supported the adoption of an ABS protocol which provides for transparent and practicable ABS rules, as well as legal certainty for companies.

Finally, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has established a set of 'Guidelines for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization'.³⁰

³⁰ <http://www.ifpma.org/innovation/biodiversity/article/biodiversity-genetic-resources.html>

6.3 Experiences with ABS policies in provider countries

According to EU-based stakeholders, multiple difficulties exist in provider countries in terms of ABS. Many of the problems in provider countries have been developing since 20 years, though much of the new legislation on ABS has been put in place over the past five years.

In countries that have set up centralised ABS systems (e.g. Brazil and South Africa), it has become difficult for European organisations to arrange agreements. Some countries, such as Malaysia, have banned access altogether, eliminating a source of genetic resources for European organisations. Other countries require strict terms and conditions; for example, China requires that all specimens are repatriated after a specified period. This creates problems for organisations where a large number of samples are collected and/or where samples are transmitted to third parties. In India, it has become so difficult to obtain access that it can be impossible to be certain that specimens are accessed legally. As a consequence, collection activities in India are generally avoided. Finally, the Philippines Executive Order No 247 had very stringent requirements, which effectively stopped R&D in this country. This has meanwhile been replaced by a new regulatory framework comprising the 2001 Wildlife Act, implementing Rules and Regulations issued in 2004 and the 2005 Bioprospecting Guidelines.

The Centre for Genetic Resources in the Netherlands (CGN) has funded and organised several collection missions in third countries. However, in some cases the CGN did not manage to set up or successfully conclude collection missions because of the unwillingness of authorities to have certain genetic material collected and transferred abroad. Dutch companies have had similar experiences.

Companies sometimes face difficulties in identifying the competent authorities in provider countries. For instance, in the Teff case (see Country Report The Netherlands) the Dutch company Health and Performance Food International (HPFI) initially negotiated an ABS agreement with the wrong Ethiopian organization and as a result had to renegotiate the contract (Secretariat of the Convention on Biological Diversity, 2008).

A 2005 German study on users of genetic resources indicated that many potential users did not enter into ABS negotiations because of difficulties in finding a contact person or because regulations were either unknown or too strict and complex (Holm-Müller *et al*, 2005).

The French biotech company Venometech highlighted major problems linked to the current legal vacuum/complexity surrounding ABS implementation. Due to legislative/procedural barriers to obtaining access permits in third countries, it has opted to conduct collection activities within the EU where possible and is negotiating separately with administrations in different French Overseas Territories. Where necessary, it sources its material for research and development from commercial suppliers (which means that as a purchaser, it would not be bound by the Protocol's provisions). The company noted the high number of intermediaries importing biological resources (from which genetic resources could be obtained) for different commercial purposes and the difficulty of finding out whether these were obtained under appropriate permits or not.

In sum, the adoption and implementation of legislative, policy and administrative measures in developing countries has often increased restrictions on the access and use of genetic resources. These access procedures can result in lengthy delays in obtaining genetic material, as they may lack transparency and be quite complicated (Dedeurwaerdere, 2010). In Brazil for instance, obtaining a permit lasts about three years. Legal uncertainties and the risks of public blame of bio-piracy also have an impact. As a result, companies and scientists are discouraged to access genetic resources and traditional knowledge.

6.4 Examples of ABS agreements

Most ABS agreements in the Netherlands make use of sMTAs, either the sMTA of the IT-PGRFA regime in relation to genetic resources for food and agriculture, the sMTA of the IPEN regime (though botanic gardens which are member of IPEN do not need to sign an sMTA) or the sMTA used by the *Centraal Bureau voor Schimmelcultures* (CBS) Fungal Biodiversity Centre which maintains a world-renowned collection of living filamentous fungi, yeasts and bacteria. However, ABS agreements concluded beyond these regimes are rather scarce. The ABS agreement mentioned below in relation to Ethiopian tef is to be considered as exceptional.

In 2007, Danish biotech company Novozymes entered a five year partnership with Kenya Wildlife Service (KWS) for the collection, identification and characterisation of micro-organism from Kenya's national parks. It should be noted that rather than being motivated by a particular bioprospecting goal, the partnership was aimed to negotiate benefit-sharing agreement for the commercialisation of earlier collections which were done outside any agreement. Partnership's provision included setting up a microbial laboratory for KWS researchers, upfront financial coverage of sample collections and laboratory work and securing royalties on any commercial product developed. Any intellectual property that results from the partnership will be co-owned by both parties (TEEB, 2011).

In 2004 a small Netherlands-based company (HFPI) and the Ethiopian competent national authority (IBC) concluded an ABS agreement for the breeding and development of tef, which is one of the most significant cereal crop species in Ethiopia and Eritrea. The scope of the agreement is limited to the provision by IBC (on behalf of Ethiopia) to HFPI of tef for the purpose of developing food and beverage products. The agreement includes among others a commitment by HFPI to pay a lump sum of profits, to pay royalties of 30% of net profit from the sale of seeds of tef varieties, to pay a license fee linked to the amount of tef grown by HFPI, and contributions by HFPI of 5% net profit to a fund established to improve the living conditions of local farming communities and for developing tef business in Ethiopia (Secretariat of the Convention on Biological Diversity, 2008).

Coartem is a highly effective and widely used malaria treatment based on the extracts of the *Artemisia annua* plant originating in China. To secure the access to the resource the Swiss-based healthcare company Novartis has set up a partnership with the Chinese government. The benefit-sharing features of the agreement included payments of about \$US 150-160 million for the supply of raw material from the Artemisia producers, technology transfer and additional royalties and other payments to Chinese scientific partners (TEEB, 2011).

Next to these commercial ABS agreements, several non-commercial agreements or projects have been identified through the EU country studies. Please find some below.

The Eden Project (UK) has been working with the Seychelles government and other conservation organisations since 2000 on projects to promote ecological restoration and sustainable livelihoods on the islands.³¹ The Eden Project has since developed a new ornamental hybrid using the endangered *Impatiens gordonii* from the Seychelles and crossing it with a more common type (Hannah, 2011). The new hybrid is called *Impatiens* 'Ray of Hope' and is being bred by the Eden Project and sold in the UK in order to raise funds and awareness for rare and endangered plant conservation (BGCI, no date). Prior informed consent was obtained from the Seychelles Ministry of Environment through the botanical garden in Mahé; half of any profits from retail sales of the new variety are given back to the Seychelles to support plant conservation for rare and endangered species.

Several botanic gardens, including the Royal Botanic Gardens, Kew, have partnered with the Australian government and Wollemi Pine International Pty Ltd to commercialise the Wollemi Pine. The Pine was discovered in 1994 near Sydney, Australia and is one of the world's oldest and rarest plants (BGCI, no date). There are currently thought to be fewer than 100 adult trees existing in the wild; research is now focused on ensuring the conservation of the Wollemi Pine. The Pine is being grown and sold to the public as a way to generate funds for conservation of wild plants in Australia.

³¹ www.edenproject.com

7 POLICIES OF NON-EU COUNTRIES – SYNTHESIS OF COUNTRY REPORTS

In the following paragraphs a brief synthesis of the non-EU country reports is given. The full reports can be found in the annexes to this interim report. The following countries have been studied: Australia, Switzerland, Uganda, the Philippines, Brazil and India.³²

7.1 Provider legislation and policies

All of the countries examined, except for Switzerland which is primarily a user country, have developed provider legislation.

Access to genetic resources and traditional knowledge

In all the non-EU countries examined, except for Switzerland, a permit is required to get access to genetic resources.

In the Philippines bio-prospecting activities – i.e. research, collection and use of genetic resources for commercial purposes – by any user is subject to permit. Therefore a 'Bioprospecting Undertaking' needs to be concluded with the CNAs. In addition, prior informed consent must be obtained from the resource provider, defined to include the local community, indigenous peoples, protected area management boards or private land owner from where the genetic resources were collected.

In Australia each government manages access to genetic resources under its jurisdiction according to its own laws. Ownership rights to native genetic resources depend on whether they are in Commonwealth, State or Territory governments' lands, or waters, indigenous lands, freehold or leasehold lands. A permit is required for any access to 'biological resources of native species for research and development of any genetic resources, or biochemical compounds, comprising or contained in the biological resource' in Commonwealth areas. At sub-national level, only Queensland and the Northern Territory have dedicated ABS laws. In the Northern Territory for instance prior informed consent and mutually agreed terms must be agreed with the private landholder but the Northern Territory government also requires a permit for all resources collection to avoid significant environmental damage.

The *National Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* is a non-binding framework adopted in 2002 by 14 Commonwealth, State and Territory Ministers to endorse the Bonn Guidelines and to guide action by governments to develop or review ABS measures. The National Consistent Approach had only limited success as only the Northern Territory and Queensland have adopted ABS legislation and each jurisdiction have different rules for accessing genetic resources.

³² Please note that the country studies have been conducted in the second half of 2011 and have not been updated since then. Therefore the country studies may not take into account recent legislative and policy developments in the countries studied.

In Uganda an access permit from the Uganda National Council for Science and Technology (UNCST) is required in order to access genetic resources. The access procedure is quite complex and requires several steps: first, the applicant pays a fee to the UNCST; second, it negotiates an Accessory Agreement with the resource owner; third, it enters into a time-limited MTA with the Lead Agency responsible for managing the genetic resources concerned, thereby paying a fee; lastly, the applicant submits the completed application to the UNCST which can issue or refuse the permit. If the permit is granted a further fee of 300,000 Ugandan shillings is to be paid to the UNCST.

In Brazil the access authorization and additional normative acts are issued by the Genetic Patrimony Management Council (CGEN). Access to genetic resources and traditional knowledge can only be granted following the previous consent by indigenous people, an environmental agency or the owner of private land. According to the Brazilian Constitution, indigenous people have the right to the exclusive use of the natural resources located in their traditional lands and the right to defend their interests in courts.

In India the National Biodiversity Authority acts as the competent authority for all access requests from foreign nationals, research organisations or companies. Foreign applicants must apply to be granted approval by the National Biodiversity Authority by completing a form and paying a fee. This applies to access for both commercial and research purposes. Indian citizens and organisations registered in India do not need to apply for any approval for access to biological resources for research purposes. When seeking access for commercial purposes, Indian citizens and organisations registered in India only need to give 'prior intimation' to the State Biodiversity Board about their planned activities. However, the State Biodiversity Board may in consultation with the local bodies concerned prohibit or restrict any such activity if it is of the opinion that such activity is detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or equitable sharing of benefits arising out of such activity.

Access to traditional knowledge

In Uganda PIC is mandatory for access to indigenous knowledge. Benefit-sharing arrangements must not negatively interfere with traditional knowledge systems and practices of indigenous peoples and local communities. Indigenous and local communities have exclusive rights over their traditional knowledge and only they may surrender it to the UNCST. Moreover, indigenous and local communities are guaranteed the right to: have the origin of traditional knowledge access mentioned in all publications, uses, exploitation and disclosures; prevent unauthorized third parties from using or carrying out tests, research or investigations relating to traditional knowledge or disclosing, broadcasting, data or information that incorporate or constitute associated traditional knowledge; and to derive profit from economic exploitation by third parties of associated traditional knowledge in which the community owns rights as provided for under Uganda laws and international legislation.

Despite the existence of Biodiversity Management Committees established to promote conservation and sustainable resource use as well as to document local knowledge, traditional knowledge in India does not benefit from effective protection under the national

legislation. The government has developed an online resource tool which documents information on traditional knowledge related to genetic resources, but there is no guarantee that the knowledge will truly be respected and protected.

In Australia there is currently no measure in place to protect traditional knowledge. It is a main challenge to strike an appropriate balance between indigenous peoples' prerogatives of self-determination and ensuring appropriate legislative safeguards consistent with the Protocol. A possible option under consideration would involve developing a standard protocol for traditional knowledge, using the existing model benefit-sharing contracts as a starting point. This type of mechanism would support government oversight of due process, but the competent national authority would not be privy to the traditional knowledge content covered by the agreement. This type of format could be coordinated with the indigenous people's section of Australia's National Biodiversity Fund which supports development of traditional knowledge recording and protocols.

In Brazil the rights regarding traditional knowledge related to genetic resources are considered collective or diffuse. Most importantly the Brazilian Constitution recognizes the right of indigenous people to the exclusive use of the natural resources located in their traditional lands and the right of standing to defend their rights and interests in courts. However, the need remains to develop specific legislation establishing a system for the protection of the knowledge, innovation and practice. Such instruments are still in the early stages of discussion with indigenous and traditional peoples. Generally there are mechanisms in place to allow the participation of traditional knowledge holders in decision-making. For example the Genetic Patrimony Management Council, the National Biodiversity Commission, and the National Environmental Council guarantee specific rights to indigenous and local communities. In access negotiation, communities must be clearly informed in an accessible language about the proposed research activities and on the responsibilities of each party. They have the right to refuse the access to their knowledge during the process of consent. Traditional knowledge cannot be protected through patents in Brazil.

In the Philippines access to genetic resources and to traditional knowledge related to the conservation, utilisation and enhancement of these resources is to be allowed within ancestral lands and domains of the indigenous people only with a free and prior informed consent (FPIC) of such communities, obtained in accordance with customary laws of the concerned community. Access to genetic resources does not imply automatic access to associated traditional knowledge: access to traditional knowledge must be explicitly set out in the FPIC application and reflected in the Prior Informed Consent Certificate.

Access to ex situ genetic resources

Australia, the Philippines and Uganda provide for exemptions to the permit requirement for *ex situ* collections of genetic resources.

In Australia case-by-case exemptions may be made for *ex situ* collections of biological resources (including future additions) held by a public department or agency where these are administered consistent with the purpose of the EPBC Regulations; or where use of the resources is required to be controlled under any international agreement to which Australia is a party.

Ex situ collections currently accessed under international agreements to which the Philippines is a party are exempted from the permit/access rules in the legislation. Access to any other *ex situ* collections sourced from the Philippines is not exempted. Collectors are required to undertake to comply with the legislative provisions if the resources are subsequently used in bio-prospecting.

In Uganda access to *ex situ* resources is handled directly by UNCST, including for genetic resources overseas where Uganda is the country of origin. It is required to keep an inventory of relevant conservation centres. MTAs in accordance with the 2005 Regulations should be entered into between such centres and the relevant third parties in or outside Uganda.

Prior informed consent by indigenous and local communities

In Brazil permission for access is issued primarily by the CGEN. However, access to genetic resources located in indigenous territories and access to traditional knowledge require the prior consent of indigenous people. When indigenous people do not give their consent, the CGEN is not allowed to authorize access. In access negotiations, communities must be clearly informed in an accessible language about the proposed research activities and on the rights and responsibilities of each party. They have the right to refuse the access to their knowledge during the process of consent. Similar rules exist in Uganda.

In the Philippines prior informed consent must be obtained from indigenous peoples and local communities if they are the providers of the genetic resources. Specific procedures apply based on free and prior informed consent to be evidenced by a certificate. Mutually agreed terms must also be negotiated with indigenous people if they are the providers and must also be evidenced by a certificate. These certificates need to be included in the application dossier when applying for a permit from the competent national authorities.

In Australia prior informed consent is required from the indigenous owner or native title holder where access is to genetic resources on indigenous people's land in the case of their commercial use. Although prior informed consent is operational, the NCA indicated that there is little experience of accessing traditional knowledge, given the difficulty of developing a framework to give scientists legal certainty and overcome distrust. A possible option under consideration would involve developing a Standard Protocol for traditional knowledge, using the existing model benefit-sharing contracts as a starting point (see next paragraph).

As far as India is concerned, it can be concluded from the country report, there seems to be no explicit provisions in the Indian ABS legislation which require the prior informed consent of indigenous and local communities.

Indigenous and local communities in Brazil that create, develop, detain or conserve traditional knowledge associated to genetic resources are entitled to an indication of origin of the traditional knowledge in every single publication, to impede non-authorized third parties to use or disseminate traditional knowledge and to receive benefits arising from the

economic use by third parties of traditional knowledge to which they hold rights. Indigenous and local communities in Uganda enjoy the same rights.

In Uganda prior informed consent is mandatory for access to indigenous knowledge: holders must be actively included in negotiation of benefits on the basis of full disclosure of potential benefits and risk arising from resources use. The right to grant and charge for prior informed consent follows tenure: cultural/local communities on ancestral domains; Uganda Wildlife Authority for protected areas or private land owners.

Requirements for domestic versus foreign users

Link with domestic institution

In order to access genetic resources in Brazil, foreign users need to be associated with a Brazilian institution. There is a new law under preparation which does not foresee bilateral contracts between users and providers of genetic resources if the user is based in Brazil: they would have to contribute to a public benefit-sharing fund a fixed percentage rate of benefits arising from commercial sale or licensed patents.

In the Philippines a Bioprospecting Undertaking (access permit) may only be made with a foreign user if a local collaborator has been engaged to participate in the bioprospecting activity. The CNAs may recommend qualified Filipino scientists as research collaborators in the process of product development or technology transfer.

In Australia there no distinction is made between national and foreign applicants.

In order to access genetic resources and associated traditional knowledge for research or commercial utilisation, foreign applicants in India must complete a form and make a payment of 10,000 rupees (€146) to the NBA. By contrast, citizens or organisation registered in India intending to obtain genetic resources for commercial utilisation do not have to apply for approval. However, collaborative research projects between Indian organisations and public sector organisations of third countries do not require authorisation from the National Biodiversity Authority as long as the projects have been approved by the Central Government and comply with their policy guidelines on the matter.

Application or permit fees

In Brazil no **fees** for access permits are to be paid.

In the Philippines though, several fees are charged under the access regime: an application filing fee, a rehabilitation bond (surety) and a bioprospecting fee. Filipino users without foreign collaborators only pay 10% of the bioprospecting fee, whereas students carrying out academic research pay only 3% of this fee.

In Uganda the applicant has to pay several fees when going through the long access procedure. First, the applicant is required to pay the competent national authority a fee of 50,000 Ugandan shillings to obtain the application form. Second, the applicant/recipient pays a fee of 120,000 Ugandan shillings to the resource owner once the prior informed consent has been granted and an Accessory Agreement has been signed. Third, the

applicant pays a negotiable fee to the Lead Agency upon signature of an MTA. Lastly, the applicant pays a further fee of 300,000 Ugandan shillings to the UNCST if the permit is granted.

In Australia applicants for commercial or potentially commercial uses are required to pay a permit fee of AUS\$ 50.

In India foreign applicants must pay 10,000 rupees to the National Biodiversity Authority when applying for approval to access genetic resources. In addition, the local Biodiversity Management Committees are also authorized to levy charges by way of collection fees from any person collecting biological resources for commercial purpose from areas falling within their territorial jurisdiction to be accrued in Local Biodiversity Funds.

Simplified access procedures for non-commercial research

Brazil has put faster authorization procedures in place for those willing to access genetic resources for strictly scientific purposes. For these cases, authorizations are not issued by the Genetic Patrimony Management Council (CGEN), but either by the Brazilian Institute of Environment and Natural Resources (IBAMA) or the National Council for Scientific and Technological Development (CNPq).

In the Philippines scientific research on wildlife and on agro-biodiversity for academic and taxonomic purposes are exempted from the access/permit rules. However, the subsequent transfer of resources collected from non-commercial research and the use of research findings for commercial purposes must comply with the Bioprospecting Guidelines, i.e. no spin-off technology may be developed from the results of the scientific work.

In Australia the application process distinguishes between research and non-research purposes. Applicants for non-commercial research permits (no fee) do not need to negotiate a benefit-sharing agreement and need only to obtain written permission from the access provider. Permit for commercial or potentially commercial uses require instead the applicant to enter into a benefit-sharing agreement with the resource provider (50 AUS\$ fee is applied). If the purpose of research changes, non-commercial researchers are required to undertake to conclude a benefit-sharing agreement.

In India, besides being a distinction between domestic and foreign users, there is also a distinction between research and non-research genetic resources utilisation purposes. While foreign applicants do not have any exemption, Indian citizens benefit of a simplified procedure, in fact they do not need to apply for any approval for access to genetic resources for research purposes.

In Uganda the ABS Regulations do not apply to the exchange of genetic resources for research activities intended for educational purposes by Ugandan institutions recognised by the competent national authority and which do not result in access to genetic resources for commercial purposes or export to other countries. If the use is changed to commercial, the procedure for obtaining an access permit under the Regulations must then be followed.

Benefit-sharing on mutually agreed terms

In Brazil benefit-sharing contracts need to be signed between the providers and the users of genetic resources and associated traditional knowledge, when genetic resources are accessed for **commercial** purposes. These contracts must be approved by the CGEN. Brazilian legislation puts forward **mandatory elements** for benefit-sharing agreements, among others on the period of duration and intellectual property. It also requires, in specific cases, benefits to be dedicated to specified public funds.

In the Philippines the authorities impose minimum requirements for monetary benefits. For instance a minimum 2% of total global gross sales of the product made or derived from the collected genetic resources must be paid annually (royalties) and users need to pay US\$ 1,000 annually per collection for the duration of the collection activity as advance from royalties. All payments are non-reimbursable even if no profit is eventually realized. Non-monetary benefits may be negotiated on top of the monetary benefits. Users are also required to deposit all voucher specimens with the National Museum of the Philippines and all living specimens in mutually agreed depositories.

In Australia, there are no minimum benefit sharing requirements; parties to the contract agree benefits on a case-by-case basis. In the case of commercial use of genetic resources, a benefit-sharing agreement must provide for 'reasonable' benefit-sharing arrangements, including protection for and valuing of indigenous people's knowledge to be used. Moreover SEWPAC has published two model contracts to facilitate the process and reduce transaction costs associated with developing arrangements.

In India mutually agreed terms must be established before genetic resources can be accessed (by foreign users). When granting approvals for access to genetic resources, the National Biodiversity Authority needs to ensure that the terms and conditions subject to which approval is granted secure equitable sharing of benefits arising out of the use of the accessed genetic resources, by-products, innovations and practices associated with their use. It is the National Biodiversity Authority which has the ultimate authority over the type and quantum of benefits to be shared. Although access is granted in consultation with local Biodiversity Management Committees, the Authority is not obliged to consult with the Committees with regards to the benefits they shall receive. The Authority is due to publish official guidelines on benefit-sharing. In the meantime a working template for the sharing of monetary benefits has been developed by the Expert Committee on Access and Benefit Sharing and is being used for general guidance until official guidelines for this purpose are duly notified.

In Uganda the 2005 Regulations provide for the sharing of all benefits accruing from the collection, modification and use of genetic resources based on the principle of fairness and equity on mutually agreed terms. Guidelines set out an indicative list of direct and indirect benefits to be negotiated on a case-by-case basis.

Monitoring

In Brazil and the Philippines the recipient of an access permit is required to present annual reports to the competent authority. In the Philippines three certificates need to be attested and attached to the annual progress report and the recipient must also present an audited annual gross sales report to the CNAs for the calculation of the royalty.

In Australia reporting is foreseen according to the SEWPAC model contracts where the Commonwealth and when indigenous people are the access provider. Other monitoring arrangements are under development.

Indian regulation does not provide many concrete guidelines on monitoring. The Biological Diversity Rules only state that the National Biodiversity Authority shall take steps to widely publicise the approvals granted, through print or electronic media and shall periodically monitor compliance of conditions on which the approval was granted. Furthermore the rules state that the Authority shall monitor the flow of benefits. The design and implementation of the Indian Biodiversity Information System has been planned. The system would include online submission/processing and monitoring of applications, agreements and funds flow.

In Uganda the Lead Agencies are required to implement a monitoring system to track and keep record on the genetic resources accessed in the country and the extent of benefit sharing achieved. Permit holders must submit regular status reports on research and development relating to the genetic resources accessed under the permit. The information and experience gained will form the basis for review and updating the Guidelines after the first five years of implementation.

Intellectual property rights

In Brazil every patent application in relation to an invention built on genetic resources needs to declare whether access to the genetic resources concerned was in accordance with the laws. Brazilian legislation allows for the suspension or cancelling of patents in case of non-compliance with the ABS legislation, but traditional knowledge cannot be protected through patents.

In Uganda intellectual property rights with respect to products or processes related to traditional knowledge must not be recognised if access took place in breach of the ABS rules.

The Filipino Bioprospecting Guidelines encourage the Department of Foreign Affairs to make representations with foreign authorities on requiring disclosure of origin and presentation of Bioprospecting Undertakings (permits) in patent applications.

IPR legislation in India has a strong link to the ABS provisions. Indian Patents Act establishes a framework in which both oral and written traditional knowledge are protected. Patents applications must disclose a number of information related to genetic resources and traditional knowledge and can be denied or revoked if they do not disclose or wrongly mention the source of geographical origin or if the invention is anticipated having regard to the knowledge available within any local or indigenous community in India or elsewhere. In addition, the Protection of Plant Varieties and Farmers' Rights Act foresees the protections of farmers and plant breeders' rights over the genetic resources they have developed and improved over many generations. This Act is a retro-active way of allocating benefits as it is not based on prior informed consent and mutually agreed terms.

Art 49(a) of the Swiss Patent Law contains an obligation to disclose the source of genetic resources and traditional knowledge used in an invention when a patent application is filed, provided the invention is directly based on these resources. If the patent applicant does not provide the information relating to the indication of source, the Swiss Federal Institute of Intellectual Property will set a deadline for the applicant in order to provide the lacking information. If the information is still not provided at the end of that deadline, the patent will not be granted.

Inventories and depositaries

In Uganda the competent national authority (i.e. the UNCST) must maintain a national reference file where indigenous and local communities and any other interested parties may deposit records of knowledge associated with genetic resources. Indigenous and local communities have exclusive rights over their traditional knowledge and only they may surrender it to the UNCST.

In the Philippines users are required to deposit all voucher specimens with the National Museum of the Philippines and all living specimens in mutually agreed depositaries.

In Australia transparency is ensured through the Genetic Resources Information Database (GRID) which provides a low-cost mechanism or 'virtual' certificates of origin and evidence of legal provenance. The legislation encourages that commercial permit requirements place samples, at the end of the research, into collections or museums (e.g. BioResources Library).

In India a Traditional Knowledge Digital Library which collects and stores information on prior art has been created. This is an online-resource which documents information on traditional knowledge related to medicinal plants and their uses. As it helps to establish prior art for patent searches, the Digital Library may help to direct the flow of benefits arising from the use of these resources to the source community. However, despite access and non-disclosure agreements between the international patent offices and the Indian government, there is no guarantee that the knowledge in the TKDL will truly be respected and protected.

Enforcement

Enforcement in some countries appears to have been quite strict. In Brazil for instance, the competent authorities have allegedly been imposing substantial fines since the end of 2010 on cosmetics, pharmaceutical and other companies suspected of violating ABS legislation. In Brazil the permit might be suspended and sanctions may be imposed if the permit is misused.

Often enforcement rules are rather general and lack operational detail. The Filipino 2005 Bioprospecting Guidelines for instance encourage the Department of Foreign Affairs, through its Embassies and Missions abroad, to report any breaches of Bioprospecting Undertakings (BUs) to the CNAs and to make representations with foreign authorities on: preventing biological resources from entering countries without a BU; requiring disclosure of origin and presentation of BU (access permits) in patent applications; and, facilitating enforcement of claims against collectors or commercialising entities.

In Australia permit variations, transfers and penalties for breach of conditions are governed by Regulation. The current penalty for non-authorized access in Commonwealth areas is 50 penalty units. Very few cases of non-compliance have been recorded, and the number of permit applications is rising.

The Indian State can take action against parties who have not adhered to India's rules of prior informed consent and mutually agreed terms. India has fought high profile and high cost intellectual property rights cases, however is now tending towards challenging patents through less resource intensive methods of pre-grant opposition.

7.2 User-side legislative and policy measures

Following the adoption of the Protocol, the competent national authority in Australia is currently preparing appropriate user-side measures. It is envisaged that the future legislative framework would introduce a cover-all offence of using foreign genetic resources without prior informed consent or mutually agreed terms, and authorise the designated checkpoint to oversee compliance with foreign country user legislation.

Switzerland has taken a number of legislative and other measures concerning the use of genetic resources from other countries. The patent law contains an obligation to disclose the source of genetic resources and traditional knowledge used in an invention when a patent application is filed, provided the invention is directly based on these resources. Besides this legal norm, other non-legal measures have been adopted. (e.g. 'Access and Benefit Sharing – Good Practice for academic research on genetic resources', Swiss Academy of Sciences).

The other countries studied have not put into place user-side measures.

8 COMPETENCES OF THE EU AND MEMBER STATES WITH REGARD TO PROTOCOL OBLIGATIONS

The operational provisions of the international ABS regime established by the Nagoya Protocol touch on several areas under EU competence and will become relevant for existing legislation, particularly in the fields of research, external trade and the internal market.

Chapters 3, 4 and 5 have provided an analysis of Protocol provisions most relevant to this study and an overview of existing EU and national legislation available for or potentially affected by the Protocol's implementation. This showed that the EU currently has only a limited range of ABS-relevant legislative provisions, only one of which explicitly addresses Article 15 of the CBD.³³ However, several EU policies, legislation and parts of the *acquis* are potentially affected by future implementation measures.

This chapter outlines general issues for implementation related to EU competence, subsidiarity and proportionality (section 8.1) before considering, in broad terms, EU competence in policy areas to which the Protocol is particularly relevant (sections 8.2 to 8.8). It should be noted that the overview provided here on EU competences is broad and general. Whether the EU has competence for adopting EU-level measures to implement the Nagoya Protocol can only be analysed in view of the concrete (system of) EU-level implementing measures eventually proposed by the Commission. This is beyond the scope of this study.

8.1 General considerations

The Council of the EU authorised the Commission in 2009 and again in 2010 to participate in the Nagoya Protocol negotiations on behalf of the Union with respect to matters falling within Union competence (CEU, 2011). Art 175(1) EC (now Art 192(2) TFEU), the environmental competence norm, in conjunction with Art 300(1) EC (now Art 218(1) TFEU) (on external competence for the conclusion of international agreements) provided the legal basis for the conduct of negotiations by the Commission (CEU, 2009).

The negotiating directives issued by the Council recognised that the Protocol's operational provisions would affect several areas under EU competence. These include environment, public health, common commercial policy, customs cooperation, free movement of persons, agriculture, approximation of laws, development cooperation and research and technological development. Nearly all of these are areas of shared competence between the Union and the Member States, as defined in the Lisbon Treaty. The only area explicitly excluded from the Commission's negotiating mandate was traditional knowledge associated with genetic resources held by indigenous and local communities, which was directly handled by the Member State holding the Presidency of the Council (CEU, 2009).

Following the Protocol's adoption, two questions need to be addressed:

³³ Directive 98/44/EC on the legal protection of biotechnological inventions.

- the extent of the EU's duty, under international law, to take implementation measures itself as compared to delegating responsibility for such measures to Member States; and
- the internal division of competences between the EU and Member States for implementation.

As a matter of international law, the division of competences between the Union and its Member States is an internal question for the EU. According to Art 34(2) CBD, the EU, as a regional economic integration organization that is a Contracting Party to the Convention, is also entitled to become a Party to its Protocols. If it were to do so without any of its Member States being a Party it would be bound by all the obligations arising from the Protocol. Since the Council, in its above-mentioned decisions, has recognised that the Protocol is to be regarded as a mixed agreement from the perspective of EU law, the Union cannot consent to be bound by the Protocol before at least one or more of the Member States have also expressed their consent to be bound, either prior to the Union or at the same time. Art 34(2) CBD further provides that where a regional economic integration organization becomes a Contracting Party together with one or more of its Member States, "the organization and its member States shall decide on their respective responsibilities for the performance of their obligations" under the Protocol. In its instrument of approval, according to Art 34(3) CBD, the EU shall declare the extent of its competence with respect to the matters governed by the Protocol. This declaration of competence, whose substance is an internal matter for the Union, serves to inform the other Parties of the division of competences between the EU and the Member States, so that the Parties to the Protocol are fully aware of who is responsible for the performance of the various obligations and exercise of the rights arising from the Protocol. Since the legal position may evolve depending on developments in the internal law of the EU, the same provision of the CBD puts an obligation on the Union to "inform the Depositary of any relevant modification in the extent of [its] competence" that may occur after it has become a Party.

It results from these provisions that it is necessary for the EU and the Member States to agree on the internal division of competences between them before ratifying the Protocol. This agreement shall be formalised in the declaration of competence that is to be included in the Union's instrument of approval. Such declaration of competence is normally annexed to the Council Decision authorising approval that is adopted pursuant to Art 218(6) TFEU. The Commission's proposal for such a decision shall therefore include a draft declaration of competence. Since the entry into force of the Lisbon Treaty, the European Parliament's consent is required for the Council to be able to adopt decisions concluding international agreements covering fields to which the ordinary legislative procedure applies, as is the case for environmental agreements referred to in Art 191(4) TFEU.

With regard to the internal division of competence, Articles 2-6 of the Treaty on the Functioning of the European Union (TFEU) specify categories and areas of Union competence. Where the Treaties confer shared competence in a specific area, both the Union and the Member States may legislate and adopt legally binding acts in that area but the Member States may only exercise their competence to the extent that the Union has not exercised its own.³⁴ In areas which fall outside the scope of EU competence, it will be for

³⁴ Art 2(2) Treaty on the Functioning of the European Union (TFEU), OJ C 115/129 of 9.5.2008.

the individual Member States to adopt national rules for the full implementation of the Protocol, for which they will share responsibility with the Union. The division of competences is discussed in detail below for those areas considered particularly relevant in relation to the Protocol, including research, technological development and industry (8.2); internal market and intellectual property rights (8.3); external, common commercial policy and customs union (8.4); environment (8.5); agriculture (8.6); forestry (8.7) and other areas of competence, including development aid and justice (8.8).

The exercise of the EU's legislative competence is subject to Art 5(1) TEU which provides that:

- the limits of Union competence are governed by the principle of conferral;³⁵ and
- the use of Union competences is governed by the principles of subsidiarity and proportionality.

The principles of subsidiarity and proportionality provide criteria to determine the most appropriate division of competences (Foster 2009). Deciding what aspects of implementation should be centrally determined at EU level and what aspects are better left to the individual Member States involves intricate issues of political judgement based on the relevant Treaty provisions.

According to Art 5(3) TEU the principle of subsidiarity implies that “in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.” Further guidance is laid down in the Protocol on the application of the principles of subsidiarity and proportionality annexed to the Treaties, which also provides for the involvement of national parliaments in ensuring compliance with the principle of subsidiarity. Art 5 of this Protocol requires the Commission to provide, in its legislative proposals “a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality”, which shall, *inter alia*, substantiate “the reasons for concluding that a Union objective can be better achieved at Union level”. But, ultimately, it falls on the European Parliament and Council, with possible input from national parliaments in accordance with the specific procedure laid down in the above-mentioned Protocol, and subject to review by the Court of Justice of the EU, to appreciate the merit and validity of those reasons. There is no hard-and-fast legal rule governing this question.

Legislative action at EU level is usually deemed to be justified under the principle of subsidiarity where:

- The transnational aspects of the matter at hand cannot be satisfactorily regulated by the individual Member States;
- Either no action by the Union or action by individual Member States conflicts with specific Treaty requirements; and

³⁵ That is, the EU can only act to the extent that competences have been conferred on it to do so.

- Where Union action provides clear benefits over national action.³⁶

In the following sections of this chapter, we shall examine successively the different fields of Union competence which are related to matters falling within the scope of the Nagoya Protocol.

8.2 Research, technological development and industry

Research activities, whether commercial or non-commercial, are the bedrock of the Protocol. Its objective (Art 1 NP) is fair and equitable benefit-sharing arising from 'utilisation of genetic resources', which is defined by reference to research and development activities.³⁷ The Protocol's operational provisions cover a range of issues directly relevant to EU research and innovation, including frameworks for access to genetic resources, research funding, joint ventures, protection of research results through relevant intellectual property rights, scientific collaboration with provider countries and other monetary and non-monetary benefits.³⁸ Indeed, it has also been argued that a key rationale for developing the Protocol was to establish an enforceable framework of user measures to enhance legal certainty for both providers and users and reduce barriers to access to genetic resources. Thus, it has been observed that some Parties aimed at avoiding obstacles to free research and development (Kamau and Winter, 2010), rather than the protection of the environment when negotiating the Protocol.

In the area of research and technological development, the EU has competence to carry out activities, in particular to define and implement programmes, but its exercise of that competence does not prevent Member States from exercising theirs.³⁹ The Union's objective is to strengthen its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry. EU measures should specifically support efforts to permit researchers to cooperate freely across borders and enable undertakings to exploit the internal market potential to the full.⁴⁰ The EU and Member States are required to coordinate their R&D activities to ensure that national policies and Union policy are mutually consistent.

The EU has legislative powers to establish multi-annual Research Framework Programmes.⁴¹ These may also be used to leverage 'cooperation in the field of Union research, technological development and demonstration with third countries and international

³⁶ Protocol on the application of the principles of subsidiarity and proportionality (Treaty of Amsterdam) (OJ C 310/27 of 16.12.2004).

³⁷ Art 2(c) NP.

³⁸ The Annex to the Protocol sets out non-exhaustive lists of monetary and non-monetary benefits.

³⁹ Art 4.3 TFEU.

⁴⁰ Art 179 et seq. TFEU.

⁴¹ Art 186 TFEU.

organisations'.⁴² These powers could provide a basis for the EU to include ABS safeguards in conditions for the award of EU funding to research and technological development projects and to prioritise research on genetic resources that contributes to biodiversity conservation and sustainable use, particularly in developing countries. Integration of ABS requirements as a conditionality of EU-funded programmes could not be delegated to Member States.

With regard to MS research policies, the EU, according to Art 181(2) has a competence to takes measures to support coordination.

Industrial policy is classified as an area in which the Union shall have competence only to support, coordinate or supplement the actions of the Member States. Member States must work with the EU and each other to generate the conditions necessary for ensuring the competitiveness of EU industry.⁴³ The actions of the Member States and the EU should aim *inter alia* at encouraging an environment favourable to cooperation between undertakings and at fostering better exploitation of the industrial potential of policies of innovation, research and technological development. The Commission may take initiatives to promote such coordination, for example by establishing guidelines and indicators, organising the exchange of best practices and preparing the necessary elements for periodic monitoring and evaluation.⁴⁴

8.3 Internal market and intellectual property rights

The EU has exclusive competence for establishing the competition rules necessary for the functioning of the internal market⁴⁵ and shared competence for other aspects related to the internal market⁴⁶ and consumer protection.⁴⁷ Legislative acts setting forth the rules for market approval for certain products (e.g. pharmaceuticals for human health) are based on the internal market competence of the EU.

The EU also has competence, in the context of the internal market, for establishing measures for the creation of European intellectual property rights to provide uniform protection and for establishing centralised, Union-wide authorisation, coordination and supervision arrangements.⁴⁸ In 2004, the EU established a common enforcement framework aimed at harmonising Member States' legislation to ensure that intellectual property rights enjoy an equivalent level of protection across the internal market and to avoid negative impacts on consumer protection, particularly with regard to public health and safety, from

⁴² Art 180(b), TFEU .

⁴³ Art 173(1) TFEU.

⁴⁴ Art 173(2) TFEU.

⁴⁵ Art 3(1)(b) TFEU.

⁴⁶ Art 4(2)(a) and 26-27, Art 114 TFEU.

⁴⁷ Art 4(2)(f) and 169 TFEU.

⁴⁸ Art 118 TFEU.

counterfeiting and piracy.⁴⁹ More recently, the Commission introduced proposals to develop an industrial property rights strategy.⁵⁰

In the ABS context, the most relevant IPR-related measure is Directive 98/44/EC on the legal protection of biotechnological inventions (the biopatent Directive) based on the internal market provisions of the Treaty. To protect biotechnological inventions, Member States must ensure that their national patent laws conform to the provisions of the Directive.

The EU's intellectual property rights regime is further discussed below in section 9, in the context of checkpoints and monitoring requirements under the Protocol.

8.4 External action, common commercial policy and Customs union

The common commercial policy (i.e. external trade) and the customs union are a matter of exclusive Union competence.⁵¹ Although one view holds that ABS transactions are less about external trade and more about valorising genetic resources and traditional knowledge (Kamau *et al*, 2010), there are several ways in which implementation of the Protocol could impinge on EU trade-related policy areas. For example, the trade aspects of intellectual property come under the common commercial policy and the categorisation of genetic resources for imports and exports (e.g. to monitor volumes of transfers for trade purposes) would be governed by the EU Customs Code.

The TFEU provides the EU with a general external competence to negotiate and conclude agreements with third countries or international organisations, including agreements establishing an association involving reciprocal rights and obligations, common action and special procedures.⁵² These powers have already been used to develop an EU framework linking natural resource provider countries and EU Member States to combat illegal logging and associated trade.

8.5 Environment

The EU has shared competence with Member States for environmental policy, which must contribute to the objectives set out in Art 191(1) TFEU. These include the “prudent and rational utilisation of natural resources”. The Treaty also mandates environmental policy coherence across all EU policies and activities to promote sustainable development.⁵³

⁴⁹ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

⁵⁰ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - An Industrial Property Rights Strategy for Europe (COM/2008/0465 final).

⁵¹ Art 3(1)(a) and (e) TFEU

⁵² Art 216 TFEU) on international agreements.

⁵³ Art 11, TFEU: “Environmental protection requirements must be integrated into the definition and implementation of the Union policies and activities, in particular with a view to promoting sustainable development”.

The Nagoya Protocol itself – consistent with the CBD – identifies that benefit-sharing for the utilisation of genetic resources aims at contributing to the conservation of biological diversity and to the sustainable use of its components.⁵⁴ This is echoed in the EU’s directives for the Nagoya Protocol negotiation that included the need for the future ABS regime to contribute to the conservation and sustainable use of biodiversity (CEU, 2009).

The EU commitment to the Protocol’s environmental objectives is enshrined in the EU Biodiversity Strategy to 2020 and the implementation target in Target 20 (EC, 2011). The EU has already used its environmental competence to adopt legislative acts for cooperative management of Europe’s biodiversity (e.g. Birds Directive⁵⁵ and Habitats Directive⁵⁶) and shared ecosystems (e.g. the Water Framework Directive⁵⁷ and the Marine Strategy Framework Directive⁵⁸).

8.6 Agriculture

According to Art 4 TFEU, the Common Agricultural Policy (CAP) is a shared competence between the EU and the Member States.

The CAP originally strongly focused on maintaining commodity prices above a politically determined threshold on guaranteeing stable food supplies. The CAP has since been subject to several major reforms that take increasing account of the environmental impacts of agricultural production. The CAP’s current structure has two ‘pillars’. Pillar 1 is mainly used for direct payments to farmers. Pillar 2 covers the European Agricultural Fund for Rural Development (EAFRD),⁵⁹ used by Member States to support seven-year rural development programmes (currently 2007-2013). Art 39 of the EAFRD Regulation sets out requirements for implementing agri-environmental measures which support, *inter alia*, actions for the conservation of genetic resources.

Following the publication of the Biodiversity Action Plan for Agriculture (COM(2001)162 final), the EU launched a Community Programme on the Conservation, Characterisation, Collection and Utilisation of Genetic Resources in Agriculture in 2004⁶⁰ with the justification

⁵⁴ Article 1 Nagoya Protocol.

⁵⁵ Council Directive 79/409/EEC on the conservation of wild birds

⁵⁶ Council Directive 92/43/EEC on the Conservation of natural habitats and of wild fauna and flora

⁵⁷ Water Framework Directive (2000/60/EC)

⁵⁸ Marine Strategy Framework Directive (2008/56/EC)

⁵⁹ Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD), available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2005R1698:20070101:EN:PDF>

⁶⁰ Council Regulation (EC) No 870/2004 of 24 April 2004 establishing a Community programme on the conservation, characterisation, collection and utilisation of genetic resources in agriculture and repealing Regulation (EC) No 1467/94, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:162:0018:0028:EN:PDF>

of highlighting the importance of genetic diversity for the sustainable development of agricultural production and rural areas. The Programme promotes genetic diversity, information exchange and close coordination between Member States and between the Member States and the Commission for the conservation and sustainable use of genetic resources in agriculture.

8.7 Forestry

Forestry is mainly a competence of the Member States, consistent with the principle of subsidiarity. Nevertheless, several EU policies affect forestry directly or indirectly. These include the CAP, cohesion policy, common commercial policy as well as environmental policies (e.g. nature protection, air quality or climate change). For these reasons and in the light of its international commitments, the EU has become active on forestry-related issues to support coherence and coordinated action on forest policy across Member States.

At the international level, the EU subscribed to the FOREST EUROPE initiative⁶¹ which explicitly addressed the issue of genetic resources in 1990. Resolution 2 referred to general principles and called for the implementation of a functional but voluntary international cooperation instrument to address *in situ* and *ex situ* methods for genetic diversity conservation, monitoring and exchanges of reproductive materials.⁶² Negotiations on a legally binding pan-European agreement on forests are currently under way and likely to address the sustainable use of genetic resources.

In 1999, the EU adopted Directive 1999/105/EC covering the use of reproductive material in forestry within the framework of the CAP, more specifically based on its responsibilities in the area of plant health.⁶³ The Directive refers *inter alia* to the approval and marketing of recognised reproductive material, including the development of national registers and development of a Community list to facilitate tracing, including from third countries.

At EU level, the CAP offers a range of opportunities to finance forestry under Pillar 2, including forest-specific measures to foster competitiveness of the sector and improve environmental conditions. DG Agriculture is responsible for improving coordination of forestry-related measures across Member States via the EU Forest Strategy (Council Resolution 1999/C 56/01)⁶⁴ and the related EU Forest Action Plan (COM(2006) 302 final). These refer to the implementation of *in situ* and *ex situ* measures on the conservation of forest genetic resources, though without quantifiable objectives and binding commitments.

⁶¹ Former Ministerial Conference on the Protection of Forests in Europe, a pan European Initiative which led to the release of nineteen non-binding resolutions.

⁶²

http://www.foresteurope.org/filestore/foresteurope/Conferences/Strasbourg/strasbourg_resolution_s2.pdf

⁶³ Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:011:0017:0040:EN:PDF>

⁶⁴ Council Resolution of 15 December 1998 on a forestry strategy for the European Union 1999/C 56/01, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:1999:056:0001:0004:EN:PDF>

8.8 Other areas of competence

In its **development cooperation** policy, based on Art 208 TFEU, the EU has increasingly integrated an environmental dimension, especially since the 1992 UN Conference on Environment and Development in Rio. Development cooperation is an area in which the Union has competence to conduct a common policy to complement and reinforce the national development cooperation policies of the Member States. The EU's policy in the field of development cooperation is to be conducted within the framework of the general principles and objectives of the Union's external action, as laid down in Art 21 TEU. These objectives specifically include "foster[ing] the sustainable economic, social and environmental development of developing countries" (Art 21(2)(d) TEU) and "help[ing] develop international measures to preserve and improve the quality of the environment and the sustainable management of global natural resources, in order to ensure sustainable development" (Art 21(2)(f) TEU). Especially the latter objective – which encompasses the conservation and sustainable use of genetic resources worldwide – is directly relevant to the implementation of the Nagoya Protocol. Art 209(2) TFEU, in conjunction with Art 21(2)(f) TEU, clearly provides a legal basis for the adoption of EU measures to support developing countries in promoting the conservation and sustainable use of genetic resources through the full implementation of the Protocol.

The objectives of development cooperation policy were further specified in 'The European Consensus on Development' adopted in 2005.⁶⁵ This joint policy statement of the EU institutions and the Member States provides that the EU "will support the efforts undertaken by its partner countries to incorporate environmental considerations into development, and help increase their capacity to implement multilateral environmental agreements." Particular attention is to be given to "initiatives ensuring the sustainable management and preservation of natural resources, including as a source of income, and as a means to safeguard and develop jobs, rural livelihoods and environmental goods and services." Specific reference is made in this context to support for the implementation of the CBD.⁶⁶ These policy objectives are reflected in the 2006 Regulation establishing the Development Cooperation Instrument (DCI).⁶⁷

Finally, some of the provisions of the Protocol relate to matters falling within the scope of **judicial cooperation in civil matters**, one of the aspects of the area of freedom, security and justice to be established under Title V of Part Three of the TFEU (the former 'third pillar'). Art 67(4) TFEU provides that the EU shall facilitate access to justice, in particular through the principle of mutual recognition of judicial decisions in civil matters. Art 81 TFEU calls for the development of judicial cooperation in "civil matters having cross-border implications", including through the adoption of measures for the approximation of the laws and

⁶⁵ Joint statement by the Council and the representatives of the governments of the Member States meeting within the Council, the European Parliament and the Commission on European Union Development Policy, available at: http://ec.europa.eu/development/icenter/repository/european_consensus_2005_en.pdf

⁶⁶ *Ibid.*, para. 75.

⁶⁷ Regulation (EC) No 1905/2006 of the European Parliament and of the Council of 18 December 2006 establishing a financing instrument for development cooperation, in particular Art 13(2)(b), available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1905:EN:NOT>

regulations of the Member States. Specific legislative competence is conferred on the European Parliament and Council for the purpose of adopting measures aimed at ensuring, *inter alia*, the mutual recognition and enforcement of judgments, the compatibility of the rules applicable in the Member States concerning jurisdiction of courts and conflict of laws, and effective access to justice. These competences may be relevant for the implementation of certain provisions of the Protocol, especially Art 18 NP, which require Parties to take measures in these areas in order to facilitate the enforcement of mutually agreed terms.

9 IDENTIFICATION AND ANALYSIS OF OPTIONS FOR IMPLEMENTATION

The following section presents different options on how the EU could implement the Nagoya Protocol. This part describes them and discusses some of the legal issues involved; Chapter 11 then describes their impact.

In the following we discuss first the scope of a future EU ABS regime (section 9.1). This is followed by a discussion of options for the EU to take in its capacity as a provider of GR/TKaGR; while the EU is primarily a user of GR/TKaGR and not a provider, some MS are providers and hence the EU needs to consider how to deal with this issue (9.2). This is followed by the discussion of options on EU user compliance measures (9.3). Separate sections discuss bilateral agreements (9.4) and supplementary measures (9.5), which are relevant for both a user and provider context.

9.1 Scope of the future EU ABS regime

The future EU framework needs to take account of the Protocol's substantive, temporal and geographic scope. Issues related to scope were some of the most complex aspects of the Protocol negotiations. The three most challenging questions related to the definition of genetic resources (i.e. the degree to which biological resources in the broad sense are also covered); the regime's application to derivatives and biotechnology; and its temporal scope (i.e. whether the Protocol is applicable retroactively).

The following sections summarise the relevant provisions of the Protocol, and highlight where unresolved issues or ambiguities remain following the Protocol's conclusion, indicating the EU position during the negotiations where relevant. Some of these issues will be re-visited during the later discussion of concrete implementation options.

9.1.1 *Definition of genetic resources*

The Nagoya Protocol does not define "genetic resources". However, it does contain a definition of the term "utilization of genetic resources". According to Art 2 (c) NP the "utilization of genetic resources" means to "conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention".

Article 2 CBD defines "genetic resources" as "genetic material of actual or potential value". It further defines "genetic material" as "any material of plant, animal, microbial or other origin containing functional units of heredity". Biological resources, in turn, are according to Art 2 CBD "[...] genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity".

Genetic resources can thus be thought of as a subset of biological resources: its genetic components are sought when accessing biological material for its genetic information.

Current national practice on definitions is variable, with no emerging consensus (MED New Zealand, 2011). Within Member States, different practices may also lead to ambiguity: in France, for example, some Overseas Territories' frameworks refer to "biological resources", whereas its emerging national framework focuses specifically on genetic resources (see country study, Annex II).

The Nagoya Protocol negotiations focused on whether the treaty should apply to biological resources, explicitly cover genetic and biological resources, or be restricted to genetic resources. The agreed text incorporates the third and narrowest of these options. This reflects the user countries' preference, including that of the EU, that the Protocol should cover genetic resources within the scope of Art 15 CBD, rather than the broader categorisation which potentially covers biological resources as commodities (Yun, 2010).

In terms of implementation, the EU has only a limited number of choices. From a legal point of view, it could, if it wanted, go beyond the Protocol's narrow definition at least in user compliance legislation; however, there is no obvious reason for doing so. Applying a broader definition in user compliance legislation would impose additional burdens on EU actors when using resources from abroad. Moreover, the definition used in EU legislation should be harmonised to the extent feasible with provider country legislation. Problems might arise if the EU or the Member States were to use a broader definition than provider countries (e.g. if provider countries only issue certificates of compliance for access to genetic resources, but the EU or its Member States require users to submit such certificates wherever biological resources are used).

Using a broader definition than genetic resources in EU legislation might also create legal uncertainty with regard to Member States' regulations on access to "biological resources" (including but not limited to protected species) under nature conservation or other legislation. Future legislation should therefore adopt the "genetic resources" terminology used in Art 2 of the Protocol's text.

9.1.2 Genetic resources to which the Protocol applies

Future legislation should also be clear about what genetic resources it covers. This aspect will also have repercussions on the way that EU rules applying for EU users of genetic resources and for the EU as a provider need to be formulated. Thus, some issues relating to scope will also be discussed more in detail in the sections below.

Several specific limitations of the scope of the Nagoya Protocol are of overarching importance: limitations on the geographic scope of the Protocol, the priority of existing specialised ABS regimes such as the ITPGRFA, the application of the NP to genetic resources acquired after the entry into force of the CBD, but before the entry into force of the Protocol, and the situation of *ex situ* resources not acquired in line with the CBD.

Substantive scope of the Protocol

With regard to the substantive scope of the Protocol, two categories of GR require special attention, those from areas beyond national jurisdiction and those subject to a specialised ABS regime.

Genetic resources from areas beyond national jurisdiction: Whether to include genetic resources from areas beyond national jurisdiction into the Protocol's scope was an issue during the negotiations (Buck and Hamilton, 2011). The Protocol, according to Art 3, applies to genetic resources within the scope of Art 15 of the CBD, i.e. to genetic resources over which states exercise sovereign rights (Buck and Hamilton, 2011). As set forth in Art 3 and 4(a) CBD, this is only the case for genetic resources found within the limits of national jurisdiction. This means that the Protocol does not apply to genetic resources in areas beyond national sovereignty or jurisdiction, notably the high seas or Antarctica (Buck and Hamilton, 2011). Options for a future legal regime for marine genetic resources in the high seas are being studied in separate fora (see Box 9.1).

Box 9.1: ABS discussions outside the NP

Researchers are not only interested in terrestrial, but also in marine GR, notably micro-organisms. Micro-organisms living, for example, on the ocean floor often have adapted to extreme conditions. The same is true for Antarctic genetic resources, for which there is growing research interest. Countries have diverging views, however, on whether marine and Antarctic GR and related ABS require regulation. Like in the NP negotiations, developing countries are the ones to push for a BS mechanism for such resources.

In principle, ABS concerning such GR could be regulated under existing international agreements, notably the United Nations Convention on the Law of the Sea (UNCLOS) and the Antarctic Treaty System (ATS).

UNCLOS establishes a comprehensive legal order for the seas and oceans. Currently, discussions on marine GR take place within several working groups. The Ad Hoc Open-ended Informal Working Group on marine biological diversity beyond areas of national jurisdiction in June 2011 recommended that the UN General Assembly initiate discussions on biodiversity beyond national jurisdiction under UNCLOS. These should address the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction “including through the implementation of existing instruments and the possible development of a multilateral agreement under the United Nations Convention on the Law of the Sea”. The process should address conservation, sustainable use, equitable BS, capacity-building and transfer of marine technology.⁶⁸

The ATS consists of several international agreements, including the Convention on the Conservation of Antarctic Marine Living Resources (1980). GR and related ABS have been discussed under the ATS, so far without a firm result.

⁶⁸ Recommendations of the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction and Co-Chairs' summary of discussions, Document A /66/119, 30 June 2011

It would, hence, be a wise decision for the EU not to pre-empt any decisions in these other fora. Moreover, Art. 10 of the Protocol states that parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism in order to address situations in which it is not possible to grant or obtain prior informed consent. This is the case with GR beyond national jurisdiction, as these GR are not within the sovereignty of any specific state and thus no one can grant PIC (IUCN, 2012, 24). In order not to pre-empt further negotiations either within the NP framework or outside it, future regulation in the EU should, in principle, exclude resources from the high seas or Antarctica. This could be done by referring to genetic resources within the scope of the Protocol, or, preferably, by explicitly excluding from its scope genetic resources from the high seas or Antarctica. An exception could be made when it comes to monitoring the utilisation of such resources. Monitoring would not pre-empt any decisions to be taken in other fora or under the Protocol in the future, but would rather inform and facilitate them.

Genetic resources subject to a specialised ABS regime: Art 4(4), 2nd sentence of the Protocol holds that where a specialized ABS regime that does not run counter to the objectives of the Nagoya Protocol exists, the Protocol does not bind the parties to that specialized regime. The most important specialised ABS regime currently in place is the system of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The EU and its member states are parties to the ITPGRFA, and to the extent that the ITPGRFA covers certain genetic resources are thus bound by that treaty rather than the Nagoya Protocol. This could be stated as a general aspect of the scope of EU legislation, but will also have to be taken into account when devising EU measures on non-compliance with provider state's ABS legislation. No double burdens should be imposed on those utilising genetic resources that are under the ITPGRFA and the EU only needs to take non-compliance measures relating to genetic resources under the NP.

Box 9.2: The ITPGRFA multilateral ABS system

The ITPGRFA was adopted in 2001 and entered into force in 2004. According to Art 1 ITPGRFA its objectives are “the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the CBD, for sustainable agriculture and food security.” Different from the Nagoya Protocol, which relates to genetic resources in general, the ITPGRFA only focuses on plant genetic resources for food and agriculture (Art 3 ITPGRFA).

As PGRFA have frequently been developed by breeders and farmers in many countries over extended periods of time, the ITPGRFA follows a multilateral approach towards benefit-sharing rather than pursuing the bilateral one underlying the Nagoya Protocol and the CBD. Benefit-sharing under the ITPGRFA is done through the Multilateral System for Access and Benefit-sharing established by Art 10(2) ITPGRFA. The Multilateral System is to facilitate access to genetic resources of major food crops and forage species and ensure the fair and equitable sharing of the benefits arising from the utilization of these resources. The crops that belong to the Multilateral System are listed in Annex I ITPGRFA (Art. 11(1)); they are included under the condition that they are under the management and control of a contracting party or in the public domain. Global staple crops such as wheat, maize, rice, lentils and beans are all included in the list in Annex I. Moreover, the crops contained in the *ex situ* collections of the International Agricultural Research Centres of the Consultative

Group on International Agricultural Research (CGIAR) have been included in the Multilateral System according to Art 11(5) ITPGRFA.

In practical terms, countries need to notify to the ITPGRFA Secretariat *ex situ* collections that they want to become part of the ITPGRFA. These are listed on the ITPGRFA website;⁶⁹ however, not all parties have notified their collections.⁷⁰ Access to these resources is, as set forth by 12(4) ITPGRFA, on the basis of a standard material transfer agreement (SMTA) which fulfils certain conditions defined in Art 12(3) ITPGRFA.⁷¹ The SMTA is used wherever an *ex situ* collection provides a PGRFA from the Multilateral System to a third party. While the SMTA also contains clauses on non-monetary benefit-sharing, it stipulates that in the event a product containing material obtained from the Multilateral System is commercialised and no longer available to others for research and breeding purposes, a defined share of the sale revenues must be paid to the Benefit Sharing Fund operated under the ITPGRFA system; voluntary payments are encouraged in other cases where PGRFA from the system are used. The Benefit Sharing Fund supports projects to conserve and enhance agricultural biodiversity. However, so far hardly any payments from benefit-sharing have been received.⁷²

In terms of monitoring, the SMTA contains a reporting duty for the recipients of material to the Governing Body of the ITPGRFA, which has decided that recipients must report annually. Moreover, some databases, such as the EURISCO catalogue, which provides information on *ex situ* resources in the EU, indicate whether a certain genetic resource is included in the Multilateral System.

Moreover, the World Health Organisation (WHO) has recently developed a new framework entitled “Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (PIP Framework)”.⁷³ It includes two legally binding standard material transfer agreements for regulating ABS between the provider of influenza viruses and institutions within the “Global Influenza Surveillance and Response System (GISRS)” as well as between the WHO and third parties respectively. However, it is not entirely clear whether the PIP Framework qualifies as a specialised instrument in accordance with Article 4(4) NP (IUCN 2012). The EU should thus consider if and how to take account of the GISRS framework in its legislation.

The following table provides an overview of the different categories.

Table 9.1: Substantive scope of the NP

⁶⁹ At <http://www.planttreaty.org/inclusions>

⁷⁰ ITPGRFA, Report on the Implementation of the Multilateral System of Access and Benefit-Sharing, IT/GB-4/11/12, Fourth Session of the Governing Body, Bali, Indonesia, 14 – 18 March 2011

⁷¹ The text of the SMTA is available at <http://www.planttreaty.org/content/what-smta>

⁷² ITPGRFA, Reviews and Assessments under the Multilateral System, and of the implementation and operation of the Standard Material Transfer Agreement, IT/GB-4/11/13, Fourth Session of the Governing Body, Bali, Indonesia, 14 – 18 March 2011

⁷³ <http://www.who.int/influenza/pip/en/>

	Legal status	Relevance for EU
Plant GR for food and agriculture that are part of the ML of the ITPGRFA	Not covered by NP	<ul style="list-style-type: none"> • User compliance measures cannot extend to such resources • Monitoring of the utilization of such genetic resources not obligatory, and probably not required because done under the ITPGRFA • PGRFA should not be covered by ABS legislation of the EU/MS as providers
GR access beyond the scope of national jurisdiction (high seas, Antarctica)	Not covered by NP	<ul style="list-style-type: none"> • User compliance measures not to extend to such resources • Monitoring of the utilization of such genetic resources not obligatory, but may be expedient in light of potential further development of specialised ABS regimes for such spaces or Art 10 negotiations under NP
GR included in PIP Framework	Unclear	<ul style="list-style-type: none"> • EU should consider whether to exclude them from scope of legislation

Temporal scope of the Protocol

Certain limitations on which genetic resources are covered also result from the temporal scope of the Protocol which was another contentious issue during the negotiations. Obviously, the Protocol applies to genetic resources and associated traditional knowledge accessed and utilised after its entry into force.

However, biodiversity-rich developing countries preferred the Protocol to have retroactive effect, that is, to also apply to genetic resources that were accessed and used before the entry into force of the Protocol. Options considered by negotiators included four possible scenarios with retroactive effect, namely that the Protocol should:

- Apply to genetic resources accessed before the entry into force of the CBD;
- Apply to genetic resources accessed before the Protocol if no benefit-sharing agreement existed according to the CBD requirements;
- Apply to continuing and new uses of genetic resources and/or traditional knowledge associated with genetic resources accessed before the CBD; and
- Apply to traditional knowledge associated with genetic resources accessed before the Protocol (Kamau *et al.*, 2010).

The Protocol now contains no explicit provision on temporal scope. This reflects the EU's negotiating position along with that of other industrialised user countries (IEED, 2010). The Council noted in 2010 that "the operational provisions of the Protocol do not apply to pre-Protocol acquisitions of genetic resources. Nothing in the Protocol establishes the intention to provide for retroactive application. On the contrary, the key provisions (Art. 4, 5 and 12) all relate to genetic resources provided by a Party to the Protocol. Logically, this cannot apply to genes that have been acquired prior to the Protocol's entry into force".⁷⁴ Contrary views have been taken by other commentators (e.g. Nijar, 2011).

Generally, the NP is a Protocol to another international treaty, the CBD, which also contains rules for access and benefit-sharing and to which the NP contains numerous links. Any interpretation of the NP thus also needs to take account of the relevant rules of the CBD. Thus, three time periods should be distinguished: the time before the entry into force of the CBD, the time after entry into force of the CBD, but before the entry into force of the NP ("interim period") and the time after the entry into force of the NP. Moreover, it is also useful to distinguish between access and benefit-sharing.

GR accessed before entry into force of the CBD

Concerning GR **accessed** before the entry into force of the CBD, Article 28 of the Vienna Convention on the Law of Treaties (VCLT) establishes that unless a different intention appears from a treaty or is otherwise established, a treaty "does not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of entry into force of the treaty with respect to that party". Before the entry into force of the Convention on Biological Diversity, international law did not unambiguously support eventual sovereignty or benefit-sharing claims of countries where genetic resources were collected. Thus, GR accessed before the entry into force of the CBD cannot *ex post* be made subject to any PIC requirements in the sense of the Protocol⁷⁵ and Parties have no legal obligations from the Protocol to take any user compliance measures in that regard.

Concerning **benefit-sharing**, several commentators opine that Art 28 VCLT would allow interpreting the Protocol to mean that benefit-sharing is required for a "new" utilisation of existing genetic resources or a utilisation continuing after the entry into force of the NP, as a "new" utilisation is not a fact that took place or a situation that ceased to exist before the entry into force of the NP (Winter and Kamau, 2012; Meienberg, 2011; Nijar 2011). However, Art 3 NP stipulates that the NP applies "to genetic resources within the scope of

⁷⁴ Council of the European Union (DS 1803/10 dated 12 November 2010), cited in Meienberg, 2011.

⁷⁵ With regard to *ex situ* collections this view is implicit in several CBD COP decisions. For example CBD Decision IV/8, para. 2 of 1998 requests the collection of certain information relating to "ex situ collections which were acquired prior to the entry into force of the Convention on Biological Diversity and which are not addressed by the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization to help the inter-sessional meeting to make recommendations to the fifth meeting of the Conference of the Parties for future work on resolving the issue of such ex situ collections, with due regard to the provisions of the Convention" and CBD Decision V/26, section C confirms this decision and sets forth details on the information to be collected. The fact that a recommendation needs to be made on those *ex situ* collections implies that they are not covered by existing rules of the CBD.

Article 15 of the Convention and to the benefits arising from the utilization of such resources”. Art 15 CBD, in turn, does not indicate any intention of the Parties to the CBD to include in the scope of the CBD genetic resources accessed and utilise before the entry into force of the CBD. This in turn means that in line with Art 28 VCLT, the CBD does not apply retroactively to such GR, and hence they are not within the temporal scope of the NP, either. The NP provisions on benefit-sharing therefore do not extend to these resources; however, the EU could encourage voluntary sharing of benefits for such resources.

There is no obligation for Parties to take user compliance measures with regard to GR accessed and utilised only before the entry into force of the CBD. In practice, future EU monitoring measures are likely to extend to genetic resources acquired before the entry into force of the Convention as there is often no way for public authorities to *ex ante* determine when a GR was acquired; even where a user claims it has acquired a GR before the entry into force of the CBD an authority may need to double-check this claim.

GR accessed in the interim period in line with the CBD

The same arguments do not necessarily apply for the interim period after the entry into force of the CBD and before the entry into force of the NP. Again, it is useful to distinguish between access and benefit-sharing.

With regard to **access**, Art 6(1) NP states that PIC is to be given by the Party providing such resources “that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention.” This clause by its wording provides for two different possibilities on *who* can grant PIC, either “the country of origin” of a GR or “a Party that has acquired genetic resources in accordance with the Convention”. The first alternative is clear; the second one begs the question when precisely a GR was “acquired in accordance” with the Convention. The same clause appears also in Art 5(1) and 23 NP as well as Art 15(3) CBD, but none these makes explicit what is meant by the formulation. It is thus necessary to take a closer look at what the CBD says on the “acquisition” of GR.

Art 15(5) CBD specifies that access to GR shall be subject to the PIC of the Party providing such resources and Art 15(4) stipulates that PIC shall be granted on MAT; from that it can be inferred that where an *ex situ* resource has been accessed in line with existing PIC and MAT requirements the *ex situ* country has “acquired” the GR “in accordance” with the Convention.⁷⁶ Conversely, a user having obtained (e.g. in 2006) a genetic resource from a country (e.g. Brazil) where ABS legislation is in place without obtaining PIC and concluding MAT must be considered not to have “acquired a GR in accordance with the Convention”.

A more difficult category is the case where a country has not adopted any ABS legislation in the interim period. For example, if a user from France had collected in 1997 a genetic resource from the Democratic Republic of Congo, a mega-diverse country and Party to the CBD⁷⁷ - but so far without ABS legislation⁷⁸ - without obtaining PIC and sharing MAT, would

⁷⁶ This interpretation is also shared by IUCN 2012, version 3.0, 96.

⁷⁷ See <http://www.cbd.int/countries/?country=cd>

he have acted in “accordance with the Convention”? This is not an easy question to answer, and the answer depends on whether one takes the CBD to establish that PIC is only required where a country explicitly requires it or unless the country explicitly declares that no PIC is required. Art. 15(5) CBD, which deals with access, stipulates that “access to genetic resources shall be subject to prior informed consent of the [...] Party providing such resources, *unless otherwise determined by that Party*” [emphasis added]. This sentence is phrased in terms of rule and exception⁷⁹: normally, PIC is required, and only exceptionally, when a Party determines otherwise, PIC is not required. A draft guide to the NP argues with regard to the identical wording in Art 6(1) NP that the formulation “suggests that PIC is mandatory unless waived by the relevant Party” and that “the general assumption that genetic resources can be accessed in such countries without any need to consult State authorities is risky”, as “the reasons might not be clear as to why a particular country does not regulate access”.⁸⁰ According to this view, GR accessed during the interim period in countries with neither ABS legislation in place nor an explicit waiver regarding PIC requirement are to be considered for the purpose of Art 6(1) to have *not* been accessed “in accordance with the Convention”⁸¹ (i.e. not in accordance with the access procedures established by the Convention). On the other hand, this reading of the access rules of the Convention and the NP does not necessarily facilitate access and hence the sharing of benefits for the utilization of GR resources, the explicit aims of the NP. Thus, the question of whether GR from a country where there is neither ABS nor an explicit waiver of PIC have been acquired “in accordance with the Convention” remains rather unclear.⁸²

What does all this mean for who can grant PIC under Art 6(1) NP? First of all, by its wording, Art 6(1) clearly does not allow anyone but the country of origin to grant PIC in cases where existing domestic ABS legislation implementing the CBD has *not* been complied with; indeed it has been observed that the identical clause in Art 15(3) CBD is aimed precisely at preventing countries with *ex situ* collections from granting PIC in such cases.⁸³ Moreover, even in cases where GR have been acquired in accordance with the CBD and transferred to an *ex situ* collection in another country, that other country cannot grant PIC and conclude MAT, if MAT previously concluded impose countervailing limitations on what can be done with the respective GR. For example, if in the above example the French user had concluded in 2006 MAT with a Brazilian authority requiring him or her to only pass on the GR under the

⁷⁸ See the list of ABS measures at <http://www.cbd.int/abs/measures/>

⁷⁹ Glowka *et al.*, 1994, 97.

⁸⁰ IUCN 2012, Version 3.0, p. 93.

⁸¹ While access to GR in those countries during the interim period is to be considered “*not* in accordance with the Convention”, given the absence of access legislation in the country of origin the users that accessed those GR would nonetheless normally not be considered to have violated any ABS rules, given the absence of any specific access rules and procedures in the country of origin.

⁸² For example the CBD guidebook by Glowka *et al.* 1994, 97 does not take a position on the matter and just argues that in order to ensure practically control over their GR, states should adopt ABS legislation.

⁸³ See Glowka *et al.*, 1994, 77f.

condition that the new user again turn to the Brazilian authorities for new PIC and MAT, France could not grant PIC.

That leaves two categories of cases: the first are cases where a GR has indeed been acquired “in accordance with the Convention”, i.e. in line with existing ABS legislation and where no MAT previously concluded prevent the *ex situ* country from providing GR to future users, or where a country has explicitly waived the right to request PIC. The second may include – arguably – cases where simply no ABS legislation existed in the country of origin at the time of access (in case one does not consider access in the absence of PIC requirements to be “not in accordance with the Convention”).⁸⁴

What is the role, in such a case, of the *ex situ* country (i.e. the country in which the GR acquired in the above cases is held *ex situ*), in granting PIC, according to Art 15(3) CBD and 6(1) NP? First of all, it should be noted that an *ex situ* country in such a situation is certainly not *obliged* to assume competences for requiring and granting PIC as whether or not to adopt PIC legislation is, according to the NP, a sovereign choice of any country. The more difficult question is whether an *ex situ* country in the situations described wanting to grant PIC is *allowed* to do so at all. One argument against that is the notion that the right to require PIC and MAT is anchored in the sovereign rights of a state over relevant genetic resources and that, if a user acquires a resource in accordance with domestic ABS legislation, those sovereign rights are not relinquished. The country of origin allows a certain limited use of the resource in the exercise of its sovereign right while the right to grant PIC is not transferred to a different country. Moreover, allowing a country other than the country of origin to grant PIC could lead to an indefinite chain of PICs being required and granted, whenever a GR is acquired in line with ABS legislation or in the absence thereof (and hence in accordance with the CBD), moved to a new country and included in a *ex situ* collection there. However, none of these arguments is conclusive: if a country in the interim period decided not to require PIC, it could be argued that that was precisely an exercise of its sovereign rights; if it had wanted to prevent other countries from granting PIC, it could have required PIC and concluded MAT preventing precisely that. Similarly, a “chain of PICs” could be ended by any country through appropriate MAT. The arguments above are also at odds with the existence of two clear textual alternatives in Art 6(1) NP. These also already exist in the CBD and have not been changed during the NP negotiations and therefore must both be taken to be meaningful and apply to certain real world situations.

However, as discussed above, while in cases of *ex situ* GR acquired in accordance with the CBD the *ex situ* state could, from the viewpoint of the CBD and the NP, grant PIC (where not barred by MAT from doing so) does not mean it has to assume that competence. Politically, it would indeed likely be controversial if the EU or any other state where resources are held *ex situ* decided to grant PIC on such resources or – even worse – request benefit-sharing. Moreover, practical difficulties would also be entailed, as distinguishing between such resources acquired before the entry into force of the CBD or not in accordance with the CBD (for which *ex situ* countries can clearly not grant PIC) and those acquired in the interim

⁸⁴ As argued above, while one interpretation of the wording of (Art 15(3)) CBD and (Art 6(1)) NP leads to the result that those GR should not be considered as having been acquired “in accordance to the Convention”, the ambiguous formulation of Art 6(1) leaves the door open to alternative views.

period and in line with the CBD will often be difficult in practice. Thus, referring users back to the countries of origin in cases of doubt would certainly be the preferable option which is also clearly in line with NP. It is also for example, the current practice under the IPEN code of conduct adopted by a large number of European botanical gardens which host huge *ex situ* collections. When a GR is requested for commercial utilisation from an IPEN member, implying a change of use as compared to the original (non-commercial) act of collecting a GR for inclusion into the collection of a botanical garden, prospective users are referred back to the country of origin of such a resources, given that the original MAT would in any case not cover such use.

With regard to **benefit sharing**, a distinction must be made between those cases where MAT has been concluded previously and cover a new or ongoing utilisation and where that is not the case.

Where MAT cover a new or ongoing utilisation, benefits must be shared in line with previously concluded MAT.

Where this is not the case, the question arises whether benefits of an on-going or new utilisation of GR acquired in the interim period must be shared. An important aspect in this respect is Art 15 CBD. Art 15(7) CBD stipulates that “[e]ach Contracting Party shall take legislative, administrative or policy measures, as appropriate, ... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources”. It could be argued from this that user countries did have already under the CBD an obligation similar to the one contained now in Art 5(1) and 5(3) NP to take measures to ensure that benefits arising from the utilisation of genetic resources are shared. If Art 5(1) and 5(3) NP are read to be as a concretisation of Art 15(7) CBD, one could make the point that the obligation in 5(1) and 5(3) NP also extends to utilising genetic resources accessed in the interim period, particularly, because Article 5(1) itself explicitly refers back to Article 15(3) and 15(7) CBD. Moreover, Art 3 states that the Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. GR accessed after the entry into force of the CBD are clearly within the scope of Art 3 of the Convention. Thus, there is much to be said in favour of the view that benefits must be shared with the country of origin when EU users utilise GR acquired in the interim period and if benefits have not already been shared in line with previously concluded MAT.

Concerning user compliance measures, future EU monitoring measures will, again, in practice also extend to genetic resources acquired in the interim period. In many cases, public authorities will not *ex ante* know when a GR was acquired; even where a user claims it has acquired a GR before the entry into force of the CBD an authority may need to double-check this claim. In contrast to what has been observed to GR acquired before the entry into force of the CBD, there are, however, also good arguments to extend the full range of user compliance measures to GR accessed in the interim period.

Summary

The different aspects of the temporal scope of the Protocol and their relevance for future EU/MS measures are summarised in the following overview. In all of these cases the challenge is not only to make clear the substantive limitations of the respective legislation within the EU, but also to consider how users of GR and competent authorities can verify in which category a GR falls.

Table 9.2: Overview of temporal scope of NP

	EU measures provider side	EU measures user side (compliance measures)
GR/TKaGR acquired before CBD		
GR and TKaGR	No right to require PIC Exclude GR from scope of EU/MS provider (access) legislation	EU not required to take compliance measures Monitoring: no obligation for EU to take EU user compliance measures, but deliberate exclusion from monitoring measures not practicable Option: Encourage voluntary BS
GR accessed post CBD and pre-NP		
Ex situ GR accessed in line with provider ABS legislation	Access: Countries where resource is <i>ex situ</i> must act in line with existing MAT; situation legally unclear where no MAT exist or existing MAT do not prevent passing on GR to new users Political and practical: Refer users back to country of origin for PIC/MAT	Benefit-sharing with countries of origin: Situation legally unclear, but Article 5(1) NP and Article 28 VCLT can be interpreted to support benefit-sharing claims for GR resources accessed in interim period and where no MAT have previously been concluded Monitoring: exclusion from monitoring measures not practicable
Ex situ GR not accessed in line with provider ABS legislation	Access: Countries where resource is <i>ex situ</i> has no right to request PIC/ conclude MAT	Benefit-sharing with countries of origin: Situation legally unclear, but Article 5(1) NP and Article 28 VCLT can be interpreted to support benefit-sharing claims for GR resources accessed in interim period Monitoring: exclusion from monitoring measures not practicable
GR accessed post NP		
Ex situ and in situ GR and TKaGR	Included in scope	

9.1.3 Definition of utilisation of genetic resources and its implications for EU measures

A further issue concerning scope is which activities involving genetic resources trigger obligations under the Protocol. This is relevant for the EU when adopting user compliance measures. The central term of the Protocol in this regard is “utilisation of genetic resources” as defined in Article 2(c). According to Art 6(1) it is access to genetic resources for their utilisation that Parties can make conditional on prior informed consent. Also, according to

Art 5(1) Protocol, it is the utilisation of genetic resources that triggers benefit-sharing obligations. Thus, the term “utilisation” has a central position in the Protocol.

With regard to utilisation, three interlinked definitions are laid down in Art 2 of the Protocol:

- “Utilisation of genetic resources” means “to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the [CBD]” (Art 2(c) NP);
- “Biotechnology” as defined in Art 2 CBD means “any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use” (Art 2(d) NP);⁸⁵ and
- “Derivative” is defined as “a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity” (Art 2(e) NP).

Thus the definition of “utilisation” is focused on R&D activities. Thus e.g. bioprospecting activities in provider countries would as such not fall under this definition if, for example, a researcher interviews indigenous healers about a plant’s properties. This is ethno-botanical research, but it does not constitute utilisation of GR in the sense of the Protocol. However, such an activity could likely be considered an utilisation of TKaGR, a term which the NP does not define. The term “utilisation” is thus more narrowly defined than in some of the discussions leading up to the adoption of the Nagoya Protocol (see for an overview IUCN, 2012, 66ff). For example, it excludes mere transport from one country to another, conservation or storage without any research component.

The inclusion in the Protocol of an explicit reference to 'derivatives' was a demand of provider countries, because the economic value of genetic resources is increasingly understood to lie not only in the genes of species, but also in the proteins that genes produce or are induced to produce (e.g. through DNA/RNA interference) and in their subsequent development into new products (e.g. for drugs or industrial enzymes) (Burton 2011). The biochemical compounds of genetic resources, once identified, can be chemically synthesised and do not require further physical access to such resources. These extracts or isolated material are the real marketable products of genetic resources and include all kinds of secondary metabolites such as gums, resins or latex (Nijar, 2011). One contribution noted that the inclusion of derivatives increased the value of the Protocol for provider countries by at least 20 fold (Buck and Hamilton 2011). It is therefore not surprising that the inclusion of derivatives was one of the most contested issues during the Protocol negotiations. The EU wanted derivatives to be excluded from the Protocol and left for negotiation in bilateral ‘mutually agreed terms’ (i.e. contracts). Whereas biochemicals that do not contain hereditary traits fall outside the term ‘genetic resource’ (and are not subject to PIC requirements), they can be captured by the term, ‘utilisation of genetic resources’ which

⁸⁵ The indication in the chapeau of Art 2 Protocol that the Protocol’s definitions apply “in addition” to the CBD’s definition is superfluous in the case of Art 2 d) as the definitions in both agreements are identical. However, it should be noted that the CBD does not use the term “biotechnology” in its main provision on ABS (Art. 15).

clearly triggers benefit-sharing duties (Tvedt and Young, 2007). In practice, many existing ABS or material transfer agreements already extended to sales or other use of derivatives of genetic resources (ten Kate and Laird, 2000).

In terms of EU implementation measures, most of the current commercial uses of genetic resources would likely be covered by the term “utilisation” as defined in the Protocol. Only specific cases raise issues. For example, in the industrial biotechnology sector genetic resources are sometimes investigated by firm “A”, which identifies certain traits of a genetic resource through biochemical research. What it passes on to other firms downstream is, however, not the genetic resource itself, but a blueprint of the genetic resource which firm “B” then re-produces synthetically (DIB, pers. comm., 2012). In this case, one might question whether firm “B” utilises the genetic resource itself; such a “blueprint” would potentially not be covered by the term “derivative” in Art 2(c) NP anymore, as this term presupposes something “physical”, i.e. a biochemical compound. However, what firm “A” does, is certainly a utilisation in terms of the NP, and thus firm “A” would have to obtain PIC on MAT from the original provider. The latter would thus be able to obtain a share of the benefits from firm “A”, rather than “B”, and is thus not left without protection, even though it may be difficult for the provider to predict all potential uses. It would be up to the original provider to make sure that it receives from firm “A” a share of the benefits that also reflects that “A” passes on research results relating to the genetic resource to “B”, and makes a profit from this transaction; obviously, the provider could also seek the inclusion of clauses on use restriction or change of use in the MAT. Indeed, the Protocol in Art 6(3)(g) states that MAT may include rules on subsequent third-party use; MAT could thus cover the entire utilisation chain of a GR to the extent it can be predicted at the time the GR is accessed, or at least a part of it.

Against that background, and given the broad range of possible uses of genetic resources, it seems advisable for the EU to integrate the “utilisation” terminology of the NP into its legislation.

9.2 Access and BS relating to genetic resources and/or associated traditional knowledge within the EU

This section deals with the implementation of the Protocol in as far as the EU is a provider of GR and TKaGR. It first provides some background on the Protocol’s history and the EU’s role as a provider (9.2.1) and then presents the relevant legal obligations contained in the Protocol (9.2.2). Subsequently, three different basic options for implementation are described (9.2.3). These are then spelt out with regard to what they would entail with regard to access to *ex situ* GR, *in situ* GR and TKaGR and related MAT (9.2.4 to 9.2.6). Finally, some measures to address Art 8(a) are briefly discussed (9.2.7) and necessary institutional provisions described (9.2.8).

9.2.1 Background

Before the adoption of the Nagoya Protocol, Art 15 CBD contained rules on access, and also mentioned that access, where granted, had to be on MAT. The legislative trend to regulate access to GR was initiated by a small number of provider states outside the EU. The

Philippines was the first country to adopt specific access rules: its first generation of legislation (Executive Order 247) created a procedure that turned out to be very long, exhaustive and costly, resulting in delay, uncertainty and high transaction costs for users and thereby frustrating basic research and bio-prospecting projects. Similar patterns were observed in other countries adopting ABS regimes (Kamau and Winter, 2009, citing country reports from Brazil, Kenya and South Africa).

Against this background, the EU's negotiating position on the Protocol focused strongly on reciprocity. It sought initially to obtain international access standards (i.e. minimum rules for application in national laws and procedures) in return for user states accepting more robust compliance measures. This was a sensitive issue for biodiversity-rich developing countries, which regarded the EU position as erring too far towards business interests and as an infringement of national sovereignty. As finally adopted, the Protocol contains in Art 6(3) some legal standards on how national access rules need to be designed. Essentially, national PIC procedures, where put in place, need to fulfil certain rule of law standards: legal clarity and certainty, fairness, transparency, effectiveness. However, the Protocol does not spell out in similar detail standards for benefit-sharing. Thus, the basic paradigm under the Protocol is the *ad hoc* bilateral negotiation between those seeking access to a genetic resource and providers. However, provider states are required to develop clear rules and procedures for the conclusion of MAT (Art 6(3)), and in this context could also set forth minimum benefit-sharing conditions and/or procedures for MAT negotiations. For example, the Indian ABS legislation foresees such minimum standards (see cases study India, Annex 2).

During negotiations, the EU also strongly supported the inclusion of provisions to facilitate non-commercial research into the Protocol (Art 8(a)). This was seen as an important element of the Protocol's delicate balancing act between valorisation of genetic resources and long-term conservation and sustainable use of biodiversity. Given the strong economic role of sectors using genetic resources in the EU, the EU position in the Nagoya Protocol negotiation was, as noted by EU officials, particularly sensitive to the potential impacts of user-compliance measures on the research and development interests of EU-users.

In the context of the NP, the EU is currently overall more a user of genetic resources than a provider. However, the EU and its MS have some GR (and to a lesser extent TKaGR) of interest to various users. Moreover, several Member States are clearly both providers and users (e.g. countries in the Mediterranean region and with Overseas Territories). Even in countries not manifestly rich in biodiversity or TKaGR *in situ* genetic resources are used in some cases. One example cited during the study was that of a small German biotechnology company using micro-organisms from the soil on its own premises to develop a marketable product (DIB, pers. comm., 2012).

While the EU does have some GR of interest to users, TKaGR appears to be much less prominent. In the EU, few communities exist that could be classified as ILCs. However, as the NP does not define the terms TKaGR or ILCs, parties have some leeway on defining these terms themselves. Our analysis of the situation in several MS suggests that France and Spain are the only countries from those studied in which TKaGR-related measures are being developed; for France this applies only to the different Overseas Territories (for a detailed

analysis, see FRB, 2011). Looking beyond these cases, ILCs also exist in the 'Nordic' states (Finland and Sweden (sharing with Norway)); arguably the Inuit in Greenland would also qualify as ILC, even though they have a very particular status under Danish and EU law. However, verifying if GR to which these communities have established rights are of interest for users and whether ILCs based in the EU hold any TKaGR are questions that go beyond the scope of this study.

Box 9.3: Traditional knowledge in Spain

In Spain, there is significant knowledge concerning the use of biological resources which is considered as 'traditional knowledge'.⁸⁶ More than 2,000 species are still used traditionally in Spain, many for medicinal and food purposes.⁸⁷ Research efforts are being undertaken to recover knowledge about, for example, the use of herbal plants, and to facilitate access to such knowledge.⁸⁸

Traditional knowledge is addressed in Art 9 of Ley 42/2007. Art 9(1) mandates that an inventory of the natural heritage and biodiversity (in the following: IEPNB) is to be established. Art 9(2) sets forth that the IEPNB is to include traditional knowledge on natural heritage and biodiversity. Art 70 of Ley 42/2007 comprises an obligation for authorities to preserve, maintain and support traditional knowledge and practices. Moreover, they must support the fair sharing of benefits arising out of the use of traditional knowledge. Art 70 also requires the establishment of inventories of traditional knowledge, to be integrated into the IEPNB. More detailed rules on the IEPNB are contained in Real Decreto 556/2011. Annex I 4.b of this Decreto specifies which type of traditional knowledge is to be included in the IEPNB and describes the information to be recorded, which includes a narrative description of the knowledge and the evaluation of the "conservation status" of the traditional knowledge, measured for example by the amount of people using it. So far, the inventory on traditional knowledge has not yet been established, while some other parts of the IEPNB are already being filled gradually.

In terms of existing regulation, access to *in situ* genetic resources within a Member State's territory is not currently regulated under EU legislation except for specific types of genetic resources from the agriculture sector and access to/ exchange of genetic resources that are associated with animal, plant or human health. At the Member State level, very few countries have access-related domestic legislation, although this is under development in at least three (France, Bulgaria and Spain).

9.2.2 Summary of obligations for provider Parties on ABS

This section provides an overview of relevant obligations for provider Parties under the NP.

⁸⁶ See for example <http://conocimientostradicionales.info>

⁸⁷ See <http://www.cbd.int/countries/profile.shtml?country=es#thematic>

⁸⁸ See for example the website of the HERBAM research project in Catalonia, <http://www.herbam.net>

There are two main cases in which the provider-related provisions of the Protocol are relevant to the EU and Member States:

- Where a Member State is the country of origin of a genetic resource, whether found *in situ* or *ex situ*, including in cases where ILCs hold established rights to such resources;
- Where ILCs within a Member State's territory hold TKaGR.

In the following, we provide an overview of the core obligations relating to access and benefit-sharing. Supplementary obligations and the way they could be implemented are discussed below in section 9.5.

In terms of core obligations, **Art 6(1)** gives the provider Party discretion to require prior informed consent (PIC) for “**access to genetic resources** for their utilisation”. Where this right is activated, the Party must, according to **Art 6(3)**, adopt appropriate legislative, administrative or policy measures that fulfil certain minimum requirements laid down in that article. Accordingly, access rules must:

- Provide for legal certainty, clarity and transparency with regard to PIC and MAT (Art 6(3)(a) and (g));
- Be fair and non-arbitrary with regard to access (Art 6(3)(b));
- Provide for a clear and transparent written decision by a competent authority, in a cost-effective manner and within a reasonable period of time, which in case access is granted and MAT are concluded also serves as evidence of the decisions taken by the provider state and needs to be passed on to the international ABS CH (Art 6(3)(d) and (e)). According to Art 13(2) a competent national authority is responsible for issuing such a decision and thus needs to be designated;
- Clarify, where applicable, the criteria and processes for obtaining PIC from ILCs or other involvement of ILCs in access to GR (Art 6(3)(f)).

Moreover, providers must make available information on how to obtain PIC (Art 6(3)(c)). This task, according to Art 13(1), is to be performed by focal points.

Basically, the requirements in Art 6(3) are rule of law and good governance standards. As such, the EU would be required to meet most of them under its own rule of law and proportionality principles anyway. Art 6(3) hence does not impose much extra-burden on the EU or the MS when implementing the Protocol. The same is also likely to be the case under the constitutional law of individual MS.

A further important article in the context of EU provider measures regarding access to GR is **Art 8(a)** NP. It requires parties to promote and encourage research that contributes to the conservation and sustainable use of biological diversity, including through simplified measures on access for non-commercial research purposes.

In addition, **Art 11** NP contains a duty to cooperate where GR are found *in situ* on the territory of more than one Party (11(1)) and/or TKaGR is shared by ILCs in several Parties (11(2)).

On **benefit-sharing and MAT**, Art 5 NP generally contains the core provisions. Accordingly, in case a country requires PIC, benefit-sharing will have to be on mutually agreed terms. However, only some of the provisions contained in Art 5 are directed at provider states and many of them concern the involvement ILCs which is discussed in the next paragraph. With regard to benefit sharing provisions to be included in MAT, Art 5(4) holds that benefits to be shared could be monetary and non-monetary and refers to a list in the Annex of the NP, which gives examples of monetary and non-monetary benefits. Further MAT-related provisions are contained elsewhere in the Protocol. Notably, Art 6(3)(g) provides that parties to MAT should be encouraged to include a dispute settlement clause, terms on benefit-sharing (including in relation to IPRs) as well as provisions determining subsequent third-party use of the relevant GR and changes of intent related to the utilisation of the GR acquired. Art. 17(1)(b) further requires parties to encourage the introduction of clauses on the sharing of information on the implementation of MAT, including through reporting requirements. Moreover Art 18(1) stipulates that parties shall encourage the inclusion of terms on jurisdiction, applicable law and/or alternative forms of dispute resolution in MAT. While the introduction of the above provisions in MAT is not compulsory, they might still inspire the EU and MS when negotiating MAT as providers (in case they decide to do so). In terms of binding rules on MAT, Art 18(2) is relevant. Accordingly, each Party shall ensure that an opportunity to seek recourse is available under its legal system in cases of MAT-related disputes. While this obligation is, in an EU context, generally likely to be more relevant regarding MAT where EU actors are users, it is not restricted to such cases. As the EU has no courts to deal with such cases – both the ECJ and the General Court have very specific mandates related to European law – such access to courts or alternative dispute resolution mechanisms will have to be ensured at the level of member states.

On the **involvement of ILCs** in decision-making on access and benefit sharing regarding both GR and TKaGR, there are several relevant paragraphs in the NP. The NP, however, does not define what TKaGR is, who ILCs are or what it means that TKaGR is “held” by them. In the EU context, these norms may be of little relevance for many MS where there are mostly no communities clearly identifiable as “indigenous” or “local”. With regard to **access** to GR, Art 6(2) stipulates that parties will have to ensure that ILCs having established rights over a certain genetic resource will either be given the right to grant PIC themselves or be involved in the decision-making on access to GR. Art 7 contains the core obligation with regard to access to TKaGR. Parties must take appropriate measures to ensure that ILCs grant PIC when TKaGR they hold is used and MAT are established. With regard to **benefit-sharing**, Art 5(2) NP requires each Party to take legislative, administrative or policy measures, as appropriate, “with the aim of ensuring” that benefits arising from the utilization of genetic resources held by indigenous and local communities are shared in a fair and equitable way with the communities concerned, where they hold established rights to such GR. Art 5(5) NP covers benefit-sharing related to traditional knowledge. Each Party is required to take legislative, administrative or policy measures, as appropriate, “in order that the benefits arising from the utilisation of traditional knowledge associated with genetic resources are shared in a fair and equitable way” with the ILCs holding such knowledge. Such benefit-sharing shall be on mutually agreed terms. This is independent of any “established rights” of the ILCs. Generally, there is a degree of overlap between Art 5(5) and 7 NP, because both deal, *inter alia*, with ensuring that benefits are shared with ILCs. Art 12(1), finally, holds that in implementing the Protocol, Parties shall take into consideration applicable ILCs’ customary

laws, community protocols and procedures with respect to traditional knowledge associated with genetic resources. Again, it is not evident that many such customary or community laws and procedures exist within in the EU and the rule is likely to be of relevance in only a few MS.

Depending on how some of these questions are answered, competent authorities will have to be designated at the EU or MS level (Art. 13 (2)). Obviously, an MS that does not require PIC does not need a competent national authority for this purpose.

MS CNAs will have to issue written evidence that PIC has been obtained, if an MS decides to require PIC. Moreover, focal points (or one EU focal point) to provide prospective users with information on procedures also have to be created (Art 13(1)).

Table 9.3: Summary of Protocol obligations relating to access and benefit-sharing for providers

Article	Core obligations on access to genetic resources and associated traditional knowledge	Applicable to GR/TKaGR
5(2)	Take measures to ensure benefit-sharing, upon MAT, with ILCs having established rights over GR	GR
5(5)	Take measures to ensure benefit-sharing arising from TKaGR, upon MAT, with ILCs holding such TK.	TKaGR
6(3)(a-e), (g)	If PIC required under 6.1, take measures for: -legal certainty, clarity and transparency; -non-arbitrary rules/procedures for access and MAT establishment	GR
6(2), 6(3)(f)	Take measures for ILCs to obtain PIC/approval & involvement for access if ILCs have the established right to grant access to GR. Set out criteria/processes for obtaining PIC/approval & involvement of ILCs for GR access	GR
6(3)(g), 17(1)(b), 18(1)	Set out procedures for establishing MAT and encourage minimum content of MAT	GR, TKaGR
7, 12(1)	Take measures aimed at ensuring PIC/approval & involvement of ILCs for access to TK associated with GR that is held by ILCs in accordance with domestic law, in accordance with domestic law take into consideration ILCs' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources	TKaGR
8(a)	Create conditions to promote and encourage biodiversity research, particularly in developing countries, including through simplified access for non-commercial purposes.	GR
12(2)	Inform users about their obligations with regard to TKaGR, with effective participation of ILCs	TKaGR
Article	Institutional provisions	Applicable to GR/TKaGR
13(1)	Create ABS focal point to share information on ABS	GR, TKaGR
13(2)	Create competent national authority to grant PIC and issue evidence of PIC/MAT	GR, TKaGR
14(2)	Provide information on permits issued to CH	GR, TKaGR

17(1)(a)	Take measures to monitor and enhance transparency on GR utilisation, including designation of checkpoint(s) to receive information on PIC and MAT at any stage of research, development, innovation, pre-commercialisation or commercialisation.	GR
Article	Supplementary obligations on access to genetic resources and associated traditional knowledge	Applicable to GR/TKaGR
8(b)	Pay due regard to emergencies that threaten or damage human, animal or plant health	GR
8(c)	Consider importance of genetic resources for food and agriculture and their special role for food security	GR
9	Encourage users and providers to direct benefits arising from utilisation of GR to biodiversity conservation/sustainable use	GR
11	Endeavour to cooperate where: GR found <i>in situ</i> on territory of more than one Party (11.1) and/or TK shared by ILCs in several Parties (11.2)	GR, TKaGR
12(3)	Support, as appropriate, the development by ILCs of community protocols, minimum requirements for MAT, model contract clauses benefits arising out of the utilization of such knowledge	GR, TKaGR
19, 20	Encourage development, update and use of: -model contractual terms for MAT -voluntary codes of conduct, guidelines and best practices and/or standards	GR, TKaGR

9.2.3 Scenarios on EU provider measures

The current situation is that in the EU a few countries (e.g. France, Spain, Bulgaria) have adopted framework legislation envisaging to require PIC/MAT but implementing measures have not yet been taken. Other countries (e.g. Netherlands) have opted for a free access policy. For the purpose of this study, in line with the relevant obligations arising from the Protocol we have identified different possible scenarios for EU action which will be further considered in the impact assessment (chapter 11).

- Option A: In Option A, the EU does nothing or, at most, takes very soft measures such as on awareness-raising or the provision of information, leaving the adoption and implementation of legally binding access measures to MS.
- Option B: In this option, the EU uses the Open Method of Coordination (OMC) to achieve a measure of coordination among MS. Thus, MS states would agree on objectives and/or procedures, and the activities and progress in each MS would be monitored.
- Option C: In this option, the EU sets minimum standards for those MS that decide to require PIC for access to their genetic resources. Thus, the EU legislation would replicate the “if... then” approach of the NP. If a MS adopts a PIC requirement, it would have to observe certain requirements on PIC and MAT set out in EU law.

These options are structured along a growing degree of EU intervention. However, under each of the options, individual Member States can decide to adopt or not adopt access legislation. In each of the options except for A, the EU could also take additional, “soft” supporting measures which are discussed in a separate section, including measures relating to Art 8(a) NP. Institutional provisions are also discussed in a separate section as they do not differ much for B and C.

Other options are theoretically feasible, but have not been considered in greater detail in this study. One such option would be an **EU wide waiver of the PIC requirement** for access to genetic resources. This would be in line with Art 8(a) NP, as researchers would have easy access not only for non-commercial, but for any purposes. Users, including those from the EU, would also benefit from the fact that they would not have to comply with any legislative requirements at all when accessing EU genetic resources. Some stakeholders have thus indeed expressed that this is their favourite course of EU action on access. On the other hand, the EU would forego the possibility to gain any benefits through MAT if it adopted an EU wide PIC waiver. In any event, this option is not further considered in this study, as some member states have already indicated that they would like to adopt a PIC requirement; therefore this option does not seem to be politically feasible and its potential economic impacts hence are not given further consideration in this study.

On the opposite side of the spectrum, the **EU could assume full competence for granting PIC and concluding MAT** for the access to genetic resources on the entire territory of the EU itself or could oblige MS to introduce a PIC requirement into their national legislation.

However, as some of the MS are almost exclusively users of genetic resources, whereas others are also providers, an approach giving MS flexibility as to which approach they consider best suited to their needs seems warranted. From the point of view of the subsidiarity principle, there is no very good argument to be found for the EU assuming full competence either. Users from MS have no considerable disadvantage if the MS they are based in requires PIC, whereas another MS does not, as sourcing of genetic resources in the EU is not normally guided by a rationale of obtaining them within the same member state. Rather, sourcing of GR is generally dominated by considerations on which genetic resource is likely to be best suited for the specific purpose of the particular user and the transparency of access legislation in provider countries. Thus, there is no compelling need to create equal competitive conditions throughout the EU.

9.2.4 Option A: No or minimal EU action

In this option, the EU would refrain from taking any provider-side measures, giving maximum freedom to Member States. For example, a Member State could choose to adopt measures for biodiversity-rich overseas territories but not for the mainland.

This option potentially leads to different situations in different member states, and possibly even within some MS. In several Member States, competence for determining access lies with sub-national authorities. Whilst some Member States (e.g. Spain) have an overarching legislative framework, which could support basic consistency of approach, others do not, but have already identified the need for some kind of intergovernmental political coordination between regions (e.g. Belgium).

It should be noted that under Option A, different access regulations or the absence of them are likely to be mainly an issue for EU *in situ* resources. *Ex situ* collections will normally have procedures in place for allowing third parties to obtain material from their collection and would thus have to give some kind of approval when the material is taken out of the collection. Networks such as the IPEN network of botanic gardens have already standardised approaches for this in place. Where MS do not adopt any specific ABS provider measures these self-regulatory practices will just continue. While a decision of an *ex situ* collection does not constitute PIC in the sense of the NP (unless a MS determines otherwise), such self-regulatory means still lead, to a degree, to harmonising physical access to GR in practice and through contractual means, irrespective of what MS do.

Box 9.4: Implications of regionally inconsistent ABS frameworks for opportunities of states to benefit from their GR

The diverse genetic resources within the Mesoamerican region from Mexico to Columbia are similar (Richerzhagen and Karin, 2005). The region consists of more than 15 countries and in many cases access is not regulated. This enables potential users to pick the provider country with the least stringent access regime.

The American Bioindustry Alliance (ABIA) has clearly stated that researchers will go to countries where the regulation is less stringent. When Brazil began to strictly regulate its

access policies, the ABIA commented that, “this has all but shut down both academic and commercial research in Brazil in favour of better operating environments in neighbouring states.”

Source: Joseph (2010)

Under this option, the EU has no substantive role in adopting access legislation or making decisions on access. It could still, however, play a role in the dissemination of information to prospective users by creating an EU focal point. It could also support the MS by providing model MATs, without any obligation for MS to use these.

9.2.5 Option B: OMC (Open Method of Coordination)

Under Option B, EU action would be based on the Open Method of Coordination (OMC). The OMC, generally, takes different forms depending on the sector and purpose it is used for. Mostly, an agreement on policy objectives is sought, but MS are left the choice to determine the means for achieving it. The Lisbon Council of 2000 described the OMC as involving – in the context of social and economic policies – the following elements:

- “Fixing guidelines for the Union combined with specific timetables for achieving the goals which they set in the short, medium and long terms;
- Establishing, where appropriate, quantitative and qualitative indicators and benchmarks against the best in the world and tailored to the needs of different Member States and sectors as a means of comparing best practice;
- Translating these European guidelines into national and regional policies by setting specific targets and adopting measures, taking into account national and regional differences;
- Periodic monitoring, evaluation and peer review organised as mutual learning processes.”⁸⁹

A similar process is now codified in Art 148-150 TFEU for employment policy. However, in fact the OMC has been applied in a variety of fields. It has not been applied frequently in the environmental field, but some elements of the OMC can, for example, be found in the EU Water Framework Directive. Concrete steps and measures depend on the relevant field. In principle, under the OMC either the EU or MS can take the lead, so the EU could have a stronger or weaker role in the coordination effort. For example, the EU could lead the general effort on coordinating MS access rules, but a MS could lead on TKaGR related efforts, given that this may be only relevant for a limited number of MS.

Broad policy goals and guidelines would be agreed at EU level and applied by Member States in their national and regional policies and administrative procedures. The closest precedent identified is from Australia (see box below).⁹⁰

Box 9.5 Nationally Consistent Approach for access to and the utilisation of Australia’s GR

In 2002, Australia’s 14 Commonwealth, State and Territory Ministers constituting the Natural Resource Management Ministerial Council endorsed the *Nationally Consistent Approach for Access to and the Utilisation of Australia’s Native Genetic and Biochemical Resources* (DEH Australia, 2002). This non-binding framework endorses the Bonn Guidelines and was intended to guide action by governments to develop or review ABS measures. It sets out general principles for each jurisdiction’s legislative, administrative or policy frameworks, including to “*introduce terms and conditions of access to Australian resources that Australia would be prepared to meet if introduced by other countries.*”

⁸⁹ Presidency Conclusions, Lisbon European Council, 23 and 24 March 2000, para. 37

⁹⁰ <http://www.environment.gov.au/biodiversity/publications/access/nca/index.html>.

However, the approach has only had limited success - only Northern Territory and Queensland have adopted ABS legislation; Victoria and Tasmania have some recent measures for this purpose. The 'Hawke Review', an independent review commissioned by the national government (DEWHA, 2009), noted that as each jurisdiction has different rules for accessing biological resources, this is a potential source of confusion for permit applicants and land managers and creates an unnecessary need for multiple permits for larger research projects. It recommended reinvigorating the Nationally Consistent Approach to reduce legal uncertainty and avoid multiple permit applications for bioprospecting across jurisdictional boundaries.

Sources: DEH Australia (2002); DEWHA (2009)

Coordination under the OMC could address, for example:

Definition of access: Access in the sense of the Protocol is always access to genetic resources with the purpose of utilising them. MS could agree on ways to clarify this in their legislation and thus avoid any legal uncertainty relating e.g. to access to biological resources in a wider sense and for other purposes (e.g. trading of vegetables for consumption or selling of pets).

Access to in situ GR and TKaGR: Those member states opting for granting PIC could agree on similar procedures concerning e.g. the information required from applicants, procedures for informing each other and cooperating in case of GR found in more than one MS. With a view to Art 8(a), a common approach towards exempting non-commercial research from a PIC requirement and, for example, replacing it by a notification requirement, could also be discussed. This may, however, mean that many users would not be subject to a PIC requirement as most research on *in situ* genetic resources starts off as non-commercial.⁹¹

One point that might also merit a joint approach is which other actors might be involved in PIC procedures (apart from ILCs, if any are identified). These could be e.g. nature protection authorities where access to a GR in a protected area is sought, a private landowner where a GR is on private territory or an animal plant breeder. A uniform template for a Certificate of Compliance/PIC decision to be used by MS could also be developed by the MS. Moreover, MS could also exchange best practices on ensuring that PGRFA that are in the Multilateral System of the ITPGRFA are not made subject to the PIC. Concerning TKaGR, MS could think about a joint definition and exchange best practices in identifying TKaGR.

Access to ex situ GR: The roles of *ex situ* collections and competent national authorities in granting PIC could be defined in a similar way in different MS – for the sake of making the procedures easier for prospective users. In the case of most genetic resources, an *ex situ* collection will have to physically hand over a GR to a prospective user and thus agree to a GR being taken from the collection. This act could be recognised formally by the CNA without further checking; this could be done in the case of all *ex situ* collections or –

⁹¹ For example, in Australia, the vast majority of access permits granted by the Commonwealth to date have been for non-commercial purposes. Pers. comm, Ben Philips, Director of Protected Areas Policy, Parks Australia, 28 October 2011. See also the EU baseline, chapter 10.

preferably in the case of collections fulfilling certain standards concerning documentation and management. Alternatively, users wishing to utilise a GR from an *ex situ* collection could be required to first obtain PIC, and then on this basis obtain physical access to the desired GR. Again, the option of exempting non-commercial research from a PIC requirement could be considered.

Box 9.6: Exemption of *ex situ* collections of biological resources in Australia

Under the Environment Protection and Biodiversity Conservation Regulations 2000, exemptions may be made on a case by case basis for *ex situ* collections of biological resources (including future additions to the collection) held by a public department/agency where:

- These are administered consistently with applicable regulations; or
- Their use is required to be controlled under any international agreement to which Australia is a party (e.g. the International Treaty on Plant Genetic Resources for Food and Agriculture) (Reg.8A.05).

As currently drafted, these regulations use the term ‘taking’ in the context of *ex situ* collections. The independent Hawke Review 2009 noted that the concept of ‘taking’ is not generally relevant to this context and recommends the regulations should be amended for legal clarity to bring persons who “receive or hold” biological resources from Commonwealth *ex situ* collections within the scope of the Regulations (§5.110, DEWHA 2009).

A recent study of the Australian ABS framework (Burton 2009) recommends that the adoption of institutional accreditation to international standards should be further considered in the light of Australian practical experience (see country report Australia, Annex II).

Content of MAT: Another element where coordination among MS could be beneficial for prospective users would be the content of MAT. For example, MS could jointly and with support from the EU, develop model MAT which define the type of benefits to be shared (monetary/non-monetary), set forth when and with whom they need to be shared, clarify the applicable jurisdiction and/or alternative ways of dispute resolution, etc. In this context, a coordinated approach to non-commercial research could also be sought, e.g. in the form of an agreement that MS will not require any benefit-sharing as long as the research remains non-commercial, but with a come-back clause when it turns commercial.⁹² Criteria

⁹² Several provider countries (including the Philippines, Australia and Uganda) have adopted regulatory measures on change of use. Australia’s national legislation requires non-commercial researchers to undertake to conclude a benefit-sharing agreement if the purpose of research changes. This is considered a strength as it “takes into account that most work starts as non-commercial biodiversity research, that accidental or serendipitous discovery is a continuous feature of science” and also addresses the risk of simplified non-commercial procedures being used to circumvent the purpose of the legislation (Burton, 2009). In Uganda the procedure for obtaining an access permit under its ABS Regulations must be followed if the use is changed to commercial.

could be developed to build capacity and consistency in differentiating between the two types of research.⁹³ Specific MAT for SMEs could also be considered.

Implementation of Art 8(a): Member States, including those not wishing to grant PIC, could also cooperate in implementing Art 8(a), i.e. creating conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, in particular in developing countries. This could be done through MS agreeing on dedicating a certain amount of funding to non-commercial research on GR. Moreover, MS could also engage in joint efforts (possibly supported by the EU) in identifying obstacles to such research (e.g. created by existing bio-patents). Obviously, similar measures could also be adopted at the EU level.

Involvement of ILCs and definition of TKaGR: Furthermore, MS could also agree on a joint approach to ILCs and TKaGR. Notably, this could extend to agreeing on the criteria by which a community is recognised as ILC. Moreover, MS could seek to develop criteria on what they consider TKaGR, which takes into account the international debate on these issues, and cooperate on compiling documentation of knowledge they would qualify as TKaGR. Moreover, procedures for the involvement of ILCs (where applicable) could also be agreed on, relating *inter alia* to whether the competent authority would seek to obtain their PIC or whether prospective users would need to show evidence of PIC they obtained to the competent authority, who in a community would be considered to be entitled to give PIC and how benefit-sharing with ILCs is ensured.

Compliance with provider side measures and monitoring: A further aspect that MS could consider is how to ensure compliance with their provider ABS regulation and engage in monitoring. Depending on which course of action the EU takes with regard to user compliance measures, the general EU user-side compliance system will also help ensuring that EU users have complied with EU ABS legislation. If the EU takes an ambitious approach to user compliance measures, monitoring activities could extend to GR collected within the EU; irrespective of whether a certain GR is from within the EU or from outside the EU.

One possible course of action is also a combination of a reporting duty for users included in MAT and independent monitoring by the MS authorities. For example, the German Federal Office for Food and Agriculture and the German Federal Plant Variety Office have recently started an initiative to undertake “biopatent monitoring”⁹⁴ on the agricultural sector; the results of research in patents databases will be reported monthly and evaluated with regard

⁹³ Working documents during Protocol negotiations characterised *non-commercial research* by a) public availability, b) purely non-commercial intentions c) results benefit providers, conservation, ecosystem analysis and characterisation of organisms and d) generation of near-term non-monetary benefits. Examples included conservation, taxonomy, production of natural compounds and DNA synthesis. In contrast, *commercial research* often restricts access, generates market products, primary benefits users and generates long-term monetary benefits (Concepts, Terms, Working Definitions and Sectoral Approaches relating to the International Regime on Access and benefit-sharing (UNEP/CBD/ABS/GTLE/I/INF/2(2008, p.5) and Report of WG-ABS 7 (UNEP/CBD/WG-ABS/7/2 2008, §13 and §43-44.)

⁹⁴ Press release: BLE und Bundessortenamt starten Biopatent-Monitoring, 29 Feb 2012, http://www.ble.de/SharedDocs/Downloads/08_Service/04_Pressemitteilungen/120229_BiopatenteMonitorin g.pdf?__blob=publicationFile

to their impact on agriculture. A similar monitoring might help the MS to verify if any of their GR have been used without PIC being obtained; such monitoring could also extend to relevant academic publications, for example. Even under the OMC the EU could have a role in monitoring, e.g. by commissioning surveys. Moreover, MS could also agree on the type of sanctions they consider appropriate.

In practical terms, some of the instruments sometimes used under the OMC, such as benchmarking, are not suitable in the present context. However, once ABS systems have been put in place, MS could exchange experiences on how their respective systems function. From this, MS that initially do not adopt a PIC requirement could also benefit, and might decide on this basis at a later stage to adopt a PIC requirement. MS could also discuss practical implementation questions such as e.g. how to verify whether research is commercial or non-commercial. Also, information could be exchanged on whether any difficulties arise with access to courts in MS in MAT-related cases, and what legal situation they result from. This might help other MS to avoid similar obstacles.

Overall, as this option involves only non-binding EU action, it cannot guarantee MS buy-in. Australia's experience (see box above) showed a take-up of access elements in sub-national legislation by only half of the sub-national entities involved. However, EU Member States have extensive experience of cooperative implementation of EU environmental instruments, with technical support from the Commission. Thus, the picture may be more optimistic in the case of the EU.

In any case, the EU could take some or all of the **supportive measures** described in greater detail below in section 9.5. Whether or not the EU adopts such measures, should also be a function of how many MS adopt ABS requirements. The less MS engage in e.g. providing information on their PIC procedures, in developing standardised model MAT where they do and take other access-related measures, the more urgent EU actions become.

9.2.6 Option C: EU minimum requirements for MS wishing to grant PIC

Under Option C, the EU would adopt minimum standards on the different aspects of MS provider ABS measures. However, member states could still “opt-in” by adopting a PIC requirement or “opt-out” by not doing so. Generally, some of the aspects that under Option B would, optimally, be approached in a coordinated manner by MS as results of efforts under the OMC, would in this option be subject to a minimum requirement. Thus, the issues to be addressed and measures suggested are mostly not fundamentally different in Options B and C. What is different is their binding nature.

Whether these requirements should be in form of a directive or regulation depends on what further measures the EU takes. If they are part of a broader EU ABS framework through which EU institutions are created and assigned certain responsibilities, this broader framework should preferably be in the form of a regulation. However, if the EU does not opt for such a broader framework, a directive would be the more appropriate legal form for such minimum requirements, as directives are typically used where no EU institutions are

created or entrusted with additional responsibilities and where MS need to reach certain objectives, but have a degree of freedom how to do so.

Minimum requirements for PIC for in situ resources and TKaGR

Art 6(3) NP contains minimum substantive requirements for Parties that wish to require PIC. However, as pointed out above, these hardly go beyond general rule of law/good governance criteria. It seems questionable whether as such they should be re-iterated as minimum requirements in future EU legislation. Of course, the EU needs to ensure that its own legislation complies with these criteria; it is, however, not evident that any of the following suggestions would not be line with the Art 6 (3) criteria.

EU minimum requirements on access to *in situ* GR and TKaGR would mainly relate to procedures and scope. They should relate to the following aspects:

Definition of access: As under Option C, access should be defined in order to avoid any legal confusion relating e.g. to access to biological resources for other purposes than utilising GR.

Scope: As under the OMC, an exemption for non-commercial research needs to be considered. As this option is about minimum requirements, the legislation should not proscribe any specific MS duty in this regard, but contain the options and provisions for implementing them, if chosen. For example, the legislation could include criteria for distinguishing commercial from non-commercial research. The legislation should also include a provision excluding from PIC requirements PGRFA that are covered by the multilateral system of the ITPGRFA.

Procedures: Procedural aspects amenable to harmonisation are the information requested from applicants and the form/wording of the decision to grant PIC and a certificate of compliance. Moreover, procedures should also be clarified, i.e. a duty of MS should be stipulated to ensure that their CNAs report CoC to the international ABS clearing-house. At the same time, CoCs could also be reported to other MS and the EU without creating much extra administrative burden.

Moreover, procedures for addressing cases of a GR existing in more than one MS should be set forth in order to comply with the cooperation requirement in Art 11(1) NP. This could take, e.g. the form of a duty of one MS to inform other MS with PIC requirements of its intention to grant access for a genetic resource that is known to be shared for a specific purpose, and a possibility of other MS to intervene before this decision is taken. Similar models exist in other pieces of EU environmental legislation, e.g. the GMO deliberate release directive, even though, obviously, for different purposes.

Involvement of other actors: The EU could also set minimum standards on how/when other actors should be involved in PIC decision-making. For example, prospective users could be required to demonstrate the consent of the authority responsible for protected areas when applying for access to a genetic resource in such an area. Alternatively, the MS competent authority could seek that approval which would, of course, be easier from a user perspective. Obviously, ILCs, where they exist and users want to access “their” GR or TKaGR,

must also be involved in decision-making. For the sake of legal clarity, MS could be required to report to the EU which ILCs they have identified on their territory. Finally, the involvement of private actors who physically own genetic resources may also have to be regulated. For example, in the animal breeding sector, there are hardly any *ex situ* genetic resources; basically the living animals are the genetic “resources” (see EU Baseline, chapter 10). Thus, the selling and purchasing of animals *de facto* regulates access to animal genetic resources, and involving an MS authority in decisions on whether such commercial transactions can be made would considerably restrict the contractual freedom of animal breeders. In such cases, rules allowing private actors to grant PIC and specifying under which conditions PIC cannot be granted, may be the most appropriate option. Alternatively, such resources could be exempt from the scope of access legislation.

Minimum requirements for PIC for ex situ resources

Much of what has been said with regard to minimum standards for PIC in the case of *in situ* genetic resources also applies with regard to *ex situ* resources.

As already discussed in Option B, the **role of *ex situ* collections** should be clarified. *Ex situ* collections will have to physically hand over a GR to prospective users and thus agree to a GR being taken from the collection. This act could be recognised formally by the CNA without further checking; this could be done in the case of all *ex situ* collections or - preferably - in the case of collections fulfilling certain standards concerning documentation and management or being members of networks that have established a sound ABS approach themselves (such as the IPEN network, see box below). EU minimum requirements could thus describe what criteria *ex situ* collections would have to fulfil to be able to assume this kind of responsibility and include a requirement for MS to notify the *ex situ* collections on their territory that qualify. Alternatively, users wishing to utilise a GR from an *ex situ* collection could be required to first obtain PIC from the CNA, where the MS holds the sovereign right, and then on this basis obtain physical access to the desired GR from the *ex situ* collection.

Box 9.7 The International Plant Exchange Network (IPEN) Code of Conduct

IPEN is a registration system open for botanic gardens that adopt a common policy (Code of Conduct) regarding access to genetic resources and sharing of the resulting benefits. It was developed by the *Verband Botanischer Gärten* (an association of gardens in German speaking countries) and taken over by the European Consortium of Botanic Gardens.

The IPEN network facilitates the non-commercial exchange of plant material between member gardens while respecting the CBD’s ABS provisions. It “aims to create a climate of confidence between the countries owning the genetic resources and the botanic gardens”. Gardens that wish to join the network must sign and abide by a Code of Conduct that sets out gardens’ responsibilities for acquisition, maintenance and supply of living plant material and associated benefit-sharing. Acquisition or supply of material with extra terms and conditions, or any use for commercial purposes, is not covered by the network and requires the use of appropriate Material Transfer Agreements.

IPEN provides for prior informed consent to be granted and obtained for genetic resources accessed in the past. It has developed standardised mutually agreed terms which include the following paragraph:

“By signing this Agreement the recipients commit themselves to act in compliance with the CBD and its agreed provisions on Access and Benefit- Sharing. This includes a new Prior Informed Consent (PIC) of the country of origin for any uses not covered by terms under which it has been acquired (such as commercialisation).”

Source: <http://www.bgci.org/resources/ipen/>

Minimum requirements for MAT

The EU could also set minimum requirements on MAT, for example by developing a list of benefits that may be required from prospective users. An approach tailored to certain groups of prospective users, such as SMEs or those seeking access for non-commercial purposes would be expedient in light of the EU proportionality principle. According to the Parties are to encourage the inclusion of certain issues into MAT; a requirement to address these issues in MS MAT should be explicitly included in the minimum requirements. The issues include the jurisdiction under which MAT related disputes are to be handled, the applicable law and/or options for alternative dispute resolution, such as mediation or arbitration (Art 18(1)).

Box 9.8 National approaches to benefit-sharing

The national case studies performed for this study reveal diverging approaches to benefit-sharing in the non-EU countries analysed.

In the Philippines, the authorities impose minimum requirements for monetary benefits. For instance a minimum 2% of total global gross sales of the product made or derived from the collected genetic resources must be paid annually (royalties) and users need to pay US\$ 1,000 annually per collection for the duration of the collection activity as advance from royalties. All payments are non-reimbursable even if no profit is eventually realized. Non-monetary benefits may be negotiated on top of the monetary benefits. Users are also required to deposit all voucher specimens with the National Museum of the Philippines and all living specimens in mutually agreed depositories.

In India, mutually agreed terms must be established before genetic resources can be accessed (by foreign users). When granting approvals for access to genetic resources, the National Biodiversity Authority needs to ensure that the terms and conditions subject to which approval is granted secure equitable sharing of benefits arising out of the use of the accessed genetic resources, by-products, innovations and practices associated with their use. It is the National Biodiversity Authority which has the ultimate authority over the type and quantum of benefits to be shared. The Authority is due to publish official guidelines on benefit-sharing. In the meantime a working template for the sharing of monetary benefits has been developed by the Expert Committee on Access and Benefit Sharing and is being used for general guidance until official guidelines for this purpose are duly notified.

In Uganda, the 2005 Regulations provide for the sharing of all benefits accruing from the collection, modification and use of genetic resources based on the principle of fairness and equity on mutually agreed terms. Guidelines set out an indicative list of direct and indirect benefits to be negotiated on a case-by-case basis.

In Australia, there are no minimum benefit sharing requirements; parties to the contract agree on benefits on a case-by-case basis. In the case of commercial use of genetic resources, a benefit-sharing agreement must provide for 'reasonable' benefit-sharing arrangements, including protection for and valuing of indigenous people's knowledge to be used. Moreover, the competent national authority has published two model contracts to facilitate the process and reduce transaction costs associated with developing arrangements.

Source: Country Reports on non-EU Countries, Annex II

Compliance and monitoring

As discussed for Option B, an ambitious EU user-side compliance system would also go some way towards ensuring that EU users have complied with MS ABS legislation and would help MS in monitoring. For example, monitoring activities should, in principle, extend to GR collected within the EU. This is discussed more in-depth below (see Box 9.13).

If the EU does not opt for an ambitious system of user compliance measures, EU defined minimum requirements may extend to defining types of sanctions MS could impose on users not complying with their access regime. For example, administrative fines could be included in such a list, whereas criminal sanctions could be excluded for not being proportionate. Moreover, minimum provisions on how MS would monitor the utilisation of the GR from their territory could be included. However, the EU could itself also take measures relating to monitoring the utilisation of GR from the EU, e. g. through independent surveys.

Obligation for all MS to provide CoC to users upon request

In addition, EU measures may be needed in the case **of MS not adopting PIC requirements.**

In this respect, the EU could consider creating procedures for issuing, upon request by users, a "negative" CoC. A negative CoC would confirm that users acted legally by accessing the respective GR in PIC-free member states. Such a CoC would be most expedient in combination with such user compliance measures that require users to comply with certain specific prohibitions and obligations relating to upstream or downstream uses of genetic resources such as discussed in Option B and C on user compliance. Negative CoCs could make it easier for authorities to ascertain whether users comply with such specific prohibitions and obligations and for users to show compliance.

In line with the overall approach under Option C, this could be formulated as an obligation on all MS, irrespective of whether or not they opt for a PIC requirement. However, MS that do not opt for adopting PIC requirements may not wish to create specific administrative procedures for that purpose. Thus, the EU could also assume the task of issuing such CoCs itself.

In addition, the EU could engage in monitoring the utilisation of local GR, e.g. through independent surveys, in case this is not anyway achieved through EU user compliance measures (see Box 9.13 below).

9.2.7 Option B and C: Measures to address Art 8(a)

Under all of the approaches discussed in the preceding section, the EU could take supplementary measures to address Art 8(a). Some options related to waiving the PIC requirement or less far-reaching MAT for non-commercial research have already been discussed above. Some additional measures could be the following:

- The EU could consider whether and how to encourage users and/or providers to share (monetary) benefits even where they are not under an obligation to do so, for example by creating a fund to which they could pay and which would then fund further research for the benefit of the conservation of GR, for example. A similar system is in place under the ITPGRFA.
- The EU could provide funding specifically for non-commercial research on GR, in the through its research framework programme or as a part of the common agricultural policy.
- The EU could identify what obstacles to research for the benefit of the conservation of genetic resources exist currently and seek ways of removing them.

9.2.8 Institutional set up

The NP provides in Art 13 for two types of institutions that Parties to the Protocol need to set up: focal points and competent national authorities. However, one entity can fulfil both functions (Art 13(3)).

Focal points, according to Art 13(1), have the function to provide those seeking access to GR or TKaGR with information on the procedures for obtaining it. CNAs, according to Art 13(2) have the task to grant PIC and provide evidence that PIC has been granted, as well as for advising on the conclusion of MAT. Even though Art 13(2) does not mention the conclusion of MAT as an explicit competence of the CNAs, it seems logical to assume that they would have that competence as well, as, according to the Protocol, PIC is to be granted on mutually agreed terms. The rights of ILCs in this context need to be respected, and the conclusion of MAT could also be delegated to them. Moreover, the EU/MS could also decide

to delegate that competence to other actors that have some rights over biological resources incorporating GR, such as private landowners.

What will be needed in the EU and MS in terms of provider side institutions depends obviously on the options chosen. The broad lines are as follows:

- Those MS wishing to grant PIC will have to set up CNAs.
- The EU only needs a CNA for provider purposes in case it is to issue upon request CoCs and that function is not performed by all MS.
- According to Art 13 NP each party must establish a focal point with the purpose of providing users with information on access procedures. This could imply that no focal point is required where there is no access requirement. However, this does not seem to be a convincing interpretation, given that also the fact that there is no access requirement is relevant for users. Thus, an EU focal point should be a one-stop source provide for information concerning, *inter alia*, which MS require PIC and which do not, the type of administrative procedures in place for accessing GR in each MS and the CNAs and focal point set up in each MS.

Box 9.9 Uganda: example of a Competent National Authority's mandate

The Uganda National Council for Science and Technology (UNCST) was established in 1990 within the Ministry of Finance, Planning and Economic Development (see country report Uganda, Annex II). Under the National Environment Regulations (Access to Genetic Resources and Benefit Sharing) 2005, it is mandated *inter alia* to:

- Assist in rationalising the use of foreign science and technology;
- Coordinate ABS-related activities across institutions and sectors;
- Act as a clearing house for information on research and development in scientific institutions, other enterprises and on the potential application of their results;
- Protect intellectual property through appropriate patent laws and operate a national patent office;
- Coordinate Lead Agency activities related to access to GR and support the negotiation of prior informed consent and MAT, ensuring that Ugandans benefit from sufficient benefit-sharing provisions;
- Operate the access permit system consistent with the Regulations and establish a procedure for accessing relevant information;
- Monitor the use of GR in and transferred outside Uganda, including supervision of compliance with contractual conditions, and establish monitoring and evaluation mechanisms for this purpose; and
- Ensure that Uganda keeps representative samples and specimen of genetic resources collected under the Regulations and approve the depository.

9.3 Options for user compliance and monitoring measures

In this chapter, options for EU user compliance and monitoring measures are discussed. The structure is similar to that of the previous chapter. Thus, we start with some background on the issue at hand and the negotiations (9.3.1), summarise the core obligations (9.3.2) and discuss some existing regulatory approaches and their usefulness for the present purpose (9.3.3). We then introduce three options for user compliance measures (9.3.4) and subsequently discuss each of them in depth (9.3.5 to 9.3.7). Finally, we analyse options relating to the enforcement of MAT and access to justice (9.3.8).

9.3.1 *Background*

The contribution of user countries to ensuring that PIC/MAT requirements of provider countries are actually observed was one of the important issues in the negotiations on the Nagoya Protocol. This relates back to the nature of GR and particular TKaGR – resources whose movement across borders and whose utilisation is difficult to monitor. Most R&D on genetic resources as well as the marketing of products derived from such GR does not occur in the countries of origin of GR/TKaGR. Consequently, benefits are mainly generated outside these countries. Thus, it is an important question what user countries can do to ensure that provider countries can make informed choices about the use of “their” GR/TKaGR that are actually enforced and obtain a share of the benefits, if they wish so.

Developing countries in the negotiations on the Protocol argued, in particular, in favour of the designation of checkpoints – institutions to monitor the utilisation of genetic resources in user countries as the principal mechanism to ensure user compliance with the ABS requirements of countries of origin of GR. The proposal to designate specific institutions, notably IP offices, as checkpoints in the Protocol, however did not prevail in the end. In the Protocol as it now stands, Parties have considerable leeway as to which compliance measures to take, even if they have no discretion as to whether to adopt such measures. Some developing countries have expressed dissatisfaction with this result, which they perceive as one of the main weaknesses of the Protocol’s provisions (Nijar, 2011).

As the EU is primarily a user of genetic resources, the implementation of the obligations relating to user compliance measures will be the bulk of what the EU needs to do concerning implementation. Some observers have indicated that the willingness of provider countries to quickly implement the Protocol could depend on the willingness of users such as the EU to take quick and effective measures for implementing the Protocol (EED, 2012, 17).

9.3.2 *Summary of obligations*

Articles 5, 15 to 18 of the Protocol contain the **core obligations** for all Parties on measures relating to user compliance with the domestic ABS frameworks of provider countries.

Art 5(3) requires all parties to take measures for implementing the basic obligation in Art 5(1) that benefits arising from the utilization of GR are shared on mutually agreed terms. Art 5(2) and 5(5) specifically require the sharing of benefits for the utilization of GR and TKaGR with ILCs in cases where ILCs have rights over or hold such resources.

Articles 15 and 16 contain obligations concerning measures to ensure that GR and TKaGR which are utilized in a certain country have been accessed in accordance with PIC and that MAT were established at the time of access, as required by the domestic ABS requirements of “the other Party”, i.e. the provider state. Art 15 relates to GR and Art 16 to TKaGR; otherwise, both are formulated in a largely identical manner. The first paragraphs of each of the two articles oblige Parties to take “appropriate, effective and proportionate legislative, administrative or policy measures” for the above purpose. The second paragraphs of each of the two articles contain an obligation for parties to address situations of non-compliance with such measures. The third paragraphs contain a weakly formulated duty to cooperate in cases of alleged violations of ABS provisions. Art 16(1) relating to TKaGR is worded slightly more softly than Art 15(1) and mentions the involvement of ILCs; otherwise there are no differences in wording between both articles. While the obligations are unconditional, they use terminology such as “appropriate measures” in Art 15(1), 15(2), 16(1) and 16(2) or “as far as possible” in Art 15(3) and 16(3). This gives Parties significant discretion as to the way they implement these provisions.

The title of Art 17 indicates that the article is about the monitoring of the utilization of genetic resources. In fact, only Art 17(1) addresses this issue directly, while Arts 17(2)-(4) focus on certificates of compliance. Art 17(1) sets forth that each Party shall take measures, as appropriate, to monitor and enhance transparency regarding the utilization of genetic resources in order to support compliance. Art 17(1)(a) refers to the designation of one or more checkpoints as one of these measures. Sub-paragraphs (1)(a)(i) to (iv) describe the character and function of designated checkpoints. Art 17(1)(a)(i) sets forth what type of information checkpoints should collect or receive, as appropriate. The information explicitly mentioned relates to PIC, the source of a genetic resource, the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate. However, there is nothing in the Protocol to indicate that checkpoints could not be given the mandate to collect or receive further information. What type of information a specific checkpoint can usefully process will obviously depend on the checkpoint itself - it will be different for a research funding organisation, a customs authority or an IP office, which were all discussed as potential checkpoints in the negotiations. Art 17(1)(a)(ii) obliges Parties to, as appropriate, require users of genetic resources to provide the information specified in Art 17(1)(a)(ii) at designated checkpoints, while Art 17(1)(a)(i) leaves Parties discretion as to whether they will require users to disclose information at a checkpoint or whether a designated checkpoint will actively gather relevant information. Both therefore do not seem to be entirely consistent with each other. Art 17(1)(a)(ii) also requires Parties to address situations of non-compliance with disclosure duties. Art 17(1)(a)(iii) stipulates that information provided to checkpoints shall, in principle, be passed on to the international ABS CH and to relevant competent authorities. According to Art 17(1)(a)(iv) checkpoints should have functions relevant to the utilization of GR, or to the collection of relevant information at, *inter alia*, any stage of R&D, innovation, pre-commercialisation or commercialisation.

The Protocol does not specify which institutions will perform the function of checkpoints, and whether there are to be one or more checkpoints in each Party. Institutions discussed as checkpoints in the negotiations included customs authorities, patent offices, market approval offices (e.g. for pharmaceuticals, cosmetics, seeds, GMOs), research funding agencies, and indigenous and local community representatives. The last option does not appear to be readily applicable in an EU context where in most countries there are no ILCs with established rights to genetic resources; the other four options are discussed below. In addition, as the Protocol text does not elaborate on the institutions that are to act as checkpoints, Parties have discretion to designate a type of checkpoint not referred to in the negotiations. Given that more than one checkpoint can be designated, it is also legally feasible for the EU and Member States to each have their own checkpoints.

Art 17(1)(b) and (c) hold, respectively, that parties should encourage users and providers of genetic resources to include provisions in MAT to share information on the implementation of such terms, including through reporting requirements, and should, generally, encourage the use of cost-effective communication tools and systems. While Art 17(1)(b) is primarily addressed at provider states the wording does not exclude that this practice should also be encouraged by user states e.g. through the production of model MAT or guidelines.

It is also important to note that the scope of Art 17 does not include measures to monitor or create transparency about the utilisation of TKaGR. However, as Art 16 also requires measures to support compliance with the TK-related provisions of the Protocol, it would still make sense to include traditional knowledge into the information received/collected by checkpoints. The Nagoya Protocol does not preclude parties from taking such actions relating to TKaGR.

All in all, there is an inherent connection between the obligations in Art 15, 16 and the monitoring obligations in Art 17(1). Without monitoring, compliance with ABS regulations in provider countries is difficult to verify. Moreover, addressing cases of non-compliance through sanctions as required by Art 15(2) and 16(2) presupposes that such non-compliance has been first established and thus also requires some kind of monitoring or checking of what users do with GR. Moreover, Parties must address both instances of non-compliance with provider country ABS according to Art 15(2) and 16(2) and instances of non-compliance of users with a duty to provide certain information to checkpoints according to 17(1)(a)(ii). Similar sanctions may be considered in both cases. In sum, while Arts 15-17 do not prescribe a specific approach to user compliance measures or monitoring, and are neither explicit on how the two sets of measures should be linked, in practice they will likely be closely intertwined.

Arts 17(2)-17(4) NP contain rules on the internationally recognised certificate of compliance. According to Art 17(2) an access permit issued by a competent authority turns into a CoC when made available to the international ABS CH. According to Art 17(3), CoCs serve as evidence of a genetic resource having been acquired in line with provider country ABS legislation. Art 17(4) defines which information shall be included in a CoC, namely the issuing authority, date of issuance, provider, a unique identifier of the certificate, the person or entity to whom prior informed consent was granted, the subject-matter or genetic

resources covered by the certificate, a confirmation that PIC was obtained and MAT were established and information on commercial and/or non-commercial use. From the perspective of user side compliance measures, such CoCs are relevant as a means of facilitating determination in user countries on whether ABS legislation in provider countries has been complied with. However, they need, according to Art 6(3) be issued by provider countries, not by user countries. Thus, Arts 17(2)-17(4) do not set forth obligations for user countries, except that all Parties must accept internationally recognised certificates of compliance in their domestic law as evidence that genetic resources covered have been accessed in accordance with PIC and that MAT have been established (Article 17(3)).

Art 18 addresses “compliance with mutually agreed terms”. Art 18(1) obliges parties to encourage users to include certain clauses in MAT, defining the jurisdiction to which they will subject any disputes, applicable law and/or options for alternative dispute resolution, such as mediation or arbitration. While provider countries clearly have more influence over the clauses to be included in MAT, because they can make access to GR conditional upon the prospective user agreeing to such MAT, user countries such as the EU could take measures aimed at creating awareness among their nationals about the necessity of such provisions and aimed at providing assistance in form of model provisions. Art 18(2) NP requires Parties “to ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.” It is thus essentially an access to justice obligation. Art 18(3), in turn, obliges Parties to “take effective measures, as appropriate” regarding both access to justice and mutual recognition and enforcement of foreign judgments and arbitral awards.

Concerning the scope of Art 18, there is a general obligation on parties to take measures within their legal system to ensure that at least providers and users of GR and TKaGR who are parties to mutually agreed terms have access to the courts of a country where one party to a BS contract is based, in order to be able to seek enforcement of their rights under those mutually agreed terms. While it is clear that a Party to a MAT must have access to justice, the wording of the provisions of Art 18 NP is ambiguous as to whether measures for the benefit of stakeholders who are not parties to a MAT agreement are also needed. In practice, in some cases prospective users may not request PIC or conclude MAT with ILCs, even where those ILCs have established rights. This would violate the rights of these ILCs who then might want to seek remedies in court. In this context, the fact that Art 18(3) contains an access to justice duty which, contrary to Art 18(2), is not related to MAT specifically, is an indicator that actors that have ABS related rights, but are not a party to MAT, also need to have access to courts. This notably applies for ILCs.

It also appears from the wording of those provisions that mutually agreed terms are to be treated as international contracts under private law, and disputes between providers and users as private contractual disputes between parties to a contract.

Table 9.4: Core and supplementary obligations on user compliance and monitoring

Article	Core obligations on user compliance and monitoring
5(3)	Take measures to implement the basic benefit-sharing obligation in Art 5(1)
5(2), 5(5)	Take measures to ensure benefit-sharing, upon MAT with ILCs with established rights over GR or for

	TKaGR held by ILCs
15(1)	Take appropriate, effective and proportionate measures to provide that GR utilised within jurisdiction were accessed in accordance with PIC, and that MAT was established, as required by domestic ABS legislation/regulations of provider party
15(2)	Take appropriate, effective and proportionate measures to address situations of non-compliance with measures under 15(1)
16(1)	Take appropriate, effective and proportionate measures to provide that TK utilised within jurisdiction was accessed in accordance with PIC/approval & involvement and that MAT was established, as required by domestic legislation of provider party where ILCs are located
16(2)	Take appropriate, effective and proportionate measures to address situations of non-compliance with measures under Art 16(1)
17(1)(a)	Take measures to monitor and enhance transparency on GR utilisation, including designation of checkpoint(s) to receive information on PIC and MAT at any stage of research, development, innovation, pre-commercialisation or commercialisation
18(2)	Ensure opportunity to seek recourse under domestic legal system when disputes arise from MAT
18(3)	Take, as appropriate, effective measures regarding: access to justice; mechanisms for mutual recognition and enforcement of foreign judgments and arbitral awards
Article	Institutional provisions
15(3), 16(3)	Cooperate, as far as possible and as appropriate, on alleged violation of domestic ABS requirements relating to GR and TKaGR
Article	Supplementary obligations on user compliance and monitoring
9	Encourage users and providers to direct benefits arising from utilisation of GR to biodiversity conservation/sustainable use
17(1)(c)	Encourage use of cost-effective communication tools and systems
17(1)(b), 18(1)	Encourage inclusion into MAT of provisions on information on the implementation of MAT, applicable law, dispute resolution etc.
19, 20	Encourage development, update and use of: -model contractual terms for MAT -voluntary codes of conduct, guidelines and best practices and/or standards
21	Take awareness-raising measures
22, 23	Cooperate on capacity-building and R&D, engage in technology transfer.

9.3.3 Examples of legislation on proper sourcing of other natural resources

Before discussing more in-depth different options for EU user compliance measures, it is worth taking a look at three schemes already in place, which set forth measures that the EU or other users of certain natural resources need to take in order to ensure that such resources have been sourced in compliance with standards adopted by the countries of origin or at the international level. While none of these schemes can be adopted as such for GR, they have relevance as far as they illustrate a range of possible regulatory approaches that the EU could consider for the present purposes. The schemes discussed are the EU Timber Regulation,⁹⁵ the EU Kimberley Regulation⁹⁶ relating to “blood diamonds” and the OECD Due Diligence Guidance for Responsible Supply Chains of Minerals.⁹⁷

⁹⁵ Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market, online at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:295:0023:0034:EN:PDF>

⁹⁶ Regulation (EC) No 2368/2002 of the Council 20 December 2002 implementing the Kimberley Process certification scheme for the international trade in rough diamonds

⁹⁷ Adopted in December 2011, online at: http://www.oecd.org/document/36/0,3746,en_2649_34889_44307940_1_1_1_1,00.html

EU Timber Regulation

The **Timber Regulation**⁹⁸ establishes a due diligence system for imports of timber into the EU. As the Regulation will only start to apply from 2013, there is so far no practical experience regarding its implementation. The Commission published on 6 July 2012 more detailed rules on due diligence as well as checks on monitoring organisations.⁹⁹

Art 4 of the Timber Regulation states that the placing on the EU market of illegally harvested timber or timber products derived from such timber is prohibited. Moreover, it requires “operators”¹⁰⁰ to exercise due diligence when placing timber or timber products on the market, using a framework of procedures and measures (the “due diligence system”). Each operator must maintain and regularly evaluate the due diligence system used, except where the operator makes use of a due diligence system established by a monitoring organisation. Art. 5 Timber Regulation contains an “obligation of traceability”, according to which timber traders must be able to identify throughout the supply chain those traders from whom they received the timber and those to whom they supplied it.

Art 6 Timber Regulation specifies the elements of the due diligence system that any natural or legal person placing timber on the market must establish. These elements are:

- Measures and procedures providing access to certain information concerning the supply of timber or timber products placed on the market (e.g. the country of harvest);
- Risk assessment procedures for analysing and evaluating the risk of illegally harvested timber or timber products derived from such timber being placed on the market; and
- Risk mitigation procedures which consist of a set of measures and procedures that are adequate and proportionate to effectively minimise that risk. They may include the practice of requiring additional information or documents and/or requiring third party verification.

The implementing Regulation further specifies, in Art 5, that operators must keep records on their supply for a period of five years and that those records must be available to competent authorities for checks. Instead of setting up their own due diligence system, operators may use a system set up by a monitoring organisation. Besides setting up a due diligence system, monitoring organisations also need to verify that the system is properly

⁹⁸ Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market, online at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:295:0023:0034:EN:PDF>

⁹⁹ Commission implementing regulation (EU) No 607/2012 of 6 July 2012 on the detailed rules concerning the due diligence system and the frequency and nature of the checks on monitoring organisations as provided for in Regulation (EU) No 995/2010 of the European Parliament and of the Council laying down the obligations

¹⁰⁰ Operators are, according to the Regulation, natural or legal persons intending to place timber on the EU market.

used by operators. Monitoring organisations need to be recognised by the MS competent authority, which shall also carry out regular checks to verify that a monitoring organisation fulfils its obligations under the Regulation (Art 8 Timber Regulation). According to Art 6(1) of the implementing Regulation these checks are to be carried out every two years as a minimum and in addition in cases of major changes in the monitoring organisation or detected shortcoming in its effectiveness. According to Art 6(3) checks shall be carried out without prior warning, except where prior notification of the monitoring organization is necessary in order to ensure the effectiveness of the checks. The regulation also clarifies that checks by competent authorities should include spot checks, including field audits, examination of documentation and records of monitoring organizations, interviews with the management and staff of the monitoring organization, interviews with operators and traders or any other relevant person, examination of documentation and records of operators, and examination of samples of the supply of operators using the due diligence system of the monitoring organisation concerned.

A list of monitoring organisations is published on the internet (Art 9 Timber Regulation). The Regulation furthermore stipulates that the competent authorities need to check regularly whether operators comply with the Regulation. These checks shall be on the basis of a “risk-based” plan or be carried out when there are substantiated concerns of non-compliance based on, for example, third-party complaints (Art 10 Timber Regulation). According to Art 19 Timber Regulation, MS shall lay down the rules on penalties for infringements which must be effective, proportionate and dissuasive. The Regulation also gives some examples for sanctions, namely fines, seizure of timber products or a prohibition to trade.

The Timber Regulation provides an interesting example for the purposes of the Nagoya Protocol as it deals with the import into the EU of a natural product which must be acquired legally in the country of origin. The basic constellation is thus similar to the case of genetic resources. As with genetic resources, tracking the origin of timber can be complicated. However, the utilisation of genetic resources is different from timber trade as timber is a commodity which producers in the country of origin sell to traders that place it on the EU market. The supply chains in sectors utilising genetic resources are more complex, as many more types of users and uses are involved (see sectoral sheets, Annex 3). Moreover, the movement of timber can be more easily monitored than the one of genetic resources as moving timber physically is much more difficult and obvious than transfers of GR/TKaGR.

EU Kimberley Regulation

The **Kimberley Regulation** establishes, according to its Art 1, essentially a certification system for rough diamonds. It covers diamond imports into and exports from the EU.

With regard to imports, the Regulation in Art 3 sets out a general prohibition on importing rough diamonds into the EU, unless they are accompanied by a certificate of a competent authority in the country of origin which clearly identifies the diamonds to which it refers, and unless the diamonds are contained in a sealed container. These containers are to be investigated by a competent authority of a MS, which, in case it finds that the rough diamonds comply with the requirements of the Regulation, issues a confirmation to this

end. If the authority finds “that the failure to fulfil the conditions is not made knowingly or intentionally or is the result of an action by another authority in the exercise of its proper duties, it may proceed with the confirmation and release the shipment, after the necessary remedial measures have been taken to ensure that the conditions are met” (Art 5(2) Kimberley Regulation). According to Art 6(1) Kimberley Regulation the competent authority may also certify stocks of rough diamonds already on the territory of the EU before the Regulation entered into force. According to Art 9 Kimberley Regulation the Commission is to provide the competent authorities with examples of the exporting countries’ certificates. Art 10 Kimberley Regulation obliges competent authorities to provide the Commission with a monthly report on the certificates submitted to it for verification.

For the purpose of exports of rough diamonds from the EU, rough diamonds need, again, to be accompanied by a certificate (Art 11 Kimberley Regulation) – this time by a certificate issued by a competent authority of an MS stating that the diamonds were lawfully imported into the EU (and some other facts) (Art 12 Kimberley Regulation). Also, at the time of export, authorities shall actually inspect/check the containers with rough diamonds (Art 12 Kimberley Regulation). However, diamond traders may also become members of a self-regulation organisation (Art 13 Kimberley Regulation). Such an organisation can apply for inclusion into a list if it provides conclusive evidence that it has measures in place to ensure that it only buys diamonds from proper sources (Art 17 Kimberley Regulation). Where an exporter is a member of such an organisation, export is considerably facilitated. Moreover, according to Art 24 Kimberley Regulation, anyone “providing services directly or indirectly” related to diamond trade shall “shall exercise due diligence for establishing that the activities for which it provides services comply with the provisions” of the Regulation. Effective, proportionate and dissuasive sanctions are to be determined by MS (Art 27 Kimberley Regulation).

Like the Timber Regulation, the Kimberley Regulation provides an interesting example for purposes of the Nagoya Protocol as it deals with the import into the EU of a natural product which must be acquired legally in the country of origin and the origin of which may be difficult to track. Again, the basic situation is thus similar as in the case of genetic resources. However, the overall quantity of diamonds used within the EU is likely much smaller than the quantity of genetic resources; moreover, diamonds are likely to be used in less manifold ways than GR.

OECD Due Diligence Guidance for Responsible Supply Chains

The OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas is obviously not an EU legislative act, but is interesting as it deals with due diligence relating to a (natural) resource which is traded along complex supply chains. The guidance sets forth a due diligence framework involving five steps:

- (1) Strong management systems: Companies should adopt and communicate publicly a clear policy for the supply chain of minerals, including due diligence standards. Procedures for controlling supply chains and a grievance mechanism must be established (at company level or general industry level)

- (2) Identification and assessment of risks in the supply chain
- (3) Designing and implementing a strategy to respond to identified risks
- (4) Independent third-party audit of supply chain due diligence at identified points in the supply chain
- (5) Public reports on supply chain due diligence

A model supply chain policy and a document entitled “Measures for Risk Mitigation and Indicators for Measuring Improvement” are also included in the guidance.

Interestingly, specific guidance is provided for supply chain due diligence for tin, tantalum and tungsten. The document differentiates between upstream and downstream companies. The reason for this distinction is that while upstream users have the factual possibility to check the source of the metals, this is virtually impossible for downstream users after smelting.

“Upstream companies” include miners (artisanal and small-scale or large-scale producers), local traders or exporters from the country of mineral origin, international concentrate traders, mineral re-processors and smelters/refiners. All other companies involved in the supply chain are considered to be “downstream”. The guidance elaborates on how both types of actors need to comply with the five steps above. Upstream companies need to establish a system of internal control over the minerals in their possession. They should generate and share verifiable, reliable and up-to-date information on the circumstance of mineral extraction, trade, handling, and export from the high risk areas. Downstream user activities in turn are to focus on identifying and reviewing the due diligence process of the upstream users in their supply chain; upstream users for this purpose are to provide certain information to them. Downstream users can fulfil their duty by adhering to an industry-wide scheme.

The OECD Guidance thus provides an interesting example of how a due diligence system may apply to all the actors involved in a certain supply chain while retaining flexibility with regard to concrete duties of the actors involved in the different steps of the value chain.

9.3.4 Options on EU user compliance and monitoring measures

Currently in the EU no MS has taken legal measures with the aim of ensuring compliance with provider country ABS legislation. While some users have taken steps to establish sectoral self-regulatory systems, guidelines and other voluntary measures to ensure their sourcing conduct is CBD-compliant, no systematic monitoring is carried out by public authorities on the utilisation of genetic resources by EU users and no sanctions are currently imposed. Under the current legal situation, MS and the EU would be in breach of several core obligations of the NP, including, *inter alia*, Arts 5, 15, 16 and 17. Thus, business as usual is not an option. Three options have been developed which will be spelt out in greater detail

subsequently. This distinction builds on the characterisation of upstream and downstream activities as described in the EU Baseline in chapter 10.

Option A ("OMC"): In this option, the EU uses the Open Method of Coordination (OMC) to achieve a certain degree of coordination among MS. Thus, MS states ideally would agree on adopting similar measures on user compliance and monitoring. However, it is unlikely that measures will be fully harmonised.

Option B ("upstream focus"): Under this option the EU takes legislative action (most likely in form of a regulation) focused on the beginning of the user chain of GR under EU jurisdiction. Thus, specific EU measures address upstream activities which are not a "utilisation" of GR in the sense of the Protocol. Upstream activities are access to *in situ* genetic resources, importing GR into the EU, storing GR in *ex situ* collections (including their identification and documentation for this purpose) and handing out GR from such *ex situ* collections. Under this system, the EU also establishes a general due diligence obligation for all users of genetic resources and associated traditional knowledge. A due diligence obligation means that users need to take measures to ensure that the GR/TKaGR they "utilise" are of good legal status, i.e. have either been acquired in line with provider countries' ABS legislation or are not subject to such legislation, either because a provider country does not require PIC or because the resources do not come within the purview of the Protocol.

Option C ("downstream focus"): Under this option the EU takes legislative action (most likely in form of a regulation) focused on the end of the utilisation chain under EU jurisdiction. Thus, the target here are downstream uses of GR, i.e. R&D of either commercial or non-commercial nature and marketing/commercialisation. The core of this option is a general prohibition for all EU users to utilise illegally acquired genetic resources or associated traditional knowledge; compliance with the general prohibition is ensured by a system of checkpoints and related disclosure requirements at the time when an intellectual property right is sought or a company seeks to obtain an approval for the marketing of a product based on genetic resources or associated traditional knowledge.

9.3.5 Option A: EU OMC/MS take measures

Under Option A, the EU would again use the OMC for achieving a degree of coordination among MS. The OMC as such has been described above in section 9.2.5.

In the case of user compliance measures, some elements typically employed in the context of the OMC are not relevant as the objective of the OMC in this case would not be agreeing on broad policy goals, but on detailed administrative procedures. Thus, indicators and benchmarks are likely to be of little relevance; and it is also questionable whether targets are needed beyond the objectives of complying with the Nagoya Protocol and achieving a high degree of harmonisation between the MS.

However, the coordination under the OMC could extend to the following aspects:

- Basic approach to be adopted (e.g. a due diligence system or not, differentiated duties for different sectors/groups of users or not)

- Institutions to be designated as checkpoints and the type of information users may have to present to them
- Mechanisms for verifying users' compliance with pertinent EU MS legislation and provider country ABS where no CoC exists (e.g. inspections to be performed by CNAs or third-parties), options for users to demonstrate to checkpoints/CNAs that GR/TKaGR they utilise have been acquired legally
- Sanctions to be applied in case of non-fulfilment of provider country ABS legislation or MS user compliance measures (e.g. administrative sanctions)
- Procedures for information exchange between MS

In all of the cases, the EU could support these efforts by developing different options and discussing their respective merits. Once MS have taken measures the EU could help them assess and compare their experiences. Moreover, the EU under the OMC usually takes some responsibility to compile reports on MS progress, based on information received from the MS and could also do so in this case. Moreover, the EU under this approach could also assist MS in assessing the legality of a specific GR, e.g. by providing information on the legal situation in different provider countries outside the EU.

One step that the EU could take in Option A in addition to supporting coordination among MS is to ensure user compliance through its own research funding provisions and other relevant funding provisions (e.g. for development cooperation or CAP 2nd pillar funding supporting the conservation of GR). Such provisions should include a clause to the end that in order for a project to be accepted and granted funding, applicants need to show, in relevant cases, if and how they have complied with provider countries' ABS legislation. In some cases, notably in research projects, it may only become clear during the research activities if GR/TKaGR need to be accessed and where; therefore the grant agreement that the EU concludes with the researcher should include a duty to notify the EU if in the course of the research GR/TKaGR are accessed and inform the EU how provider country ABS legislation has been complied with. The final instalment of the payment of a research grant could be made contingent on providing such evidence. For cases where it becomes only clear after the research project has ended which benefits the utilisation of GR has yielded, a possibility for the EU to require researchers to pay back the grant received fully or partially, in case they do not share the benefits in line with MAT, should also be integrated into the relevant legislation. By taking these measures, the EU does not in any case impinge on competences of the MS: whenever the EU has a competence to provide grant funding, it also has a competence to decide on the conditions under which such funding is granted. For example, designing its own research programmes is a competence of the EU according to Art 180(a) TFEU. These measures would mainly affect public research institutions. While the EU also provides, in principle, funding to private companies, there is evidence that most R&D funding in the private sector is also from private sources, whereas public research institutions are mostly funded by public sources (see EU baseline, chapter 10).

Besides taking funding-related measures, the EU could also engage in some of the supportive activities which will be discussed more in-depth below in section 9.5, such as developing model MAT and codes of conduct and engage in awareness-raising.

Concerning institutional arrangements in Option A most of the institutions entrusted with compliance-related responsibilities would be located at the MS level. Thus MS would have to create competent national authorities. However, the EU could still consider using the focal point which it needs to establish for interacting with the international CBD CH. Such focal point could, for example, have a role in bundling and passing on information received from the MS as part of their monitoring efforts. If the EU compiled and disseminated such information for the EU as a whole, this might make it easier for third parties to assess the effectiveness of the EU compliance system. This could, e.g., improve the EU's negotiating position in further ABS related negotiations by convincing provider countries that in sum the MS of EU have taken effective measures for user compliance under the Protocol. It may also make it easier for other countries to identify best-practices to follow.

9.3.6 Option B: EU takes measures with focus upstream

As explained above, under this option the EU takes legislative action (most likely in form of a regulation) focused on the beginning of the user chain of GR under EU jurisdiction. Such upstream activities are access to *in situ* genetic resources, importing GR into the EU, storing GR in *ex situ* collections (including identifying and documenting them for this purpose), and handing out GR from such *ex situ* collections. Under this system, the EU also establishes a general due diligence obligation for all users of genetic resources and associated traditional knowledge with regard to the utilisation of GR/TKaGR. A due diligence obligation means that users need to take measures to ensure that the GR/TKaGR they utilise are of good legal status, i.e. have either been acquired in line with provider countries' ABS legislation or are not subject to such legislation, either because a provider country does not require PIC or because the resources do not come within the purview of the Protocol.

Such an approach would have the obvious advantage that the legal status of GR that are brought into and made available to EU users is "controlled" from the point where the genetic resources enter the EU system. Thus, if the system is effective, only GR that have been properly acquired would circulate in the EU in the mid-term future. This would be complemented and reinforced by a general obligation on all users to take active steps to the best of their ability to ensure that they do not utilise illegally acquired genetic resources or associated traditional knowledge.

In the following, different elements of this regulatory approach will be discussed. As to the scope of the future EU regime, measures relating to GR and TKaGR are discussed together, as they would be subject to the same rules. However, if, for example, the EU was considered not to have competence on TKaGR-related measures, the scope of any of the elements discussed below could simply exclude TKaGR. The temporal scope of EU user compliance measures has been discussed above in section 9.1.2.

Element 1: Measures relating to certain upstream-activities

Under this option, the EU should stipulate in its legislation a prohibition to engage within the EU in certain upstream activities involving GR that have not been accessed on the basis of PIC and/or where no mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the provider country. In practical terms, such a prohibition would mostly be relevant for EU public and private *ex situ* collections, notably botanic gardens, culture collections, genebanks and other sector-specific collections. In addition, those engaging directly in bio-prospecting in countries of origin would be targeted, i.e. academic research institutions, and some commercial sectors engaging in bio-prospecting such as the bio-control sector, the cosmetics and food industry, and those pharmaceutical companies involved in natural products research.

In the context of targeted upstream measures, the wording of such a clause would specifically focus on upstream activities that do not qualify as “utilisation of GR” under the Protocol, but enable such later utilisation. The clause would prohibit the import into the EU of GR that have not been acquired legally in their country of origin, as well as their inclusion and storing in and transfer from *ex situ* collections. Such a clause mirrors the basic user-compliance-related obligations on the EU in Art 15(1) and 16(1) NP. The general prohibition should be spelt out more in detail to achieve legal certainty for users who need to know precisely what acts in relations to which GR are forbidden and allowed. Such rules could include the following:

- A prohibition to import, acquire, include in an *ex situ* collection and pass on a genetic resource if it does not come with a certificate of compliance of the provider country or it can be shown by the user through alternative means that the GR is of good legal status, i.e. either in compliance with provider country ABS regulation or not subject to such legislation. Possible ways of doing that are discussed in Box 9. below.
- An obligation to, whenever a GR is included in an *ex situ* collection, document the fact and date of its inclusion, add a description and marker allowing its later identification (e.g. a number), and information on the source from where it was obtained (e.g. a private donor or university). The obligation should also extend to transactions involving the passing on of a GR to third parties, including the name of that party and the date of the transaction. Obviously, all other information supplied with the GR (e.g. its country of origin) should also be saved.
- A duty to pass on to anyone acquiring the GR above documentation on the GR, including evidence of PIC and a copy of MAT. This could also be formulated as an obligation of traceability such as in Art 5 of the Kimberley Regulation.

Furthermore, a prohibition to engage in bio-prospecting in third countries without obtaining PIC/MAT (where required) could be considered. Such a prohibition may, at first sight, appear problematic from the viewpoint of sovereignty of these countries. As a general rule, countries under international law have the competence to set rules on individuals' behaviour on their own territory, but not on the territory of third countries. However this rule comes with exceptions. In practice, states in some regards do regulate the behaviour of

their nationals on the territories of third states and provide for related sanctions. For example, under some jurisdictions nationals may be held responsible for a crime even if the crime has not been committed on the territory of the respective states. Rules prohibiting corruption vis-à-vis foreign officials are a case in point as in many countries they have extraterritorial effect. However, in the case of bribery there is also an international agreement explicitly requiring its parties to take measures against acts of corruption committed abroad.¹⁰¹ The US Lacey Act (see Box 9. below) is also an interesting example for rules on individuals' behaviour on the territory of third countries and obligations to comply with foreign legislation. Thus, a prohibition on EU nationals to engage in bioprospecting outside the EU seems feasible from an international law point of view.

However, it is questionable whether it is needed. The EU is not required under the Protocol to prohibit certain actions of its citizens and companies outside the EU. The NP in Art 15/16 only requires user states to take measures with regard to GR/TKaGR utilised "within their jurisdiction" and the EU's jurisdiction does not extend to these countries. In practical terms a prohibition to engage in bio-prospecting in breach of the provider country's ABS legislation would only become practically relevant if an EU researcher/company A engages in bio-prospecting in a third country, and then passes on, within that third country, the GR/TKaGR to another EU national/entity that imports it into the EU. EU researcher/company A could then not be punished, because he/she is not the importer of the resource. However, the sectoral studies have not provided any evidence of this being a highly relevant scenario in practical terms. There do not, currently, seem to be many or even any EU actors systematically engaged in bio-prospecting in third countries that sell or transfer the resources to EU users as part of a transaction entirely made in a third country. In other words, the EU bio-prospectors regularly seem to be also the importers. They would thus be subject to the prohibition to import illegally sourced GR into the EU, and they could be punished if they act against this prohibition. In principle and for present purpose, thus, a prohibition to import illegally sourced GR would seem to fulfil the requirement of the NP to provide for effective measures to ensure compliance with provider country ABS legislation. However, the EU may still consider whether to prohibit bio-prospecting in third countries without obtaining PIC. This would close loopholes that may arise, for example, if EU nationals engage in bio-prospecting and trading of GR in third countries.

Box 9.10: The US Lacey Act

The US Lacey Act deals with illegally sourced wildlife, fish, plants and their products. It contains a prohibition to trade in plant and plant products that are illegally sourced from any U.S. state or any foreign country. "Illegal" in this case means in contravention of pertinent laws of the US or any other country. Thus, similar to what the implementation of the Nagoya Protocol requires, the Lacey Act aims at ensuring compliance of US actors with environmental legislation of another country.

Importers are required to declare the country of origin of harvest and species name of plants contained in their products in a declaration accompanying each shipment of the

¹⁰¹ See the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, <http://www.oecd.org/dataoecd/4/18/38028044.pdf>

relevant resources. Other than the prohibitions and the declaration requirements the Lacey Act does not contain any specific duties (e.g. due diligence duties) for users.

However, whether due care was exercised matters in the context of penalties. Acts committed knowingly in contravention of the Act may be punished through fines, a prison sentence and the forfeiture of goods. For acts committed unknowingly, the severity of the penalty will, in the case of trading illegally source resources, depend on whether “due care” was exercised or not.

Sources: <http://www.eia-global.org/lacey/P6.EIA.LaceyReport.pdf> and http://www.aphis.usda.gov/plant_health/lacey_act/

Another measure that could be considered would be a prohibition to pass on GR for uses which are not covered by the original MAT. Obviously, such a prohibition would strongly restrict the freedom of contract of those holding or wishing to acquire such resources; the freedom of contract is recognised in Art 16 of the EU Charter of Fundamental Rights. However, such freedom is not unrestricted; it can be and has been¹⁰² restricted by the EU for achieving certain public policy objectives. It could be considered whether the objective of enabling the EU to fulfil its obligations from an international agreement is a sufficient policy objective for this purpose. In this context, one relevant aspect is that the function of private contracts (in the form of MAT) under the NP is a very central, albeit specific and unusual one. The conclusion of a private contract, according to the Protocol, is a prerequisite for a certain administrative decision. Thus, a private law instrument such as a contract in a sense is “integrated” into administrative decision-making. If the EU decided to adopt the above prohibition, it would in a sense “mirror” this blending of administrative and private law.

The above clauses, could, in principle and provided the EU has competence to do so, also be extended to TKaGR with the additional requirement that the rights of ILCs under the NP must have been respected. However, it could be considered whether, in light of the difficulties of knowing who qualifies as ILC and what qualifies as TKaGR, such a prohibition should only kick in if TKaGR has been acquired intentionally or grossly negligently in breach of applicable domestic laws. Alternatively, one could limit the scope of such clauses to situations where TKaGR is clearly described in MAT that result from lawful interaction with ILCs according to the domestic law of the country where the ILC is located.

Moreover, the EU should take positive measures to support users in being able to comply with their upstream obligations, notably by providing funding for *ex situ* collections and where necessary training.

Element 2: Due diligence obligation for EU users

The second element for supporting that GR/TKaGR is utilised within the EU in line with provider country ABS legislation would be a due diligence obligation for EU users of GR/TKaGR. This option has already been discussed at expert level within the EU prior to the adoption of the Protocol. Basically, under such obligation all those utilising genetic

¹⁰² See for example Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts

resources or associated TK would have to take active steps to their best knowledge/ best of their ability to ensure that they only utilise GR that have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the provider party.

How EU users will achieve this aim is largely left to them. It should be noted that actors already targeted by specific rules addressing upstream activities as described in Element 1 above, would in most, if not all cases fulfil their due diligence duty already by complying with these rules. Nonetheless, the due diligence obligation should be formulated as an obligation on all actors engaging in utilisation of GR, as it will be legally and practically difficult to clearly distinguish for regulatory purposes between users that have a due diligence obligation and those that do not. For example, an academic researcher engaging in bio-prospecting in a third country would be subject to the targeted rules for upstream uses described above in Element 1. Where the same researcher is part of a joint-venture with a commercial company and for this purpose acquires GR from an EU *ex situ* collection, he/she would have to become subject to a due diligence duty.

Due diligence is a concept widely used in international law, but also in other fields of law (e.g. environmental protection, the medical sector, banking or antiques trade). It also a term used in commercial transactions (e.g. mergers and acquisitions) and thus a concept that many companies are familiar with. Apart from the examples discussed above in section 9.3.3 other EU legal instruments also establish due diligence rules. One example is Directive 2005/60 on money laundering which contains an extensive list of due diligence measures that credit and financial institutions must take when dealing with customers (some as basic as verifying the identity of a customer).¹⁰³ It is thus not an unusual approach for the EU to adopt.

Due diligence rules normally require a reasonable standard of care. As evident from the example of the OECD Guidance on supply chains for minerals the standard is flexible, depending on the concrete actor, sector and situation. With regard to EU user compliance measures, someone regularly trading in genetic resources for commercial purposes could be deemed to have a different standard of care from a junior researcher involved in bio-prospecting; a large multinational enterprise could have different duties than a small or medium sized enterprise. Another important characteristic of a due diligence system is that a user who has acted in line with that system to his/her best knowledge and capacity will not be punished, even if eventually it turns out that a GR utilised was acquired in violation of provider country ABS legislation. In such cases, the user should be requested to *ex post* obtain PIC and conclude MAT with the country of origin; where the country of origin does not provide its PIC, a GR may have to be seized in order to prevent further “illegal” utilisation. Further sanctions would, however, not be warranted in such cases.

¹⁰³ Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing, OJ L 309, 25.11.2005, p. 15–36

In legal terms, the future legislation would have to contain a general duty for EU users to only utilise GR if they have been acquired in line with PIC/MAT, and for this purpose, to exercise due diligence when acquiring or passing on a genetic resource or otherwise utilising them (e.g. if the GR itself is not passed on, but a blueprint for it resulting directly from research performed on a GR). EU legislation could indicate how to comply with this DD requirement by referring to some of the obligations set forth above as minimum standards, and a requirement that the due diligence system be documented in a written form.

Similar to what is set forth in the Timber Regulation users should be able to comply by using (sectoral) DD systems developed by accredited entities. Such an entity would be obliged to check that an organisation/company using its system actually complies with that system. For example, the IPEN Code of Conduct, which is widely used by EU botanic gardens, could qualify as such a system.

Box 9.11: Possibilities to verify the “good legal status” of a GR

The question how it can be verified that a GR and related TKaGR have been acquired in line with a provider country’s ABS legislation is a difficult one. Such verification is not only relevant in transactions between different users that need to fulfil a due diligence duty. It is also relevant in the context of monitoring and in cases where competent authorities need to decide, for example, whether a GR is within the temporal scope of the NP, before imposing a sanction on a user.

The Nagoya Protocol provides for the issuance of a permit by the provider country in case PIC has been granted on MAT, which, once submitted to the international ABS CH will transform into a certificate of compliance. CoCs are to be recognised internationally as evidence that a provider country’s ABS legislation has been complied with. However, the opposite is not true: A GR that does not come with a CoC has not automatically been accessed in contravention of applicable ABS legislation. It may have been acquired before the entry into force of the CBD and the adoption of ABS legislation in a given country or it may be from a country with no ABS legislation at all. It may also come from an extraterritorial area or the Multilateral System of the ITPGRFA, and thus not be covered by the NP. Hence, there needs to be a possibility besides CoCs for users of GR/TKaGR to show that the resources they use are of good legal status, i.e. have either been acquired in line with provider country ABS legislation or do not come within the purview of the Nagoya Protocol.

How that can be achieved in case of a specific GR also depends on what evidence exists on the country of origin of the GR and the date a GR was acquired. Some possible mechanisms are the following:

ITPGRFA SMTA: Collections that are part of the ITPGRFA’s multilateral system (ML) hand out material on the basis of the SMTA developed under the ITPGRFA. Where the user of a genetic resource can show such an SMTA, there is thus a great likelihood that such a GR does not fall under the NP. Matters are complicated by the fact that some *ex situ* collections use the ITPGRFA SMTA also for material that is not part of the ML. In cases of doubt whether a PGRFA is covered by the ML or not, a competent authority could contact the *ex*

situ collection providing the resource to clarify whether or not the resource is part of the ML.

Verification through international ABS CH/country of origin: Where a user can show the country of origin of a GR (e.g. because that GR is endemic to a certain country), a competent authority within the EU should seek to verify the legal status of that resource either through the international ABS CH or through seeking feedback from the country of origin's competent authority. For example, the ABS CH could provide the information that in a certain country there has never been any ABS legislation, in which case the GR has been legally acquired. Once the legal status of a GR has been ascertained, the CNA should, upon request, issue a confirmation to the user that for purposes of EU law, the GR is considered legal. This is similar to the approach under the Kimberley Regulation where diamonds already in the EU on a certain day can receive an official confirmation as of no legal concern. This confirmation could then also be passed on along the utilisation chain if further transactions are undertaken.

Documentation provided by *ex situ* collections: Many, and in particular larger EU *ex situ* collections by now have a good documentation system in place. Consequently they can provide documentation on a resource's origin and the date when it was entered into the collection whenever they hand out a resource. This is true, notably, for material in the IPEN system and for the majority of culture collections. A written document of an *ex situ* collection could also be accepted as evidence that the respective material does not fall under the NP. To reinforce this system, the EU could compile a list with *ex situ* collections having a reliable documentation system in place and only documentation provided by such collections would be accepted as evidence. Obviously, *ex situ* collections which do not yet have such a system in place should be supported in developing it.

Existing tracking/identification systems: Similarly to *ex situ* collections, many laboratories/private companies already have so called multi-user laboratory information management systems (LIMS) in place. As part of such LIMS, unique identifiers assigned to GR allow tracking the use of GR in the laboratory (Garrity *et al*, 2009). If a company can show that it has such a system in place and plausibly explain that the identifier for a specific GR indicates that it does not fall within the scope of NP, this evidence should also be accepted. As the checking of such evidence may require a very good understanding of biotechnological research, which not all competent national authorities may have, it may be considered whether the task should be entrusted to a specific institution or unit at MS or EU level specialised on such matters. At the EU level, the Joint Research Centre may be able to assume responsibility for such tasks.

Publications: In some cases, a user may also be able to show that he/she has acquired a genetic resource prior to the entry into force of the CBD through publications. This notably applies to academic researchers who usually seek to publish the results of their non-commercial research as quickly as possible. If a publication dates back a few years, this is a good indication that a GR was not accessed after the entry into the force of the NP.

Private contracts: Private law contracts other than the SMTA could also serve in some cases as evidence on when a GR was acquired, provided the GR is sufficiently clearly described and the contract is dated.

The above are unlikely to cover all constellations occurring practically. For example, in the animal breeding sector, breeding material occasionally seems to be exchanged on the basis of a gentlemen's agreement, which is unlikely to come in a written form (see sectoral sheet on animal breeding, Annex 3). Thus, the relevant legal norms should be flexible enough to allow users to demonstrate through other means than the above that they have acquired a GR legally. The above could be named in an exemplary way, but such a list should not be exhaustive. Authorities under national law are usually allowed to use certain types of evidence in ascertaining facts or there are rules on which evidence is admissible in administrative court proceedings. These types of evidence could also be used with regard to finding out the legal status of a genetic resource.

In order to help users and enhance legal certainty, procedures should be created whereby users can seek assistance on ascertaining the legal status of a GR from a competent authority and request a related confirmation if the GR is found to be of good legal status. This could, for example, be very useful for SMEs with limited resources. The competent authority should liaise with the international ABS CH and/or the competent authorities of a (potential) provider states to ascertain the legal status of the GR.

Element 3: Monitoring

According to the Nagoya Protocol, monitoring is to support user compliance measures. Monitoring whether EU user compliance measures are complied with is, in addition, a precondition for sanctioning non-compliance. Where instances of non-compliance are not identified by or brought to the attention of competent authorities, sanctions cannot be imposed either. We therefore discuss in this section how the EU could fulfil its obligation on monitoring contained in Art 17(1) NP, before we turn to measures to address non-compliance in the subsequent section. Monitoring measures for the upstream activities focus on specific acquisitions and transactions of genetic resources, whereas monitoring of compliance with the due diligence obligation would more generally focus on whether those engaging in utilisation activities within the EU have taken specific steps to the best of their ability to ensure that only legally acquired genetic resources and TKaGR are utilised.

With regard to monitoring the upstream activities, different approaches are, again, conceivable. Not all of those options are mutually exclusive or mutually combinable; this will also be discussed in the following. One option theoretically conceivable, namely the involvement of **customs authorities** in the case GR are imported into the EU, is not discussed in depth.¹⁰⁴ In general it seems questionable whether customs authorities could practically and effectively monitor the import of GR into the EU. There are some example of genetic resources that actually proceed through customs inspections e.g. for sanitary

¹⁰⁴ On the use of customs procedures as user country measures, see generally Barber et al. 2003, p.26ff.

reasons (see sectoral sheet on culture collections, Annex 3). However, genetic resources are not necessarily needed in large quantities to perform research on them. There is thus a considerable chance that misappropriation of genetic resources may go undetected at the border. Moreover, customs inspections can *per se* not relate to the “import” of traditional knowledge into the EU, or to the case where analysis of a genetic resource is carried out in the provider country and only knowledge is “imported” into the EU.¹⁰⁵

Option B 3.1: DG Research and Innovation and other EU entities as checkpoints

One action that the EU could take is to use its research funding and other relevant funding procedures to monitor compliance with the upstream measures (element 1 above) within the EU, as discussed already in option A. The EU should include a clause in the relevant provisions to the end that in order for a project to be accepted and granted funding, applicants need to show, in relevant cases, if and how they have complied with provider countries’ ABS legislation. Thus, the competent DGs (Research & Innovation, Development & Cooperation) could monitor the behaviour of those users that actually receive funding from the EU. EU research funding could also be used for monitoring whether recipients of funds comply with their general due diligence obligation.

As in cases of some research projects it may only become clear during the project if GR/TKaGR need to be accessed and where, EU research grant agreements should include a duty to notify the EU if in the course of the research GR/TKaGR are accessed and inform the EU how provider country ABS legislation has been complied with. The final instalment of the payment of a research grant could be made contingent on providing such evidence.

The EU, in principle, provides research grants to both public institutions and commercial companies. Thus, in principle all sectors discussed in this study, with the potential exception of *ex situ* collections that merely include GR in their collections and do not engage in any research, could be subject to such monitoring, in particular in the context of research funding. In practice, it is likely to be more relevant for the public sector, as private companies are funding most of their research through other than public sources (see EU baseline, chapter 10). Botanic gardens, in particular, also seem to engage in cooperation with *ex situ* collections in developing countries, and may thus potentially receive development cooperation funding (see sectoral sheet on botanic gardens, Annex 3).

From a legal point of view, the EU could take the measures discussed here independently of what other steps it takes with regard to monitoring.

Option B 3.2 Monitoring through inspection by independent CNAs

Monitoring on whether users comply with obligations on upstream activities and their due diligence obligations in this option would be done by the CNAs. CNAs would check whether the general prohibitions on upstream activities are complied with, but also whether users have taken active steps to comply with their due diligence obligation, including the

¹⁰⁵ It is unclear how many case of “import” of TKaGR (without the related GR) exist. One example is given in the sectoral sheet on botanic gardens.

establishment and/or use of due diligence systems. Thus, all the different sectors discussed in this study could become subject to such monitoring.

The Timber Regulation could serve here as a model once more. It provides that checks “shall be conducted in accordance with a periodically reviewed plan following a risk-based approach. In addition, checks may be conducted when a competent authority is in possession of relevant information, including on the basis of substantiated concerns provided by third parties, concerning compliance by an operator with this Regulation”. Thus, in the current context, competent authorities could embark on regular inspections, based on an analysis of where the risk of non-compliance is greatest. The research on different sectors in the framework of this study indicates that some sectors engage more in bio-prospecting than others do, and in some there is less awareness of ABS matters than in others (see EU baseline, chapter 10). Also, severely underfunded or small *ex situ* collections are more likely to have no sufficient documentation system or appropriate ABS policies in place, creating higher risks of non-compliance with EU user compliance legislation. Thus, particular attention could be given to monitoring such sectors and institutions. In addition, CNAs could accept complaints from a wide range of actors from within and outside the EU and, where there is a substantiated complaint on non-compliance, proceed to carry out checks on the respective users.

It could be considered whether in order to enable CNAs to more effectively perform their monitoring tasks, *ex situ* collections should be required to make public to the CNAs whenever they include a GR into the collection or transfer a GR to outside users. This would, for example, enable CNAs to verify where most transactions take place and where, hence, controls may be most needed.

Option B 3.3 Monitoring through CNAs in combination with third parties

As a third option, which is alternative to the Option 3.2, but could be combined with Option 3.1, some of the monitoring tasks could be performed by third parties, notably accredited due diligence organisations. This would be the preferable approach if the EU decides that users can fulfil their due diligence obligations by resorting to the system provided by an accredited due diligence organization, as suggested above. Such third parties could, for example, be required to report in regular intervals or when they find users not to comply with their duties to CNAs, which could then take appropriate action. CNAs under this system would still be required to carry out independent checks on users, but could do so less frequently. In addition, the CNA would have to ensure that third parties adequately perform their monitoring duties.

Besides accredited due diligence organisations, other entities could also be entrusted with certain tasks in monitoring, where particular expertise is required. For example, the sectoral analysis of botanic gardens indicates that representative of botanic garden only consider experts from botanic gardens to be qualified to undertake monitoring of documentation systems and transactions in GR carried out by botanic gardens.

Monitoring by accredited due diligence organisations would become particularly relevant for those sectors that do not have specific obligations (as described in element 1), but a general due diligence duty. Basically, these would be all commercial users of GR. Depending on which other third parties are involved in monitoring, other non-commercial sectors (e.g. botanic gardens) may be subject to monitoring by such third parties as well. Such third parties would monitor compliance with whatever duties are relevant for the respective user, e.g. prohibitions relating to *ex situ* collections.

A model for this approach is provided by the Timber Regulation. According to Art 8(4) Timber Regulation competent authorities “shall carry out checks at regular intervals to verify that the monitoring organisations operating within the competent authorities’ jurisdiction” continue to fulfil the functions they have within the Regulation’s due diligence scheme. A monitoring organisation under the Timber Regulation must, according to Art 8(1)(b), verify the proper use of its due diligence system by those using it. In addition, competent authorities according to Art 10 Timber Regulation are to check companies to examine their due diligence system as well as the documentation and records that demonstrate the proper functioning of that system. In addition, the authorities are to carry out “spot checks, including field audits”. Thus, the competent authorities monitor both monitoring organisations – which would assume part of the responsibility for monitoring companies using due diligence systems – and timber companies directly. Under the present sub-option, a system built on those principles would be developed for monitoring user compliance in the context of ABS.

Element 4: Sanctions for non-compliance

With regard to sanctions, different options are discussed in the following. Obviously, such sanctions can only be imposed after a breach of EU obligations has been established in the course of monitoring, as described above. These sanctions may come in response to a breach of different obligations. For example, in a due diligence system, a user could be sanctioned either for failure to establish a DD system or because of failing to act consistently with the DD system established. Thus, EU legislation would have to make clear, for the breach of which clauses of EU legislation MS may or would have to impose sanctions.

A legally and practically very important question relates to the burden of proof. Does a competent national authority need to show that a user is breaching EU legislation for her/him to be sanctioned or does the user have to prove that he has acted consistently with EU legislation? Technically, who bears the burden of proof is a consequence of formulating the relevant legal obligations in a certain way.

Generally, in criminal law the burden of proof is on the state authorities that need to prove the misbehaviour of an alleged perpetrator. Anything else is not compatible with the presumption of innocence, which is a fundamental principle of EU law. However, the same is not necessarily true in administrative law. Here, the burden of proof depends on the situation. A citizen requesting something (e.g. a permit or a subsidy) from the state usually needs to demonstrate that he/she fulfils the necessary requirements. However, if an authority wants to impose sanctions or restrict the freedom of a citizen, it is normally the

authority that would have to prove that the factual requirements of the norm on which it bases its actions are fulfilled.

Among the two elements discussed above – the specific upstream measures (element 1) and the general due diligence obligation (element 2) – the due diligence system lends itself more easily to imposing the burden of proof for compliance on users. In fact, it is the very essence of such a system that users actively take measures to ensure they only utilise GR/TKaGR of good legal status. If they comply with their obligations and indeed take such measures, this also implies that they should be able to demonstrate which measures they have taken and that they should have knowledge on a GR before using it. As a due diligence system does not prescribe specific actions, it is actually ONLY the users that can provide evidence to a competent authority on what measures they have taken and hence, how they have complied with their due diligence duty. It therefore seems warranted to consider a user not able or willing to provide evidence on the due diligence system established in general and on its use in the case of a specific GR as non-complying with the due diligence obligation. Hence such a user could be subject to sanctions. The situation is different for a prohibition on certain upstream uses. A prohibition requires a “non-act” of users. However a “non-act” is virtually impossible to prove; hence, it seems appropriate in these cases that a competent authority must establish an actual violation of the related EU norms before imposing a sanction. Thus a competent authority would, for example, have to find a GR in an *ex situ* collection and show that the GR has been taken from a country with a PIC requirement, but without PIC actually having been granted, before it imposes a sanction.

Different sanctions and allocations of burden of proof could also be envisaged for violations concerning GR and TKaGR respectively, given that it may be more difficult for users to ensure they are in line with TKaGR-related provisions. The example of the US Lacey Act is interesting in this regard, as it contains a nuanced system of sanctions, depending on which norms were violated and what the user knew when violating the Act (see Box 9.).

Option B 4.1: Obligation on MS to provide for sanctions

A first option is to include into an EU legislative act an obligation for MS to provide for appropriate, effective and proportionate measures in cases of non-compliance with the EU provisions, thus mirroring the wording of Art 15(2) and 16(2). This model is found in the Kimberley Regulation, but EU environmental law provides other examples for such an approach.¹⁰⁶ This approach would ensure that the principle of subsidiarity is observed, while the EU at the same time complies with its obligations under Art 15(2) and 16(2) NP. Alternatively, the EU could also, besides setting forth this general option, indicate a non-

¹⁰⁶ See, e.g., Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC, OJ L 033 , 04/02/2006, p. 1-17. Art 20 of this Regulation (which implements at EU level a Protocol to the Aarhus Convention) provides that Member States shall: lay down the rules on penalties applicable to infringements of the provisions of this Regulation and take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive and the relevant provisions must be notified to the Commission one year after entry into force of this Regulation at the latest.

conclusive list of sanctions, such as in the Timber Regulation. This list could comprise any of the sanctions discussed in the subsequent section.

Option B 4.2: Conclusive list of sanctions defined in EU regulation

A second option would be to define a closed list of sanctions which can be taken by competent authorities. There is no very good case for going one step further and stating in EU regulation which sanctions should be imposed in relation to the breach of which obligation. As each case is individual, proportionality requirements require the consideration of the circumstances in each case and a tailored response. Moreover, to the extent that MS authorities act as competent national authorities, they should be able to choose sanctions that are best in line with their national system of sanctions for non-compliance with administrative rules. Thus, which sanction would be expedient and proportional in case of the violation of a specific user obligation would be for the competent national authority to decide. In the upstream option, all or some of the following sanctions could be envisaged:

- **Obligation to *ex post* require consent/conclude MAT/share benefits:** The most obvious sanction, which is probably also best in line with the objectives of the Protocol, would be to *ex post* require a user of a GR or TKaGR to bring his/her behaviour in compliance with the Protocol, by *ex post* requesting the consent of the provider country/ILCs and conclude MAT. If such consent is denied, the respective GR would have to be seized. If possible, it could be reverted to the country of origin. This sanction seems to be most appropriate in the cases of actors that actually have contact with the countries of origin of a GR, e.g., because they engage in bio-prospecting or acquire GR from an *ex situ* collection in such a country. It does not make sense in cases where a user does not know the country of origin of a GR.
- **“Naming and shaming”:** Where the reputation of actors is an important factor, one potential sanction could also be public naming and shaming, i.e. the Commission or MS publishing a list with actors that have not sourced GR correctly, have not taken any remedial measure to prevent future similar cases or have no due diligence system in place. Other users could then be considered to be violating their DD duties when acquiring a GR from actors on that list, unless they have water-proof evidence that a GR acquired from them is of good legal status.
- **Administrative sanctions:** Typical administrative sanctions are fines, seizure of good or closing of businesses. In line with the overall purpose of the NP of fostering the sustainable use of genetic resources and in light of proportionality considerations, a temporary or even permanent closing of an institution does not appear as an appropriate sanction. For example, closing an *ex situ* collection for handing out GR in a manner inconsistent with EU legislation would not benefit the conservation of GR or facilitate related research in a long term. However, fines, the seizure of a GR or an injunction to stop using a certain GR are all theoretically feasible, even though some of them may pose practical problems in some cases. Fines are a particular interesting option as they could be paid into a fund out of which projects for the conservation of GR, notably in developing countries, are funded. Such sanctions can be applied both

in cases of violations of the specific prohibitions and obligations relating to upstream uses and in cases of violation of due diligence related provisions.

- **Criminal sanctions:** Criminal sanctions, while theoretically feasible, appear as a rather far-reaching measure in the case of violations of EU user compliance measures, as the actual damage done by utilisation in contravention of EU legislation is limited and often more of a loss to be measured in monetary terms for the country of origin (even though it may have a more profound cultural significance for ILCs). Unless these violations are deliberate, systematic and continued, criminal sanctions are thus likely to raise proportionality issues, and in addition would benefit provider countries at most at the level of providing non-material satisfaction. The proportionality concern becomes evident from a comparison with the environmental crimes directive of the EU. Under this directive, the actions that MS are required to treat as crimes in their national legal orders mostly are likely to cause serious injury or the death of a person or substantial damage to the environment. None of that is the case when EU user compliance obligations are not respected.

In general, the balance between the strength of the EU system for monitoring and the extent of sanctions should be considered. If the system for monitoring is relatively weak, potential sanctions may have to be more far-reaching, in order to deter users from acting inconsistently with EU legislation.

Option B 3.3 Sanctions relating to EU funding

A last sanction, which has been discussed above already, is the non-approval of an EU grant or withholding of payments in cases researchers do not comply with the ABS legislation of a provider country. This could become relevant for different types of activities, including bio-prospecting, conservation activities, basic or applied research. However, it would obviously only apply to a limited number of users, i.e. those receiving EU funding, which are mostly from the public sector.

Element 5: Institutional provisions

The above options would require the establishment of competent authorities in MS (which obviously could also perform the function of provider side focal points). Theoretically, an EU CNA could instead or additionally be created and assume e.g. a role in monitoring. However, there is no very good reason to do so as authorities at the MS are obviously better suited to perform certain tasks in light of their knowledge of the situation and language in the respective MS. Also, the standard practice in EU environmental legislation is to assign the responsibility for implementation of EU law to MS. Thus, MS would have to designate competent authorities.

These would have the following responsibilities with regard to upstream uses:

- To be involved in monitoring of upstream uses in the way described above, depending on the option chosen.

- To be involved in the monitoring of whether users comply with their due diligence duty, or, if accredited entities creating due diligence systems are foreseen in the future regulatory approach, monitor these accredited entities and potentially other third parties involved in monitoring, and to a lesser extent, users.
- To address cases of non-compliance and cooperate with competent authorities in other Parties in cases of alleged violations of the Protocol as stipulated in Art 15(3) and 16(3).
- Optionally, to help users to clarify the legal status of a genetic resource upon request, where needed interacting with the international ABS CH and the competent authorities of provider countries.
- Depending on the implementation option chosen, to accredit organisations entertaining a due diligence system.

In addition, the Protocol requires all parties to establish a focal point with the function, *inter alia*, to provide information on competent national authorities, relevant indigenous and local communities and relevant stakeholders. In addition, such a focal point could disseminate information on access to MS courts in MAT-related cases. The EU should thus establish such a focal point at EU level, even if it has no CNA.

9.3.7 Option C: EU takes measures with downstream focus

Under this option, the EU focuses its monitoring and non-compliance measures on the end of the utilisation chain, i.e. the stage where users seek market approval or intellectual property protection. This model is thus close to what developing countries sought in the negotiations on the Nagoya Protocol.

Element 1: Prohibition to utilise illegally acquired genetic resources

Under this option, the central piece of EU legislative action (most likely in form of a regulation) is a general prohibition for all EU users to utilise illegally acquired genetic resources or associated traditional knowledge. As for option B, this could be broken down into some more concrete prohibitions and obligations, which serve the fulfilment of the basic obligation, notably:

- A prohibition to engage in research and development on GR which lack documentation allowing ascertaining their good legal status
- A duty to pass on to anyone acquiring the GR documentation on the GR, including – where relevant - evidence of PIC and a copy of MAT. This could also be formulated as an obligation of traceability such as in Art 5 of the Kimberley Regulation.

- A duty to include in any type of publications presenting research results resulting from the utilisation of GR and/ or TKaGR a reference to the provider country and/ or ILCs providing the TKaGR.

A prohibition to utilise a GR in a manner not covered by MAT and, where needed, conclude new MAT, could be considered. Again, this needs to be carefully assessed against the freedom of contract guaranteed by the EU. However, as discussed for Option B, a restriction of that freedom is, in principle, possible.

Element 2: Monitoring compliance with the prohibition through checkpoints

Some of the options for monitoring in Option C are the same as in Option B (2.1 and 2.4). However, entrusting IP offices and market approval authorities with monitoring are additional options in the case of downstream uses (2.2 and 2.3).

Option C 2.1: DG Research and Innovation as a checkpoint

As discussed both for Option A and Option B, the EU could include in its research funding provisions safeguards requiring grant applicants to provide evidence that GR utilised during the research were of good legal status in relation to ABS. Again, the EU, from a legal point of view, could take this measure independently of what other steps it takes with regard to monitoring.

Option C 2.2 Monitoring through intellectual property offices

The option favoured by developing countries in the negotiations on the Protocol was appointing IPR authorities as checkpoints. The EU did not subscribe to this position, arguing that issues relating to IPR should be discussed in the relevant fora, notably WIPO and the WTO. Besides patent offices, offices for plant variety protection could also become relevant, as plant varieties may also be developed using genetic resources acquired elsewhere.¹⁰⁷ However, many plant varieties are likely to be covered by the ITPGRFA rather than the NP, making patent offices the more relevant institutions in this context.

Using IP offices as checkpoints would be in line with the notion in the Protocol that checkpoints should be relevant to the utilization of genetic resources, as applying for intellectual property rights is a step in commercialising respective products.

IP offices would monitor compliance with the prohibitions above. Obviously IP offices can only monitor the behaviour of those users of GR that develop products for which they seek IP protection. As described above (see EU baseline, chapter 10), plant variety rights are mostly relevant for the seed industry (conventional breeding) and horticulture, whereas patents are relevant for the pharmaceutical and biotechnology sectors, and to a lesser

¹⁰⁷ The case of the Enola bean is one example. In this case, a US American business man bought colored beans on a Mexican market, and developed from it, through conventional breeding methods, of uniformly yellow beans for which he thought IP protection in the US, for more information see Rattray (2008).

extent, the cosmetic and food & beverage industries, the academic sector and the animal breeding industry.¹⁰⁸ However, only a small part of innovations resulting from the utilisation of GR are ultimately subject to IP protection: For example, less than 14% of the varieties registered on the EU Common Catalogues for agricultural crops and vegetables are protected through community plant variety rights. In the pharmaceutical industry, patent applications are only submitted by the time lead compounds have entered the lead optimisation stage (EU baseline, chapter 10). For the seed industry it may take thousands of plant breeding crosses for the development of a new wheat variety (EU baseline, chapter 10).

At the European level, the relevant authorities are the European Patent Office (EPO) and the Community Plant Variety Office (CVPO). The EPO is not an EU institution, however, but has been established pursuant to the European Patent Convention (EPC). The EPC is an international agreement with 38 contracting parties, including all of the EU Member States. The EPO is thus not bound by EU law, and it could not therefore be given any tasks in the context of the Protocol's implementation by an EU legislative act. Proper EPC decision-making procedures, involving all the Parties to the Convention, would have to be followed for this purpose. It should also be noted that patents granted before the EPO are not granted for the entire EPC area, but are limited territorially to individual Member States where the applicant wishes to obtain the patent.

For IP offices to effectively monitor the utilisation of genetic resources with a view to the legality of the utilisation of the GR in an invention/variety for which IP protection is sought, applicants would have to disclose certain information which would allow the IP offices to ascertain whether a certain GR has been used in conformity with the applicable EU law.

Some options for such information duties are discussed in Box 9.12 below. Currently, the origin of genetic resources used in inventions is often disclosed in patent application for a variety of reasons already (Queen Mary Intellectual Property Research Institute 2004; WIPO 2001). To which extent such information could be helpful in investigating compliance with EU legislation and the NP is, however, an open question.

Finally, the burden of proof is, again, an important issue. As stated above, the usual standard is that, an authority wanting to impose sanctions or restrict the freedom of a citizen will have to prove that the requirements of the norm on which it bases its actions are fulfilled. In principle, thus, a competent authority would, for example, have to find a GR in the laboratory of a company and show that the GR has no documentation showing its good legal status and that the company has nevertheless engaged in R&D on the GR. This is likely to be often difficult for public authorities given the largely intangible nature of genetic resources and related information. The introduction of disclosure requirements on users would hence greatly facilitate the monitoring task of public authorities. Users could be obliged to disclose information on the relevance of their activities to ABS and in case of such

¹⁰⁸ According to the sectoral sheet on the academic sector, the government and the higher education sectors are responsible for only 3.2% of the patent applications to the EPO, whereas the business sector is responsible for 85.7% of them.

relevance provide documentation on the good legal status of the resources utilised (see Box 9.12).

Obviously, as discussed in relation to the prohibition on certain upstream activities under Option B, a careful analysis will be required on how to address situations where users would be obliged to provide information for genetic resources that are outside the scope of the Nagoya Protocol system, be it because they were acquired prior to the entry into force of the Convention or because they were acquired in "free access" jurisdictions or from areas beyond national jurisdiction (high seas, Antarctica). In such cases users might not be in possession of the information to be disclosed and it might also be difficult for them to prove that their activities do not come within the purview of user compliance measures adopted to implement the Nagoya Protocol. One idea for addressing such cases could be to oblige users to indicate that there is no documentation if according to their information a GR is not within the scope of the NP and implementing legislation. Then, it would fall on the competent authority to investigate the situation through ordinary administrative procedures (e.g. witness statements).

Box 9.12: Options for disclosure requirements

Designing disclosure requirements involves fundamental choices as to who has to disclose which information.

Concerning who has to disclose information, one sensible restriction would be requiring information only from those (individual researchers or companies) that have developed a product or innovation based on genetic resources. If those affected by such obligation need to self-identify as being subject to a disclosure obligation, a thorough description of activities falling within and outside the notion of "utilisation of genetic resources" will be needed to allow users to undertake such self-identification with any reasonable degree of certainty. Thus, legal norms involving disclosure requirements would have to clarify how closely utilisation activities must be related to the innovation or the product to trigger the disclosure obligation.

A further question that must be addressed is whether all users of genetic resources/TKaGR at a certain checkpoint will have to disclose such information, irrespective of whether these resources are under the Nagoya Protocol or not. For the purpose of monitoring, it is likely more effective, but also more costly and burdensome to require disclosure from ALL users of GR, whether these come within the scope of the Nagoya Protocol or not. It could thus be considered that only those users which, based on a prior self-assessment, arrive at the conclusion that the NP applies to them, would be asked to disclose information. Users could base such a self-assessment on using any of the documentation described in Box 9.11 above to identify when and where the resources were acquired and then cross-check that information with e.g. the list of different countries' ABS measures made available through the CHM. In that way, it would be possible for a user to find out in a relatively simple manner whether the country where a GR is from had ABS legislation in place when it was acquired. In cases of doubt, users should be requested to disclose information. Some middle-way could also be chosen, e.g. by in principle allowing users to self-assess whether

or not their GR are within the scope of the Protocol, but by requiring the checkpoint to request additional information in case there is a suspicion that the self-assessment is wrong, for example as result of the way an invention is described in a patent application. Alternatively, certain information (e.g. date of acquisition) could be requested from all users and more far-reaching information (e.g. on PIC/MAT) only from certain users.

The second choice, which is interlinked with the first, is what information must be provided. The NP in Art 17(1)(a)(i) and (ii) mentions PIC, the source of the genetic resource, the establishment of MAT and the utilization of the GR as relevant information. However, ultimately such information would be required for ensuring a user's compliance with provider country ABS legislation. Thus, instead of requiring from users evidence that would allow authorities to then ascertain compliance, the more direct way may be to require users to directly provide any evidence they have which shows that they are in compliance with the NP. Which types of evidence besides certificates of compliance could serve as evidence of compliance has been discussed above in Box 9.11.

Only where users have no such evidence showing compliance, they should provide information which allows the authority to ascertain compliance, such as the source of the genetic resource, the date of acquisition and so forth.

The inclusion of a meaningful disclosure requirement in IP law raises important legal issues both from an international legal viewpoint and regarding the role of the EPO.

An exhaustive analysis of **international legal issues** would go well beyond the scope of this study. However, some important aspects can be noted here. The relevant international agreements are the WTO TRIPS Agreement, the WIPO Patent Cooperation Treaty (PCT) and the WIPO Patent Law Treaty (PLT). The TRIPS Agreement has been ratified by the EC and its Member States and the PCT has been ratified by all Member States. By contrast, only a dozen EU Member States have ratified the PLT. All these treaties contain requirements on patents. The TRIPS Agreement contains, in its Art 27(f), substantive minimum requirements for patentability, in Art 29 conditions for patent applications, and, in Art 62, general (and generic) procedural requirements. The PCT, in turn, contains procedural requirements relating to international patent applications under the WIPO system, but does not set forth any substantive rules on patentability. Finally, the PLT sets forth predominantly procedural rules on national patent applications. None of them currently refers to the disclosure of any information relating to the legal status of a genetic resource.

Adding a disclosure requirement to EU law that is formal in nature and not a precondition for the granting of a patent is unlikely to violate the TRIPS Agreement (Queen Mary Intellectual Property Research Institute 2004); the TRIPS Agreement contains only rather general procedural standards for patent applications. The situation under the PCT and the PLT is somewhat more complex. Art 6 PLT states that parties of the PLT may not require in patent applications compliance with any requirement relating to the form or contents of an application different from or additional to what is required under the PCT. The PCT, in turn, states in Art 27 that no national law shall require compliance with requirements relating to the form or contents of an international application different from or additional to those contained in the PCT or the PCT regulations. There are diverging views on whether this clause prevents a formal disclosure requirement in national law (see Curchod, 2005).

From an EU law point of view, the implementation of a disclosure requirement in patent legislation is also complex. As noted above, in 2004, the EU established a common enforcement framework aimed at harmonising Member States' legislation to ensure that intellectual property enjoys an equivalent level of protection across the internal market and to reduce counterfeiting.¹⁰⁹ More recently, it introduced proposals to develop an industrial property rights system¹¹⁰ and a regulation for the creation of a unitary EU patent, based on Art 118(1) TFEU is on the table.¹¹¹

While these initiatives are of potential future relevance in an ABS context, the most relevant piece of legislation already in force is Directive 98/44/EC on the legal protection of biotechnological inventions (the biopatent Directive), discussed in chapter 4 of this report. The Directive's preamble mentions that if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known. This is not a binding legal requirement under EU law, even though some Member States such as Denmark, Belgium and Germany have turned it into a binding legal requirement in their respective transposing legislative measures. Still, the biopatent Directive appears to be the most logical entry point for integrating a disclosure requirement into EU patent law, given that it already mentions disclosure and also deals specifically with biopatents.

While such a requirement in the biopatents Directive would be binding upon Member States, it would have no immediate effect on patent procedures at the EPO, which are governed by the EPC, and regulations implementing the EPC. As only an estimated 20-25% of patent applications for biotechnological inventions are submitted at the national level (Hoare and Tarasofsky, 2006), a requirement becoming effective only in MS patent offices, but not at the EU level, would have a limited impact. Thus, a corresponding requirement should also be integrated into the law governing the operation of the EPO for reasons of effectiveness.

The biopatents Directive was originally made applicable by the EPO through a decision by the Administrative Council of the European Patent Organisation.¹¹² In this decision, the Administrative Council set forth that the Implementing Regulation to the EPC should be

¹⁰⁹ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

¹¹⁰ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - An Industrial Property Rights Strategy for Europe (COM/2008/0465 final).

¹¹¹ Proposal for a regulation on implementing enhanced cooperation in the area of the creation of unitary patent, Brussels, 13.4.2011, COM(2011) 215 final. As not all member states agreed originally agreed to the idea of a unitary EU patent, this proposal was adopted as part of an enhanced cooperation procedure.

¹¹² Decision of the Administrative Council of 16 June 1999 amending the Implementing Regulations to the European Patent Convention, Official Journal of the EPO, 1999, p. 437, http://archive.epo.org/epo/pubs/oj99/7_99/index.htm

amended to include Art 23(b) to 23(e).¹¹³ These articles stipulate that relevant provisions of the EPC are to be interpreted in line with the biopatent Directive, and set forth rules on what was to be considered patentable subject matter. The legality of this move was, to some extent, controversial; some claim that the Administrative Council exceeded its competences when changing the Implementing Regulation, claiming that the Administrative Council's authority extends to changing the Implementing Regulation, but not adding new regulatory contents (Bauer, 1999).

An additional requirement in EPO procedures on the disclosure of information requested in the Protocol is likely to require a change in the EPC itself, rather than the Implementing Regulation. The relevant provisions dealing with patent applications (Art 78 and Art 83 EPC) so far require a description of the invention. While a requirement to describe the origin of a genetic resource may be considered part of a description of an invention, other information such as the establishment of mutually agreed terms, go beyond the mere description of the invention. Requiring this information from applicants would thus likely require a legal provision to this end in the EPC. According to its Art 172(1), the EPC can be revised by a Conference of the Parties of the European Patent Organisation. An amendment of the EPC requires a three quarters majority of the Contracting States voting at the Conference. Currently, 27 out of 38 Member States of the European Patent Organisation are EU Member States, constituting slightly less than a three quarter majority.

Concerning amendments to the EU plant variety legislation, the situation is less complex. The basic rules of community plant variety protection are set forth in Council Regulation No. 2100/94 on Community Plant Variety Rights (CPVR). According to Art 50, the application must include "the name of the breeder and an assurance that no further persons have been involved in the breeding, or discovery and development, of the variety; if the applicant is not the breeder, or not the only breeder, he shall provide the relevant documentary evidence as to how the entitlement to the Community plant variety right came into his possession" (Art 50(I)(d)). Moreover, the geographical origin of a variety must also be disclosed (Art 50(I)(g)). There is currently no legal requirement in EU law for applicants to provide additional information, concerning MAT, for example. However, the UPOV 1991, which is an international agreement containing rules on plant variety protection that the EU has ratified, does not contain any rules forbidding the EU from incorporating additional disclosure requirements into its legislation. However, plant variety protection is not only granted at the EU level, but also in various member states at the national level. Thus, EU measures would also have to extend to harmonising of MS legislation with the purpose of turning the relevant national authorities into checkpoints.

Option C 2.3 Monitoring through market approval authorities

Another option would be to entrust the authorities responsible for market approval for certain products with the task of monitoring, hence turning them into checkpoints. Relevant products which build on genetic resources include medicinal products, cosmetics, seeds and

¹¹³ Today, the numbering in the Implementing Regulation is slightly different, but the rules are still applicable, see Rules 26ff of the Implementing Regulations, available at <http://www.epo.org/law-practice/legal-texts/archive/documentation/implementing-regulations.html>

plant propagating materials, novel foods (e.g. dietary supplements) and genetically modified organisms. Like IP offices, market approval authorities would monitor compliance with the general prohibition above. Their reach would be limited to those users of GR that develop products for which they are required to go through market approval procedures. As in the case of IP, this is unlikely to be the case for purely academic research, culture collections, botanic gardens, and the animal breeding industry at least.

As in the case of IP offices, effective monitoring of the utilisation of genetic resources with a view to the legality of the utilisation of the GR for a product for which market approval is sought, a disclosure requirement would have to be integrated in EU legislation. Different possible options are discussed in Box 9..

As the following overview will make clear, EU law contains different approval procedures for different products, involving different authorities:

- There are different procedures for market approval for **medicinal products** for human and veterinary use in the EU. Regulation No 726/2004 sets out the approval procedure for those medicinal products for human uses which have been developed using certain biotechnological processes, for medicinal products for several specific diseases including AIDS, cancer and diabetes and for some other medicinal products.¹¹⁴

A recommendation on market approval for pharmaceuticals for human use is issued by the Committee for Medicinal Products for Human Use (CHMP) which is a part of the European Medicines Agency (EMA). Applicants must submit the documentation mentioned in Art 8 of Directive 2001/83.¹¹⁵ This includes documents describing the characteristics of the product, particulars of all the constituents of the medicinal product, indications etc. The actual authorisation, according to Art 10 of Regulation No 726/2004, is issued by the Commission, based on the CHMP's opinion.

For other medicinal products, Art 6 Directive 2001/83/EC sets forth that approval by competent national authorities is required, which is to be given according to the standards and procedures set forth in the directive. According to definitions in Art 1 of Directive 2001/83, medicinal products in the sense of this directive also include 'micro-organisms, plants, parts of plants, vegetable secretions and, extracts' (i.e. herbal or plant medicines), to which the Protocol is of potentially huge significance. Thus, not all pharmaceutical products are approved at the EU level or by the same authority.

- The marketing of **cosmetics** is currently governed by Council Directive 76/768/EEC.¹¹⁶ This Directive is to be replaced in 2013 by Regulation 223/2009.¹¹⁷ The Regulation

¹¹⁴ Regulation No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004.

¹¹⁵ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001

¹¹⁶ Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976

¹¹⁷ Regulation No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009

contains no pre-market approval requirement, but its Art 13 sets out a pre-marketing notification duty. The notification is to be made to the Commission, which then shares the information with all competent national authorities. Thus either the Commission or the MS authorities could fulfil a checkpoint function here. The notification duty currently does not extend to any of the information that would be relevant under the Protocol.

- The central piece of legislation for the approval of so called **novel food** is Regulation 258/97.¹¹⁸ According to its Art 1, this regulation applies *inter alia* to “foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use”. Such food or food ingredients would be derivatives in the sense of the Protocol, making the EU novel food regulation a very relevant piece of legislation in the context of the implementation of the Protocol.¹¹⁹

According to the novel food regulation, someone wishing to place a novel food on the EU market must notify both the competent Member State authority and the Commission of this intent (Art 4(1)). An initial assessment is then carried out by the authority and the responsible scientific body at the Member State level as to whether the criteria for placing the food on the market are satisfied (Art 4(2) and Art 6). Other Member States and the Commission are given an opportunity for comments during this procedure (Art 6(4)).

In case the Member State handling the procedure is not convinced that the conditions of the novel food regulations are satisfied or other Member States or the Commission raise objections, a full authorization procedure is carried out at the EU level (Art 7.1, 13). The relevant checkpoints in the case of novel food could either be the competent authorities at Member State level, or the Commission since both of them are fully informed about all approval procedures.

- The EU legislative framework for the placing of the market of **seed/plant propagating material** is currently under revision. It is presently composed of a rather complex set of directives, which relate to specific crops.¹²⁰ One important element is that the EU maintains the Common Catalogue of varieties of agricultural plant species, which is based on similar catalogues at the Member State level. The varieties included in these catalogues are varieties of beet, fodder plant, cereal, potato and oil.¹²¹ The varieties included in the catalogue may be placed freely on the market; the decision to admit a plants to the catalogue is made at Member State level. Similar rules are in place, for the

¹¹⁸ Regulation No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients OJ L 43, 14.2.1997

¹¹⁹ A recent relevant example showing the relevance of the novel food regulation is the stevia plant, which was admitted as a sweetener under the novel food regulation in November 2011. Stevia is originally from South America and its use has been branded as a case of biopiracy as allegedly no ABS agreement was concluded with the original users of Stevia, Guarani communities living in several South American countries.

¹²⁰ See the overview at http://ec.europa.eu/food/plant/propagation/evaluation/index_en.htm

¹²¹ See Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species

marketing of vegetable seed.¹²² Hence, the authorities deciding on the market approval of seed/plant propagating material are located at the level of the Member States. However, in light of recent development at the ECJ (see section 4.2), marketing approval for seed may soon not be required any longer.

- The central legislative act regulating market approval for **genetically modified organisms** for food and feed is Regulation 1829/2003.¹²³ According to this regulation, approval is granted by Member States authorities; however, the European Food Safety Authority (EFSA) conducts a risk assessment. The information to be submitted by applicants according to Art 5(3) of the regulation and then supplied to EFSA by the national competent authorities is quite broad. While applicants are not currently required to submit any of the information relevant to the implementation of the Protocol, such information would not appear to be categorically different from that provided anyway under the current GMO legislation.

In sum, EU-level authorities which could be potential checkpoints as they are involved in pre-market approval or notification are the Commission, the European Medicines Authority and EFSA. In several areas market approvals are given by Member States authorities which, however, must pass on certain information to the EU level. If market approval authorities were to be given responsibility for monitoring compliance with a prohibition to utilise illegally acquired genetic resources, many different authorities would have to become involved.

Option C 2.4 Monitoring through inspection by CNAs

Apart from using IP offices and market approval authorities, monitoring could, again, be the task of CNAs. As in Option B, CNAs could conduct inspections at users' premises, ascertain the legal status of GR found there and hence whether the above prohibitions have been violated. Such monitoring could be on the basis of an analysis of where risks are greatest or when third parties complaint about alleged misbehaviour.

Who needs to be monitored and to which extent would depend on whether other checkpoints exist and which ones. For example, academic researchers only engaging in disciplines which usually do not produce commercially applicable results would not be subject to monitoring at IP offices or market approval authorities. Nonetheless, they may be utilising genetic resources. Thus, a competent authority could focus on the academic sector, if IP offices and market approval authorities are also entrusted with checkpoint functions. By contrast, if the latter is not the case, CNAs may have to more broadly monitor the behaviour of different sectors, commercial and non-commercial alike. Under a risk-based approach they may then monitor e.g. more intensively big commercial users or those sectors known to rely heavily on imported GR.

Combining of the options

¹²² Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed, Official Journal L 193 , 20/07/2002 p, 33 -59

¹²³ Regulation 1829/2003 of 22 September 2003 on genetically modified food and feed

From a legal point of view, in terms of combining the options, 2.1 is distinct from and combinable with all the other options. 2.2 and 2.3 could be combined, but double burdens on individual users would have to be avoided for proportionality reasons. The option involving CNAs (2.4) and those involving IP offices or market approval authorities (2.2 and 2.3) are in principle combinable. To which extent that should be done in practice is discussed as part of the IA below (chapter 11).

Element 3: Sanctions for non-compliance

In Options B and C, sanctions are largely the same. Thus, options for sanctions in the downstream approach would be essentially the same as in the upstream approach, with the EU either leaving the MS discretion as to which sanctions to take or prescribing an enumerative list of sanction. Again, such sanctions can of course only be imposed after a breach of EU obligations has been established, in the course of monitoring, as described above.

Again, the sanctions may be foreseen in response to a breach of different obligations, depending, *inter alia*, on which options are chosen. For example, sanctions could be imposed for a failure to comply with the general prohibition on utilising GR that are not of good legal status or for a failure to disclose information to the checkpoints where disclosure is required. Again, legislation would have to specify the breach of which clauses of EU legislation MS would have to provide for sanctions for.

In principle, all of the sanctions discussed above – i.e., a requirement to *ex post* seek PIC, administrative sanctions (in particular fines) and naming and shaming can be applied in response to a violation of different user duties, but some may not make sense in some cases. For example, a duty to *ex post* seek PIC and conclude MAT does not make sense in a case where a user fails to comply with a disclosure duty, as in such cases PIC may already have been granted. Determining which sanctions are expedient and proportional in a given case would be within the responsibility of the competent authorities.

However, there is one set of additional sanctions that could be considered with regard to downstream uses, namely measures relating to IPRs and marketing approval. Such sanctions would have to be regulated at EU level, as relevant marketing approval procedures are mostly set forth by EU law and most relevant IPRs are also granted at the European, rather than the national level. The basic approach here would be to deny users of genetic resources the approval or right they demand where they cannot demonstrate the good legal status of the genetic resources on which their activities or products are based at some of the checkpoints discussed above. Also, such a right could be revoked *ex post* if non-compliance only becomes evident then; it is plausible that such cases would exist, because frequently provider states will only become aware of the utilisation of certain GR, once products based on them are widely marketed. Such sanctions could be taken both in response to a non-fulfilment of disclosure duties (until the information requested has been disclosed) or to sanction the utilisation of GR/TKaGR without PIC/MAT.

Box 9.13: EU user compliance measures and MS access measures – a complex interface

For the reasons described above, the EU should at most set minimum standards on access measures. At the same time, options B and C on user compliance measures involve the EU taking a quite active role. Obviously, the scope of EU user compliance measures would not be restricted to GR acquired from outside the EU, but also cover GR from those MS that have PIC requirements in place. Thus, EU user compliance measures would contribute to enforcing MS access legislation. This creates a complex interface in several regards, which any future EU and MS legislation will have to take into account:

First, there could be overlap and potentially friction between EU user compliance and MS access measures in cases where EU institutions are given authority to impose sanctions. This would be the case in particular where Option C on user compliance measures is adopted and IP offices or market approval authorities at EU level are given a role in imposing sanctions. To make this clearer a fictive example is helpful:

EU user U, a seed company, collects a genetic resource from MS X. MS X has a PIC requirement in place; however, U does not request nor obtain PIC from that MS. User U later seeks to obtain a plant variety protection right from the Community Plant Variety Office (CVPO). In line with disclosure requirements in place, user U is asked to provide evidence that the respective GR was acquired in line with PIC requirements of the country of origin. User U indicates that the origin of the GR is MS X, but cannot provide evidence of PIC. Thus, the CVPO detects that user U is not in compliance with EU user compliance measures forbidding the utilization of GR without PIC. At the same time, user U has violated the access legislation of MS X. Hence, the question is what sanctions should be imposed on user U and who should impose them. If the CVPO imposed, e.g. a fine itself, this would mean that the CVPO in fact enforces the access legislation of MS X. This is problematic from a subsidiarity point of view and a very unusual constellation in EU law, where normally MS enforce EU law, not the other way round. If the CVPO imposes a sanction, this may also lead to a situation where user U is treated differently from user V whose violation of PIC requirements MS X may have detected and sanctioned itself. If, on the other hand, the CVPO alerts the CNA of MS X of the fact that user U violated the access regulation and subsequently the competent authority of MS X imposes a sanction on user U, this means that user U may be treated differently from user Z who has also been found to violate EU user compliance legislation by the CVPO, but has acquired the GR from a country outside the EU. In the case of Z, the CVPO would have to impose a sanction itself.

There is no easy solution here. A relatively unproblematic option would be that the CVPO sends user U back to the access CNA in MS X with a request for *ex post* consent. However, when MS X does not wish to grant this access, the above problems persist.

The example above illustrates a second interface between MS access and EU user compliance: EU user compliance measures will inevitably contribute to monitoring compliance with MS PIC legislation. Thus, irrespective of who imposes sanctions, procedures would have to be created whereby EU authorities involved in monitoring (if that option is chosen) share information with the competent MS access authorities.

A third interface between MS access and EU user compliance measures concerns who, besides the CNA, may have a role in granting PIC at MS level. Above, the option of involving

ex situ collections in granting PIC was discussed. Practically, *ex situ* collections need to agree to a user using a GR from their collection, as they need to physically hand out the resource. If the EU adopts user compliance measures that ensure that only GR of good legal status are included in and passed on from *ex situ* collections and the origin of all GR is documented, this is an argument in favour of involving *ex situ* collections in PIC procedures, because it reduces the risk that PIC would be granted for resources where the EU MS is not, from the viewpoint of the Nagoya Protocol, allowed to grant such PIC.

In **IP legislation**, the processing of a patent or plant variety application could be made conditional on the provision of information and evidence of compliance with PIC/MAT regulations in user countries. However, there are some doubts as to whether international IP agreements would allow the introduction of such additional requirements. Changing international IP agreements would likely be a cumbersome procedure, with the potential exception of the TRIPS Agreement where disclosure of origin have been discussed for a while and seem to have garnered some support from WTO Members.

It has been argued that the TRIPS contains an exhaustive list of the requirements that an invention must fulfil to be patentable, which means that WTO Members are not allowed to set forth additional requirements in national law. According to this view, if the granting of a patent was to be made conditional on the fulfilment of a (procedural) disclosure of origin requirement, this would amount to an additional condition for patentability. Some consider this to be incompatible with TRIPS (Carvalho, 2000), while others do not (e.g. Godt, 2007). The EU in a 2004 submission to the WIPO stated that if the information on the origin of genetic resources provided in a patent application was incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged *outside the field of patent law* (emphasis added). This indicates that the EU, at least at that time, did not favour the idea of using IP-related sanctions in the case of non-fulfilment of disclosure duties.¹²⁴ A final possibility is that states could refuse the enforcement of intellectual property rights which were granted even though disclosure requirements were not met. This would, at least according to one view, not violate the TRIPS Agreement (Carvalho, 2000).

Obviously, IP offices besides acting as checkpoints and imposing IP-related sanctions, could also be authorised to impose a non IP-related sanction (e.g. a fine). Alternatively, they could just report to a CNA that is responsible for deciding on sanctions.

Box 9.14 Sanctions for non-compliance with disclosure requirements under Swiss patent law

Currently, Art 49a of the Swiss patent law contains an obligation to disclose the source of genetic resources and traditional knowledge used in an invention when a patent application is filed, provided the invention is directly based on these resources. Normally, the source

¹²⁴ Proposal of the European Community and its Member States to WIPO, 16.12.2004, http://www.wipo.int/export/sites/www/tk/en/genetic/proposals/european_community.pdf

will be the country of origin; however, a seed bank or the ITPGRFA Multilateral System are also sources within the meaning of this article.

According to Kraus and Rüssli (2009), the following measures may be taken in case of non-compliance with the disclosure requirement:

“If a patent applicant does not provide the information relating to the indication of source, the Swiss Federal Institute of Intellectual Property will set a deadline for the applicant in order to provide the lacking information. If the information is still not provided at the end of that deadline, the patents will not be granted. Art. 81a of the patent law foresees that anyone who deliberately provides false information under Article 49a is liable to a fine of up to 100,000 Swiss francs. The courts may also order the publication of the judgment.”

Market approval legislation does not present similar problems related to international law. Assuming the EU has legislative competence in the relevant area, marketing approval for products developed from genetic resources could be made contingent on compliance with ABS requirements in provider countries and, potentially, with EU reporting requirements. In the case of products such as cosmetics where the EU requires notification rather than pre-market approval, competent authorities could be required to screen the information provided immediately after submission and be empowered to prohibit the placing on the market of the product, if the genetic resources used in its development were not of good legal status.

One issue to be considered in making market approval conditional on the good legal status of a genetic resource would be the proportionality of such a measure. An applicant (e.g. for marketing approval for a pharmaceutical product) could potentially face considerable financial losses as a result of a delay in approval. Taking necessary steps to be able to demonstrate compliance - such as concluding an *ex post* benefit sharing agreement with ILCs - can be a time-consuming procedure. The user has no full control over such a procedure as other actors, including provider country competent national authorities or indigenous and local communities, are also involved. The foreseeable financial losses from a delay in marketing approval could even be counterproductive from a benefit-sharing point of view, as they might reduce the benefits to be shared with the resource providers.

Thus, other sanctions than non-approval of marketing may be preferable in some cases. Like IP offices, market approval authorities, besides acting as checkpoints and imposing marketing-related sanctions, could also be authorised to impose a non IP-related sanction (e.g. a fine). Alternatively, and probably preferably, they could just report to a CNA that is responsible for deciding on such sanctions.

Element 4: Institutional provisions

The institutional provisions regarding CNAs and focal points would be mostly the same as in Option B.

One additional feature would be that in case IP offices or market approval authorities are given a function as checkpoints and depending on the type of sanction chosen, the checkpoints may have to report to the CNA for the CNA to impose sanction on users. For example, if fines are foreseen as a sanction, in order for fines to be applied consistently, it would be more appropriate for them to be imposed by CNAs, and not by several different IP or market approval authorities. However, sanctions such as the non-proceeding of an IP application would have to be applied by an IP office.

Box 9.15: SMEs and the future EU policy framework

As the analysis of different sectors has shown, there are various sectors within the EU where small and medium-sized enterprises (SMEs) using GR play an important role. This raises the issue on how any of the EU measures discussed in this study would achieve the objectives outlined in the “Think Small First – A Small Business Act for Europe” Communication.¹²⁵ These include taking into account SMEs’ characteristics when designing legislation, and using specific measures for small and micro-enterprises, such as derogations, transition periods and exemptions.

- 1) The due diligence approach discussed in Option B leaves all users, including SMEs, considerable flexibility as to how to comply with their due diligence duty. Moreover, due diligence requires the best-efforts of users; thus the standards is less strict for an SME with 10 employees than for a multinational corporation with a huge research department.
- 2) The suggested risk-based approach to monitoring through CNAs allows focusing monitoring and non-compliance measures on users where non-compliance has the largest effects. At the same time, the proposed flexible system for sanctions allows making sanctions proportional to the size and situation of a user.
- 3) In terms of access to GR within MS, MAT and the benefit-sharing required from SME could take their specific characteristics into account.
- 4) Finally, the different options suggested on how authorities could assist users in ascertaining the legal status (see Box 9.11) of a GR and the different ways in which users could be allowed to demonstrate the good legal status of a GR (e.g. through the issuance of a “negative” certificate of compliance) would also substantially enhance legal certainty for SMEs, without imposing additional costs on them.

9.3.8 Enforcement of MAT, access to justice & alternative dispute resolution mechanisms

¹²⁵ Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, Brussels, 25.6.2008, COM(2008) 394 final

Enforcement of MAT and access to justice for actors from provider countries in user countries are an important element in a system of user compliance measures. Some international agreements with mostly limited membership exist as regards the mutual recognition and enforcement of court decisions across countries. Art 18(3) also requires parties to take measures regarding the recognition and enforcement of foreign judgements. However, enforcing a judgement of a court in a second country is normally even more costly and difficult than enforcing a judgment in the country where it was issued. Thus, in order to enable providers to take effective measures against EU users that do not comply with MAT, courts in the EU must be in a position to decide MAT-related cases.

It should be noted that “courts in the EU” in this case means MS courts. The two EU courts, the ECJ and the General Court, each have very specific functions related to EU law, but do not decide cases involving two private parties; hence, they are certainly no appropriate fora for MAT-related disputes. Moreover, the use of the term MAT in the NP, which implies an agreement between two equal partners, indicates that MAT are (international) civil law contracts and it would thus be within the competence of civil courts to decide about them. However, in some cases where the content of MAT is pre-determined by provider countries legislative or administrative rules, the legal nature of specific MAT may have to be re-considered.¹²⁶ In such cases, MAT may have to be considered, at least in some jurisdictions, a public law contract, with the consequence that administrative, rather than civil law courts would be responsible for adjudicating related disputes.

Ensuring that parties from a provider state can start MAT-related judicial procedures in the country of residence/seat of an EU user, entails various aspects:

Jurisdiction: The court of the provider country must have jurisdiction over the case it intends to hear, i.e. must be competent to decide on it. In cases involving international contracts, parties can, in principle, choose in which country they would like to settle their disputes. For this reason, Art 18(1)(a) NP states that Parties shall encourage the inclusion of provisions on the jurisdiction in MAT. In case where no such rule is included in a contract and the case is of a transboundary nature, jurisdiction is determined by conflicts of law rules. Normally, under such rules legal actions in civil and commercial matters can be brought before the courts of the state where the defendant is domiciled, regardless of his nationality. This is also the rule in most EU continental legal systems (Godt 2009, 421).

Standing: The provider must have legal standing, i.e. be entitled to participate in a court case. This is not addressed as a separate issue in the Nagoya Protocol, but is implied in the obligations to ensure that an opportunity to seek recourse is available in cases of disputes on MAT (Art 18(2)) and that countries shall take effective measures regarding access to justice (Art 18(3)). However, standing for non-EU actors should be mostly unproblematic as in most countries standing in civil law procedures is not linked to nationality (Isozaki 2009, 442). A particular problem is whether ILCs as such have legal standing, because collectives that are not legally incorporated are not necessarily

¹²⁶ Godt 2009, 422 argues, for example, that if legislation provides for benefit-sharing on the basis of lump sums, the legal nature of remuneration claims is unclear.

recognised legal actors. However, there is increasing recognition that communities also have legal standing in court procedures, at least in cases where they have a recognised legal status under their home country's legal order (Godt 2009, 442).

Applicable law: In civil law cases involving parties from more than one country, applicable law is always an issue. There is no general rule that the law of the jurisdiction of which the civil court hearing the case is part applies. By contrast, different legal orders may be even applicable to individual claims that are part of one civil law case (Godt 2009, 423). Therefore, the NP requires Parties in Art 18(1)(b) to encourage providers and users to include in MAT provisions on the applicable law. Where parties to a MAT do not do so, general conflict of laws rules on applicable law will apply. In concrete cases, it may be very difficult to decide which legal rules apply to a specific problem as it is not immediately clear how a MAT agreement is to be classified under these rules. Is an agreement for the provision of access to genetic resources on mutually agreed terms to be regarded as a contract for the sale of goods, a contract for the provision of services, or a *sui generis* contract which does not fall within either of these traditional categories? Does it concern material rights or immaterial rights (see Godt 2009, 424ff)?

Practicalities: Another issue are the practical hurdles to initiating court proceedings in a different country, in particular in cases where actors from poorer developing countries or ILCs are involved. Such hurdles include the costs and efforts for hiring a lawyer and communicating with him/her, costs of translation, difficulties of proving a claim and eventual travel costs to participate in court sessions. Under national law, assistance is frequently provided to citizens who lack the necessary resources to engage in a court case (e.g. financial support or *pro bono* assistance).¹²⁷ No such mechanisms currently exist at the international level (except for private initiatives, e.g. human rights NGOs supporting victims of human rights violations *pro bono*).

In terms of existing EU law, the basic rules of EU law governing these matters, in as far as potentially relevant to MAT, are laid down in Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (the so-called 'Brussels I' Regulation), which is currently under revision, and in Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (the so-called 'Rome I' Regulation). These regulations are primarily, but not exclusively, relevant for contractual relations between parties domiciled in EU Member States. For example Art. 2 of the Brussels I Regulation sets forth that "persons domiciled in a Member State shall, whatever their nationality, be sued in the courts of that Member State". This rule is also applicable in cases where the complainant is from outside the EU (Augenstein 2010, para. 234).

Judicial cooperation in civil matters between MS and third countries has traditionally been governed by bilateral or multilateral agreements between MS and these countries. There is a wide range of such agreements, concluded by Member States independently of the EU. Some agreements have been concluded within the framework of international organisations

¹²⁷ Such practical obstacles so far have been primarily discussed in the context of business and human rights, see for example Augenstein 2010, para. 238 for the EU and Ruggie 2010, paras 109 -112 more generally.

such as the Hague Conference on Private International Law, the Council of Europe or even the United Nations Commission on International Trade Law (UNCITRAL), but none of them is of universal applicability. More recently, the EU has adopted a Regulation laying down a procedure to be applied by Member States in concluding agreements with third countries on specific civil justice issues falling within the exclusive competence of the Union, in particular where the EU itself has not indicated its intention to exercise its external competence.¹²⁸

The basic principles enshrined in the above-mentioned EU Regulations and in relevant international conventions are generally quite similar and correspond to what has been described above with regard to the freedom to choose a jurisdiction, applicable law, standing etc. Thus, while none of the above deals with ABS issues specifically and legal clarification may be advisable in light of the very specific character of MAT, there are in principle rules in place on access to justice, applicable laws and other measures for cases of MAT-related disputes. However, they are unlikely to be the same in all MS.

Moreover, cases may arise (and have arisen in the past) where users fail to conclude MAT, e.g. with ILCs, even though they are under an obligation to do so. Obviously, complainants in such cases cannot base any of their claims on MAT. The legal base for their claims for the purpose of civil law proceedings is rather unclear. For example, tort claims relating to TKaGR could be considered, but it is rather unclear how damage could be measured in ABS cases (see Godt 2009). Thus, in cases where not MAT has been concluded, access to justice and its different facets become an even more complex legal issue. As noted above, it is also somewhat unclear whether Art 18 requires Parties to take measures with regard to cases where no MAT have been concluded.

Besides rules on access to justice, the Nagoya Protocol also deals with alternative dispute resolution mechanisms, such as mediation or arbitration. These are often a cheaper and quicker alternative to court proceedings. Moreover, they are likely also particularly well-suited for the needs of ILCs. As they allow parties a great flexibility on agreeing on the procedures by which a dispute is to be settled, customary practices of ILCs could be taken into account. Moreover, ILCs can without problems be a party to such procedures, whereas narrowly defined rules on legal standing may bar them from taking part in court procedures in certain instances.

Art 18(1)(c) NP obliges Parties to encourage users to include in MAT provisions on alternative dispute resolution. It is interesting in this context that the Permanent Court of Arbitration (PCA) in Den Hague in 2001 adopted “Optional Rules for Arbitration of Disputes Relating to Natural Resources”¹²⁹ and “Optional Rules for Conciliation of Disputes Relating to the Environment and/or Natural Resources”¹³⁰ in 2002. The PCA claims them to be “the

¹²⁸ Regulation (EC) No 662/2009 of the European Parliament and of the Council of 13 July 2009 establishing a procedure for the negotiation and conclusion of agreements between Member States and third countries on particular matters concerning the law applicable to contractual and non-contractual obligations, OJ L 200, 31.7.2009, p. 25–30.

¹²⁹ Online at http://www.pca-cpa.org/showfile.asp?fil_id=42

¹³⁰ Online at http://www.pca-cpa.org/showfile.asp?fil_id=43

most comprehensive set of environmentally tailored dispute resolution procedural rules presently available”.¹³¹ Both sets of norms are primarily designed for cases involving states; however, as MAT will frequently be concluded with a provider state, they may still be an appropriate set of rules for MAT parties to agree on (see also Isozaki 2009, 447f). Lessons may also be learnt from the ITPGRFA SMTA which in Art 8 states that any disputes shall be solved through alternative dispute resolution, such as amicable dispute settlement or mediation, and if both fail, under the arbitration rules of an international body that the parties to the dispute agree on.

Art 18(3) obliges Parties to take measures concerning the utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards. In this context the 1958 “Convention on the Recognition and Enforcement of Foreign Arbitral Awards” (New York Convention) should be mentioned.¹³² It obliges Contracting Parties to recognize and enforce foreign arbitral awards. It currently has 146 members, meaning that many, if not most, present and future Parties to the Nagoya Protocol already have a legal duty to recognize and enforce foreign arbitral awards. All EU MS are Contracting Parties.¹³³

For purposes of this study, it is impossible to analyse these complex legal issues exhaustively. To which extent changes to the legal systems of MS are actually required, will thus require some further investigation. Thus, while we have identified two basic options for the EU to address the implementation of the obligations contained in Art 18 NP, a more in-depth analysis of the different legal issues involved will certainly have to be conducted before concrete steps are taken.

Option A fits most closely with Option A on other user compliance measure above, as it entails no legislative action at the EU level; however, the EU could take “soft”, non-legislative measures. Option B involves the EU taking action and thus has certain parallels with both Options B and C above.

Option A: No legislative action at EU level (+ EU soft measures)

Member States are primarily responsible for the jurisdiction of their national courts and for matters related to access to justice, applicable law, and the recognition and enforcement of foreign judgments and arbitral awards. Moreover, in relations with non-EU countries, these matters are largely governed by the internal law of each Member State and any international treaties it is a Party to. Therefore, any EU legislative initiative would raise legal and political difficulties.

The domestic law of the Member States and most relevant international agreements are largely based on a common approach that normally ensures that non-EU providers of genetic resources would have access to justice in the EU Member State in which the user is

¹³¹ Environmental Dispute Resolution, http://www.pca-cpa.org/showpage.asp?pag_id=1058

¹³² The text of the Convention is online at <http://www.uncitral.org/pdf/1958NYConvention.pdf>.

¹³³ A list of Contracting Parties is available at http://www.uncitral.org/uncitral/en/uncitral_texts/arbitration/NYConvention_status.html.

domiciled. Thus, there seems to be no immediate need for EU measures to ensure compliance with the Protocol. To the extent that any difficulties may exist in individual Member States, it would be left to the Member State concerned to take whatever action may be required to comply with its obligations under Art 18 NP through national legislation and/or amendment of relevant bilateral or multilateral agreements with provider countries on judicial cooperation in civil matters. However, it should be recognised that this approach may not remove disparities between the legal situations in different Member States.

Even though the EU under this option does not take legislative action, it could still consider taking non-legislative action. First, it could support member states in coordinating amongst themselves, for example by providing expertise on the legal situation in different countries, providing opportunities for exchange among MS on appropriate legal clauses for ensuring access to courts or sharing experiences on alternative dispute resolution mechanisms.

Moreover, the EU could consider supporting actors from provider countries, and in particular ILCs, that seek to enforce MAT via courts in the EU through providing legal aid. There is no model for such support; however, similar suggestions have been discussed in the context of supporting victims of human rights violations committed by EU companies abroad. If the EU does not wish to create such a mechanism itself – which could be sensitive, as the EU may be perceived to directly support legal action against EU actors – it could also undertake efforts to ensure that financial support for this purpose can in certain cases be granted out of the recently created Nagoya Protocol Implementation Fund, which is administered by the Global Environment Facility (GEF).¹³⁴ This would obviously be a novelty in terms of what the GEF funds; however, the Protocol is in some respect also an innovative international agreement.

In terms of alternative dispute resolution, the EU might consider offering inexpensive procedures for such alternative dispute resolution. While no precedent for this seems to exist at EU level, such mechanisms are part of, for example, the German legal system in certain areas of law. One example from the environmental sector is the German “Clearingstelle EEG”, which offers arbitration and other services to parties on certain contractual disputes relating to the interpretation of the German renewable energies law.¹³⁵ The German renewable energies law provides explicitly for the establishment of the institution. The services are offered cost-free; parties only need to cover their own costs (e.g. lawyers’ fees), thus making settling of disputes through the Clearingstelle cheaper. Moreover, disputes are also settled more quickly than through normal court proceedings.

Option B: Harmonised approach to access to justice under TFEU provisions on judicial cooperation in civil matters

As an alternative, the EU could consider that ensuring effective access to justice in uniform conditions throughout the EU for foreign providers of genetic resources and/or traditional knowledge associated with genetic resources to users based in the EU is a crucial aspect of

¹³⁴ On the fund see http://www.thegef.org/gef/Press_release/GEF_establishes_NPIF. So far France seems to be the only EU MS which has made a significant contribution to this fund.

¹³⁵ See for more information <http://www.clearingstelle-eege.de/english>

good faith efforts to comply with its obligations under the Protocol, and that therefore a harmonised approach to this matter would be desirable. The EU could thus consider whether the rules contained in the Brussels I and the Rome I Regulations are sufficient to ensure access of non-EU nationals to courts in MS in MAT-related cases.

In order to secure reciprocity and adequate judicial protection for EU-based parties to MAT agreements, the conclusion or revision of international agreements concerning questions as applicable law and access to EU courts with the main third countries that are providing genetic resources to users in the EU may also have to be considered.

In addition, the EU could take measures to practically facilitate access to courts or alternative dispute resolution in the EU, as described for Option A.

9.4 Bilateral agreements

Another action that the EU could take for complementing and enhancing the effectiveness of its measures for implementing the Nagoya Protocol, would be to conclude bilateral agreements with major provider countries or regions. These agreements could serve the following purposes:

- Providing the framework for capacity-building on ABS in provider countries, in a partial fulfilment of the EU's obligation under Art 22. Such capacity-building may indirectly benefit users of GR in as far as it contributes to improving provider countries' legislative frameworks on ABS and authorities' implementation capacity. Art 22 contains a list of concrete topics to which such capacity-building could refer, including implementation capacity and negotiations on MAT.
- Providing the framework for the EU to contribute to capacity-building for ILCs: Several of the articles of the Nagoya Protocol relate to an obligation for parties to ensure the involvement of ILCs. Art. 5(2) and 5(5) NP say that "each Party" shall take appropriate measures with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by ILCs and the utilization of TKaGR are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms. More concretely, Art. 12(3) NP says that Parties shall support ILCs in developing community protocols in relation to TK-related ABS, minimum requirements for MAT and model contract clauses. These obligations are obviously primarily on the countries where those ILCs live; related efforts should be closely coordinated with these states in order to ensure that measures at community level and national legislation are mutually compatible. Nonetheless, the EU could still make a positive contribution to the aim of adequately involving ILCs in decision-making and ensuring that they receive part of the benefits through contributing to capacity-building among these ILCs.
- Providing the framework for technology transfer and cooperation on R&D: Art 23 NP requires Parties to collaborate and cooperate on technical and scientific R&D programs, in particular through activities in developing countries. Moreover,

developing countries' access to technology is to be promoted. The EU could fulfil this obligation through bilateral science and technology cooperation (S&T) agreements with third countries. The EU in the past has already concluded numerous such agreements.¹³⁶ One such agreement with a biodiversity-rich country – Brazil – is described in the box below. This example shows that current EU S&T agreements will likely need some amendments with a view to R&D relating to GR. For example, activity areas mentioned in the agreements could specifically include research involving GR. Moreover, the EU may wish to seek negotiate clauses that facilitate access to GR where projects are conducted as joint research activities under such agreements. Finally, the objective of technology transfer may have to be dealt with more explicitly in such agreements than is the case for the EU Brazil S&T agreement which is based on the idea of equal benefits and burdens of partners. Pertinent clauses may need to be tailored to the needs of different partner countries and their level of technological development.

- Finally, the EU could also consider bilateral agreements as an instrument to “encourage providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components”, as required in Art 9. Related clauses could be combined with EU incentives for provider countries to dedicate a share of their benefits for such purposes, e.g. by providing additional funding for such purposes.

Box 1: The EU-Brazil Science and Technology Agreement¹³⁷

The EU-Brazil Science and Technology Agreement was concluded in 2004 and entered into force in 2007.

In Art III it sets forth principles of cooperation, including that activities need to be of mutual benefit, that there is reciprocal access to the activities of R&D undertaken by each Party and IPRs of those involved are adequately protected. In Art IV the agreement describes certain focus areas for joint activities, including several sectors where GR are used, including biotechnology, bio-safety and health and medicine. Art V sets out that both Parties shall encourage the participation of researchers from the respective other country to participate in their research programmes; Art VII sets out that funding for activities “shall not, as a general rule, be settled by the transfer of funds from one Party to the other”.

An Annex regulates issues of intellectual property. It clarifies, for example, IPRs of visiting researchers and requires researchers involved in joint research projects to clarify IP issues through joint technology management.

¹³⁶ A list of such agreements is available at <http://ec.europa.eu/research/iscp/index.cfm?lg=en&pg=countries>

¹³⁷ The text of the agreement is online at <http://ec.europa.eu/world/agreements/prepareCreateTreatiesWorkspace/treatiesGeneralData.do?step=0&redirect=true&treatyId=2041>

9.5 Supportive measures of the EU as provider and user

The Nagoya Protocol contains a number of provisions which do not contain “core” obligations for Parties, but rather set rules for additional measures that Parties should take. The obligations and possible ways for the EU to implement them are considered in this chapter. Supportive EU measures can relate both to the EU facilitating access to its own genetic resources or serve the purpose of fostering the compliance of EU users of GR/TKaGR with provider country legislation. They are in principle combinable with any of the provider or user compliance options discussed above; however, some of them will be of more relevance, if the EU does not adopt binding legislation itself.

Art 8(b) NP requires parties to pay, when they develop their ABS legislation, due regard to emergencies that threaten or damage human, animal or plant health, and the role of access and BS in such cases. This is only relevant in the context of provider measures. It is unclear whether there is a very good case for immediate EU action in this regard. The WHO is already undertaking efforts on ABS in some areas relevant to human health emergencies through its Global Influenza Surveillance and Response System (GISRS). How many MS will require PIC to their genetic resources is unclear presently; in a situation where access to GR is free in most MS or the entire EU, there is no necessity for specific rules on this matter. If the EU decides to adopt minimum requirements for MS access legislation (as suggested in Option C on provider measures) the EU could consider integrating a clause in its minimum access requirements to the end that health emergencies shall be a factor to be taken into account in access decisions. Practically, MS can always decide *ad hoc* to provide certain genetic resources in emergency cases.

Art 8(c) NP contains a soft obligation for parties to consider the importance of genetic resources for food and agriculture and their special role for food security. Obviously, “consideration” can mean a lot. The EU could, for example, consider continuing funding measures that serve the conservation and improvement of agricultural biodiversity in the context of a reformed CAP. It could also establish funding schemes outside of the CAP for this purpose, e.g. for farmers and breeders in developing countries in the context of food-security related aspects of its development cooperation.

Art 9 NP establishes a best-effort obligation for Parties to “encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components”. This article can be most easily implemented in the context of provider side measures, because a related clause could be included in MAT before access is granted. To the extent that the EU takes provider measures, the EU could consider to encourage MS to pay monetary benefits gained from BS directly into a fund dedicated to the objectives mentioned in Art 9 NP. For example, a specific fund could be created for this purpose at EU level which would fund projects for the conservation of biological diversity. In the context of user compliance measures, EU users could also be encouraged to make voluntary contributions to this fund in case where benefit-sharing is not compulsory, e.g. because they utilise GR from a MS which decided not to require PIC. Moreover, MS could also be encouraged to pass on any fines imposed on users of GR within the EU for wrongful behaviour into such a fund. While this may not be

the preferred option in cases where PIC can be requested *ex post* from a provider country, it would be an option to support the Protocol's objectives where the original country of origin cannot be established.

Similar funds have been created by some other countries (e.g. Peru).

Art 12(2) requires parties, with the effective participation of ILCs concerned, to inform potential users of TKaGR about their ABS related obligations. This obligation is relevant both for provider and user countries. For the EU as a provider, it is likely to be of only minor relevance, as there are not many ILCs within the EU. However, an EU focal point could still inform prospective users about the existence of such ILCs and TKaGR. As Art 12(2) requires the effective participation of ILCs in this, consultations with ILCs will first have to be conducted, possibly involving MS authorities. In the context of EU user compliance measures, information on duties of users regarding ILCs should become part of awareness-raising efforts under Art 21.

Art 12(3) requires parties to support, as appropriate, the development by ILCs of community protocols, minimum requirements for MAT, model contract clauses benefits arising out of the utilization of such knowledge. This clause is primarily relevant for provider countries where ILCs play significant role, which is not true for the EU. However, as discussed in the previous section, the EU could still support the development of such instrument in the context of its development cooperation. This should be closely coordinated with provider countries in order to ensure that measures at community level and national legislation are mutually compatible.

Art 19(1) stipulates that Parties shall encourage the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms. While in deciding on the actual use of such model contractual clauses for MAT, provider countries play the main role, the EU could still take a leading role in developing such model contractual clauses. Through such efforts, it could also support developing countries in taking informed PIC/MAT decisions. Such model contractual clauses should certainly cover aspects mentioned explicitly in the Protocol, such as choice of applicable law (Art 18(1)) or provisions on monitoring (Art 17(1)(b)). Moreover, they should be based on an evaluation of the experience with existing MAT/BS agreements such as the ITPGRFA SMTA and should be drafted in a way to be easily enforceable in courts or through alternative ways of dispute resolution.

Art 20 obliges Parties to encourage the development of voluntary codes of conduct, guidelines and best practices and/or standards respectively. In the context of EU provider measures, this may become relevant, *inter alia*, where the EU takes a coordinating role, but does not impose any binding access-related requirements on MS. In the context of user compliance measures, EU efforts should build on instruments developed already for different sectors in the EU such as the IPEN Code of Conduct for botanic gardens, the MOSAICC Code of Conduct for micro-organisms, the guidelines on good practice for

academic research on genetic resources developed by the Swiss Academy of Sciences or the standard of the Union for Ethical Biobanking for private companies.

In fact, given that instruments exist already in many sectors, it may be more important for the EU to collect them and provide easy access to them (e.g. through the website of a focal point), rather than starting to build new guidelines from scratch. For example, the Swiss Academy of Sciences has published an overview of such instruments online.¹³⁸ Many companies also seem to have internal codes and guidelines in place already which are, however, not published (pers. comm., DIB). Efforts to obtain such internal documents and publish and disseminate best practices should also be undertaken. Such codes of conduct could also guide users on how design due diligence systems for different sectors, if a due diligence approach is taken by the EU. Obviously, the use of (voluntary) codes of conduct developed by the EU does not have to be limited to the EU territory or EU users; the EU could also promote their use in other major user countries.

Art. 21 contains a general obligations for Parties to engage in awareness-raising activities on the importance of GR and TKaGR and related ABS issues. Art 21 also suggests concrete measures, such as the promotion of the NP, information dissemination through a national clearing-house, promotion of exchange of experiences, education and training of users and providers of GR and TKaGR. Many of the measures suggested here are not additional to measures that the EU would anyway have to take when implementing the Protocol. For example, the EU would likely promote the exchange of experiences between MS in some way; and capacity-building efforts in developing countries are likely to include an exchange of experiences. Additional measures could address both EU users and representatives of non-EU provider countries. For example, the EU could publish brochures to explain the importance of ABS and relevant procedures to prospective EU users. It could provide funding for representatives of provider countries, including ILCs, to visit the EU and share their experiences, but also visit e.g. MS national competent authorities and learn from them. Many other concrete dissemination activities are conceivable.

Art 22 on capacity-building and **Art 23** on R&D cooperation with third countries and technology transfer also contain supplementary obligations. The implementation of these provisions in the context of agreements with third countries has been discussed in section 9.4.

Table 9.5 provides an overview of the relevant paragraphs and their relevance in the context of provider and user compliance measures and other policy fields or for other purposes.

¹³⁸ See http://abs.scnat.ch/downloads/documents/ABS_Guidelines_non-commercial.pdf

Table 9.5: Overview of supplementary obligations

Art.	Content	EU provider measures	EU user compliance measures	Other
8(b)	Pay regard to health emergencies	X		
8(c)	Consider importance of GR for food security	X		CAP Development cooperation
9	Encourage directing benefits towards conservation of biological diversity and the sustainable use of its components	x	x	Bilateral agreements with third countries
12(2)	Inform users about duties relating to GR/TKaGR and ILC involvement	x		
12(3)	Support development of community instruments	(x)		Development cooperation
9	Development of model clause for MAT	x	x	
20	Development of voluntary codes of conduct etc.	(x)	x	
21	Awareness-raising		x	
22	Capacity-building			Development cooperation Facilitating access to GR in third countries
23	R&D cooperation and technology transfer			Development cooperation

Synthesis Table 9.6: Provider Measures

		EU Baseline/ Reference Scenario / BaU	Option A: Max Member State Action + no EU		Option B: EU OMC		Option C: EU Minimum Legal Standards	
			A1. MS requiring PIC/MAT	A2. MS not requiring PIC/MAT	B1. MS requiring PIC/MAT	B2. MS not requiring PIC/MAT	C1. MS requiring PIC/MAT	B2. MS not requiring PIC/MAT
1	<p>ABS measures in EU as a provider</p> <p><u>Core Obligations on access to GR/TKaGR</u></p> <p><u>Art 6 (3)(a-e):</u></p> <ul style="list-style-type: none"> Rules on good governance, cost-effectiveness etc. Issuance of permits <p><u>Art 6(3)(g), 17(1)(b), 18(1)</u> Setting out procedures for establishing MAT and encouraging minimum content of contracts for their effective enforcement</p> <p><u>Art 6(2), 6(3)(f):</u> Measures allowing ILCs to give PIC for access to GR where they have established rights over GR (where ILCs exist)</p> <p><u>Art 7, 12:</u> Measures allowing ILCs to give PIC when TKaGR they hold is accessed (where ILCs exist)</p>	<p>Few MS develop PIC/MAT framework requirements (Fr, SP, BL), some with free access (NL)</p> <p>No PIC requirement at EU level</p> <p>Few ILCs in EU</p>	EU : Do nothing		<p>EU OMC to enhance coordination and consistency</p> <p>MS adopt regulation, implement, issue permits etc.</p>		<p>EU minimum standards on PIC and MAT applying to MS that decide to require PIC</p> <p>MS implement, issue permits</p>	MS or EU issue CoC upon request by users (to give evidence that no PIC/MAT is required)

	<p><u>Core obligations on BS</u></p> <p><u>Art 5 (2), 5(5)</u> Benefits for use of GR and TkaGR to be shared with ILCs holding established rights and in accordance with MAT</p> <p><u>Supplementary obligations</u></p> <p>Encourage that benefits arising from utilisation of genetic resources are directed to the conservation and sustainable use of biodiversity (Art 9)</p> <p>Pay due regard to threats or damage to human, animal or plant health (Art 8(b))</p> <p>Consider importance of importance of GR for food and agriculture (Art 8 (c))</p> <p>Support development by ILCs of community protocols, minimum requirements for MAT, model contract clauses benefits arising out of the utilization of such knowledge (Art 12(3))</p>						
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2	<p>Further obligations to promote research</p> <p>Art 8(a): Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, ..., including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research</p>	<p>Research funding under FP7 and national research programmes</p>	<p>EU: Do nothing additional</p>	<p>Promotion of guidelines and/or best practices for facilitating non-commercial access as part of OMC</p> <p>Create fund to support biodiversity-related research (on the model of the ITPGRFA, i.e. also accepting voluntary contributions)</p> <p>Inclusion of ABS component into bilateral relations with important partners, e.g. in context of science and technology agreements</p>	<p>Create fund to support biodiversity-related research (on the model of the ITPGRFA, i.e. also accepting voluntary contributions)</p> <p>Inclusion of ABS component into bilateral relations with important partners, e.g. in context of science and technology agreements</p>	<p>EU sets minimum legal standards to facilitate access for non-commercial research</p> <p>Create fund to support biodiversity-related research (on the model of the ITPGRFA, i.e. also accepting voluntary contributions)</p> <p>Inclusion of ABS component into bilateral relations with important partners, e.g. in context of science and technology agreements</p>	<p>Create fund to support biodiversity-related research (on the model of the ITPGRFA, i.e. also accepting voluntary contributions)</p> <p>Inclusion of ABS component into bilateral relations with important partners, e.g. in context of science and technology agreements</p>
3	<p>Additional measures to address supplementary obligations</p> <p>Art 17(1)(c): Encourage use of cost-effective communication tools and systems</p> <p>Art 19: Encourage use of model contracts</p> <p>Art 20: Encourage development and use of codes of conduct</p>	<p>Some are being addressed by existing measures</p>	<p>EU soft measures, e.g. providing funding for development of codes of conduct, model MTAs</p>	<p>EU soft measures, e.g. providing funding for development of codes of conduct, model MTAs</p>	<p>EU soft measures, e.g. providing funding for development of codes of conduct, model MTAs</p>	<p>EU soft measures, e.g. providing funding for development of codes of conduct, model MTAs</p>	<p>EU soft measures, e.g. providing funding for development of codes of conduct, model MTAs</p>

4	<p>Institutional and monitoring provisions</p> <p><u>Core Obligations:</u> Art 13: Establishment of national focal points and competent national authorities</p> <p>Art 14(2): Providing certain information to Clearing House (CH)</p> <p>Art 17(1)(a): Measures to monitor and enhance transparency of GR use, including designation of checkpoint(s)</p> <p><u>Supplementary Obligations:</u></p> <p>Art 11: Cooperate where GR/TKaGR found in territories of two countries</p>		Establishment of focal point at EU level	<p>Establishment of focal point/CNA at MS level</p> <p>Establishment of focal point at EU level</p> <p>Monitoring in the context of EU user compliance measures (user compliance options B/C) OR MS agree to monitor the utilisation of GR and possibly report to the EU the results of the monitoring in an aggregated way (e.g. annual report)</p>	<p>Establishment of focal point/CNA at EU level</p> <p>Monitoring of the utilisation of in the context of EU user compliance measures (user compliance option B/C) or EU monitoring through independent surveys, studies</p>	<p>Establishment of focal point/CNA at MS level</p> <p>Establishment of focal point at EU level</p> <p>Monitoring in the context of EU user compliance measures (user compliance options B/C) OR requirement on MS to monitor the utilisation of local GR and possibly report to the EU the results of the monitoring in an aggregated way (e.g. annual report)</p>	<p>Establishment of focal point/CNA at EU level</p> <p>Monitoring of the utilisation of in the context of EU user compliance measures (user compliance option B/C) or EU monitoring through independent surveys, studies</p>
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Synthesis Table 9.7: User Compliance Measures

		EU Baseline/ Business as usual (BAU)	Option A: Max Member State Action + EU <u>OMC</u>	Option B: EU Action with Upstream Focus	Option C: EU Action with <u>Downstream Focus</u>
1	<p>User compliance measures</p> <p><u>Core Obligations:</u> Art 15(1)/Art 16(1): measures to provide that GR (TKaGR) utilised within EU accessed in accordance with applicable PIC/MAT requirements</p> <p>Art 5(1) Measures to implement benefit-sharing obligation in 5(1)</p> <p>Art 5(2), 5(5) Measures to ensure BS for TK with ILCs</p>	<p>No EU/MS user compliance measures, but some voluntary CBD consistent practice of some user groups (e.g. IPEN).</p> <p>MAT may be enforced through existing contract law</p> <p>Some MS in process of regulating user compliance (e.g. Spain)</p>	<p><u>MS level</u></p> <p>MS implement Art. 15(1) and 16(1) NP</p> <p>Different MS likely to take different approaches and measures</p> <p><u>EU level</u></p> <p>Commitment to comply with applicable ABS rules of provider country as precondition for receiving EU research funding and other relevant funding + wider OMC</p>	<p>Defined prohibitions and obligations on upstream use, including prohibition on EU nationals to <u>import</u> GR/TKaGR into EU without complying with provider ABS legislation or <u>include, store and transfer</u> from ex situ collections</p> <p>AND</p> <p>DD system on GR and TKaGR : obligation to ensure for all users that GR/TKaGR are utilised in line with provider country ABS legislation; flexibility as to how to achieve this aim (including through membership in accredited organisation)</p> <p>AND</p> <p>EU support for <i>ex situ</i> collections on improving documentation etc.</p> <p>AND</p> <p>Commitment to comply with applicable ABS rules of provider country as precondition for receiving EU research funding and other relevant funding</p>	<p>Prohibition to <u>utilise</u> GR/TKaGR within EU without complying with provider ABS legislation + specific obligations relating e.g. to <u>passing on information</u></p> <p>AND</p> <p>Commitment to comply with applicable ABS rules of provider country as precondition for receiving EU research funding and other relevant funding</p>

2	<p>Monitoring utilisation of GR</p> <p><u>Core Obligations:</u> Art. 17(1)(a): measures to monitor and enhance transparency of GR use, including designation of at least one checkpoint</p>	<p>No measures for systematic monitoring in place, but some MS have limited patent disclosure requirements</p>	<p><u>MS level:</u> MS designate one or more checkpoints and report to EU</p> <p><u>EU level</u> EU measures to coordinate/support measures at MS level</p> <p>EU-level checks of ABS compliance by recipients of EU research funding and other relevant funding</p>	<p>Monitoring and transparency</p> <p>Research funding as a checkpoint: EU authorities check ABS compliance by recipients of EU research funding or other relevant funding</p> <p>AND</p> <p>Monitoring (e.g. via on the spot inspection) of prohibitions and due diligence systems by designated authorities (e.g. competent national authorities, CNAs) of users' behaviour</p> <p>OR</p> <p>Monitoring of prohibitions and due diligence systems by designated authorities (e.g. CNAs) and third parties (e.g. accredited organisations) of users' behaviour</p>	<p>Monitoring and transparency/downstream checkpoints</p> <p>EU level checks of ABS compliance by recipients of EU research funding (research funding as a checkpoint)</p> <p>AND/OR</p> <p>IP offices check compliance in the context of IP applications (including disclosure requirement) (IP Office as checkpoint)</p> <p>AND/OR</p> <p>Market approval authorities (sector specific checkpoints) check compliance in the context of market approval applications (including disclosure requirement)</p> <p>AND/OR</p> <p>Regular compliance checks (e.g. <i>on the spot inspections</i>) by designated authorities (CNAs) of MS on users</p>
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3	<p>Measures to address non-compliance with user compliance obligations</p> <p><u>NP Core Obligations:</u></p> <p>Art. 15(2) for GR</p> <p>Art. 16(2) for TKaGR</p> <p>Take appropriate, effective and proportionate measures to address non-compliance</p> <p><u>Supplementary obligations:</u></p> <p>Art. 15(3), 16(3): (Weak) obligation to cooperate between provider and user countries in cases of alleged violation of ABS frameworks of provider countries</p>	<p>No system for user compliance measures, consequently no measures to address non-compliance</p>	<p>MS establish sanctions consistent with their specific national and regional legal contexts, most likely resulting in different approaches and measures across the EU</p> <p>MS establish mechanisms for cooperation with provider countries</p> <p>EU OMC to support MS led measures</p> <p>AND</p> <p>Refusal/ex-post repayment of EU research funding and other relevant funding</p>	<p>EU obligation on MS to provide for appropriate, effective and proportionate sanctions (levied at Member State level) for cases of non-compliance with EU rules and cooperation with provider country authorities.</p> <p>Possible sanctions could be left entirely for Member States to decide, or EU rules could include a closed list of possible sanctions – i.e. MS to choose from a list which could include, for example:</p> <p>Ex post require PIC/conclude MAT “Name and shame” Administrative sanctions</p> <p>AND</p> <p>Refusal/ex-post repayment of EU research funding and other relevant funding (EU level sanction)</p>	<p>EU obligation on MS to provide for appropriate, effective and proportionate sanctions (levied at Member State level) for cases of non-compliance with EU rules and cooperation with provider country authorities.</p> <p>Possible sanctions could be left entirely for Member States to decide, or EU rules could include a closed list of possible sanctions – i.e. MS to choose from a list which could include, for example:</p> <p>Ex post require PIC/conclude MAT “Name and shame” Administrative sanctions Sanctions relating to IPR (e.g. non-processing of patent application) Sanctions relating to market approval (e.g. non-processing of market approval application)</p> <p>AND</p> <p>Refusal/ex-post repayment of EU research funding and other relevant funding</p>
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4	<p>Measures on compliance with MAT</p> <p><u>Core Obligations:</u></p> <p>Art 18(2): Each Party shall ensure an opportunity for recourse under its domestic legal system</p> <p>Art 18(3): Each Party shall take effective measures regarding access to justice and mechanism for mutual recognition and enforcement</p>	<p>General rules on legal standing and applicable law for contractual disputes</p> <p>Brussels I and Rome I Regulation</p>	<p><u>MS level</u></p> <p>MS have full discretion to decide on whether or not to further develop applicable rules on e.g. access to courts specifically for ABS</p> <p><u>EU level:</u></p> <p>EU measures to support MS to adapt their legal system</p> <p>AND</p> <p>EU soft measures: e.g. legal aid, alternative measures for disputes resolution</p>	<p>No EU legislative action</p> <p>OR</p> <p>Harmonised approach: Consider whether Brussels I and Rome I Regulations need to be changed</p> <p>AND</p> <p>EU soft measures: e.g. legal aid, alternative measures for disputes resolution</p>	<p>No EU legislative action</p> <p>OR</p> <p>Harmonised approach: Consider whether Brussels I and Rome I Regulations need to be changed</p> <p>AND</p> <p>EU soft measures: e.g. legal aid, alternative measures for disputes resolution</p>
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5	<p>Measures to address supplementary obligations</p> <p>Art 9: Encourage that benefits arising from utilisation of genetic resources are directed to the conservation and sustainable use of biodiversity (Art 9)</p> <p>17(1)(b), 18(1): Encourage inclusion into MAT of provisions on information on the implementation of MAT, applicable law, dispute resolution</p> <p>Art 17(1)(c): Encourage cost-effective communication tools and systems</p> <p>Art 19: Encourage development and use of model contractual clauses</p> <p>Art 20: Encourage development and use of codes of conduct, and best practices or standards</p> <p>Art 21: Awareness-raising</p> <p>Art 22(1): Capacity-building</p> <p>Art 23: Technology transfer, research cooperation</p>	Some existing, voluntary measures by users	EU soft measures, e.g. development of codes of conduct, awareness-raising, capacity building through development cooperation, support for EU intermediaries, model MTAs, bilateral agreements	EU soft measures, e.g. development of codes of conduct, awareness-raising, capacity building through development cooperation, support for EU intermediaries, model MTAs, bilateral agreements	EU soft measures, e.g. development of codes of conduct, awareness-raising, capacity building through development cooperation, support for EU intermediaries, model MTAs, bilateral agreements
6	<p>Institutional provisions</p> <p><u>Supplementary Obligations:</u></p> <p>Art 15(3), 16(3): Cooperate, as far as possible and as appropriate, on alleged violation of domestic ABS requirements relating to GR and TKaGR</p>		Establishment of CNA at MS level and focal point at EU level, with roles depending on responsibilities and tasks between MS and Union level	Establishment of CNA at EU and/or at MS level, with roles depending on responsibilities and tasks	Establishment of CNA at EU and/or at MS level, with roles depending on responsibilities and tasks

10 EU BASELINE

10.1 Introduction

This EU baseline provides an overview of the use and exchange of genetic resources (falling within the scope of the Nagoya Protocol) for both the commercial and non-commercial sectors affected by ABS issues in Europe. This builds on the sectoral studies that are included in a separate Annex to this report. Sectors involved are academic research, botanic gardens, culture collections, pharmaceutical industry, cosmetics industry, food and beverage industry, seed industry, animal breeding industry, horticulture, biological control (“biocontrol”) and industrial biotechnology.

The baseline deals with issues such as the relevance of genetic resources and access and benefit sharing for each of these sectors, the different activities involved in the genetic resource user chain, the size and characteristics of the sectors, the types and role of genetic resources in the sectors, the relevance of research and development on genetic resources for innovation in the sectors, the sourcing of genetic resources and the sectoral approaches and practices regarding ABS.

Data collection methods for the sectoral studies involved a review of published and ‘grey’ literature, a review of the replies of stakeholders to the European Commission’s public consultation on the implementation of the Nagoya Protocol and semi-structured interviews, phone calls and e-mail correspondence with stakeholders from each of the sectors (industry, government, NGOs and research institutions).

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

The EU baseline and associated sectoral studies present the context and foundation for subsequent analysis of impacts of the possible measures to help implement the Protocol.

10.2 EU sectors involved in or affected by ABS activities

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

The following “sectors” were analysed in developing the EU baseline:

- Botanic gardens, defined as “institutions holding documented collections of living plants for the purposes of scientific research, conservation, display and education”;
- Culture collections, defined as “organizations established to acquire, conserve and distribute microorganisms and information about them to foster research and education”;¹³⁹
- Academic research (universities and research institutes);
- The biocontrol sector, which mainly develops techniques for crop protection whereby predatory or parasitic living organisms (so-called “biocontrol agents”) are being used to control pests;
- The industrial biotechnology sector, where companies develop, manufacture and sell products and services that “use or contain biological material as catalysts or feedstock to make industrial products”, some of which develop enzymes, apply enzymes in biotransformation, develop whole cell catalysts and apply these in fermentation systems (HM Government, 2010);
- The plant breeding or seed industry, which engages in developing seeds which are an essential input in crop production;¹⁴⁰
- The horticulture sector, which includes a range of activities from amateur plant breeding for ornamental purposes (e.g. hobby gardening) to commercial vegetable production. The distinction between horticultural and agricultural production is difficult to make, but can be judged based on the scale of production;
- The cosmetics industry, which develops, manufactures and sells a range of products that include “traditional” cosmetics products, such as make-up and perfumes, as well as personal hygiene products such as tooth-care products, shampoos and soaps;
- The pharmaceutical industry, which engages in the discovery, development, and manufacture of drugs and medications;
- The farm animal breeding industry, which engages in the breeding and reproduction of farmed and companion animals. The five most important species for global agriculture are cattle, sheep, goats, pigs and chickens; and
- The food and beverage industry.

Relevance of genetic resources and ABS for the sectors

Issues related to access and benefit-sharing to genetic resources affect many activities and sectors of the EU economy. While demand for access to ‘wild’ genetic resources has declined in most sectors, interest in research and development on genetic resources has increased overall (Laird and Wynberg, 2012). While some sectors, such as the biocontrol sector, rely heavily on genetic resources sourced from the wild, other sectors build most of their innovation on genetic resources that have already been subjected to improvements.

¹³⁹ Botanic gardens and culture collections (and other *ex situ* collections) are very much linked because they are often hosted by the same institutions, generally universities or public research institutes. In 2001, for example, 30% of the world’s botanic gardens belonged to universities or higher education research institutes (Wyse Jackson *et al*, 2001). As for culture collections, 75% are estimated to belong to public sector entities (FAO, 2009).

¹⁴⁰ “Seed” refers to all planting material used in crop production, including seed grains, cuttings, seedlings, and other plant propagation materials.

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

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

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

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

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

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

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

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

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

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

Figures 10.1 and 10.2 give a general cross-sectoral overview of the use and exchange of genetic resources in the EU. For the purpose of this study, a distinction has been made between “upstream” and “downstream” activities in the genetic resources user chain. “Upstream” activities include collecting *in situ* genetic resources, importing genetic resources into the EU, storing genetic resources in *ex situ* collections (including identifying and documenting them for this purpose) and handing out genetic resources (see Figure 10.). “Downstream” activities include research (basic and applied) and development on genetic resources for both commercial and non-commercial purposes – i.e. activities that fall within the Protocol’s definition of “utilization” of genetic resources – and the commercialization of products that are based on the utilisation of genetic resources or associated traditional knowledge (see Figure 10.2).

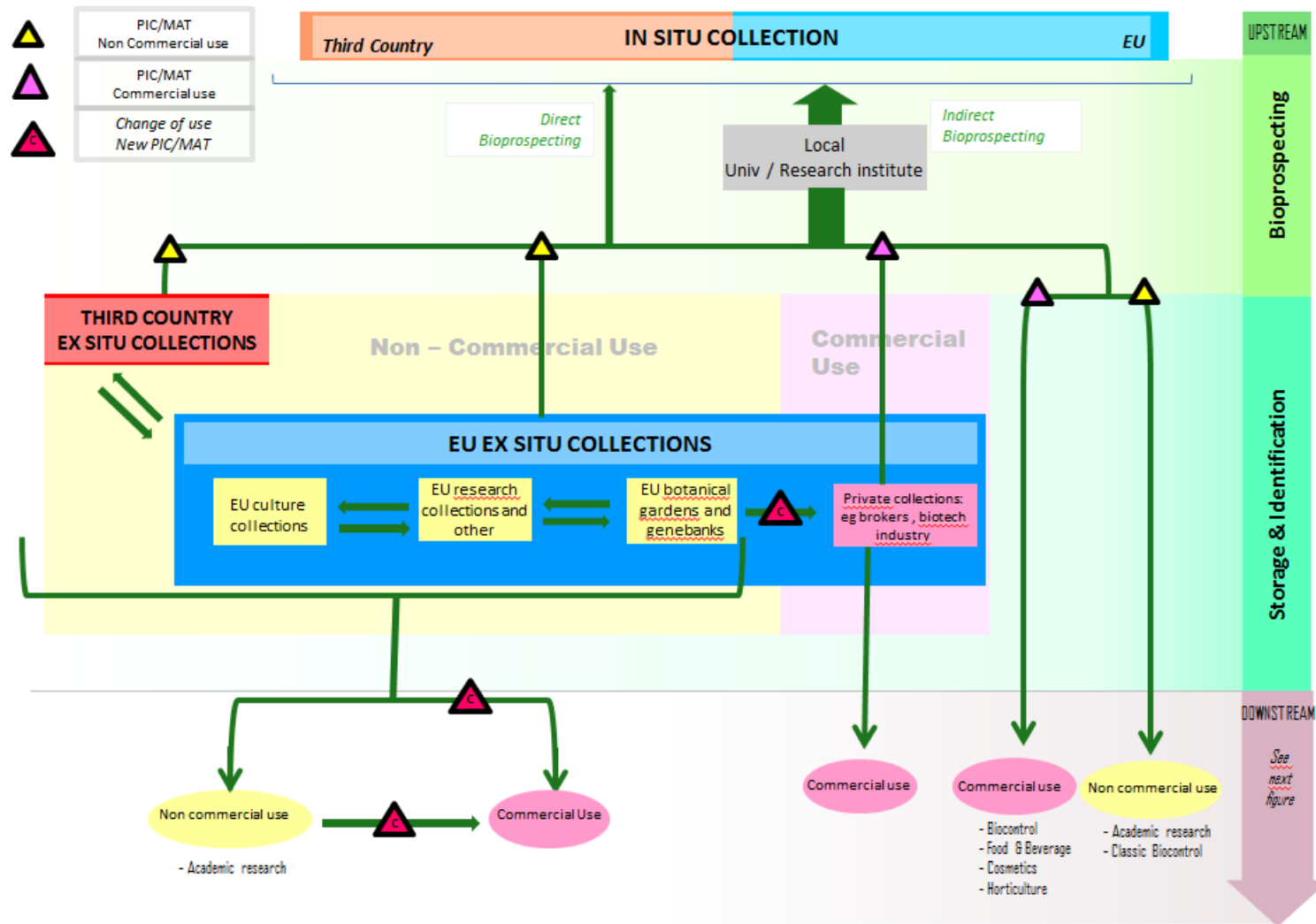
Figures 10.1 and 10.2 indicate that some players in the genetic resources user chain are typically involved in upstream activities, whereas others are typically involved in downstream activities. Actors typically involved in upstream activities include botanic gardens, culture collections, seed banks and other public or private *ex situ* collections. They are mainly involved in bioprospecting, collecting, identifying and storing genetic resources for public good purposes. These activities are also often linked because different collection types are often hosted by the same institutions, generally universities or public research institutes. A wide range of industries such as the biotechnology industry, the pharmaceutical industry, the plant breeding industry, the horticultural industry, the biocontrol industry, the cosmetic industry and the food & beverage industry are involved in downstream uses of genetic resources.

The distinction between upstream and downstream activities is useful for analytical purposes and for effectively implementing the Protocol in the EU. Firstly, actors engaged in the upstream part of the genetic resources user chain typically supply downstream users with genetic resource samples or valuable data related to genetic resources that may subsequently be used for commercial R&D and eventually become the basis for a product. Secondly, the Protocol as it stands does not distinguish between upstream and downstream; it simply establishes a general obligation on Parties to ensure that genetic resources utilised in their jurisdiction were legally acquired in the country of origin. In the EU, it seems that upstream users, such as culture collections or botanic gardens, assume a major role as intermediaries in that they constitute the link between concrete access activities in source countries and subsequent utilization activities within the EU.

The upstream/downstream distinction applies to “types of activity” in the genetic resources user chain. While some sectors only engage in upstream or in downstream activities, other sectors (e.g. horticulture and academic research) are both involved in the upstream and downstream activities. Figures 10.1 and 10.2 below indicate the typical “placement” of sectors upstream and downstream.

In the following sections, we explain in more detail the upstream and downstream parts of the EU genetic resource user chain on the basis of the flowcharts in Figures 10.1 and 10.2.

Figure 10.1: EU upstream activities and actors involved



EU upstream activities and actors concerned

The first flow chart (Figure 10.1) focuses on the upstream activities within the EU user chain. "Upstream" activities include collecting *in situ* genetic resources, importing genetic resources into the EU, storing genetic resources in *ex situ* collections (including identifying and documenting them for this purpose) and handing out genetic resources to downstream users or other *ex situ* collections. Actors typically involved in upstream activities include botanic gardens, culture collections, seed banks and other public or private *ex situ* collections. They are mainly involved in bioprospecting, collecting, identifying and storing genetic resources for public good purposes, except for private collections held by companies to support their commercial R&D. *Ex situ* collections (at least the public ones) are very much linked because they are often hosted by the same institutions, generally universities or public research institutes.

The flow chart shows that the bioprospecting or collecting of genetic resources *in situ* (either within or outside the EU) is mainly undertaken by botanic gardens, culture collections, universities and research institutes (referred to as "research collections" in the flow chart) and other *ex situ* collections (e.g. genebanks).¹⁴¹ However, actors which engage more in commercial downstream activities (e.g. R&D) may also undertake bioprospecting; these include biocontrol companies and healthcare biotech companies. Bioprospecting can be done either directly or indirectly through partnerships with local universities and research institutes.

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

¹⁴¹ Plant genebanks provide safe storage to ensure that the varieties and landraces of crops that underpin our food supply are secure and that they are easily available for use by farmers, plant breeders and researchers. Though genebanks are mainly used by universities, small companies and national agricultural research systems in developing countries, they are also sources of genetic material for plant breeding companies (Fowler *et al*, 2001; sCBD, 2008). Animal genebanks mainly fulfill conservation purposes and are less involved in the exchange of genetic material and its provision for breeding purposes (FAO, 2009; Schloen *et al*, 2011).

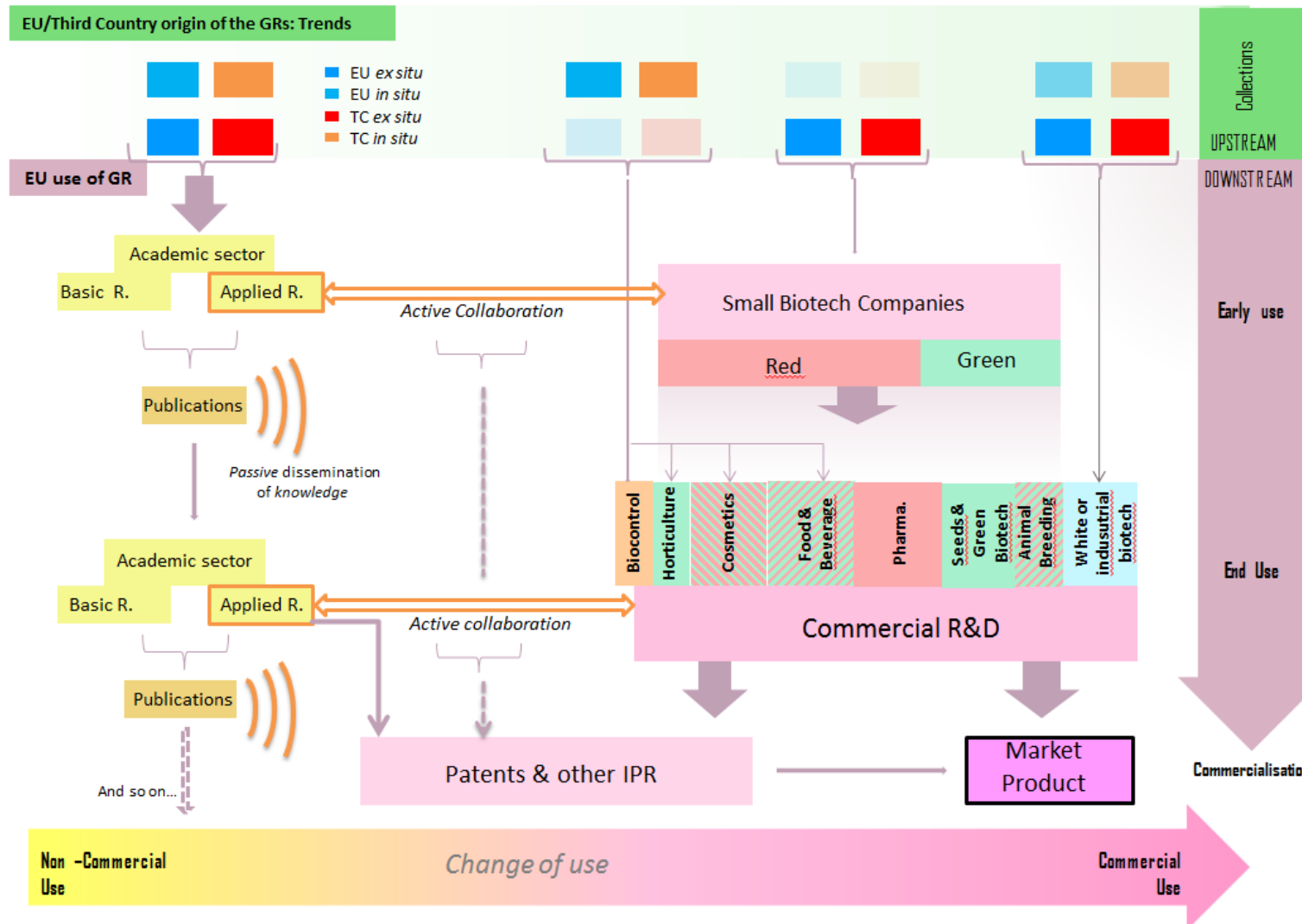
It should also be noted that EU actors (whether mostly active at the upstream or downstream level) might also source genetic resources from third country *ex situ* collections.

Major exchanges of genetic resources occur among the various *ex situ* collections both among EU *ex situ* collections and between EU and non-EU *ex situ* collections. This results *inter alia* from the need for identification of genetic resources by the collections. As this requires the scarce expertise of highly specialised taxonomists, international transfers of genetic resources are indispensable.

As Figure 10.1 shows, the actors that engage primarily in downstream activities (such as research and development on genetic resources) either obtain their genetic material directly from provider countries (through bioprospecting or third country *ex situ* collections) or indirectly through the EU *ex situ* collections.

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

Figure 10.2: EU downstream activities and actors involved



EU downstream activities and actors concerned

The second flow chart (Figure 10.2) focuses on the downstream activities within the EU user chain. "Downstream" activities include research (basic and applied) and development on genetic resources for both commercial and non-commercial purposes – i.e. activities that fall within the Protocol's definition of "utilization" of genetic resources – and commercialization of genetic resource based products which falls under the Protocol's provision for a fair and equitable benefit sharing. A wide range of industries such as the biotechnology industry, the pharmaceutical industry, the plant breeding industry, the horticultural industry, the biocontrol industry, the cosmetics industry and the food & beverage industry are involved in the downstream part of the genetic resources value chain.

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

Another noteworthy sector in the downstream part of the user chain is the biotechnology sector. The sector is very much linked with agricultural input industries (such as the seed and animal breeding industry), the pharmaceutical industry and others, such as manufacturing industries, the "bioenergy" industry and the biomaterials industry, as it contributes directly to their research and development. Biotechnology can be subdivided as green, red and white biotechnology: green biotechnology refers to agricultural biotechnology; red biotechnology refers to pharmaceutical and medical biotechnology; and white biotechnology refers to industrial biotechnology. In reality, these subsectors may overlap. White biotechnology firms are separate in the flow chart as they are less dependent of the more downstream industries for the completion of a marketable product. This is different for instance from the red biotechnology companies which usually take care of the first stages of pharmaceutical research¹⁴² and subsequently pass on – through outlicensing or acquisition – their products to the big pharmaceutical companies for further R&D and other subsequent stages in the value chain such as marketing (see also Figure 10.3).

¹⁴² Biotechnology companies are active across the user chain in the pharmaceutical industry, but their primary area of expertise is in the gene identification and target identification and validation stages upstream of product development and commercialisation.

At the most downstream part of the user chain one finds industries which undertake more downstream R&D and commercialize products; in terms of size the pharmaceutical industry and the food and beverage industries are the most significant, and the biocontrol industry is the smallest (see section 1.3 for more details). As far as the sourcing of genetic material is concerned, the industrial biotechnology sector differs from the agriculture and pharmaceutical biotechnology sectors. Industry biotechnology researchers regularly collect their own samples of materials, contrary to the case in the agricultural and pharmaceutical sectors (ten Kate & Laird, 1999). The biocontrol sector is also a special case as it relies heavily on its own bioprospecting activities (see section 10.5 for more details on sourcing).

10.3 Size and characteristics of relevant sectors

Global market/size and development prospects

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

Conversely, downstream users of genetic resources generally operate in larger markets. For instance, the global food and beverage industry was valued at \$5.7 trillion in 2008, the global pharmaceutical market at \$808 billion in 2009 (IMAP, 2011), the cosmetics market at \$136 billion in 2006 (Global Insight, 2007), the global biotechnology industry revenues at \$84.6 billion in 2010 (Ernst & Young, 2011) and the commercial seed market at \$42 billion (ISF, 2011d). Market data in the horticulture sector are hard to obtain for several reasons, though some general comparisons can be made. Overall, the market size for vegetable seed is much bigger than for ornamental products. Flower seed value totalled \$249 million in 2010 amongst the 32 countries worldwide reporting more than \$1 million in imports (ISF, 2011a). By comparison, vegetable seed value totalled more than \$2.8 billion in 2010 amongst the 100 countries worldwide reporting more than \$1 million in imports (ISF, 2011b). The global market for augmentative biocontrol was estimated at US\$100-135 million in 2008 (FAO, 2009).

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

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

Non-commercial sectors in the EU are quite important in terms of their share in their sectors' activities globally. For botanic gardens, of 3,021 botanic gardens worldwide, around 550 are based in the EU (van den Wollenberg et al, pers. comm., 2012).¹⁴³ In 2001, moreover, it was estimated that 50% of all living plant accessions in the world were

¹⁴³ For details on numbers of botanic gardens worldwide and in the EU see http://www.bgci.org/garden_search.php

collected in Europe (Wyse Jackson, 2001). Kew Gardens in the UK holds the largest living plant collection and one of the largest herbaria in the world.¹⁴⁴ As far as culture collections are concerned, of 593 worldwide, 158 collections are based in the EU, holding 33% of the global collection of strains. Japan follows with 13% and the US with 12% of the global share of strains collected.¹⁴⁵

The commercial sectors in the EU utilizing genetic resources also tend to have significant shares in their respective global markets, with the highest shares in the animal breeding, cosmetics and biocontrol sectors¹⁴⁶:

- Pharmaceutical industry: size of the global market was \$808 billion in 2009 with global market share for the EU of nearly 15% (IMAP, 2011);¹⁴⁷
- Food and beverage industry: size of the EU market was €954 billion in 2009 with a share of global exports of 18.6% in 2009 (CIAA, 2010);
- Cosmetics industry: size of the EU market was \$63.5 billion in 2006 with a global market share of 46.6% (Global Insight, 2007);¹⁴⁸
- Biotechnology industry: revenues of the EU biotechnology industry amounted to \$13 billion in 2010 with a share in global revenues of 15% and a share of 34.5% of global biotechnology patent applications at the European Patent Office (Ernst&Young, 2011; EC, 2007);
- Seed industry: size of the EU market was \$6.8 billion in 2009 with a global market share of more than 20% (www.esa.org);
- Biocontrol industry: the EU is the largest market in the world for beneficial insects and the second largest for microbial biopesticides (FAO, 2009);
- Animal breeding industry: the economic gain (or added value) of animal breeding in Europe amounts to €1.89 billion per year, with global market shares of 90% for ducks, 100% for turkeys, 72% for broilers (poultry), 95% for layers (poultry) and 28.5% for pigs (figures from 2007) (FARBE-TP, 2008).

The Netherlands was the global leader in vegetable crop seed exports in 2010 (\$1 billion) and was second to the US in flower seed exports (US exports were \$72 million, and Dutch exports were \$57 million) (ISF, 2010c and 2010d). The top ten exporters of vegetable crops

¹⁴⁴ <http://www.kew.org/collections/index.htm>

¹⁴⁵ WFCC website (<http://wdcm.nig.ac.jp/statistics.html#1>)

¹⁴⁶ Note that figures/numbers and percentages in relation to EU markets do not necessarily match the figures on global markets. For some sectors the sources for global and EU figures differ (and hence the methods for generating these figures), for others the reference years differ. Only for some sectors have figures been found that entirely match. Also note that the percentages usually refer to the EU's share in the global market in terms of sales, but in some cases might refer to other types of shares such as the share in global number of patents or the share in global exports.

¹⁴⁷ Note that the IMAP report does not provide a figure for the size of the EU market. It only provides a figure for the global market and the EU's global market share as a percentage. On the basis of these data, the size of the EU market can be calculated (about \$121 billion).

¹⁴⁸ The "global" market *in casu* refers to the whole of the markets of the US, the EU27, Norway, Switzerland, Japan and China (Global Insight, 2007).

seeds also include France, Italy, Germany and Denmark; the top ten exporters of flower seeds include Germany, France and the UK.

Economic relevance of “utilization” of genetic resources for the sector in Europe

The Nagoya Protocol defines “utilization of genetic resources” as “the conduct of research and development on the genetic or biochemical composition of genetic resources”. While there is virtually no data specifically on the economic relevance of the utilisation of genetic resources, figures on R&D expenditure that are provided below, when combined with the qualitative information on the relevance of genetic resources for each sector under section 10.2, provide an indicative picture on the economic importance of the utilisation of genetic resources. A more qualitative assessment of the role of research and development on genetic resources for innovation in the sectors is provided in section 10.4.

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

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

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

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

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

The activities of *ex situ* collections such as botanic gardens or culture collections are primarily non-commercial and relate to the collection (*in situ* or *ex situ*), storage, and further transfer of genetic resources to downstream users. Genetic resources are “utilised” by those actors as far as the majority of *ex situ* collections engage in basic research on the genetic or biochemical composition of the material collected *inter alia* to identify and cataloguing new genetic material (Wyse Jackson *et al*, 2001). *Ex situ* collections further engage in utilization through scientific collaborations with academic institutions and downstream industrial users. For culture collections in particular, moreover, basic research activities consist not only of identifying the taxonomic nature of microbial strains, but also characterising their biological function and sequencing them to identify the genetic code (Stromberg *et al*, 2012). Thus, they clearly engage in the utilization of genetic resources in the sense of the Protocol. Apart from public funding, well organized culture collections generate additional income through the sale of microbial genetic resource samples and the provision of scientific services to customers (identification, characterization of strains, creation of databases with information on the genetic and biochemical composition of microbial genetic resources held in the collection) (Stromberg *et al*, 2012).

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

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

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

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

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

With regard to botanic gardens, the Royal Botanic Gardens Kew (UK) hold the largest living plant collection in the world and one of the largest herbaria. It also significantly engages in scientific research on plant material, producing around 350 publications per year. The garden employs 744 staff and has an annual income of €55.7 million (year 2010/2011), more than half of which originates from public funding with the rest mostly coming from private grants and fees charged for visiting the gardens (1.6 million visitors in 2010-11).¹⁴⁹

Relevance of SMEs

The role of SMEs in the sectors varies. While some EU sectors such as the green biotechnology sector are dominated by big multinational enterprises, others such as the biocontrol sector are dominated by SMEs. SMEs also play different roles in relation to utilisation of genetic resources for innovation. While the field of pharmaceutical biotechnology, for example, is dominated by research-intensive SMEs, research on genetic resources for innovation in the horticulture industry is mostly carried out by large multinationals.

The pharmaceutical industry is dominated by large multinational companies, though SMEs (especially biotechnology companies) do also play a major role, especially in the early stages of the user chain (see Figure 10.3). On the one hand there are large pharmaceutical companies which need to be big because of uncertainties in the drug development process. On the other hand, there are smaller biotechnology companies, most of which do not have the capital or market access to commercialize a product (IMAP, 2011). A large proportion of companies working in healthcare biotechnology are research-intensive SMEs (Degen *et al*, 2011; Croplife, pers. comm., 2012). Many of these SMEs are micro-enterprises consisting of 10 or fewer employees (Degen *et al*, 2011). Currently, some very large companies with big sales/marketing organizations and the capital and knowledge for late-stage clinical developments are systematically acquiring small biotechnology companies with interesting candidate products. Licensing deals with small biotech companies are also becoming increasingly important (IMAP, 2011).

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

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

¹⁴⁹Kew Annual Report and Accounts 2010/11, Available at: http://www.kew.org/ucm/groups/public/documents/document/kppcont_038136.pdf

resources by investing significant resources into the development of new products (ten Kate, 1999).

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

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

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

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

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

Types and role of genetic resources used in the various sectors

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

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

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

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

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

In the animal breeding sector, exchange of (animal) genetic material between owners is crucial for the development of livestock breeds and the livestock sector in many parts of the world. Genetic variation within lines or breeds is the main source for genetic improvement. Although (new) breeds and lines are being developed continuously in commercial breeding programmes, the introduction of “foreign” genetic material or “wild relatives” is much less relevant in animal breeding than in plant breeding (Kaal-Lansbergen and Hiemstra, 2003). For many domesticated livestock species no wild relatives exist, as they have become extinct, and for others wild relatives are very rare (Schloen *et al*, 2011). Furthermore, little or no demand exists in developed countries for breeding animals or specific (adaptive) traits from developing countries. This situation could however change as a result of climate change. Many of the traits necessary to adapt to climate change may be found in locally adapted breeds. Climate change is therefore likely to increase the exchange of genetic material across the board, but might also lead to a bigger flow of genetic material from the South to the North (FAO, 2009; Schloen *et al*, 2011).

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

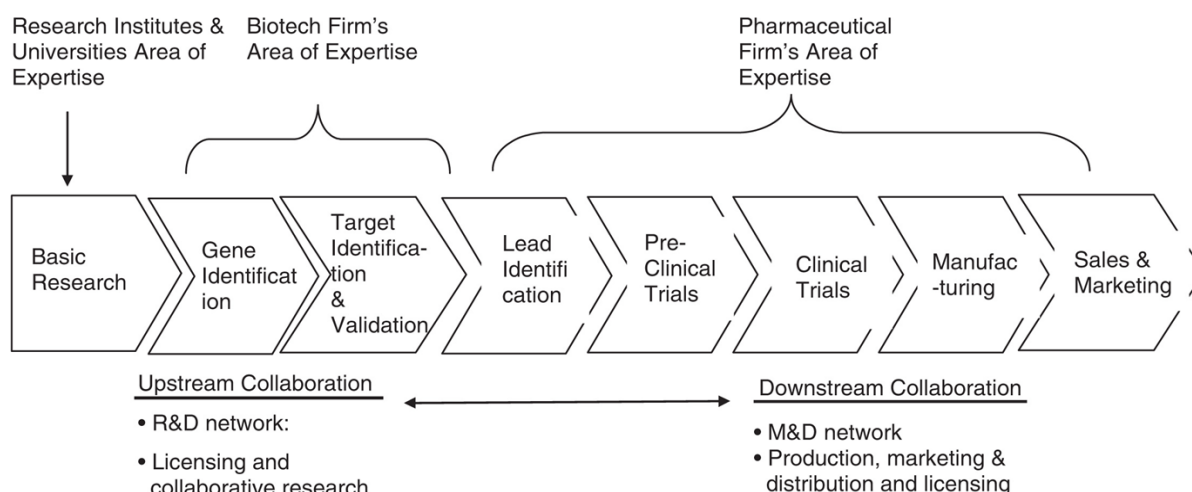
Research and development of commercial products from genetic resources is important for a wide range of sectors. However, the ways in which and the extent to which the sectors undertake research and development vary.

The pharmaceutical industry, for instance, is very R&D intensive. Drug development relies on the collaboration and effort of highly trained scientists at universities and private companies (see also Figure 10.1 which shows how the value chain in the sector might look). It takes about 10 to 15 years for a compound to make its way through R&D into commercialization. Only one in approximately 10,000 compounds screened is commercialized (PhRMA, 2005; Laird and Wynberg, 2008). According to EFPIA (2007), many thousands or even hundreds of thousands of samples must be screened to identify potential leads for investigation. Identified leads rarely generate compounds that merit serious

research. Even fewer generate compounds that possess properties that merit the filing of a patent application; from these, only some are commercialized. As noted before, the research-based pharmaceutical industry amounts to 18.9% of the total worldwide business R&D expenditure. In 2010 an estimated €27 million was invested in pharmaceutical R&D in Europe (EFPIA, 2011). Nevertheless, R&D productivity of the big pharmaceutical companies declined by 20% in the 2001-2007 period (IMAP, 2011).

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

Figure 10.3: Value chain in the pharmaceutical industry



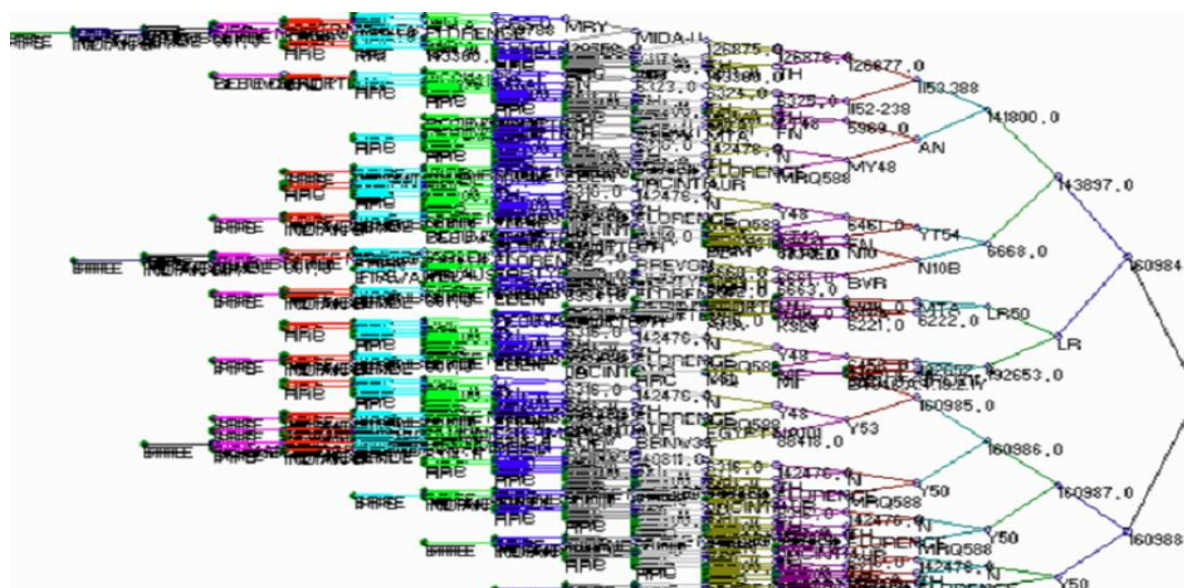
Source: Advances in Strategic Management

The seed or plant breeding industry, which relies entirely on genetic resources, is characterised by important R&D investments. It is estimated that 10-14% of turnover is spent on R&D (ESA, 2012). Research intensity (R&D spending as a percentage of sales) for seed increased during the 1990s (related to the increasing dominance of modern biotechnology or genetic engineering) and has fallen since 2000, though it is still higher than for other “agricultural input industries” with high research intensities such as animal genetics and animal health. R&D investment varies by crop (Smolders, 2005). R&D investments in the European seed and biotechnology sector are both focused on biotechnology and conventional breeding. Plant breeding is traditionally characterised by long time horizons over which research and development of new products evolves from the original point of access to genetic resources. Often multiple plant genetic resources are used

in species improvement (see Figure 10.4): the development of one wheat variety may involve “thousands of plant breeding crosses and dozens of different individual lines, including wild ones, from many countries and over many centuries” (Beattie et al, 2005; Schloen *et al*, 2011). In other words, plant breeding is a global activity in which many breeders from many different countries are involved.

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

Figure 10.4: pedigree picture of a particular wheat line



Source: CIMMYT

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

In the biocontrol sector the relevance of research and development on genetic resources is very high. At the planning stage, surveys about the pest and its natural enemies need to be undertaken to obtain information about the area of origin of the pest and the best places to

look for natural enemies. Subsequently, natural enemies are identified and detailed studies undertaken to assess their potential use as biocontrol agents. This includes developing breeding methods for use in the laboratory and conducting impact studies in the field or in the laboratory (FAO, 2009). The last step consists of an evaluation by the target country authority of the risks and potential benefits of the introduction of the relevant pest. Permission for release may or may not be given. When permission is granted, release strategies and protocols will be developed together with monitoring and evaluation procedures (FAO, 2009).

In the cosmetics and food and beverage industries, R&D investments are much lower than in the pharmaceutical and biotechnology sectors. However, investments in R&D have increased in recent years as a result of rising demand for proven, effective and safe products. Research and development of new products, however, varies significantly. In some cases time horizons are very short and the input of science and technology is minimal (e.g. when companies sell bulk unprocessed herbs and as such may or may not “utilise” genetic resources, or when companies process plants into extracts). In other cases time horizons may be considerably longer, e.g. when cosmetics companies run screens involving as many as 100 substances to identify active compounds and undertake clinical trials. In those cases it may take 6 to 8 years to bring a product to market (EC public consultation, 2012; Laird and Wynberg, 2012).

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

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

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

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

Academic research institutes can also be actively involved in commercial R&D through partnerships with the private sector. The business sector indeed finances up to 6.6% of

higher education R&D in the EU (EC, 2005). For instance, to improve knowledge sharing and to cut costs, pharmaceutical companies are highly interested in collaborating with academic laboratories. Partly funded by the government, academia invests effort in basic research to identify potential new targets for drugs (e.g. membrane or intracellular receptors and their signalling pathways) and biomarkers to monitor the effect of a drug. Furthermore, academia can contribute by optimizing technology to accelerate drug development. In addition, academic laboratories are highly stimulated to collaborate with pharmaceutical companies. In the EU FP7 Health program for instance, projects are only selected for funding if a certain percentage of the EU budget goes to SMEs. Furthermore, in project application forms from national governmental agencies, academic researchers have to describe how they will valorise the results of the project. Other initiatives to stimulate interaction between academia and industry include platforms such as the Innovative Medicines Initiative (IMI), a European public-private initiative that supports collaborative research projects and builds networks of industrial and academic experts to boost pharmaceutical innovation in Europe (Smits, pers. comm., 2012).

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

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

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

As botanic gardens and culture collections also provide economic sectors with their genetic resources, the basic research carried out by them in terms of identification, documentation, profiling and further scientific research on the properties of genetic resources held in their collections is definitely relevant for some sectors. In a survey carried out in 2005, it was

found that 23% of the genetic material provided by culture collections went directly to private sector users, whereas the other 77% went to universities, research institutes and other culture collections (Stromberg *et al*, 2006). The relevance of microbial genetic resources held in culture collections for commercial sectors is likely to be higher when one considers the further linkages down the utilisation chain between academic research institutes and private companies. The microbial genetic resources and information on their properties and genetic profiles held by culture collections are mostly used for the biological control of pests and diseases in agriculture and horticulture, the production of natural products (e.g. valuable drugs, enzymes, and metabolites) for pharmaceutical, food and other applications, as well as the production of biofuels and bioplastics (agricultural and industrial biotechnology) (WFCC, 2008). Botanic gardens are mostly providers of genetic resources and related taxonomic information to universities and public research institutes, though they might also less frequently supply other downstream sectors such as green biotechnology, plant breeders, horticulture and the pharmaceutical sector (Wyse Jackson, 2001; van den Wollenberg *et al*, 2012).

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

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

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

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

Plant variety rights: Innovations in the conventional plant breeding industry and horticulture sector are mostly protected through the plant variety protection system. As mentioned above, however, the development of a new wheat variety may involve thousands of plant breeding crosses and dozens of different individual lines (Schloen *et al*, 2011). EU legislation authorises only the protection of a new plant variety by means of the

community plant variety right system (CPVR – Regulation (EC) No 2100/94) or national systems, in accordance with UPOV (*Union pour la Protection des Obtentions Végétales*); the CPVR system protects mainly ornamental species (60%), agricultural crops (25%), vegetable crops (12%) and fruit species. Currently, less than 14% of registered varieties on the EU Common Catalogues (agricultural and vegetable crops) are protected within the CPVR. More than 18,000 protection titles are in force at EU level. The CPVR and UPOV systems are open systems because the variety, even protected for commercial use, remains free for research and breeding (compulsory breeder exemption) and for private use.

Patents: Among the sectors covered by the present study, one of the most reliant on patents for protecting innovations is the pharmaceutical industry. In 2011, pharmaceuticals operators based in Europe filed 5,759 applications before the European Patent Office (EPO), representing 4% of the overall number of European patent applications before the EPO. Those figures represent a strong decline compared to the previous year (6,879 applications, representing 4.5% of the overall number of European patent applications).¹⁵⁰ In this sector, while only a small number of new chemical entities are approved annually, thousands of patents are applied for to protect variants of existing products and manufacturing processes. Patents are usually obtained by the time lead compounds have entered the stage of lead optimisation, even though many uncertainties with respect to commercial return remain (EFPIA, 2007).

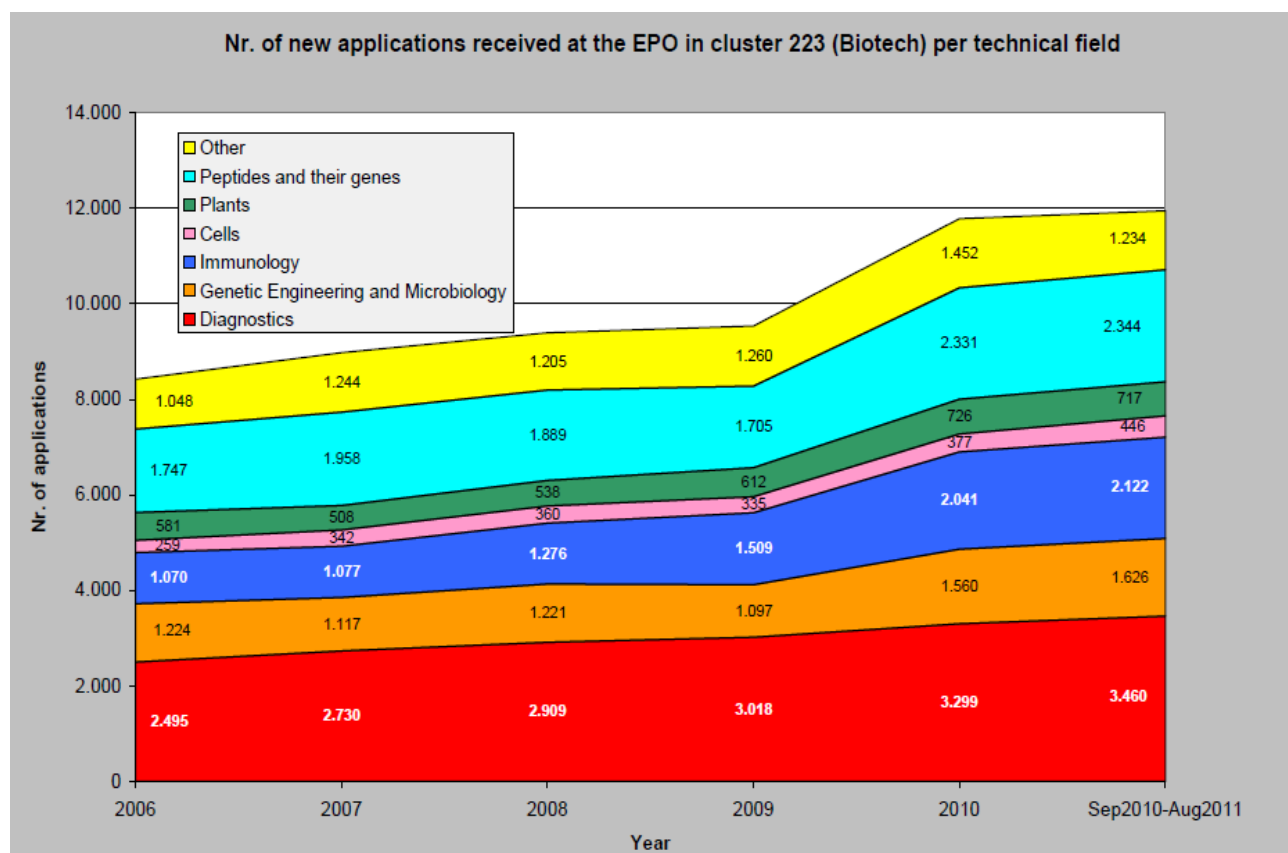
The number of patent protection applications has grown significantly in recent years in the field of biotechnology (Ugalde, 2007), which is now among the 10 most active fields for applications before the EPO. In 2011, biotechnology operators based in Europe filed 5,865 applications before the EPO, representing 4.1% of the overall number of European patent applications before the EPO.¹⁵¹ While a number of innovations in the academic research sector are not protected because the main aim of academic research is to increase scientific knowledge by disseminating research results through publications, patenting has increased in this sector since the 1990s in the field of biotechnology, where basic research is often likely to lead to industrial applicability (van Zeebroeck *et al*, 2008). In 2005, patent applications before the EPO from the government and higher education sectors amounted to merely 3.2%, whereas business enterprise sectors were responsible for 85.7% of the overall number of patent applications (Eurostat, 2010). In the field of biotechnology in 2002 university patent filings before the EPO accounted for 13% of the overall number of applications (van Zeebroeck, 2008).

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

¹⁵⁰ <http://www.epo.org/about-us/statistics/patent-applications.html>

¹⁵¹ *Ibid.*

Figure 10.5: Overall number of new applications received at the EPO in the field of Biotechnology



Source: S. Yeats EPO, 2011

Trade secret: Protection of inventions through trade secrets is carried out by a number of sectors including the cosmetics, food & beverages, animal breeding, plant breeding and biocontrol industries. Information covered by trade secrets may range from production know-how in the biocontrol industry (i.e. the rearing methods used in the laboratory) to genetic information on crop varieties in the plant breeding industry (e.g. the genetic information contained in the seeds of the parental inbred lines that are used to produce proprietary hybrid varieties) (Kratiger, 2007).

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

The relevance of traditional knowledge varies by sector. The role of traditional knowledge in pharmaceutical discovery has been relatively small in recent decades and is likely to become even smaller. Several reasons are put forward for this trend: the emphasis of pharmaceutical drug development on disease categories that do not feature prominently in traditional medicine; the decreased role of plants in discovery; the increasing role of micro-organisms in discovery; and the fact that new research approaches do not easily integrate the type of information available through traditional knowledge (sCBD, 2008; Laird and Wynberg, 2012).

In the seed and plant biotechnology sector, companies prefer to avoid collecting traditional/farmer knowledge as far as possible because of legal and ethical implications. Most prefer to pass the responsibility of resolving these difficult benefit-sharing issues on to the gene banks, governments or intermediary institutions with whom they work (Laird and Wynberg, 2012).

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

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

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

10.5 Sourcing of genetic resources (genes or naturally occurring biochemicals)

Relevance of bioprospecting

Bioprospecting involves searching for, collecting, and deriving genetic material from samples of biodiversity (plants, animals, microorganisms) for scientific research or commercial development. As Figure 10.1 shows, EU users engage either in direct or indirect bioprospecting. The reliance on 'wild' genetic resources and hence the relevance of bioprospecting varies across sectors (see also section 10.2).

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

For culture collections, *in situ* collection of microbial samples is also fundamental due to the fact that more than 99% of existing microbial genetic resources are still unknown.¹⁵² 45% of genetic resources deposited every year come from the direct bioprospecting efforts of the collection itself (Stromberg *et al.*, 2006). As micro-organisms easily develop novel properties in response to different environmental stresses, collection from industrial regions may often be as important as collection from gene-rich countries (Fritze, 2010).

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

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

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

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

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

¹⁵² <http://www.mirri.org/background.html>

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

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

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

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

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

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

In the seed sector, conventional breeders usually source their material (mostly modern varieties) from private collections (i.e. breeding collections of private companies) and from other breeding companies (i.e. from their varieties available on the market in which case the breeder’s exemption applies). Genebanks – such as national public genebanks and the

centres of the Consultative Group on International Agricultural Research (CGIAR) – are also sources, but these are mainly used by universities, small companies and national agricultural research systems in developing countries (Fowler *et al*, 2001; sCBD, 2008). Most green biotechnology companies mainly source their material from their own collections, followed by national genebanks, ‘in trust’ collections maintained by CGIAR centres, and university collections (ten Kate & Laird, 1999). They only rarely source from botanic gardens. Many green biotech companies leverage investment in smaller companies and track exploratory work done in universities and small companies. Green biotech companies might enter into an in-licensing agreement with universities or small companies. Conventional breeding companies and green biotech companies source from both within and outside the EU. Green biotech companies source the majority of genetic resources from outside the EU (Croplife, pers. comm., 2012).

It is difficult to get a clear picture of the exact significance of *ex situ* collections for pharmaceutical companies. The value creation chain in the sector is complex and continuously reshaped: many different steps need to be taken and many intermediaries are involved. A pharmaceutical company might outsource several activities or buy and/or sell certain intermediate products (IMAP, 2012). The following information might give some indication as to where companies source their genetic R&D material and the role of *ex situ* collections within the sector. Aside from direct bioprospecting, pharmaceutical companies that intend to develop drugs on the basis of natural products may source the required genetic resources from: academic and government research institutes engaged in natural products research; the collections of smaller discovery/biotech companies (such as Pharmamar); culture collections (see above); or private suppliers of chemical compounds whose libraries/collections may include natural products or their derivatives and from in-house collections. As pharmaceutical companies are global players they source from both EU and non-EU *ex situ* collections.

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

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

Next to bioprospecting, the industrial biotechnology sector relies heavily on culture collections to obtain genetic resources. Most of the cultures held in these collections predate the CBD (CABI, pers. comm., 2011). Samples are also obtained by companies and organisations from intermediaries including universities or from external collectors based in the country that provides the resources. Companies also maintain their own collections of genetic resources and their derivatives. For some of these, building and improving their collections is their primary activity, in order to license these to other users for research and product development (i.e. culture collections). For others, their collections form the basis for in-house product development (ten Kate & Laird, 1999).

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

EU *ex situ* collections are not only relevant with regard to the provision of genetic resources to downstream users, but also for supplying genetic resources to other *ex situ* collections around the world. For example, it was estimated in 2003 that 58% of the plant material entering botanic gardens in the EU every year comes from other gardens through international exchange networks (Krebs *et al*, 2003). These benefit all members as they have the primary aim of keeping the collections around the world alive (Van den Wollenberg *et al*, pers. comm., 2012). The number of non-commercial transactions in plant material between botanic gardens in the EU is estimated to fluctuate around two million per year (Van den Wollenberg *et al*, pers. comm., 2012; see also Krebs *et al*, 2003). Transactions with botanic gardens outside the EU are considerably lower but on the increase, with limitations imposed by legal uncertainties and low scientific standards in some collections and countries (Van den Wollenberg *et al*, pers. comm., 2012). For culture collections the proportion of material coming from other service collections is lower (20%); a further estimated 30% however is actively deposited from research collections and individual scientists to maintain a safe backup copy of important reference material (Stromberg *et al*, 2006).¹⁵³ The majority of the latter transactions are carried out nationally. However, a substantial number of depositors from India, the Philippines, China, Brazil, Columbia and Uruguay directly deposit strains from their countries in OECD collections, including EU collections (FAO, 2009).

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

10.6 Existing approaches to ABS in each sector

¹⁵³The number of deposits in 119 WFCC culture collections in 2005 was approximately 10,000 overall.

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

As regards sectors primarily operating upstream, since the CBD, botanic gardens and culture collections have taken substantial steps towards the establishment of codes of conduct for bioprospecting and the formalization of transactions through the use of formal networks and MTAs to ensure compliance of users with local PIC and MAT requirements and ensure a climate of confidence in provider countries with regard to their practices. However, smaller gardens and collections lacking the necessary financial and human resources still engage in a high number of informal transactions (i.e. transactions of genetic material that are not subject to any written contract or agreement) (van den Wollenberg *et al*, pers. comm., 2012; FAO, 2009; Stromberg *et al*, 2006). In 2005 it was found that only 13% of culture collections had a written policy for complying with the CBD and only 40% of the strains received were estimated to be accompanied by a formal MTA (Stromberg *et al*, 2006). With regard to botanic gardens, around 10 years since the development of the IPEN network only 130 out of 550 gardens in the EU are taking part in its code of conduct and formalised transactions.¹⁵⁴ The aim of this network is to facilitate the exchange of living plant material between members while respecting the ABS requirements of the CBD.

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

With regard to the state of documentation systems in *ex situ* collections, in 2009 it was estimated that around 90% of all living plant collections of botanic gardens around the

¹⁵⁴<http://www.bgci.org/resources/ipen/>

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

The approach to ABS of universities and research institutes in the EU is generally characterised by informal transactions and relationships based on mutual trust, except when collaborating with other entities with well-established ABS practices (e.g. botanic gardens, culture collections, pharmaceutical firms, etc.) (Desmeth, pers. comm., 2012). Microbial research collections, for example, are estimated to contain a much higher quantity of microbial strains than culture collections, which is nevertheless often not thoroughly documented and exchanged with other research institutes on an informal basis (FAO, 2009).¹⁵⁵ That said, sector specific voluntary instruments have recently been developed, including the “Guidelines on the Access to Genetic Resources and their Transfer” (2011) developed by CIRAD, INRAD and IRND (three major French public research institutes engaging with genetic resources) and the “Agreement on ABS for Non-Commercial Research” (2012), a standard contract developed by the Swiss Academy of Sciences to guide researchers in the negotiation of MAT.

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

In the pharmaceutical industry, the level of awareness and compliance with ABS requirements is high only for large pharmaceutical and pharmaceutical biotechnology companies that still substantially engage in natural products research (e.g. Novartis, Merck & Co.) (EFPIA *et al*, pers. comm., 2012). For pharmaceutical companies in general, while the IFPMA (the International Federation for Pharmaceutical Manufacturers and Associations) has developed “Guidelines on Access to Genetic resources and Equitable Sharing of Benefits Arising out of their Utilisation”, these are purely voluntary and were mostly conceived to respond to external political pressures rather than a reflection of common practice. The exercise of due diligence when sourcing genetic resources from intermediaries, for example, is not covered by the guidelines and is outside the practice of most pharmaceutical companies. Exercising due diligence over the origin of genetic resources sourced from intermediaries is considered impractical by most pharmaceutical companies due to the complexity of the utilisation chain (EFPIA *et al*, pers. comm., 2012). The “Guidelines for Bioprospecting for BIO Members” are relevant for pharmaceutical biotechnology companies. Those guidelines are more far reaching than the ones developed by the IFPMA,

¹⁵⁵ <http://www.mirri.org/background.html>

establishing best practices for documentation and prohibiting the acquisition of genetic resources from intermediaries when unable to provide evidence on PIC and MAT. Regarding the general state of documentation systems in chemical libraries of pharmaceutical companies, apart from the specialised internal collections of companies systematically engaging in natural product research, it is estimated that the origin of collected compounds is often not documented (EFPIA *et al*, pers. comm., 2012).

In the seed industry, while many exchanges between breeders take place informally because of the breeder's exemption under the CPVR and UPOV plant variety protection systems, there is a general trend towards formalization of transactions (MTAs) in transfers from genebanks and other *ex situ* collections (Scholen *et al*, 2011). As far as PGRFA listed under Annex I of the IT-PGRFA are concerned, sourcing and transfers within the seed industry are carried out under the sMTA established under the multilateral system, covering around 440,000 transfers of genetic material per year (IT-PGRFA, 2012). The same sMTA is also used by several genebanks for transfers of plant genetic resources falling outside the scope of Annex I. SMTAs are used *inter alia* because standard contracts keep transaction costs low compared to *ad hoc* bilateral agreements (Scholen *et al*, 2011).

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

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

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

The horticulture sector, on the other hand, is considered to have low levels of awareness concerning ABS requirements. This may be partially due to the sector's low overall reliance

on wild genetic resources (Laird and Wynberg, 2012). As a result, no specific sectoral code of conduct with regard to ABS has yet been developed, although there is ample evidence of ABS agreements being concluded in provider countries in partnerships with botanic gardens and local organisations.

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

10.7 Conclusion

The above discussions of the “EU Baseline” underline that:

- Genetic resources and issues relating to ABS affect many activities and sectors of the EU economy - from botanic gardens, culture collections and research collections, to biocontrol, seed banks, agriculture/green biotech, to pharmaceuticals and industrial biotech, to cosmetics, horticulture, and the food and beverage sector (see also sectoral sheets in Annex 3).
- There are common issues facing this wide range of sectors. These include: compliance with legislation in countries of origin related to the access to genetic resources and/or traditional knowledge associated with genetic resources; the difficulty of tracing the country of origin of genetic resources and conditions attached to their utilisation when resources are accessed through intermediaries; the issue of development costs and related issues of benefit sharing and good governance.
- There is a diversity both across and within sectors (e.g. across large and small players and across subsectors) of the role and importance of genetic resources and traditional knowledge, used both for commercial and non-commercial activities.
- It is possible to differentiate between upstream players/activities (botanical gardens, cultural collections and research collections & private collectors) and downstream sectors/players (biocontrol, seed banks, agriculture/green biotech, pharmaceuticals and industrial biotech, cosmetics, horticulture, and the food and beverage sector) as they face many common challenges as regards the Protocol and have some common or at least inter-related activities.
- Some sectors have undertaken activities related to ABS issues of the Protocol – these are generally voluntary sector measures (e.g. codes of conduct and some *ad hoc* ABS agreements) in response to growing PIC/MAT requirements by providers in third countries.

- There is a significant gap between current practice and the requirements of the Protocol. As will be demonstrated in the following chapter, there is a need for a range of EU wide solutions related to both provider measures and user compliance measures to enable the EU and MS to most effectively fulfil their commitments under the Protocol.

11 IMPACT ASSESSMENT

The chapter presents the results of the impact assessment of the legal options presented in chapter 9. It should be noted that the impact assessment analyses the impacts of the main legal options presented in chapter 9 and explores the broad impacts across a range of criteria (see section 11.1). While a range of sub-options for legal measures were presented in chapter 9 to help illustrate the legal options, the impact assessment focuses on the main options rather exploring details of impacts of each of sub-options and/or specific measures listed in Chapter 9.

Section 11.1 presents the **assessment criteria** used in the analysis.

Section 11.2 focuses on the impact assessment of the range of **provider measures options**

Section 11.3 focuses on the assessment of the **user compliance options**; and

Section 11.4 presents the **overall synthesis** of the assessment.

11.1 Assessment criteria used in the analysis

The assessment of the options for both the *Provider Measures* and for *User compliance measures* was carried out using a range of criteria within the following criteria categories:

- Addressing the ABS objectives;
- Legal conformity, certainty, coherence with other legislation and enforceability;
- Sector compatibility with existing practices;
- Sector costs / impacts;
- Specific issues: SMEs;
- Public Costs;
- Governance;
- Health, Environment & Biodiversity.

The assessment is a mix of qualitative and quantitative. Note that for some areas (e.g. environment, which was outside the ToR) the assessment is purely qualitative. The assessments in the table make use of qualitative summary indicators:

↗↗↗	Very positive
↗↗	Positive
↗	Somewhat positive
→	Neutral. In some cases there are a mix of ↗ and ↘ and the colour coding is used also in these instances
↘	Somewhat negative
↘↘	Negative
↘↘↘	Very negative

The full list of criteria is presented below.

Addressing the ABS objectives

- **Implementing the objectives behind the Nagoya Protocol:** e.g. Ensuring access to resources – for EU sectors to GR in third countries mainly (mainly related to user compliance measures) and for general access to EU genetic resources (mainly related to provider measures) and **benefit sharing** (e.g. via encouraging compliance with the MAT; this is where the opportunity to agree sharing of benefits can be articulated)

Legal certainty, coherence with other international obligations and enforceability

- **Legal certainty** – for example for downstream users looking to use material from intermediaries (such as botanic gardens or culture collections) or fully upstream sources (e.g. in situ) to be sure that they have due PIC/MAT and hence that they in compliance with NP rules. In other words there is a lesser risk of non-compliance with the NP and potential repercussions (e.g. fines, delays in authorisations, etc...). Legal certainty may also relate to the complexity of legal requirements across the EU. For example, fragmentation of legal requirements may increase complexity and result in confusion as to which legislative framework applies to which circumstance/GR exchanged.
- **Coherence with other international obligations** – does the option affect any existing international standards, treaties or areas where international negotiations are taking place? This can cover MEAs to indigenous peoples rights as regards traditional knowledge as well as WTO and IPR (see also earlier chapters).
- **Enforceability** – the suitability of the option in terms of the ability of the competent authorities to use legal and administrative means at their disposal to encourage or compel individual addressees to comply with their obligations under the option. This may include considerations on whether sanctions and enforcement measures are sufficiently stringent to achieve compliance, the likelihood of detection of a violation, the extent compliance is or may be encouraged by non-coercive means e.g. for user compliance– to what extent a certain monitoring solution is likely to spot non-compliance with prohibition to utilise GR in absence of PIC/MAT;

Compatibility of proposed options with existing sectoral practices — how easy or difficult a transition would be implied by the NP options in light of existing sectoral practices. In other words, if the actors in the sector and associated public authorities could build on existing processes, then this would suggest a fair compatibility. If new and potentially complex processes are needed then the likelihood of a lesser level of compatibility increases. In other words, compatibility is the feasibility for the individual addressees of the option to easily comply with their obligations as defined.

Sector costs / impacts — Sector costs includes organisation costs (e.g. setting up an information systems), management costs (management system and management time including negotiation of PIC/MAT), and administrative costs (paper work, authorisation/permits, potentially fees for CoCs) each of which contribute to transaction costs, as well as potential losses due to fines, delays and market access refusal. As regards impacts, this includes impact on general competitiveness productivity of EU sectors,

potential relocation, barriers to the internal market, impact on innovation and research. E.g. In long term, under an international system on ABS that is functional, an EU compliance with NP (spirit and law) would likely facilitate EU access and competitiveness.

Specific issues: SMEs – whether certain SMEs will be particularly disadvantaged by the proposed option compared to large companies.

Public costs

- **Recurring Costs: EU-level** - regular cost of paperwork, management et al.
- **One-off costs: EU-level** - setting up digital systems to record information, setting up new institutions/oversight bodies, etc.
- **Recurring costs: MS-level**
- **One-off costs: MS-level**

Governance

- **Practicability** – the suitability of the option for the purpose of its practical application by competent authorities at EU level or in the Member States, taking account of the infrastructure and resources needed in order to implement the option.
- **International political acceptability** - (multilateral negotiations and political acceptability). The NP was a much delayed international agreement given difference of interests. There is significant potential to create positive political capital by due commitment to NP or lose political capital by a poor commitment or perceived weak prospects of implementation. This political capital is important for a wider set of international negotiations.
- **Acceptability** – Member States e.g. subsidiarity, different impacts on different MS; providers and users e.g. to what extent the option respects the different needs and practices of different sectors, proportionality of measures under the option for different groups of users. Comment on extra EU users can be included where relevant.
- **Consistency** – For provider measures: to what extent the option ensures a consistent and coherent approach to access and benefit sharing across the internal market.
- **Transparency & understandability** – transparency of the system to the providers (*in situ*), to the users, to the regulator, and parties to the NP. The Understandability criterion is important as if, for example, a Member of Parliament or key members of his/her constituency cannot understand how the measure will work in practice then there may be resistance to the measure in the parliament. Similarly if a user cannot understand the measure easily then this creates opportunities for bad implementation.

Health, Environment & Biodiversity

- **Health** – qualitative only as not a specific objective of the work. Useful to distinguish short, medium and long term. Impacts relate e.g. to the question of whether a certain option facilitates access to GR and related research and/or product development that may result in health benefits in due course.

- **Environment & Biodiversity** - e.g. dynamic good governance ABS system could lead to increased appreciation of the “value” of biodiversity and hence protect the natural capital over time.

11.2 Assessment of the Provider Measures

11.2.1 Provider Measures: Introduction

This section presents the impact analysis of the provider measures options that were presented in detail in Chapter 9. To reiterate, three main options are assessed and compared against the current situation / business as usual scenarios. These options are:

- Option A: No or Minimal EU Action (diverse approaches by different Member States)
- Option B: EU use of the Open Method of Coordination (OMC) to complement MS actions
- Option C: EU Minimum Legal Standards

The options are outlined below, followed by an option by option analysis (sections 11.2.2 to 11.2.4), with each subsection presenting a summary table of the assessment against the impact assessment criteria (as outlined in section 11.1) and associated discussion as to the results. Section 11.2.5 presents a synthesis of the results of the impact analysis of the three options.

Business as Usual

In the EU a few countries (e.g. France, Spain, Bulgaria) have adopted framework legislation envisaging to require PIC/MAT but implementing measures have not yet been taken. The legal status on GR from those member states is therefore still unclear. Other countries (e.g. Netherlands) have opted for a “free access” policy. MS that have opted for the “free access” option, would in principle still have to take measures to ensure that established rights of ILCs over GR/TKaGR (see e.g. Art 6(2)) are respected.

Option A: No or Minimal EU Action

In Option A, the EU does nothing or, at most, takes very soft measures such as on awareness-raising or the provision of information, leaving MS the freedom if they want to adopt a PIC requirement or not. Under the NP, parties can generally decide whether or not to require PIC, and most other provider side obligations under the Protocol only become relevant once the decision on PIC has been taken. Under Option A the assumption is that MS deciding to require PIC and MAT for access to their genetic resources will individually comply with the NP core obligations particularly under 6(3), 6(2) and Art 8(a), by taking the implementing measures that are best in line with their national access policy. MS opting for a “free access” policy (no requirements for PIC/MAT), on the other hand, will only take measures under Art 8(a) and Art 6(2) as far as ILCs are involved.

Option B: EU OMC

Under this option, the EU uses (in collaboration with MS) the Open Method of Coordination (OMC) to encourage harmonisation of provider measures among MS. Thus, MS deciding to require PIC and MAT would agree, e.g. on objectives, definitions and procedures and the

activities and progress in each MS would be monitored, reported and discussed, benefitting from peer review. This would encourage accelerated “mutual learning”. While it is doubtful whether the EU competence extends to TKaGR, some OMC action could still be pursued as the OMC may also deal with areas outside of EU competence. In line with Art 8(a), the EU will promote best practices and guidelines to encourage MS to facilitate non-commercial research on GR.

Option C: EU Minimum Legal Standards

MS Requiring PIC and MAT: In this option, the EU sets minimum standards for those MS that chose to opt for requiring PIC and MAT for access to their genetic resources in order to achieve a harmonised access system throughout the EU, which complies with the requirements in Art 6(3) NP. Under this option, procedures and certificates of compliance issued by CNAs from the different MS are standardised; the scope of the access legislation would likely also be harmonised across the EU Member States. EU minimum standards would also include provisions aimed at facilitating access to GR for non-commercial research under Art 8(a).

MS not requiring PIC and MAT: While respecting the MS choice to provide free access to GR to prospective users without PIC/MAT, the EU in this option imposes an administrative requirement on the MS to issue, upon request from users, a certificate of compliance for genetic resources under their sovereignty that have been accessed by prospective users.

11.2.2 Provider Measures: “Option A” No or Minimal EU Action

Table 11.1: Synthesis: overview of impacts associated with implementation of option A

IA Criteria	Business as Usual Scenario	Option A: No or Minimal EU Action, Max Member State Action
Addressing the ABS objective		
Addressing the ABS objectives	Legal status of GR originating from MS remains unclear. Framework legislation has been drafted in certain MS (Spain, France, Bulgaria) but not yet implemented, thus no access and benefit sharing procedures yet put in place in any MS.	EU: ↘↘
		MS: → to ↗↗↗ (no negative arrows as the assumption is that all MS comply)
Ensuring access to resources (in the EU)	Despite the unclear legal situation, stakeholders did not report any particular problems regarding access to <i>in situ</i> GR from EU MS (as access is currently unregulated).	Access to the EU as a block: ↘↘
		<i>In situ</i> access in MS requiring PIC: ↗ to ↘ depending on stringency and complexity of procedures implemented by MS requiring PIC and MAT and scope of access legislation
		Access in MS with free access policy: →
		Access to <i>ex situ</i> collections: → to ↘↘ depending on the scope of access legislation, future ABS practise of <i>ex situ</i> collections and approach to PIC and MAT.
Ensuring benefit-sharing	No benefit-sharing provisions currently in place	MS: ↗ to ↗↗ (expected to be substantial only in long term)
Legal conformity, certainty, coherence with other legislation and enforceability		
Legal certainty – for users	Lack of ABS legislation across EU MS. Status of GR acquired by <i>ex situ</i> collections post-CBD from the EU is unclear.	For users across EU: ↘↘
		Within individual MS: ↗ to ↗↗↗
		For MS not requiring PIC and MAT: →
Coherence with other international obligations	Because no operational PIC legislation in place there is no interference with the ITPGRFA. MS inaction potentially incompatible with internationally recognized indigenous peoples’ rights as far as GR held by ILCs and TKaGR are concerned, e.g. Art 26, 31 and 32 UN Declaration on the Rights of Indigenous People, ILO Convention 169, Art 6 and 15.	ITPGRFA →
		Indigenous peoples’ rights →
Enforceability	No enforcement of access rules so far in MS that have expressed an interest in regulating access.	EU: ↘ to ↗ (largely depends on future EU user compliance regime)
		MS: ↗↗ for those adopting access measures
Costs: Public		
Recurring costs: EU-level	No costs – no action taken.	EU: → (marginal costs)
Costs (one-off): EU-level	No costs – no action taken.	EU: → (marginal costs)
Recurring costs : MS	Variable, depending on efforts being currently undertaken by different MS.	MS with PIC/MAT: ↘ to ↘↘↘
		MS with free access: →

level		
Costs (one-off): MS-level	Variable, depending on efforts being currently undertaken by different MS.	MS with PIC/MAT: ↘ to ↘↘↘ depending on implementation measures
		MS with free access: →
Costs: Sectors		
Expected costs for sectors	No particular costs incurred (not quantifiable).	Generally: ↘ to ↘↘
		e.g. <i>Ex situ</i> collections and academic research: ↘ to ↘↘
		Commercial sectors relying on <i>ex situ</i> collections e.g. industrial and green biotech, seed industry, horticulture → to ↘
SMEs	No particular costs incurred (not quantifiable).	Generally: ↘↘
		Specifically: Biocontrol ↘↘ to ↘↘↘
Governance		
Practicability	Issue does not arise as no operational access legislation is in place.	EU: ↗ to ↗↗
Acceptability (MS/Sectors)	Issue does not arise as no operational access legislation in place, therefore not acceptable from legal point of view in case of ratification by EU or MS. Acceptable for EU sectors as they are currently not strongly affected as no implementation is in place.	MS: ↗↗
		Sectors: ↘↘
Consistency	No consistent approach across EU MS.	↘↘
Transparency & Understandability	Status of GR already acquired by users after the entry into force of the CBD and <i>ex situ</i> within EU very unclear.	↘ to ↗
International Political Acceptability		
International acceptability and impacts	Currently, lack of operational provider measures in place. Internationally however countries more interested in EU taking strong user compliance measures.	→
Health, Environment and Biodiversity		
Health	Currently no interference with WHO GISRS health emergency regime. No interference with pharma R&D.	→ Unforeseeable
Environment & Biodiversity	No BS incentive for conservation currently at MS level.	→ Unforeseeable

Option's overall ability to address the ABS challenge

Addressing the ABS objective

As to addressing the general objectives of the Protocol relating to access (facilitating access, legal certainty for users and protection of ILCs' rights while providing an incentive for the conservation of biodiversity through benefit sharing), the implementation of access procedures consistent with Art 6(3) is expected to have some positive impacts particularly when applied in biodiversity-rich territories of the EU, where GR are being regularly sourced. This is the case for France (10 % of world's coral reefs are situated in French territorial waters)¹⁵⁶ and particularly its Overseas Territories, where the valorisation of traditional pharmacopeia and marine biodiversity is one of the pillars for locally-driven economic development, some Mediterranean countries such as Spain, where 54% of all known species in Europe can be found and 2000 species are still used traditionally for food and medicinal purposes, and other biodiversity-rich MS such as Bulgaria, with endemic species representing approximately 5% of vascular plants and 8.8% of vertebrates (see EU Country Reports, Annex 1).

The result is different when looking at the EU in its entirety. In fact, without a harmonised approach to access procedures at EU level, access to GR for users sourcing across different MS will likely be a highly burdensome and complex exercise because of the different procedural requirements and institutional arrangements that are expected to be developed in different MS. From this perspective, therefore, the overall result is that at EU level Option A will not effectively achieve the abovementioned objectives (see sections below).

Ensuring access to resources in the EU

In light of the intention of certain MS (Spain, France, Bulgaria...) to start regulating access to their GR (through PIC requirements and MAT), the result in those MS will be a likely restriction of access to *in situ* GR compared to the baseline scenario (i.e. unregulated access). If those procedures will not impose a high administrative burden on the prospective user, however, the enhanced legal certainty created by the delivery of clear documentation attached to GR sourced *in situ* in those countries may partly compensate the disincentives provided by the restriction on access.

The impacts of access legislation on access to GR held in *ex situ* collections based in those MS are highly variable under Option A as they will largely depend on the scope of the new access legislation and the approach different MS will take with regard to PIC and MAT requirements for GR held *ex situ*.

As no MS had applicable access legislation in place until now, MS would not be allowed to retrospectively impose PIC requirements for *ex situ* collections in relation to GR that have been freely accessed by collections. However they could in principle provide that MAT would have to be established for future utilisations of GR that have been originally sourced post-CBD and are now in *ex situ* collections.

¹⁵⁶ http://www.developpement-durable.gouv.fr/spip.php?page=article&id_article=19989 (2010)

It is worth noting that with regard to culture collections, for example, in 2009 it was estimated that around 50% of GR in the collections worldwide were collected after the entry into force of the CBD. Concerning botanic gardens, in 2001 it was estimated that 10% of plant GR in their collections were collected after the CBD entered into force (the proportion is now expected to have increased). The fact that in 2009 it was found that 42% of European threatened taxa are accessible *ex situ* within their region of origin generally suggests an important role of *ex situ* collections in the collection of MS GR (see EU Baseline, chapter 10). Moreover, the overall annual number of transfers of GR from EU *ex situ* collections to other collections or non-commercial users is estimated to be in the scale of millions for botanic gardens and tens of thousands for culture collections (see EU Baseline, chapter 10).

As a result, if a requirement to conclude MAT and engage in benefit-sharing was to be imposed in relation to every future utilisation of all post-CBD GR originating from a MS and stored in EU collections, access to *ex situ* collections by other non-commercial users could potentially be delayed and even disrupted in relation to a substantial number of GR; in this case, prospective users would have to negotiate new MAT with the competent authorities for thousands of transfers from *ex situ* collections. At present, transfers from an *ex situ* collection to other collections or non-commercial users, in fact, often work on the basis that once PIC and MAT (for non-commercial use) have been established between the country of origin of a certain GR and an *ex situ* collection, all subsequent transfers for non-commercial purposes will be done through standard MTAs and new negotiations with the country of origin will not be needed unless there is a change of use (e.g. IPEN Code of Conduct, MOSAICC, ECCO Core MTA). This negative impact on access would be mitigated considerably in case the establishment of MAT was to be required only for transfers relating to new *commercial* uses of those GR, as this would broadly be consistent with the existing practice of culture collections and botanic gardens, requiring new commercial users to look for a new PIC and MAT from the country of origin of the GR they wish to access.

The streamlining of PIC procedures for prospective non-commercial users, i.e. by recognising as PIC the transfer of a GR from an *ex situ* collection that fulfils certain standards of documentation and management, together with the creation of standardised MAT agreements for non-commercial research that could be negotiated directly with the collection would also mitigate to a large extent the abovementioned risks of heavy burdens on existing networks for exchange of GR for non-commercial purposes. In light of the fact that a number of *ex situ* collections (e.g. botanic gardens with limited financial and human resources) have not consistently documented the country of origin and date of access of genetic resources acquired until now (see EU Baseline, chapter 10), however, access to GR held by those actors would be likely restricted.

In case the temporal scope of PIC and MAT requirements was to be restricted to post-NP GR, no significant impact is expected on access to *ex situ* collections, except from the fact that newly collected genetic material from a certain MS held in *ex situ* collections would be subject to MAT and benefit sharing obligations.

With regard MS opting for a “free access” policy, access to GR held by those MS is expected to be unchanged.

In sum, while access to GR from some MS will remain unchanged, for others it may improve or decrease depending on the procedural measures adopted and the scope of access legislation. However, when looking at EU-wide sourcing of GR across MS, the overall result is that Option A will likely fail to improve access to GR. The presence of different legal standards, institutional set-ups and procedural requirements in different MS, in fact, will likely make sourcing of GR in the EU much less attractive for users that source GR from different MS (e.g. the biocontrol sector).

Ensuring benefit sharing

Benefit sharing related to the utilisation of GR will obviously increase in the long term as at present no benefits are shared with any EU MS as no legislation to that effect is in force. The types of benefits related to certain utilisations of GR will likely vary depending on the GR and the provider state. The capacity of national authorities or ILCs to ensure that benefits agreed upon under MAT will be shared will also depend on the terms established under MAT (e.g. reporting requirements, upfront vs. royalty payments) as well as on the approach taken by the EU in relation to user compliance measures.

Legal certainty, coherence with other international obligations and enforceability

Legal certainty for users

Legal certainty for users is expected to improve in individual MS. In fact, the legal status of GR originating from MS is at the moment undefined. The introduction of access legislation would improve legal certainty, particularly in light of eventual documentation requirements related to GR under future user compliance measures that MS/EU are expected to implement under the Protocol (see User Compliance Measures, Ch. 9). Moreover, if measures adopted comply with the NP core obligations (i.e. Art 6(3)), the procedures will be fair and transparent in all MS.

In MS opting for “free access” the situation will likely remain unchanged - as long as ILCs are not present in their jurisdiction - as they will not be required to take any measure under Art 6(3).

From the perspective of the EU as a block nevertheless, Option A will undoubtedly have negative implications in terms of legal certainty for users across the internal market. In fact, Option A will likely result in the fragmentation of procedural requirements and standards across EU MS. As a result, users will have to comply with different procedures in every MS they source from. Additional costs and delays linked to the need to comply with different procedural and documentation requirements, different scope of the access legislation and different institutional set-ups are expected under Option A.

EU *ex situ* collections could also theoretically face legal uncertainties related to the potentially different legal status of different GR held in their collections that have been collected across the EU after the coming into force of the CBD. While some MS could be claiming the establishment of new MAT for all future uses of GR under their sovereignty held in EU *ex situ* collections, others would just apply new access requirements to new commercial uses of such GR or merely to the collection of GR post-NP. Given the less than

perfect status of documentation systems of many *ex situ* collections (see EU Baseline, chapter 10) complemented by the fact that access to *in situ* GR in the EU has always been unrestricted, it can be expected that the lack of agreement on the scope of GR to be subject to PIC and/or MAT will increase complexity and have negative repercussions on the existing high number of transfers and exchange networks between *ex situ* collections and from *ex situ* collections to other non-commercial users (see section on access above).

The fact that MS providing “free access” have no obligation to document GR accessed could also lead to further uncertainties for users under an eventual EU-wide user-compliance system requiring users to have documentation on GR.

While it could be argued in theory that EU inaction may push certain MS to simplify access standards in the medium and long term – i.e. MS simplifying access procedures in order to attract more users – this would not necessarily resolve the problem of legal uncertainty linked to fragmented access procedures and the related transaction costs. The negative impacts on legal certainty of Option A may be only partially mitigated by the EU taking the role of providing information to users about the different requirements in each MS.

Coherence with other international obligations

As to the EU and MS compliance with the ITPGRFA, Option A is unlikely to have any impact on the baseline scenario. In fact Art 4(4) NP *de facto* excludes GR covered by the ITPGRFA from the application of the NP. As the EU and all the EU MS are parties to the ITPGRFA it can be assumed that it will be highly unlikely that MS measures will directly interfere with the functioning of the multilateral system.

EU inaction combined with MS restrictive interpretation of the expressions “established rights” and “in accordance with domestic legislation” in Art 6(2) and 5(2) NP may however result in measures inconsistent with international indigenous peoples’ rights recognised under, *inter alia*, the UN Declaration on the Rights of Indigenous People (Art 26 on rights over their resources, Art 31 on rights over TK and Art 32 on free and informed consent), the ILO Convention No.169 (Art 6 on consultation rights and Art 15 on rights over their natural resources) and other international and regional conventions. Under Art 26 UNDRIP, for example, states have a clear international obligation to give legal recognition in their domestic law to the lands, territories and resources that have been traditionally owned by indigenous people and under Art 31 have a duty to recognise and protect the exercise of their internationally recognised rights over TK and GR. It is to be noted, however, that very few groups residing within the EU jurisdiction qualify as “indigenous peoples”.

Enforceability

Enforceability of PIC and MAT requirements by MS authorities will obviously improve compared to the baseline scenario for countries opting for regulating access. Under Option A however the EU would not take any additional measure to directly facilitate MS enforcement of its access measures. Enforceability however will also be contingent on the user compliance system that will be adopted by the EU, which would likely cover also GR sourced from within the EU.

Public Costs

Recurring Costs - EU level

Recurring costs at EU level will be minor under Option A and will only relate to the management of an EU focal point with the role and capacity of disseminating information to prospective users on MS access procedures. This would most probably be in the form of a web portal simply providing links to national focal points and explanations of the main procedural requirements and scope of access legislation in the different MS.

One-off costs - EU level

One-off costs at EU level will relate to minor costs linked to awareness raising activities, production and promotion of guidelines or model MAT as well as the minor costs of setting up the EU focal point.

Recurring Costs - MS level

Recurring costs for MS requiring PIC and MAT will be highly variable depending on implementation measures being taken and institutional arrangements.

MS not requiring PIC and MAT will not incur any substantial costs under this Option.

One-off costs - MS level

One-off costs for MS requiring PIC and MAT will be highly variable depending on implementation measures being taken and institutional arrangements.

MS not requiring PIC and MAT will not incur any substantial costs under this Option.

Sector Costs

Expected costs for sectors

Expected costs for sectors when sourcing GR in the country in which they are based (this is for example the case for certain culture collections or botanic gardens) are highly variable. This will depend on whether the MS requires PIC and MAT or not, the stringency of PIC procedures, the type of GR accessed and the type of use envisaged (commercial or non-commercial), the substantive and temporal scope of the access legislation (see considerations on access above).

Nevertheless, at EU level increased costs can be expected for sectors sourcing *in situ* from multiple MS, mostly because of the transaction costs linked to the likely fragmentation of access procedures under Option A and the resulting need to comply with different procedural and institutional arrangements. In terms of *in situ* collection of GR, the most negatively affected sectors from the implementation of Option A are expected to be biocontrol companies. In fact an estimated 50% of the insects and mites collected by EU biocontrol companies are sourced *in situ* across different EU MS (see Biocontrol Baseline, Annex 3). EU *ex situ* collections will also be affected to a certain extent as they also sometimes source GR from different EU MS. With regard culture collections, for example, sourcing from industrial regions is often be as important as sourcing from biodiversity-rich developing countries because of the different properties microbial GR develop in relation to different environmental stresses (see EU Baseline, chapter 10). Compared to the biocontrol

sector, the increased transaction costs for *ex situ* collections with regard EU-wide bioprospecting are nevertheless expected to be less significant. As access of those users is mostly for non-commercial purposes, they will be more likely to benefit from facilitated access procedures for non-commercial purposes in different MS compared to biocontrol companies.

Ex situ collections and other non-commercial users of GR (universities, research institutes) would also potentially face an increase in transaction costs both when sourcing from other EU *ex situ* collections and when acting as providers of GR that have been originally sourced (post-CBD) from an EU MS and could require new MAT negotiations for new or continuing uses under future access rules. In light of the high volume of transactions between collections and non-commercial users within the EU and the fact that EU *ex situ* collections hold genetic resources that since the CBD may have been sourced throughout the EU without conditions attached, the lack of harmonisation with regard the temporal scope of access legislation in relation to those GR may result in additional transaction costs. Those costs would be caused by a significant degree of complexity and legal uncertainty related to the different rules and procedures that would have to be complied with for the transfer and/or acquisition of each of those GR (i.e. while those initially sourced in one MS may be freely accessible, the GR originally sourced from another MS post-CBD may be subject to the negotiation of new MAT with the CNA of the MS of origin).

A more limited increase in transaction costs is expected for commercial sectors that regularly source from EU *ex situ* collections, such as the conventional and biotech plant breeding companies, the horticultural industry and the industrial biotechnology sector (relying on culture collections to obtain genetic resources) (see EU Baseline, chapter 10). In fact, as the majority of *ex situ* collections originally sourced *in situ* genetic material for non-commercial purposes, it is already an established practice that prospective commercial users will have to go back to the country of origin to establish new MAT for utilising the same GR. As a result, the lack of harmonisation of the temporal scope of MS access measures would not have any substantial impact on those sectors. Moreover, the extent to which some of those sectors rely on genetic material covered by the NP and originally sourced in EU MS is expected to be limited overall. For green biotechnology companies and, in particular, the plant breeding companies, in fact, a high proportion of GR utilised are PGRFA falling outside the scope of the NP as those GR are covered by the ITPGRFA. As to the other sectors, the reliance on GR originally sourced from EU MS is expected to be limited. The industrial biotechnology industry, for example, primarily uses GR originally found in areas with high species diversity as well as in extreme or unique environments (see EU Baseline, chapter 10).

SMEs

The majority of biocontrol companies are SMEs with between 2 and 10 employees (see EU Baseline, chapter 10). As mentioned in the section above, biocontrol industries based in the EU rely substantially on *in situ* collection of GR in different MS. The fact that the biocontrol industry has very limited profit margins for the provision of its products and services increases the vulnerability of the sector to the expected transaction costs associated with fragmentation of procedural requirements across the EU internal market. Other sectors

where an important number of SMEs are expected to use genetic resources are the industrial and pharmaceutical biotechnology, seed, cosmetics and food & beverage industries (see EU Baseline, chapter 10). Nevertheless, as those sectors mostly source from *ex situ* collections in the EU for commercial purposes (when sourcing *in situ* it would generally be outside the EU) and the majority of those GR sourced by those sectors are not expected to be originally from EU MS and/or outside the substantive scope of the NP (e.g. within the remit of the ITPGRFA for the seed industry), it is unlikely that the adoption of access measures by individual MS will substantially interfere with their sourcing practices (see section on sector costs above).

Governance

Practicability

Option A is practicable for the EU as the responsibility for regulating access to national genetic resources is left to MS together with most of the costs associated with enacting new legislation, granting CoCs, etc.

Acceptability (MS/Sectors)

MS: Some MS with important biodiversity hotspots, including France (with Overseas Territories) and Spain, are keen to adopt PIC and MAT procedures. Others, including the Netherlands, have opted for a “free access” policy (see Country Reports, Annex 1). Option A, fully respecting the principle of subsidiarity, would be consistent with the divergent positions on access of different MS while leaving open the possibility for MS to voluntarily harmonise their access procedures to facilitate access to GR across the EU. As a result, this option is likely to be considered acceptable by most MS as it does not raise any controversy nor does it interfere in any way with the national interests of any MS.

Sectors: All sectors consulted and interviewed argued in favour of harmonisation and opposed the idea of fragmented implementation of ABS legislation because of concerns over higher transaction costs and delays in the transfer of GR. In particular, the seed and green biotechnology industry, the horticulture industry, the academic research sector relating to agriculture, botanic gardens, and culture collections have pleaded for the introduction of a multilateral system akin to the ITPGRFA Multilateral System within the EU. Sectors with SMEs and operators with limited financial or organisational means have expressed concern over the increasing administrative burden in the case of fragmented legislation within the EU (biocontrol, botanic gardens, cosmetics) (EC public consultation, 2011 and EU Baseline, chapter 10). As a result, Option A is unlikely to be considered favourably by the majority of the sectors involved in ABS and transfers of GR across the EU.

Consistency

Given the flexibility of NP provisions as to how they are implemented, the adoption of Option A would result in the least consistent approach in access procedures within the EU, with a high likelihood of a fragmentation in access standards, procedures and institutional arrangements across the EU internal market.

Transparency & Understandability

Transparency will be enhanced in individual MS by the introduction of access procedures compliant with Art 6(3) i.e. procedures will have to comply with general principles of transparency, fairness, provision of information, etc. The EU focal point will increase transparency by sharing information on MS procedures with all prospective users. For the EU as a block, however, the different legal and procedural requirements and institutional set-ups in different MS are expected to make the “EU access system” very complex and difficult to understand for future users sourcing across different MS, which would have to become familiar with different access systems for every MS jurisdiction they source from.

International Political Acceptability

This option complies with the NP; yet the inconsistent access standards and procedures across MS are unlikely to place the EU in a strong position in international *fora*. As the EU is undoubtedly one of the most influential international players among the NP signatories, a harmonised approach in relation to access procedures would likely put the EU in a stronger position to propose its access model to third countries as best practice to be followed.

Health, Environment & Biodiversity

Impacts of Option A on health, environment and biodiversity are highly speculative and will not be considered in this section.

11.2.3 Provider Measures: “Option B” EU OMC

Table 11.2: Synthesis: overview of impacts associated with implementation of option B

IA Criteria	Business as Usual Scenario	Option B: EU OMC
Addressing the ABS objective		
Addressing the ABS objective	Legal status of GR originating from MS remains unclear. Framework legislation has been drafted in certain MS (Spain, France, Bulgaria) but not yet implemented, thus no access and benefit sharing procedures yet put in place in any MS.	EU: → to ↗
		MS: → to ↗↗↗ (no negative arrows as the assumption is that all MS comply)
Ensuring access to resources (in the EU)	Despite the unclear legal situation, stakeholders did not report any particular problems regarding access to <i>in situ</i> GR from EU MS (as access is currently unregulated).	EU: ↘ to ↗
		<i>In situ</i> access in MS requiring PIC: → to ↗ sharing of best practices under OMC likely to generally improve MS access measures
		Access in MS with free access policy: →
		Access to <i>ex situ</i> collections ↘ to ↗ depending on level of harmonisation
Ensuring benefit-sharing	No benefit-sharing provisions currently in place	MS requiring PIC and MAT: ↗ to ↗↗
Legal conformity, certainty, coherence with other legislation and enforceability		
Legal certainty – for users	Lack of ABS legislation across EU MS. Status of GR acquired by <i>ex situ</i> collections post-CBD from the EU is unclear.	For users across the EU: ↘ to ↗
		Within individual MS: ↗ to ↗↗
		In MS not requiring PIC and MAT: →
Coherence with other international obligations	Because no operational PIC legislation in place there is no interference with the ITPGRFA. MS inaction potentially incompatible with internationally recognized indigenous peoples’ rights as far as GR held by ILCs and TKaGR are concerned, e.g. Art 26, 31 and 32 UN Declaration on the Rights of Indigenous People, ILO Convention 169, Art 6 and 15.	ITPGRFA →
		Indigenous peoples’ rights → to ↗
Enforceability	No enforcement of access rules so far in MS that have expressed an interest in regulating access.	EU: ↘ to ↗ (largely depends on future EU user compliance regime)
		MS: ↗↗
Costs: Public		
Recurring Costs: EU-level	No costs – no action taken.	EU: ↘
Costs (one-off): EU-level	No costs – no action taken.	EU: → (marginal costs)
Recurring Costs: MS level	Variable, depending on efforts being currently undertaken by different MS.	MS with PIC/MAT: ↘ to ↘↘↘
		MS with free access: →
Costs (one-off): MS-level	Variable, depending on efforts being currently undertaken by different MS.	MS with PIC/MAT: ↘ to ↘↘↘
		MS with free access: →
Costs: Sectors		
Expected costs for sectors	No particular costs incurred (not quantifiable).	Generally ↘
		e.g. <i>Ex situ</i> collections, academic research,

		other non-commercial users: ↘ to →
SMEs	No particular costs incurred (not quantifiable).	Generally ↘
		Specifically: Biocontrol ↘↘
Governance		
Practicability	Issue does not arise as no operational access legislation is in place.	→ to ↗
Acceptability (EU/MS/Sectors)	Issue does not arise as no operational access legislation in place, therefore not acceptable from legal point of view in case of ratification by EU or MS. Acceptable for EU sectors as they are currently not strongly affected as no implementation is in place.	MS: ↗ to ↗↗
		Sectors: ↘
Consistency	No consistent approach across EU MS.	↗
Transparency & Understandability	Status of GR already acquired by users after the entry into force of the CBD and <i>ex situ</i> within EU very unclear.	→ to ↗
International Political Acceptability		
International political acceptability	Currently, lack of operational provider measures in place. Internationally however countries more interested in EU taking strong user compliance measures.	↗
Health, Environment & Biodiversity		
Health	Currently no interference with WHO GISRS health emergency regime. No interference with pharma R&D.	→ unforeseeable
Environment & Biodiversity	No BS incentive for conservation currently at MS level.	→ to ↗

Option's overall ability to address the ABS challenge

Addressing the ABS objective

As to addressing the objective behind provider measures under the NP (facilitating access procedures, legal certainty for users and protection of ILCs' property rights while providing an incentive for the conservation of biodiversity), on top of the considerations under Option A above (section 11.2.2), the soft harmonisation of access standards and procedures led by the EU through the Open Method of Coordination would have particularly positive impacts on access to the EU as a whole. Harmonisation would in fact enhance the predictability of procedures and legal certainty for users sourcing across EU MS. Thus, while not ensuring full harmonisation across EU MS choosing to require PIC and MAT, the OMC compared to Option A has the potential to lead to a certain level of convergence over time through the identification and adoption of best practices and the standardisation of access procedures for certain users or uses of GR. In sum, it can be concluded that Option B, as opposed to Option A, would partially address the challenge of access measures from a more holistic perspective and lead to a higher degree of consistency across the EU.

Ensuring access to resources in the EU

On top of the considerations on individual MS under Option A above (section 11.2.2), Option B has the potential to improve access both at the level of individual MS and at the level of the EU in its entirety.

With regard MS choosing to require PIC and MAT for access to their GR, access measures in relation to their *in situ* and *ex situ* GR would likely improve to the extent that an OMC would promote the sharing of best practices and a process of mutual learning between MS authorities and EU wide stakeholders.

An EU-led OMC related to access measures is likely to overall facilitate access for users sourcing across the EU. The extent of the benefits of this approach will clearly depend on the extent of convergence of MS access policies and procedures. In fact, because the OMC does not involve an EU legal intervention, the adoption of Option B by the EU is unlikely to ensure full harmonisation of rules and practices across MS. Australia's experience (see Chapter 9 above), for example, showed a take-up of access elements in sub-national legislation by only half of the sub-national entities involved. However, EU Member States have extensive experience of cooperative implementation of EU environmental instruments, with technical support from the Commission. Thus, the picture may be more optimistic in the case of the EU. Convergence however could happen over one or several policy goals and across all or just a group of MS depending on the interests at stake. Arguably, the maximum benefits for access to GR across the EU would happen if biodiversity-rich MS reached some level of convergence for their access legislation under the OMC.

The adoption of similar PIC and/or MAT procedures respectively for access to *in situ* and *ex situ* GR under the sovereignty of different MS would have clear advantages. This would be of utmost importance for users wishing to access GR across the EU as similar procedures

would apply in every MS (e.g. concerning the documents users are to submit), thus significantly reducing uncertainties and transaction costs linked to having to comply with different requirements in different MS.

Secondly, a common approach to PIC and MAT requirements for access to GR for the purpose of non-commercial research would serve the important purpose of avoiding the risk of hampering EU wide research on GR and could also serve as a model for third countries, thus ensuring that GR are easily accessed by EU researchers in third countries (see considerations on international political acceptability below).

Lastly, with regard access to *ex situ* GR in the EU, a common approach to the (temporal/substantive) scope of PIC and/or MAT requirements on the basis of best practices and the standardisation of MAT with regard non-commercial uses of GR sourced from *ex situ* collections would avoid obstructing the currently high number of free transactions between *ex situ* collections across the EU (see considerations under Option A above, section 11.2.2).

With regard MS choosing a “free access” approach to GR, access will likely remain unchanged.

Ensuring benefit sharing

Benefit sharing related to the utilisation of GR will increase in the long term, if MS choose to require BS at the time of access, as at the moment no benefits are shared with any EU MS as no legislation to that effect is in force. The types of benefits related to certain utilisations of GR will likely vary depending on the GR and the provider state. The capacity of national authorities or ILCs to ensure that benefits established under MAT will be shared will also depend on the terms established under MAT (e.g. reporting requirements, upfront vs. royalty payments) as well as on the approach taken by the EU in relation to user compliance measures.

Legal conformity and impacts

Legal certainty for users

Legal certainty for users sourcing across the EU is expected to improve overall through an OMC approach. Nevertheless, as mentioned in the section above, the extent to which legal certainty will exist for users is difficult to predict under this option as it will be highly contingent, *inter alia*, on the level and extent of convergence reached between MS. For users sourcing GR *in situ* in different MS (e.g. the biocontrol sector), the main benefits would come from the harmonisation and streamlining of PIC procedures across the EU, as this would reduce uncertainties and related transaction costs linked to having to comply with different requirements in every MS in which they conduct bioprospecting activities.

Some level of convergence on the scope of GR covered (temporal scope) and facilitated procedures for non-commercial users of GR would clearly mostly be for the benefit of *ex situ* collections (e.g. botanic gardens, culture collections) that engage in high numbers of transactions among themselves and with other non-commercial users across the EU (in the

order of millions for EU botanic gardens and tens of thousands for culture collections). In the case of botanic gardens in particular, a common approach to the status of GR under the sovereignty of MS held *ex situ* (and collected between the entry into force of the CBD and the NP) or GR whose source is unknown, would have the benefit of improving legal certainty concerning existing practices. On the contrary, a fragmented approach to this issue could introduce serious uncertainties in existing practices with the potential of at least temporarily complicating the practices of existing networks (e.g. by forcing prospective users to go around MS to ask for different PIC and MAT or forcing collections to go through their often less than perfectly documented collections to find out which GR may require new PIC from the MS in which they are based or from other MS) (see considerations under Option A above, section 11.2.2).

As regards MS choosing a “free access” approach to GR legal certainty for users will likely remain unchanged in terms of access, although they may face complications when required to prove the origin of such GR under future user compliance rules in case the “free access” MS would fail to set up a system for the provision of certificates proving the origin of the GR freely acquired.

Coherence with other international obligations

As to EU and MS compliance with the ITPGRFA, Option B is also unlikely to have any substantial impacts on the baseline scenario. In fact, Art 4(4) NP excludes GR covered by the ITPGRFA from the application of the NP. As the EU and all the EU MS are parties to the ITPGRFA it can be assumed that it will be highly unlikely that MS measures will directly interfere with the functioning of the latter treaty. Through the OMC the EU could however promote best practices to ensure that access measures will not interfere with the exchange of PGRFA covered by the ITPGRFA.

MS inaction or their restrictive interpretation of Art 6(2) and 5(2) NP may result in measures inconsistent with international indigenous peoples’ rights (see Option A above, section 11.2.2) recognised under, *inter alia*, the UN Declaration on the Rights of Indigenous People (Arts 26, on rights over their resources, Art 31 on rights over TK and Art 32 on free and informed consent) and the ILO Convention No.169 (Art 6 on consultation rights and Art 15 on rights over their natural resources) and other international and regional obligations. It is to be noted, however, that very few groups residing within the EU jurisdiction qualify as “indigenous peoples”. Through the OMC, the EU would provide a platform where MS concerned could agree on a common approach towards involvement of ILCs and access to TKaGR and where the EU could promote best practices in that regard. This would enable, for example, relevant MS to address eventual transboundary situations related to access to GR and TKaGR held by ILCs, as required under Art 11 NP. An OMC approach, while enhancing the awareness of MS authorities and facilitating the exchange of best practice, will however not necessarily ensure the implementation of high standards in relation to indigenous rights.

Enforceability

Enforceability of PIC and MAT requirements by MS authorities will obviously improve compared to the baseline scenario for countries opting for regulating access. Under Option B however the EU would not take any additional measure to directly facilitate MS

enforcement of their access measures. Enforceability of PIC however may be enhanced by EU user compliance measures; the extent to which this is the case depends on the user compliance system adopted by the EU. In fact, ambitious user compliance measures by the EU (options B and C below) would likely cover also GR sourced from within the EU (see Box 9.13, chapter 9).

Public Costs

Recurring Costs - EU level

Recurring costs at EU level will still be limited under Option B. Costs will mostly relate to the management of an EU focal point with the role and capacity of disseminating information to prospective users on MS administrative procedures. This would most probably be in the form of a web portal simply providing links to national focal points and explanations of the main procedural requirements and scope of access legislation in the different MS. In addition, the OMC itself would involve administrative costs including, among others, the organisation of MS, stakeholders and expert meetings and costs associated with the evaluation of MS reports.

Costs (one-off): EU level

One-off costs at EU level will relate to minor costs linked to awareness raising activities, production and promotion of guidelines or model MAT as well as the minor costs of setting up the EU focal point (see above).

Recurring Costs: MS level

Recurring costs for MS requiring PIC and MAT will be highly variable depending on implementation measures being undertaken and institutional arrangements. Additional minor administrative costs can be expected for participating in the OMC process (participation in expert meetings, monitoring and reporting activities).

Costs (one-off): MS level

One-off costs for MS requiring PIC and MAT will be highly variable depending on implementation measures being taken and institutional arrangements.

Sector Costs

Expected costs for sectors

As mentioned in the sections above, the expected costs for sectors sourcing across EU MS are expected overall to be lower under Option B compared to Option A. This is due to a higher degree of consistency among MS access measures, procedures and institutional arrangements. In general terms, the higher the level of convergence, the lower the transaction costs for users sourcing from different MS as they will not be required to comply with different rules and procedures in every MS they source from. Because of the uncertainties on eventual MS measures taken under Option B, it is unlikely that PIC/MAT procedures in all MS will be fully harmonised. Therefore it can still be expected that the biggest costs will be borne by the sectors that are most likely to source *in situ* from different MS, i.e. biocontrol companies (an estimated 50% of the insects and mites collected by biocontrol companies are sourced across EU MS) (see Biocontrol Baseline, Annex 3). Lack of

convergence on PIC and MAT procedures may also – though to a lesser extent – result in some costs for other commercial sectors sourcing from EU *ex situ* collections such as the conventional and biotech plant breeding industry, the horticultural industry and the industrial biotechnology sector (see Option A above for further considerations, section 11.2.2).

On the other hand, with regard *ex situ* collections, academic research institutes and other non-commercial users, it is more likely that under the OMC MS will agree on a certain degree of harmonisation of simplified procedures for non-commercial use of GR. Not only is this specifically encouraged under the NP (Art 8(a)), but particularly simplified access to GR held by *ex situ* collections (as long as the envisaged use is for non-commercial research) for non-commercial purposes is also an already widespread and longstanding established practice (see IPEN Network, ECCO Core MTAs) that MS would have no interest to change. As a result it is expected that costs for the abovementioned sectors will be likely to remain the same under Option B compared to the baseline scenario.

SMEs

The majority of biocontrol industries are SMEs with between 2 and 10 employees (see Biocontrol Baseline, Annex 3). As mentioned in the section above, biocontrol industries based in the EU rely substantially on *in situ* collection of GR sourced from different EU MS. The fact that the biocontrol industry has very limited profit margins on the provision of its products and services increases the vulnerability of the sector to the expected transaction costs associated with the fragmentation of procedural requirements across the EU internal market. Option B is therefore expected involve lower transaction costs compared to Option A. Other sectors where an important number of SMEs making use of genetic resources are the industrial and pharmaceutical biotechnology, seed, cosmetics and food & beverage industries (see EU Baseline, chapter 10). Nevertheless, as those sectors mostly source from *ex situ* collections in the EU for commercial purposes (when sourcing *in situ* it would generally be outside the EU) and the majority of GR used by those sectors are not originally from EU MS and/or outside the substantive scope of the NP (e.g. within the remit of the ITPGRFA), it is unlikely that the adoption of access measures by individual MS will substantially interfere with their sourcing practices (see Option A above for further considerations, section 11.2.2).

Governance

Practicability

By taking a soft coordinating role, the EU would still leave the primary responsibility and competence for regulating access to GR to MS. From an administrative point of view this option would still be practicable as it would involve relatively light administrative burdens on EU institutions.

Acceptability (MS/Sectors)

MS: Some MS with important biodiversity hotspots, including France (with Overseas Territories) and Spain, are keen to adopt PIC and MAT procedures. Others, including the Netherlands, have opted for a “free access” policy (see Country Reports, Annex 2). While the general tendency is to regulate access to GR domestically, the OMC solution under

Option B could provide an acceptable compromise with the demands of users from different sectors for an EU-wide coordinated approach. Moreover, with MS becoming the main drivers of the process and the EU simply playing a coordinating and supporting role, Option B is likely to be considered acceptable by most MS as it does not raise any political controversy nor does it interfere in any way with the national interests of any MS. Under the OMC each MS, would also have the freedom to disagree and take different measures from the mainstream position in the case an agreement or compromise cannot be reached.

Sectors: All sectors consulted and interviewed argued in favour of harmonisation and opposed the idea of fragmented implementation of ABS legislation because of concerns over higher transaction costs and delays in the transfer of GR. In particular, the seed and green biotechnology industry, the horticulture industry, the academic research sector relating to agriculture, botanic gardens, and culture collections have pleaded for the introduction of a multilateral system akin to the IT-PGRFA Multilateral System within the EU. Sectors with SMEs and operators with limited financial or organisational means have expressed concern over the increasing administrative burden in the case of fragmented legislation within the EU (biocontrol, botanic gardens, cosmetics) (see Sectoral Sheets, Annex 3). As analysed above, an EU led OMC would only partially address these issues and may not lead to full harmonisation; therefore it may still be met by opposition. The OMC however would provide opportunities for stakeholders to have an active and continuous input in the harmonisation process. Policy convergence therefore is more likely to be shaped by sectoral practices and needs in the long term.

Consistency

As already mentioned, an OMC approach is generally expected to improve the consistency of access practices across MS while fully respecting subsidiarity. Full harmonisation of procedures and policies however cannot be expected under this option. The level of consistency across the EU therefore will depend on the willingness of MS to agree on common standards. Being a continuous process, an increasing level of consistency is to be expected in the long term.

Transparency & Understandability

Transparency will be enhanced in individual MS by the introduction of access procedures compliant with Art 6(3) i.e. procedures will have to comply with general principles of transparency, fairness, provision of information, etc. The EU focal point will increase transparency by sharing information on MS procedures with all prospective users. Because of the uncertainties as to the level of policy convergence across MS that may be achieved under the OMC, the understandability of different MS access policies for users sourcing GR across the EU may remain problematic (although to a lesser extent than for Option A).

International Political Acceptability

Compared to the baseline scenario and to Option A, Option B is more likely to put the EU in a stronger position with regard other parties to the NP. As the EU is undoubtedly one of the most influential international players among the NP signatories, a harmonised approach in relation to access procedures would likely put the EU in a stronger position to propose its access model to third countries as best practice to be followed. The development of a consistent practice related to Art 8(a), for example, would have the potential to set an

international standard practice that could also benefit EU non-commercial users internationally.

Health, Environment & Biodiversity

Health

Impacts of Option B on health are highly speculative and will not be considered in this section.

Environment & Biodiversity

The creation of a fund by the EU on the model of the ITPGRFA, to which users and MS are encouraged to contribute voluntarily by sharing some monetary benefits coming from the utilisation of GR, would enable the EU to support research projects benefitting the conservation of biodiversity. Thus an indirect positive impact on the environment is expected from this initiative.

11.2.4 Provider Measures: “Option C” EU Minimum Legal Standards

Table 11.3: Synthesis: overview of impacts associated with implementation of option C

IA Criteria	Business as Usual Scenario	Option C: EU Minimum Legal Standards
Addressing the ABS objective		
Addressing the ABS objective	Legal status of GR originating from MS remains unclear. Framework legislation has been drafted in certain MS (Spain, France, Bulgaria) but not yet implemented, thus no access and benefit sharing procedures yet put in place in any MS.	EU: ↗↗ to ↗↗↗
Ensuring access to resources (in the EU)	Despite the unclear legal situation, stakeholders did not report any particular problems regarding access to <i>in situ</i> GR from EU MS (as access is currently unregulated).	EU as a block: ↗
		Access in MS with free access policy: ↗
		Access to <i>ex situ</i> collections ↗
Ensuring benefit-sharing	No benefit-sharing provisions currently in place	EU (MS requiring PIC and MAT) ↗ to ↗↗ EU (free access MS) N/A
Legal conformity, certainty, coherence with other legislation and enforceability		
Legal certainty – for users	Lack of ABS legislation across EU MS. Status of GR acquired by <i>ex situ</i> collections post-CBD from the EU is unclear.	EU wide ↗↗ to ↗↗↗
Coherence with other international obligations	Because no operational PIC legislation in place there is no interference with the ITPGRFA. MS inaction potentially incompatible with internationally recognized indigenous peoples’ rights as far as GR held by ILCs and TKaGR are concerned, e.g. Art 26, 31 and 32 UN Declaration on the Rights of Indigenous People, ILO Convention 169, Art 6 and 15.	ITPGRFA → to ↗
		Indigenous peoples’ rights: → to ↗
Enforceability	No enforcement of access rules so far in MS that have expressed an interest in regulating access.	EU ↗
		MS: ↗↗ for those adopting access measures
Costs: Public		
Recurring Costs: EU-level	No costs – no action taken.	EU: ↘↘
		If EU authority tasked with granting “negative” CoC ↘↘↘
Costs (one-off): EU-level	No costs – no action taken.	EU: ↘
		If EU authority tasked with granting “negative” CoC ↘↘
Recurring Costs: MS level	Variable, depending on efforts being currently undertaken by different MS.	MS requiring PIC/MAT: ↘ to ↘↘↘
		MS with free access: → to ↘↘ depending on whether the authority tasked with granting “negative” CoC is established at MS or EU level
Costs (one-off): MS-	Variable, depending on efforts being	MS requiring PIC/MAT: ↘ to ↘↘↘

level	currently undertaken by different MS.	MS with free access: → to ∇ depending on whether the authority tasked with granting “negative” CoC is established at MS or EU level
Sector Costs		
Expected costs for sectors	No particular costs incurred (not quantifiable).	Generally: →
		e.g. <i>Ex situ</i> and academic research institutions: →
		e.g. Plant breeders → to ↗, Animal Breeders: →
SMEs	No particular costs incurred (not quantifiable).	Generally: →
		Specifically: Biocontrol → to ↗ (positive arrow due to increased legal certainty)
Governance		
Practicability	Issue does not arise as no operational access legislation is in place.	EU: →
Acceptability (MS/Sectors/Internal Market)	Issue does not arise as no operational access legislation in place, therefore not acceptable from legal point of view in case of ratification by EU or MS. Acceptable for EU sectors as they are currently not strongly affected as no implementation is in place.	MS requiring PIC and MAT: → to ∇
		MS with free access: → to ∇ negative arrow in case of legal obligation to establish a competent authority with the capacity of granting “negative” CoCs to users
		Sectors: ↗ to ↗↗
Consistency	No consistent approach across EU MS.	EU: ↗↗
Transparency & Understandability	Status of GR already acquired by users after the entry into force of the CBD and <i>ex situ</i> within EU very unclear.	EU: ↗↗
International Political Acceptability		
International Political Acceptability	Currently, lack of operational provider measures in place. Internationally however countries more interested in EU taking strong user compliance measures.	EU: ↗↗↗
Health, Environment & Biodiversity		
Health	Currently no interference with WHO GISRS health emergency regime. No interference with pharma R&D.	→ Unforeseeable: but potential benefits in longer term through greater access ↗ + ?
Environment & Biodiversity	No BS incentive for conservation currently at MS level.	→ to ↗

Option's overall ability to address the ABS challenge

Addressing the ABS objective

As to addressing the objective behind provider measures under the NP (facilitating access procedures, legal certainty for users and protection of ILCs' rights while providing an incentive for the conservation of biodiversity), the implementation of harmonised minimum standards on PIC procedures, the status of GR held *ex situ*, facilitated access procedures for non-commercial research and standard MAT requirements for non-commercial use of GR would resolve most of the problems of legal uncertainty and related transaction costs that have been identified under Option A, and to a lesser extent, under Option B as consequences of a potential lack of consistency in MS ABS regulations. In fact with broadly the same access rules and procedures applying across MS that have opted for requiring PIC and MAT, access for prospective users to EU genetic resources would be very much facilitated and legal uncertainty related to the status and legal requirements attached to a specific GR minimised.

Ensuring access to resources

Under Option C, the overall EU-wide access to genetic resources will be much facilitated for prospective users when compared to Option A and Option B. Compared to the baseline scenario where no access rules are in place, access and transactions in GR under Option C are nevertheless expected to be enhanced as legal uncertainties and grey areas are addressed under a uniform legislation, thus helping prospective users to exercise due diligence or comply with other user compliance rules in or outside the EU.

More specifically, sourcing GR *in situ* in MS requiring PIC and MAT procedures will be facilitated by the harmonised standards, which will include, *inter alia*, the standardisation of information requested from prospective users as well as standard application forms and MAT. Having the same procedures in each MS deciding to regulate access to its GR is likely to make the overall access to MS *in situ* GR much more simple and "user-friendly" for users sourcing GR from different MS.

Sourcing from *ex situ* collections and transactions among *ex situ* collections will also be facilitated (or at the very least will not be substantially impeded) by the EU providing for common minimum standards, particularly as to the temporal and substantive scope of GR that may be subjected to PIC and/or MAT requirements and the standardisation of MAT for non-commercial uses (see considerations under Option A, section 11.2.2 above).

Access will also be enhanced for GR in "free access" MS compared to the baseline scenario, by requiring those MS to issue, upon request from users, a "negative" CoC to users that access GR in the respective MS, thus enhancing the legal certainty for users that will be subject to user compliance measures.

Ensuring benefit sharing

Benefit sharing related to the utilisation of GR will increase in the long term, provided that MS required prospective users to share benefits; at the moment no benefits are shared with any MS as no legislation to that effect is in force. The types of benefits related to certain utilisations of GR will likely vary depending on the GR and the provider state. The capacity of national authorities or ILCs to ensure that benefits established under MAT will be shared will also depend on the terms established under MAT (e.g. reporting requirements, upfront vs. royalty payments) as well as on the approach taken by the EU in relation to user compliance measures.

Legal conformity and impacts

Legal certainty for users

Through harmonised standards and procedures, Option C is likely to increase legal certainty for all sectors, which will be able to source in different MS under standardised rules and procedures. Sectors that will particularly benefit from Option C are the biocontrol industries, as they engage in substantial bioprospecting of *in situ* GR across different MS (Biocontrol Baseline, Annex 3), and EU *ex situ* collections which engage in a high number of transactions in GR among themselves and with other users (culture collections, botanic gardens). In terms of legal certainty, the former will benefit particularly from the standardisation of PIC and MAT requirements across MS, while the latter will mostly benefit from a common approach to facilitated access to GR for non-commercial uses and from a common approach over the scope of GR upon which PIC and MAT may be required.

Coherence with other international obligations

As to the EU and MS compliance with the ITPGRFA, Option C is also unlikely to have any substantial impacts as compared to the baseline scenario. In fact Art 4(4) NP excludes GR covered by the ITPGRFA from the scope of the NP. The suggested exclusion of PGRFA covered by Annex I of the Treaty from the scope of PIC and MAT requirements ensures that the status of those GR will be clear under Option C.

MS inaction or a restrictive interpretation of Art 6(2) and 5(2) NP may result in measures inconsistent with international indigenous peoples' rights (see Option A above) recognised, *inter alia*, by the UN Declaration on the Rights of Indigenous People (Arts 26, on rights over their resources, Art 31 on rights over TK and Art 32 on free and informed consent) and the ILO Convention No.169 (Art 6 on consultation rights and Art 15 on rights over their natural resources). It is to be noted, however, that very few groups residing within the EU qualify as "indigenous peoples". As a result under Option C no specific legislative action to implement ILC-related provisions under the NP is expected from the EU unless specific problems are detected in specific MS. A general duty on MS to identify ILCs on their territory and make sure that their rights are adequately safeguarded may nevertheless put some additional pressure on the MS concerned to address the issue of access to GR and TKaGR held by ILCs residing in their jurisdiction.

Enforceability

Minimum standards to be observed by all MS when legislating on ABS and the obligation on “free access” MS to issue a “negative” CoC upon request by the user could facilitate the monitoring of the utilisation of GR accessed in EU MS. This will be particularly in the case when the EU adopts an ambitious EU-wide approach to user compliance measures which also covers GR from within the EU. It is to be noted however that Option C will not necessarily entail better enforceability of PIC and MAT requirements with regard to non-EU users of GR sourcing in MS but operating otherwise outside the EU jurisdiction.

Public Costs

Recurring Costs - EU level

Recurring costs at EU level will be relatively low under Option C. Costs will mostly relate to the setting up and management of an EU focal point with the role and capacity of disseminating information to prospective users on MS access procedures. This would most probably be in the form of a web portal simply providing links to national focal points and explanations of the main procedural requirements and scope of EU access legislation. Additional costs relate to monitoring the correct implementation of EU law in the MS.

In case an EU authority was to be tasked with granting “negative” CoCs in relation to GR originating from “free access” countries, recurring costs could significantly increase as an efficient documentation system would need to be managed. This authority would also need some capacity to check whether the particular GR has been really sourced from a “free access” country. While on the one hand this would facilitate users’ proof of compliance within eventual user compliance systems, the costs of this system may potentially outweigh the benefits in terms of legal certainty, as in any event the proportion of GR accessed from “free access” countries is expected to be fractional.

One-off Costs: EU level

One-off costs for the EU expected under Option C will be higher compared to previous options as they will include, in addition, the costs of enacting legislation containing minimum standards. Other minor costs will be linked to soft measures such as awareness raising activities and the production and promotion of guidelines.

In case an EU authority was to be tasked with granting “negative” CoCs in relation to GR originating from “free access” countries, further one-off costs would be related to the setting up of an efficient documentation system.

Recurring Costs: MS level

For MS requiring PIC and MAT the costs will be mostly associated with the introduction of access rules, monitoring and institutional arrangements. Costs will be different from one MS to the other depending on the existing rules and institutional set-ups, etc.

Under Option C EU legislation may impose some costs also for MS opting for a “free access” policy. Those costs are mostly associated with the obligation on those MS to grant a CoC to users requesting it when accessing GR under their sovereign rights. Such a system would require an efficient documentation system together with some capacity to carry out eventual checks on whether the GR accessed was in fact under the jurisdiction of that MS.

One-off Costs: MS level

While one-off costs for MS requiring PIC and MAT are highly variable, significantly under Option C the EU measures could also lead to some costs for MS with free access to GR. One-off costs would mostly relate to the setting up of the CoC system.

Sector Costs

Expected costs for sectors

Harmonisation of procedural standards and basic access rules will increase legal certainty for sectors sourcing GR from different MS and as a result reduce the associated transaction costs. Sectors that will particularly benefit in terms of reduced costs from the increased legal certainty under Option C are the biocontrol industries, as they engage in substantial bioprospecting of *in situ* GR across the EU (see EU baseline, chapter 10), and upstream users that engage in a high number of transaction in GR between themselves and with other non-commercial users (*ex situ* collections, academic research). In terms of legal certainty, the former will benefit particularly from the standardisation of PIC and MAT requirements across MS, while the latter will mostly benefit from a common approach to facilitated access to GR for non-commercial uses (Art 8(a) NP) and from a common approach over the scope of GR upon which PIC and MAT may be required.

A further group of commercial users that could benefit from the introduction of minimum standards is the plant breeding sector. In fact, through harmonised standards the EU could also implement a common approach towards PGRFA, ensuring that sectors dealing with PGRFA are not subjected to double regulatory burdens under both NP access rules and the ITPGRFA. Lastly, other sectoral practices such as the ones of the animal breeding industry, where the selling and purchasing of animals *de facto* regulates access to animal genetic resources, could also benefit from a common approach with the aim of avoiding unnecessary restrictions on contractual freedom and commercial transactions by some MS; such restrictions could create unnecessary administrative costs for sectors in the EU (see animal breeding sectoral sheet, Annex 3).

It is to be noted however that the aggregate benefits of Option C for all EU users of GR are still expected to be limited compared to the baseline scenario. The majority of GR accessed by EU users are in fact being collected from biodiversity-rich countries outside the EU. Moreover, as under the baseline scenario there no access-related costs for EU users, Option

C will merely ensure that costs are limited for EU users under a future regime of regulated access.

SMEs

The majority of biocontrol industries are SMEs with between 2 and 10 employees (see biocontrol sectoral sheet, Annex 3). As mentioned under Option A above, biocontrol industries based in the EU rely substantially on *in situ* collection of GR sourced from different EU MS. The fact that the biocontrol industry has very limited profit margins on the provision of its products and services increases the vulnerability of the sector to the expected transaction costs associated with the fragmentation of procedural requirements across the EU internal market. As a result, the present option would particularly benefit SMEs operating in this sector (i.e. ensure that their business practices are not unnecessarily disrupted by the creation of different access regimes in different MS). Other sectors where an important number of SMEs deal with genetic resources are the industrial and pharmaceutical biotechnology, seed, cosmetics and food & beverage industries (see EU Baseline, chapter 10). With regard SMEs operating in the industrial and pharmaceutical biotechnology sectors, which mostly source GR from EU *ex situ* collections for commercial purposes, it is expected that minimum standards for access will not provide substantial additional benefits to the sector's existing sourcing practices except from simplifying and clarifying the scope of PIC and MAT requirements in MS. On the other hand, SMEs engaging in plant breeding could benefit from the introduction of harmonised minimum standards in case the EU decided to adopt a common approach towards PGRFA, thus avoiding potentially double regulatory burdens.

Governance

Practicability

Option C is also practicable, although it would clearly require a more proactive approach from the EU compared to Options A and B. Under this option in fact the EU would enact legislation, thus going through all the related institutional and procedural steps of the EU legislative process.

Acceptability (MS/Sectors)

MS requiring PIC and MAT: MS with important biodiversity hotspots such as Spain and France are inclined to adopt PIC and MAT procedures and regulate domestically the access to GR over which they have jurisdiction. This does not mean, however, that Option C would automatically be regarded as unacceptable by MS. Firstly, because no MS has yet taken steps to complete the framework legislation in place by introducing specific operational rules, Option C would not involve any significant additional burdens on those countries in terms of legal and institutional reforms. Moreover, Option C would primarily harmonise procedural standards with the aim of facilitating access for users accessing GR in different MS, thus leaving discretion to MS on the choice of whether or not requiring PIC and MAT at all. Partially, MS would also be left the substantive choice as to which *in situ* GR will be covered or what type of benefit sharing would be required for the use of certain GR.

MS not requiring PIC and MAT: The costs for MS not requiring PIC and MAT linked to the obligation to set up a system for providing users of “freely accessible GR” with a “negative”

CoC if they so wish, may be considered unacceptable from certain states not requiring PIC and MAT, as under the NP they do not have any obligation to provide such a CoC. This cost could however also be considered necessary in connection with the proper functioning of an EU user compliance system and the increased legal certainty for users of GR if all EU countries were to supply a CoC regardless of whether GR were accessed under PIC and MAT or not. In this light, the costs associated with Option C may be considered more acceptable by “free access” countries.

Sectors: All sectors consulted and interviewed argued in favour of harmonisation and opposed the idea of fragmented implementation of ABS legislation because of concerns over higher transaction costs and delays in the transfer of GR. In particular, the seed and green biotechnology industry, the horticulture industry, the academic research sector relating to agriculture, botanic gardens, and culture collections have pleaded for the introduction of a multilateral system akin to the IT-PGRFA Multilateral System within the EU. Sectors with SMEs and operators with limited financial or organisational means have expressed concern with the increasing administrative burden in the case of fragmented legislation within the EU (biocontrol, botanic gardens, cosmetics) (EC public consultation, 2011 and EU Baseline, Annex 3). As analysed above, Option C would be likely accepted by all sectors as the option that best addresses their concerns.

Consistency

Harmonisation of rules and procedures through the EU-wide introduction of minimum legal standards would lead to a high level of consistency in ABS requirements across the EU in terms of definitions, legal requirements and institutional arrangements.

Transparency & Understandability

The overall transparency and understandability of access measures at EU level will be clearly enhanced by Option C. Standard procedures and forms being used across MS would in fact make the overall access system more user-friendly and transparent. The provision of information on those standard forms and procedures by an EU focal point would moreover further increase the transparency of the access system at EU level.

International Political Acceptability

Option C is likely to put the EU in a strong position internationally. The adoption of efficient and user-friendly access procedures will likely make the EU a frontrunner internationally. As the EU is undoubtedly one of the most influential international players among the NP signatories, the introduction of EU-wide legally binding access standards and procedures would likely put the EU in a stronger position to propose its access model to third countries as best practice to be followed, particularly if combined with ambitious user compliance measures. In that case Option C may also indirectly benefit EU users when sourcing from third countries.

Health, Environment & Biodiversity

Health

Impacts of Option C on health remain speculative. However as the likely result of Option C is an overall improvement of access to GR in the EU together with the likely indirect effect of some improvements in access systems in third countries, it can be assumed that Option C also promotes health-related research which may result in overall benefits for health in the EU in the long term. Short and medium term benefits are unlikely to be significant.

Environment & Biodiversity

The creation of a fund by the EU following the model of the fund under the ITPGRFA, to which users and MS are encouraged to contribute voluntarily by sharing some monetary benefits coming from the utilisation of GR, would have the main function of supporting research projects benefitting the conservation of biodiversity. Thus an indirect positive impact on the environment is expected from this initiative in the long term. Option C moreover will minimise the risks of negative impacts of access measures on the free exchanges of GR between EU *ex situ* collections and other non-commercial users, thus avoiding interference with the conservation activities of collections (botanic gardens in particular).

11.2.5 Provider Measures: Synthesis of impact assessment results with regard Option A, B and C

Table 11.4 below presents the synthesis of the provider measure options and the performance against the impact assessment criteria. It is followed by a synthesis discussion of the costs and benefits of each option.

Table 11.4: Synthesis of impacts assessment results with regard Option A, B and C

IA Criteria	Business as Usual Scenario	Option A: No or Minimal EU Action, Max MS Action	Option B: EU OMC	Option C: EU Minimum Legal Standards
Addressing the ABS objective				
Addressing the ABS objective	Legal status of GR originating from MS remains unclear. Framework legislation has been drafted in certain MS (Spain, France, Bulgaria) but not yet implemented, thus no access and benefit sharing procedures yet put in place in any MS.	EU as a block: ↘↘	EU: → to ↗	EU: ↗↗ to ↗↗↗
		MS: → to ↗↗↗ (no negative arrows as the option assumption is that all MS comply)	MS: → to ↗↗↗ (no negative arrows as the option assumption is that all MS comply)	
Ensuring access to resources (in the EU)	Despite the unclear legal situation, stakeholders did not report any particular problems regarding access to <i>in situ</i> GR from EU MS (as access is currently unregulated).	EU: ↘↘	EU: ↘ to ↗	EU: ↗
		<i>In situ</i> access in MS requiring PIC: ↗ to ↘ depending on stringency and complexity of procedures implemented by MS requiring PIC and MAT	<i>In situ</i> access in MS requiring PIC: → to ↗ sharing of best practices under OMC likely to generally improve MS access measures	
		Access in MS with free access policy: →	Access in MS with free access policy: →	Access in MS with free access policy: ↗
		Access to <i>ex situ</i> collections: → to ↘↘ depending on the scope of access legislation, future ABS practise of <i>ex situ</i> collections and approach to PIC and MAT.	Access to <i>ex situ</i> collections ↘ to ↗ depending on level of harmonisation	Access to <i>ex situ</i> collections ↗
Ensuring benefit-sharing	No benefit-sharing provisions currently in place	MS: ↗ to ↗↗ (expected to be substantial only in long term)	MS requiring PIC and MAT: ↗ to ↗↗	EU (MS requiring PIC and MAT) ↗ to ↗↗
				EU (free access MS) N/A
Legal conformity and impacts				
Legal certainty – for users	Lack of ABS legislation across EU MS. Status of GR acquired by <i>ex situ</i> collections post-CBD from the EU is unclear.	For users across EU: ↘↘	For users across the EU: ↘ to ↗	EU wide ↗↗ to ↗↗↗
		Within individual MS: ↗ to ↗↗↗	Within individual MS: ↗ to ↗↗↗	
		For MS not requiring PIC and MAT: →	In MS not requiring PIC and MAT: →	

Coherence with other international obligations	Because no operational PIC legislation in place there is no interference with the ITPGRFA. MS inaction potentially incompatible with internationally recognized indigenous peoples’ rights as far as GR held by ILCs and TKaGR are concerned, e.g. Art 26, 31 and 32 UN Declaration on the Rights of Indigenous People, ILO Convention 169, Art 6 and 15.	ITPGRFA →	ITPGRFA →	ITPGRFA → to ↗
		Indigenous peoples’ rights →	Indigenous peoples’ rights: → to ↗	Indigenous peoples’ rights: → to ↗
Enforceability	No enforcement of access rules so far in MS that have expressed an interest in regulating access	EU: ↘ to ↗ (largely depends on future EU user compliance regime)	EU: ↘ to ↗ (largely depends on future EU user compliance regime)	EU ↗
		MS: ↗↗ for those adopting access measures	MS: ↗↗ for those adopting access measures	MS: ↗↗ for those adopting access measures
Costs: Public				
Recurring Costs: EU-level	No costs – no action taken.	EU: → (marginal costs)	EU: ↘	EU: ↘↘
				IF EU authority tasked with granting “negative” CoC ↘↘↘
Costs (one-off): EU-level	No costs – no action taken.	EU: → (marginal costs)	EU: → (marginal costs)	EU: ↘
				If EU authority tasked with granting “negative” CoC ↘↘
Recurring Costs: MS level	Variable, depending on efforts being currently undertaken by different MS.	MS with PIC/MAT: ↘ to ↘↘↘	MS with PIC/MAT: ↘ to ↘↘↘	MS requiring PIC/MAT: ↘ to ↘↘↘
		MS with free access: →	MS with free access: →	MS with free access: → to ↘↘ depending on whether the authority tasked with granting “negative” CoC is established at MS or EU level
Costs (one-off): MS-level	Variable, depending on efforts being currently undertaken by different MS.	MS with PIC/MAT: ↘ to ↘↘↘ depending on implementation measures	MS with PIC/MAT: ↘ to ↘↘↘	MS requiring PIC/MAT: ↘ to ↘↘↘
		MS with free access: →	MS with free access: →	MS with free access: → to ↘ depending on whether the

				authority tasked with granting “negative” CoC is established at MS or EU level
Sector Costs				
Expected costs for sectors	No particular costs incurred (not quantifiable).	Generally: ↘ to ↘↘ (legal uncertainty : transaction costs)	Generally ↘	Generally: →
		e.g. <i>Ex situ</i> collections and academic research: ↘ to ↘↘	e.g. <i>Ex situ</i> collections, academic research, other non-commercial users: ↘ to →	e.g. <i>Ex situ</i> and academic research institutions: →
		Commercial sectors relying on EU <i>ex situ</i> collections (industrial and green biotech, seed industry, horticulture) → to ↘		e.g. Plant breeders → to ↗, Animal Breeders: →
SMEs	No particular costs incurred (not quantifiable).	Generally: ↘↘	Generally: ↘	Generally: →
		Specifically: Biocontrol ↘↘ to ↘↘↘	Specifically: Biocontrol ↘↘	Specifically: Biocontrol: → to ↗ (positive arrow due to increased legal certainty)
Governance				
Practicability	Issue does not arise as no operational access legislation is in place.	EU: ↗ to ↗↗	→ to ↗	EU: →
Acceptability (MS/Sectors/Internal Market)	Issue does not arise as no operational access legislation in place, therefore not acceptable from legal point of view in case of ratification by EU or MS. Acceptable for EU sectors as they are currently not strongly affected as no implementation is in place.	MS: ↗↗	MS: ↗ to ↗↗	MS requiring PIC and MAT: → to ↘
		Sectors: ↘↘	Sectors: ↘	MS with free access: → to ↘ negative arrow in case of legal obligation to establish a competent authority with the capacity of granting “negative” CoCs to users
Consistency	No consistent approach across EU MS.	↘↘	↗	↗↗
Transparency & Understandability	Status of GR already acquired by users after the entry into force of the CBD and <i>ex situ</i> within EU very unclear.	↘ to ↗	→ to ↗	↗↗

International Political Acceptability				
International Political Acceptability	Currently, lack of operational provider measures in place. Internationally however countries more interested in EU taking strong user compliance measures.	→	↗	EU: ↗↗↗
Health, Environment & Biodiversity				
Health	Currently no interference with WHO GISRS health emergency regime. No interference with Pharma R&D.	→ Unforeseeable	→ unforeseeable	→ Unforeseeable: but potential benefits in longer term through greater access ↗ + ?
Environment & Biodiversity	No BS incentive for conservation currently at MS level.	→ Unforeseeable	→ to ↗	→ to ↗

As the above table (and the earlier discussion of the performance against criteria) shows, each option analysed presents overall a (different) mix of costs and benefits. The broad messages from the assessment is that the more the EU intervenes in harmonising access standards, the higher the benefits will be for sectors sourcing GR from different MS - in terms of legal certainty and related reduced transaction costs.

In addition, the introduction of harmonised access standards would also potentially entail increasing international benefits as the EU would be able to lead by example, creating a precedent that is likely to influence access measures in third countries in the future, thus indirectly benefiting all EU users of GR in the long term.

The downside of more active EU intervention has been identified particularly in terms of administrative and financial costs that EU institutions would have to bear and the potential political opposition from certain MS (e.g. MS opting for “free access”, which may potentially consider the obligation to issue “negative CoCs” a disproportionate bureaucratic burden or MS which would consider EU intervention in procedures regarding access to their natural resources an unnecessary intrusion on national sovereignty).

In sum, under Option A, EU inaction would likely entail a fragmentation of access standards throughout the EU leading to a likely increase of transaction costs for sectors sourcing GR (particularly *in situ*) across EU MS.

Looking at sectors from an aggregate perspective this option would seem at first sight appropriate as most GR with particular scientific and economic value are located outside the EU. However, the option is less appropriate when taking into account the impact of potential transaction costs associated with Option A on certain specific sectors, which could be very significant.

For example, research and commercial activities within the biocontrol sector, which is mostly composed of SMEs with very limited profit margins and which sources 50% of GR across EU MS, could be seriously undermined by the fragmentation of access standards.

Option B on the other hand seems to better balance, through soft harmonisation under an OMC, the costs for the EU and potential costs for users relating to legal uncertainties and fragmentation, while fully respecting the principle of subsidiarity. The downsides of this option seem to be mostly the uncertainties as to the end result of the OMC process.

Lastly Option C is the one with that offers the most apparent benefits for sectors dealing with GR, in particular biocontrol, *ex situ* collections and small seed breeding companies, but also leaves MS the least flexibility.

Moreover, as mentioned above, **this option would also potentially entail international benefits for all EU users of GR as it would put the EU in a leading position in terms of access to GR standard setting.** Political opposition from certain MS and the relatively high costs related to enacting and monitoring the compliance with a new piece of legislation could potentially counter-balance the benefits of such a system, at least in the short term.

In conclusion, it is worth noting that the above analysis while pointing at Options “B” and “C” as being more in line with the spirit of the NP access provisions (i.e. facilitating access to GR), does not exclude the possibility for the EU to adopt option “A” as a short term solution.

Option “A”, “B” and “C” should not in fact be seen as mutually exclusive over time. In the event that Option “A” is adopted in the short term, harmonisation across the EU should follow as soon as practical and politically possible – first through the adoption of Option B (which can itself evolve over time to become increasingly ambitious), and when the conditions are right to minimum legal standards under Option C.

While adopting Option A, in fact, the EU through its focal point and/or its user compliance system could further collect information on the use of GR that are sourced in the EU and the problems that fragmentation of standards may entail in practice. On this basis the EU could later opt for and design an OMC under Option B or minimum standards under Option C that could be targeted to the issues encountered. Finally Option B and Option C could also be combinable, by, for example, adopting an “OMC” type of soft harmonisation in the areas which have raised controversy in the discussion of Option C or to issues in relation to which the EU has less competence or where more flexibility is needed (e.g. access to GR/TKaGR held by ILCs or access to GR in overseas territories).

The above recognition of the complementary of Options A, B and C does not suggest that the ideal approach is to start with Option A. The above assessment suggested that overall Option C offers the greatest benefits, albeit with the greatest costs. It is clearly a political decision whether to start immediately with Option C, or alternatively adopt Option B with a view to potentially moving to Options C in due course (either planned or with review period), or indeed start with no immediate EU action, learn from experience in the Member States and then harmonise in later stages.

11.3 User Compliance Measures

11.3.1 User Compliance Measures: Introduction

This section focuses on impact assessment of the three user compliance options that were presented in detail in chapter 9. The three main options are assessed and compared against the current (baseline) situation (as described in chapter 10) and in some cases also directly among each other. These options are:

Option A: Maximum Member State Action + EU OMC

Option B: EU Upstream Focused Action

Option C: EU Downstream Focused Action

The options are outlined below (see also Figures 11.1 and 11.2 presenting Option B and Option C respectively), and are followed by analysis of each option (sections 11.3.2 to 11.3.4), with each subsection presenting a summary table of the assessment against the impact assessment criteria (as outlined in chapter 11.1) and associated discussion as to the results. Section 11.3.5 presents the summary across the three options.

Business as Usual

Currently in the EU no MS has taken legal measures with the aim of ensuring compliance with provider country ABS legislation. While some users have taken steps to establish sectoral self-regulatory systems, guidelines and other voluntary measures to ensure their sourcing conduct is CBD-compliant, no systematic monitoring is carried out by public authorities on the utilisation of genetic resources by EU users and no sanctions are currently imposed. Under the current legal situation, MS and the EU would be in breach of several core obligations of the NP, including, *inter alia*, Arts 5, 15, 16 and 17. Therefore, the business as usual scenario is not an option for ensuring compliance with the Protocol and is not considered as such in this assessment.

Option A: Maximum Member State Action + EU OMC

In this option, the EU uses the Open Method of Coordination (OMC) to achieve a certain degree of coordination among MS. Thus, MS states ideally would agree on adopting similar measures on user compliance and monitoring. However, it is unlikely that measures will be fully harmonised.

Option B: EU Upstream Focused Action

Under this option the EU takes legislative action (most likely in form of a regulation) focused on the beginning of the user chain of GR under EU jurisdiction. Thus, specific EU measures address upstream activities which are not a “utilisation” of GR in the sense of the Protocol. Upstream activities are access to *in situ* genetic resources, importing GR into the EU, storing GR in *ex situ* collections (including their identification and documentation for this purpose) and handing out GR from such *ex situ* collections. Under this system, the EU also establishes a general due diligence obligation for all users of genetic resources and associated traditional knowledge. A due diligence obligation means that users need to take measures to ensure that the GR/TKaGR they “utilise” are of good legal status, i.e. have either been acquired in line with provider countries’ ABS legislation or are not subject to such

legislation, either because a provider country does not require PIC or because the resources do not come within the purview of the Protocol.

Option C: EU Downstream Focused Action

Under this option the EU takes legislative action (most likely in form of a regulation) focused on the end of the utilisation chain under EU jurisdiction. Thus, the targets here are downstream uses of GR, i.e. R&D of both commercial or non-commercial nature and marketing/commercialisation. The core of this option is a general prohibition for all EU users to utilise illegally acquired genetic resources or associated traditional knowledge; compliance with the general prohibition is ensured by a system of checkpoints and related disclosure requirements at the time when an intellectual property right is sought or a company seeks to obtain an approval for the marketing of a product based on genetic resources or associated traditional knowledge.

11.3.2 User Compliance Measures: “Option A” Max MS Action with EU OMC

The table below presents the overview of the assessment against the range of criteria of the *Maximum Member State action with EU OMC* option, set against the pre-Protocol business-as-usual scenario (mix of current status and expected change in the absence of action on the Protocol).

Table 11.5: Synthesis: overview of impacts associated with implementation of option A

IA Criteria	Business as Usual Scenario	Option A: Max member State Action + EU OMC
Addressing the ABS objective		
Implementing the Protocol objectives	No action to date at MS and EU level on user compliance, but some actions expected from some MS Self-regulation by some user groups Private law governs benefit-sharing agreements No systematic monitoring at EU or MS level No sanctions for non-compliance with provider measures at EU or MS level	Objectives are partially, but incompletely addressed. EU as a whole: ↘
		Variation across Member States concerning implementation will have both positive and negative impacts Across MS: ↘↘ to ↗↗
Legal certainty, coherence with other legislation and enforceability		
Legal certainty	N/A: No user compliance regime in place in EU MS	Does not provide legal certainty for users regarding Protocol obligations at EU level; mitigated where MS action is taken EU-level: ↘↘↘ to ↘↘ depending on level of variation across MS
		MS-level: ↘↘ to ↗↗
Coherence with other international obligations - ITPGRFA	No action, therefore coherence maintained with ITPGRFA	→
Enforceability – user compliance provisions and MAT	MS may develop their own enforcement measures to comply with the Protocol	User compliance provisions: EU plays a supporting role which can enhance enforceability, but does not significantly improve enforceability at EU-level
	ABS agreements enforceable through contract law for MAT	MAT: → to ↗
Compatibility of proposed options with existing practices		
Compatibility	Wide variation in the volume and type of use, extent of commercial vs. non-commercial use, awareness of NP obligations and existing ABS practices	↘↘↘ to ↗↗
Sector costs / impacts		
Sector costs / impacts	No costs related to action – as no EU-level action required / taken	Costs will vary by sector ↘↘↘ to ↘
	However, risks over time of sectors losses from reduced access to GR given lack of legal framework and impacts on collaboration with third countries. Over time this could be very significant for some sectors if a working global ABS system is in place: Short term ↘ Risk in long term ↘↘↘	

Specific issues: SMEs		
SMEs	<p>No costs at EU level - no action taken</p> <p>Costs where MS decide to take action</p>	<p>Costs will vary at MS level, but MS must keep Small Business Act for Europe (SBA) in mind in any regulation proposed, however potential transaction costs for lack of harmonisation</p> <p>↘↘↘ to ↘</p>
Public costs		
Recurring costs: EU-level	No costs – no action taken	Costs are minimal – require little administrative action: ↘
One-off costs: EU-level	No costs – no action taken	Costs are minimal – requires few one-off costs: ↘
Recurring costs: MS level	Costs where MS decide to take action	Costs will vary depending on actions taken by MS ↘↘↘ to ↘
One-off costs: MS-level	Costs where MS decide to take action	Costs will vary depending on actions taken by MS ↘↘↘ to ↘
Governance		
Practicability	Practical – no action required	EU-level: Requires coordination at EU-level; may require multiple arrangements for different sectors ↗↗
		MS-level: ↘↘↘ to ↗↗↗
International political acceptability	No action taken - unacceptable	Acceptable to some third countries, but others will expect EU-level legislative action ↘↘
Acceptability	MS – Unacceptable as Parties to the NP	MS – Acceptable for some; unacceptable for some ↘ to ↗↗
	Sectors – Acceptable for most sectors	Sectors – Most sectors want coordinated EU legislative action rather than MS only approach ↘↘
Transparency & understandability	Complete transparency – no action taken	Transparency for providers and users likely to be limited due to variation in approaches undertaken at MS level. Coordinated efforts at EU-level might however increase overall transparency. ↘↘ to ↗
Health, environment and biodiversity		
Health	No interference with WHO GISRS health emergency regime. No interference with pharma R&D.	Impacts are speculative and cannot be assessed
Environment & Biodiversity	No change as no action taken	Depends partially of MS action. No EU legislative action may discourage provider countries to protect biodiversity. ↘ to ↗

Addressing the ABS objective

Implementing the Protocol objectives

Under this option, the Protocol's objectives are not completely met at EU-level. Voluntary approaches adopted at EU-level can help facilitate monitoring and reporting, and provide assistance to MS and sectors in developing Protocol-compliant approaches to ABS requirements. Protocol implementation at EU-level occurs to a certain degree; non-legislative actions alone, however, do not introduce binding requirements on Member States to ensure effective implementation. While individual MS will take responsibility for implementing the Protocol core obligations relating to user compliance, the EU will have limited leverage to ensure that effective, appropriate and proportionate measures are in fact being taken throughout the EU jurisdiction to achieve the aims of the Protocol. Where individual Member States do not meet their obligations, the EU as a Party to the Protocol may be non-compliant with its international obligations, because the EU did not take sufficient steps to prevent MS non-compliance.

Variation in MS approaches is expected under this scenario. Some Member States are likely to take action to fully implement the Protocol, while others may take little or no action at all. The range of future MS actions is unknown. The overall impact of this variation on users in individual MS will depend on the concentration of user groups in the different Member States. Some MS have a high concentration of industries that rely on access to genetic resources from provider countries (e.g. the biocontrol industry) and end use that relies heavily on access via intermediaries (e.g. the pharmaceutical industry). Exchange of genetic resources between research and educational institutions such as botanic gardens and culture collections is also very important in some Member States. Effective measures will be more important in these Member States than in those that are less reliant on the use and exchange of genetic resources obtained from third countries or other EU Member States.

Legal certainty, coherence with other international obligations and enforceability

Legal certainty

Without legislative action, legal certainty for users cannot be guaranteed at EU-level. The negative effects of this situation will be mitigated to some degree where Member State legislative action provides legal certainty for the sectors within their jurisdiction. Where MS take legislative action to implement the Protocol, there will be legal certainty for sectors, but only for their operations within that Member State.

Most sectors engage in transactions of GR/TKaGR across Member States. Transfers between different *ex situ* collections occur frequently between users in different EU Member States. For example, genetic resources are often exchanged for identification purposes, and identification requires the expertise of highly specialised taxonomists located in different countries. The benefits of MS action will be reduced where organisations that work across the EU must find out about procedures and legal requirements in different national contexts and develop practices to work with and around the variation. A coordinating role of the EU combined with soft measures such as the dissemination of best practices, awareness-

raising, requirements for projects funded by the EU, etc. may to some extent mitigate the effects of the lack of an EU harmonised legal framework.

Nevertheless, stakeholders across all of the user groups that responded to the European Commission public consultation indicated that ensuring legal certainty is of primary importance. The Protocol provisions are flexible as to which implementation measures are taken, and by adopting this option, heterogeneous implementation is highly likely across Member States. As a result, GR/TKaGR transactions between user groups are likely to be made more difficult due to variation of rules and procedures. Notably, botanic gardens, culture collections and other *ex situ* collections engage every year in thousands of transactions through self-regulated networks cutting across Member States. Legal uncertainty associated with different legal standards in each MS would likely complicate these exchanges and networks.

Coherence with other international obligations

Genetic resources covered by the ITPGRFA are excluded from the application of the Protocol. The EU and the 27 Member States are parties to the Treaty. Option A is unlikely to impact on the baseline scenario as MS measures are unlikely to directly interfere with the functioning of the Treaty.

Enforceability

Enforcement rules and procedures related to non-compliance with user compliance obligations will be established by individual Member States. There is likely to be variation in these approaches across the EU. The EU OMC will help to support MS-led measures.

The EU may also refuse payment or require repayment of EU research funding or other grant funding (i.e. development and cooperation funds) in cases of non-compliance with user country ABS legislation. These actions at EU level can facilitate the enforcement of provider countries' access legislation, but will not ensure effective EU-wide enforceability of the Protocol across sectors. In practice, enforcement will be mostly enhanced for the public sector i.e. research and development carried out by the academic sector or cooperation projects carried out by botanic gardens in developing countries (see EU Baseline, chapter 10 and relevant sectoral sheets, Annex 3). Private companies are funding most of their research through other than public sources: out of the approximately €137.4 billion that was spent on R&D by private companies in 2006, only €9.8 billion (7.1%) was funded by the government sector, whereas €113.6 billion (or 82.7%) was funded by companies themselves (see sectoral sheet on academic research, Annex 3). Under this EU measure, the burden of information is on operators through notification requirements and provision of information as to whether GR will be accessed/utilised and whether third country access legislation has been complied with. It will be easy for the European Commission to check whether GR have been utilised by the operator, as this will likely become apparent from the description of the research project and/or the research results.

As MAT-related cases will be handled by MS courts, and related procedural provisions are primarily within the area of MS competence, the direct influence of EU action on the enforceability of MAT is limited under the three options. It will be enhanced if the EU takes

some of the supporting measures discussed, such as providing legal aid for ILCs or developing model provisions for MAT that are formulated in a way to be judiciable.

Compatibility of proposed options with existing sectoral practices

Sectors that use GR/TKaGR in the EU vary considerably in the volume of their use of GR/TKaGR, in the commercial and non-commercial applications for those resources, the extent of existing practices for ABS compliance and in their coordination of these activities within each industry or sector.

For example, botanic gardens have some of the most well-established practices amongst the sectors for documenting the resources in their collections, although documentation standards may vary significantly depending on the resources available to individual gardens. Botanic gardens in the EU have well-developed procedures that are internationally recognised within the sector for ensuring compliance with ABS requirements under the CBD (130 botanic gardens in the EU, i.e. about one fourth of all EU botanic gardens, have subscribed to the IPEN code of conduct and take active part in exchanges of plant GR under the IPEN network). This sector also represents some of the highest volume use of genetic resources (stakeholders estimated around 2 million transaction in seeds per year in the EU, see EU baseline, chapter 10 and sectoral sheet on botanic gardens, Annex 3) in the EU and a high proportion of botanic gardens operate with constrained financial and human resources. Variation in implementation measures across EU Member States may make exchange activities by botanic gardens considerably more difficult. EU-coordinated action can help to mitigate some of these effects where the well-established practices already within the sector are promoted as best practice and/or encouraged as models for incorporation into MS systems. Coordinated action can also help support relevant institutions to improve their ABS practices (e.g. in the form of funding and training).

EU-level coordinated action is likely to have an overall positive impact on users in different sectors as it will help to facilitate best practice through standardised approaches to compliance. But as most implementation activity will be delegated to Member States, there is likely to be a high degree of variation in the extent to which MS implementation is compatible with existing practices in the different sectors. Positive impacts for different sectors from EU-level coordination will therefore be reduced by uncertainty and/or the complexity of understanding and complying with individual MS rules and procedures, particularly where these differ from already established approaches.

A soft EU OMC approach under Option A has the potential of enhancing and spreading best practices across the sectors but will fall short of addressing the challenges raised by heterogeneous implementation. EU-coordinated action can improve these practices, particularly where it builds on existing systems and standardises practices.

Sector costs / impacts

Legal uncertainty at EU-level across the sectors will increase the costs of compliance and obstruct existing practices. Coordination of voluntary measures at EU-level and promotion

of some of these in the development of MS approaches can enhance best practice and facilitate compliance within the different sectors. This can help reduce the costs to the users in the different sectors of adapting to new regulatory regimes and the potentially high transaction costs for exchange of GR/TKaGR if MS approaches vary significantly.

For example, biotechnology companies are engaged in commercially high-risk activities. They require legal certainty to understand the steps required to comply with the Protocol. Lack of harmonisation at EU-level may result in significant costs to these companies, depending on the variation in approaches by individual MS. Where EU-level practices have been developed voluntarily, EU-level support can help to reduce some of these costs.

But the users within the different sectors will still need to determine what the requirements are at MS level and develop approaches to comply in each case. This could result in significant administrative burdens and costs for the different sectors depending on the extent of variation and the particular measures introduced. All of the organisations providing responses to the EC public consultation indicated that coordinated EU-level legislative action is preferred to a variety of MS-level responses in order to reduce administrative burdens and costs.

Specific issues: SMEs

The "Think Small First" principle under the Small Business Act for Europe (SBA) (COM/2008/394) applies to all EU policy making. The SBA is based on the disproportionate regulatory and administrative burden faced by SMEs as compared to larger businesses. The SBA observes that for every €1 per employee spent by a large company to comply with a regulatory requirement, it might cost up to €10 per employee for a small business to comply with the same requirement. Any new legislative and administrative initiatives should therefore be assessed to determine their impacts on SMEs. Micro-enterprises in particular should be excluded from the scope of proposed legislation unless their inclusion can be deemed necessary and the burden proportionate.

The proportion of SMEs likely to be affected by the Protocol varies by sector. The pharmaceutical industry is dominated by large multinational companies, though SMEs (especially biotechnology companies) play a major role as well. Sectors dealing with GR that have substantial numbers of SMEs include: biocontrol, plant breeders and industrial biotechnology (see EU baseline, Annex 3). Moreover, a large number of SMEs dominate the food industry: 99% of the enterprises are SMEs, which employ 61% of the workers in the industry and account for 49% of the industry's total turnover. More specifically, micro-enterprises (1-9 employees) represent 79% of all companies. The small (10-49 employees) and medium sized (50-249 employees) companies account for 17% and 4% respectively, while the large companies (250+ employees) account for close to 1% of all the companies in the European food industry (see EU baseline, chapter 10).¹⁵⁷

¹⁵⁷ European Monitoring Centre on Change (EMCC) dossier on the European food and beverage sector, <http://www.eurofound.europa.eu/emcc/content/source/eu06026a.htm>

Under Option A to implement the Protocol in the EU, the administrative burden and costs for SMEs will be zero at EU-level, since no legislative action is taken. Nevertheless, when operating across the EU, the legal uncertainty and complexity created by different user compliance systems will increase transaction costs for those sectors. At MS-level, SMEs may face a variety of regulatory requirements, depending on the approach taken by the individual Member State. The burden on SMEs will vary in this case depending on the action taken by Member States. Nonetheless, all MS should consider the SBA in their legislative decision-making to reduce the burden where and to the extent possible.

Public costs

Recurring and one-off costs: EU-level

Recurring and one-off costs are likely to be minimal at EU-level. This option is the least costly for the EU to implement amongst the three options. One-off costs will be incurred to pay for meetings of stakeholders to discuss approaches, publications or other information dissemination approaches undertaken (e.g. websites, brochures, booklets, etc.). There will be recurring costs for staffing and for setting up and managing the EU focal point in order to carry out tasks such as supporting MS efforts by developing different options and discussing their respective merits, assessing and comparing MS measures and experiences, compiling reports on MS progress, based on information received from the MS.

Additionally some minor recurrent costs will be incurred as the EU will use its research funding and other relevant funding procedures to monitor compliance with provider countries' ABS legislation. More precisely some additional recurring costs would be made by DG Research & Innovation and other EU entities (such as DG Development & Cooperation) when acting as checkpoints, as they will have to read and evaluate some additional information in the proposals and to check project reports at later stages. Also some minor one-off costs will have to be made at EU-level to include a clause in the relevant provisions to that end.

Recurring and one-off costs: MS-level

Under Option A most of the institutions entrusted with compliance-related responsibilities (such as CNAs) would be located at the MS level. Recurring and one-off costs to Member States will vary considerably depending on the approach that each takes to implementing the Protocol. Heavily regulated systems will have high recurring and one-off costs (e.g. to develop new institutions to monitor compliance) whereas light or no regulation will have low (or no) recurring and one-off costs.

Member States will face some additional recurring costs to participate in EU-level coordination activities (participation in expert meetings, monitoring and reporting activities).

Governance

Practicability

This option is the most practical of all the three options for the EU, as very little action is required. The option will require some coordination at EU-level and there may be multiple arrangements that have to be agreed amongst different sectors. Nonetheless, it will be fairly straightforward to implement. At Member State level, there will be challenges to determine the best approach to implementation, and practicability will depend on the approach taken.

International political acceptability

This option will be acceptable to some but not all third countries. Provider countries in particular are likely to look to the EU for coordinated action toward full implementation of the Protocol. Non-legislative actions alone are likely to be considered insufficient by some countries.

Acceptability

Most Member States are likely to accept this option as they are signatories to the Protocol themselves, and have therefore signalled willingness to implement the Protocol. Some Member States, however, will prefer to have a harmonised approach across the EU and will find Option A less acceptable.

Most of the sectors, however, have expressed a clear wish to see coordinated legislative action at EU-level. This approach will therefore be unacceptable to most of the sectors primarily because of a general concern that lack of harmonised legislation will lead to high increase in transaction costs.

Transparency and understandability

This option can be very transparent to other Protocol Parties and to parties that use GR/TKaGR at EU-level, where well-coordinated action is taken. Transparency will be improved where the EU supports enforcement and monitoring of GR/TKaGR by compiling information received from national checkpoints through the establishment of an EU focal point. Compiling information from national checkpoints/CNAs at EU level would potentially improve the transparency for provider countries so that they can more easily monitor GR/TKaGR use.

The option may also encourage users to be more transparent about their approach to implementation.

Overall transparency is likely to be reduced as each Member State will take its own approach to implementation. It is likely to be less clear to third countries and to user groups within the EU what the requirements are amongst all 27 Member States.

Environment, biodiversity and health

Health

Impacts of Option A on health are far too speculative to be discussed in this section.

Environment & Biodiversity

The impact on environment and biodiversity under this option is very difficult to assess given that it would depend on the nature of individual Member State ABS rules and cooperation agreements. In principle one would expect an improvement in the environment compared to the baseline, though of the options it is the least likely to have a significant positive impact on environment/biodiversity conservation as it does the least at EU-level to ensure the good legal status of GR/TKaGR in the EU and therefore facilitate exchange amongst users across the user chain and across Member States. This option cannot ensure at EU-level that the ABS legislation of provider countries is respected, so provider countries have less of an incentive to protect their biodiversity as they will have a lower expectation or greater uncertainty that benefit sharing will take place. Furthermore, having different Member State approaches, this option leads to potentially high transaction costs which may reduce exchanges/ sharing of genetic resources, due to a high level of complexity in a fragmented EU regulatory environment. This might lead to a lesser value from the exchanges overall and hence less investment in nature within provider countries.

11.3.3 User Compliance Measures: “Option B” EU Action with Upstream Focus

Figure 11.1 presents the key measures under this Option and Table 11.6 presents a synthesis of the assessment against the criteria.

Figure 11.1: Flowchart of Upstream Measures

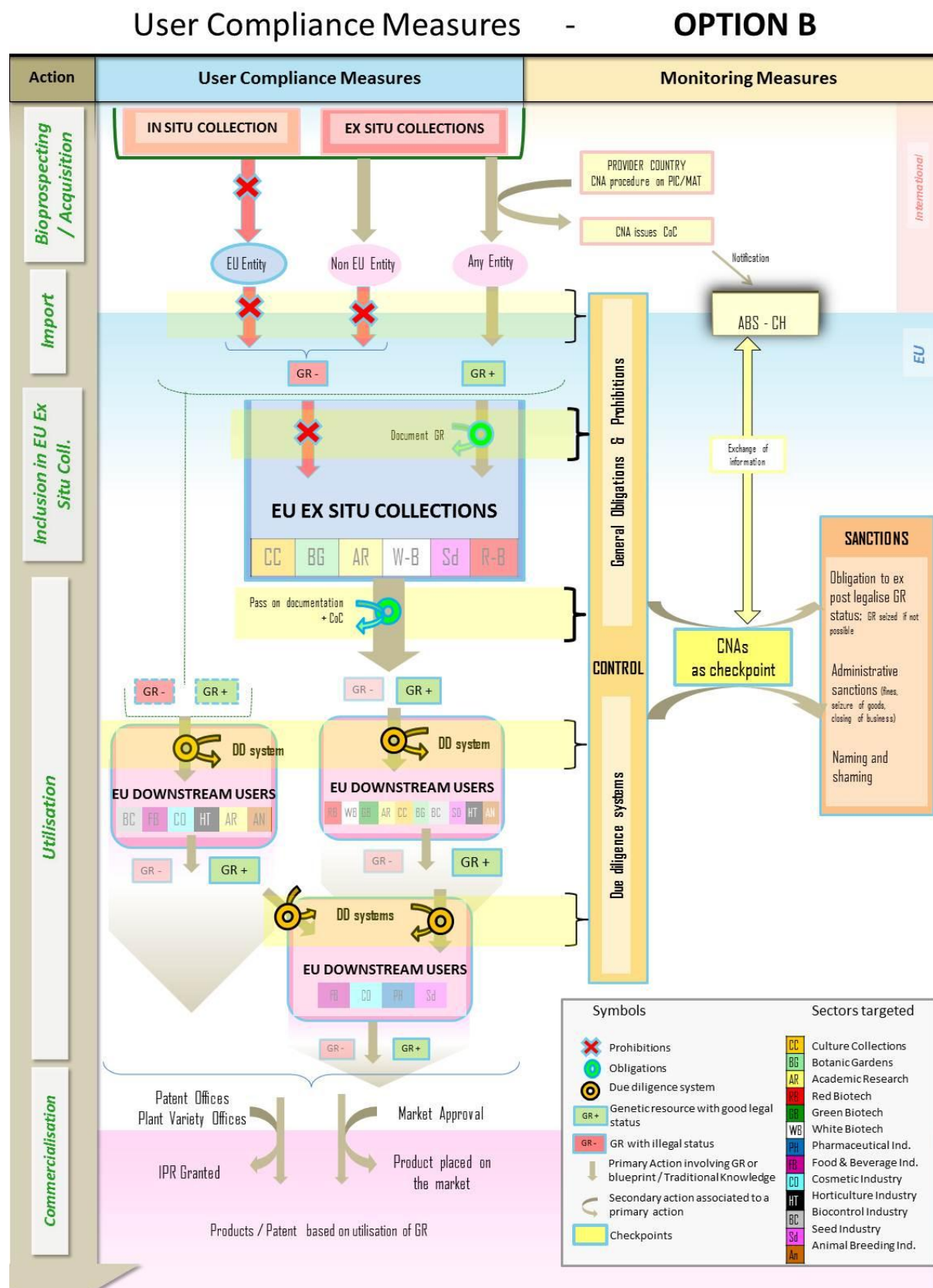


Table 11.6: Synthesis: overview of impacts associated with implementation of option B

IA Criteria	Business as Usual Scenario	Option B: EU Action with Upstream Focus
Addressing the ABS objective		
Implementing the Protocol objectives	No action to date at MS and EU level on user compliance, but some actions expected from some MS. Self-regulation by some user groups Private law governs benefit-sharing agreements No systematic monitoring at EU or MS level No sanctions for non-compliance with provider measures at EU or MS level	↗↗↗
Legal certainty, coherence with other legislation and enforceability		
Legal certainty	N/A: no user compliance regime in place in EU MS	Good legal certainty ↗↗
Coherence with other international obligations - ITPGRFA	No action, therefore coherence maintained with ITPGRFA	→
Enforceability - user compliance provisions and MAT	No enforcement for non-compliance with provider measures MAT enforceable through contract law	Upstream Prohibitions and obligations: ↘↘ in short term (as some GR documentation will be lacking) to ↘ in medium-long term (as national and international documentation improves)
		Due diligence: ↗↗ to ↗↗↗
		MAT: → to ↗
Compatibility of proposed options with existing practices		
Compatibility	Wide variation in the volume and type of use, extent of commercial vs. non-commercial use, Protocol awareness and existing ABS practices	Compatibility varies across and within sectors. Due diligence rules more likely to complement existing practices in downstream sectors: ↗↗. Compatibility likely to be an issue mostly in relation to upstream obligations (e.g. documentation requirements) imposed on users with limited financial and organisational resources (e.g. small botanic gardens and culture collections): ↘ Some upstream already have good information systems (e.g. large botanical gardens) → Overall: ↗
Sector costs / impacts		
Sector costs / impacts	No costs related to action – as no EU-level action required / taken	Upstream users (mostly <i>ex situ</i> collections with limited financial and organisational resources) likely to face higher costs in implementing upstream obligations, though costs will vary by sector and within sectors. Those already implementing good practices would face lowest costs. ↘↘ to ↘
	However, risks over time of sectors losses from reduced access to GR given lack of legal	Downstream users: Costs will vary by sector, but due diligence and upstream documentation obligations likely to entail moderate financial

	framework and impacts on collaboration with third countries. Over time this could be very significant for some sectors if a working global ABS system is in place: Short term↘ Risk in long term ↘↘↘	burdens on downstream users. For many downstream users due diligence is a familiar concept and routines are already in place where only an ABS facet would need to be added. ↘
Specific issues: SMEs		
SMEs	No costs at EU level - no action taken Costs where MS decide to take action	SMEs: ↘ limited costs as most SMEs are downstream and subject to more flexible due diligence systems
Public costs		
Recurring costs: EU-level	No costs – no action taken	↘
One-off costs: EU-level	No costs – no action taken	↘
Recurring costs: MS-level	Costs where MS decide to take action	Significant monitoring costs. Involvement of third parties in monitoring might limit rise in public costs. ↘↘
One-off costs: MS-level	Costs where MS decide to take action	↘↘
Governance		
Practicability	Practical – no action required	In terms of institutional setup (new CNAs) and monitoring (inspections) potentially less practicable than option C ↘
		In terms of EU law-making process more practicable than option C ↘ to ↗↗
International political acceptability	No action taken - unacceptable	Provider countries likely to perceive stringent EU implementation positively, but approach under Option B at variance with preferred implementation approach pursued by many provider countries during Protocol negotiations. ↗↗
Acceptability	MS – Unacceptable as Parties to the NP	<u>MS</u> : ↘ to ↗↗
	Sectors – Acceptable for most sectors	<u>Sectors</u> : ↗ to ↗↗
Transparency & understandability	Complete transparency – no action taken	<u>Users</u> : ↗↗↗
		<u>Providers</u> : ↗↗
Health, Environment and Biodiversity		
Health	No interference with WHO GISRS health emergency regime. No interference with pharma R&D.	Impacts are speculative and cannot be assessed
Environment & Biodiversity	No change as no action taken	Ensures incentive for biodiversity conservation but may burden activities and research aimed at the conservation of biodiversity Overall → to ↗↗

Addressing the ABS objective

Implementing the Protocol objectives

Under this option, the EU meets all of its compliance obligations under the Protocol. A prohibition is put in place to restrict upstream use of genetic resources and associated traditional knowledge only to those cases where resources were obtained legally. A due diligence system is also required for all users to take active steps to ensure that GR and associated TK are only accessed in accordance with PIC and that MAT are established as required by provider country regulation. Monitoring will be undertaken by CNAs and/or third parties. Implementation at EU-level is fully compliant with the EU's compliance obligations as this option introduces binding (i.e. enforceable) requirements on users.

This option controls the use of GR/TKaGR from an early stage in the user chain. An effectively implemented system ensures that only those resources acquired in compliance with the Protocol are likely to circulate in the EU in the future. Users will have high legal certainty when utilising GR/TKaGR, at least in the mid-term. This will be particularly important for downstream users such as pharmaceutical companies that face a high degree of uncertainty regarding the legal status of GR and TKaGR where this is not secured upstream and transmitted via intermediaries.

Bilateral agreements with individual provider countries on providing a framework for capacity-building on ABS or a framework for technology transfer and cooperation on R&D can indirectly improve access to genetic resources in those third countries. Such capacity-building may for instance indirectly benefit users of GR in as far as it contributes to improving provider countries' legislative frameworks on ABS and authorities' implementation capacity. Bilateral agreements can also help EU *ex-situ* collections cope with some of the challenges of an upstream-focused intervention.

Legal certainty, coherence with other international obligations and enforceability

Legal certainty

Legislative action can provide legal certainty for users because an upstream prohibition against acquiring or including GR and TKaGR in a collection or passing these on to other users without appropriate documentation will create a 'chain of custody' for all GR/TKaGR acquired after the rules come into force. This approach is more likely than one that focuses downstream to ensure legal certainty for downstream users of GR and TKaGR, who often obtain these from intermediaries and not directly from provider countries. This option can also benefit upstream users because they have duties to ensure that provider country requirements are followed for all uses of GR/TKaGR.

Information obligations will be uniform across uses; therefore, the information transmitted across the user chain should be consistent. Furthermore, establishing the burden of proof (whether on the public authority for upstream uses, and on operators for downstream due diligence requirements) will provide users with predictability about enforcement procedures, which is a core component of establishing legal certainty. Similarly, specifying sanctions provides predictability regarding the likely outcome of any enforcement action.

An EU-wide, harmonised approach to Protocol implementation will help EU organisations have legal certainty across different national contexts. Stakeholders from all of the user groups that responded to the European Commission public consultation indicated that ensuring legal certainty is of primary importance for them when the Protocol is implemented. This option will be important to fulfilling this primary need of users of genetic resources and associated traditional knowledge.

Coherence with other international obligations:

Genetic resources covered by the ITPGRFA are excluded from the application of the Protocol. The EU and its 27 Member States are parties to the Treaty. Option B is unlikely to impact on the baseline scenario if harmonised EU-level measures exclude GR covered by the ITPGRFA from their scope; in that case, they will be unlikely to directly interfere with the functioning of the Treaty.

Enforceability

Generally, the benefit of Option B is that focusing the monitoring and enforcement efforts at the top of the utilisation chain through inspections by a CNA will ensure that the majority of GR being utilised and circulating down the utilisation chain will also be properly sourced and documented.

In terms of enforceability, however, there are considerable disadvantages compared to Option C. Inspection activities under Option B will focus on a very large number of genetic resources at a very early stage of the value chain, where potential benefits have not yet become apparent. A high volume of GR transactions occur upstream and a large number of GR are stored in *ex situ* collections; moreover, actors operating upstream are often difficult to identify (particularly in the horticulture and academic research sectors) (see EU Baseline, chapter 10). In light of the fact that detection of non-compliance under Option B will require a proactive approach by national authorities, it is likely that considerable efforts by the public authority will be needed to detect cases of non-compliance, and this will only cover a small proportion of the likely cases. As inspections will be on the basis of a risk-based approach, efficiency in detecting non-compliance is however expected to increase in the medium and long term as knowledge of risks of non-compliance across sectors will likely improve over time.

Specific issues:

Upstream prohibitions: the prohibition to import, acquire or include in a collection and pass on to other users genetic material without appropriate documentation are the least problematic in terms of enforceability for public authorities under Option B. Compliance can be directly checked through inspections on GR samples held by a certain operator. Nevertheless, in addition to the general considerations in the paragraph above, if, as recommended, the burden of proof is on the public authorities to prove that GR included in the collection or passed on to other users lack appropriate documentation, in the short term this could result in time consuming and costly investigations on the legal and administrative procedures on PIC in every country providing GR. The creation of a system of internationally recognized CoCs is likely to considerably reduce some of these problems, but will not

introduce any means to efficiently check, in the short term, situations in which GRs collected fall outside the remit of the NP, and thus are not accompanied by any PIC/MAT documentation.

Problematic in terms of enforceability is also the prohibition to engage in bioprospecting in third countries without obtaining PIC/MAT, which the EU could adopt. As the prohibited activity, by definition, takes place outside the EU, it is likely that this prohibition will be only enforced on request of and in cooperation with competent authorities of the countries of origin of the GR. In fact, inspection of *ex situ* collections or other users engaging in bioprospecting is likely to only spot the *lack of* documentation related to a genetic resource, something that does not directly allow the tracing of the individual or company engaged in illegal bioprospecting.

Upstream Obligations: Enforcement of obligations to document the date of inclusion in the collection, the country of origin, etc. is expected to be relatively straightforward in the long term. In the short term, enforceability is expected to be less efficient because of the likely initial knowledge gap for competent authorities as to how genetic resources are documented in different *ex situ* collections. The extent of this problem is therefore also contingent on the level of detail of documentation obligations imposed on *ex situ* collections (i.e. more detailed and standardised documentation requirements are easier to check, although with potentially negative effects in terms of flexibility and adaptation to existing sectoral practices).

Downstream due diligence system: Generally, enforcing the obligation on operators utilising genetic resources to set up due diligence systems with the aim of ensuring that GR utilised have been appropriately sourced is expected to be easier compared to the inspections of compliance with the upstream prohibitions, although the number and variety of operators to be checked may be considerably higher (see generally EU Baseline, chapter 10). In fact, the monitoring carried out by a competent authority or an accredited due diligence organisation will not be primarily directed at the checking of GR samples and whether they were legally acquired but will mostly focus on ensuring that operators have put in place effective systems for ascertaining that GR utilised have been appropriately sourced. Enforcement of the due diligence system will also be facilitated by the fact that the burden of proof will likely be on the operators to show that GR they utilise are acquired in compliance with their due diligence obligation.

The use of private accredited sectoral organisations to carry out checks on the due diligence performance of their members has the advantage of shifting part of the monitoring burden onto the private sector, thus enabling competent authorities to engage in more targeted checks. Moreover accredited organisations would likely be able to more effectively check the due diligence performance of their members on the basis of their greater knowledge of sectoral practices.

Enforcement of MAT: As MAT-related cases will be handled by MS courts, and related procedural provisions are primarily within the area of MS competence, the direct influence of EU action on the enforceability of MAT is limited. It will be enhanced if the EU takes some

of the supporting measures discussed, such as providing legal aid for ILCs or developing model provisions for MAT that are formulated in a way to be judiciable.

Sanctions: Criminal sanctions are expected to be the least enforceable type of sanction. While it could be argued that the threat of criminal penalties has a more powerful deterrent effect on users, the standard of proof for enforcing a criminal sanction is generally very high (i.e. beyond reasonable doubt), making the enforcement process and lawsuits more expensive and with a lower probability of successful prosecutions. In light of doubts as to the proportionality and appropriateness of criminal sanctions in this area and the potentially very high number of violations in the short and medium term in certain sectors (see considerations below on compatibility with existing sectoral practices), it is likely that an enforcement system based on criminal penalties would be inefficient and thus lose credibility together with its deterrence effect.

Civil and/or administrative fines are expected to be more easily enforceable (lower standard of proof and cost of prosecution) and flexible compared to criminal sanctions.

The obligation to *ex post* require PIC/conclude MAT would also be an appropriate sanction to ensure compliance under Option B, although it would only be practical with regard to enforcement of upstream obligations (i.e. following the discovery of a GR sample without appropriate documentation) and in cases where it is easy to ascertain the origin of a certain undocumented GR. As a result civil/administrative penalties would likely be needed to complement this type of sanction.

While “naming and shaming” may be considered as too soft on its own to bring about effective compliance of all operators with user compliance legislation, if combined with other sanctions (e.g. civil/administrative fines) it may improve compliance of upstream and downstream operators when their reputation is an important factor in the user chain, while being very easy to enforce for public authorities. For upstream operators, being “named and shamed” could result in downstream operators not sourcing from them anymore because of the risk of violating their due diligence duties. Amongst downstream operators, large companies (e.g. big biotechnology companies, food and beverage or cosmetic companies) are most likely to be pushed towards effective compliance as they place a high value on their reputation with consumers and the public, more generally.

DG Research & Innovation, Development & Cooperation as checkpoints: making EU funding for research and innovation/ development and cooperation contingent on compliance with provider countries legislation will only enhance enforceability of upstream measures for operators making use of EU funding. Those operators primarily belong to the public sector (see Option A above), i.e. research and development carried out by the academic sector or cooperation projects carried out by botanic gardens in developing countries (see EU baseline chapter 10 and relevant sectoral sheets, Annex 3). Under this sub-option the burden of proof is on operators through notification requirements and provision of information as to whether GR will be accessed/utilised and whether third country access legislation has been complied with. It will be easy for the European Commission to check whether GR have been utilised by the operator, as this will likely become apparent from the description of the research project and/or the research results.

Compatibility of proposed options with existing sectoral practices

Sectors that use GR/TKaGR in the EU vary considerably in the volume of their use of GR/TKaGR, in the commercial and non-commercial applications for those resources, the extent of existing practices for ABS compliance and in their coordination of these activities within each industry or sector. The compatibility of option B with existing practices will thus vary accordingly.

For example, the biotechnology sectors represent commercially-focused activity, with high costs and low likelihood of developing a product with commercial viability (commercially high-risk sector). The sector faces additional risk where it cannot be certain that genetic resources have been accessed in accordance with the Protocol, and where the terms of use are not clearly indicated. The sector will therefore benefit from measures that ensure the use of GR/TKaGR within the EU is controlled from an early stage when these resources enter the EU. As intermediaries engaged in commercially high-risk activities, the sector will benefit further from being able to ensure the good legal status of any GR/TKaGR that may be passed on, particularly for further R&D and/or product development by other companies. Due diligence rules for these users will provide flexibility in the approach they take to compliance, which allows them to tailor their practices according to the needs and capacity of the sector and individual companies.

The horticulture sector relies heavily on the improvement/transformation of a relatively limited number of plant species that were acquired pre-CBD. Most uses within the sector, however, do not fall under the ITPGRFA and there is little experience with voluntary ABS measures in the sector. There are a small number of users in this sector that rely on bioprospecting to introduce novelty in the system, and these users are largely thought not to comply with ABS requirements under the CBD. Overall, the sector will benefit from measures that ensure the use of GR/TKaGR within the EU is controlled from an early stage when they enter EU jurisdiction, but bioprospectors will have more difficulty adapting new rules to existing practices.

Heavy upstream users of GR/TKaGR such as botanic gardens and culture collections are likely to be the most affected by this option as they will have specific obligations to fulfil. For example, members of the WFCC (one third of which are based in the EU) have been estimated to distribute 500.000 samples of microbial GR annually. The degree to which these organisations will be affected by upstream measures will depend on the extent to which they have already documented the origin of the materials in their collections and the extent to which the requirements imposed by the EU to implement the Protocol deviate from existing exchange practices (e.g. those set up under the IPEN system, MOSAICC international code of conduct; ECCO core MTA). Small botanic gardens and culture collections are likely to have less documentation due to lack of resources and are less likely to participate in voluntary ABS systems within the sector (see EU baseline, chapter 10). It is likely to be more of a challenge for these smaller organisations to comply with new rules.

Due diligence rules are more likely to complement existing practices in downstream sectors overall because it is largely up to the user to determine the steps required to comply with requirements. Due diligence rules can also benefit small organisations as they can adopt an approach tailored to their capacities and needs.

Sector costs / impacts

Legal certainty is facilitated at EU-level across the relevant sectors, which will help to reduce the costs of compliance. A due diligence system is also likely to help keep costs for users in the different sectors low as it allows flexibility depending on the actor, sector and situation; EU users are able to determine what is required of them, which can help reduce the costs to the sectors of adapting to the new regulatory regime and to keep transaction costs low.

Overall, this option will increase costs for all sectors, though there will be variation in the degree to which costs rise depending on a user's position in the value chain and use of genetic resources. Upstream users, particularly *ex situ* collections, are likely to face higher costs, as they will be responsible for the setting up of efficient internal documentation systems and for ensuring that all GR meet provider country ABS rules and to only pass on GR of good legal status. The highest costs will be faced by those upstream users that do not have systems in place already for ensuring the good legal status of their materials, such as companies within the horticulture sector, universities/research institutions and small botanic gardens and culture collections with limited financial and organisational resources. Costs for the heaviest upstream users such as large botanic gardens and culture collections should not be considerable as these sectors generally already have advanced documentation systems in place (see EU baseline, chapter 10).

Apart from the costs flowing from the obligation on upstream users to adapt and upgrade their documentation systems, with regard the other obligations under Option B the extent of costs imposed on the users within the different sectors will be largely dependent on the specific information obligations required under this option. Costs of demonstrating compliance for sectors are overall expected to be moderate for the compliance of both upstream and downstream obligations. As to upstream obligations to acquire and pass on properly acquired GR with the appropriate documentation, the burden of proof will be on public authorities, which will have to bear the cost of demonstrating that a certain GR falls under the NP and has not been appropriately collected. As regards downstream obligations, the burden of proof for demonstrating compliance with the due diligence system will be on operators. Operators, however, will merely have to demonstrate their procedural compliance (e.g. that appropriate steps have been taken to ensure compliance) and will not have to bear the burdensome obligation to prove that individual GR they have utilised have been appropriately sourced. Given the flexibility of the due diligence standards (see considerations above) and the familiarity with the concept of due diligence by a number of downstream users (in particular pharmaceutical and biotechnology MNEs), the costs of setting up as well as for operating the due diligence system for downstream users are expected to be moderate overall. The setting up and running of accredited due diligence organisations to monitor certain groups of operators will clearly increase the costs for the operators involved (while decreasing the costs for public authorities). The setting up of

those organisations is, however, entirely voluntary; as a result no problem of acceptability is likely to arise from the associated costs.

Specific issues: SMEs

The Commission will need to consider how to accommodate SMEs under the SBA to implement the Protocol in the EU. Under Option B, the due diligence obligation leaves SMEs considerable flexibility as to how to comply with their due diligence duty. Moreover, due diligence requires the best-efforts of users; thus the standards are less strict for an SME with 10 employees than for a multinational corporation with a huge research department. Exemptions may also be possible— for example, where an SME is judged to be at low-risk of non-compliance or where the steps to prove compliance can be adjusted to reduce the burden on these businesses to provide information. A due diligence system, thus, is likely to constrain the costs to SMEs to implement the Protocol and in particular will keep costs lower for downstream SMEs compared to option C. As option B covers the entire user chain, however, upstream users will likely have a greater burden to ensure compliance requirements are met under provider country rules and that collected GR are properly documented. This might be the case for small pharmaceutical and industrial biotech companies that engage in bioprospecting (see EU baseline, chapter 10). Nevertheless, increased costs for upstream SMEs in relation to compliance with upstream obligations are likely to be contained. In fact, unlike botanic gardens or culture collections, SMEs are less likely to have large collections of GR requiring the setting up of an efficient and elaborated documentation/tracking system.

Public costs

Recurring and one-off costs: EU-level

Recurring and one-off public costs will be incurred at EU-level. Option B is more costly for the EU to implement than the non-legislative Option A. It is not entirely clear whether Option B will be more costly for the EU to implement than Option C. On the one hand, under Option B a completely new regulatory framework is to be established. On the other hand, Option C may require the application of new rules by a large number of different institutions as well as legislative changes to many different existing legislative acts, which could also be very costly.

Measures relating to upstream uses:

One-off costs will be incurred to develop new legislation stipulating a prohibition to engage within the EU in certain upstream activities involving GR that have not been accessed on the basis of PIC and/or where no MAT have been established. As the new regulatory framework is likely to be included in one single Regulation, those one-off costs for the EU will lower than under Option C.

Recurring costs are unlikely to be incurred for monitoring compliance of upstream obligations, unless the EU decides to establish a CNA for this purpose. Optionally some minor costs might be incurred if the EU decides to use its research funding and other relevant funding procedures to monitor compliance with the upstream measures. In that case some additional recurring costs might be made by DG Research and Innovation and

other EU entities when acting as checkpoints. Note that the EU might also take this measure under options A and C.

The EU will also incur recurrent costs if it would take measures to support users in complying with their upstream obligations, notably by providing funding and training for *ex situ* collections.

Due diligence system for EU users

In order to set up a due diligence system for EU users, EU legislation will have to be developed imposing due diligence obligations upon EU users and therefore one-off costs will be incurred at EU level. These due diligence obligations are likely to be inserted in one single Regulation incorporating the new regulatory framework for the whole of Option B, including the rules with respect to upstream uses. Therefore, as mentioned already above, one-off costs for the EU for developing new legislation will be lower than under Option C.

The EU might also incur costs for accrediting sectoral due diligence organisations, if this task is assigned to the EU rather than to the Member States.

Recurring and one-off costs: MS-level

Recurring and one-off financial costs to Member States will increase compared to the baseline and Option A. The balance of costs will depend on the extent to which monitoring and reporting are delegated to MS authorities. As mentioned earlier, it is however very likely that monitoring and reporting will be done at MS level.

Option B would require the establishment of independent competent authorities in MS and therefore MS will incur significant one-off costs. As the monitoring of compliance with the upstream obligations and the due diligence system for downstream users will be done by these MS CNAs, MS will also incur most of the related recurring costs. CNAs would have to embark on regular inspections, based on an analysis of where the risk of non-compliance is greatest. This might require significant resources, especially in the short term – in the medium and long-term this might incur lesser costs as the knowledge of risks of non-compliance across sectors will likely improve over time. Checks on upstream users are likely to generate most of the recurrent costs for the CNAs. A high volume of GR transactions occur upstream – member culture collections of the WFCC (one third of which are based in the EU) have been estimated to distribute 500.000 samples of microbial GR annually – and a large number of GR are stored in *ex situ* collections (see EU baseline, chapter 10).

Third parties (e.g. accredited due diligence organisations) however may be involved in monitoring compliance of the due diligence obligations. This may limit the increase of monitoring-related public costs, shifting part of the regulatory costs on operators. CNAs would still be required to carry out independent checks on users, but could do so less frequently. The CNA however would have to ensure that third parties adequately perform their monitoring duties and therefore would have to carry out spot checks of those organisations.

Furthermore, checks carried out by accredited organisations might be cheaper overall as those organisations generally have better knowledge of the way GR are documented and

exchanged in their sector. As the focus of compliance and enforcement is not directed at checking of GR samples, but merely on verification whether effective due diligence systems have been put in place by operators for ascertaining that the genetic resources are legally acquired, the public costs of the due diligence system for downstream use would be considerably lower in comparison with a situation whereby user prohibitions would be enforced through inspections by public authorities directed at checking GR samples (such as in the case of the measures relating to upstream uses). However, public costs in relation to monitoring and enforcement are likely to be higher compared to the monitoring activities by the checkpoints under Option C (as existing regulatory frameworks and institutions are to be used).

Governance

Practicability

From the point of view of institutional set-up this option is less practical than Option A and potentially also less practical than Option C, depending on the specific provisions taken under the latter. Under Option B, new self-standing institutions are to be set up. In terms of monitoring, the proactive role given to MS CNAs in monitoring and enforcing the compliance of operators with upstream obligations under Option B is likely to be resource-intensive for public authorities. This option will in fact require public authorities with initially little knowledge of sectors' activities and documentation systems to conduct inspections in potentially enormous collections and number of transfers of GR. In addition, given the current inexistence of a working system of internationally recognised certificates of compliance, checks on documentation will require a good knowledge of legal requirements relating to access to GR in third countries. Those barriers to the practicability of Option B in terms of enforcement by public authorities are therefore expected to be significantly reduced in the medium-long term. Monitoring and enforcement related to the due diligence obligations are expected to be easier, particularly when the monitoring system is complemented with accredited due diligence organisations (see enforceability above). The practicability of Option B is expected to increase in the medium or long term, once the majority of upstream documentation systems are in line with legal requirements and GR circulating down the chain are easily traceable.

This option is nevertheless more practicable than Option C from the point of view of EU level law-making process. While Option B, in fact, could be easily implemented through just one comprehensive Directive or Regulation, Option C would require the amendment of a number of existing EU as well as international rules.

International political acceptability

Provider countries are more likely to trust in an EU-wide legislative approach than in a coordinated approach, with implementation delegated to MS. This option will be acceptable to many third countries, but may be less acceptable than option C which is closer to the preferences of many developing countries in the Protocol negotiations. Provider countries in particular are likely to look to the EU for coordinated action toward full implementation of the Protocol. ABS legislation that covers the entire user chain for GR/TKaGR will be a significant step towards international acceptability of implementation.

Acceptability

At Member State level, this approach will be acceptable for some Member States, where they prefer to have EU-level legislation, rather than developing their own, which could be costly and time-consuming. This option will be unacceptable for other Member States that prefer to develop their own measures. This is supported by the fact that Member States are themselves Parties to the Protocol and that some MS have commissioned their own studies to assess the options for implementation of the Protocol.

Users in most of the sectors have expressed a clear wish to see coordinated legislative action at EU-level. This approach will therefore be acceptable to most of the sectors primarily because of a generalised concern that lack of harmonised legislation will lead to high increase in transaction costs. The approach will likely also be more acceptable to users in some of the sectors than option C, since it improves legal certainty throughout the user chain. Some sectors are also opposed against the use of IP offices as checkpoints as proposed under option C. A due diligence system is likely to have higher support from users within the different sectors as it can accommodate already existing practices in the different sectors (e.g. biotech companies already engage in due diligence), or as at least some commercial users are familiar with the concept of due diligence (e.g. in the pharmaceutical industry).

Transparency & understandability

This option provides a high degree of transparency at EU-level. Dedicated EU ABS regulation is the most transparent option to ensure that other Parties can determine that implementation has occurred and the extent of implementation. This option will also be more transparent for users regarding the actions they need to take compared with option A.

Option B and C are more or less equal as far as transparency for users are concerned. As to transparency and understandability for providers, option B might be slightly less transparent and understandable compared to option C as the due diligence system for EU users under option B allows several approaches. Indeed, how EU users would achieve the aim of due diligence is largely left to them.

Environment, biodiversity and health

Health

Impacts of option B on health are far too speculative to be discussed in this section.

Environment & biodiversity

This option is the most likely to have a positive impact on environment/biodiversity conservation as it helps to ensure the good legal status of GR/TKaGR in the EU and therefore facilitates exchange amongst users. By ensuring that ABS legislation of provider countries is respected, this option generally ensures that provider countries will have an incentive to protect their biodiversity as they will have a stronger expectation that benefit sharing will take place. By placing the burden on public research and *ex situ* collections,

however, this option may also indirectly place a burden on research and activities benefitting the conservation of biodiversity.

11.3.4 User Compliance Measures: “Option C” EU Action with Downstream Focus

Figure 11.2 presents the key measures under this Option and Table 11.7 presents a synthesis of the assessment against the criteria.

Figure 11.2: Flowchart of Downstream Measures

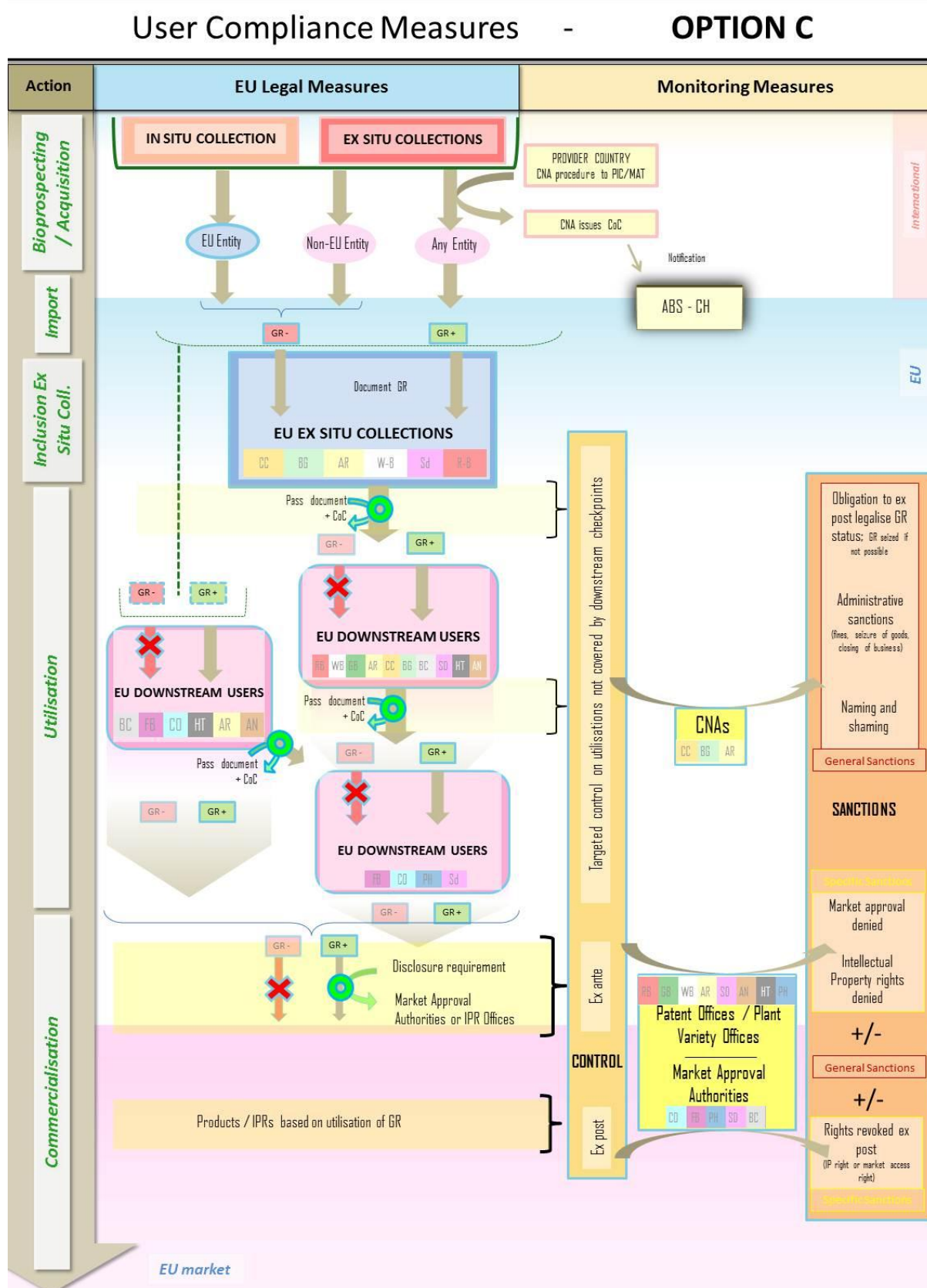


Table 11.7: Synthesis: overview of impacts associated with implementation of option C

IA Criteria	Business as Usual Scenario	Option C: EU Action with Downstream Focus
Addressing the ABS objective		
Implementing the Protocol objectives	No action to date at MS and EU level on user compliance, but some actions expected from some MS Self-regulation by some user groups Private law governs benefit-sharing agreements No systematic monitoring at EU or MS levels No sanctions for non-compliance with provider measures at EU or MS levels	↗↗ to ↗↗↗
Legal conformity, certainty, coherence with other legislation and enforceability		
Legal certainty	N/A: No user compliance regime in place in EU MS	EU-harmonisation to provide some legal certainty. However, the challenge of downstream users that obtain material from earlier upstream users is not addressed with potential negative effects in terms of investments in R&D and costs on downstream users for tracing back GR in potentially long utilisation chains. ↘↘ to ↗
Coherence with other international obligations - ITPGRFA	No action, therefore coherence maintained with ITPGRFA	→
Enforceability - user compliance provisions and MAT	No enforcement for non-compliance with provider measures MAT enforceable through contract law	Checks are strategically integrated in user chain. However, substantial number of utilisation activities might fall outside scope of monitoring/enforcement activities, unless CNA is established to cover those. Problems of enforceability, as with option B (upstream) also relate (particularly in short term) to difficult investigations of public authorities into situations where GR utilised lack documentation. ↗ to ↘↘
		MAT: → to ↗
Compatibility of proposed options with existing practices		
Compatibility	Wide variation in the volume and type of use, extent of commercial vs. non-commercial use, Protocol awareness and existing ABS practices	Compatibility of option with existing practices will vary across and within sectors. ↘↘ (Downstream users) to ↗↗ (Upstream users)
Sector costs / impacts		
Sector costs / impacts	No costs related to action – as no EU-level action required / taken	Limited costs for upstream users, though may vary by sector. Some upstream users may see no change. ↘ to →

	However, risks over time of sectors losses from reduced access to GR given lack of legal framework and impacts on collaboration with third countries. Over time this could be very significant for some sectors if a working global ABS system is in place: Short term↘ Risk in long term ↘↘↘	Downstream users (particularly those making high use of IPR Offices or Market Approval authorities) likely to face higher costs in general than upstream users ↘↘ to ↘
Specific issues: SMEs		
SMEs	No costs at EU level - no action taken Costs where MS decide to take action	Upstream SMEs: ↘
		Downstream SMEs: ↘↘↘ to ↘
Costs: Public		
Recurring costs: EU-level	No costs – no action taken	↘↘ to ↘
One-off costs: EU-level	No costs – no action taken	↘↘ to ↘
Recurring costs: MS-level	Costs where MS decide to take action	Monitoring costs at MS level are likely to slightly less than under Option B. ↘↘ to ↘
One-off costs: MS-level	Costs where MS decide to take action	↘↘ to ↘
Governance		
Practicability	Practical – no action required	In terms of institutional set-up and monitoring: ↗↗
		In terms of EU law-making process less practicable than option B ↘↘ to ↗
International acceptability	No action taken – unacceptable	Option C reflects the preferences of many developing countries in the Protocol negotiations most closely ↗↗↗
Acceptability	MS – Unacceptable as Parties to the NP Sectors – Acceptable for most sectors	MS: ↘↘ to ↗↗
		Sectors operating upstream: ↗
		Sectors operating downstream: ↘↘↘
Transparency & understandability	Complete transparency – no action taken	Users: ↗↗↗
		Providers: ↗↗↗
Health, Environment and Biodiversity		
Health	No interference with WHO GISRS health emergency regime. No interference with pharma R&D.	Impacts are speculative and cannot be assessed
Environment & Biodiversity	No change as no action taken	High potential costs downstream in value chain may reduce use/exchange of GR in the EU, but legal certainty may improve exchange. Overall → to ↗↗

Addressing the ABS objective

Implementing the Protocol objectives

Under this option, the EU meets all of its compliance obligations under the Protocol. Supporting measures adopted at EU-level can help facilitate monitoring and reporting, and provide assistance to MS and sectors in developing compliant approaches to ABS requirements. Option C is fully compliant with the EU's compliance obligations as this option introduces binding (i.e. enforceable) requirements on users, though there will be some gaps in coverage of upstream users since most of the use occurs early on in the user chain and this option focuses on checking downstream use. There will also be gaps in the coverage of downstream users, as not all products that utilise GR/TKaGR pass through IPR systems or require market approvals. These products however might be covered through monitoring by independent CNAs, though this type of monitoring is likely to be less intensive than monitoring through IP offices and/or market approval authorities.

This option controls the use of GR/TKaGR at a late stage in the user chain. In this system, there is a high likelihood of resources circulating in the EU that were not acquired in compliance with the Protocol. These resources are most likely to be of low or non-commercial value, however, since the focus of activities under this option will be on activities likely to generate the most commercial value. As the use of GR/TKaGR is mostly only controlled towards the end of the user chain, some companies in certain sectors (such as the pharmaceutical industry) might be discouraged to utilise genetic resources. This could result into a reduced demand for genetic resources and hence less benefits to be shared, thereby potentially undermining one of the purposes of the Nagoya Protocol (i.e. facilitating the exchange of genetic material and related benefit sharing with the aim of providing an incentive to the preservation of genetic and biological diversity).

Nonetheless, this option is likely to improve trust between provider countries and EU users, which may motivate provider countries to provide or facilitate greater access for EU users to GR/TKaGR. In addition, bilateral agreements with individual provider countries on capacity-building on ABS in the provider countries concerned or technology transfer and cooperation on R&D can indirectly improve access to genetic resources in those third countries. Such capacity-building may for instance indirectly benefit users of GR in as far as it contributes to improving provider countries' legislative frameworks on ABS and authorities' implementation capacity. This facilitated access to genetic resources may, in turn, lead to more legal use of GR/TKaGR and subsequent fair and equitable sharing of benefits.

Legal certainty, coherence with other international obligations and enforceability

Legal certainty

Stakeholders across each of the user groups that responded to the European Commission public consultation indicated that ensuring legal certainty is of primary importance for implementing the Protocol. Legislative action under option C may provide some legal certainty for users as an EU-wide harmonised approach to Protocol implementation will help organisations that work across the EU to have legal certainty across different national contexts.

Nevertheless, by focusing downstream, this option will not fully address the problem of legal certainty for GR obtained by downstream users from upstream users. This option creates an obligation to demonstrate compliance at a late stage in product development or at the point of commercialisation, but does not provide effective mechanism to guarantee the legal status of genetic resources and TKaGR that pass through intermediaries to the end user. Downstream users (such as pharmaceutical and green biotech companies) may therefore have to make considerable efforts to ensure that GR transferred down the user chain were originally sourced legally from the provider country. These users may also find it difficult to locate and obtain GR from upstream users that already have a sufficient contractual guarantee to verify the legal status of the materials. Typically, upstream players in the utilisation chain will be individual researchers, SMEs or micro-enterprises that may not have the means of giving a credible contractual guarantee of good legal status of material provided. Under this option, many of these earlier users would not be subjected to monitoring measures and thus not have a direct incentive to take on legal responsibility for the good status of legal genetic resources utilised. An additional challenge for downstream users is that their obligations to disclose would kick in not only if they themselves have used genetic resources in a relevant way, but might also be triggered through relevant utilisations of genetic resources by earlier users in the chain that may or may not be properly documented and reported.

This will create a particular problem for downstream users engaged in high risk and high cost uses of GR. Some sectors, particularly pharmaceuticals, have already indicated a move away from the use of GR as a result of legal uncertainty arising from the CBD. This situation is likely to continue or become more acute under the Protocol without sufficient legal certainty for these users. These difficulties may be mediated to an extent by the practices of *ex situ* collections that already apply codes of conduct (e.g. the IPEN Code of Conduct) to ensure that GR they pass on have been acquired in line with provider country ABS measures. Thus, downstream users may focus on acquiring resources from intermediaries who apply such codes, which in the long term could also motivate other intermediaries to adopt similar practices.

Similar to Option B, Option C places uniform information obligations on GR/ TKaGR uses for which documentation will be required (i.e. for uses that pass through a particular checkpoint). The information required and transmitted to checkpoints should be consistent as a result. Establishing the burden of proof (in this case on operators) and specifying sanctions provides predictability regarding the likely outcome of any enforcement action.

Coherence with other international obligations

Genetic resources covered by the ITPGRFA are excluded from the application of the Protocol. The EU and its 27 Member States are Parties to the Treaty. Option C is unlikely to impact on the baseline scenario if harmonised EU-level measures exclude GR covered by the ITPGRFA from their scope; in that case, they will be unlikely to directly interfere with the functioning of the Treaty.

Enforceability

Compared with Option B, there is one major benefit in focusing enforcement action downstream, notably by entrusting market approval authorities and IPR offices with monitoring and enforcement functions. Checks on compliance with Option C obligations are strategically integrated in the utilisation chain, focusing enforcement measures on the utilisation of genetic resources where it creates the highest commercial value (i.e. the activities that are likely to yield the most substantial benefits to provider countries). As a result, monitoring and enforcement authorities integrated in the user chain, as provided for by the protocol, will not need to actively seek information on GR from users as disclosure requirements at the level of IPR applications/market approval ensure that information will flow directly from users to enforcement authorities. As those procedures are a *sine qua non* condition for marketing or legally protecting certain products or processes, users have a strong incentive to go through them and thus comply with their procedural requirements.

One of the problems in terms of enforceability is the situation in which the lack of documentation in relation to a GR is due to the fact that it has been sourced from a free access jurisdiction, it has been sourced in a country before ABS legislation was put in place or has been sourced from areas beyond national jurisdiction. While the burden under Option C is on users to provide appropriate documentation demonstrating the good legal status of the GR, once the operator declares that the GR lacks documentation it will be for the relevant checkpoint to make sure the declaration is correct.¹⁵⁸ This may involve, as in Option B (upstream inspections measures), time consuming and costly investigations from enforcement authorities. Other downsides in terms of enforceability compared to Option B largely depend on the combination of checkpoints under this option. In case only market approval authorities and IPR offices were to be given monitoring and enforcement powers, a substantial number of utilisation activities that could potentially breach legal requirements under Option C would systematically fall outside the scope of monitoring and enforcement activities. Those would be mostly activities that do not lead to marketable products or products for which IP protection is sought. In case a CNA was to be tasked with conducting targeted inspections on the sectors and activities more likely to fall outside the remit of IPR offices and market approval authorities, enforceability of obligations/prohibitions under Option C would considerably improve.

Specific issues:

Enforceability of the prohibition to utilise GR lacking appropriate documentation in Option C
IPR Offices: Virtually all sectors utilising genetic resources protect some of their innovations through patents or plant variety rights. Reliance on IPR offices however is highly variable across sectors. For example, while the pharmaceutical industry frequently seeks patents for protecting innovations, the academic research sector, despite some growing trends in the field of biotechnology, has a much lower reliance on patents, as the primary aim of their research is to contribute to scientific knowledge (EU baseline, chapter 10). Even in commercial sectors, not all research and/or development result in patent protection. In the pharmaceutical industry, for example, patents applications are only submitted by the time lead compounds have entered the lead optimisation stage (EU Baseline, chapter 10). For the

¹⁵⁸ Different means to verify the good legal status of GR have been outlined in Box 9.11, Ch.9 of this report.

seed industry it may take thousands of plant breeding crosses for the development of a new wheat variety (EU Baseline, chapter 10). Moreover, currently less than 14% of registered varieties on the EU Common Catalogues (agricultural and vegetable crops) are protected within the CPVR (EU Baseline, Chapter 10). Microbial collections and botanic gardens do not make use of patent protection, their main “utilisation” activity being basic research on the properties and/or biochemical composition of GR (EU Baseline, chapter 10). In sum, IPR offices would be able to enforce the above prohibition only for a fraction of activities involving utilisation of GR in the EU. The fact that the European Patent Office is not bound by EU law would likely exacerbate the enforcement gap. In fact only 20-25% of patent applications for biotechnological inventions within the EU are submitted to patent offices at national level (Hoare and Tarasofsky, 2006).

Market Approval Authorities: products that build on GR that are subject to market approval include medicinal products, cosmetics, seeds and plant propagating material, novel foods, and GMOs (see section 4.2 and chapter 9 for details). Similarly to IPR offices, enforcement of the prohibition by market approval authorities would leave out from its scope a number of sectors, including academic research, *ex situ* collections and a significant amount of research and development on GR by commercial users that does not result in a marketable product. For example, in pharmaceutical industry R&D, only a fraction of identified leads generate compounds that are eventually commercialised (see EU baseline, chapter 10).

Effective enforceability by IPR offices and market approval authorities is also dependent on additional funding and capacity building for those institutions. Establishing non-compliance with the prohibition to conduct research and development on GR lacking appropriate documentation is unproblematic in the case the applicant can provide no documentation at all on certain GR. By contrast, where the applicant can provide documentation, appropriate resources and legal expertise may be required to make further checks on whether documentation provided by operators is in line with the legal and administrative requirements of the country of origin of the GR.

CNA: Enforceability under Option C would substantially improve in case a CNA was entrusted with the responsibility of checking compliance with the prohibition to engage in research and development on GR lacking appropriate documentation, in addition to IPR offices and/or market approval authorities. While noting the general disadvantages of using a CNA to inspect compliance considered under Option B (e.g. lack of in depth knowledge of sectoral research/documentation practices, isolation from the utilisation chain), a CNA under Option C could target inspections towards activities and operators that have a lower probability of being controlled through market approval or IPR-related procedures.

DG Research & Innovation, Development & Cooperation as checkpoints: the same considerations under Options A and B apply under Option C.

Enforcement of the “obligation of traceability”

Under Option C, an obligation of traceability is unlikely to be effectively enforced directly by downstream enforcement authorities. Compliance with this obligation could in fact only be directly monitored through inspections from CNAs; these would follow the same approach as described under Option B for the monitoring of the prohibitions and obligations on

upstream uses. In any case, the presence of enforcement authorities operating at the end of the utilisation chain, however, incentivises downstream operators to request such documentation when sourcing GR from intermediaries, and, as a result, to only source their genetic material from upstream operators with reliable documentation systems.

Enforcement of MAT: the same considerations as under Options A and B apply under Option C.

Sanctions: Refusal at the stage of intellectual property protection and market approval to grant the license to market/intellectual property protection on e.g. a product that has been produced through the utilisation of GR without appropriate documentation, appears to provide a very strong incentive on operators to ensure from an early stage that GR utilised in the R&D stage have been appropriately sourced. Research-intensive sectors spend substantial financial resources on R&D and the timeframe for developing a marketable product can be long (e.g. in the pharmaceutical sector it takes about 10 to 15 years for a compound to make its way through R&D into commercialisation) (see EU baseline, chapter 10). Accordingly, these sectors would have a great interest in ensuring that GR utilised in the R&D process have been appropriately sourced and documented because of the potentially high financial losses associated with a lack of approval for marketing the final product. As already analysed in chapter 9 the denial of IP rights would likely come into conflict with international IP obligations (TRIPS Agreement), thus this type of sanctions would only be a possibility in relation to the refusal of market access. Moreover, as discussed above, using the approval of marketing products as a sanction may raise issues of proportionality.

With regard to other sanctions, similar considerations on effectiveness apply under Option B and C (see Option B above and legal analysis of sanctions under option C, section 9.3). Option C additionally provides the possibility to require an operator to *ex post* conclude PIC/MAT, which may have a much more deterrent effect on non-compliance. While this sanction under Option B, when applied to upstream users, would simply have the function of bringing the operator's behaviour into compliance with the NP, when applied to a marketable product or patented product or process, *ex post* MAT are likely to involve serious financial consequences for the operator.

Compatibility of proposed options with existing sectoral practices

Sectors that use GR/TKaGR in the EU vary considerably in the volume of their use of GR/TKaGR, in the commercial and non-commercial applications for those resources, the extent of existing practices for ABS compliance and in their coordination of these activities within each industry or sector. The compatibility of option C with existing practices will thus vary accordingly.

For example, downstream focused implementation is likely to have significant impacts on the pharmaceutical industry and agriculture/seeds sector. The pharmaceutical sector has reduced the use of natural products in its product development over time (though there is renewed interest in natural products in recent years) (see EU baseline, chapter 10). The sector is likely to further decrease such use as a downstream-focused approach does not

secure the legal status of resources at an early stage in the value chain which can then be maintained through the lengthy product development stages before commercialisation. As a result, there will be a significant volume of materials circulating in the EU whose status cannot be verified. This sector is particularly risk-averse to GR use in such circumstances.

Most of the GR/TKaGR used in agricultural biotechnology sector is sourced from *ex situ* collections. *In situ* bioprospecting activities are rare in the sector. Significant exchange of materials occurs across the EU. Similarly to pharmaceuticals, the sector generally will not work with materials for which there is doubt regarding their legal status (see EU baseline, chapter 10) and therefore downstream-focused measures that do not secure the legal status of GR/TKaGR at an earlier stage in the value chain will be a challenge for this sector. This will prove to be a particular problem where monitoring occurs in IPR institutions or at marketing approvals stage only.

In other sectors, the proposed measures under option C will have significant impacts on a small proportion of a sector but less so overall. For example, in the horticulture sector there are a small number of users that rely on bioprospecting to introduce novelty in the system, and these users are largely thought not to comply with ABS requirements under the CBD. For those companies that rely on new GR/TKaGR, the impacts of option C may be significant, particularly if the plant variety rights system is used to monitor compliance and this imposes significant new information requirements on users.

Similarly, in the cosmetics industry reliance on genetic resources is high in some parts of this sector, but low overall. Where new natural products are required or desired in this sector, there is a relatively high degree of familiarity with ABS requirements and existing approaches within companies (though no sector-wide approaches as such) (see EU baseline, chapter 10). For those companies that do rely on new natural products, the impacts of option C may be significant, particularly if market approvals for cosmetics products are used to monitor compliance and companies cannot ensure the good legal status of the resources from an early stage in the value chain.

The impacts will depend in large part on the legislative frameworks underpinning checkpoints for overseeing compliance with the rules under option C. The extent to which sectors rely on obtaining GR from intermediaries as opposed to directly from the provider country will also influence the impacts on the sector. Users who source GR/TKaGR directly from provider countries can conclude MAT and obtain PIC to ensure compliance, while those that source from intermediaries are likely to find this much more difficult. It will also be important to consider the potential of a 'double burden' on users that may pass through multiple checkpoints, such as IPR and market approval authorities.

Sector costs / impacts

Downstream focused measures under option C are likely to increase the costs for most if not all downstream users. As this option will not fully address the problem of legal certainty for GR obtained by downstream users from upstream users, downstream users (such as pharmaceutical companies) may therefore have to make considerable efforts and thus costs

to ensure that GR transferred down the user chain were originally sourced legally from the provider country. However, as this option implies an EU-wide harmonised approach to Protocol implementation, legal certainty is facilitated to a certain degree for the most affected sectors, which will help to reduce the costs of compliance. EU users are able to determine what is required of them, which can help reduce the costs to the sectors of adapting to the new regulatory regime and to keep transaction costs low.

The plants/seeds and industrial biotechnology sectors may face particularly high costs due to their high reliance on GR (see EU baseline, chapter 10). In the plant/seeds sector, companies will face no additional costs as far as plant GR and uses are concerned that fall under the ITPGRFA because in these cases users do not need to comply with Protocol obligations. However, as far as plant GR that are not listed on Annex I to the ITPGRFA or non-food & agricultural uses are concerned, the sector may face significant costs as it may have to adopt new practices and may be subject to new checks at IPR offices or market approval authorities. Where IPR offices (particularly plant variety right offices) and seed and other plant propagating materials market approval authorities are deployed to monitor use, there will be administrative costs associated with obtaining and completing documents to accompany the applications.

The industrial biotechnology sector relies heavily on the use of GR in its activities. A significant proportion of the material used in the sector has been recently collected or will be collected. This sector has relatively little experience with voluntary ABS measures and may face the most significant costs amongst the biotechnology sectors in complying with downstream focused requirements particularly where this requires verification of legal status or where sanctions involve revocation of a right or refusal of product marketing approval.

In other sectors, cost impacts are likely to be more moderate. For example, in the cosmetics industry, costs will increase where new natural products are required or desired in order to comply with Protocol requirements. This will be the case particularly if non-compliance results in a requirement to obtain PIC/MAT for a resource for which the legal status is not assured and this delays product approval or where the sanction includes rejection of market approval.

The pharmaceutical sector in particular may have to make considerable efforts and thus costs to ensure that GR transferred down the user chain were originally sourced legally from the provider country. However, the sector is likely to move away from the use of natural products rather than face potentially high costs to comply with the Protocol or where sanctions may create high costs in situations of non-compliance. The associated costs for this sector are therefore mitigated by the degree of substitutability in this sector away from genetic resources.

Where the burden of proof is placed on users, the costs will be higher in cases of potential non-compliance than where the burden is placed on the public authorities. Under this option, the burden of proof will be on operators to prove that they have complied with the prohibition (i.e. by providing the required information to authorities at a checkpoint). This

will create higher costs for downstream users than for upstream users, as upstream users are likely to be largely unaffected by this option, with few associated costs.

Specific issues: SMEs

Under option C, the administrative burden and costs will increase for SMEs required to implement the Protocol, especially for those SMEs operating downstream in the user chain. SMEs which only operate upstream will incur limited costs. The biocontrol sector, for example, has a high reliance on GR and is primarily composed of SMEs employing an average of 2 to 10 employees (see EU baseline, chapter 10). Given the very low profit margins of the sector, direct regulatory requirements downstream may present a heavy burden for this industry. Exemptions may be possible, however—for example, where an SME is judged to be at low-risk of non-compliance or where the steps to prove compliance can be adjusted to reduce the burden on these businesses to provide information.

Public costs

Recurring and one-off costs: EU-level

Recurring and one-off costs for the EU will increase compared to the baseline scenario. This option is more costly to implement than the non-legislative option A. It may be more or less costly than option B, depending on the number of affected institutions and legislative frameworks that must be changed (see below). Recurring costs will include monitoring and enforcing compliance which will probably be higher for the EU than under Option B where most costs in relation to monitoring and enforcement will be incurred at MS level. One-off costs will be incurred to make legislative changes and to equip institutions with the information/training/personnel required to implement the measures.

The EU is expected to incur significant one-off costs to make changes to the various legislative frameworks at EU level (e.g. Directive 98/44/EC on biopatents; Regulation No 726/2004 on medicinal products for human and veterinary use; Regulation No 258/97 on novel foods and novel food ingredients; and, Council Directive 76/768/EEC on cosmetic products, to be replaced in 2013 by Regulation No 1223/2009) in order to ascertain monitoring tasks to IP offices and market approval authorities. Furthermore, in order to ascertain monitoring tasks to the European Patent Office (EPO) changes would have to be made to the European Patent Convention (EPC). Therefore proper EPC decision-making procedures, involving all the 38 Parties to the EPC, will have to be followed for this purpose. In addition, one-off costs will also be incurred to equip institutions with the information/training/personnel required to carry out the monitoring tasks.

As in options A and B some minor costs might be incurred if the EU decides to use its research funding and other relevant funding procedures to monitor compliance with the upstream measures. In that case some additional recurring costs might be made by DG Research and Innovation and other EU entities when acting as checkpoints.

Monitoring through IP offices and market approval authorities will incur recurring costs which are very likely to be lower than the monitoring costs under option B. These

checkpoints will not have to search actively themselves for information about the utilisation of GR by the users within the different sectors (e.g. by conducting on-the-spot inspections) but will rather receive information from the users as part of existing administrative procedures. However, under option C monitoring could be again the task of CNAs at MS level. In that case public costs would increase considerably, but these additional costs would be mostly borne at MS level (see paragraph below). Further costs in relation to monitoring will be associated with the need of enforcement authorities to conduct further potentially lengthy investigations on the origin of GR that have no PIC/MAT document attached due to the fact that they have been collected in areas beyond national jurisdiction, before the introduction of ABS requirements or in countries with free access policies.

Monitoring through IP offices will mostly incur one-off and recurring costs at EU and international level. Monitoring through market approval authorities will incur one-off and recurring costs at both MS and EU level, as for some products either EU institutions/agencies (e.g. Commission, European Medicines Agency and European Food Safety Authority) or MS authorities are involved in market approval procedures and for other products both EU and MS authorities are involved. The exact balance of costs between EU and MS level will depend of the choices made

Recurring and one-off costs: MS-level

Member States will incur significant recurring and one-off costs under Option C. Whether these will be higher or lower than under Option B will depend of the choices made when making changes to the EU legislative frameworks and whether (independent) CNAs at MS level would be entrusted with monitoring tasks instead of IP offices or market approval authorities.

These costs may be relatively low at MS level if most of the responsibility for implementation falls to EU institutions, but it is more likely that there will be a mix between measures that affect legislative frameworks and institutions that fall under EU competency and those that will require MS implementation. But even then monitoring through national IP offices and market approval authorities will likely incur lower recurring monitoring costs than under option B as these checkpoints will be able to work more cost-efficiently than the independent CNAs (see paragraph above).

However, in case independent CNAs at MS level would be entrusted with the task to monitor those sectors which are not covered by IP procedures and/or market approval procedures or because it is decided to combine this CNA monitoring option with either monitoring by IP offices only or monitoring by market approval authorities only, recurrent and one-off public costs at MS level will increase considerably. As in Option B, CNAs could conduct inspections at users' premises, ascertain the legal status of GR found there and hence whether the prohibitions anchored in EU legislation have been violated.

Governance

Practicability

This option is less practical than option A but potentially more practical than option B from the point of view of institutional set-ups. The EU and MS would not necessarily need to set up new authorities with new powers to control and inspect compliance in order to implement this option. Existing market approval authorities and IPR offices would be entrusted with monitoring and enforcement powers. Those authorities, being already part of the utilisation chain, would also need fewer resources for the monitoring of the utilisation of GR (checkpoints would not have to engage in active collection of information through inspections). Information will directly flow to those authorities, with the burden to provide information being primarily on operators to provide appropriate documentation demonstrating that GR utilised in the process have been appropriately sourced (although they will likely also have to engage in time consuming investigations in case the operator disclosing the utilisation of a certain genetic resource maintains that the lack of documentation is due to the fact that the GR falls outside PIC and MAT requirements). The practicability of this option will clearly decrease in the case also an independent CNA was to be entrusted monitoring and enforcement powers to complement the checks at the level of downstream checkpoints. The general problems related to CNAs taking up monitoring and enforcement powers have been explained under Option B above.

From the point of view of EU level law-making process there are two main disadvantages to this option in terms of practicability compared to Option B. First, to implement Option C the EU would need to make adjustments to several existing legislative acts in order to grant new powers and responsibilities to existing institutions (e.g. IPR offices/market approval authorities) (see chapter 9). Reforming existing legislation may have the side-effect of reopening a range of political debates and negotiations pertaining to the amended legislation. There are also specific problems for the reform of the European IPR regime (EPC) in terms of EU and international law, which have been presented in the previous chapter discussing the legal options.

Acceptability

At Member State level, this approach will be acceptable for some Member States that prefer to have EU-level legislation rather than developing their own, which could be costly and time-consuming. This option will be unacceptable for other Member States that prefer to develop their own measures. This is supported by the fact that Member States are themselves signatories of the Protocol and that some MS have commissioned their own studies to assess the options for implementation of the Protocol.

Most of the users from different sectors have expressed a clear wish to see coordinated legislative action at EU-level. This approach will therefore be acceptable to many users from different sectors, primarily because of a generalised concern that lack of harmonised legislation will lead to high increase in transaction costs. The approach, however, is likely to be less acceptable for some sectors (particularly for economically important sectors such as the pharmaceutical industry) than option B, since it puts a high burden on downstream users without ensuring the good legal status of materials upstream in the value chain.

Transparency & understandability

Dedicated ABS regulation is the most transparent option to ensure that other Parties can determine that the EU and its MS have implemented the Protocol and to what extent. This

option will also be more transparent for users regarding the actions they need to take compared with option A.

Option B and C are more or less equal as far as transparency for users are concerned. As to transparency and understandability for providers, option B might be slightly less transparent and understandable compared to option C as the due diligence system for EU users under option B allows several approaches. Indeed, how EU users would exercise due diligence is largely left to them.

International political acceptability

This option will be acceptable to many third countries. Provider countries in particular are likely to look to the EU for coordinated action toward full implementation of the Protocol and this option reflects the preferences of many developing countries in the Protocol negotiations most closely in particular on checkpoints/monitoring.

Environment, biodiversity and health

Health

Impacts of option C on health are far too speculative to be discussed in this section.

Environment & Biodiversity

This option may create high costs for downstream users, and in some cases this may result in sectors reducing their use of GR/TKaGR or engaging in less exchange of these resources due to high costs of compliance at a late stage in the user chain – this may lead to a reduction in the investment in the natural resources and hence impact in the quality of the environment – this can be negative where the investment would have led to conservation, and it can be positive, where the investment would have been linked to resource extraction. On the other hand however, by avoiding placing the burden on non-commercial upstream uses and transactions of GR, option C is unlikely to obstruct research and activities benefitting the conservation of biodiversity. In addition, by ensuring that ABS legislation of provider countries is respected, this option generally ensures that provider countries will have an incentive to protect their biodiversity as they will have a stronger expectation that benefit sharing will take place.

11.3.5 User Compliance Measures: Synthesis of impact assessment results with regard Option A, B and C

Table 11.8: Synthesis of impacts assessment results with regard Option A, B and C

IA Criteria	Business as Usual Scenario	Option A: Max member State Action + EU OMC	Option B: EU Action with Upstream Focus	Option C: EU Action with Downstream Focus
Addressing the ABS objective				
Implementing the Protocol objectives	No action to date at MS and EU level on user compliance, but some actions expected from some MS Self-regulation by some user groups Private law governs benefit-sharing agreements No systematic monitoring at EU or MS level No sanctions for non-compliance with provider measures at EU or MS level	Objectives are partially, but incompletely addressed. EU as a whole: ↘	↗↗↗	↗↗ to ↗↗↗
		Variation across Member States concerning implementation will have both positive and negative impacts Across MS: ↘↘ to ↗↗		
Legal certainty, coherence with other international obligations and enforceability				
Legal certainty	N/A: no user compliance regime in place in EU MS	Does not provide legal certainty for users regarding Protocol obligations at EU level; EU-level: ↘↘↘ to ↘↘ depending on level of variation across MS	Good legal certainty ↗↗	EU-harmonisation to provide some legal certainty. However, challenge of downstream users that obtain material from earlier upstream users not addressed with potential negative effects in terms of investments in R&D and costs on downstream users for tracing back GR in potentially long utilisation chains. ↘↘ to ↗
		MS-level: ↘↘ to ↗↗		
Coherence with other international	No action, therefore coherence maintained with ITPGRFA	→	→	→

obligations - ITGRFA				
Enforceability – user compliance provisions and MAT	MS may develop their own enforcement measures to comply with the Protocol ABS agreements enforceable through contract law for MAT	<u>User compliance provisions</u> : EU plays a supporting role which can enhance enforceability, but does not significantly improve enforceability at EU-level	<u>Upstream Prohibitions and obligations</u> : ↘↘ in short term (as some GR documentation will be lacking) to ↘ in medium-long term (as national and international documentation improves)	Checks are strategically integrated in user chain. However, substantial number of utilisation activities might fall outside scope of monitoring/enforcement activities, unless CNA is established to cover those. Problems of enforceability, as with option B (upstream) also relate (particularly in short term) to difficult investigations of public authorities into situations where GR utilised lack documentation. ↗ to ↘↘
			Due diligence: ↗↗ to ↗↗↗	
		<u>MAT</u> : → to ↗	<u>MAT</u> : → to ↗	<u>MAT</u> : → to ↗
Compatibility of proposed options with existing practices				
Compatibility	Wide variation in the volume and type of use, extent of commercial vs. non-commercial use, awareness of NP obligations and existing ABS practices	↘↘↘ to ↗↗	Compatibility varies across and within sectors. Due diligence rules more likely to complement existing practices in downstream sectors: ↗↗. Compatibility likely to be an issue mostly in relation to upstream obligations (e.g. documentation requirements) imposed on users with limited financial and organisational resources (e.g. small botanic gardens and culture collections): ↘. Some upstream already have good information systems (e.g. large botanical gardens) → Overall: ↗	Compatibility of option with existing practices will vary across and within sectors. ↘↘ (Downstream users) to ↗↗ (Upstream users)

Sector costs / impacts				
Sector costs / impacts	No costs related to action – as no EU-level action required / taken	Costs will vary by sector ↘↘↘ to ↘	Upstream users (mostly <i>ex situ</i> collections with limited financial and organisational resources) likely to face higher costs in implementing upstream obligations, though costs will vary by sector and within sectors. Those already implementing good practices would face lowest costs. ↘↘ to ↘	Limited costs for upstream users, though may vary by sector. Some upstream users may see no change. ↘ to →
	However, risks over time of sectors losses from reduced access to GR given lack of legal framework and impacts on collaboration with third countries. Over time this could be very significant for some sectors if a working global ABS system is in place: Short term ↘ Risk in long term ↘↘↘		Downstream users: Costs will vary by sector, but due diligence and upstream documentation obligations likely to entail moderate financial burdens on downstream users. For many downstream users due diligence is a familiar concept and routines are already in place where only an ABS facet would need to be added. ↘	Downstream users (particularly those making high use of IPR Offices or Market Approval authorities) likely to face higher costs in general than upstream users ↘↘ to ↘
Specific issues: SMEs				
SMEs	No costs at EU level - no action taken Costs where MS decide to take action	Costs will vary at MS level, but MS must keep Small Business Act for Europe (SBA) in mind in any regulation proposed, however potential transaction costs for lack of harmonisation ↘↘↘ to ↘	SMEs: ↘ limited costs as most SMEs are downstream and subject to more flexible due diligence systems	Upstream SMEs: ↘
				Downstream SMEs: ↘↘↘ to ↘
Public costs				
Recurring costs: EU-level	No costs – no action taken	Costs are minimal – require little administrative action:↘	↘	↘↘ to ↘
One-off costs: EU-level	No costs – no action taken	Costs are minimal – requires few one-off costs: ↘	↘	↘↘ to ↘

Recurring costs: MS level	Costs where MS decide to take action	Costs will vary depending on actions taken by MS ∩∩∩ to ∩	Significant monitoring costs. Involvement of third parties in monitoring might limit rise in public costs. ∩∩	Monitoring costs at MS level are likely to be slightly less than under Option B. ∩∩ to ∩
One-off costs: MS-level	Costs where MS decide to take action	Costs will vary depending on actions taken by MS ∩∩∩ to ∩	∩∩	∩∩ to ∩
Governance				
Practicability	Practical – no action required	EU-level: Requires coordination at EU-level; may require multiple arrangements for different sectors: ∩∩	In terms of institutional setup (new CNAs) and monitoring (inspections) potentially less practicable than option C: ∩	In terms of institutional set-up and monitoring: ∩∩
		MS-level: ∩∩∩ to ∩∩∩	In terms of EU law-making process more practicable than option C ∩ to ∩∩	In terms of EU law-making process less practicable than option B ∩∩ to ∩
International political acceptability	No action taken - unacceptable	Acceptable to some third countries, but others will expect EU-level legislative action ∩∩	Provider countries likely to perceive stringent EU implementation positively, but approach under Option B at variance with preferred implementation approach pursued by many provider countries during Protocol negotiations. ∩∩	Option C reflects the preferences of many developing countries in the Protocol negotiations most closely ∩∩∩
Acceptability	MS – Unacceptable as Parties to the NP	<u>MS</u> : Acceptable for some; unacceptable for some ∩ to ∩∩	<u>MS</u> : ∩ to ∩∩	<u>MS</u> : ∩∩ to ∩∩
	Sectors – Acceptable for most sectors	<u>Sectors</u> : Most sectors want coordinated EU legislative action rather than MS only approach ∩∩	<u>Sectors</u> : ∩ to ∩∩	<u>Sectors</u> : ∩∩∩ to ∩
Transparency & understandability	Complete transparency – no action taken	Transparency for providers and users likely to be limited due to variation in approaches	<u>Users</u> : ∩∩∩	Users: ∩∩∩

		undertaken at MS level. Coordinated efforts at EU-level might however increase overall transparency. ↘↘ to ↗	Providers: ↗↗	Providers: ↗↗↗
Health, environment and biodiversity				
Health	No interference with WHO GISRS health emergency regime. No interference with pharma R&D.	Impacts are speculative and cannot be assessed	Impacts are speculative and cannot be assessed	Impacts are speculative and cannot be assessed
Environment & Biodiversity	No change as no action taken	Depends partially of MS action. No EU legislative action may discourage provider countries to protect biodiversity. ↘ to ↗	Ensures incentive for biodiversity conservation but may burden activities and research aimed at the conservation of biodiversity. Overall → to ↗↗	High potential costs downstream in value chain may reduce use/exchange of GR in the EU, but legal certainty may improve exchange. Overall → to ↗↗

As the assessment of user compliance measures shows, each option is likely to result in a mix of costs and benefits.

Option A only partially addresses the Protocol objectives related to user compliance. It does not provide legal certainty for users regarding their obligations at EU level, though any associated problems may be mitigated to some degree by action taken by individual Member States. The option potentially lacks transparency across EU Member States due to likely variation in the approaches taken at this level. Additionally, Option A will not be acceptable to users of GR/TKaGR from different sectors who want coordinated EU legislative action rather than a Member State-by-Member State approach, with its likely variation in the rules and procedures adopted. Many third countries are also likely to find this approach unacceptable as many provider countries expect ambitious EU-level legislative action to implement the Protocol.

Option B meets all of the EU's user compliance obligations under the Protocol and fully promotes the Protocol's objectives. The costs and benefits for users of GR/TKaGR will vary depending on the point along the user chain where they primarily operate. Users engaging mostly in upstream and non-commercial activities are high-volume users of GR/TKaGR and often act as intermediaries for GR/TKaGR to downstream users with a commercial focus. Upstream-focused measures will increase costs to these users more than to downstream users. The highest costs will be faced by those upstream users that do not have systems in place already for ensuring the good legal status of their materials, such as universities, research institutions, companies within the horticulture sector and small botanic gardens and culture collections lacking the organisational resources to develop efficient documentation systems. EU support (e.g. funding) to upstream users to fulfil their obligations could mitigate these impacts. Users engaging in downstream activities will also incur costs, but due diligence will limit the financial burden on those users as it allows flexibility depending on the actor, sector and position in the user chain.

The significant benefit of Option B is that it is focused on securing the good legal status of GR/TKaGR from an early point in the user chain, thus ensuring that materials circulating in the EU can be 'trusted' for utilisation by users engaged in downstream activities. This will particularly benefit companies (such companies in the pharmaceutical and green biotechnology sectors) that engage in commercially high-risk R&D activities and hence are highly averse to utilising GR whose legal status is uncertain.

A major drawback of this option is the lack of integration of checkpoints in the user chain which may reduce the effectiveness of this approach in monitoring and addressing non-compliance with upstream obligations. This is however likely to be mitigated in the medium-long term, once monitoring and enforcement authorities develop a good knowledge of the practices of relevant sectors. Monitoring through independent CNAs also incurs more public costs compared to Option C, though mostly at MS level; at EU-level, Option B is less costly than Option C. Few legislative changes will be required at EU level, making Option B more practicable than Option C in this regard.

Option C also meets all of the EU's user compliance obligations under the Protocol. Here, too, the benefits and costs to users of GR/TKaGR will vary depending on the point in the

user chain where they primarily operate. Upstream users will largely be unaffected by implementation requirements in the EU, and will face few costs. Downstream users, conversely, may face significant costs and problems of legal uncertainty where reliance on GR/TKaGR and is high. Monitoring and enforcement activities are conducted at a very late stage in the user chain after significant time and resource investments. As a result, there is a risk that under this option many operators may substitute away from GR/TKaGR use where compliance costs or the risk of facing sanctions for non-compliance are too high. The impact on downstream sectors in terms of costs under Option C will largely depend on the stringency of the sanctions applied at the level of downstream checkpoints, but are likely to be highest for those uses that pass through IPR offices or market approval authorities..

The major benefit of this option is that it reduces or removes the burden of implementation from research activities that have a largely public good function and places it on commercial activities, thus helping to facilitate R&D and scientific research carried out at an early stage in the user chain. This option is likely to be most acceptable to provider countries outside of the EU, but is likely to face significant opposition from a number of downstream sectors within the EU.

Overall, the assessment indicates that both options B and C will allow the Commission to implement the user compliance obligations under the Protocol. The benefits and costs to different user groups vary significantly, and will depend in large part on the specific approach adopted and specific measures undertaken to implement each element of the options. Generally, in terms of costs for operators, Option B will likely place more costs on users primarily operating upstream (*ex situ* collections in particular), whereas Option C will mostly place the burden on operators engaging in commercial uses of GR (e.g. pharmaceutical and biotechnology companies). In terms of public costs, while Option C will entail more costs at the level of EU institutions and administration, it will likely involve lower implementation costs for Member States' enforcement and monitoring authorities. Option B, however, will likely ensure a higher level of legal certainty throughout the utilisation stage and envisages the monitoring of a much larger number of GR.

Both options B and C will be transparent to Parties to the Protocol, to providers in third countries and users operating in the EU. Both options are likely to be acceptable to the international community, though developing countries might prefer Option C above Option B as it reflects their preferences as expressed during the Protocol negotiations most closely. **Nevertheless, Option C is likely to face significant opposition from EU sectors primarily operating downstream.**

11.4 Overall Synthesis of the assessment of measures to implement the Nagoya Protocol

As noted in Section 11.2.5 on the synthesis of provider measures:

- Under Option A, EU inaction would likely entail a fragmentation of access standards throughout the internal market leading to a likely increase of transaction costs for sectors sourcing GR (particularly *in situ*) across EU MS.

- Option B on the other hand seems to better balance, through soft harmonisation under an OMC, the concerns about costs for the EU and potential costs for users relating to legal uncertainties and fragmentation. The downsides of this option seem to be mostly the uncertainties as to the end result of the OMC process.
- Lastly Option C is the one with that offers the most apparent benefits for sectors dealing with GR, in particular biocontrol, *ex situ* collections and small seed breeding companies.
- Option C would also potentially entail international benefits for all EU users of GR as it would put the EU in a leading position in terms of access to GR standard setting. Political opposition from certain MS and the relatively high costs related to enacting and monitoring the compliance with a new piece of legislation could potentially counter-balance the benefits of such a system, at least in the short term.

Options “B” and “C” should not in fact be seen as mutually exclusive – as they can be adopted in sequence.

As noted in Section 11.3.5 on the synthesis of user compliance measures:

- Option A, which assumes that all Member States implement the NP in national law, only partially addresses the Protocol objectives related to user compliance. It does not provide legal certainty for users regarding their obligations at EU level. The option potentially lacks transparency across EU MS due to likely variation in the approaches taken at this level. As a result Option A would be likely opposed by the sectors involved.
- Option B will necessarily increase costs for publicly-funded sectors. The significant benefit of Option B is the ability to secure the good legal status of GR/TKaGR from an early point in the value chain, thus ensuring that materials circulating in the EU can be ‘trusted’ for use by the different sectors involved in high-cost and high-risk downstream activities. A major drawback of this option is the lack of integration of checkpoints in the user chain which may reduce the effectiveness of this approach in monitoring and addressing non-compliance with upstream obligations.
- Option C on the contrary will have a light impact on upstream users in the EU, and these users will face few costs. Downstream users relying on GR, conversely, will face significant costs as monitoring and enforcement activities are conducted at a later stage in the user chain after significant time and resource investments. The major benefit of this option is that it reduces or removes the burden of implementation from research activities and places it on commercial activities, thus helping to facilitate R&D at any early stage in the value chain. This option nevertheless presents drawbacks in terms of legal certainty for downstream operators. For this reason

several EU commercial operators have expressed significant opposition to this option.

- It is likely that in the short to medium term the upstream focused option would be less onerous and more feasible than the downstream focused options given the existing state of knowledge, documentation of genetic resources and practices. An upstream focus would facilitate and reduce the costs of an eventual future downstream focused option. In sum, the assessment would support the case for a phasing of options, starting with “B” and then adding monitoring elements (checkpoints) from “C”.

The provider access measures and the user compliance measures have been assessed apart given the different nature of the measures. However, they are not alternatives, but relate to different components of Nagoya Protocol implementation. While all Parties must take measures for implementing the user-compliance pillar of the Protocol, Parties have discretion whether or not to require prior informed consent for access to and benefit-sharing for the utilisation of genetic resources over which they hold sovereign rights. In case a Party decides to require prior informed consent and benefit-sharing it must implement the fairly detailed access provisions of the Protocol.

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INTERVIEWS¹⁵⁹

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¹⁵⁹ This list does not include the interviews conducted for the country studies in the second half of 2011. More information on these can be found in Annex 1 and 2.

ANNEXES

See separate electronic file.

ANNEX 1: COUNTRY REPORTS EU MEMBER STATES

- Belgium
- Bulgaria
- France
- Germany
- Poland
- Spain
- The Netherlands
- United Kingdom

ANNEX 2: COUNTRY REPORTS NON-EU COUNTRIES

- Australia
- Brazil
- India
- The Philippines
- Switzerland
- Uganda

ANNEX 3: SECTORAL SHEETS

This section includes sheets for:

- Pharmaceutical Industry
- Culture collections
- Botanic gardens
- Plant Breeding/Seed sector
- Biocontrol
- Horticulture
- Academic Research
- Cosmetics Industry
- Animal Breeding Industry
- Industrial Biotechnology
- Food and Beverage Industry